"Agrobiodiversity conservation and plant improvement : adjustments in intellectual property rights reclaiming the public domain towards sustainability and equity"

Batur, Fulya

Abstract

Intellectual property rights, mostly in the form of patents and plant variety protection, have increasingly become an integral part of plant improvement efforts. With the advent of the TRIPS Agreement and the dominant interpretative implementation of its minimum standards, actors who use, conserve and improve agricultural biodiversity are faced with a strong property rights paradigm, which has been thoroughly criticised in the doctrine. However, these critics have not created the advocated regulatory shift. The dissertation defends that this is due to the lack of socio-technological contextualisation of applicable laws and judicial interpretation. Indeed, the intellectual property paradigm applies to very different innovation contexts and confronts plant improvement actors stretching from mass selectors, small-scaled private conventional plant breeders, public molecular researchers, specialised start-ups and integrated biotechnology giants. By applying the paradigm to such contexts, ...

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AGROBIODIVERSITY CONSERVATION AND PLANT IMPROVEMENT:
ADJUSTMENTS IN INTELLECTUAL PROPERTY RIGHTS RECLAIMING THE PUBLIC DOMAIN TOWARDS SUSTAINABILITY AND EQUITY

Dissertation présentée en vue de l'obtention du grade de docteur en sciences juridiques

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AGROBIODIVERSITY CONSERVATION AND PLANT IMPROVEMENT: ADJUSTMENTS IN INTELLECTUAL PROPERTY RIGHTS RECLAIMING THE PUBLIC DOMAIN TOWARDS SUSTAINABILITY AND EQUITY

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"It seems to me that men cannot live conveniently where all things are common: how can there be any plenty, where every man will excuse himself from labour? For as the hope of gain doth not excite him, so the confidence that he has in other men's industry may make him slothful: if people come to be pinched with want, and yet cannot dispose of anything as their own; what can follow upon this but perpetual sedition and bloodshed?"

Thomas MORE, Utopia

INTRODUCTION

The diversity of life is primordial to all societies. Agricultural plant biodiversity is the foundation of undoubtedly the most critical human right of all, that of food, as seeds represent the paramount input for food and feed cultivation. Plant genetic diversity is in this context the foundation of all crop improvement endeavours, which not only attempt to respond to our nutritional needs but also to ever-greater biotic and abiotic stresses. The conservation, use and development of agrobiodiversity are primordial to offset the growing pressure put on land by a soaring human population and changing climate. Agriculture is definitively under growing pressure, stemming not only from soaring population growth estimates, from the shrinking availability of cultivated land, but also from changing and increasingly more difficult climatic conditions. The debate on the strategic choices and postulates of the **"agriculture of the future"** takes place in this context of mounting environmental and socio-economic pressure, divided in two seemingly contradictory but possibly harmonious approaches. Emphasis is on the one hand put on the necessity to increase yields or useful resistances through high-technology infused crop improvement programs relying on enriched germplasm pools[1]. On the other hand, focus is put on the need for multi-faceted approaches incorporating concerns over economic profitability, but also ecological suitability and social acceptability[2]. The latter approach takes the plea of bottom-up participatory or agro-

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[1] MARK TESTER and PETER LANGRIDGE, "Breeding Technologies to Increase Crop Production in a Changing World," *Science* 327, no. 5967, 2010., where the authors highlight the importance of new molecular breeding techniques for the future need of yield improvements, conditional however to the necessary widening of the general germplasm pool and enrichment of the improved resources pool through landraces or wild relatives. See also the International Seed Federation's "Agriculture under Pressure" video, hinting that the solution for population and environmental pressures will come from modern crop improvement, through the hands of breeders and molecular biologists: http://www.worldseed.org/isf/agriculture_under_pressure.html (accessed July 2011).

[2] See for instance Pashupati CHAUDHARY's response to the aforementioned article by TESTER and LANDRIDGE, where the author stresses the importance of local innovation based on the selection of appropriate traits by the custodians and caretakers of agrobiodiversity: PASHUPATI CHAUDHARY, "Bottom-up and Need-Based Approach for Crop Improvement," ibid.published 27 April 2010. In a parallel stance, the 2009 multi-stakeholder expert led "International Assessment of Agricultural Knowledge, Science and Technology for Development: Agriculture at a Crossroads (IAASTD)" also promotes the need to embrace the "multi-functionality" of agricultural production and knowledge, addressing the distributional impacts of currently dominant narratives focused on high-technlogy laden productivity gains.

ecology-based[3] crop improvement systems, and so-called “socio-ecological production landscapes”[4].

Biodiversity is used for cultivation and innovation in a framework of fierce competition between industrialised and emerging economies, where economic development has arguably been granted the status of human right, and where steadily increasing population figures have propelled an urging need to increase agricultural production. Stepping away from the quite depreciatively described "backward repository of unskilled people locked in traditional ways of living"[5], discoveries related to agricultural plant genetic resources have revolutionised food production and cultivation. They have produced impressive results in terms of yield or uniform performance, increasing all the while opportunities for land sparing and for controlling environmental stresses[6]. Albeit the initial impetus which guides research activities that use and create new agricultural genetic diversity, neither farmers nor consumers have unreservedly benefited from the revolutionary added values of agricultural technological strides. Technological progresses have brought about challenging societal and structural issues, transforming the entire organisation of agricultural input production, professionalising the development of plant varieties and production of seeds, and distancing them from farms. The ecological and socio-economics benefits brought by the worlds of genetics and genomics have been levied by high costs and sacrifices on the field. The modern biological information quests lying behind the groundbreaking discoveries of genomics and genetics science bear significant industrial impacts, with distributional effects in terms of access to technology and assimilation capacity[7]. Opposition movements[8] fearing for farmers' livelihoods and the ecological downfalls of homogenisation have considerably tainted both the revolutionary hybrids of the Green Revolution and the subsequent "pro-poor biotechnology" narratives[9]. Detrimental effects have been raised in social allocation, pointing to the significant

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[3] The approach has for instance been advocated by the latest United Nations Special Rapporteur on the Right to Food, OLIVIER DE SCHUTTER, "*Agroecology and the Right to Food*", Report presented at the 16th Session of the United Nations Human Rights Council, A/HRC/16/49, 2011.

[4] This idiom has been studied and advocated by the United Nations University Institute of Advanced Studies; see NADIA BERGAMINI et al., "*Indicators of Resilience in Socio-Ecological Production Landscapes (Sepls)*", http://www.ias.unu.edu/resource_centre/Indicators-of-resilience-in-sepls_ev.pdf, 2013.

[5] ROBERT E. EVENSON, "Besting Malthus: The Green Revolution," *Proceedings Of The American Philosophical Society* 149, no. 4, 2005. (pp. 469)

[6] For a quick and complete overview of the benefits brought about by plant breeding and the growing use of genetic improvement in general, see MARCEL BRUINS, "The Evolution and Contribution of Plant Breeding to Global Agriculture," in *Responding to the Challenges of a Changing World: The Role of New Plant varieties and High Quality Seeds in Agriculture, Proceedings of the Second World Seed Conference* (Rome, September 8-102009). pp.18-31, especially at pp. 23-27, where the author underlines the contributions of methodical selection and breeding in terms of yield, nutritional quality, biotic stress resistance, abiotic stress tolerance and land sparing.

[7] See the results of the workshop on Environmental Policy, Agriculture and Technology held in Rome in May 2000 as related by TIMOTHY SWANSON, *The Economics of Managing Biotechnology* Dordrecht: Kluwer, 2001. Preface, whereby the author distinguishes the environmental impacts of biotechnological innovation (in terms of resistance, unintended effects and irreversible uncertainties) and those related to industrial structure (in terms of efficiency and distribution). For environmental impacts, see Parts B and C of the aforementioned monograph (pp. 99 – 197) and see Part D for the industrial impacts (pp. 197-250), as well as TIMOTHY SWANSON, *Biotechnology, Agriculture and the Developing World: The Distributional Impacts of Technological Change* London: Edward Elgar, 2002.

[8] The most notable voice with regards to the concerns of the detrimental effects of all private sector induced genetic improvement, whether through hybridisation or biotechnological tools such as genetic engineering is without a doubt Vandana SHIVA and the Grain association; VANDANA SHIVA, *The Violence of the Green Revolution: Third World Agriculture, Ecology and Politics: Ecological Degradation and Political Conflict* London: Zed Books, 1991.

[9] See for instance respectively assessments with regards to the first modern varieties and to the promise of biotechnology, M. LIPTON and R. LONGHURST, *New Seeds and Poor People*: Routledge Library Editions:

decreases in farm income attributed to the higher costs of obtaining more expensive seeds and accompanying chemicals.

Agricultural production, in order to be ecologically and economically sustainable, needs to be carried out through various channels and economic models, driving away from a "one-size-fits-all" approach. The annihilation and depreciation of biodiversity maintainers on farm or in conventional breeding programmes, cannot serve objectives of sustainability, even in the most modern crop innovation chains. Agricultural production cannot at any time, destroy the genetic diversity that it creates or is derived from. Indeed, plant improvement steadily relies on a sound influx of new genetic variability, stemming primarily from improved varieties but also from resources selected and maintained on farm. Furthermore, a forced homogenisation in innovation models cannot serve the collective good unequivocally. Indeed, cultivation schemes and seed development should remain genuine choices, adapted to local socio-economic and environmental conditions, focusing either on farm-based selection, or more conventional plant breeding activities sustained through small or medium enterprises, or the currently dominant molecular-based integrated industry. It is therefore in this delicate yet vital framework of sensitiveness, anchored in pleas for biodiversity conservation on the one hand, and for equitable rights to development and the survival of adequate economic realities on the other, that a set of complex, but for many agrobiodiversity users crucial, problems have emerged concerning the appropriate legal frameworks that allocate property rights to agricultural plant genetic resources.

Policies need in this sense to bear multiple layers, addressing all components of plant genetic diversity, from improved stable varieties to landraces and wild relatives[10]. They also need to concede the diversity of actors relying on, improving and using living organisms, which is not only primordial to all democratic but also sustainable societies. Based on such premises, our focus will lie on the management of agricultural biodiversity, more specifically on the promotion of innovative yet sustainable and equitable variety development activities. The argumentative constructs revolve around the **actors and stakeholders who conserve, use and improve agrobiodiversity (A)** and thereby contribute to social welfare in different socio-technological contexts of innovation. In the political economy tradition, the stakeholders active in the so-called "PGRFA system"[11] are customarily understood to encompass international organisations, national States (whether in the bioresource-rich South or knowledge-rich North), non-governmental organisations representing specific interests (whether lobbying or environmental groups), and farmers. We argue that such an approach, albeit providing useful insights as to the influences that carve the content of regulatory regimes, has inherent limitations and fails to inform on the concrete means through which the goods in questions are produced. That is why we believe that the starting point of an analysis that strives to highlight the concrete shortcomings of a specific regulatory regime, and as a result provide efficient adjustments to such regime, should be grounded on the

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Development 1989 (second edition 2011)., and M. LIPTON, "Reviving Global Poverty Reduction: What Role for Genetically Modified Plants?," *Journal of International Development* 13, 2001.

[10] While improved stable plant varieties are produced by the industrialised seed development model relying on modern plant breeding techniques, landraces are the result of millena of both intentional and unintentional cultivation and crossings in fields, and designate populations that have been "domesticated" away from wild plant, coined wild relatives; see notably A.C. ZEVEN, "Landraces: A Review of Definitions and Classifications," *Euphytica* 104, 1998..

[11] CARLOS CORREA, "In Situ Conservation and Intellectual Property Rights," in *Genes in the Field: On-Farm Conservation of Crop Diversity*, ed. STEPHEN BRUSH, Boca Raton: IPGRI/International Development Research Corporation/Lewis Publishers 2000.

analysis of the **actual users of the goods under study**, i.e., plant genetic diversity. It should not only study the means through which such users have forged certain interpretations of applicable property regimes, but also underscore how they have thereafter built social innovation to overcome the shortcomings caused by the dominant interpretation in certain socio-technological innovation contexts. Indeed, amongst the diverse range of actors of plant improvement, an important proportion of agrobiodiversity user groups concede great importance to the public domain[12] both within and outside informational enclosure mechanisms, understood in a pluralistic approach that includes the structural and functional domains created by applicable intellectual property rights ("IPR") legislation. As a result, these social actors face **adverse regulatory trends (B),** as the legal structures that currently surround the formal seed market, notably the strong developmental-oriented and arguably distorted property rights regimes, disregard and fail to recognise some of these stakeholders. Consequently, these actors turn to self-regulation, build **pathways, practices and coping strategies (C)** that strive to re-adjust the strong property paradigm[13] and re-appropriate a wider public domain, a multi-faceted concept that may as a result prove to be the most efficient means towards the salvation of these overlooked users of agrobiodiversity. Our analysis is in this sense based on a triangulation of applicable regulatory regimes, socio-technological plant innovation contexts, and social actors who develop a wide array of tools to counter the adverse effects of regulation by using the flexibilities offered by the bendable boundaries of the property paradigm as applied to agricultural plant genetic resources.

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[12] We approach the "public domain" through a pluralist understanding, encompassing not only the knowledge, products and processes where no ownership claims have been drawn upon, either because of the lapse of legal protection in time, or by the effective choice of associated creators or inventors, but also embracing the public domains created by the law itself, delineating the object and scope of intellectual property protection, defined by James BOYLE as the "outside of the intellectual property system, the material that is free for all to use and build upon", markedly inspired by the work of JAMES BOYLE, "The Opposite of Property?," *Law & Contemporary Problems* 66, no. 1-2, 2003., DAVID LANGE, "Reimagining the Public Domain," ibid.463., PAMELA SAMUELSON, "Enriching Discourse on Public Domains," *Duke Law Journal* 55, no. 101, 2006., and SÉVERINE DUSOLLIER, "Le Domaine Public: Garant De L'interêt Public En Propriété Intellectuelle?," in *L'interêt Général Et L'accès À L'information En Propriété Intellectuelle*, ed. MIREILLE BUYDENS and SÉVERINE DUSSOLIER, Bruxelles: Bruylant, 2008. This understanding will be more thoroughly described in the first Chapter of this study.

[13] We understand « paradigm » in the footsteps of Thomas KUHN's seminal work (THOMAS S. KUHN, *The Structure of Scientific Revolutions* Chicago: University of Chicago Press, 1962., not only as the structure legitimising scientific methods, but also as a means to model future practice upon it, even though the word itself, and the notion of "paradigm shift" has been used and abused in various forms following Kuhn's publications; see Ian HACKING's introductory essay to the 50th Anniversary edition of Thomas Kuhn's aforementioned seminal book, T.S. KUHN and I. HACKING, *The Structure of Scientific Revolutions: 50th Anniversary Edition*: University of Chicago Press, 2012. Indeed, Kuhn's paradigm is most often mistaken so as to mean something like "world-view", whereas the notion of paradigm steps away from sets of assumptions or a perspective, and rather represents an actual example of scientific work which serves as a model", SUSAN M. WOLF, "Shifting Paradigms in Bioethics and Health Law: The Rise of a New Pragmatism " *American Journal of Law and Medicine* 20, 1994. We therefore use the term to demonstrate the development-oriented approach to plant-related intellectual property rights that was established as a guiding principle reified through internationally agreed minimum standards and later corroborated by adequate stakeholders and legislative practice. We do so in the footsteps of numerous intellectual property scholars, such as ARTI K. RAI, "Regulating Scientific Research: Intellectual Property Rights and the Norms of Science," *Northwestern University Law Review* 94, no. 1, 1999., ROCHELLE C DREYFUSS, "Does Ip Need Ip? Accommodating Intellectual Production Outside the Intellectual Property Paradigm," *NYU School of Law Public Law and Legal Theory Research Paper Series, Working paper no. 10-43*, 2010., but also MICHAEL A CARRIER, "Cabining Intellectual Property through a Property Paradigm," *Duke Law Journal*, 2004.

A. Key biodiversity actors and stakeholders: benefits of agrobiodiversity protection and use in diverse contexts

The mere existence and conservation of biological diversity retains both anthropocentric and ecocentric values for humankind. It directly provides habitat, food, recreation, while also providing other ecosystem services, contributing for instance to air and soil quality or to carbon sequestration. Agricultural biodiversity in this sense produces numerous public goods[14], such as environmental preservation, food security, knowledge dissemination and societal welfare. As a crucial requisite of agricultural input development, plant genetic resources[15] irremediably influence food production, which needs to rise to the challenge of nourishing seven billion people today, and probably around nine billion in 2050[16]. These resources are a primordial input for both public and private research. Their diversity is thus of special importance for humankind's necessary adaptation to new environmental challenges such as climate change and its accompanying effects on agricultural production[17], as well as probable land, water and fossil fuel shortages. Furthermore, agrobiodiversity preserves traditional cultures and provides the livelihoods of local communities throughout the world. As a result, the importance of conserving and using agricultural plant genetic resources ("PGRFA")[18] sustainably cannot be stressed enough.

Several actors conserve and use agrobiodiversity. They all rely on the ability to access wild, domesticated and improved PGRFA and associated information, either for cultivation, or solely for research and development. The **eldest user-stakeholders, i.e. farmers**, have been selecting and improving plant varieties for more than ten thousand years, relying on a wide array of traditional varieties for their own production, as well as on opportunities for saving and freely exchanging seeds at local or regional levels[19]. Even today a large proportion of the seed planted is either saved by farmers or exchanged on a farmer-to-farmer basis. In the mid-1980s farmer-saved seed accounted for an estimated thirty five per cent (or eighteen billion USD) of the total estimated

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[14] We refer to the traditional three-folded definition pertaining to the inherent characterisation of public goods as accessible and non-rival in consumption; INGE KAUL, ISABELLE GRUNBERG, and MARC A. STERN, "Defining Global Public Goods," in *Global Public Goods: International Cooperation in the 21st Century*, ed. INGE KAUL, ISABELLE GRUNBERG, and MARC A. STERN, New York: Oxford University Press, 1999. In this context, institutional analysis focus upon the impact of normative endeavours over the accessibility of the goods in question, referring to the desirable production levels through political or legal perspectives in a governance mindset; see RENATE MAYNTZ, "Common Goods and Governance," in *Common Goods: Reinventing European and International Governance*, ed. ADRIENNE WINDHOFF-HERITIER, Boston: Rowman & Littlefield, 2002, 15-28.

[15] Biological diversity is traditionally divided into three distinct categories through a hierarchical and structural approach: ecosystems, species and genetic resources. EDWARD O. WILSON, *The Diversity of Life* New York: Norton, 1992.

[16] FOOD AND AGRICULTURAL ORGANISATION FAO, "*How to Feed the World in 2050*", FAO, Food and Agricultural Organisation of the United Nations, Rome, 2009.

[17] Aside from the wide array of ecosystem services provided by agricultural biodiversity, such as pest regulation or erosion control, the sustainable use of plant genetic resources for food and agriculture bears great potential in both the adaptation and the mitigation of the effects of climate change, by responding to biotic and abiotic stress, or to extreme climate events. FOOD AND AGRICULTURAL ORGANISATION, "*Climate Change and Biodiversity for Food and Agriculture: Technical Background Document for Expert Consultation*", FAO, Rome, 2008.

[18] Plant genetic resources destined to the agricultural sector shall be herein equally referred to as PGRFA, agricultural plant germplasm or agricultural plant genetic resources. The research shall only delve on agricultural plant genetic diversity management and the correlated rules of access and use, willingly setting animal and aquatic genetic resources (which also constitute an integral part of agricultural diversity), but also all industrial uses of such resources (such as energy) aside.

[19] MIGUEL A. ALTIERI, K.M. ANDERSON, and L.C. MERRICK, "Peasant Agriculture and the Conservation of Crop and Wild Plant Resources," *Conservation Biology* 1, no. 1, 1987.

value of fifty billion USD for all agricultural seed used worldwide, proprietary or not[20]. In developing countries, the importance of seed exchange networks and re-use is seemingly more enhanced, as an estimated eigthy per cent of the seed used in the early 1980s was farmer-saved seed[21]. With the advent of genetics and genomics science, the primary agricultural input that are seeds have started to also be **developed off farm and delivered by plant breeders**, and increasingly **molecular biologists**. Conventional plant breeders, by combining interesting genetic resources in lengthy and tedious research programmes, deliver new plant varieties with greater productivity rates, abiotic or biotic stress resistances, and even longer shelf life. They do so by relying on a constant input of both improved and traditional varieties to meet the latest challenges of food supply, even though they tend to predominantly rely on proven market successes and stable varieties[22]. But they also build upon material and knowledge that is publicly available and has been developed and maintained through informal channels and different communities. It has for instance been shown that Turkish wheat landraces have supplied genes used for stem nematode, bunt and hessian fly resistance but also for stripe rust resistance[23]. In a parallel fashion, a study conducted in 2000 showed that seventy one per cent of screened biotechnology patents had citations originating solely at **publicly funded scientific institutions,** universities, medical schools, or research institutes, corroborating the reliance on publicly available knowledge in even the most recent plant improvement models[24]. Just as traditional farming systems wholly rely on nature and its inherent variability in order to produce foodstuff, modern agricultural input production also depends upon the constant use and regeneration of PGRFA. All plant improvement actors extensively build upon the public domain, even the integrated genetic engineering giants with impressive intellectual property ("IP") portfolios.

B. Adverse regulatory trends: disregard and failures of legal structures in certain socio-technological innovation contexts

The **research and development investment-heavy industry** that was gradually built upon the use of agrobiodiversity has rapidly expanded since the major biotechnology breakthroughs in the 1980s. Markets relying upon biological diversity as raw material today amount to benefits that reach five hundred billion USD annually[25]. This share has expanded not only with new technological opportunities such as hybridisation, molecular precision breeding or genetic engineering, but also through the deliberate withdrawal of the public sector from so-called "applied research" endeavours. With the advent of modern genetics and genomics science, the development of plant varieties has become an increasingly knowledge-intensive activity. It exponentially depends not only on the use of tangible genetic material, but also on the access to

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[20] TON GROOSMAN, ANITA R. LINNEMANN, and HOLKE S.M. WIEREMA, *Technology Development and Changing Seed Supply Systems: Seminar Proceedings, 22-23 June 1988*: Development Research Institute (IVO), 1988.

[21] CARL PRAY and BBARAT RAMASWAMI, *A Framework for Seed Policy Analysis in Developing Countries* Washington D.C.: International Food Policy Research Institute, 1991.

[22] TIMOTHY SWANSON, *Global Action for Biodiversity, an International Framework for Implementing the Convention on Biological Diversity* London: Earthscan, 1997, pp.73-75.

[23] JACK KLOPPENBURG, *First the Seed: The Political Economy of Plant Biotechnology 1492-2000* Madison: University of Wisconsin Press, 2004, pp.167-168.

[24] This study was conducted on 2334 biotechnology patents, which had 23,286 NPR on their front pages, see McMILLAN et al, 2000,

[25] This estimate was drawn in 1999 for all sectors concerned with biodiversity, including agriculture but also the pharmaceutical and other industries; See KATE TEN KATE and SARAH A. LAIRD, *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing* London: Earthscan, 1999, p.1.

new breeding or genetic manipulation techniques, molecular research tools, and requires colossal financial investments. However, plant improvement remains void of inherent protection mechanisms and natural lead-time contraction. Furthermore, seeds are of self-reproducing nature[26] and are accompanied by inherent dilemmas attached to the production of informational public goods[27].

As a result, regulatory action ought to be taken in order to reward research results and avoid speedy copying. To cater such needs, **intellectual property rights** in the form of temporary exclusive prerogatives were awarded to the products and processes of plant breeding. The property layers that ensued resulted on the one hand from the “emulation” of need-specific protection regimes, i.e. plant variety or breeders’ rights, mainly designed to protect stable and uniform plant varieties, and from the “accretion” or expansion of traditional patent protection scopes to cater the needs of biotechnology on the other[28]. All traditional IPR operate an intricate balance between the grant of monopoly rights and the safeguarding of the public domain, between private reward and collective good. However, both the international reification[29] and the implementation of strong IPR instruments have distorted this inherent balance for certain agrobiodiversity users, significantly yet separately raising the costs relevant to the creation and development of inventions[30]. With the adoption of the World Trade Organisation-linked Agreement on Trade Related Intellectual Property rights (TRIPS) in 1994, a **strong intellectual property paradigm** was legally reified through minimal protection standards responding mostly to the needs of molecular biology and gene technology. This paradigm, enshrined in the Agreement’s article 27§3b, has clearly helped develop knowledge on biodiversity and improved farming practices, albeit limited to a specific kind of knowledge, all the while raising new environmental and socio-economic issues. More significantly, its content and implementation have undermined and expunged existing practices of certain plant improvement actors. Great pressure has been put on conventional plant breeders relying on generous and wide-ranged biodiversity inputs (from the pool of existing domesticated seeds or from landraces), on the public research sector favouring greater public domain approaches, and at last on traditional farmers operating through informal seed exchanges. In particular, the strong property paradigm has raised new challenges to the breeders’ and researchers’ sacrosanct freedom to operate, notably because the essential research and breeding

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[26] TIMOTHY SWANSON, "The Reliance of Northern Economies on Southern Biodiversity: Biodiversity as Information," *Ecological Economics* 17, 1996: 1-8; NIELS LOUWAARS, "Controls over Plant Genetic Resources: A Double-Edged Sword," *Nature Reviews Genetics* 7, 2006..

[27] Plant genetic resources for food and agriculture in general and improved varieties in particular are indeed part of a public goods supply problem, more specifically vis-à-vis the management of the research and development process, whether acknowledging within a classical Samuelsonian approach to nonrivalry and nonexcludability, or within a broader perspective where some users may be excluded or charged for some uses of the commodities. See for instance BRUCE GARDNER, "Global Public Goods from the Cgiar: An Impact Assessment," in *The Cgiar at 31: An Independent Meta-Evaluation of the Consultative Group on International Agricultural Research*, ed. THE WORLD BANK, Washington: 2003. As for the need for regulatory intervention vis-à-vis such public goods supply problem, see SCOTT BARRETT, *Why Cooperate? The Incentive to Supply Global Public Goods* Oxford: Oxford University Press, 2007., and also INGE KAUL et al., *Providing Global Public Goods: Managing Globalization*, ed. UNITED NATIONS DEVELOPMENT PROGRAMME New York: Oxford University Press, 2003.

[28] W.R. CORNISH, "The International Relations of Intellectual Property," *Cambridge Law Journal* 52, no. 1, 1993.

[29] The notion of “reification” is understood here in the footsteps of Christopher MAY, who sees the process of legal reification as an analytical tool for the examination of social phenomenon, which views IPRs “as a political economic issue, not an arcane technical issue only for legal specialists », CHRISTOPHER MAY, "The Denial of History: Reification, Intellectual Property Rights and the Lessons of the Past," *Capital and Class* 30, no. 1, 2006., at pp.34-35.

[30] RAI, "Regulating Scientific Research: Intellectual Property Rights and the Norms of Science," *op.cit.*

exemptions have been increasingly obfuscated both in patents and plant variety right protection regimes. In parallel, farmers, smaller-scaled organic breeders and gardeners' seed exchange networks have gradually been pushed towards forced illegality with their landraces, not only through ever-widening intellectual property protection scopes, but also by stringent seed marketing regulations.

C. Self-regulatory coping strategies and emerging practices: towards the re-adjustment of the strong property paradigm and re-appropriation of the public domain

In reaction to the enactment, legal reification and implementation of a strong intellectual property paradigm, certain agrobiodiversity users have strived to preserve their public domain-oriented practices. In particular, some key social actors have built coping strategies and self-regulatory proposals in concrete networks to overcome the hindrances created by the dominant property paradigm on their plant innovation model. In the field of molecular biology, a number of companies or public initiatives have for instance set up voluntary licensing schemes to the benefit of certain actors, whether private persons with lower income or companies established in least developed countries, like in the case of the Rockefeller led "African Agricultural technology foundation", which shares patented technologies freely[31]. On another front, conventional plant breeders have reiterated numerous times their attachment to the breeders' exception in plant-related IPR. Plantum, the Dutch seed association has for instance very openly advocated an extensive approach to the exception in plant variety protection (just as to a lesser extent the European and French seed associations)[32], while the necessity of acknowledging such an exception in patent protection has even been recognised in the International Seed Federation's new 2012 Rules on Intellectual Property[33]. With regards to farmers' innovation, the United Kingdom based gardening and seed exchange network "Real Seeds" has for instance constituted itself as a private members' club in order to continue its activities aimed primarily at the conservation of agrobiodiversity and revival of heirloom vegetables, all the while avoiding unfair competition or IPR infringement claims, positioning itself clearly outside the boundaries of the quality, uniformity and productivity-seeking formal seed market.

However, these self-regulatory solutions will not suffice to rebalance the high protectionist regime. What may be needed is therefore a rebalance of exclusivity and access to agrobiodiversity related products and processes through formal legal change, broad public policies and governance initiatives. In light of increasingly constraining regulatory contexts, the social innovation practices of all agrobiodiversity users will need to be supported by adequate policy. Such support has arguably already been ignited, and its groundwork can be found in international environmental law. The different uses of agrobiodiversity, which all provide major benefits for humankind, have been regulated through global international environmental and agricultural law agreements that aim to support these practices, around the general principles of environmental equity and

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[31] DENNIS MURPHY, *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture* New York: Cambridge University Press, 2007, p.282.

[32] DUTCH BREEDERS' ASSOCIATION PLANTUM, "Position on Patent and Plant Breeders' Rights," (available at http://www.plantum.nl/english/plantum-nl/positions 2009)., and UNION FRANÇAISE DES SEMENCIERS UFS, "*Position on Innovation Protection in Plant Breeding: Requirement for Strong Protection and Possible Paths Towards a Harmonious Co-Existence of Protection Systems*", Paris, available at http://www.ufs-semenciers.org, 2011. .

[33] ISF, "*Isf View on Intellectual Property*", ISF, International Seed Federation, 2012. .

sustainability. These instruments, namely the Convention on Biological Diversity (CBD) and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) formally broadcasted the need to use genetic resources sustainably. They in parallel addressed these resources' property regime, constructed around sovereignty, traditional knowledge, farmers' rights and benefit sharing obligations. These idioms constitue both opportunities to draw a more equitable and sustainable agrobiodiversity public domain, and also significant threats to its viable constitution, if interpreted in a restrictively protective fashion. Indeed, policies have been applying an "eye for an eye" approach to protect national resources and local users, further commodifying and enclosing the informational goods used by all agrobiodiversity users, in order to counter the trends that have done so beforehand so as to support burgeoning seed industries.

D. Hypothesis and research design

The basis assumption of this thesis is that the incentives that are awarded to creativity and innovativeness should in principle enable the widest range of development and use of new genetic diversity, while ensuring equity and sustainability considerations have been duly complied with. As a legal approach focused on the adequacy of regulation vis-à-vis agrobiodiversity innovation chains, it shall operate a triangulating analysis of the exclusive rights granted over innovative or new products and processes that are part of the technological contexts of agrobiodiversity innovation, the corresponding socio-economic and technological contexts of such innovation, and at last the practices of social actors that use, conserve and improve genetic resources within the regulatory regime and in very different concrete innovation contexts. A first expected outcome of this methodology lies in the identification of situations of best and worst paradigmatic fit of the dominant interpretation of the property paradigm as applied in OECD countries vis-à-vis concrete innovation contexts and to analyse social innovations that have been developed to overcome some of the failures of the paradigm. The second indirect outcome of our approach would be to analyse potential concepts that would be a point of convergence for a broad set of social innovations, within the diversity of new emergent interpretations. This endeavour would avoid the present fragmentation between the different socio-technological contexts and their corresponding actors, for instance between mass selection and public biotechnology research, which are at first sight quite different from one another and currently not seen as building a common alternative, but which both suffer from the developmental paradigm. The pluralistic public domain appears to be such a converging concept, albeit in its different layers, whether through an extensive interpretation of the third-party user rights it concedes within exclusivity regimes, or through a broad negative construction of products and processes that do not comply with the strict conditions under which protection could be granted. In its effort to reclaim the balance between monopoly and the public domain within IPR regimes in accordance with the needs of all agrobiodiversity users, our research will be grounded on the normative practices of those actors who rely more greatly on the public domain and the availability of wild, domesticated and improved genetic material and associated knowledge. The method is embedded in the tradition of historical and sociological institutionalism, the ontology of which embraces an evolutionary stance on both formal and informal rules that govern social interaction[34]. Its efficiency stems from the

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[34] Coined chiefly from the 1990's onwards, the historical institutionalist approach strives to study institutions, whether in their formal or informal configurations, which both shape the participation of actors to particular schemes, but also their strategic behaviour towards such institutions, see SVEN STEINMO, "Historical Institutionalism," in *Approaches in*

accompanying process of understanding actors' preferences and offering the opportunity to reinforce agrobiodiversity use actors' coping strategies and emerging practices legally and through public policy.

The key objective of this thesis is to seek pathways to adjust the agrobiodiversity property paradigm starting from the coping strategies and normative practices of agrobiodiversity users who contribute to the conservation and sustainable use of agrobiodiversity while heavily relying on the public domain in their plant related technology or variety development process. Our key hypothesis is that in order to operate such an adjustment, a double constraint has to be satisfied, in that the negative consequences of the developmental paradigm need to be overcome for each category of actors of agrobiodiversity use, and that such adjustment needs to operate in a different way for farmers, conventional plant breeders, and public biotechnology or molecular biology researchers. This differentiation is attributed to the extremely diverse social, economic and technological features of plant innovation operated by these stakeholder-user groups. Consequently, drafting a unique solution to the shortcomings of the property paradigm will unescapably reduce its bearing to the support of certain politically active stakeholders. For this purpose, the preferences of all concrete actors of agrobiodiversity innovations will not be assumed exogenously, but shall be considered endogenously as well, determining what they "are trying to maximise and why they emphasise certain goals over others"[35], assuming in parallel that these preferences may fluctuate "as they continuously adapt to the changing socio-economic environment and critically (re-) evaluate common practices and established institutions when exposed to new information or ideas"[36] .

We argue that the challenge rests in outlining an array of resolutions that corresponds to the technological features of innovation operated by agrobiodiversity users groups, and will foster their activities adequately, owing to regional, national, or local needs. To this end, agrobiodiversity conservation and use stakeholders will be defined in accordance with the different socio-technological contexts of agrobiodiversity innovation they operate in, underscoring the common needs and informal social norms that bring them together. Some of these actors are, to different extents, disregarded by the strong property paradigm:

- ***Public agricultural biotechnology or molecular biology researchers*** operating upstream basic or applied research (which is thenceforth infused into breeding programmes to enable time, accuracy and aptitude gains), within publicly funded institutions, who rely on enlarged access

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the Social Sciences, ed. DONATELLA DELLA PORTA and MICHAEL KEATING, Cambridge and New York: Cambridge University Press, 2008. In this context, "institutional continuity and change (is) characterised by evolutionary processes in context-specific ways rather than by (linear) chains of independent events », J TIMO WEISHAUPT, *From the Manpower Revolution to the Activation Paradigm: Explaining Institutional Continuity and Change in an Integrating Europe* Amsterdam: Amsterdam University Press, 2011, p.28.

[35] SVEN STEINMO, KATHLEEN THELEN, and FRANK LONGSTRETH, *Structuring Politics: Historical Institutionalism in Comparative Analysis*: Cambridge University Press, 1992., especially Steinmo, Sven, and Thelen, Kathleen Ann (1992). "Historical Institu-tionalism in Comparative Politics", 1-32 (at p.9).

[36] WEISHAUPT, *From the Manpower Revolution to the Activation Paradigm: Explaining Institutional Continuity and Change in an Integrating Europe*, *op.cit.*, p.28, citing JOSH WHITFORD, "Pragmatism and the Untenable Dualism of Means and Ends: Why Rational Choice Theory Does Not Deserve Paradigmatic Privilege," *Theory and Society* 31, no. 3, 2002.

to genetic material and research tools, and who act upon informal norms of communalism and interdependence.

- ***Conventional plant breeders*** operating methodical crosses to develop stable and improved plant varieties, within private or public structures, who rely on access to a wide range of (mostly pre-characterised) plant diversity in their research and development programmes, including the historical contributions to international public agricultural research, and who are consequently sturdily attached to the public domain hedged by the breeders' exception present in intellectual property rights.
- ***Farmers, gardeners and low-input plant breeders*** operating mass selection to develop heterogeneous landrace populations, within traditional or contemporary local or smaller-scaled communities, who rely on informal norms surrounding access and exchange to seeds with the major goal of cultivating and preserving agrobiodiversity rather than commercialising new plant varieties.

To assess the impact of the IP regime on the agrobiodiversity use practices of these actors, we will first attempt to better define the boundaries of the public domain and property rights with regards to plant genetic resources and associated processes set out in traditional and currently applicable intellectual property rights instruments. Chiefly on account of the minimum standards set out by the TRIPS Agreement, the extensive approach to the allocation of rights over plant-related inventions has started in developed nations and spread to developing countries, which are growingly enacting standardised legislation. This geographical extension has however been already thoroughly studied in the literature, identifying the mismatch of the dominant property paradigm with local needs[37]. That is why our research will seek to identify the regulatory regime applicable in OECD countries, along with the contextual shortcomings created in such "advanced" plant improvement sectors where all agrobiodiversity innovation actors are actively present. By grounding our analysis in such manner, we wish to highlight that inadequacies may and do exist in different socio-technological plant innovation contexts, notwithstanding the level of economic development of a given country (a factor that will however highly influence the prioritisation of domestic regulatory objectives). Our positive law analysis will thus be mainly embedded within European Union ("EU") law, along with some midly comparative examples from the United States. Our research shall nonetheless draw arbitrarily a number of examples from around the globe to highlight existing social innovations, as well as the interesting attempts of other domestic legislators' to take international obligations, social, cultural, technological and economic considerations, including industry powerplays into account.

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[37] MİCHAEL BLAKENEY, *Intellectual Property Rights and Food Security* Oxfordshire CAB International, 2009.;LAURENCE R. HELFER, "Intellectual Property Rights in Plant Varieties: An Overview with Options for National Governments," (Rome: Food and Agricultural Organisation, 2002).; ERAN BİNENBAUM et al., *South-North Trade, Intellectual Property Jurisdictions, and Freedom to Operate in Agricultural Research on Staple Crops*: Environment and Production Technology Division, International Food Policy Research Institute ^ eWashington DC Washington DC, 2000.; PHİLİPPE CULLET, "Intellectual Property Rights and Food Security in the South," *The Journal of World Intellectual Property* 7, no. 3, 2004.; and to a certain extentMARE SARR and TİM SWANSON, "Economics of Intellectual Property Rights (Ipr) for Genetic Resources: North-South Cooperation in Sequential R and D," *International Journal of Ecological Economics and Statistics™* 26, no. 3, 2012..

Our study shall therefore start by procuring the tenets of the strong intellectual property paradigm and its enclosure mechanisms propelled by international trade law, which predominantly govern agrobiodiversity innovation today, and its implementation in the European Union (***PART I***).

Drawing on a historical and socio-technological account of plant improvement mechanisms and innovation contexts, we shall then identify the categories of actors who conserve, use and improve genetic resources, accessing proprietary and un-proprietary material or knowledge, and highlight the actors who heavily draw their inspiration, knowledge and tools from the public domain (***PART II***).

The analysis will subsequently confront the strong intellectual property paradigm with those identified actors of plant improvement, illustrating the impact of enclosure mechanisms on defined agrobiodiversity conservation and use groups, and highlighting experienced paradigmatic failures or partial deficiencies (***PART III***).

On the basis of such diagnosis and in order to analyse social innovation solutions to the prevailing failures of the strong property paradigm for each of the actor categories, we shall examine those regulatory tools carved by international environmental law that attempt to rebuild or merely reshape the public domain of agrobiodiversity (***PART IV***).

This exercise will thereon help us ponder on and gauge social organisational innovation, coping strategies and emerging actor practices which make use of the inherent flexibilities of intellectual property rights, and which reclaim through this course an ostensibly more relaxed public domain built to achieve sustainable and equitable crop improvement (***PART V***).

As the illustrations of these coping mechanisms and flexible endeabours inherently stand outside of any jurisdictional system, the adjustment solutions set out in this section will not be limited to the European Union legal order or to its existing specific agrobiodiversity user groups. The principal aim of this research is indeed to provide both agrobiodiversity user groups and domestic regulators with tools to mould regulatory tools that take the entire array of plant improvement actors and their accompanying socio-technological innovation contexts into account. Given the powers at play, especially the proven ability of certain stakeholders and agrobiodiversity users that positively benefit from the implementation of a strong and uniform property paradigm in the world seed trade, this exercise will hopefully offer roadmaps towards more balanced, contextualised and well-matched support of plant innovation and seed marketing regulation at national level.

PART I. AGROBIODIVERSITY PUBLIC DOMAIN AND ENCLOSURE : THE STRONG INTELLECTUAL PROPERTY PARADIGM

Plant improvement practices conserve, use and create agrobiodiversity, thereby triggering major benefits for humankind. They depend on the access to and use of the tangible and intangible features of genetic resources. Regulatory tools increasingly redefine dominion over the resources themselves, their components or related production processes, regulating the production of informational and biological public goods. Opportunities for the appropriation of the incorporeal features of agrobiodiversity have essentially surfaced with the development of novel market products and the growing importance of the informational components of genetic resources. Various intellectual property rights awarded to innovators have as a result restricted the public domain traditionally surrounding biodiversity[38]. IPR instruments, designed as temporary privileges awarding artificial lead-time to innovators, have expanded to the realm of living organisms. They protect and affect the plethora of actors involved in all plant improvement activities, which otherwise would face informational public goods dilemma in a context of easy reverse engineering. These temporary privileges are traditionally accompanied by inbuilt balances that compensate the grant of socially undesirable monopolies over useful innovations. Like all property endowment systems, they operate a delicate equilibrium between the benefits of enclosure and the social costs of exclusivity. This equilibrium has been notoriously reified at the international arena through the contentious enactment of Article 27§3b of the TRIPS Agreement, which solidified the inherent balance between exclusivity and open access, between monopoly rights and the public domain, arguably trumping the latter through a product development-oriented approach. Accordingly, a strong intellectual property paradigm emerged, characterised by the official advent of IPR on living organisms, layered exclusivity tools and strict market regulation linking a particular variety or technology to a specific actor, with extensive controls over the distribution of biological material in the marketplace.

For the purpose of our analysis, the informational public domain will be defined in the footsteps of James BOYLE[39], as the "outside of the intellectual property system, the material that is free for all to use and build upon"[40]. It will be approached in a broad and negative fashion, as the whole sphere of creativity and inventiveness that is not covered by individual, collective or sovereign

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[38] As we shall see in the fourth part of this study, a number of international environmental agreements have also delineated the dominion surrounding the use of biodiversity, starting from the 1983 FAO International Undertaking on Agricultural Plant Genetic Resources and the 1992 Convention on Biological Diversity. However, the property regimes carved by these instruments of environmental and agricultural law will rather be viewed within their capacity of "regime-shifting" and reclaiming a public domain that has been limited by international trade law and national regulation pertaining to intellectual property or to seed marketing, but also the correlated practice hindering the inherent balance of intellectual property structures. These agreements have indeed attempted to reshape enclosures and disclosures within a framework of sustainability, equity and interdependency, rather than innovational protection and diffusion. See LAURENCE R. HELFER, "Regime Shifting: The Trips Agreement and New Dynamics of Intellectual Property Lawmaking," *Yale Journal of International Law* 29, 2004.

[39] Providing a definition for the public domain is no easy task and has been a constant effort of many eminent scholars, such as James BOYLE, who argues that its definitions ought to be manifold and reflect its elasticity, as there are many public domains, see JAMES BOYLE, "The Second Enclosure Movement and the Construction of the Public Domain " *Law and Contemporary Problems* 66, 2003. The restrictive definition of the public domain as favoured in this research however does not limit its reach to an "affirmative defence against allegations of infringement", but also retains a constructive aspect; see LANGE, "Reimagining the Public Domain," *op.cit.*

For an overview of different definitions of the public domain, see also SAMUELSON, "Enriching Discourse on Public Domains," *op.cit.*, where the author surveys at least thirteen different approaches to the public domain.

[40] BOYLE, "The Opposite of Property?," *op.cit.*

rights. This sphere will embody the domain purposefully left outside the reach of recognised exclusive rights, as a result of the limits put on the realm and protection scope awarded to right-holders, or through the in-built diffusion mechanisms that may take for instance the form of liability rules[41]. As we envisage it, the informational public domain regroups the whole array of public domains created either structurally and negatively, the ontological public domain for which no exclusive rights have been awarded, just as it encompasses the regulatory public domain, purposefully set outside the boundaries of exclusive appropriation by laws and regulations such as subject-matter exclusions, the temporal public domain that is constituted at the end of protection terms, and last but not least, the assented public domain, where rightholders have purposefully renounced to exclusivity over their creations or inventions[42].

In order to exhaustively portray the enclosures and disclosures that fence the agrobiodiversity public domain that finds its origins in intellectual property law, we shall first delve upon the inherent balance that is traditionally built by these property rights, between the urge to protect innovations on the one hand and the concern to diffuse them on the other *(Chapter 1).* After having converged on the international reification and extension of agrobiodiversity intellectual property rights into a virtually unilaterally imposed strong paradigm *(Chapter 2),* we shall finally appoint further considerations to the exact substance of prerogatives and obligations deriving from plant-related intellectual property rights, i.e. mainly patents and plant variety rights in the European Union *(Chapter 3).*

[41] In our analysis, we understand liability rules as hybrid approach between the traditional doctrine regarding them as protection mechanisms stemming from the law of torts that involve a collective decision as to the value of the entitlement (GUIDO CALABRESI and DOUGLAS A. MELAMED, "Property Rules, Liability Rules and Inalienability: One View of the Cathedral," *Harvard Law Review* 85, no. 6, 1972.), and those addressing purely bilateral bargaining based *ad hoc* rules that allow the concerned party to "take now and pay later" (ROBERT P. MERGES, "Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations " *California Law Review* 84, no. 5, 1996.). But liability regimes have also been viewed and studied as a mixture of these two approaches. Such mixtures can take the form of stand-alone entitlements that offer alternatives to purely exclusive property rights, through either unwound intellectual property entitlements or mandatory registration processes, which generally include automated licenses without the power to exclude and a specific modality of the "take now, pay later" rules (JEROME H. REICHMAN, "Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation," *Vanderbilt Law Review* 53, no. 6, 2000.). Building upon this latter work, we argue that this last type of liability regime can also be carved within codified yet unwound intellectual property entitlements, where different trigger points are established ex ante for compensation through prior user rights. That is why we consider that the defence mechanisms that have been built into IPR systems to protect follow-on users against infringement claims within a classical property-based entitlement regime also constitute liability rules that determine in effect allocations and split asset entitlements (DAN L. BURK, "Muddy Rules for Cyberspace," *Cardozo Law Review* 21, 1999.). They are in this sense "prior user rights" or "codified liability rules" within a property regime, where either a compulsory license is set at zero royalty, or a trigger for compensation is defined ex ante by the legislator ("Critical Analysis: Property Rules, Liability Rules and Molecular Futures," in *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Regimes*, ed. GEERTRUI VAN OVERWALLE, Cambridge: Cambridge University Press, 2009.).

[42] DUSOLLIER, "Le Domaine Public: Garant De L'interêt Public En Propriété Intellectuelle?," *op.cit.*, pp.121-123.

1. CHAPTER 1: BALANCING THE PUBLIC DOMAIN IN INTELLECTUAL PROPERTY RIGHTS ON LIVING ORGANISMS OR PROCESSES

The stimulus of scientific knowledge and technological change is indispensable to mould technical solutions to the problems observed on farm, in shelves or all other stages of the food production or distribution mechanisms. However, the process of innovation itself does not solely rely on scientific progress. It also heavily depends on the institutions surrounding, endorsing or levelling technological improvements[43]. Relying on the premise that market based licensing negotiations do lead to social net benefit, by producing the optimum quantity and quality of products at optimum prices[44], the main rights and obligations that have been shaped around innovation aim at **granting artificial lead-time to innovators**, especially those who develop easily reverse-engineered products. Improved seeds in this context embody inherent obstacles to the natural procurement of lead-time by those actors having invested colossal financial and human means to research and development activities, notably on account of the seeds' self-reproducing nature[45]. They remain void of inherent protection mechanisms strong enough to reward research results and avoid speedy copying. Furthermore, the public good character of the information generated through the characterisation of genetic resources and all subsequent research and development activities carried out with and on these resources, generating further diversity within the global agricultural gene pool, also demands for regulatory action in order to maintain adequate production levels[46]. In light of these features, regulatory intervention to grant artificial monopoly rights is deemed inevitable to foster innovation and thus promote sustainable agricultural production, as well as economic and human development. Institutional frameworks drive social and economic development[47]. Intellectual property rights are in this sense viewed as the quanta of innovation, as highlighted by Adam HOLBROOK[48].

Prior to the end of the 20th century, IPR instruments had nonetheless traditionally received relatively little consideration in the world of agricultural biodiversity, enabling public and private

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[43] On the relationship between technological innovation and institutional change, especially with regards to regulatory change, technological systems and thus the institutional dimensions of knowledge through an innovation system approach, see notably CHARLES EDQUIST, *Systems of Innovation: Technologies, Institutions and Organisations*, Science, Technology and the International Political Economy Series: Routledge, 2005 (second edition).; and also more specifically DAVID SUNDING and DAVID ZILBERMAN, "The Agricultural Innovation Process: Research and Technology Adoption in a Changing Agricultural Sector"," *Handbook of Agricultural Economics* 1, no. 1, 2001: 207-261.

[44] GARY LEA and PETER HALL, "Standards and Intellectual Property Rights: An Economic and Legal Perspective," *Information Economics and Policy* 16, no. 1, 2004: p.72.

[45] SWANSON, "The Reliance of Northern Economies on Southern Biodiversity: Biodiversity as Information," *op.cit.*, 1-8.

[46] Plant genetic resources for food and agriculture in general and improved varieties in particular are indeed part of a public goods supply problem, more specifically vis-à-vis the management of the research and development process within a classical Samuelsonian approach to nonrivalry and nonexcludability, or within a broader perspective where some users may be excluded or charged for some uses of the commodities. See for instance GARDNER, "Global Public Goods from the Cgiar: An Impact Assessment," *op.cit.*As for the need for regulatory intervention vis-à-vis such public goods supply problem, see BARRETT, *Why Cooperate? The Incentive to Supply Global Public Goods*, *op.cit.*, and also KAUL et al., *Providing Global Public Goods: Managing Globalization*, *op.cit.*

[47] ANDREW HALL et al., "From Measuring Impact to Learning Institutional Lessons: An Innovation Systems Perspetive on Improving the Management of International Agricultural Research," *Agricultural Systems* 78, no. 2, 2003: pp.213-241; D.J. SPIELMAN, "A Critique of Innovation Systems Perspectives on Agricultural Research in Developing Countries," *Innovation Strategy Today* 2, no. 1, 2006: pp.41-54.

[48] ADAM HOLBROOK, "Are Intellectual Property Rights Quanta of Innovation?," in *The Role of Intellectual Property Rights in Biotechnology Innovation*, ed. DAVID CASTLE, Cheltenham: Edward Elgar, 2009, pp.24-36.

breeders alike to freely use, improve and commercialise genetic material and new plant varieties, without fear of third party infringement suits[49]. In contrast, the national and international agricultural research centres having led the Green Revolution[50] today face an "increasingly pervasive ownership of intellectual property rights", which require gleaming new caution in research operations[51]. These rights have been assigned through various international agreements and national laws, which have been constructed around private and exclusive rights regimes, where “individuals can exclude other from the benefit of their property”, rather than common property approaches, where the collective body’s members each have separate entitlements but “no one user has the right to abuse or dispose of the property”[52]. The limited supply of genetic resources and the growing importance allocated to their informational character, along with the desire to provide incentives for their commercial exploitation, have all influenced the choice of private property against common property regimes. Exclusive prerogatives are however a double-edged sword; as they may enhance “dynamic efficiency” through the incentives awarded for innovation, while also may potentially undermine “static efficiency” by placing too much market power in the hands of the innovator[53]. In *Mayo Collaborative Services v. Prometheus Laboratories,* the United States Supreme Court brilliantly illustrated the delicate thread upon which the delineation of protection and exclusivity stand in all property regimes, be it copyright, patent or plant variety protection, as these regimes should be understood as

> “a two-edged sword”: while “the promise of exclusive rights provides monetary incentives lead to creation, invention, and discovery, […] that very exclusivity can impede the flow of information that might permit, indeed spur, invention”[54].

1.1. Why Balance Protection and Diffusion? Channelling the appraisal of public domains

Private property rights are carved around protection rules, which grant exclusive monopoly rights[55] to an individual as an incentive to create, innovate or market a product that is expensive to produce and easy to replicate. They are nonetheless also accompanied by diffusion rules, which compensate for the social cost of monopoly and preserve the public domain by minimising the restrictions surrounding the use of proprietary products by third parties, whether follow-on inventors or buyers. In all property endowment systems, an intricate balance needs to be struck between the **individual and collective good.** Between the economic and ecological benefits of crop improvement research on one hand and its social costs on the other. It needs to weigh in

[49] MICHAEL BLAKENEY, "Trips and Agriculture," in *ADB Intensive Course on the WTO TRIPS Agreement* (Bangkok, 24-28 November2003).
[50] The Green revolution refers to the development and dissemination of improved uniform cultivars, at first mostly by public agricultural research institutes, see Chapter 5 of this study.
[51] JOHN BARTON and PETER BERGER, "Patenting Agriculture," *Issues in Science and Technology* 17, no. 4, 2001: p.44.
[52] PHILIPPE CULLET, "Property-Rights Regimes over Biological Resources," *Environment and Planning C: Government and Policy* 19, 2001: p.652.
[53] LEA and HALL, "Standards and Intellectual Property Rights: An Economic and Legal Perspective," *op.cit.,* p.67.
[54] United States Supreme Court, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.,* 566 U.S, 132 S. Ct. 1289, 1304 (2012).
[55] It has been successfully argued that intellectual property rights do not grant monopoly rights in their economic understanding. Indeed, the ability of IPR holders to extract monopoly rents will depend on market factors, and not just legal endowment, considerably reducing the price that could be obtained in a traditional economic monopoly. See EDMUND KITCH, "Patents: Monopolies or Property Rights?," *Research in Law and Economics* 8, 1986. For the purpose of this study however, we shall understand monopoly rights through a legal stance of exclusivity and individual control over the fate of intangibles, just as James BOYLE, "The Opposite of Property?," *op.cit.,* p.8.

private reward on the one hand, granted through rules that protect innovations, and public interest on the other, guaranteed by rules enabling the diffusion of innovations[56]. The former protection rules delineate the rights awarded to the titleholder, whether as rights to exclude others from using the invention, or rights to authorise certain uses. The latter diffusion mechanisms allow third parties to have access to the protected intangibles in certain circumstances, whether these are statutorily determined (such as publication requirements or formal use exceptions) or need to be negotiated further in a bilateral fashion. The award of exclusive rights over creative works or innovative products should, within a wider perspective of global social welfare and equity, always stand conditional to a fair amount of opportunities to benefit from the creation or innovation itself, and from the natural resources used in the process. It should stand conditional to the creation and maintenance of a sound public domain, fenced by both the scope of protection delineating the object of protection and extent of monopoly rights, but also by the scope of diffusion mechanisms as well, since these are inherently designed as compensation for legal exclusivity. Both protection and diffusion should thus be seen as means to define the contours of the public domain in intellectual property rights, building both a "commons that set off against the fences that delimit the interests of individual rights holders" in James BOYLE's understanding, and also a "sanctuary conferring affirmative protection against the forces of private appropriation that threaten [individual creative] expression" in David LANGE's understanding[57]. The prerogative allocation game is in its essence anchored within the greater debate around

> "the scope of the public domain and the extent of exclusive private rights in information, [at the centre of the] battle over the shape of institutional ecology [confronting two competing] modes of information production", the increasingly industrial model and the non-proprietary production scheme[58].

If **imbalances exist between protection and diffusion rules**, the incentives to create or innovate found in ownership regimes bear the risk of transforming into "teleologies of intellectual property maximalism"[59]. It flares the threat of under-producing public goods caused by "**hyperownership**"[60], surrounding the access to a single genetic resource with numerous actors with diverging rights and obligations. In the state where agrobiodiversity stands today, both legislation and practice corroborate the cumulative recourse to various IPR tools, mostly in the

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[56] The diffusion of innovations shall in this regard merely be understood in a legal perspective, within the context of an existing intellectual property right setting the boundaries and opportunities for the use of the innovation by third parties. It will deliberately set aside the commonly use sociology theory pertaining to the diffusion of innovations in terms of general population use, and the spread of inventions throughout cultures and time, epitomised by the colossal work of Everett ROGERS from 1962 onwards, establishing a distinction between early adopters, early and late majorities and laggards in the adoption of innovations (EVERETT ROGERS, *Diffusion of Innovations* New York: Free Press, 2003 (5th edition).

[57] Both definitions can be found in David LANGE's essay responding the James BOYLE's early comment on his work "Recognising the Public Domain", see LANGE, "Reimagining the Public Domain," *op.cit.,* at pp. 463-466. (referring to "Recognizing the Public Domain," *Law & Contemporary Problems* 44, 1981.

[58] YOCHAI BENKLER, "Through the Looking Glass: Alice and the Constitutional Foundations of the Public Domain," *Law & Contemporary Problems* 66, no. 1-2, 2003. Where the author confronts the different means to produce cultural goods, and highlights the inherent tensions of copyright law between exclusive rights, which "make institutional conditions more conducive for some approaches to information production" and the freedom to read and express oneself.

[59] BOYLE, "The Second Enclosure Movement and the Construction of the Public Domain " *op.cit.*, p.42.

[60] SABRINA SAFRIN, "Hyperownership in a Time of Biotechnological Promise: The International Conflict to Control the Building Blocks of Life," *The American Journal of International Law* 98, no. 4, 2004.

form of patents and plant variety rights[61]. Absolute certification requirements which link a single applicant to distribution rights pertaining to a particular plant variety[62], without any time limitations, may also be viewed as an additional appropriation tool, as "quasi intellectual property rights" that in practice reinforce those exclusive titles that are awarded on stricter conditions and rationale[63]. The impact of such seed certification mechanisms is heightened by the fact that they are designed to cover all commercialised plant varieties, whether these are protected through IPR titles or not, questioning whether quasi-IPR have actually become even stronger than IPR. At any rate, maximalist enclosure approaches are only (or mainly) concerned with the low cost of (illicit) reproduction of the creation, pushing for stronger rights upstream. They sturdily disregard negative counter-effects vis-à-vis downstream production opportunities, which can mainly be caused by the restrictive limits and high costs surrounding the access to raw material, creating an under-producing "anti-commons" landscape[64]. The ultimate challenge in this debate comes forth by the disparity between marginal private returns created through monopoly rewards and the social returns, which should, but in reality may not, coincide. The assessment of transaction costs and distributional effects of exclusive rights over informational resources accordingly constitute the greatest unsolved balancing puzzle in doctrinal debates both in economic, legal and political theory. Indeed, prudence and even hostility over the ability of strong patent protection to foster innovation dates back to the 1960's, even before its reification in the international trade order[65]. Stemming from non-governmental organisations but also from academic circles, the main apprehensions vis-à-vis appropriation underline the fundamental importance of the diffusion of knowledge for progress, research and innovation, which finds itself battered against the red tape of intellectual property systems. Critics have not only spurred over the extensional tendencies of intangibles' appropriation regimes, but have also been expressed over their mere existence and their globalisation[66]. While proponents of enclosure ensure that "private property saves lives"[67]

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[61] The regulatory framework surrounding such cumulative opportunities shall be studied in Chapter 3 of this study, while the dominant practices shall be elaborated through various examples shaping this research's Chapters 7, 8 and 9, analysed in their socio-technological innovation contexts.

[62] This applicant may not necessarily be the owner of the variety in terms of intellectual property, but rather corresponds to the entity possessing the variety's distribution rights and maintenance obligations, often times dubbed "the maintainer" in certification or registration forms. See Chapter 2.1. of this study.

[63] This concept was chiefly developed in the field of database protection, copyrights and studies focusing on information society, where technical means have been considered to form "quasi-intellectual property", where "owners" capture the new uses of the protected data or innovation through technical means. Examples include online data uses, web servers or golf handicap systems like the proprietary nature granted to the PGA Tour's real-time online scoring system, MARK LEMLEY, "Property, Intellectual Property and Free Riding," *Texas Law Review* 83, 2004-2005: pp.1044-1045. The term "quasi intellectual property" has also been used where technological constraints appeared as a distinct source of rules for information flows, as the background of so-called "Lex Informatica", see JOEL R. REIDENBERG, "Lex Informatica: The Formulation of Information Policy Rules through Technology," ibid.76, no. 3, 1998: pp.553-594.

[64] The tragedy of the anticommons and the underuse caused by the multiplicity of exclusive rights to exclude has been demonstrated by Michael A. HELLER through the framework of post-socialist transition economies, MICHAEL HELLER, "The Tragedy of the Anticommons: Property in the Transition from Marx to Markets," *Harvard Law Review* 111, no. 3, 1998. The term has been since then reprised numerous times.

[65] F. MACHLUP, "*An Economic Review of the Patent System*", Study of the Subcommittee on Patents, Trademarks, and Copyrights of the Committee on the Judiciary, Washington, DC 1958.

[66] For critics over the mere existence of the patent systems through an examination of the actors reaping the benefits of IPR protection and the costs incurred through its establishment and enforcement, see STUART MACDONALD, "Exploring the Hidden Costs of Patents," in *Global Intellectual Property Rights: Knowledge, Access and Development*, ed. PETER DRAHOS and RUTH MAYNE, New York: Palgrave MacMilan, 2002, 13-39. For critics of the system's extension and internationalisation, see SUSAN K. SELL, *Private Power, Public Law: The Globalisation of Intellectual Property Rights*, Cambridge Studies in International Relations No.88 Cambridge Cambridge University Press, 2003.; REBECCA S. EISENBERG, "Bargaining over the Transfer of Proprietary Research Tools: Is This Market

and also safeguards appropriate research and development investment, others assert that limited monopolies could "impede follow-on innovation and create barriers to entry"[68].

Provisional privileges granting extended control over different components of agricultural biodiversity have been steadily invading crop improvement chains. They have been viewed as an important driver of innovation and open information, mostly based on the theory of incomplete capture of the social value of information commons[69]. By maximising economic utility and creating a market for knowledge and information goods, intellectual property rights cater the need for social efficiency in the allocation of resources, ensuring that truly valuable information goods are created[70]. However, they may also be critically viewed as "a grab bag of rights, powers, privileges and immunities held together by nothing stronger than nominalism"[71], or as a reification process "imposing duties, restricting freedom and inflicting burdens" on individuals[72]. Notwithstanding inherent notional disputes, all justifications of IP monopoly adopt various degrees of social justice and equity considerations. They all unequivocally support the essential need for balance in the recognition of exclusive rights. Whether rooted in the recognition itself of rights, or on their implementation by rightholders, numerous limits surround industrial property titles[73]. Temporary privileges exceptionally procure exclusive rights over physically un-appropriable intangibles, but as compensation, they also constrain monopoly rights in time, and provide additional conditions or exceptions ensuring the innovation or creation's use in specific circumstances. The greatest bargain over the control of living organisms is struck between the extent of enclosure and reach of disclosure in intellectual property rights and other forms of proprietary or semi-proprietary control. And the greatest difficulty in this bargain stems from the nature of the good itself, as a private good that produces tangible and informational public goods with intergenerational and interregional dimensions[74].

Failing or Emerging?," in *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Information Society*, ed. ROCHELLE COOPER DREYFUSS, DIANE L. ZIMMERMAN, and HARRY FIRST, Oxford: Oxford University Press, 2001, 223-249.

[67] Indeed, the main IPR proponent argument declares that it is only through an extension of the reach of private property rights that the State may "guarantee the kind of investment of time, ingenuity and capital necessary to produce new drugs or therapies", or to feed the world, using the expression favoured by BOYLE, "The Second Enclosure Movement and the Construction of the Public Domain " *op.cit.,* pp.37 and 39-40. For a specific address of the instrument of patent protection, see the section "the Dark Side of Patents" in ADAM JAFFE and JOSH LERNER, *Innovation and Its Discontents: How Our Broken Patent System Is Endangering Innovation and Progress, and What to Do About It* Princeton: Princeton University Press, 2004, pp.56-77.

[68] REICHMAN, "Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation," *op.cit.,* 1743-1798 (at p.1743).

[69] R. POLK WAGNER, "Information Wants to Be Free: Intellectual Property and the Mythologies of Control," *Columbia Law Review* 103, no. 4, 2003: pp.995-1034.

[70] The most prominent figure of such traditional "allocative" justification is Harold DEMSETZ, "Towards a Theory of Property Rights," *American Economic Review* 57, 1967., and "Information and Efficiency: Another Viewpoint," *Journal of Law and Economics* 12, no. 1, 1969.

[71] BOYLE, "The Second Enclosure Movement and the Construction of the Public Domain " *op.cit.,* p.68.

[72] J. WALDRON, "From Authors to Copiers: Individual Rights and Social Values in Intellectual Property," *Chicago-Kent Law Review* 68, 1993: p.862.

[73] GEERTRUI VAN OVERWALLE, "L'interêt Général, Le Domaine Public, Les Commons Et Le Droit Des Brevets D'invention," in *L'interêt Général Et L'accès À L'information En Propriété Intellectuelle*, ed. MIREILLE BUYDENS and SÉVERINE DUSSOLIER, Bruxelles: Bruylant, 2008.

[74] PABLO B EYZAGUIRRE and EVAN M DENNIS, "The Impacts of Collective Action and Property Rights on Plant Genetic Resources," *World Development* 35, no. 9, 2007., p.1490.

1.2. Why protect? Private reward, innovation incentives and the tragedy of the commons

Having started as **censorship tools and privileges distributed by the realm** in order to finance warfare or other pursuits, intellectual property rights are today justified either on utilitarian grounds as a means to foster innovation and thus economic growth, as a Lockean natural right linked to the right to liberty, or rather anchored around Rawlsian theories of justice[75]. Fiery doctrinal debates have surrounded the **justification, enforcement and internationalisation of intellectual property rights**. Ownership, defined as the "sum of duties, privileges and mutualities which bind the owners to the object and to each other"[76], can be understood through different approaches. Within a traditional utilitarian approach, the legitimacy of intellectual protection stems from the necessity to maximise net social welfare. Here balance should be struck between the stimulation of creative endeavours through the recognition of exclusive rights on the one hand, and the widespread enjoyment of creative or innovative products by tools offsetting overly monopolistic tendencies on the other[77]. Another justification stems from Lockean labour theory, which asserts that the addition of labour into common resources validates the recognition of natural exclusive property rights as long as "enough and as good" resources are left "in common to others"[78]. Other rationale include the personality and human needs theory inspired by the likes of Hegel and Kant, whereby highly expressive intellectual activities ought to be formally recognised and valued. The "social planning" theory considers that loose intellectual property rights are needed and can be used to create a robust and pluralist society[79]. In economic theory, property rights are traditionally viewed as means to internalise the external costs and benefits conferred to a party through others' actions, in order to fully capture the social value of one's action and thereby grant optimal incentives to act[80]. In this context, intellectual property rights create an "artificial scarcity through temporary monopoly rights granted by the state as an incentive to fuel innovations that are in the interest of the public"[81]. Regardless of the wide array of justifications that surround intellectual property prerogatives[82], two main elements of plant innovation lay in the heart of their challenging parallel enclosure and disclosure needs, i.e. their informational public good character and the ease of reverse engineering.

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[75] PETER DRAHOS, *A Philosophy of Intellectual Property* Burlington: Ashgate, 1996.

[76] This assertion was made by Bronislaw MALINOWSKI, studying understandings of property in primitive societies through the lens of legal anthropology; see *Crime and Custom in Savage Society*, (Kegan Paul, London, 1926), p.21.

[77] For a very comprehensive account of the different approaches to the justification of intellectual property rights, including the utilitarian viewpoint, see WILLIAM FISHER, "Theories of Intellectual Property," in *New Essays in the Legal and Political Theory of Property*, ed. STEPHEN E. MUNZER, New York Cambridge University Press, 2001, 168-200; DRAHOS, *A Philosophy of Intellectual Property*, *op.cit.*; and also EDWIN C. HETTINGER, "Justifying Intellectual Property," *Philosophy and Public Affairs* 18, no. 1, 1989: 31-52.

[78] For a more detailed account of this natural-rights based theory of property, see SEANA V. SHIFFRIN, "Lockean Arguments for Private Intellectual Property," in *New Essays in the Legal and Political Theory of Property*, ed. STEPHEN E. MUNZER, New York Cambridge University Press, 2001, 138-167.

For proponents of such theory, see LAURENCE E. BECKER, "Deserving to Own Intellectual Property," *University of Chicago-Kent Law Review* 68, 1993: 609-629.; and ADAM MOORE, "Toward a Lockean Theory of Intellectual Property," in *Intellectual Property,*, ed. ADAM MOORE, Lanham: Rowman and Littlefield, 1997, 81-103.

[79] For this last approach close to utilitarianism, see FISHER, "Theories of Intellectual Property," *op.cit.,* pp.172-173.; or NEIL NETANEL, "Copyright and a Democratic Civil Society," *Yale Law Journal* 106, 1996: 283-387.

[80] This traditional approach stems from the work of Harold DEMSETZ, "Towards a Theory of Property Rights," *op.cit.*

[81] S. PICCIOTTO, "Private Rights Vs. Public Interests in the Trips Agreement," *Proceedings Of The Annual Meeting of the American Society of International Law* 97, 2003.

[82] Faced by different forms of IPR tools and the different values and needs surrounding their justification, there is a need to assess the competing moral values to factual elements; see DB RESNIK, "A Pluralistic Account of Intellectual Property," *Journal of Business Ethics* 46, no. 4, 2003.

1.2.1. __Informational public goods__

Intellectual property rights do not appoint their affiliated bundle of rights and prerogatives on physical or tangible objects, but rather target "intellectual creations as such, [applying] to pieces of knowledge or information that belong to a special category of goods called 'public goods'"[83]. Seeds embody an inherent duality, as they are not only commercial commodities in their own right, but they also constitute an instrument for technology transfer through their **informational public good** nature[84], which farmers and breeders alike seek to improve daily. First and foremost, their cultivation produces numerous public goods, including but not limited to ecosystem resistance and resilience increases, or the maintenance of cultural preferences[85]. Seeds are not only the tangible inputs for agricultural production or tangible outputs of research and development, they also directly contain knowledge that represents the key inputs for further R&D for the titleholder, licensees or third parties, as potential sources of innovation. Science-based controlled plant breeding and the subsequent support it received from molecular biology have heightened the dual reality of plant genetic diversity[86]. Plant breeding has indeed become an increasingly knowledge-based activity. The informational component of agricultural biodiversity has become both the input and the output of its production process. The information generated through the characterisation of genetic resources and all subsequent research carried out on and with these resources, retains the nature of a public good, being purely non-rival and partially non-excludable once it is produced, thus requiring regulatory involvement in order to maintain adequate production levels[87]. **Information flows indeed suffer from inherent uncertainty and indivisibility paradoxes,** since information's value cannot be determined without acquiring it, which can nonetheless be done without or with very little cost[88], and that the "very use of information in any productive way is bound to reveal it"[89].

These paradoxes create bottlenecks for the optimal allocation of resources, as information becomes a commodity that cannot be simply sold on the open market without prior negotiation. They drag an information use monopoly in the hands of the original possessor that is in reality socially inefficient, having contributed very little to the development of such information, or even perhaps not at all[90]. Vis-à-vis public goods, intellectual property rights have often been seen in economic theory as a means to escape what has been commonly referred to as **the "tragedy of the commons",** ever since the publication of the ground-breaking article by the same name[91]. The

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[83] NICOLAS BRAHY, "The Property Regime of Biodiversity and Traditional Knowledge: Institutions for Conservation and Innovation" (Université Catholique de Louvain, 2008), p.21.
[84] NIELS LOUWAARS, *Seed Policy, Legislation and Law: Widening a Narrow Focus* New York: The Haworth Press, 2002.
[85] EYZAGUIRRE and DENNIS, "The Impacts of Collective Action and Property Rights on Plant Genetic Resources," *op.cit.*, p. 1490.
[86] See Chapters 5 and 6 for an account of technological strides that have allowed and amplified such reverse-engineering capabilities.
[87] BRUCE GARDNER and W. LESSER, "International Agricultural Research as a Global Public Good," *American Journal of Agricultural Economics* 85, no. 3, 2003.; BARRETT, *Why Cooperate? The Incentive to Supply Global Public Goods*, *op.cit.*; and KAUL et al., *Providing Global Public Goods: Managing Globalization*, *op.cit.*
[88] SIVARAMJANI THAMBISETTY, "Patents as Credence Goods," *Oxford Journal of Legal Studies* 27, no. 4, 2007.
[89] K.J. ARROW, "Economic Welfare and the Allocation of Resources for Invention," in *Rate and Direction of Inventive Activity*, ed. R.R. NELSON, Princeton: Princeton University Press, 1962, p.615.
[90] "Economic Welfare and the Allocation of Resources for Invention," in *Rate and Direction of Inventive Activity*, ed. R.R. NELSON, Princeton: Princeton University Press, 1962, pp. 609-619, notably at p.614.
[91] GARRETT HARDIN, "The Tragedy of the Commons," *Science* 162, 1968: 1243-1248.

grant of ownership is to be viewed as an attempt to solve the so-called 'free-rider' problem, whereby no sufficient incentive to contribute to protection or creation efforts would exist if the enjoyment of these efforts' benefits were not to be restricted, hampering at length with the production and supply of the public goods[92]. International regulation has exponentially spurred in fields related to the 'global commons', whose traditional *res nullius* status (and the consequent absence of private appropriation) seemed to have been slowly shelved away in favour of the concession of jurisdiction, sovereignty and property over such resources and their intangible content. This development has been compared to the '**enclosure movement**', which established private land property through fencing and regulatory tools[93]. The constriction of the "public domain", whether defined as those materials not subject to material or intellectual appropriation (within a characterisation effort), or those owned by the public (within a more general property approach)[94], was considered to be the only means for efficient management of land, but also informational resources, such as genetic resources. Exclusive prerogatives that surround agrobiodiversity therefore stem from the "classical" public goods problem that is inherent to the management of PGRFA[95].

1.2.2. <u>Reverse engineering and the grant of artificial lead-time</u>

Owing to the technological developments infused into crop improvement by genetics and genomics science, seeds cannot today be merely viewed as inputs for agricultural production. Genetic resources also represent the key input of agricultural research and development activities, as a potential source of innovation. Both Schumpeterian creative destruction and biology-grounded "adaptative destruction" theories call in this context for innovative response mechanisms, because

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[92] For a brief overview of public goods' inherent dilemmas; see KAUL, GRUNBERG, and STERN, "Defining Global Public Goods," *op.cit.,* 2-19.

[93] BOYLE, "The Second Enclosure Movement and the Construction of the Public Domain " *op.cit.,* 33-74., who reveals that the analogy between the traditional enclosure movement regarding private property (through fencing) and the "second" enclosure movement regarding the intellectual appropriation of " the commons of the mind" has been made by numerous scholars. These include but are not limited to Benjamin KAPLAN ("An Unhurried View of Copyright: Proposals and Prospects," *Columbia Law Review* 66, no. 5, 1966: 831-854.), Jerome H. REICHMAN and Pamela SAMUELSON ("Intellectual Property Rights in Data?," *Vanderbilt Law Review* 50, 1997: 51-166.), Yochai BENKLER ("Free as the Air to Common Use: First Amendment Constraints on Enclosure of the Public Domain," *New York University Law Review* 74, no. 2, 1999: 354-446.), David LANGE ("Recognizing the Public Domain," *op.cit.,* 147-178.), Christopher MAY (*The Global Political Economy of Intellectual Property Rights: The New Enclosures* Taylor & Francis2000., David BOLLIER (*Silent Theft: The Private Plunder of Our Common Wealth* New York: Taylor & Francis, 2003. and Keith AOKI (KEITH AOKI, "Neocolonialism, Anticommons Property and Biopiracy in the (Not So Brave) New World Order of International Intellectual Property Protection," *Indiana Journal of Global Legal Studies* 6, 1998-1999: pp.11-58.

[94] For the typical or more traditional approach to the concept of the public domain, see BOYLE, "The Second Enclosure Movement and the Construction of the Public Domain " *op.cit.* For a property- driven approach to the public domain, see TYLER OCHOA, "The Origins and Meanings of the Public Domain," *University of Dayton Law Review* 28, 2002-2003: 215-268., and also CHRISTINE GALBRAITH, "A Panoptic Approach to Information Policy: Utilising a More Balanced Theory of Property in Order to Ensure the Existence of a Prodigious Public Domain," *Journal of Intellectual Property Law & Practice* 15, no. 1, 2007: 1-38 (esp. 25 onwards). Even though slightly different, both approaches reveal the constitutional dimensions of the public domain, through the appraisal of public ownership and its irrevocable nature.

[95] The grant of exclusive monopoly rights to informational components is naturally not the sole regulatory and institutional solution to this public goods problem and the anti-commons tragedy that ensues, other intermediary responses have been successfully drawn up, especially on account of the work of Elinor OSTROM (ELINOR OSTROM, *Governing the Commons: The Evolution of Institutions for Collective Action*: Cambridge university press, 1990; *Understanding Institutional Diversity*: Princeton University Press, 2009. Some roadmaps shall be to a certain extent studied in the adjustments presented in Part V of this study.

of the too-rapid obsolescence of commercial or ecological successes, which disallow market actors to "stand still"[96]. Continuous innovation is thus an imperative necessity for crop improvement and indirectly, food security[97]. The inherent feature of agricultural genetic resources that allows for the accelerated selection and improvement of varieties, i.e. the biological transfer of traits or desirable characteristics by sexual reproduction, may thus very well act against the creation and dissemination of this new genetic diversity's potential social and environmental benefits. **Reverse engineering** often proves too easy in the world of plant breeding, since competitors have an unfettered ability to appropriate the fruits of costly investment through merely trivial efforts[98]. Therefore, the developer of those innovations who continues to significantly contribute to social welfare, sustainable or more productive agricultural production, may actually be quickly driven out of the market through the sale of the same or excessively similar products at considerably lower prices. Their competitors indeed need not recoup substantial research costs but rather merely need to recover the trivial duplication expenditure before commercialising "copied" or "excessively inspired" plant varieties.

Science-based and investment-heavy crop genetic improvement activities fall thus unfortunately short in terms of **natural lead-time contraction**. Reverse engineering of plant-related innovations indeed remains simpler than most other technologies and has become significantly easier through the development of biotechnological tools enabling scientists to understand and reach organisms at their barest levels[99]. Molecular biology has rendered the resort to plagiaristic breeding less costly and time-consuming, as varieties can be screened and "opened" much more easily than ever. Agrobiodiversity innovation thus remains void of inherent protection mechanisms strong enough to reward research results and avoid speedy copying, with the notable exception of hybrids, where saved seeds do not perform as well as the original seed released by the breeder. Especially in the case of self-pollinating crops where hybrids have generally been less developed, "a small sample of a new variety can be multiplied or bulked up in a short time at a low cost"[100]. The benefits generated by investments towards research and development activities in controlled plant breeding are are a result usually un-appropriable, or if they are, their collection remains very inexact, threatening to lead towards sub-optimal levels of investment without regulatory intervention[101]. **Artificial lead-time** thus needs to be awarded to initial product developers by regulatory tools in order to ensure the production of agrobiodiversity innovations that are socially important and generate public goods. Such lead-time has traditionally been conferred through the recognition of exclusive privileges defining one's control over the innovation's use and re-use conditions. The traditional economic defence of intellectual property rights builds upon such premise, acknowledging that in their absence, "inventions or creations with potentially great social benefit

[96] TIM GOESCHL and TIMOTHY SWANSON, "*Endogenous Growth and Biodiversity: The Social Value of Genetic Resources to Research and Development*", Centre for Social and Economic Research on the Global Environment, London, 1999.
[97] Crop innovation may or may not resolve the challenge of food security on its own, but can in any case rather be seen as an element of response to the issue, within a wider range of instruments that have to be activated, BLAKENEY, *Intellectual Property Rights and Food Security*, *op.cit.*.
[98] JEROME H. REICHMAN, "Legal Hybrids between the Patent and Copyright Paradigms," *Columbia Law Review* 94, 1994.
[99] YUNBI XU, *Molecular Plant Breeding* Wallingford, UK, : CAB International, 2010.
[100] RUSSELL THOMSON, "The Yield of Plant Variety Protection," in *Working Paper no.6/13*, ed. UNIVERSITY OF MELBOURNE INTELLECTUAL PROPERTY RESEARCH INSTITUTE OF AUSTRALIA (Melbourne2013), pp.4-5.
[101] GOESCHL and SWANSON, *op.cit.*, 1999.

might be delayed or might never come about at all, [… while also allowing the] maximisation of the social benefit that can be derived from the invention by creating value that survives the disclosure of the invention"[102].

Many factors may hinder the **intensification of research and development,** such as biological constraints in the controlled hybridisation process. This was for instance the case of former tomato breeding research, where the extremely labour-intensive necessities of deliberate sexual crossing led to sky-rocketing seed prices but to yield gains significantly less impressive than those experienced in corn for instance. Even so, weak intellectual property rights are considered frontrunners in the range of culprits for innovation obstruction. Their existence and efficient enforcement draws in a direct contribution as to the **expectation of successful financial returns.** They are viewed as a variable reducing the astounding costs attributed to sophisticated genomics research and development activities. These costs rise to around one hundred million USD for the introduction of a biotech-recombined trait into the market, from the trait's initial generation to its optimisation, its field trials, registration and initial marketing efforts[103]. These gargantuan investments are usually recouped by annual gross returns from sales, but the compensatory contribution of their intellectual property rights within sales figures cannot be overlooked. The incentive to innovate stands here at the level of the promise of a royalty check if the new variety is effectively used. This promise is realised through a strong set of properly enforced intellectual property rights.

> "Where cutting edge and easy to imitate technologies are at stake, such is the case of biotechnology, and where 'tacit' non-codified knowledge is an essential component of the technology package, [technology] transfer is more likely to take place if it is bundled with patents or other IPRs"[104].

The complex and time-consuming nature of IPR enforcement cases may nonetheless lead to sub-optimal levels of investment in agrobiodiversity research from the private sector[105]. A recent court case in the Milano district in Italy, concerned with the illegal reproduction of the lettuce variety Ballerina RZ, ruled for two hundred thousand EUR damages from the illicit sales and unjustified profit stemming from the unauthorised reproduction of seeds and their sale under a different commercial name, six years after the facts of the case[106]. The existence of stronger enforcement mechanisms, such as centralised royalty collection systems, has in this context proven to

[102] RAI, "Regulating Scientific Research: Intellectual Property Rights and the Norms of Science," *op.cit.,* p.117.

[103] See DERMOT J HAYES, SERGIO H LENCE, and SUSANA GOGGI, "Impact of Intellectual Property Rights in the Seed Sector on Crop Yield Growth and Social Welfare: A Case Study Approach," 2009. using the example of root-worn resistant corn, an "educated guess" for the development of a high value trait. These findings corroborate those of BELL and SHELMAN in a Brazilian case study, DE BELL and M SHELMAN, "Monsanto: Realizing Biotech Value in Brazil (Harvard Business School Case 507-018)," *Cambridge, MA: Harvard University*, 2006.

[104] CARLOS CORREA, "Can the Trips Agreement Foster Technology Transfer to Developing Countries?," *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime, Cambridge University Press, Cambridge*, 2005: at p.231. The author does go on to state that such premise should nonetheless not be overstated, as "fairly simple and robust contracts can also accomplish an efficient transfer of know-how".

[105] This reality has for instance set in motion the establishment of royalty-collecting agencies, infringement bureaux and common platforms for dispute resolution, an evolution that we shall tackle in the further course of this study (Chapters 8.1 and 13.1).

[106] Rijk Zwaan first noticed the violation in 2005, and the Court ruled in January 2011 for the decision on the existence of infringement and in October 2012 for the decision on the damages award, see http://www.rijkzwaan.be/wps/wcm/connect/rz+au/rijk+zwaan/news+and+events/news/news+items/rijk+zwaan+wins+landmark+case+against+illegal+reproduction (accessed May 2013).

considerably **propel private sector involvement in research and development,** by externalising the often times discouragingly high transactional, but also reputational costs of IPR enforcement post commercialisation, factors that have led companies out of certain research areas in the past, such as wheat[107].

In light of the uncapturable nature of genetic resources, the production dilemmas caused by such nature, the relative ease with which inventions that are costly to develop can be copied, and the strong incentive created by promised exclusivity over the fate of such inventions, robust intellectual property protection seems to be called for in the context of plant improvement.

1.3. Why diffuse? Public interest, disclosure and third party uses

Even the traditional strong "patent-induced invention" theory, which conditions innovative action to the grant of exclusive rights over the fate of its outcomes, recognises that such exclusivity comes at many costs. This is especially true seeing that the benefit of invention stimulus "is reduced by the fact that these grants do limit the full productive use of these inventions"[108]. Confronted to the strong impetus to protect the products of agrobiodiversity innovation, the need to set **limits to commodification** appears necessary and inherent to the construction of "scarcity of use" with regards to resources or ideas that are not in essence necessarily rivalrous, like knowledge[109]. Boundaries ought in this sense to be built between the "property interest embodied in an intangible *res"* and the public domain, in order to avoid impediments to creativity or innovativeness by "encroachments" to the latter[110]. As opposed to classical private property, intellectual property remains inherently omnipresent once granted, as it "cannot be limited to a particular physical body incorporating the right, [it is rather] attached to all material or virtual occurrences of the protected work"[111]. This far-reaching potential is considerably enhanced in the field of biotechnology, since "there is a significant amount of 'information character' to a genomic invention", opening an alarming and social cost-heavy door to a monopoly on an "infinite number of possible applications"[112]. Especially in cumulative (and therefore not stand-alone) innovation,

> "secondary inventions, including essential design improvements, refinements, and adaptations to various uses, often play as great a role in providing social benefits as the initial discovery. Patent law must ensure the diffusion of current innovations and the development of future innovation by enabling follow-on inventors to secure rights on improvements and build upon innovations in their entirety within a relatively short period of time"[113].

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[107] HAYES, LENCE, and GOGGI, "Impact of Intellectual Property Rights in the Seed Sector on Crop Yield Growth and Social Welfare: A Case Study Approach," *op.cit.*

[108] RAI, "Regulating Scientific Research: Intellectual Property Rights and the Norms of Science," *op.cit.*, p.117.

[109] MAY, "The Denial of History: Reification, Intellectual Property Rights and the Lessons of the Past," *op.cit.*, p.37.

[110] LANGE, "Recognizing the Public Domain," *op.cit.*, and also the follow-up to the 1981 article in 2003 by the same author, reacting to the theorisation efforts operated in the doctrine on the concept of the public domain that he advocated for, "Reimagining the Public Domain," *op.cit.*

[111] PHILIPPE CULLET et al., "Intellectual Property Rights, Plant Genetic Resources and Traditional Knowledge," in *Rights to Plant Genetic Resources and Traditional Knowledge: Basic Issues and Perspectives*, ed. SUSETTE BIBER-KLEMM, THOMAS COTTIER, and DANUTA BERGLAS, Oxforshire: CAB International 2006, pp.112-151 (at 114).

[112] BRIAN A. JACKSON, "Innovation and Intellectual Property: The Case of Genomic Patenting," *Journal of Policy Analysis and Management* 22, no. 1, 2003: p.10.

[113] JASON SAVICH, "Monsanto V. Scruggs: The Negative Impact of Patent Exhaustion on Self-Replicating Technology," *Berkeley Tech. LJ* 22, 2007.

To this end, IP regimes "moderate their exclusionary principles with limitations and exceptions [that are] in part designed to construct a public domain of resources and in part support uses that generate socially beneficial spillovers"[114]. These spillovers, traditionally ill-viewed externalities of enclosure, have conversely been considered to bear positive impacts, as "external benefits [that] are a ubiquitous boon to society", in a context where "it is impossible to exclude competitors or other researchers entirely from the intellectual benefits of an innovation"[115]. This viewpoint bears strong arguments in favour of enclosure, but it advocates an enclosure that is inherently construed so as to maintain its externalities and inherent innovation diffusion mechanisms. Therefore, as a counterpart of exclusive monopoly rights, all institutions protecting intangibles contain **carefully framed rules ensuring enough accommodation for social justice**. Accordingly, all intellectual property regimes offer limited protection in time, while specific flexibilities are included within each category of rights.

1.3.1. Social Compensation for Enclosure and Monopoly rights

The enclosure stemming from intellectual property rights therefore establishes inherent limits to the reach of protection, most straightforwardly set out in the **time boundaries and the revelation of the invention to the public,** in order to ensure follow-on innovators to develop new socially beneficial products. IPR constructs, by encouraging the inventor who controls the fate of the invention to disclose the innovative knowledge, offer social compensation for the incorporeal enclosure they create. The grant of reward for innovation is indeed not only limited in time, but it is also always accompanied by the publication of the innovation, accessible through the claim documents for patents, or through the application dossier containing phenotypic observations and field trials results in the case of plant variety protection. The limitation of monopoly in time, as well as the access to primary information on the innovation indeed allows other innovators to build on or build around socially useful innovations, creating new socially useful products or methods. The construction of a **solid public domain** is vital for inspiration, which has always been an undeniably immense and unstoppable fuel for human creativity but also inventiveness, in its holiest understanding[116]. It is vital for all creative and innovative endeavours, whether it entails access to the products or processes themselves at the end of a protection period, or whether it connects users and improvers to technical information linked to their existence.

Patents, probably the strongest of informational proprietary rights, not only avoid underinvestment in costly but socially beneficiary research and development activities, but also **prevent the detrimental withholding of knowledge**[117]. When the development and dissemination of innovations present high commercial interest, such as research tools, companies may be more likely to resort to trade secrecy than to dedicate their innovation to the public domain in the absence of patent or other statutory protection[118]. For instance, certain national practices as to

[114] MICHAEL J. MADISON, BRETT M. FRISCHMANN, and KATHERINE STRANDBURG, "Constructing Commons in the Cultural Environment," *Cornell Law Review* 95, no. 4, 2010: pp.668-669.
[115] BRETT M. FRISCHMANN and MARK LEMLEY, "Spillovers," *Columbia Law Review* 107, no. 1, 2007.
[116] LANGE, "Reimagining the Public Domain," *op.cit.*
[117] J. WENDT and J. IZQUIERDO, "Biotechnology and Development: A Balance between Ipr Protection and Benefit-Sharing," *Electronic Journal of Biotechnolog* 4, no. 3, 2001.
[118] REBECCA S. EISENBERG, "Patenting Research Tools and the Law," in *Intellectual property rights and research tools in molecular biology,*, ed. NATIONAL RESEARCH COUNCIL NRC (Summary of Workshop held at the Academy of Sciences, National Academy Press, Washington D.C.1997).

patentability requirements, which consider the publication of research results in academic journals as "prior art", have often times been viewed as counter-innovative, pushing for greater resort to trade secrecy within companies' or universities' IP strategy in early stages of research and development[119]. This practice may as a result block information that would have typically been shared and could have potentially been utilised by other researchers and produce socially useful innovations. The argument built around the need to avoid trade secrets is nonetheless less prevalent in plant variety protection, since the element of disclosure is also present at the moment of marketing, especially in countries where seed certification is based on very similar criteria. Notwithstanding this temperament, the disclosure of the innovation or new plant variety does still generate spillovers that are beneficial to society, compensating for the creation of market exclusivity. Since "the technical aspects of patents are made known, others are free to incorporate the information into new inventions that do not violate the patent claim"[120]. Keith MASKUS adds that "the narrower the claim, the easier it is to invent around the patent", raising the contentious issue of patent breadth to ensure that strong IPR titles do not run counter to their initial objectives. Even though the disclosure element of plant variety protection is less strict than patents, it stills provides at least "a description of the genealogy and breeding procedure, when known"[121]. The various disclosure elements found in IPR legislation are grounded on the premise that the relaxation of the artificial monopoly will "drastically change the incentives for an incumbent to license its technology to potential [market] entrants", triggering greater technology transfer[122].

1.3.2. Use-specific considerations and extensions of the public domain

Absolute permission rules delineate informational property titles. To this effect, the permission of the monopoly-owner ought to be sought for using the protected information. Exclusive rights to exclude third parties from using the innovation nonetheless bear **the risk of raising the cost of knowledge** through licensing fees, creating excessive monopolisation and patent thickets, thereby distorting the patterns of production. In order to balance the extensive rights awarded to innovators, In-built balances have often been crafted as liability rules[123], and also reflected in the controversial yet imperative concept of "compulsory licensing". Arguably, regulatory intervention carving all these third party uses aims at enhancing the free flow of ideas, and indirectly recognises that "intellectual activity is not creation *ex nihilo*"[124], refusing the attribution of full market value to a single innovator and allowing society to benefit from the invention and its spillovers. The interpretations favoured with regards to the scope of protections granted through IPR regimes and the inherent limitations to the bundle of exclusive rights awarded to right holders

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[119] RM CUMMINGS, "Some Aspects of Trade Secrets and Their Protection: The Public Domain and the Unified Description Requirement," *Ky. LJ* 54, 1965.
[120] KEITH MASKUS, *Intellectual Property Rights in the Global Economy* Washington DC: Institute for International Economics, 2000, p.41.
[121] 7 U.S.C. 2422, Section 52, emphasis added, see JULIAN M ALSTON and RAYMOND J VENNER, "The Effects of the Us Plant Variety Protection Act on Wheat Genetic Improvement," *Research Policy* 31, no. 4, 2002. This requirement only calls for enough disclosure to enable a skilled artisan to "identify" the new variety and distinguish it from others, MARK D JANIS and JAY P KESAN, "Us Plant Variety Protection: Sound and Fury," *Hous. L. Rev.* 39, 2002.
[122] ASHISH ARORA, ANDREA FOSFURI, and ALFONSO GAMBARDELLA, "Markets for Technology and Their Implications for Corporate Strategy," *Industrial and corporate change* 10, no. 2, 2001.
[123] Understood in a hybrid approach between the traditional doctrine regarding them as protection mechanisms stemming from the law of torts that involve a collective decision as to the value of the entitlement (see footnote 26 supra).
[124] HETTINGER, "Justifying Intellectual Property," *op.cit.*, p.38.

will reveal the extent to which our societies foster creativity while ensuring pluralism, equality and welfare. Within copyrights law one finds the first sale doctrine, preventing control over subsequent movements of the protected material, and educational exemptions[125]. In this context, infringers should "not be punished for exercising their imagination [but] for failing to exercise their imagination, for failing to add any imaginative content to the copied material"[126]. Copyrights in parallel also retain the extremely versatile fair use doctrine, which not only serves as an alleviating force against market failures, or as a mediation tool between exclusivity and freedom of speech, but also operates as a bargaining facilitator between the right holder and the potential users[127]. Different sets of liability rules, in accordance to which the entitlement can be used without permission so long as adequate compensation in granted later, in parallel also embody the specificity of cumulative plant breeding innovation[128]. Two possibilities surround the use of the plant-related innovation by third parties, whether breeders, researchers or growers. While the first set of possibilities are rather inscribed within the legal regimes as such, as prospectively undeniable statutory uses of the invention, such as the research exception or fair use doctrine; the second set of possibility requires the signature of a licensing agreement with the developer, standing out as a negotiated use of the invention. Both derive from the regulatory IPR environment, even though the latter retains a strictly more private nature, since no statutory boundaries exist as to the content of licensing agreements except for those set out by contracts law.

The marginal social return of rewarding innovators through IPR is to have innovation available earlier than it would have been under trade secrets; whereas exclusive rights seem to be granted on the entire value of the innovation, and not only such marginal return[129]. The rising costs of access to information have been considered as a **blockage** not only against non-mercantile research activities but also to economic development as a whole. Indeed, it prevents developing countries from using the free-riding strategies used by developed countries to reach high stages of welfare before the crowning of strong IPR, propelling charges of "information feudalism"[130]. Indeed, successful "catch-up experiences" have been recorded in countries where IPR regimes allowed (or did not restrict too strictly) the ability of their companies to replicate technologies that had been developed in more developed countries[131]. The distributional consequences of extensive monopoly

[125] For a quick overview of these limitations of exclusive rights, see BRUCE A. LEHMAN and RONAL H. BROWN, "*Intellectual Property and the National Information Infrastructure: The Report of the Working Group on Intellectual Property Rights,*" Diane Publishing, 1995. .

[126] JED RUBENFELD, "The Freedom of Imagination: Copyright's Constitutionality," *Yale Law Journal* 112, no. 1, 2002: p.48.

[127] See DAN L. BURK and JULIE E. COHEN, "Fair Use Infrastructure for Copyright Management Systems," *Harvard Journal of Law and Technology* 15, 2001: 41-83., which focuses on the issue of market failure. In more general terms, see also WILLIAM W. FISHER III, "Reconstructing the Fair Use Doctrine," *Harvard Law Review* 101, no. 8, 1988., and PIERRE N. LEVAL, "Toward a Fair Use Standard," ibid.103, no. 5, 1990.; for comprehensive accounts of the fair use doctrine's reach. For a critic of extensive practices limiting the reach of the doctrine and raising equity concerns vis-à-vis access to copyrighted works, see TOM W. BELL, "Fair Use Vs. Fared Use: The Impact of Automated Rights Management on Copyright's Fair Use Doctrine," *North Carolina Law Review* 76, 1997-98.

[128] ROBERT P. MERGES, "Institutions for Intellectual Property Transactions: The Case of Patent Pools," in *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society*, ed. R. DREYFUSS, D.L. ZIMMERMAN, and H. FIRST, Oxford Oxford University Press, 2001, pp.123-166.

[129] JOSEPH STIGLITZ, "Economic Foundations of Intellectual Property Rights," *Duke Law Journal* 57, 2007-2008: pp.1706-1712.

[130] PETER DRAHOS and RUTH MAYNE, *Global Intellectual Property Rights: Knowledge, Access and Development* New York: Palgrave MacMilan, 2002.especially Peter DRAHOS "Introduction", pp. 1-13 (esp. 4-5)

[131] Indeed, "even when licensing agreements were involved, these were for the most part vehicles through which the right to imitate or technology transfer was given effect for a fee or other considerations, rather than instances of

rights[132] have triggered a reminiscence of feudal times in plant improvement innovation. Notwithstanding the inherent criticisms on the control of nature, the rising commodification and restrictive appropriation trend has grown exponentially in agrobiodiversity management. As aforementioned, there indeed exists an essential need to grant artificial lead time to plant innovators (whether farmers, breeders or microbiologists) through the award of IPR, in order to foster the development of improved varieties that are easily reverse-engineered, yet costly to develop. While on the other hand, it has gotten extremely difficult to use and re-use the pool of improved and protected material for cultivation, research or breeding purposes. This trend may have extremely detrimental effects within the majority of agrobiodiversity innovation chains that remain primarily incremental. Indeed, all intellectual property policy

> "should aim towards privatising only that range of invention that would be used effectively through allocation to a single rightholder, [while] invention that would be used most effectively through open access should be left in the public domain"[133].

Notwithstanding the need to carefully enclose the informational public goods created by plant imporevement efforts, the need to ensure concrete and certain opportunities to use these goods cannot be set-aside in cumulative innovation chains. The latter concern, which calls for a solid and wide public domain, has even been stretched so as to shake down the rationale behind the need to protect certain products under strict exclusivity.

CONCLUSION. The notional balance between exclusive rights and the public domain

Intellectual property instruments protect and support creative and innovative activities that do not necessarily lead to the development of tangible objects, but rather settle in intangible forms**.** These characteristics rule out the possibility of physical control over the products of the creative or innovative mind, begging for active legislative action to foster private sector involvement under a liberal economy. Such legislative action has commonly taken the form of exclusive yet limited rights to innovators and creators, ever since the grant of privileges in medieval times. In line with the complete range of philosophical theories justifying the existence of intellectual property regimes, balance needs to be struck between the promotion of creative endeavours and the access and enjoyment of the wider public to both the resources used and the final informational "product" created by innovative individuals. From the inherent need for protection to the actual scope of enacted regulatory tools, an intricate balance thus operates between exclusive rules of appropriation and those of diffusion, which are designed to alleviate the social cost of monopoly. Private reward and artificial lead-time rely in this context on rules of protection, which grant prerogatives to creative or innovative individuals to control the products of their ingenuity for a limited period. The social cost of monopoly is conversely lessened by rules enabling the diffusion

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aggressive protection of intellectual property by the company in the advanced country". ROBERTO MAZZOLENI and RICHARD R. NELSON, "Public Research Institutions and Economic Catch-Up," *Research Policy* 36, no. 10, 2007.

[132] See for instance AOKI, "Neocolonialism, Anticommons Property and Biopiracy in the (Not So Brave) New World Order of International Intellectual Property Protection," *op.cit.*; and JEROME H. REICHMAN, "Charting the Collapse of the Patent- Copyright Dichotomy: Premises for a Restructured International Intellectual Property System," *Cardozo Arts and Entertainment Law Journal* 13, 1995.; or from the same author, "From Free Traders to Fair Followers: Global Competition under the Trips Agreement," *New York University Journal of International Law and Politics* 29, 1997.

[133] RAI, "Regulating Scientific Research: Intellectual Property Rights and the Norms of Science," *op.cit.*, p.135.

of innovations, setting the boundaries and opportunities for the use of the innovation by third parties. Both protection and diffusion rules delineate the public domain available for creators and innovators to build upon. They are inscribed in the conditions surrounding the grant of IP titles, but also in the scope and limits of rights awarded to the titleholder, whether as rights to exclude others from using the invention, or rights to authorise certain uses.

The determination of the most equitable boundaries for intellectual property protection for successful agrobiodiversity use should not be solely perceived as one related to the extent of protection as such, but rather also as one of dissemination, allowing for socially useful innovations to fulfil their purpose and be productively used by the largest possible range of scientists, breeders and farmers. All intellectual property rights retain a number of constraints and obligations directly targeted towards the right holders, as a means to counterbalance the bundle of exclusive rights obtained through the award of the protection title. Indeed, restrictive exclusive rights that are attributed to a single physical or moral person are limited in time, while even the strongest patent protection systems remain based upon the disclosure of the innovation. Certain inherent mechanisms will also allow third parties to have access to protected intangibles, whether in statutorily determined circumstances (such as publication requirements or formal use exceptions) or through bilateral negotiations. The inherent balances embodied in the ontology of intellectual property have nonetheless been put to the test of international reification, and have unfortunately led to a clear bias for developmental arguments embedded in protection and enclosure rules. Follow-on uses of plant material or plant breeding techniques by farmers, breeders and scientists alike, have become remarkably complex on account of the growing number of property titles and the extensive nature of prerogatives bestowed upon biological material or breeding techniques.

2. CHAPTER 2: DISPROVING THE PUBLIC DOMAIN THROUGH THE STRONG PROPERTY PARADIGM

The seed market essentially deals with the trade of tangible goods that are produced by the actors of different innovation contexts. Trade regulations thus first and foremost address the seed packs that identify the species or the plant variety that are the object of commercial transactions. However, in light of the specificities of the products, i.e. their self-replicating nature, and of the investments required in research and development, regulation has concomitantly taken the path of granting artificial lead-time in the form of exclusive rights in order to foster innovation. The temporary privileges set out by IPR directly influence “competitiveness, the pace and focus of innovation, and affordable access to new technologies, knowledge or creative works”, both within and between national legal orders[134]. The relative simplicity of modern property rights, characterised by private property and contractual freedom, also make them easily tradable commodities in the global market, encouraging actors to look for competitive advantages[135]. The commodification of information and knowledge goods into forms of property actively “removes

[134] CAROLYN DEERE, *The Implementation Game: The Trips Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* Oxford: Oxford University Press, 2009, p.5.
[135] CAROL M. ROSE, "Liberty, Property, Environmentalism," *Social Philosophy & Policy* 26, no. 1, 2009: p.16.

them from the sphere of social interactions, and places them in the realm of marketised interactions"[136].

Property rights over the intangible components of agrobiodiversity accordingly today complement almost all transactions that involve tangible agrobiodiversity goods, while having become a market in their own right as well. They form an additional and inescapable layer of formal seed markets. Trade-related regulatory instruments impact agrobiodiversity innovation contexts on two counts, through seed marketing laws and intellectual property rights legislation. Both apparatus have been dispensed in the international arena, respectively through the OECD Seed Schemes and the World Trade Organisation-backed Agreement on Trade-Related Intellectual Property Rights ("TRIPS"). Quite significantly, the latter has laid out the **foundations of the strong intellectual property paradigm for plant innovation** through its Article 27§3b. This paradigm is characterised by a combination of lenient patentability requirements on biological products and processes, coupled with strong plant variety rights stretching to harvested material and varieties essentially derived from protected phenotypes. The strong intellectual property paradigm is based on the need to grant artificial lead-time to developers and avoid the tragic fate of commons in the absence of proprietary delineation, while ensuring goods are traded in a cohesive and responsible market. But it also builds on the premise that exclusive rights ought to be "granted early on in the inventive process and should be very broad, so as to provide a hedge against competition and losses that would be incurred later if another company attempted to develop and commercialise the same invention"[137]. These prerogatives, which had started out as mere invention stimuli tools, have gradually become preventive commercial defence or strike mechanisms securing greater market control. While "intellectual property was tolerated in international trade as a private monopoly, it is now perceived by the companies controlling the major part of technology as the guarantor of this trade"[138]. The shift from mere tolerance into crucial vector manifests itself in the post 1980's strong intellectual property paradigm, comprising of a complex web of bundled and essentially national rights and obligations, where protection scopes have been considerably expanded through the reification of minimal standards in the TRIPS Agreement.

2.1. <u>Tangible seed trade and certification schemes</u>

The most straightforward aspect of trade regulation that impacts agrobiodiversity innovation relates to the rules governing the marketplace where the tangible goods generated by the various innovation contexts are exchanged, either freely or for financial reward. In this context, "appropriate seed legislation at the national and regional levels is [considered] essential to create an enabling environment for the development of the seed sector"[139]. The law has as a result set the backdrop of conditions for the production and release of the agricultural inputs that are plant varieties, thereby dressing the **contours of the national or global seed marketplace** in order to resolve the inherently asymmetrical nature of information flows. Aside from regulation targeting

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[136] MAY, "The Denial of History: Reification, Intellectual Property Rights and the Lessons of the Past," *op.cit.,* p.40.; analysing Karl Marx's account of reification as magic tool for the capitalist organization of society, based on the depiction of the role of commodities as naturally occurring things, in need of acknowledgment and regulation.
[137] RAI, "Regulating Scientific Research: Intellectual Property Rights and the Norms of Science," *op.cit.,* p.120.
[138] BERNARD REMICHE, "Révolution Technologique, Mondialisation Et Droit Des Brevets," *Revue internationale de droit économique* 16, no. 1, 2002: English abstract, at p. 83.
[139] Plant Production and Protection Division of FAO (AGP) on Seed Rules and Regulatory Frameworks, available at http://www.fao.org/agriculture/crops/core-themes/theme/seeds-pgr/seed_sys/rules/en/

biosafety issues[140] or seed production and packaging rules, the seed market is therefore essentially constructed around registration and certification requirements. Stringent seed certification schemes, which carve the formal seed market, impact the relationships between variety maintainers, producers, distributors and owners, and have also at times reduced the traditional fencing of the public domain with very stringent requirements and exclusivity over the fate of improved varieties. In plant improvement innovation chains, strong IPR have as a result been combined and enhanced through stringent seed market regulations. Propelled greatly at the international level by the "OECD Schemes for the Varietal Certification of Seed Moving in International Trade", which aim to "*promote the use of agriculture seed of consistently high quality*", seed certification marks the initial condition for entry into the market in most developed countries, and increasingly more various developing countries.

2.1.1. Rationale of seed legislation: towards registration and certification

While seed laws had already been enacted by the end of the 18th century in Europe, the **first certification attempts** go back to the beginning of the 20th century, as a means to control diseases in potato production, in order to stop the spread of breakdowns and important losses in the early 1900's[141]. The first certification rules were for instance enacted in 1888 in Sweden[142], in 1934 in Germany[143], where variety lists were kept as early as 1905, and in 1923 in the United Kingdom[144]. Certification was introduced in the USA in the 1960's, as an answer to "the haphazard, inefficient and often inequitable basis" upon which new varieties developed by universities or public institutions were distributed[145]. Certification requirements are especially important for field crops, more particularly hybrid corn, where varieties have "traditionally been publicly released and their seed sold on the open market", requiring greater control and maintenance of varietal identity[146]. The informal seed markets' practice of "white bags", untagged and unverified, was indeed not considered to reliably communicate the content of seed bags. Their quality was thus likely to be compromised, but according to certain commentators, "their proliferation [could have also] wiped out the formal sector supply because they were priced lower and did not include licensing and other technology fees"[147]. The choice of a regulated seed market would thus not only be directly towards transparency and quality control, but might also be an active political choice espousing a particular agrobiodiversity innovation context.

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140 The World Trade Organization's Agreements on Agriculture and on Technical Barriers to Trade or Sanitary or Phytosanitary Measures indeed impact seed trade. The WTO Agreement on Agriculture is as such not a seed or genetic resources-specific instrument, and rather essentially governs the trade of foodstuffs, whether harvested or processed. National phytosanitary requirements, especially for the screening of known diseases by plant protection agencies, as well as for treated seeds or genetically modified organisms that also need to comply with the terms of WTO SPS Agreement.

141 O. APPEL, "Vitality and Vitality Determination in Potatoes," *Phytopathology* 24, 1934.

142 R. TRIPP, *Seed Provision and Agricultural Development: The Institutions of Rural Change* London: ODI, 2001.

143 H.W. RUTZ, "Seed Certification in the Federal Republic of Germany," *Plant Varieties and Seed* 3, no. 3, 1990.

144 A.F. KELLY and J.D.C. BOWRING, "The Development of Seed Certification in England and Wales," ibid.

145 MILLER MCDONALD, "*Seed Certification in the United States*", available at http://seedbiology.osu.edu/HCS630_files/April%2010/Seed%20Certification%20USA,%20text.pdf

146 LARRY O. COPELAND and MILLER MCDONALD, "Seed Certification " *Principles of Seed Science and Technology*, no. pp.277-295., 1999.

147 SAKIKO FUKUDA-PARR, "Emergence and Global Spread of Gm Crops: Explaining the Role of Institutional Change," in *The Gene Revolution: Gm Crops and Unequal Development*, ed. SAKIKO FUKUDA-PARR, London: Earthscan, p.203.

Commonly based on the registration of varieties into a national or regional catalogue or registrar, seed marketing rules are a "**quality assurance process**, where seeds intended for domestic or international markets are controlled and inspected by official sources in order to guarantee consistent high quality for consumers"[148]. National seed lists put an ostensible focus on the identification of plant varieties and on performance pre-requisites for the global benefit of consumers and producers. They attempt to **resolve the asymmetry of information flows** between all actors involved (especially between the buyer and seller), which would create incentives for cheating and opportunistic behaviour if not addressed properly[149]. In order to take their place in the seed market, plant varieties and propagating material, whether imported or not, need as a result to comply with a number of criteria. These criteria depend on regional or national characteristics, but they all include examination or inspection procedures together with a maintenance clause, ensuring that the registered variety continues to be actively cultivated and maintained by at least one "maintainer"[150]. This approach ensures the variety remains available for all actors concerned, but also that it is adaptable to environmental changes[151]. In this context, certified seed should be produced using "pedigreed planting stock, careful quality control, field inspections during the growing season, and seed inspections following harvest", and be viewed as "an officially recognised method for maintaining varietal identity of seed on the open market"[152]. The desire to regulate seed markets and ensure their swift functioning has also led to the establishment of standard quality criteria vis-à-vis products of agrobiodiversity innovation, and the construction of a clear chain of liability vis-à-vis actors involved in seed trade. Requirements are usually two-fold, first concerning the registration of varieties into national lists of cultivars, and second having regard to the certification of varieties as quality bearers. National seed laws determine the extent to which these two market regulations interact with each other and thereby influence the varieties offered to farmers and consumers. There are a number of regional attempts to harmonise formal seed systems regulation, such as the European Union's Common Catalogue[153] or the rationalisation efforts of Eastern and Central Africa[154]. These attempts all corroborate the increasingly important role of international standards in the establishment of an effective and

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[148] ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT, "*Oecd Seed Schemes: A Synthesis of International Regulatory Aspects That Affect Seed Trade*", OECD, Paris, 2012.

[149] Incentives to cheat are propelled by high information asymmetries and prevent the smooth functioning of markets, see FRIEDERIKE ALBERSMEIER et al., "The Reliability of Third-Party Certification in the Food Chain: From Checklists to Risk-Oriented Auditing," *Food Control* 20, no. 10, 2009: p.930., for an analysis of food certification schemes in general.

[150] Such maintenance is for instance provided for in Article 11 of Brazilian Law Nº 10.711 on a National Seed and Seedling System dated as of August 5, 2003;

[151] See for instance the argument made for the need to actively maintain one of the first high-yielding rice varieties that was released in 1966, IR8, coined "miracle rice"; SHAOBING PENG et al., "The Importance of Maintenance Breeding: A Case-Study of the First Miracle Rice Variety - Ir 8," *Field Crops Research* 119, 2010.

[152] MCDONALD, *op.cit.*, , and also MILLER MCDONALD and W.D. PARDEE, *The Role of Seed Certification in the Seed Industry*, ed. CROP SCIENCE SOCIETY OF AMERICA Madison1985.

[153] See notably Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species, *OJL* 193, 20 July 2002, pp. 1-11. The European seed market is regulated by 12 different instruments: Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seeds, *(OJL* 193, 20 July 2002, pp. 33-59), Directive 66/401/EEC regulates the marketing of fodder plant seed, Directive 66/402/EEC cereal seed, Directive 2002/54/EC beet seed, Directive 2002/56/EC of seed potatoes, Directive 2002/57/EC seed of oil and fibre plants, Directive 2008/72/EC for material for the propagation of the vine, Directive 1998/56/EC for the marketing of propagating material of ornamental plants, Directive 92/33/EEC for vegetable material, other than seed, Directive 2008/90/EC for fruit propagating material and fruit plants for fruit production, and finally Directive 1999/105/EC for the marketing of forest reproductive material.

[154] MICHAEL WAITHAKA et al., "*Impacts of an Improved Seed Policy Environment in Eastern and Central Africa*", 2011.

transparent seed market, allowing their actors to easily trade their goods outside national or regional borders.

Even though variety registration is unequivocally viewed as a prerequisite to certification, the latter may not be required for the entry of the variety into the market, although these two aspects do overlap in most developed countries. Seed distribution is indeed generally only allowed after certification procedures based on the distinctness, uniformity and stability of plant varieties (so-called DUS testing), and the inclusion of either actors and/or varieties into official catalogues[155]. Seed certification, in its most traditional sense, encompasses notions of genetic improvement, and aims at facilitating "the provision of high quality seed from superior crop plants with similar genetic identity and purity"[156]. A number of seed marketing laws also include performance requirements, coined "*value for cultivation and use* of the variety", based on yield, resistance to harmful organisms, response to the environment and quality characteristics, for instance regarding agricultural crops in the European Union's Common Catalogue[157]. This approach to seed regulations stems from the standardisation of practices through international standards. Based upon the degree of variety purity, the production, conditioning and the overall quality of seed, centralised seed certification and quality control, should, in principle, be delegated to a legally sanctioned or chartered public or quasi-private institution[158].

2.1.2. Reification of stringent certification schemes through OECD efforts

Seed registration, which marks the initial condition for entry into the market in most developed countries, and increasingly more various developing countries, has been greatly propelled by the "**OECD Schemes for the Varietal Certification of Seed Moving in International Trade**", which aim to "promote the use of agriculture seed of consistently high quality"[159]. Negotiated in the 1960's and gradually enacted for different species, the OECD Seed Schemes unwaveringly amended existing national legislation and triggered regulatory action in countries without effective frameworks that addressed seed quality. The first OECD scheme for the varietal certification of seed moving in international trade was adopted in 1958 and only concerned herbage seeds trade. It was adopted "amongst seventeen countries which wanted a minimum guaranteed level of varietal identity and purity in their international seed transactions"[160]. The minimum OECD standards for the control of forest reproductive material was for instance adopted in 1967, then quickly adapted in 1971, and were recommended by the FAO Panel of Experts on Forest Gene Resources as a model for countries adopting national seed certification schemes[161]. Adopted gradually for a wider

[155] R. TRIPP and N. LOUWAARS, "Seed Regulation: Choices on the Road to Reform," *Food Policy* 22, no. 5, 1997.
[156] N. JONES and J. BURLEY, "Seed Certification, Provenance Nomenclature and Genetic History in Forestry," *Silvae Genetica* 22, no. 3, 1973.
[157] Article 5 §4 of Directive 2002/53/EC states that "The value of a variety for cultivation or use shall be regarded as satisfactory if, compared to other varieties accepted in the catalogue of the Member State in question, its qualities, taken as a whole, offer, at least as far as production in any given region is concerned, a clear improvement either for cultivation or as regards the uses which can be made of the crops or the products derived therefrom. Where other, superior characteristics are present, individual inferior characteristics may be disregarded."
[158] N. LOUWAARS, P. LE COENT, and T. OSBORN, "*Seed Systems and Plant Genetic Resources for Food and Agriculture*", Rome, 2010.
[159] DEVELOPMENT, *op.cit.*, 2012.
[160] JEAN-MARIE DEBOIS, "Oecd Schemes for the Varietal Certification of Seed Moving in International Trade" (paper presented at the First World Conference on Organic Seeds, Rome, 2004).
[161] JONES and BURLEY, "Seed Certification, Provenance Nomenclature and Genetic History in Forestry," *op.cit.*

range of species but also expanding their geographical reach, the compiled OECD schemes[162] now cover one hundred eighty five species and thirty three thousand varieties eligible for certification, throughout fifty-five participating countries. These instruments were also opened to non-OECD participants, and twenty-six of them have gradually joined in with the twenty nine OECD Members participating in the Schemes, even though all States do not participate for all species. For instance, only twenty-nine countries adhere and apply the Vegetables Schemes. Complaints for the non-execution of the Schemes may be lodged by a participating State to the Committee of Agriculture, which refers to issue to the OECD Council[163].

As for the content of these instruments, their focus clearly stays grounded on the **identification of varieties and their quality**. To this end, they set up official certification frameworks that extend to all stages of seed multiplication and set purity standards. They generally ensure that the OECD listed varieties have been registered in national official catalogues, thereby acknowledging this practice as a necessary first step towards certification, while assessing national grasp over procedures. Requiring the supply of official varietal description regarding essential morphological and physiological characters, the Schemes also entail an identity authentication process through field inspection, seed lots sampling and seed analysis. However, a number of regulatory differences persist between species, due to the specificities and relative successes of breeding efforts. The OECD Grass and Legume Schemes for instance state that "*tests mush establish that the variety is **distinct** and that its generations used for fodder production have **sufficiently uniform and stable characters***"[164] (emphasis added).

They should also establish that "*the varieties have an acceptable value in at least one country*"[165]. But not all agricultural goods are created equal and some have very seldom obtained complete genetic uniformity and predictability, making certification efforts not about purity but rather about identification. This is notably the case of trees, but also to a certain extent aromatic herbs. In parallel with those standards set out by the International Seed Testing Agency ("ISTA")[166], the schemes also set the criteria to be respected by authorities responsible for certification procedures. Most importantly, the Schemes establish an official guarantee of maintainer from breeder to farmer, which leads the Organisation to publish an extensive variety and maintainer database through its "Annual list of varieties eligible for OECD Certification". The link between variety ownership and maintainer has become increasingly complex, especially since the OECD does not assume any responsibility in this regard[167].

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[162] There were seven species- specific schemes governing grasses and legumes, crucifers and oil species, cereals, fodder and sugar beet, subterranean clover, maize and sorghum, and lastly vegetables. These schemes were compiled on 28 September 2000 into one comprehensive document notably providing for "Legal and General texts Common to all OECD Seed Schemes", before setting the rules and direction of the different schemes; Decision of the Council revising the OECD Schemes for the Varietal Certification or the Control of Seed Moving in International Trade, C(2000)146/FINAL.
[163] OECD Seed Schemes, Common rules, Article I.5.
[164] OECD Grass and Legume Scheme, Article 2.2 "Rules and Directions", p.28.
[165] Ibid. article 2.3.
[166] The ISTA also attests which national or regional certification agencies can deliver the Orange International Seed Lot Certificate, an international standard "quality certificate", which certifies the planting value in international seed trade.
[167] DEBOIS, *op.cit.*, p.28.

Addressing market imperfections and justified through social utility, seed market access regulations nevertheless establish excessive product testing and seed certification procedures in certain circumstances. This premise as a result may significantly **increase the costs of commercialising** the outputs of research and breeding efforts[168]. Furthermore, absolute certification requirements which link a single applicant to distribution rights pertaining to a particular variety[169], without any time limitations, may be viewed as tools curtailing the PGRFA public domain. They may in practice reinforce the exclusive titles that are awarded on stricter conditions and rationale. The impact of such seed certification mechanisms is also heightened by the fact that they are designed to cover all commercialised plant varieties, whether these are protected through IPR titles or not, questioning whether these technical regulations have actually become even stronger than IPR. Indeed, there seems to be little or no consideration for farmers' varieties in the general OECD Schemes. That is why the formerly applicable European seed legislation has been attacked because of its lack of legal recognition of seed exchange platforms, epitomised by the French case opposing *Kokopelli* to *Graines Baumaux*, which has been referenced by the Court of Nancy to the European Court of Justice in February 2011 (Case C-59/11)[170]. The latter was asked to assess whether seed catalogues violated principles of the *acquis communautaire* related to the liberty of trade, free movement of goods, proportionality, equality and non-discrimination. Since the facts pertaining to this specific case that shall be thoroughly analysed in Chapter 9 of this study, the European Union has developed specific legislation on 'conservation and amateur varieties', establishing derogations from the general principles of certification following the OECD approach to marketing requirements[171].

European seed legislation is undergoing an extensive review process and the 2013 draft for a Regulation on the "production and making available on the market of plant reproductive material"[172] is at the time of writing still being discussed before the European Parliament after an initial rejection. Replacing twelve scattered Directives by one Regulation, the draft wishes to "adapt to the technical progress of plant breeding", but also to "reduce the cost and administrative burdens and support innovation", by overcoming the "uncertainties and discrepancies in the implementation" of existing complex and fragmented legislation, which create "an uneven playing field for professional operators on the single market"[173]. Even though the draft retains a number of

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[168] CARL PRAY, "The Growing Role of the Private Sector in Agricultural Research," in *Agricultural Research Policy in an Era of Privatization*, ed. DEREK BYERLEE and R. ECHEVERRIA, Oxon: CAB International, 2002, p.42.

[169] The applicant may not necessarily be the owner of the variety in terms of intellectual property, but rather corresponds to the entity possessing the variety's distribution rights and maintenance obligations, often times dubbed "the maintainer" in certification or registration forms.

[170] European Court of Justice, C-59/11, *Association Kokopelli vs. Graines Baumaux SAS*, 12 July 2012.

[171] Commission Directive 2008/62/EC of 20 June 2008 providing for certain derogations for acceptance of agricultural landraces and varieties which are naturally adapted to the local and regional conditions and threatened by genetic erosion and for marketing of seed and seed potatoes of those landraces and varieties, *OJL*, 162, 21.06.2008, pp.13-19; Commission Directive 2009/145/EC of 26 November 2009 providing for certain derogations, for acceptance of vegetable landraces and varieties which have been traditionally grown in particular localities and regions and are threatened by genetic erosion and of vegetable varieties with no intrinsic value for commercial crop production but developed for growing under particular conditions and for marketing of seed of those landraces and varieties, *OJL*, 312, 27.11.2009, pp. 44-55; Commission Directive 2010/60/EU of 30 August 2010 providing for certain derogations for marketing of fodder plant seed mixtures intended for use in the preservation of the natural environment, *OJL*, 228, 31.08.2010, pp.10-14.

[172] Proposal for a Regulation of the European Parliament and of the Council on the production and making available on the market of plant reproductive material, COM(2013), 262 Final (dated as of 6th May 2013).

[173] Ibidem, Proposal context, p.2.

derogatory provisions that we shall delve upon in the further course of this study, its main focus remains a strictly OECD approach oriented towards the productivity driven professional seed market and the facilitation of seed movement.

The regulation of the tangible goods that are seeds to ensure their quality, purity and identity through both national and global seed registration and certification mechanisms have in effect launched and reinforced the formal seed sector. Seed quality assurance has become an important component of the vertically organised large-scale operation that is the formal seed system, along with variety development and release, seed production and seed marketing[174].

2.2. Minimal standards of strong intellectual property rights: the TRIPS Agreement

As a legally defined intangible product of human activity, intellectual property provides "exclusive or *erga omnes* rights, i.e. a bundle of legally enforceable interests vested with their owner, who can oppose them against any third party"[175]. Traditionally, intellectual property rights "only protected human creativity in law" based on a clear distinction between the products of nature and human inventions[176]. This original standpoint rapidly evolved, and opened the doors to the appropriation of plant varieties, as well as biological material and processes. It should be noted that intellectual property rights do not exist outside of the legal structures that recognise and award them. They thus depend on the strength of their reification in national or international legal orders[177], which formally and socially bring resources and related information into the market. They rest on important "political, economic and crucially ideological investments" to affect the process and content of international and national provisions fostering innovative endeavours[178].

It is in this context that "post-1980's changes in intellectual property law [have not been driven by] primary arguments of traditional invention and disclosure, [but rather as a means] to ensure the efficient development and commercialisation of valuable property"[179]. Mostly in developed

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[174] ZEWDIE BISHAW and ANTHONY J.G. VAN GASTEL, "Variety Release and Policy Options," in *Plant Breeding and Farmer Participation*, ed. S. CECARELLI, E.P. GUIMARAES, and E. WELTZIEN, Rome: ICRISAT, ICARDA and FAO, 2009, pp.565-589.

[175] CULLET et al., "Intellectual Property Rights, Plant Genetic Resources and Traditional Knowledge," *op.cit.*, p.113.

[176] CULLET, "Intellectual Property Rights and Food Security in the South," *op.cit.*, p.268.

[177] Reification describes the process through which a concept becomes a concrete reality, or through which "an idea become a thing". The concept of reification in legal scholarship has been greatly influenced by the critical legal work of Peter GABEL("Reification in Legal Reasoning," *Research in Law and Sociology* 3, 1980.; even though its strength as an analytical tool in the study of the law has been questioned (ANTHONY J. FEJFAR, "Analysis of the Term Reification as Used in Peter Gabel's Reification in Legal Reasoning," *Cap. U.L. Rev.* 25, 1996. As for the concept of reification in the justification of international law-making, analysing both naturalist and positivist approaches to the sources and the essence of the law, and stating the reification has become rather a purpose than an essence in contemporary legal thought, JAMES BOYLE, "Ideas and Things: International Legal Scholarship and the Prison-House of Language," *Harvard International Law Journal* 26, no. 2, 1985: pp.327-359. Applied more specifically to the field of intellectual property rights, reification has been fiercely criticised as a contributor to the "discourse of depolitisation and technocratic policy-making […blocking the way towards] a meaningful global politics of information and knowledge"; MAY, "The Denial of History: Reification, Intellectual Property Rights and the Lessons of the Past," *op.cit.*, p.34.

[178] SIMON WEST, "Institutionalised Exclusion: The Political Economy of Benefit-Sharing and Intellectual Property," *Law, Environment and Development Journal* 8, no. 1, 2012: p.41.

[179] RAI, "Regulating Scientific Research: Intellectual Property Rights and the Norms of Science," *op.cit.*, p.120.

countries, intellectual property legislation has navigated towards a commercial development and prospect-oriented enclosure model crowned by Edmund KITCH[180].

The most important step towards such direction was the 1980 so-called Bayh-Dole Act amending the United States Patent and Trademarks Law, with an objective "*to promote the utilisation of inventions arising from federally supported research and development*" (35 U.S.C. 200). It is rather the objective to encourage the distribution of innovative products that stands out here, rather than the more customary discourse focusing on the provision of incentives to innovate, thereby highlighting the active political will to increase the number of technologies licensed by the public to the private sector[181]. The current wrangling for patents witnessed in Universities worldwide as a result adamantly endorses the dominant discourse of the strong intellectual property paradigm, as exclusiveness tools favoured by both private and public entities alike in the brave new world trade order. Through this shift in the relationship between science and technology operated in parallel with an active regulatory push for lower government expenditure in applied research, national legislators have effectively built the groundwork for a strong property paradigm over knowledge goods. This foundation, and the associated novel approach to property, which was thereon directed towards the development and use of technology rather than a pure incentive to innovate[182], were very quickly reified at the international level, infectiously reaching States that still approached research and property allocation, especially with regards to the life sciences, very differently.

2.2.1. Linking intellectual property and trade

The reification of intellectual property rights at the international level was realised through a lengthy and multi-faceted process characterised by an undefeatable linkage between international trade and the regulation of intellectual property, and by minimum protection standards determined through so-called "circles of consensus"[183]. These features made TRIPS "a coerced agreement that should be resisted rather than embraced"[184], yet an inescapable reality for all agrobiodiversity innovation contexts. The Agreement on Trade Related Aspects of Intellectual Property Rights was incorporated as Annex 1C into the Marrakesh Agreement, which established the World Trade Organisation on 15 April 1994. The final text was adopted at the end of the so-called Uruguay Round working on the basis of the Global Agreements on Tariffs and Trade that were adopted in 1947. In this context, the TRIPS Agreement is a full-ranged instrument taking integral part in arguably the strongest nest of international legal orders, encroaching farthest within the sovereignty of States, and it is best known as a package deal pushed by developed States. Prior to its adoption, a number of international instruments were already concerned with intellectual

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[180] In Kitch's approach, exclusive rights "are granted to induce socially useful investment in developing technological prospects that inventions represent", rather than the inventions themselves; see "Regulating Scientific Research: Intellectual Property Rights and the Norms of Science," *op.cit.*, p.121. and EDMUND KITCH, "Nature and Function of the Patent System," *Journal of Law and Economics* 20, 1977.

[181] BRAHY, "The Property Regime of Biodiversity and Traditional Knowledge: Institutions for Conservation and Innovation," *op.cit.*, pp.57-58.

[182] RAI, "Regulating Scientific Research: Intellectual Property Rights and the Norms of Science," *op.cit.*

[183] PETER DRAHOS, "Developing Countries and International Intellectual Property Standard-Setting," *The Journal of World Intellectual Property* 5, no. 5, 2002.

[184] HELFER, "Regime Shifting: The Trips Agreement and New Dynamics of Intellectual Property Lawmaking," *op.cit.*, p.24.

property[185]. They however regulated the domestic grant of temporary exclusive rights, setting legal standards or ensuring cooperation amongst States[186]. Indeed, under the provisos of the 1883 Paris Convention on the Protection of Industrial Property for instance, Member States had *"the freedom to subject the recognition of patents to the local exploitation of the invention, [in an understanding] that trade and patent protection were not necessarily related*"[187]. The same principle also applied to the agrobiodiversity-specific intellectual property tool that are plant variety rights, constrained to the 1961 Convention of the Union for the Protection of New Varieties of Plants (UPOV), which did not provide for any links to international or transnational trade, but rather acted as a common denominator between national IP laws.

The novelty of the TRIPS Agreement was to **link intellectual property to international trade negotiations**. Its main rationale was to establish the ground principles for a relatively unconstrained international exchange of goods and conditions for market access. This link was "imported" from national forums, especially that of the United States, which was already prescribing commercial sanctions if IPRs were not protected adequately[188]. By linking IP to trade, developed countries and their strong industry "underscored a strong relationship between high levels of IP protection and foreign investment", which developing countries remain eager for, consequently becoming vulnerable to the agendas of the leveraged industry[189]. Even though developing countries initially fought against the overtrumping of the World Intellectual Property Organisation (WIPO), which would have been the most obvious choice for international IP standard setting, "the concept of the single undertaking of the Uruguay Round prevailed"[190]. The institutions deserted by this forum-shifting process were both the WIPO but also the United Nations Conference on Trade and Development (UNCTAD). The latter served as a forum for initiatives ensuring developing countries access to markets and technology transfer opportunities on the side-lines of IPR that were deemed unfavourable to developing countries[191]. This horizontal shift is attributed to strategic efforts of the United States to shift forums, i.e. "move a regulatory agenda from one organisation to another and other organisations"[192]. The choice of the trade order

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[185] One may for instance cite the 1883 Paris Convention for the Protection of Industrial Property or the 1886 Berne Convention for the Protection of Literary and Artistic Works, which were monitored by the "Bureaux Internationaux réunis pour lq protection de la propriété intellectuelle", coined the World Intellectual Property Organisation in 1970.

[186] See for instance the 1978 Patent Cooperation Treaty or the 1973 European Patent Convention, which does both (i.e. sets protection standards and also grants titles).

[187] PEDRO ROFFE, "Bringing Minimum Global Intellectual Property Standards into Agriculture; the Agreement on Trade-Related Intellectual Property Rights (Trips)," in *The Future Control of Food: A Guide to International Negotiations and Rules on Intellectual Property, Biodiversity and Food Security*, ed. GEOFF TANSEY and TASMIN RAJOTTE, London: Earthscan, 2008, pp.48-68, at p.49.

[188] "Bringing Minimum Global Intellectual Property Standards into Agriculture; the Agreement on Trade-Related Intellectual Property Rights (Trips)," in *The Future Control of Food: A Guide to International Negotiations and Rules on Intellectual Property, Biodiversity and Food Security*, ed. GEOFF TANSEY and TASMIN RAJOTTE, London: Earthscan, 2008, p.49. This link was in effect triggered by the infamous "Special 301 provisions" of the 1974 Trade Act which "gave the US new tools to for applying measures on countries for practices that violated IP rights protected under US domestic law (irrespective of whether these products entered the US or not)". DEERE, *The Implementation Game: The Trips Agreement and the Global Politics of Intellectual Property Reform in Developing Countries*, *op.cit.*, p.49.

[189] SUSAN K. SELL, "Corporations, Seeds and Intellectual Property Governance," in *Corporate Power in Global Agrifood Governance*, ed. JENNIFER CLAPP and DORIS FUCHS, MIT Press, 2009, pp.187-224, at p.190.

[190] ROFFE, "Bringing Minimum Global Intellectual Property Standards into Agriculture; the Agreement on Trade-Related Intellectual Property Rights (Trips)," *op.cit.*, p.50.

[191] JOHN BRAITHWAITE and PETER DRAHOS, *Global Business Regulation* Cambridge: Cambridge University Press, 2000, p.68.

[192] *Global Business Regulation* Cambridge: Cambridge University Press, 2000, p.29.

was not made lightly. It allowed the TRIPS Agreement to "have teeth" by being linked to the WTO's "hard-edged dispute settlement system in which treaty bargains are enforced through mandatory adjudication backed up by the threat of retaliatory sanctions"[193]. It also gave the future IP protection standards "fairly global coverage", ensuring business units to "locate production anywhere in the world, safe in the knowledge that their IP would be protected"[194]. Supported by Europe, Canada and Japan, the United States successfully managed to put the issue of intellectual property as a negotiating point for the Uruguay round of trade talks ignited in 1986, creating in parallel the influential "Quad Group", determining not only the forum of action but also the content of global IP standards.

The involvement of the United States based Intellectual Property Committee and its counterparts from other members of the developing world in the negotiating process alone raised concerns[195]. The TRIPS Agreement has as a result been, and still is being virulently criticised as a **post-colonial imperialist** instrument. Accordingly, the inclusion of intellectual property protection standards into the WTO legal order exemplifies the creativity through which "new mechanisms of accumulation by dispossession" have been steadily developed by dominating countries[196]. More recent commentators argue that the Agreement could rather be viewed as a **neo-federalist regime**, ensuring the resilience of the international intellectual property system by granting enough flexibility to WTO Members to take national priorities into account at the implementation stage[197]. Notwithstanding such range of action, the TRIPS Agreement marks a turning point in the conception of intellectual property both in the enterprise and society, as exclusive titles, which were formerly tolerated in international commerce as a private monopoly, are now perceived as a warrantor of such trade by companies developing competitive technology[198].

Whether post-colonial or neo-federalist, the success of forum shopping practices and of the WTO order's retaliation power is illustrated by the **appraisal of intellectual property rights in all other relevant international instruments,** especially those targeting sustainability and equity concerns, which we shall tackle in Part IV of this study. It has become inescapable. Indeed, even the Convention on Biological Diversity (CBD) recognises the

> "*need for adequate and effective protection of intellectual property rights*", even though these rights ought to remain "*supportive of and not run counter*" to the CBD system's objectives (CBD, Article 16 §§2 and 5).

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[193] HELFER, "Regime Shifting: The Trips Agreement and New Dynamics of Intellectual Property Lawmaking," *op.cit.*, p.2.

[194] BRAITHWAITE and DRAHOS, *Global Business Regulation*, *op.cit.*, p.61.; which recalls the creation of the Advisory Committee for Trade Negotiations and its Task Force on Intellectual Property.

[195] SELL, *Private Power, Public Law: The Globalisation of Intellectual Property Rights*, *op.cit.*, pp.40-51.; in a thorough account of the role of the IPC on the negotiators from developed and developing countries alike in the inclusion of wide-scoped IP standards in the subject-matter of the Uruguay Round, as well as an analysis of the private sector's direct and indirect power over civil servants involved in the process.

[196] See for instance the poignant theories of D. HARVEY, *The New Imperialism* Oxford: Oxford University Press, 2003.; where the author underlines that the TRIPS Agreement "points the way in which the patenting and licensing of genetic material, seed plasma […] can now be used against whole populations whose practices had played a crucial role in the development of those materials", pp. 147-148.

[197] GRAEME DINWOODIE and ROCHELLE D. DREYFUSS, *A Neofederalist Vision of Trips: The Resilience of the International Intellectual Property Regime*: Oxford University Press, 2012.; especially Chapters 6 and 7.

[198] REMICHE, "Révolution Technologique, Mondialisation Et Droit Des Brevets," *op.cit.*

In parallel, the Multilateral System established under the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) states that

> "*access to PGRFA protected by intellectual and other property rights shall be consistent with relevant international agreements, and with relevant national laws*", while technology transfer shall operate "*on terms which recognise and are consistent with the adequate and effective protection of IPR*" (ITPGRFA, respectively Article 12§3 (f), and 13§2(b)).

Its success is also present in the change of the content of the strong intellectual property paradigm, enlarging the scope of protection in accordance with the interests of a powerful few.

2.2.2. Developing a new paradigm in IPR on living organisms

The contentious nature of the TRIPS Agreement does not only stem from its negotiation process and the choice of the retaliation accompanied trade fora. It also significantly draws upon the reified content in itself, as a top-down collection of minimal standards considerably extending protection scopes, established amongst a luckily powerful few. The Agreement furthermore operated a clear shift from the customary state of IP protection, ironing out the major differences that existed between national approaches, even though it still left enough room for accommodation at the stage of national implementation. In this context, "revisionist readings of TRIPS' negotiating history now stress the power-based bargaining strategies that industrialised countries employed to coerce developing states into agreeing to treaty terms about which they had little understanding, let alone meaningful input"[199]. Much has indeed been written on the gradually informal groups or circles of consensus where legal provisions were actually drafted and negotiated, making the TRIPS Agreement a "hierarchical rather than democratic management of law-making"[200].

This new breed of international IPR regulation does not necessarily address "all of the issues raised by the grant of legal protection to intellectual property products", and is therefore often referred to as **"minimum standards" agreement,** as a "basic floor of legal protection to which all Member States must adhere"[201]. In this regard, the TRIPS Agreement states that its

> "*Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice"* (TRIPS, Article 1§1).

In light of the process of reification itself and its quasi-unilateral imposition on developing nations, the minimal protection standards set out by TRIPS have broken off with 19th century tradition,

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199 HELFER, "Regime Shifting: The Trips Agreement and New Dynamics of Intellectual Property Lawmaking," *op.cit.*, p.4.

200 DRAHOS, "Developing Countries and International Intellectual Property Standard-Setting," *op.cit.*p.772.

201 HELFER, "Intellectual Property Rights in Plant Varieties: An Overview with Options for National Governments," Section 1.3.4.

where the harmonisation of standards was traditionally a bottom-up approach bringing together common elements of "protection and discrimination", to the benefit of enacting overarching minimal requirements[202]. Commentators further argued that the TRIPS Agreement did "not reflect a harmonisation that had already occurred at the national level"[203]. In the post-colonial era, many new colonised countries enacted legislation that "still closely resembled earlier colonial laws, except for reactionary responses in the Americas and in Asia, where reformist efforts had "tailored IP laws to national priorities"[204]. International or regional IP standards-setting institutions and treaties date as far back as the 19th century and were at the time merely assigned to industrial innovation or to creative works, precluding or only timidly allowing their **extension to living organisms.** The major shift in informational property rights to extend to biological material was witnessed in the mid-20th century mostly in developed countries, on account of technological developments and their prevailing agricultural innovation structure[205]. The TRIPS Agreement generalised the extension of patent protection scope at least to non-biological processes and compounds, transforming it into a minimal international obligation for those States desiring to participate in the world trade order's battlefield at the same level as others. It has "been one of the triggers for the introduction of life patents" in national orders where this option was not recognised to agrobiodiversity innovators[206].

The adoption of the TRIPS Agreement should therefore be acknowledged as a **major turning point for plant improvement innovation**, since its dispositions made the recourse to IPR in plant breeding not only a reality, but also an international legal obligation. **Article 27§3b** indeed states that

> "*its "Members [should] provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof"*, as well as acknowledging the patentable nature of essentially non-biological and microbiological processes. Indeed, *Members may also exclude from patentability […] (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes"* (TRIPS, Article 27§3b).

This provision sets out the contours of a strong intellectual property paradigm in agrobiodiversity innovation, restricted only in its terms by Article 27§§ 1 and 2, which sets out the general principle of patentability for novel, inventive and non-obvious inventions capable of industrial applications,

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[202] ROFFE, "Bringing Minimum Global Intellectual Property Standards into Agriculture; the Agreement on Trade-Related Intellectual Property Rights (Trips)," *op.cit.*, p.52.

[203] DRAHOS, "Developing Countries and International Intellectual Property Standard-Setting," *op.cit.*, p.768.; illustrating this premise by figures of IP protection scope established by the WIPO in 1988 for the negotiating group dealing with TRIPS. These figures show important differences between countries adhering to the Paris Convention, which "did not stand in the way of States adopting quite different standards of industrial property protection".

[204] DEERE, *The Implementation Game: The Trips Agreement and the Global Politics of Intellectual Property Reform in Developing Countries*, *op.cit.*, pp.37-40. In the Americas, and especially in the Andean Community, "countries adopted policies with an eye to building domestic industrial capacity and shifting their comparative advantage in the international economy", while in India, the patent system was found to have "failed to stimulate inventions amongst Indians and to encourage the development and exploitation of new inventions".

[205] UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, "Integrating Intellectual Property Rights and Development Policy," (London2002), pp.58-59.

[206] CULLET, "Intellectual Property Rights and Food Security in the South," *op.cit.*, p.269.

while also setting up the conditions to be respected by Member States to exclude certain inventions from said principles[207]. Indeed,

> *"1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. (5) Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.*
> *2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law"* (TRIPS Agreement, Art. 27§§1-2).

In this context, WTO Member States need to amend their national IP legislation if necessary, in order to provide artificial lead-time at least for plant varieties, micro-organisms, non-biological and microbiological processes. Plant varieties should also be protected through an "*effective sui generis system"*, which is not defined in the Agreement. The negotiating history does not provide clear guidance either as to such "effectiveness" gauge[208]. The legal system set out under the auspices of the Union for the Protection of New Varieties of Plants (UPOV), has nonetheless in this regard been advocated as the primary regime complying with such threshold. First enacted in 1961, and amended in 1974, 1978 and 1991, the UPOV Convention in effect illustrates the relative flexibility but also the strengthening of plant variety protection. Indeed, countries had in the past the choice to apply and adhere to their preferred text, but now need to comply with the stricter terms of the 1991 text if they want to become part of the international organisation. Even though "there have been attempts to interpret the *sui generis* option as being limited to the UPOV model, […] developing countries do have the possibility to devise an alternative model"[209]. Indeed, the establishment of a *sui generis* system for the protection of traditional knowledge and the rights of indigenous communities[210] may very well fall into Article 27's requirements, just as other alternatives experimenting with breeders' rights outside the realm of the UPOV Conventions[211].

The Agreement also allows States to **act discretionally in the interpretation of its provisions**, carefully drafted to allow for such flexibility, even though a worrying trend has emerged in bilateral trade agreements that tend to include so-called "TRIPS-plus" provisions that stretch beyond the realm of the reified paradigm[212]. These features exemplify what has been called the

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[207] As we shall further delve upon in the further course of this study, its content is not unanimously agreed upon, and the 2001 Doha Ministerial Declaration has specifically called for its review: Declaration of the Fourth Ministerial Conference held in Doha, Qatar, on the 14th November 2001, WT/MIN(01)/DEC/1, paragraph 19.
[208] JOHANNA SUTHERLAND, "Trips, Cultural Politics and Law Reform," *Prometheus* 16, no. 3, 1998.
[209] CULLET, "Intellectual Property Rights and Food Security in the South," *op.cit.*, p.269.
[210] JOHANNA GIBSON, *Community Resources: Intellectual Property, International Trade and Protection of Traditional Knowledge*, Globalisation and Law Aldershot: Ashgate, 2005.
[211] HELFER, "Intellectual Property Rights in Plant Varieties: An Overview with Options for National Governments."
[212] For a historical approach identifying the trend of international reification and its bilateral enhancement, see MOHAMMED EL-SAID, "The Road from Trips-Minus, to Trips, to Trips-Plus," *The Journal of World Intellectual Property* 8, no. 1, 2005. For a more global analysis of the TRIPS-plus trend in regional and bilateral negotiations, see

"limited discretion" of Member States: the flexible opportunities we view as the main prospect for fine-tuning agrobiodiversity related IPRs to the needs of all relevant innovation contexts. The same discretion that allows States to reach further than the minimal standards of the international agreement, along with the inherent manoeuvre margin left within the content of such standards, may indeed very well, if efficiently exploited, redress the sensed and experienced inequalities from the TRIPS invasion in domestic IPR legislation. The Agreement does provide for a number of such **diffusion-oriented flexibilities**. In certain circumstances, the mere disclosure of protected innovations or the publication of creative works may not be sufficient to diffuse innovations and compensate for the excessive monopoly cost. This feature was recognised by the TRIPS Agreement in its Article 7, which allows its Members to

> "*adopt measures necessary to protect public health and nutrition; and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement*" (TRIPS, Art.7).

These measures may reveal restrictions directly targeting the rules of protection themselves, carving out exclusions to such protection (as it has been accepted for patents on biological matter), but they also may, and generally do, target the range of exclusive rights granted to innovators, in an attempt to set boundaries to their prerogatives. Indeed, intellectual property rights

> "*should contribute to the promotion of technological innovation and to the transfer and dissemination of technology […] in a manner conducive to social and economic welfare"*[213]. Article 8 goes on to state, "*appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology*" (TRIPS, Art. 8).

According to the minimal protection standard set out by the TRIPS Agreement, additional diffusion tools should therefore be built in different intellectual property instruments. With specific regards to patents, the TRIPS Agreement acknowledges for instance in its Article 30 that exceptions may be carved around exclusive rights to

> *"provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties"* (TRIPS, Article 30).

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for instance DAVID VIVAS-EUGUI, *Regional and Bilateral Agreements and a Trips-Plus World: The Free Trade Area of the Americas (Ftaa)*: Quaker United Nations Office (QUNO), 2003., BEATRICE LINDSTROM, "Scaling Back Trips-Plus: An Analysis of Intellectual Property Provisions in Trade Agreements and Implications for Asia and the Pacific," *NYUJ Int'l L. & Pol.* 42, 2009. For a study on the impact of such provisions on public health and the development of generic medicine, see MARÍA FABIANA JORGE, "Trips-Plus Provisions in Trade Agreements and Their Potential Adverse Effects on Public Health," *Journal of Generic Medicines: The Business Journal for the Generic Medicines Sector* 1, no. 3, 2004. For a public international law perspective on potential conflicts with the initial TRIPS agreement, see HENNING GROSSE RUSE-KHAN, "International Law Relation between Trips and Subsequent Trips-Plus Free Trade Agreements: Towards Safeguarding Trips Flexibilities, The," *J. Intell. Prop. L.* 18, 2010.

[213] Paragraph 19 of the 2001 Doha Ministerial Declaration specifically instructs "the Council for TRIPS, […] to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore and other relevant new developments raised by members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension."

In-built balances of intellectual property rights have also been reflected in the controversial yet imperative concept of "compulsory licensing" enshrined in TRIPS Article 31. Indeed, "*other uses without the authorisation of the right holder*" are provided for notably in cases of national emergency or public non-commercial uses, but also when the "reasonable commercial terms and conditions" offered by the third party are refused by the right holder. Compulsory licensing opportunities arise around numerous conditions that ought to be respected as a counterpart to the "transgression" of the artificial lead-time granted to innovators:

> *Where the law of a Member allows for other use (7) of the subject matter of a patent without the authorisation of the right holder, including use by the government or third parties authorised by the government, the following provisions shall be respected:*
>
> *(a) authorisation of such use shall be considered on its individual merits;*
>
> *(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.[…]*
>
> *(c) the scope and duration of such use shall be limited to the purpose for which it was authorised, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;*
>
> *(d) such use shall be non-exclusive;*
>
> *(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;*
>
> *(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use; […]*
>
> *(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;[…]*
>
> *(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur"* (TRIPS, Article 31).

Notwithstansing its provisions designed to ensure the balance between exclusivity and openness, the TRIPS Agreement comes about as an imposed bargain with levied extensive protection principles offering varying yet complex degrees of flexibility as a product of horizontal forum shifting strategies led by developed nations and powerful industry players. The Agreement effectively pushed for significant legislative and ethical changes in many legal orders, as most developing countries did not allow for the patenting of life forms and seeds before their entry into the WTO order[214]. In this sense, it may have failed to promote cultural diversity by inadequately setting the balance between producers and user of knowledge goods, thereby failing to adequately represent the values and rationale of any IPR system[215]. It is precisely these "distributive inequities" inherent to the TRIPS regime that have been vehemently disapproved, purposefully setting aside other forms of knowledge that may present a more community-oriented and free-exchange-based outlook on innovation, especially with regards to agricultural or indigenous communities[216].

CONCLUSION. The Minimal Multi-layered Intellectual Property Protection Paradigm

Most of the intervention targeting the inherent conundrums lagging private investment in plant improvement has been vested in intellectual property tools, for which minimal standards of protection have been reified at the international scale. Within a World Trade Organization and TRIPS governed international context, plant variety rights, patents and other informational proprietary mechanisms, such as trademarks or other public domain restricting tools like seed certification schemes may and do protect products and processes that stem from diverse contexts of agrobiodiversity innovation, or are used by their actors.

These tools defined a stricter public domain for human inventiveness and creativity in plant innovation; a public domain that has taken another hit through stringent seed market regulations and certification mechanisms linking a variety's future to a specific actor. Epitomised by the minimum standards set out in Article 27§3b of the TRIPS Agreement, the strong property paradigm is exemplified through different layers of protection on products and processes used in plant improvement. These layers consist *inter alia* of an effective *sui generis* plant variety rights protection scheme next to patents, awarded at minima to microorganisms, and to non-essentially biological processes. These informational monopolies have been complemented by seed certification requirements, which aim to overcome the informational imbalance between the consumer and producer, and have been tightened by the advent of compulsory certification fostering the development of improved and uniform plant varieties in a transparent and competitive marketplace. The striking feature of this paradigm has been the unequivocal linkage of regulatory solutions to the assymetrical information flows in seeds, and the lack of artificial lead-time in the hands of innovators, with international trade. Such linkage, imposed by developed nations, whether in the immediate context of the OECD and the non self-evident yet valuable context of the WTO, has tremendously reinforced the reach of a product development and trade oriented approach to agrobiodiversity innovation.

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214 PHILIPPE CULLET, "Environmental Justice in the Use and Exploitation of Genetic Resources," in *Environmental Law and Justice in Context*, ed. JONAS EBBESON and PHOEBE OKOWA, Cambridge: Cambridge University Press, 2009.
215 This view is defended by DINWOODIE and DREYFUSS, *A Neofederalist Vision of Trips: The Resilience of the International Intellectual Property Regime*, *op.cit.*
216 WEST, "Institutionalised Exclusion: The Political Economy of Benefit-Sharing and Intellectual Property," *op.cit.*, p.41.

3. CHAPTER 3: PLANT-RELATED INTELLECTUAL PROPERTY RIGHTS: PATENTS AND *SUI GENERIS* PROTECTION

Statutory or jurisprudential decisions pertaining to the extent and restrictions of patentability requirements predominantly remain a national endeavour, and therefore show important differences from one legal tradition to the other. Owing to the minimal protection standards reified in the TRIPS Agreement, a great number of similarities may nonetheless be found in the two main allocative tools that impact agrobiodiversity innovation, i.e. patents and plant variety or breeders' rights. Jerome REICHMAN, in its prominent article focusing on "legal hybrids between the patent and copyright paradigms"[217] argues that the current regulatory responses to "deviant fields of innovation" propelled by technological change, have either extended the scope and subject-matter of traditional intellectual property right paradigms such as copyrights or patents, or had recourse to "legal hybrids" and *sui generis* property rights systems built on slight modifications of these paradigms' inherent principles. The property layers that ensue result not only from the "emulation" of need-specific protection regimes, mainly designed for the products of conventional or molecular plant breeding, but also from the "accretion"[218] or expansion of the traditional IP mechanisms' protection scopes to cater the needs of biotechnology.

The products of plant improvement innovation, as well as the components and processes used throughout crop research and development, can today be appropriated through multiple instruments, used separately or collectively, according to the strategy and business model preferred by innovators[219]. A concrete example may best serve our purpose to illustrate the array of intellectual property tools that may surround a single product of agrobiodiversity innovation. Our illustration comes from the world of brown tomatoes, particularly appreciated in Mediterranean cuisine. In this particular segment, tomatoes produced in the districts of Campo de Níjar y Bajo Andarax in the province of Almería in Spain, in accordance with the "cahier des charges" set out in the application for the protected geographical indication "Tomate La Cañada", would be protected under the terms of Council Regulation EC 510/2006[220]. The tomato varieties that fall under this geographical indication may be additionally protected through plant variety rights, as it is for instance the case of two brown tomato varieties, "SX 387" and "Olmeca", granted to Syngenta by the European Community Plant Variety Office respectively through titles number 21017 in 2007 and 16595 in 2007. The parent lines of these varieties are very likely to be protected as trade secrets, while the inbred tomato lines TZ367 and TZ368, which together form the hybrid SX387, are patented by Syngenta under US Patent 7,786,358 B2 on the basis of ATCC accessions (American type culture collection). The varieties may have in parallel been developed using any molecular marker that are protected through patents granted in the United States, the European Patent Convention or any other TRIPS Member State. The tomato products of both the Olmeca and Sx387 varieties are lastly marketed under the trademark Kumato, designating fresh tomatoes and first used in 30th June 2009.

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[217] REICHMAN, "Legal Hybrids between the Patent and Copyright Paradigms," *op.cit.,* pp.2432-2558.
[218] CORNISH, "The International Relations of Intellectual Property," *op.cit.* and {Chiarolla, 2011 #529}.
[219] NIELS LOUWAARS et al., *Breeding Business: The Future of Plant Breeding in the Light of Developments in Patent Rights and Plant Breeders' Rights* Wageningen, NL: Center for Genetic Resources, 2009.
[220] Publication of an application pursuant to Article 6(2) of Council Regulation (EC) No 510/2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs, 'TOMATE LA CAÑADA', EC No: ES-PGI-0005-0664-04.12.2007, *J.O.C.*, 286/18, 30.09.2011.

Providing for a *de lege lata* overview of appropriation tools present in the European legal order, and which influence the different contexts of agrobiodiversity innovation, we shall try to convey the evolution of the inherent balance of intellectual property rights in the entire array of enclosing instruments encountered by agrobiodiversity innovation. As aforementioned, the geographical emphasis of such analysis will remain on the European legal order, to which supporting or contrasting illustrations may be additionally provided from other jurisdictions. Far from being a comparative law exercise, the sole aim of this analysis is to provide a concrete illustration of the TRIPS-propelled strong property paradigm, underlining the shrinking space left to the public domain by the concomitant recourse to plant variety and patent protection in their contemporary understanding and reach.

3.1. Plant variety protection or plant breeders' rights, the conventional breeders' copyright

Plant variety rights have been designed by those countries which recognised the need to endow some artificial lead-time to innovators in the development and commercialisation of products stemming from the new science of plant breeding, due to the built-in reverse engineering prospects carved within plant-related innovations. These countries were at the same time reluctant to bring the products of nature and life forms within the realm of patent protection. Arguably built on modified copyright principles[221], *sui generis* plant variety rights were first crafted within a few European national legal orders from the 1940's onwards, and were effectively reified at the international level through the adoption of the International Convention for the Protection of New Varieties of Plants in 1961 (known as "UPOV", acronym of the French version of the Convention's title, symbolising past geopolitical influences and the role of the French government and seed association ASSINSEL in its crafting[222]). The Convention was amended numerous times, the latest being in 1991[223]. As an intergovernmental organisation that today counts seventy signatories in total. It also includes the United States, which enacted its Variety Protection Act in 1970 and amended it in 1994. The UPOV system strives to provide and promote "an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society"[224]. While protection is granted at the national level by national institutions applying national laws, the adherence to the UPOV system is designed as a substance-oriented pledge mechanism allowing innovators to navigate international markets more freely. On account of UPOV adherence, plant breeders know how extensive a protection they will be granted in a signatory country, and also to which extent they will be allowed to actually use improved and

[221] REICHMAN, "Legal Hybrids between the Patent and Copyright Paradigms," *op.cit.*

[222] QUEEN MARY INTELLECTUAL PROPERTY RESEARCH INSTITUTE, "The Relationship between Intellectual Property Rights (Trips) and Food Security," 2004: pp.6-7. The French government was approached by ASSINSEL, the former international association of plant breeders for the protection of plant varieties, founded in 1938, in order to convene a diplomatic conference in Paris with like-minded 12 western European countries. These attempts resulted in the conclusions of the 1957 Paris Conference, which "recognised the legitimacy of breeders' rights and established the conditions for protection, that a variety had to be distinct from pre-existing varieties and sufficiently homogenous and stable in its essential characteristics" to justify the grant of exclusive prerogatives to its "creator".

[223] In the UPOV system, adherence to the latest Conventions is only mandatory for new applicants, meaning that all three Conventions (the 1961, 1978 and 1991) still in force today. For instance, Norway still applies the 1978 text, as thodose most of Latin American countries. Countries who wish to join UPOV today however need to show their national law is compliant with the 1991 Convention terms.

[224] UPOV, " *International Union for the Protection of New Varieties of Plants: What It Is, What It Does*", UPOV, International Union for the Protection of New Varieties of Plants Geneva, 2004.

protected material in their breeding programs. To this day, the only multi-State mechanism issuing certificates covering the territory of more than one State is the Community Plant Variety protection system, which extends throughout the territory of the European Union[225]. Even though none of the UPOV Conventions should be considered the "grail" of plant variety protection mandated by the TRIPS Agreement, their effectiveness has been acknowledged at the international level. This makes them an excellent starting point to study the state of plant variety rights worldwide, from protected subject matter to the rights granted to breeders, as well as third parties. The legal provisions that shall be studied as an illustration of the strong property paradigm pushed by a developmental reading of the TRIPS minimum standards therefore consist of the UPOV Conventions and the (consolidated) European Regulation 2100/94.

3.1.1. *Subject-matter and Breadth of Protection: A sui generis instrument for new plant varieties*

Notwithstanding their geographical or substantial reach, all plant breeders' rights systems **seek to protect plant varieties**. They do not protect plant specimens in their tangible forms, but rather protect the phenotypic design of a plant variety, elevated to the rank of an intellectual object that is non-exclusive by nature. This qualification is not as straightforward as in the case of creations of the mind in the form of an idea that is expressed through words, for instance. Indeed, a plant variety is inherently translated into a physical object with direct industrial use, which will undoubtedly be re-used to develop another physical object with industrial use, i.e. foodstuff, feed, fuel or other uses. Yet these physical objects, i.e. specific plant specimens, constitute in essence the mere materialisation of characteristics that have been carefully selected and developed by a plant breeder.

Plant varieties

So-called "breeders' rights" are effectively granted on very specific subject matter, i.e. on plant varieties, but not on all of them either. Under the 1961 Convention, protection is granted to

> "*any cultivar, clone, line, stock or hybrid which is capable of cultivation [in all botanical genera and species], and which satisfies the provisions of Article 6*", while the opportunities for control also extend to "*reproductive and vegetative propagating material, [including] whole plants, [as well as] to ornamental plants or parts thereof normally marketed for purposes other than propagation when they are used commercially as propagating material in the production of ornamental plants or cut flowers*" (UPOV 1961 Convention, respectively Art.2§2, and 5§1).

The 1991 Convention adopts a somewhat stricter and much more detailed definition of a plant variety, considering it

> "*a plant grouping within a single botanical taxon of the lowest known rank, […] defined by the expression of the characteristics resulting from a given genotype or combination of*

[225] Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights *OJL* 227 , 01 September 1994, pp.1-30.

genotypes, distinguished from any other plant grouping by the expression of at least one of the said characteristics and considered as a unit with regard to its suitability for being propagated unchanged" (UPOV 1991 Convention, Art.1 (vi))

In this approach, plant populations in the likes of landraces may arguably be considered as plant varieties, while wild relatives may not, since they will probably not fall under the scope of this definition of a "cultivar". The exact wording of the 1991 UPOV Convention is in this sense reprised in Article 5 of EC Regulation 2100/94, which goes on to state that

> "*a plant grouping consists of entire plants or parts of plants as far as such parts are capable of producing entire plants, both referring to hereinafter as "variety consistuents*", while "*the expression of the characteristics referred to [above] may be either invariable or variable between variety constituents of the same kind, provided that also the level of variation results from the genotype or the combination of genotypes"* (Art.5 §§3-4, EC Regulation 2100/94).

These precisions allow for more variability within the notion of a plant variety, flexibilities that are still compliant with UPOV 1991 terms. They extend the notion of plant grouping in order to also cover certain parts of plants, if they retain reproductive capacity vis-à-vis an entire plant. The grouping can also show some variation in its characteristics. However, all aforementioned texts seem to exclude specific traits, substances, or plant breeding processes from protection under "an effective" plant variety protection regime, limiting it to the global phenotype which characterises a plant variety and can be reproduced in the field.

New, distinct, uniform and stable plant varieties

It is generally accepted that PVP protection operates with regards to new, distinct, uniform and stable varieties in the dominant strong property paradigm. Protection could nonetheless for instance be awarded to so-called "extant varieties", as has notably been the case in the 2001 Indian Plant Variety Protection and Farmers' Rights Act, which targets varieties that had been developed by the public sector in the past[226]. While the TRIPS Agreement solely conditions the design of a plant variety protection system to an effectiveness threshold, thereby arguably allowing a looser approach to novelty, the development oriented dominant strong paradigm, epitomised by the 1991 UPOV Convention, does not adopt such an ample understanding towards the eligibility criteria that open the door to exclusivity for breeders. The four aforementioned conditions have indeed been designed to limit the scope of PVP legislation to the needs of conventional plant breeding in most OECD countries, including the EU.

Within the four cumulative conditions, novelty is usually sought after first. According to Article 6 of the 1961 UPOV Convention,

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[226] SHAILA SESHIA, "Plant Variety Protection and Farmers' Rights in India: Law-Making and the Cultivation of Varietal Control," *Economic and Political Weekly* 37, no. 27, 2002: p.9.The Indian registrar also allows for the registration of farmers' varieties directly, as we shall delve on in the further course of this study.

> "*the new variety must not have been offered for sale or marketed in the territory of that State, or for longer than four years in the territory of any other State*", at the time of the application for protection in a member State of the Union. (UPOV 1961 Convention, Art.6)

This wording is not completely maintained in the 1978 text of the UPOV Convention, which keeps the absence of single year marketing requirement in the territory of the State, but adds a four years' timeslot for action if the plant varieties are sold or marketed in any other State in its Article 6. Such slot is extended to six years for vines, ornamentals, forest and fruit trees, which are technically easier to "copy". This novelty criterion is maintained as such, except for minor adjustments, in article 6(1) of the 1991 Convention.

Indeed, *"The variety shall be deemed to be new if, at the date of filing of the application for a breeder's right, propagating or harvested material of the variety has not been sold or otherwise disposed of to others, by or with the consent of the breeder, for purposes of exploitation of the variety: (i) in the territory of the Contracting Party in which the application has been filed earlier than one year before that date and (ii) in a territory other than that of the Contracting Party in which the application has been filed earlier than four years or, in the case of trees or of vines, earlier than six years before the said date"* (UPOV 1991 Convention Art. 6.1).

The Convention allows for a little flexibility with regards to plant species that were not previously protected under its terms, but does not address other issues, such as contractual transfers or cultivation related to field trials, which would seemingly not affect novelty. Additional precisions have nonetheless been given in the European legal order, where, just as the UPOV 1991 text, varieties are considered novel when

> *"at the date of application determined pursuant to Article 51, variety constituents or harvested material of the variety have not been sold or otherwise disposed of to others, by or with the consent of the breeder within the meaning of Article 11, for purposes of exploitation of the variety: (a) earlier than one year before the abovementioned date, within the territory of the Community; (b) earlier than four years or, in the case of trees or of vines, earlier than six years before the said date, outside the territory of the Community"* (EC Regulation 2100/94, Art. 10§1).

However, the Regulation steps further in its interpretation of what is meant by the "disposal of material and variety constituents", by stating that the breeder retains an "*exclusive right of disposal*", in a framework where the "*exploitation of the variety*" is interpreted in a restrictive fashion. For instance, novelty is not breached when such material is transferred to official bodies, or to third parties solely for production, reproduction and multiplication, or when the material is used for non-commercial or commercial research purposes and not for further reproduction or multiplication (EC Regulation 2100/94, Art. 10§2-3). In terms of implementation, an interesting question was raised with regards to novelty in mixtures, where it was successfully argued that a variety that had been previously marketed both outside and within the EU as part of a mixture could not be protected in its own for lack of novelty[227]. Since traditional or farmers' varieties are generally commonly known and have been sold or disposed of for a long time, the novelty criteria does seemingly only address varieties that have been improved through controlled plant breeding. However, "the continued selecting and breeding efforts of rural communities" may very well generate important changes and qualify landraces as new in certain circumstances[228].

Furthermore, not only does the plant variety have to be "novel" but, according to Article 6 of the 1961 UPOV text, it shall be protected if it is also

> *"clearly distinguishable by one or more important [morphological or physiological] characteristics [capable of precise description and recognition], from any other variety whose existence is a matter of common knowledge at the time when protection is applied for"* (UPOV 1961 Convention, Art.6§1a). In this context, "*common knowledge may be established by reference to various factors such as: cultivation or marketing already in progress, entry in an official register of varieties already made or in the course of being made, inclusion in a reference collection or precise description in a publication"* (UPOV 1961 Convention, Art.6§1a).

The 1991 amendments have shrunk the disposition's text and thereby enlarged the margin of appreciation left to implementing States, by positing that the variety ought to be "*clearly distinguishable from any other variety whose existence is a matter of common knowledge at the time of the filing of the application*" (UPOV 1991 Convention, Art.7). The text adds that "*in particular, the filing of an application for the granting of a breeder's right or for the entering of another variety in an official register of varieties, in any country, shall be deemed to render that other variety a matter of common knowledge from the date of the application, provided that the application leads to the granting of a breeder's right or to the entering of the said other variety in the official register of varieties, as the case may be"* (UPOV 1991 Convention, Art.7)

In this latest version of the UPOV approach, the criterion of distinctness is therefore linked to the appreciation of "varieties of common knowledge". It does not refer to the elements that may help appreciate such distinct nature, although it seems to indicate, albeit non-exhaustively, that prior knowledge stems from the existence of procedural steps to protect said variety. EU legislation seems to provide a little more guidance, in that the distinctness is defined "*by reference to the expression of the characteristics that results from a particular genotype or combination of genotypes*" (EC Regulation 2100/94, Art. 7§1). This means that a phenotypical observation is required at this stage to assess whether not necessarily all, but at least certain characteristics differ from varieties of common knowledge, which have been "*the object of a plant variety right or entered in an official register of plant varieties, or of an application for the granting of a plant variety right*" (EC Regulation 2100/94, Art. 7§2). The determination of distinctness and qualification of an existing plant variety as of "common knowledge" has been subject to numerous

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[227] The case relates to an application to protect the "Moreya" variety of Gypsophilia, which was previously sold within a mixture under the name Morstars, Decision of the CPVO Board of Appeals filed by Danziger Dan Flower Farm, 13th October 2006 (Reference A 004/2005).
[228] DAN LESKIEN and MICHAEL FLITNER, "Intellectual Property Rights and Plant Genetic Resources: Options for a Sui Generis System," (Rome: International Plant Genetic Resources Institute (IPGRI), 1997), p.50.

interpretations by the CPVO Board of Appeals[229]. In an infamous case that was brought all the way up to the European Court of Justice, a breeder was for instance denied protection by the CPVO for protection under EC Regulation 2100/94, on the grounds that the proposed variety was in fact not dictinct enough from a wild variety originating in South Africa, and which had been marketed for years in Germany[230]. In another case, the Board of Appeals has annulled a decision to grant protection to an apple variety that was granted on an assessment of distinctness where the characteristic taken into account was the width of stripes in fruit, which was objected against due to its scientific unacceptability, even though such decision was later annulled by the Europen Court of First Instance (General Court) on different grounds[231]. National implementation also provides more explanations as to the threshold of "common knowledge", as "the existence [of a reference variety] was considered a matter of common knowledge because of its presence in the botanical garden *and* because the reference variety originated from the German horticultural company Nothhelfer who had commercialised propagating material of the reference variety between 1994 and 2000' in the Netherlands[232].

The wording of the United States PVP Act is somewhat different with regards to novelty and distinctness, as it states that a novel variety should be considered distinct when it "*clearly differs by one or more identifiable morphological, physiological, or other characteristics ... from all prior varieties of public knowledge*". Notwithstanding their differences, in all of these contexts, the contribution or value of traits or characteristics is not taken into account to assess novelty or distinctness, making the inclusion of "cosmetic traits" that do not contribute to the productivity of the crop, a sufficient condition to create a new and distinct plant variety.

In addition to their new and distinct nature, plant varieties also "*must be sufficiently <u>homogeneous</u>, having regard to the particular features of their sexual reproduction or vegetative propagation*" in the words of both the 1961 and 1978 UPOV texts (UPOV 1961 and 1978 Conventions, Art.6§1c) .

This benchmark was later coined uniformity and enshrined in Article 8 of the 1991 Convention, whereby "*the variety shall be deemed to be uniform if, subject to the variation that may be expected from the particular features of its propagation, it is sufficiently uniform in its relevant characteristics"*, (UPOV 1991 Convention, Art.8)

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[229] In accordance with Articles 71 to 73 of Regulation No 2100/94, the Board of Appeal decides on the appeal brought before it by exercising any power which lies within the competence of the CPVO, or by remitting the case to the competent body of the CPVO for further action. Actions may be brought before the Court of Justice against decisions of the Board of Appeals on the grounds of lack of competence, infringement of an essential procedural requirement, infringement of the Treaty, of Regulation No 2100/94 or of any rule of law relating to their application, or misuse of power. The Court has jurisdiction to annul or to alter the decision of the Board of Appeal.

[230] See the initial decision by the Board of Appeal of the Community Plant Variety Office (CPVO) of 2 May 2006 (Reference A 003/2004), while the Judgment of the Court of First Instance of the European Communities, T-187/06, *Schrader vs. CPVO* (*SUMCOL 01*), ECR-II- 3151, and the Judgment of the Court of Justice of the European Communities, C-38/09, *Schrader vs. CPVO* (*SUMCOL 01*), 15th April 2010.

[231] Board of Appeal of the Community Plant Variety Office (CPVO) of 21 November 2007 (Cases A 003/2007 and A 004/2007); Judgment of the Court of First Instance of the European Communities, T-135/08, *Schniga GmbH vs. CPVO*, 13th September 2010.

[232] District Court of The Hague, Netherlands, *Genplant B.V. v. Board of Appeal of the Dutch Plant Variety Office*, 22 March 2005.

The exact same wording has been maintained in EU law, as "*a variety shall be deemed to be uniform if, subject to the variation that may be expected from the particular features of its propagation, it is sufficiently uniform in the expression of those characteristics which are included in the examination for distinctness, as well as any others used for the variety description*" (EC Regulation 2100/94, Art.8).

The additional precision of the European legislation, stating that uniformity should lie in the "expression" of characteristics once again emphasises the focus on phenotypically observable traits and qualities of the varieties. Even though the UPOV interpretations and technical guidelines do offer some tolerance with regards to the maximum acceptable number of off-types, it does "not allow for the protection of plant groupings with a high degree of diversity as is typical of many landraces"[233]. This stance has been viewed as a deprivation of potential benefits to breeders and society, and directly linked to the controversial notion of genetic erosion and uniformisation of agricultural production, as we shall study in the further course of this monograph. It should however be noted that should heterogeneous plant groupings be accepted under PVP laws, this change would significantly broaden the reach of intellectual asset protection, in turn risking to severely restrict agricultural development[234].

The last criterion that plant varieties need to meet in order to fall under plant breeders' rights relate to their ***stability***. Plant varieties indeed ought to be stable in their essential characteristics; in so far as they "*must remain true to their description after repeated reproduction or propagation or, where the breeder has defined a particular cycle of reproduction or multiplication, at the end of each cycle"* (UPOV 1961 and 1978 Conventions, Art.6§1d)

The 1991 Convention mentions "relevant" rather than essential characteristics, which shall "*remain unchanged after repeated propagation*" in its Article 9. This stability requirement stems from a desire to ensure those actors who will be marketing or cultivating the protected variety that the characteristics describing the novelty will continue to be observed throughout the protection period. It does not figure in all PVP laws as a criterion for protection, as the 1982 Japanese statutes for instance rather opted for the nullity of the protection title if the characteristics of the protected variety cease to manifest themselves compared to the time of registration[235].

The European Union approach follows suit to the 1991 UPOV Convention, as: "*a variety shall be deemed to be stable if the expression of the characteristics which are included in the examination for distinctness as well as any others used for the variety description, remain unchanged after repeated propagation or, in the case of a particular cycle of propagation at the end of each cycle*" (EC Regulation 2100/94, Art.9),

Stability should therefore be assessed once the variety has been propagated, and cannot on its own serve to establish distinctness, as it is *« alongside distinctness and uniformity, an independent, necessary characteristic that makes a plant grouping a variety. Stability is also not a distinguishing characteristic within the meaning of Art. 7(1), because it is not*

[233] LESKIEN and FLITNER, "Intellectual Property Rights and Plant Genetic Resources: Options for a Sui Generis System," p.51.
[234] "Intellectual Property Rights and Plant Genetic Resources: Options for a Sui Generis System," p.53.
[235] Ibid., p.52

> *expressed. This is because a genotype characteristic of a plant is expressed only if it manifests itself in a different way compared with another plant. No statement can be made about stability until after propagation, once several generations have been compared with each other »*[236].

The four main conditions that trigger plant variety protection under UPOV 1991 rules and also their quasi-textual implementation in EC Regulation 2100/94 are cumulative and inherently require the conduct of what has been coined "Distinctness, Uniformity and Stability" (DUS) field examinations that are highly technical in nature. Interestingly, yet quite predictably, considering the technical nature of the DUS criteria for protection and the inevitability of **field trials,** PVP certificates are not granted by traditional IP offices but rather by specialised entities of the Ministry of Agriculture. These entities are generally those testing departments responsible for certification procedures when they exist. This element emphasises the *sui generis* nature of plant breeders' rights, which necessarily rely on field examinations as the single means to objectively ensure that the variety is true to word and form, based on phenotypic observations over time. This necessary phase does however considerably lengthen the procedure for obtaining protection, as it remains excessively contingent of natural farming cycles and environments.

3.1.2. <u>Bundle of Rights Awarded through Plant Variety Protection</u>

All IPR restrict methods of acquiring ideas; patents in this context restrict the use of ideas, while copyrights restrict their expression[237]. Plant variety rights stand equidistant to such premise, granting a mixture of exclusive rights to definitively exclude others from copying plant varieties, accompanied by minor rights to exclude others from using new varieties. The rights to exclude from third party uses are significantly restricted by two major counter-conditions, drafted in the shape of liability rules. The breeders' exemption grants other plant developers the possibility to use the protected information without prior consent of the titleholder, while the farmers' exemption allows growers to save and conditionally sell the protected seeds. Even though the patent-like restrictions on use are significantly alleviated by these third party prerogatives, they still remain present. Indeed, plant breeders cannot in any case use protected plant varieties to develop their own product by solely acknowledging the origin of their inspiration, as would be allowed under copyright protection. The link between the phenotype of a plant variety and the actual physical object of a seed is irremediably closer to industrial inventions than creative works. That is notably why Jerome REICHMAN has identified them as "legal hybrids"[238]. According to HEITZ[239], plant variety protection was not crafted as an artificial monopoly, since such premise would not coincide with the reality of plant breeding, where research and commercial associations are a necessity, and where competition with both breeders and farmers is inevitable, however innovative the product may be. The development of agrobiodiversity-innovation specific regime of plant breeders' rights was in this sense "based on the premise that innovations by breeders could only be sustained if the

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[236] Decision of the Board of Appeal of the Community Plant Variety Office, *Joseph en Luc Pieters BVBA vs. CPVO,* 1st April 2003 (Reference A 001-3/2002).

[237] HETTINGER, "Justifying Intellectual Property," *op.cit.,* p.35.

[238] REICHMAN, "Legal Hybrids between the Patent and Copyright Paradigms," *op.cit.*

[239] HEITZ, "Intellectual Property in New Plant Varieties and Biotechnological Inventions," *European Intellectual Property Review* 10, 1988: pp.287-293.

primary and protected material remained freely available for further research"[240]. Another premise reinforcing the resemblance of PVP to copyright protection lies in the in-built link with food security and cultivation of protected varieties, inevitably recognising the prospects of farmers to save, re-plant and sell seeds.

Considered by many as a **regulatory model for inventions with partial appropriability and excludability,** the effect of plant variety protection on production results such as yield improvement have however generally failed to generate mind-blowing figures, urging commentators to view the appropriability and excludability PVP entails as marketing tools rather than propellers of genetic enhancement[241]. On the other side of the spectrum, the introduction of PBR protection has also been associated with increased breeding activity, an increased number of new varieties and enhanced access to foreign germplasm through the breeders' exemption[242]. The reality might very well lie in between these two opposite assumptions, while the presence and growing recourse of PVP protection tools remains of inescapable actuality for all actors involved in the use of agricultural biodiversity.

Prerogatives awarded to right holders

When the aforementioned protection criteria are met, an array of prerogatives is granted to the breeder for a limited time. The protection period started out as minimum fifteen years in both the 1961 and 1978 text (Article 8), extended to eighteen for ornamentals, trees and vines. According to article 19 of the 1991 UPOV Convention, such period shall now

> "*not be shorter than twenty years from the date of the grant of the breeder's right. For trees and vines, the said period shall not be shorter than twenty five years from the said date"* (UPOV 1991 Convention, Art.19)

Throughout this period, plant breeders' rights give **various prerogatives to right holders.** The initial 1961 text indeed states in its Article 5 that the prior authorisation of the breeder should be sought

> "*for production, for purposes of commercial marketing, of the reproductive or vegetative propagating material, as such, of the new variety, and for the offering for sale or marketing of such material*". It went on to assert "*the breeder's right shall extend to ornamental plants or parts thereof normally marketed for purposes other than propagation when they are used commercially as propagating material in the production of ornamental plants or cut flowers*" (UPOV 1961 Convention, Art.5)

The special regard for the different conditions of ornamental breeding, where the plant itself or its parts may be used to recreate the variety or just sell cut flowers, is also present in the 1978

[240] CULLET, "Intellectual Property Rights and Food Security in the South," *op.cit.*, p.266.
[241] JULIAN M. ALSTON and RAYMOND J. VENNER, "*The Effects of the Us Plant Variety Protection Act on Wheat Genetic Improvement*", International Food Policy Research Institute, Washington D.C, 2000.
[242] UPOV, "*Upov Report on the Impact of Plant Variety Protection*", UPOV, International Union for the Protection of New Varieties of Plants, Geneva, 2005.

Convention. With slightly clearer wording, Article 5§1 of the 1978 text had rendered the breeders' prior authorisation mandatory in cases of

> *"production for purposes of commercial marketing, offering for sale, and marketing of the reproductive or vegetative propagating material, as such, of the variety"* (UPOV 1978 Convention, Art.5) .

The real extension of the list of actions requiring the breeder's authorisation came with the 1991 Convention's Article 14, enumerating with great detail the enlarged scope of action awarded to right holders. The list now entails the

> "*production, reproduction (multiplication), conditioning for the purpose of propagation, offering for sale, selling or other marketing, exporting, importing or stocking of the plant variety and its harvested material obtained through the unauthorized use of propagating material*" (UPOV 1991 Convention, Art.14)

This enlarged scope of prerogatives, and their conditional application is reprised in the relevant EU legislation, as:

> *"2. The following acts in respect of variety constituents, or harvested material of the protected variety, both referred to hereinafter as 'material', shall require the authorization of the holder: (a) production or reproduction (multiplication); (b) conditioning for the purpose of propagation; (c) offering for sale; (d) selling or other marketing; (e) exporting from the Community; (f) importing to the Community; (g) stocking for any of the purposes mentioned in (a) to (f).*
> *The holder may make his authorization subject to conditions and limitations" (EC Regulation 2100/94, Art.13).*

The potential limits and conditions that can be imposed upon the users by the breeder holding the rights to a variety have been interpreted quite extensively. Indeed, the judiciary has approached the manoeuvre margins left to producers restrictively, especially when these have been bound by exclusive licensing agreements. It has for instance established that the purchase of material from an agent of the breeder and not directly from him, even though the seeds bought were the same, amounted to a contractual breach; thereby affirming the supremacy of conditions that can be imposed by the right holder on the sale and use of its variety[243].

Essentially derived varieties

These principles do not only apply to propagating material such as seeds, but have also been extended to **harvested material and essentially derived varieties**, respectively answering the preoccupation of the ornamentals sector and the challenges caused by molecular breeding. In an attempt to enlarge the breadth of protection covered by PVP and safeguard the rights of plant breeders who have to compete with varieties that constitute only slight modifications of their original or initial varieties, the novel concept of essential derivation was infused in Article 14 of

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[243] Ghent Court of Appeal, Kortrijk District Court, Belgium, *R.A.G.B.*, 5 April 2006,

the 1991 UPOV Convention. As such, essentially derived varieties do not directly fall into eligibility criteria for plant variety protection, but as a concept extending breeders' prerogatives to different plant varieties, it in effect highly influences the subject matter of protection. Indeed, under the strong property paradigm, plant breeders' rights not only protect new, distinct, uniform, and stable plant varieties but also those that have been essentially derived from them. In light of the technological progresses beheld in genomics and genetics sciences, which have enlarged the possibilities of speedy and inexpensive copying of new biological material, the 1961 and 1978 Conventions were deemed insufficient to meet the globalised industry's needs[244]. As a result, the concept of "essentially derived varieties (EDV)" was considered necessary "to prevent converted lines from infringing and pirating breeder's genetic material"[245], since the "cosmetic modifications" obtained through simple backcrossing of parental lines would qualify as a new protectable plant variety.

Owing to the introduction of the EDV concept, royalties would need to be paid when a variety is

> "*predominantly derived from the initial [improved] variety, retaining the expression of the essential characteristics that result from the genotype or the combination of genotypes of the initial variety*", except for the small differences that still make it distinguishable from the initial variety" (UPOV 1991 Convention, Art.14§5)

Through this provision, licensing agreements should not only be negotiated when the protected variety's use in a breeding programme leads to the commercialisation of a new variety that is not clearly distinguishable from the initial protected variety, but also when it leads to one that is "essentially derived". This extension was also echoed in Article 13(1) and (2) of Council Regulation EC/2100/94, which reads a little differently, while retaining the same overarching goal of extending the bundle of rights stemming from plant variety protection:

> *"6. a variety shall be deemed to be essentially derived from another variety, referred to hereinafter as'the initial variety' when:*
>
> *(a) it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety;*
>
> *(b) it is distinct in accordance with the provisions of Article 7 from the initial variety; and*
>
> *(c) except for the differences which result from the act of derivation, it conforms* ***essentially*** *to the initial variety in the expression of the characteristics that results from the genotype or combination of genotypes of the initial variety."(*European Regulation EC/2100/94, Art. 13§§1-2, emphasis added)

Even though the Council Regulation reprises the UPOV definition in its main lines, the legislator has provided some minor adjustments for clarification purposes [246]. Just as the UPOV wording, it refers to predominant derivation, which implies that the alleged EDV does not have to be directly derived from the initial protected variety, and also states that an EDV could be obtained by using another variety that had already been predominantly derived from the initial variety. Both texts reprise the principle of distinctness between plant varieties, but they diverge on their approach to

[244] WENDT and IZQUIERDO, "Biotechnology and Development: A Balance between Ipr Protection and Benefit-Sharing," *op.cit.*
[245] ISF, "*Essential Derivation: Information and Guidance to Breeders*", ISF, International Seed Federation, Nyon, 2005.
[246] BART KIEWIET, "Essentially Derived Varieties," *Community plant variety office, European Union, Angers*, 2006.

conformity in the expression of the characteristics. It is the latter characteristics that ought to be essential and retained according to UPOV, but the EC rather establishes that the EDV itself need to be "essentially conform" to the initial variety. Furthermore, the differences ought to stem fro mthe act of derivation, but both texts are worryingly silent on whether these different ought to be quantitative or qualitative. As we shall see in the further course of this study, determining whether a plant variety is essentially derived from another is more than an arduous task, as epitomised by the conflicting reports submitted by conflicting firms in one of the rare cases to have been settled before the judiciary[247].

<u>Harvested material and exhaustion of rights</u>

Furthermore, just as the 1991 UPOV text, the scope of prerogatives has been extended in the EU to cover a wider range of material:

> *3. The provisions of paragraph 2 shall apply in respect of* ***harvested material*** *only if this was obtained through the unauthorized use of variety constituents of the protected variety, and unless the holder has had reasonable opportunity to exercise his right in relation to the said variety constituents" (EC Regulation 2100/94, Art.13).*

The prerogatives of the breeder are quite naturally expressly extended to those "essentially derived varieties", but also to those plant varieties that are not distinct in the sense of the legislation, or those that require its repeated use for their production (Art.13. para.5). Establishing the limit between propagating material and finished products has been arduous, especially since the width of protection does not only depend on the definition of a plant variety and the conditions that open up protection, but also on the eventuality of **exhaustion** vis-à-vis certain plants or products. This principle intends to build limits to the prerogatives awarded to right-holders under certain conditions, which render exclusivity unnecessary.

With regards to the exhaustion of plant variety rights, article 16 of the 1991 UPOV Convention thus explicitly refuses to extend protection

> "*to acts concerning any material of the protected variety, or of [an essentially derived variety], which has been sold or otherwise marketed by the breeder or with his consent […], unless such acts involve further propagation of the variety in question or an export of material allowing the propagation of the variety"* (UPOV 1991 Convention, respectively Art.16§1).

The principle of exhaustion clearly proves the emphasis of plant variety protection on a sole extension to propagating material, a protection that would only exceptionally extend to portions of said material as it is the case of cut flowers (since they can themselves may be propagating material). In no case however do plant breeders' rights extend to marketed products under the UPOV Conventions, an extension that was for instance envisaged in the proposed "Convention of

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[247] District Court of the Hague, *Astée Flowers vs. Danziger 'Dan' Flower Farm*, 13th July 2005. Indeed, Danziger had commissioned a study ascertaining the existence of essential derivation from Keygene, while Astee's report was realised by IdQ Identification Services Wageningen, which heavily criticised the latter's methodology.

Farmers and Breeders" ("CoFab") covenant[248]. Once again, applicable European law provides more specific guidance as to the instances where exhaustion may not hold up in Court.

> *"The Community plant variety right shall not extend to acts concerning any material of the protected variety, or of a variety covered by the provisions of Article 13 (5), which has been disposed of to others by the holder or with his consent, in any part of the Community, or any material derived from the said material, unless such acts: (a) involve further propagation of the variety in question, except where such propagation was intended when the material was disposed of; or (b) involve an export of variety constituents into a third country which does not protect varieties of the plant genus or species to which the variety belongs, except where the exported materials is for final consumption purposes"* (EC Regulation 2100/94, Art.16)..

However, the articulation of these two principles, i.e. the expansion of protection to harvested material and the exhaustion of rights to materials disposed or derived from protected varieties has been quite arduous in practice. The judiciary has been for instance left to consider whether the sale of cut flowers the seeds of which had been obtained from a third party who was not authorised to sell the protected variety, whether the breeders' right stopped at the use of the variety as propagating material, or to its use as a commercial end product as well[249]. In the event of a prior unauthorised sale, and only in such event, does the strong property paradigm allow for extensive protection to prevail. A strict approach to PVP exhaustion would indeed further preclude the extension of prerogatives for instance on end products destined to industrial uses or as animal feed for cereal, which could be considered harvested material when used for cultivation without the consent of the right holder, opening up royalty payments.

Judicial remedy

Notwithstanding the limits put upon the prerogatives awarded to breeders who successfully protect their plant varieties, they are unconditionally accompanied by **judicial remedy opportunities**. As an international convention that does not have a specific adjudicative body, all UPOV texts leave such issue to be determined under national or supranational jurisdiction. In this sense, European Union law provides that the Court of Justice shall be competent to hear disputes on damages linked to non-contractual liability (EC Regulation 2100/94, Art.93) on the basis of the following principles:

> "*Whosoever: (a) effects one of the acts set out in Article 13 (2) without being entitled to do so, in respect of a variety for which a Community plant variety right has been granted; or (b) omits the correct usage of a variety denomination as referred to in Article 17 (1) or omits the relevant information as referred to in Article 17 (2); or (c) contrary to Article 18 (3) uses the variety denomination of a variety for which a Community plant variety right*

[248] BISWAJIT DHAR, "*Sui Generis Systems for Plant Variety Protection: Options under Trips*", Quaker United Nations Office, 2002. The covenant was proposed by the Gene Campaign in 1998, and followed a stance close to that of UPOV 1991, but with a focus on "germplasm-owning countries of the South", presented as a "developing country alternative to UPOV", see also A. RAVISHANKAR and SUNIL ARCHAK, "Searching for Policy Options: Is Cofab a Suitable Alternative to Upov?," *Economic and Political Weekly* 34, no. 52, 1999.
[249] Tribunal of Sanremo, Italy, 13 January 1986 (Luciano Patrucco (plaintiff) vs Renato d'Ambrosio (defendant).

has been granted or a designation that may be confused with it; may be sued by the holder to enjoin such infringement or to pay reasonable compensation or both.

Whosoever acts intentionally or negligently shall moreover be liable to compensate the holder for any further damage resulting from the act in question. In cases of slight negligence, such claims may be reduced according to the degree of such slight negligence, but not however to the extent that they are less than the advantage derived therefrom by the person who committed the infringement" (EC Regulation 2100/94, Art.94).

The Regulation therefore specifies the infractions, including intentional and non-intentional violations of the breeders' prerogatives, but also infringements attributed to mere negligence that would open the door to the payment of "reasonable compensation". Such compensation can also be required "*from any person who has, in the time between publication of the application for a Community plant variety right and grant thereof, effected an act that he would be prohibited from performing subsequent thereto*" (Art.95). The interpretation of such idiom has led national Courts to refer to the Court of Justice, faced with the uncertainty surrounding the means through which the compensation should be calculated, and whether it should mirror the specific "equitable remuneration" reserved to farmers, that we shall touch upon in the next section. The recent reference to the European Court of Justice for a preliminary ruling in *Geistbeck v Saatgut*[250] has shed some light on the interpretation of the Community Regulation in this aspect, as the Bundesgerichtshof's questions were directed to the core need to calculate the amount of "reasonable compensation" owed by a farmer who unlawfully uses protected propagated material. The German Court went on to ask whether such amount should "be calculated on the basis of the average amount of the fee charged for the licensed production of a corresponding quantity of propagating material of protected varieties of the plant species concerned in the same area, or must the (lower) remuneration which would be payable in the event of authorised planting under the fourth indent of Article 14(3) of the CPVR Regulation and Article 5 of the Community Planting Regulation be taken as a basis for the calculation instead?"[251]. The answer of Luxembourg provided an interpretation favouring the breeders' interests, since the acts perpetrated by the farmers were considered to be "unauthorised", triggering considerable compensation:

"39. As a result of the infringement of the plant variety rights, STV is entitled to require payment of reasonable compensation under Article 94(1) of the basic regulation. Moreover, the referring court points out that the Geistbecks' failure to fulfil their obligation to provide information is intentional or negligent, so that STV can also claim compensation for any further damage resulting from the infringement under Article 94(2) of that regulation.

40. I must point out straight away that, for the purposes of examining Article 94 of the basic regulation, one should start from the assumption that the underlying objective of that article is full compensation based on the principle of restitutio in integrum. In other words, the compensation which is payable when plant variety rights have been infringed is intended to return the holder of those rights to the situation that existed prior to the

[250] European Court of Justice, C-509/10 *Josef Geistbeck and Thomas Geistbeck v Saatgut-Treuhandverwaltungs GmbH*, reference for a preliminary ruling from the German Bundesgerichtshof, 5th July 2012.

[251] European Court of Justice, C-509/10 *Josef Geistbeck and Thomas Geistbeck v Saatgut-Treuhandverwaltungs GmbH*, reference for a preliminary ruling from the German Bundesgerichtshof, 5th July 2012.

> infringement. However, it is not so easy to apply that principle in this case because that situation can be restored either by reference to authorised planting or by taking into account the amount charged for the licensed production of the propagating material"[252].

The judicial remedies offered by the Community Regulation is therefore quite large, based on the principle of reasonable compensation, which should enable the return to the situation which existed prior to the infringement, calculated on the basis of the "fee charged for the licensed production of a corresponding quantity of propagating material of protected varieties", which includes monitoring and supervision costs and can be supplemented by pre-litigation or litigation costs if deemed necessary.

Rights awarded to third party users

To **offset the social cost stemming from the prerogatives** awarded to breeders through PVP protection, a number of theoretically irrefutable statutory use options have been conceded in plant variety protection in all UPOV regimes. Targeting directly or indirectly researchers, breeders or farmers, PVP legislation allows for the use of protected varieties by third parties without the explicit authorisation of the breeder through the so-called breeders' exemption, the farmers' privilege and compulsory restrictions to protected rights. While these temperaments' largely unconditional nature was initially designed to balance the exceptional reward of exclusivity granted to the innovator, they also share the same tragic faith of being increasingly surrounded by stringent regulatory constrictions.

Breeders' exception

Science-based plant breeding relies on a constant and unconditional access to improved germplasm found in the market in order to generate socially, economically or environmentally interesting new agrobiodiversity on the basis of existing genetic variability. The **breeders' exception** allows variety developers to use protected varieties in their crop genetic improvement activities, acknowledging the practices of "market prospection" for genetic material. This exemption from authorisation, which can also be viewed as an exception to the bundle of property rights, formally ends at the stage of commercialisation of new varieties developed using the protected germplasm, at which point royalty negotiations can be undertaken in accordance with the product developed by the second breeder, and its closeness to the initial variety.

Under UPOV 1961 and 1978, this prerogative really transpires like a true exemption. The initial 1961 text states that the prior authorisation requirement stemming from plant variety protection shall

> "*not be required either for the utilisation of the new variety as an initial source of variation for the purpose of creating other new varieties or for the marketing of such varieties*", except "*when the repeated use of the new variety is necessary for the commercial production of another variety*" (UPOV 1961 Convention, Article 5§3), a wording that remained unchanged in the 1978 Convention.

[252] Ibidem.

Under these terms, licensing negotiations emerge as a mandatory step in cases where the protected variety's use in a breeding program leads to the commercialisation of a new variety that is not clearly distinguishable, or whose production requires the repeated use of the protected variety, i.e. if the new variety is merely an identical copy of the protected plant variety, or if the latter has been directly used as a parent of a new variety.

However, the terms of UPOV 1991 have altered such trigger. This mechanism rather emerges as a "*compulsory exception*", through which certain actions exceptionally do not fall under the breadth of PVP protection. According to Article 15§1, these actions range from

> "*acts done privately or for non-commercial purposes, acts done for experimental purposes, [to] acts done for the purpose of breeding other varieties"* (UPOV 1991 Convention, Art.15§1)

In this last scenario, the bundle of authorisation prerogatives would not be relevant, "*except where the provisions of Article 14(5) apply*". The breeders' authorisation will thus be waived provided that the breeding programme does not produce an essentially derived variety. Licensing negotiations would thus need to be undertaken when the resulting variety can be considered to be essentially derived from the protected initial variety. In this sense, the restrictive turn taken by the breeders' exemption has been effectively astounding, since the trigger point for authorisation shifted from distinctiveness to essential characterisation. In contrast to such restrictive stance, there are examples of other *sui generis* legislation that take an even lenient attitude on the breeders' exemption than the 1961 or 1978 UPOV texts, as we shall further explore in this study. The 2001 Namibian proposal for instance precludes breeders to exercise their rights also "in obtaining varieties from gene banks or plant genetic resources centres"[253]. In the European Union, applicable legislation gives a particularly large margin of appreciation to Member States, all the while maintaining its UPOV 1991 compatible approach, viewing the research and breeders' exceptions as "limitations of the effects of plant variety rights":

> "*Limitation of the effects of Community plant variety rights (a) acts done privately and for non-commercial purposes; (b) acts done for experimental purposes; (c) acts done for the purpose of breeding, or discovering and developing other varieties*" (EC Regulation 2100/94, Art. 15).

Since none of the essential terms have been actually defined in the Regulation, this provision leaves the door open to either stricter or wider appreciations of the so-called "freedom to operate" on protected varieties, which could for instance determine whether a royalty payment should operate at the end of the breeding cycle, even if the resulting product is not a plant variety essential derived from the initial one. However, as it purposefully limits the right holders' prerogatives on the inclusion of varieties into breeding programmes, it still stands at the core of the plant variety protection regime's *sui generis* nature, as a mechanism that was inherently designed to allow breeders to continue building on the pool of available improved varieties. As most of the conflicts seem to be resolved either through commercial arrangements or by means of arbitration, there is

[253] The 2001 proposal for "Access to Biological Resources and Associated Traditional Knowledge Act" was based on the "African Model Law for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources" developed by the OAU, see DHAR,, DHAR, *op.cit.*, 2002.

effectively no European case-law dealing with the reach of the breeders' exception in plant variety protection.

<u>Farmers' exception</u>

An additional liability rule, similar to the breeders' exception, concerns the use of the protected informational matter by farmers faced with varieties protected by a plant variety protection certificate. This privilege is recognised in light of ancestral traditions of seed saving and exchange. It also stems from socio-economic considerations linked to subsistence, as well as the primordial role of seeds in the further *in situ* use and conservation of agrobiodiversity. **The farmers' privilege**, allowing farmers to sow seeds for saving, using or exchanging, was essentially implied by the 1961 and 1978 UPOV Acts. Indeed, the extent of exclusive rights awarded to breeders did not reach acts perpetrated without any commercial purpose by third parties, including unmethodical selectors and farmers[254].

The formerly implicit farmers' exemption is now found in article 15§2 of the 1991 UPOV Convention, which states that

> "*each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety or [an essentially derived variety]*" (UPOV 1991 Convention, Art.15§2).

The wording clearly shows the shift taken by the approach to the farmers' privilege, which evolved into a clear and even more importantly into an ***"optional exception"*** to the exclusive rights of breeders, rather than an array of acts considered outside the scope of the IP title in itself. The restriction of the farmers' exception, or the corresponding extension of PVP protection to cover farm-saved seed or those crops grown from saved seed, have been advocated with a clear "policy objective of reducing public investment in breeding", since the private sector would not otherwise enter into costly yet less lucrative research and development segments, such as wheat breeding[255].This sharp contrast between the old and new UPOV systems has ignited virulent criticism from civil society, as well as the international community, denouncing the downgrading of the farmers' privilege[256].

However, most, if not all plant variety rights legislation generally pertain provisions enabling small farmers, the scale of whom is defined on account of national developmental specificities and

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[254] NUNO PIRES DE CARVALHO, "Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patents Applications without Infringing the Trips Agreement: The Problem and the Solution," *Washington University Journal of Law and Policy* 2, 2000: pp.371-401.

[255] THOMSON, "The Yield of Plant Variety Protection," p.5. illustrating the premise by the Australian amendment to PVP laws in 1994 to foster private investment in wheat breeding, since the 1987 statutes did not regulate farm-saved seed as strictly as breeders would have wanted, and especially did not condition its re-use to royalty payments. It is interesting to note that the royalty system is collected at the end of the chain in Australia, organized at the level of grain delivery at silos.

[256] This "accusation" was made by the FAO during the Diplomatic Conference for the Revision of the UPOV Convention, the records of which were published in 1992 by UPOV, DHAR, *op.cit.,* 2002. , they will be studied at greater length in Part III of this study.

the particular needs of the crop, to save and exchange protected improved varieties. This is also the case of the European legislation, which this time does not view this particular liability rule as a "limitation of the plant variety protection" as it did apprehend the breeders' exception, but sees the farmers' exception as a "derogation from community plant variety rights". A slight variance that clearly demonstrates the lawmaker's difference in attitude towards the two rules, as one is a clear boundary that cannot be crossed, and the other a mere derogation that could be adjusted or even retracted in time. Indeed, the principle surrounding the derogation is that:

> "*1. Notwithstanding Article 13 (2), and for the purposes of safeguarding agricultural production, farmers are authorised to use for propagating purposes in the field, on their own holding the product of the harvest which they have obtained by planting, on their own holding, propagating material of a variety other than a hybrid or synthetic variety, which is covered by a Community plant variety right*" (EC Regulation 2100/94, Art. 14.1).

This principle is nonetheless accompanied by quite substantial conditions, as it is only allowed for certain fodder plants, cereals, potatoes and oil or fibre plants, thereby excluding all species not listed in the Regulation, especially vegetables in their entirety, but also maize (Art. 14.2.). Furthermore, specific concerns are addressed in order to "safeguard the legitimate interests of breeders":

> "***Conditions** to give effect to the derogation provided for in paragraph 1 and to safeguard the legitimate interests of the breeder and of the farmer, shall be established, before the entry into force of this Regulation, in **implementing rules** pursuant to Article 114, on the basis of the following criteria:*
>
> — *there shall be no quantitative restriction of the level of the farmer's holding to the extent necessary for the requirements of the holding,*
>
> — *the product of the harvest may be processed for planting, either by the farmer himself or through services supplied to him, without prejudice to certain restrictions which Member States may establish regarding the organisation of the processing of the said product of the harvest, in particular in order to ensure identity of the product entered for processing with that resulting from processing,*
>
> — *small farmers shall not be required to pay any remuneration to the holder; small farmers shall be considered to be [...]*
>
> — *other farmers shall be required to pay an equitable remuneration to the holder, which shall be sensibly lower than the amount charged for the licensed production of propagating material of the same variety in the same area; the actual level of this equitable remuneration may be subject to variation over time, taking into account the extent to which use will be made of the derogation provided for in paragraph 1 in respect of the variety concerned,*
>
> — *monitoring compliance with the provisions of this Article or the provisions adopted pursuant to this Article shall be a matter of exclusive responsibility of holders; in organizing that monitoring, they may not provide for assistance from official bodies,*
>
> — *relevant information shall be provided to the holders on their request, by farmers and by suppliers of processing services; relevant information may equally be provided by official bodies involved in the monitoring of agricultural production, if such information has been obtained through ordinary performance of their tasks, without additional burden or costs. These provisions are without prejudice, in respect of personal data, to Community and national legislation on the protection of individuals with regard to the processing and free movement of personal data*" (EC Regulation 2100/94, Art, 14.3).

The European Regulation therefore completely **exempts** small farmers from the payment of royalties for the use of harvested product obtained by planting on their own holding for all species listed in Article 14, and also for the use of propagating material other than hybrids and synthetic varieties. They can as a result consume and replant open-pollinated varieties, which are more likely to produce interesting results due to their inherent reproductive characteristics. All other farmers who cultivate the aforementioned limited list of species ought to compensate the breeder, albeit to a lesser extent than standard royalty rates, and provide adequate information. Both the definition of small farmers and the exact content of information to be provided by farmers who desire to benefit from the so-called "agricultural exemption" have been carefully drafted in the Implementing Rules[257], while the derogatory nature of the farmers' privilege has been re-affirmed by the European Court of Justice:

> "32 Under Article 13(2)(a) of the basic regulation, the holder's authorisation is, in principle, required for the propagation of the harvested material of a protected variety
> 33. However, Article 14(1) of the basic regulation provides for a derogation from that principle. That derogation aims to safeguard agricultural production. Under that article, farmers are authorised to use the product of the harvest obtained by planting propagating material of protected varieties for propagation in the field on their own holding, provided that the criteria referred to in Article 14(3) are complied with.
> 34. The farmers' privilege does not therefore apply if the farmer does not fulfil the obligations laid down in Article 14(3) of the basic regulation, which are specified in detail in the implementing regulation"[258].

A number of additional interpretative cases have been brought before national Courts and to the European Court of Justice more specifically with regards to the "**right to information**" that breeders could be entitled to within the framework of such derogation, and the resulting reach of the "obligation to inform" incumbent upon farmers. Article 9 of the Implementing Rules already provides some guidance as to some information that may be considered relevant, albeit non-exhaustively, prompting the European Court of Justice to rule whether the Regulation creates a "general right to information" to the benefit of the breeder whose material is been saved by farmers. More specifically, the Court has had to consider whether relevant information could be requested from either farmers or from processors without any indication that the cultivator was using the farmers' privilege. With regards to the former, i.e. farmers, confirmed ECJ jurisprudence considers that, just as the derogation concerning the farmer's privilege should be interpreted restrictively, so should the accompanying obligations. Therefore, if "there is no indication that the farmer has used or will use, for propagating purposes in the field, on his own holding, the product of the harvest obtained by planting, on his own holding, propagating material of a variety other than a hybrid or synthetic variety which is covered by that right and belongs to one of the agricultural plant species listed in Article 14(2) of Regulation No 2100/94", the prerogative of

[257] Commission Regulation (EC) No 1768/95 of 24 July 1995 implementing rules on the agricultural exemption provided for in Article 14 (3) of Council Regulation (EC) No 2100/94 on Community plant variety rights, *OJ L* 173 25.07.95, p.14.
[258] European Court of Justice, C-509/10 *Josef Geistbeck and Thomas Geistbeck v Saatgut-Treuhandverwaltungs GmbH*, reference for a preliminary ruling from the German Bundesgerichtshof, 5th July 2012.

Article 14.3 may not be used by rightholders[259]. The same reasoning applies to processors as well, as information could only be requested from suppliers that have processed protected material, and thus affected by the derogation, or in those cases where the rightholder "has some indication" that such processing is about to operate[260].

Notwithstanding the inherent limitations that surround the agricultural exemption, the notion of the "**equitable remuneration**" that is due to the breeder when the privilege is used also had to be further detailed. The legislators' guidance stems from the Implementing Rules, distinguishing cases of contractual and non-contractual farming, and providing a number of criterial threshold to infuse equity in both sides of the equation:

> *« 1. The level of the equitable remuneration to be paid to the holder pursuant to Article 14(3), fourth indent of the basic regulation may form the object of a* ***contract*** *between the holder and the farmer concerned.*
>
> *2. Where such contract has not been concluded or does not apply, the level of remuneration shall be* ***sensibly lower than the amount charged for the licensed production of propagating material of the lowest category qualified for official certification, of the same variety in the same area****. If no licensed production of propagating material of the variety concerned has taken place in the area in which the holding of the farmer is located, and if there is no uniform level of the aforesaid amount throughout the Community, the level of remuneration shall be sensibly lower* ***than the amount which is normally included, for the above purpose, in the price at which propagating material of the lowest category qualified for official certification****, of that variety is sold in that area, provided that it is not higher than the aforesaid amount charged in the area in which that propagating material has been produced.*
>
> *3. The level of remuneration shall be considered to be sensibly lower within the meaning of Article 14(3), fourth indent of the basic regulation as specified in paragraph 2 above, if it does not exceed the one necessary to establish or to stabilise, as an economic factor determining the extent to which use is made of the derogation, a* ***reasonably balanced ratio between the use of licensed propagating material and the planting of the produc****t of the harvest of the respective varieties covered by a Community plant variety right. Such ratio shall be considered to be reasonably balanced, if it ensures that the holder obtains, as a whole, a legitimate compensation for the total use of his variety […]*
>
> *5. Where in the case of paragraph 2 [there is no agreement between organisations of right holders and farmers], the remuneration to be paid shall be* ***50% of the amounts charged for the licensed production of propagating material*** *as specified in paragraph 2. However, if a Member State has notified the Commission before 1 January 1999 of the imminent conclusion of an* ***agreement*** *as referred to in paragraph 4 between the relevant organisations established at national or regional level, the remuneration to be paid in the area and for the species concerned shall be* ***40%*** *instead of 50% as specified above, but*

[259] European Court of Justice, C-305/00, *Schulin vs. Saatgut Treuhandverwaltungs GmbH*, 10 April 2003, confirmed by European Court of Justice, C-182/01, *Saatgut-Treuhandverwaltungsgesellschaft ('STV') v. Werner Jäger*, 11 March 2004.

[260] European Court of Justice, C-336/02, *Saatgut-Treuhandverwaltungsgesellschaft ('STV') v. Brangewitz*, 14 October 2004, answering whether "a supplier of processing services [should] provide the information specified in [applicable] provisions where the holder has no indication that the latter has processed or intends to process the product of the harvest obtained by farmers".

> *only in respect of the use of the agricultural exemption made prior to the implementation of such agreement and not later than 1 April 1999.*
> *6. Where in the case of paragraph 5 the farmer has made use, in the relevant period, of the agricultural exemption at a ratio of* ***more than 55% of the total material of the relevant variety used for his production****, the level of the remuneration to be paid in the area and for the species concerned shall be the* ***one which would apply in respect of such a variety if it was protected in the relevant Member State under its national system*** *of plant variety rights, if a national system exists which has established such level, and provided that that level is more than 50% of the amounts charged for the licensed production of propagating material as specified in paragraph 2. In the absence of such level under the national scheme, the provisions of paragraph 5 shall apply irrespective of the ratio of use »* (Commission Regulation 1768/95, Art.5).

The European Commission would therefore consider, in absence of contractual arrangements to the contrary, that an equitable remuneration should be "sensibly lower" than the royalty rate applied to same variety in the area, viewed as a "reasonably balanced ratio" between the breeders' interests and his need to recoup his investment, and the need to cultivate such variety for sustenance and smaller-scaled production. The text also seems to fix a rate of fifty per cent of the certified seed fee, supplemented by a transitionally fixed rate of forty per cent in order to encourage the conclusion of agreements between rightholders and farmers. However, these precisions have not unlifted the nebulous veil as to what may essentially constitute an equitable remuneration, especially in cases where contractual agreements between two moral persons or between national or regional associations have fixed substantially higher rates. This issue has been duly tackled by the European Court of Justice, which has ruled that a flat rate of eighty per cent of regular royalties could not befall under such category in the specifics of the case, even though the rate of fifty per cent would only apply in absence of an agreement between organisations of holders and farmers[261]. The Court has thereon also affirmed that the rate of fifty per cent of certified seed fee is a "fixed amount which constitutes neither an upper limit nor a lower limit", as "inferred from the very wording of that provision that the value stated is mandatory"[262].

<u>Compulsory licensing</u>

Aside these liability rules that are triggered by the quality of the actors who use protected varieties and harvested material, all plant breeders' rights statutes also provide for **opportunities of compulsory licensing in order to safeguard public interests.** The UPOV Conventions in this regard « *restrict the exercise of the rights protected* », only « *for reasons of public interest […] in order to ensure the widespread distribution of new varieties* », providing for an « *equitable remuneration* » of the breeder (UPOV 1961 Convention, Art.9) .

Based on the similar prose of the 1978 UPOV Convention, the Model Law on Plant Variety Protection adopted by the Union in 1980 foresaw three choices to national law-makers for the interpretation of the public interest safeguard clause. The first does not reflect on the public

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[261] European Court of Justice, reference for a preliminary ruling, joint C-7/05 and C-9/05, Saatgut-Treuhandverwaltungs GmbH vs. Ulrich Deppe, Hanne-Rose Deppe, Thomas Deppe, Matthias Deppe, Christine Urban (née Deppe) (C-7/05), Siegfried Hennings (C-8/05), Hartmut Lübbe (C-9/05), 8th June 2006.
[262] Ibidem, para 45-47.

interest dimension at all, since it merely consist of patents-reminiscent « voluntary or contractual licenses » , and « license of rights » that need to be agreed upon parties for the exploitation of a protected variety[263]. The actual « compulsory licensing » provision of the 1980 Model Law provided that the Plant Breeders' rights office would grant a license without the consent of the right holder for "the rapid and wide distribution of new varieties and their availability to the public at adequate and reasonable prices"[264]. The compulsory license would only be granted if the applicant was in a position to actually exploit the PVP, contractual licensing was unsuccessfully tried to be obtained, the terms offered by the right holder were unreasonable, and the PVP title had at least been given three years before[265]. The compulsory license would not be given for not less than two and more than four years. The 1991 revision of the UPOV Convention saw the return of a broader account of this peculiar licensing mechanisms, as the grounds for safeguarding the public interest were not explicitly detailed, neither in Article 17 of the Convention, nor in the Model Law adopted in 1996. The latter still operated a distinction between voluntary and compulsory licensing, which leads one to believe that an initial negotiation with the right holder would be a necessary step before applying for a compulsory license.

No such distinction seems to be established by Article 29 of the EC Regulation 2100/94, which limits the grant of such licenses to "reasons of public interest" after consultation of the Administrative Council of the CPVO, all the while interestingly considering the case where such a license would be requested by the holder of an essentially derived variety, but also the more complex issue of a patent holder desiring to use the protected phenotype, a characteristic that we shall tackle in the further course of this study.

Plant breeders' rights, a relatively lesser-known intellectual property right system outside of those having recourse to its instruments regularly, are conferred either under laws enacted in view of the different UPOV Conventions, or as stand-alone national legislation. They confer a bundle of rights to a novel particular *combination* of genes manifested as a distinct, uniform and stable variety. Requiring neither proof of an inventive step or a specific utility for the concerned plant variety, protection is granted on the basis of the existence of phenotypic differences vis-à-vis known varieties, without regard for the contributed value, except for their genetic quality in terms of uniformity and stability. They are closely and expressly linked to considerations of sequential innovators relying on access to improved germplasm on the one hand, and of farming communities cultivating propagating material for their own consumption, to make ends meet, or as a viable commercial enterprise on the other hand. It is on account of this indissoluble bond that the prerogatives granted to breeders under PVP protection for new, distinct, uniform and stable plant varieties are accompanied by exceptions for both breeders and farmers, even though the reach of both these exemptions has steadily been retracted.

3.2. Patent protection, an old instrument revived for the DNA age

Plant-related patents are relatively newly expanded forms of IPR in the agrobiodiversity innovation chain, with the notable exception of the United States, where the first ever Plant Patent

[263] DHAR, *op.cit.*, 2002.
[264] See UPOV Model Law on Plant Variety Protection, UPOV/INF/6, Geneva, 1980.
[265] DHAR, *op.cit.*, 2002.

Act was designed in 1930 for asexually reproduced plants[266]. Derived from the Latin "*litterae patentes*" (open letters), patents were first introduced in the city of Venice in 1474 to attract merchants that would be given a ten years long exclusive use right to the novel technique they developed[267]. These strong instruments today grant vast exclusivity not only on inventions that would be described as classically technical or mechanical, but they also cover living organisms used for food and agriculture. The development of biotechnological characterisation, selection, insertion and recombination tools in the science of plant breeding has indeed granted patents incredible momentum. Designed as a means to procure artificial lead-time in an increasingly competitive market with extensively lofty product duplication capabilities, patent protection came across as a convenient tool for securing new market places for innovators in the biotechnology-led global seed industry. But this tool also had to be stretched to the verge of infection in order to bring in products and processes that remained incremental, cumulative and self-replicating, making them easy to reproduce yet difficult to improve singlehandedly.

Even though a number of international conventions have allowed greater cooperation or set out minimum standards[268], patents remain national legal titles, awarded to eligible inventions, and conferring a bundle of exclusive rights to title holders. Most studies nonetheless focus on the approaches favoured by the industrialised countries that have developed important biotechnology capacity. In this respect, the infamous title 35 of the United States Code concerned with both plant and utility patents[269] is generally put up against the European approach to patents in the life sciences. The latter has been harmonised outside the realm of the European Union through the 1973 European Patent Convention ("EPC"), which arguably swept away numerous national specificities. It is also carved in specific instruments that are integral part of the *acquis communautaire*[270], such as the 1975 Convention for the European Patent for the common market[271], the Directive 98/44/EC on the patentability of biotechnological inventions ("EU Biotech Directice"), for the (failed) implementation of which eight EU Member States were referred before the European Court of Justice[272], and also more recently the 2012 so-called "patent package"

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[266] 35 U.S.C. §161

[267] SHARON ORIEL, "Making a Return on R&D: A Business Perspective," in *The Role of Intellectual Property Rights in Biotechnology Innovation*, ed. DAVID CASTLE, Cheltenham: Edward Elgar, 2009, pp.118-132 (at 118).

[268] The first international convention is in this regard The 1883 Paris Convention for the Protection of Industrial Property. Important instruments also include the 1978 Patent Cooperation Treaty.

[269] The United States legislative framework recognises utility patents, which protect primarily functional aspects of an invention, but also design patents, which protect the external appearance and aesthetic of an invention.As aforementioned, it also awards plant patents since 1930, for a very limited number of inventions.

[270] The 1973 European Patent Convention is not formally integrated into the European Union *acquis communautaire*. It is neither a body of the Union, even though all EU Member States are Parties to the European Patent Convention. The Convention also includes Turkey for instance within its signatories. Its implementation is monitored and enforced through the European Patent Office, which grants the exclusive titles and also provides for dispute resolution institutions. The Convention was substantially revised in 2007, at the end of a process that started in 2000, in order "to modernise its provisions for the 21st century and to ensure its compliance with international agreements such as TRIPS"; for a longer review of the amendments, see HECTOR MACQUEEN et al., *Contemporary Intellectual Property: Law and Policy* vol. Second edition Oxford: Oxford University Press, 2011, pp.401-404.

[271]Agreement 89/695/EEC relating to Community patents, done at Luxembourg on 15 December 1989, *OJL* 401, 30th December 1989, pp.1-27., which has never entered into force, even though its content has heavily influenced the content of national intellectual property legislation, CORNISH, "The International Relations of Intellectual Property," *op.cit.*

[272] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, *OJL* 213, 30th July 1998, pp.13-21.The European Commission indeed referred Germany, Austria, Belgium, France, Italy, Luxembourg, The Netherlands and Sweden to the ECJ for failure to implement the Directive in 2003, see Press release IP/03/991, July 2003.

towards a unified patent court[273]. Starting off from the minimal thresholds set out by the TRIPS Agreeement, our analysis will mainly draw from the implementation of these standards in the European Union, touching nonetheless at times on regulatory differences in the two sides of the Atlantic. As aforementioned, such implementation and their clear focus infuse different societal concerns, guiding the assessment of the impacts of such policy choices on plant improvement actors, as well as the search for alternatives in socio-technological innovation contexts which may suffer from its stringent contours.

3.2.1. Patentable Subject Matter and Patent Breadth: Breeding Processes and Products

Patents are perhaps the oldest form of intellectual property, awarded to new and useful products, processes, structures of matter and designs in countries with no specific industrial design protection. By providing a major incentive to undertake research and bring new products to the market, patents "are a primary solution to the problem of ensuring that inventors may appropriate the returns to R&D in the area of industrial invention and innovation"[274].

> "Until 1930, one could not patent a plant. Plants were excluded from patent law for two reasons. First, plants are products of nature. Second, plants were not thought to be amenable to the written description requirement of patent law. As a result of lobbying efforts by the seed industry, the United States first recognized plants as patentable in the Plant Patent Act of 1930. Patents were limited, however, to plants which were reproduced asexually. The rationale for restricting protection to asexually reproduced plants was the belief that new plant varieties could not be reproduced reliably by seed"[275].

The question of patent eligibility has roiled the legal systems of both developed and developing nations for the last decade, not only with regards to software, but also biotechnological inventions, whether designed for agricultural inputs or pharmaceutical products.

Novel, useful and non-obvious inventions (Protectable Subject-Matter and Eligibility)

The main conditions for patentability have been reified through the minimum standards of TRIPS, even if legal orders naturally contain innate differences. Patents are nonetheless accepted to grant absolute yet temporary rights of exclusion over an invention, once the **strict substantive and cumulative pre-requisites** of novelty, utility and non-obviousness (or inventiveness) are complied with. Indeed, article 27§1 of the TRIPS Agreement states that

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[273] The package is comprised of two Regulations: Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection, *OJL*, 361, 31th December 2012, pp. 1–8; and Council Regulation (EU) No 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements, *OJL*, 361, 31th December 2012, pp. 89–92. These instruments do not in essence alter the content of the intellectual property paradigm but are rather inscribed in a desire to ensure "enhanced cooperation" in a field where common action has been difficult to undertake. Certain commentators have even argued that the reform went against the constitutional principles of European law, opening the way for a "Europe à la carte" rather than "Europe of different speeds", see MATTHIAS LAMPING, "Enhanced Cooperation-a Proper Approach to Market Integration in the Field of Unitary Patent Protection?," *International Review of Intellectual Property and Competition Law*, no. 8, 2011.

[274] MASKUS, *Intellectual Property Rights in the Global Economy*, *op.cit.*, p.40.

[275] SUSAN E GUSTAD, "Legal Ownership of Plant Genetic Resources-Fewer Options for Farmers," *Hamline L. Rev.* 18, 1994: at p.464.

> "*any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application*" can fall under patent protection. (TRIPS Agreement, Art.27§1).

Notwithstanding the respect of these conditions, an initial observation relates to the existence of two different "types" of claims in all legal orders, first those to a physical entity (as a product or a compound), and second to a physical activity (as a method or a process). The walls surrounding their fall into exclusivity are however quite different from one legal order to the other.

In the **United States** two different patents may be awarded over plant-related inventions. Indeed, the 1930 Plant Patent Act, which was modified in 1954 and 1998, reads:

> "*Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of this title*" (35 U.S.C. §161)

Alongside plant patents granted on asexually reproduced plants, the appraisal of utility patents in biological matter is attributed to the infamous *Diamond v. Chakrabarty* ruling that deemed "everything under the sun that is made by man" patentable in 1980[276], and to the analogous extension of patentable subject matter in civil law traditions. Today, plant improvers can in the United States use either the plant or utility patent protection in their innovation chain, depending on the invention at stake, and whether the object concerns asexually reproductive plants or not. The eldest protection is thus awarded through plant patents in accordance with the terms of sections 161 to 164 of 35 U.S.C., which grant exclusive rights to asexually reproductive plant varieties, with the exception of tubers. Subject matter eligibility and conditions for the more general-scoped utility patent protection are defined in section 101 of 35 U.S.C, covering

> "*any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof*" (section 101 of 35 U.S.C).

It is this particular type of protection that has been extended to cover living organisms through the aforementioned *Chakrabarty* ruling. Although such extension seemingly started in the United States, numerous developed countries, including the European Union, have followed suit rapidly, either through targeted legislation or judicial interpretations. In the **European Union,** plant-related inventions may only be protected through a utility-type patent, under stricter conditions, notably concerning excluded subject-matter, since this type of artificial monopoly may not be granted over plant varieties or essentially biological products or processes, as we shall see below.The 1973 text of the European Patent Convention states in general terms that

> *"(1) European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.*
> *(2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1: (a) discoveries, scientific theories and mathematical methods; (b) aesthetic creations; (c) schemes, rules and methods for performing mental acts, playing games or*

[276] United States Supreme Court, *Diamond v. Chakrabarty,* 447 U.S. 303 (1980), ruled on 16 June 1980. Arguing on the patentability of "a bacterium from the genus *Pseudomonas* containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway"; the Court considered the "claim not to [be] a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter – a product of human ingenuity "having a distinctive name, character [and] use".

doing business, and programs for computers; (d) presentations of information.
(3) The provisions of [paragraph 2](#) shall exclude patentability of the subject-matter or activities referred to in that provision only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such" (European Patent Convention 1973, Art. 52. 1-2).

The provision has been amended in 2000 in order to clarify that no fields of technology should be left outside of the scope of patentability, maintaining its non-exhaustive list of acts, products and processes that would not qualify as inventions:

> "(1) *European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application*" (European Patent Convention, Art. 52.1)

In this context, Article 3§1 of the European Directive 98/44/EC on the legal protection of biotechnological inventions provides more detailed conditions, mentioning that the principle enshrined in the EPC text shall be applicable to biological material and associated processes:

> "*inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used*" (European Directive 98/44/EC, Art.3§1).

Notwithstanding the formal exclusions from patentability that may be enshrined in applicable texts, three main elements thus need to be paid attention to when considering the issue of patentability in the development oriented strong property paradigm and its European implementation, i.e. whether the claim at hand concerns an invention, whether it is novel, and whether it is non-obvious and capable of industrial application.

An invention

As we have seen, first and foremost, traditional patent protection is always granted **to inventions, rather than discoveries**. The recourse to the criteria of "invention" has been advocated as performing a double function, not only restricting protected subject-matter, but also restricting the protection conferred to an individual subject-matter, thereon contributing to the public benefits objectives of the patent system[277]. With specific regards to plant-related inventions, the first interesting criteria stems from Article 52 (2) of the European Patent Convention, which states that "*discoveries, scientific theories [...or] presentations of information*" may not be regarded as inventions, opting for list of excludable subject matter rather than providing an exhaustive definition of an invention, which would prove trickier[278]. Indeed, biotechnological advances, or any advance relying on the investigation and use of living organisms, retain essential characteristics and elements "that might easily be located in the public realm of scientific

[277] JUSTINE PILA, "On the European Requirement for an Invention," *International Review of Intellectual Property and Competition Law* 41, 2010: pp.906-926.
[278] MACQUEEN et al., *Contemporary Intellectual Property: Law and Policy op.cit.*, Second edition, p.423.

discoveries"[279]. This feature would have, at least historically, not allowed for their patentability, as "much of biotechnology involves the discovery of the genetic basis of various biological functions"[280]. However, the existence of certain technological strides "essentially or only industrial in application", coupled with the deployment of "powerful corporate interests" have shifted the patentability line towards a pole dangerously closer to the fruits of basic research and discoveries[281]. In essence, an invention would need human involvement in nature to gain such qualification, notwithstanding the inanimate or living nature of material or process used, whereas a discovery would not benefit as much from human ingenuity[282]. This approach is a close descendant to the *Chakrabarty* doctrine, which ascertains the threshold of patentable invention at the level of human involvement in nature, rather than favouring a distinction between inanimate and living material. It in effect caters to the needs of the burgeoning industries of the developed countries. Following the advances in molecular biology, both the US Patent and Trademarks Office and the European Patent Office have stretched the line between discoveries and inventions, for instance generally considering isolated and purified nucleotide sequences as man-made chemicals. The particular issue of gene sequences has proven tricky since they « represent a hybrid case between discrete inventions and more general pieces of information that are useful for many, potentially very different, purposes »[283]. In the much talked about recent *Myriad Genetics* ruling of the United States Supreme Court[284], claims to DNA sequences in isolation were nonetheless held to be insufficiently distinct from naturally occurring genes in the body, and the patent attorneys were not able to circumvent such shortcoming by proving how new and useful the knowledge and process were developed. This ruling followed another much-echoing decision of the US Supreme Court, which, in *Mayo vs. Prometheus*, had held that the patent eligibility threshold had to be fulfilled in all claims in order to be considered valid. The decision highlighted that a mere recitation of a law of nature could not be subject to patent protection, "unless there were additional steps that ensured the claim was sufficiently tailored to not preempt further use of the natural law"[285].

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[279] CHRISTOPHER MAY, "On the Border: Biotechnology, the Scope of Intellectual Property and the Dissemination of Scientific Knowledge," in *The Role of Intellectual Property Rights in Biotechnology Innovation*, ed. DAVID CASTLE, Cheltenham: Edward Elgar, 2009, p.254.

[280] PETER DRAHOS, "Biotechnology Patents, Markets and Morality," *European Intellectual Property Review* 21, no. 9, 1999: pp.441-449 (at 444).

[281] MAY, "On the Border: Biotechnology, the Scope of Intellectual Property and the Dissemination of Scientific Knowledge," *op.cit.*, p.254.

[282] CULLET et al., "Intellectual Property Rights, Plant Genetic Resources and Traditional Knowledge," *op.cit.*, p.117.

[283] "Knowledge of gene sequences and their functions can be as powerful and far-reaching as any basic piece of scientific knowledge that might serve as the basis for many later discoveries and innovations » JACKSON, "Innovation and Intellectual Property: The Case of Genomic Patenting," *op.cit.* pp.5 and 11.

[284] United States Supreme Court, *Association for Molecular Pathology v. Myriad Genetics, Inc*. No. 12–398, June 13, 2013; This case has a long judicial history, having been first heard in 2010 before the Federal District Court in Manhattan, which invalidated the patents on account of the products of nature doctrine. The Court of Appeals then reversed the judgment, only to be brought before the Supreme Court, which on 15th July 2013, sided partly with the petitioners.

[285] Considering "whether a method for optimising the dosage of a drug constituted patentable subject matter […], the Court reaffirmed that the "machine or transformation test" previously espoused by the Federal Circuit was not solely determinative of patent eligibility, and rejected attempts by the patent law community and the U.S. government to render § 101 a mere formality in assessing a claim". It rather "embraced a bright-line rule: a claim that simply directs a natural law or formula to be applied is not patent eligible because it would preempt the use of the natural law or abstract idea and preclude further discovery", see JESSICA BELLE, "Prometheus Vs. Mayo: Limited Implications for §101 Jurisprudence," *Wash. JL Tech. & Arts* 8, 2013. See also United States Supreme Court, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.,* 566 U.S., 132 S. Ct. 1289, 1304 (2012), especially at 1301.

The EPC has attempted to place the tricky line between discoveries and inventions by having recourse to "a positive requirement for **technical character**", making all subject matter including some technical character an invention[286]. In the section of its Guidelines focusing on discoveries, the European Patent Office ("EPO") considers that finding "a previously unrecognised substance occurring in nature" constitutes a mere discovery, while "if a substance found in nature can be shown to produce a technical effect, it may be patentable"[287]. The stretch of the notion of invention for the needs of biotechnology patents, so far as to consider isolated and purified naturally occurring genes as no longer existing in nature, has been compared to allowing intellectual appropriation to rocks picked up in the park after being washed and polished[288]. The comparison might shudder some, as the realm of biotechnology and plant breeding remains guided by practical application and workmanship, but it definitely illustrates the evident distension first operated in industrialised countries, and then corroborated by international reification, in order to allow patent protection for living organisms. The tresholds of "human intervention" and "technical step" are prominently found in the European Patent Office's jurisprudence tackling the reach of the exclusion of essentially biological processes from the realm of patentability, as we shall study below. We can nonetheless already note that the relevant case-law has indirectly qualified processes that would fall under the criteria of an invention, when they "contain at least one essential technical step, which could not be carried out without human intervention and which had a decisive impact on the final result"[289].

The "technical step" criteria was also held up in the EU Biotech Directive, where, as a principle,

> "*biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature"* (European Directive 98/44/EC, Art.3).

In a prominent case of the EPO Board of Appeals relating to "claims to transgenic plants comprising in their genomes specific foreign genes, the expression of which results in the production of antipathogenically active substances, and to methods of preparing such plants"[290], i.e. to genetically modified plants that exterminate plant pathogens, the Board confirmed that nothing prevented inventions to be **general in their essence, and thus claims to be broad**:

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[286] JUSTINE PILA, "The Future of the Requirement for an Invention: Inherent Patentability as a Pre- and Post- Patent Determinant," in *Biotechnology and Software Patent Law: A Comparative Review of New Developments*, ed. EMANUELA AREZZO and GUSTAVO GHIDINI, Cheltenham: Edward Elgar, 2011, pp.55-91 (at 58).

[287] EUROPEAN PATENT OFFICE, "Guidelines for Examination in the European Patent Office," (2012). Part G (patentability), Chapter I, which states that the invention "*must relate to a technical field, must be concerned with a technical problem, and must have technical features in terms of which the matter for for which protection is sought can be defined in the claim*". The Implementing regulations to the Convention on the Grant of European Patentsregarding the content of description (Rule 42), where "the technical field to which the invention relates" needs to be specified in the claim, while the description shall also "disclose the invention, as claimed, in such terms that the technical problem, even if not expressly stated as such, and its solution can be understood, and state any advantageous effects of the invention with reference to the background art".

[288] DRAHOS, "Biotechnology Patents, Markets and Morality," *op.cit.*

[289] This approach was help up in Technical Board of Appeal of the European Patent Office, *Plant Cells/PLANT GENETIC SYSTEMS*, 21 February 1995, T 356/93, Official Journal of the European Patent Office (1995), at 545, which actually confirmed to so-called "Lubrizol" principles regarding the extent of human intervention needed when faced with essentially biological processes, Technical Board of Appeal of the European Patent Office, *Hybrid plant/LUBRIZOL*, 10 November 1988, T 320/87, Official Journal of the European Patent Office (1990).

[290] Enlarged Board of Appeals of the European Patent Office, *Transgenic plant/NOVARTIS II*, G-0001/98, 20.12.1999.

> "An inventor who has invented fastening means characterised in that they consist of a specific material has invented neither a nail, nor a screw, nor a bolt. Rather his invention is directed to fastening means generally. This is not a question of form but of substance: the applicant may claim his invention in the broadest possible form, ie the most general form for which all patentability requirements are fulfilled. If he has made an invention of general applicability, a generic claim is not the consequence of the verbal skill of the attorney, as the referring decision seems to suggest, but of the breadth of application of the invention"[291].

<u>A novel invention</u>

Once the existence of an invention, requiring a technical step, has been set, patent eligibility also asks for it to be **new**, "preventing the disutility of re-inventing the wheel, ensuring that matter which is already in the public domain is not brought under private monopoly control, and to protect parties who have been using products or processes publicly from being stopped from doing so"[292]. The gauge of novelty indirectly pushes patent offices, legislators and adjudicators to construct the public domain, mostly on the basis of the so-called "state of the art", checking whether the patent could have been "anticipated" through documents or even practices, "enabling" the notional skilled person to produce the invention or versions of the invention based on the disclosed information. Anticipation can in this regard either occur by use or by disclosure, if in both cases, the information made available to the public allows individuals to work the invention[293].

The legal thresholds for novelty are set as follows in the European legal order:

> *"(1) An invention shall be considered to be new if it does not form part of the* ***state of the art.***
> *(2) The state of the art shall be held to comprise everything* ***made available to the public*** *by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.*
> *(3) Additionally, the content of European patent applications as filed, the dates of filing of which are prior to the date referred to in paragraph 2 and which were published on or after that date, shall be considered as comprised in the state of the art.*
> *(4) Paragraph 3 shall be applied only in so far as a Contracting State designated in respect of the later application, was also designated in respect of the earlier application as published.*
> *(5) The provisions of paragraphs 1 to 4 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 52, paragraph 4, provided that its use for any method referred to in that paragraph is not comprised in the state of the art" (EPC, 1973, Art. 54).*

The Convention's revision in 2000 maintained the general principles related to the criteria of **novelty**, retaining its link to the state of the art, and the latter's definition. The amendments have

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[291] Ibidem, p.15.
[292] MACQUEEN et al., *Contemporary Intellectual Property: Law and Policy op.cit.,* Second edition, p.450.
[293] The manufacture of flavor concentrates has been for instance viewed as having been anticipated by traditional cooking recipes that incidentally produced the same results, Technical Board of Appeal of the European Patent Office, *CPC/Flavour Concentrates,* T303/86, *EPOR*, 2, 1989, p. 95.

nonetheless retracted the limitation that was present in former indent four, retracting the conditional designation of a Contracting State and thereby making the state of the art a supranational notion extending beyond national boundaries[294]. Novelty has proven to be a knuckle for biotechnological inventions, and especially in the context of medical research as epitomised by the abundant EPO case-law. The Board of Appeals even had to conceive into making a limited exception to the general rules for novelty in cases of second and subsequent therapeutic uses, all the while expressly indicating that such a special approach to "derivation" in novelty assessments could only be applied to claims to the use of substances or compositions intended for use in a method referred to in Article 52(4) EPC[295]**.** The Board has confirmed the restrictive nature of such exceptional approach numerous times, and developed it further when asked whether "a claim to the use of a compound for a particular non-medical purpose novel for the purpose of Article 54 EPC, having regard to a prior publication which discloses the use of that compound for a different non-medical purpose, so that the only novel feature in the claim is the purpose for which the compound is used"[296].

> "If on its proper construction the claim contains no technical feature which reflects such new use, and the wording of the claim which refers to such new use is merely mental in nature and does not define a technical feature, then the claim contains no novel technical feature and is invalid under Article 54(1) and (2) EPC (because the only technical features in the claim are known)"[297].

Notwithstanding such derogative stance, it has been difficult to draw the contours of the **state of the art** in patent applications. For instance, it is as a principle not only assessed vis-à-vis the initial content of claims, as persistent EPO case-law has also allowed disclaimers to restore novelty by delimiting claims against the state of the art or accidental anticipation[298]. In parallel, both the Technical and Appeals' Board have shed light on the epinous question of what constitutes the "state of the art" and how an invention may be considered to be a part of such realm that considerably delineates the boundaries of patentability. An approach has been to define the invention's "**availability to the public**", as prescribed by the second indent of Article 54 of the EPC, by analysing the kind of information that should be available, and whether one should seek for the rationale guiding the invention:

> "An essential purpose of any technical teaching is to enable the person skilled in the art to manufacture or use a given product by applying such teaching. Where such teaching results from a product put on the market, the person skilled in the art will have to rely on his general technical knowledge to gather all information enabling him to prepare the said product.

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[294] An additional amendment concerned the question of novelty with regards to substances or compositions used in methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods, which are in principles excluded from patentability in accordance with Art. 53(c) of the Convention (new indent 4 of Art. 54).

[295] Enlarged Board of Appeals of the European Patent Office, *Second Medical Indication*, G-05/83. 1984.

[296] Enlarged Board of Appeals of the European Patent Office, *Mobil Oil Corp v Chevron Research Co*, G-02/88, 1990, Official Journal EPO 93, p.15-16.

[297] Ibidem, p.22.

[298] Enlarged Board of Appeals of the European Patent Office,*PPG/Disclaimer*, G-01/03, and *Genetic Systems/Disclaimer*, G-02/03, both dated as of 8th April 2004.

> Where it is possible for the skilled person to discover the composition or the internal structure of the product and to reproduce it without undue burden, then both the product and its composition or internal structure become state of the art. […]
> There is no support in the EPC for the additional requirement […] that the public should have particular reasons for analysing a product put on the market, in order to identify its composition or internal structure. According to Article 54(2) EPC the state of the art shall be held to comprise everything made available to the public. It is the fact that direct and unambiguous access to some particular information is possible, which makes the latter available, whether or not there is any reason for looking for it"[299].

With regards to the availability of biological material, the Board has had to assess whether the customary exchange of material within the scientific community could be an obstacle to the novelty threshold. Even when institutional policies encouraging free exchange of biological material can be substantiated, the existence of such policies have not been considered as making the material "publicly available" for the purposes of patentability, whether contractual restrictions applied to the material or not[300]. Notwithstanding this objective evaluation of the state of the art, its time constraints have been thoroughly discussed in relevant case law, leading the Board to state that the publication of a document during the priority interval would constitute prior art for the application claiming such priority[301]. For the purposes of establishing prior art, the EPC text itself gives some indication with regards to scientific publications or other disclosures of the innovative product or process. Indeed, Article 55 states that "*a disclosure of the invention shall not be taken into consideration if it occurred no earlier than six months preceding the filing of the European patent application and if it was due to, or in consequence of: an evident abuse in relation to the applicant or its legal predecessor, […] an international exhibition".* The date to be taken into account for the calculation of the six months period has been confirmed to be the date of the actual filing of the patent application (and not the priority date)[302].

However, the determination of the "state of the art" has not been solely set to be balanced against written disclosure in specific documents, whether scientific publications or patent applications. The concept for novelty in patent application, as acknowleged by Art. 54.2 of the EPC, also allows the test to be run "in any other way". In this regard, the EPO case law has highlighted that "common general knowledge" whether found in writing, or simply as a part of the "unwritten mental furniture of the notional person skilled in the art" could also be used to overturn the patentability of an invention, as long as proof of its existence could be brought by documentary or oral evidence, and its content be obtained without a comprehensive search[303]. At least two high profile cases have raised the issue of whether naturally occurring biological material already used by man and known to foreign communities would satisfy the novelty inquiry, in the infamous cases involving the so-called Neem tree patent in 2000 and corn plants with improved oil

[299] Enlarged Board of Appeals of the European Patent Office, G-01/92. 18th December 1992, pp.5-6.
[300] Enlarged Board of Appeals of the European Patent Office,*Hepatitis A,* T-815/90, 26th February 1993, and *Plasmid,* T-576/91. 18th May 1993.
[301] Enlarged Board of Appeals of the European Patent Office, *Priority Interval*, G-03/93. 16th August 1994.
[302] Enlarged Board of Appeals of the European Patent Office, *University Patents*, G-03/98. 12h July 2000.
[303] Enlarged Board of Appeals of the European Patent Office, T-939/92. 18th December 1992, OJ 1996, p.309; T-0766/92, Decorative Laminatives/ Boeing, 29th September 1993; T-206/83, *Herbicides*, 26th March 1986.

composition in 2004[304]. In a parallel fashion, the reach of prior art in plant innovation has also been considerably tense in the example of *Oryza longistaminata*, a wild rice variety from Mali, which will be studied further in Chapters 7 and 14[305].

A non-obvious invention capable of industrial application

Novel inventions ought also to be **non-obvious or involve an inventive step, while being capable of industrial application** in order to qualify for patent protection**.** These criteria, taken collectively, may serve as watchdogs to ensure that patents are not granted on abstractions with very little technical appeal, but that they rather foster the development of useful products and processes. Taken individually, they entail different checklists. The **gauge of inventive step** requires a jump from the state of the art or the public domain sufficient enough to justify the grant of temporary monopoly. Referred to as non-obviousness in the United States and focusing on the particularities of the result[306], the criteria stems in Europe from Article 56 of the EPC, according to which the invention needs to be "*not obvious to a person skilled in the art*". The tresholds of obviousness is thus measured with regards to an individual's mastering of the state of the art. This slight difference may in practice make a great difference in an inventor's chance at patentability, as the gauge is compared once again to the state of the art, but also to those skilled individuals who might have developed the same invention, rather than just the products' contribution to said state of art. Once again, applying the inventive step criteria to biotechnological inventions has proven quite tricky, especially in the "old continent". In a leading case regarding the *Genentech* patent[307], granted on a human tissue protein that helps the dissolution of blood cloths, the EPO most imperatively defined "notional skilled persons" restrictively, and considered they were gifted with high levels of ingenuity in the knowledge intensive sector of biotechnology[308]. It deemed that having at least five other research teams working on the same material towards the same goals, using the same technology, would preclude the existence of such an inventive step. On the contrary, the United States' system rather focuses on the non-obvious results of research and development to the eyes of an expert. Claiming "a specific recombinant DNA sequence if all of the techniques necessary to produce it are known" would be obvious and therefore could not fall under patent protection[309].

As a result of persistent case-law, the EPO's Guidelines have set out a quite complete picture of the "notional skilled person", as someone "presumed to be a skilled practitioner in the relevant field of technology, who is possessed of average knowledge and ability and is aware of what was

[304] GRAHAM DUTFIELD, *Intellectual Property, Biogenetic Resources and Traditional Knowledge* London: Earthscan, 2004. The issue of misappropriation of traditional knowledge will be tackled at greater length during the further course of this study, especially in Part III.

[305] This example is examined in SUSETTE BIBER-KLEMM et al., "Flanking Policies in National and International Law," in *Rights to Plant Genetic Resources and Traditional Knowledge*, ed. SUSETTE BIBER-KLEMM and THOMAS COTTIER, CAB International, 2006, pp.239-279 (at 241-232).. It also draws in from a detailed analysis made by UNEP and WIPO, "*The Role of Intellectual Property Rights in the Sharing of Benefits Arising from the Use of Biological Resources and Associated Traditional Knowledge - Selected Case Studies*", Geneva, 2002. (case study one – Mali).

[306] 35 USC, Section 103.

[307] Technical Board of Appeal of the European Patent Office, *Polypeptide Expression/GENENTECH*, T 292/85, Official Journal of the European Patent Office 275 (1989).

[308] MACQUEEN et al., *Contemporary Intellectual Property: Law and Policy op.cit.,* Second edition.

[309] This has been the case before the EPO, *BIOGEN Inc/Hepatitis B virus* (T-886/91, *EPOR* 361, 1999), but also in the United Kingdom, Collaborative Research's Patent BL O/86/94, cited in *Contemporary Intellectual Property: Law and Policy op.cit.,* Second edition, p.517.

common general knowledge in the art at the relevant date […], presumed to have had access to everything in the "state of the art", in particular the documents cited in the search report, and to have had at his disposal the means and capacity for routine work and experimentation which are normal for the field of technology in question, […] involved in constant development in his technical field […], expected to look for suggestions in neighbouring and general technical fields [while it sometimes may be] more appropriate to think in terms of a group of persons, e.g. a research or production team, rather than a single person"[310]. This notion was recalibrated to the needs of biotechnology, since the Board took the view that the skilled person could not be expected to be a Nobel prize winner, but rather a scientist or a team of scientists carrying out of experimental work by routine means within the framework of the normal practice of filling gaps in knowledge by the application of existing knowledge:

> "The relevant question in relation to inventive step is whether, starting from the prior art information referred to in point 4 above, and based on other relevant prior art knowledge, the skilled person would have arrived in an obvious manner at the said recombinant DNA molecule, and would have reasonably expected so to arrive. […] Given the rather confused technical circumstances, in the board's judgement, the skilled person would have had no reasonable expectation of successfully finding of the gp50 gene identified in the document within the known segment of the PRV genome, nor of successfully cloning and expressing it"[311].

The notion of inventive step, balanced against the ability of a notional skilled person's ability, also involves the assessment of the technical feature of the invention, which has been elevated to the rank of an explicit requirement by the 2000 revisions to the EPC, as aforementioned in the definition of an "invention". The main issue regarding the evaluation of the inventive step (rather than the differentiation of an invention from a discovery) relates to the treatment of inventions consisting of a mix of both technical and non-technical features, where the dominance of non-technical aspects would not preclude patent protection. Indeed,

> "An invention consisting of a mixture of technical and non-technical features and having technical character as a whole is to be assessed with respect to the requirement of inventive step by taking account of all those features which contribute to said technical character whereas features making no such contribution cannot support the presence of inventive step"[312].

The requirement regarding **industrial applicability in Europe, or utility in the United States,** maintains in essence the technical nature of inventions, and has in general not proven problematic in most fields of innovation. This has, once again, not been the case of biotechnological inventions, both sides of the Atlantic. Authors and patent offices have put forward the fact that inventions relying on living organisms or biological processes should "*perform a function".* Determining a "function" has thus been seen as a condition for the protection of new gene sequences or fragments. This particular bottleneck mostly emerged in the 1990's, during the debate over the patentability of "expressed sequence tags" (EST), which represent partial gene fragments with no known or identified uses. "Central to the question of industrial application for

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[310] Guidelines for Examination, European Patent Convention, Part G, Chapter 7.3, "Person skilled in the art".
[311] Technical Board of Appeals, European Patent Office, *Pseudorabies/UPJOHN*, T-0791/96, 15.11.1999
[312] Technical Board of Appeals, European Patent Office, *Two Identities/Comvik*, T-0641/00, 26th September 2002.

claims to gene sequences or proteins is adequate description of their function, [as] merely describing existence and structure is not enough"[313]. This emphasis on the description of a function has been taken on through another legal conundrum, having regards to wheter protection should be extended to products that contain the protected innovation, whether a product or a process. Indeed, "to the extent that the patent system allows that DNA sequences are claimed *per se*, even referring to the function of the sequence […], all uses of the protected sequence would constitute an infringement if the consent of the right holder was absent"[314], without distinguishing whether it performs its function or not.

Outside of Specific Subject-Matter Exclusions (Excluded Subject-matter)

Patent eligibility criteria need to fall outside of nationally defined subject-matter exclusions, based on ethical grounds and greater considerations of merit and justice as to the appropriateness of the patent award[315]**.** These exceptions relate first to morality or the "*ordre public*", and also additional subject-matter exclusions specific to living organisms. Situated above and afore the grant of any exclusive title over an innovative product or process, ethical considerations regarding the patentability of life *per se* have been carved in the flexibilities recognised in Article 27 §2 and §3 of the TRIPS Agreement, as well as articles 53 of the EPC, and 35 U.S.C §101[316]. These provisions allow States to exclude altogether certain inventions from the realm of patent protection, and are frequently observed in national systems "where questions are asked first and patents granted later"[317].

According to Article 27§3b of TRIPS, "***plants and animals*** *other than micro-organisms****, and essentially biological processes*** *for the production of plants or animals other than non-biological and microbiological processes*" may also be excluded from patent protection.

These exclusions are once again a national regulatory choice. The breadth of claims allowed through patents thus significantly varies from one national order to the other, especially with regards to biological or plant-related inventions that molecular plant breeding science is concerned

[313] MACQUEEN et al., *Contemporary Intellectual Property: Law and Policy op.cit.*, Second edition, p.518., illustrating the premise through the English Court of Appeal's ruling on *Eli Lily & co vs Human Genome Science*, concerning a patent for a polynucleotide sequence: "the description of the invention must disclose in definite technical terms the purpose of the invention and show how it can be used to solve a technical problem", EWHC, 1903 (2008), §22.

[314] SVEN J.R. BOSTYN, "A Decade after the Birth of the Biotech Directive: Was It Worth the Trouble?," in *The Future of the Requirement for an Invention: Inherent Patentability as a Pre- and Post- Patent Determinant*, ed. EMANUELA AREZZO and GUSTAVO GHIDINI, Cheltenham: Edward Elgar, 2011, pp.221-259 (at 232).

[315] MACQUEEN et al., *Contemporary Intellectual Property: Law and Policy op.cit.*, Second edition, p.439.

[316] The first subject-matter exclusion is contained in Article 27§2 TRIPS, which declares that: "*Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment.*" (TRIPS Agreement, Art.27§2).

The aim of this provision is not "to simplify widespread public access to a commercialised invention, but to prevent commercialisation altogether"[316]. They have been primarily set forward in human and animal genome-related research[316]. In this context, "*European patents shall not be granted in respect of: (a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States*" (EPC 1973 and 2000, Art. 53).

This general scoped exception has not been raised in the case of plant innovation as much as public health related biotechnological inventions, and will therefore not be studied in the context of our analysis.

[317] MARGO BAGLEY, "Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law," *William and Mary Law Review* 45, no. 2, 2003: pp.469-547.

with. Some commentators have nonetheless argued "these exceptions were unlikely to allow states to derogate from the spirit of the treaty, which gives full IPR protection over living organisms"[318]. Patentability requirements relating to the "biomatter itself", whether non-living material such as amino acids, enzymes or DNA molecules, or living, such as cells and microorganisms, remain in this context extremely intricate to assess and apply[319]. In the 1960's, the Indian government, as a response to the high drug prices in its national market, "designed its patent law in a way which would help lower drug prices"[320]. It granted patents for processes used in the production of pharmaceuticals, but "not for chemical compounds themselves", an option that is arguably not available to States bound by the terms of the TRIPS Agreement any longer. Indeed, the flexibility offered by its minimal standards is stiffer, as biological material should as a principle fall under the scope of patent eligible products. TRIPS-compliant exclusion options have nonetheless been used in the European legal order.

Plant varieties

The first potentially excludable subject-matter relates to plant varieties, in a move to avoid double protection in legal order where plant breeders' rights are awarded on plant varieties. Such is the case of the 1973 European Patent Convention, which precludes patent protection for plant varieties, in order to avoid double protection under both patent and PVP legislation. As a result,

> "*European patents shall not be granted in respect of: […] (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof*" (EPC 1973 and 2000, Art. 53).

The first issue has been the definition of a plant variety and the reach of such concept in patent law. The EPO has found, through a comparative analysis with the relevant provisions of the UPOV Conventions (especially article 2.2 of the 1961 text), that the idiom described a "multiplicity of plants which are largely the same in their characteristics and remain the same within specific tolerances after every propagation or every propagation cycle"[321]. With the advent of biotechnology, a new issue arose as to whether product claims that extended farther than plant varieties and were not limited to a sole plant variety, and could therefore apply to all plants, could be included in this exception or be considered within the realm of patentability. In the aforementioned *Novartis* decision, the Technical Board of Appeal had refused to grant patent protection as

> "[It] could not accept the appellant's argument that a claim comprising more than a single variety was permissible. It did not appear to the Board to comply with the normal rules of logic. If the argument were accepted, the prohibition of Article 53(b) EPC could be avoided by drafting a claim to a plant with some characteristics of any actual embodiment left

[318] E. LOUKA, *Biodiversity & Human Rights: The International Rules for the Protection of Biodiversity*: Transnational Publishers, 2002, p.142.
[319] WORLD INTELLECTUAL PROPERTY RIGHTS ORGANIZATION WIPO, "*Patent-Related Flexibilities in the Multilateral Legal Framework and Their Legislative Implementation at the National and Regional Levels- Part Ii,*" Secretariat to the Committee on Development and Intellectual Property, 7th Session,, Geneva, 2011 (18th March).
[320] BRAITHWAITE and DRAHOS, *Global Business Regulation*, *op.cit.*, p.61.
[321] EPO Technical Board, T 49/83, *Propagating material/CIBA-GEIGY*, OJ EPO 1984, 112 (Reasons, point 2), a finding later confirmed in EPO Technical Board, T 320/87, *Hybrid plants/LUBRIZOL*, OJ EPO 1990, 71.

unspecified. The concept that specific embodiments of an invention, namely the actual plant varieties, should not be patentable, but that it should be possible to have a broad claim to plants, the scope of which would include all such varieties, was a notion quite alien to patent law in general. It would leave a fundamental anomaly at the heart of patent law as it related to plants"[322].

In this contextual prospect of double protection that "the Community Plant Variety Office (CPVO) preferred the approach according to which a claim covering, or potentially covering, a plant variety should be rejected whether or not the variety was the product of a microbiological process. The exclusion of plant varieties from patentability would be seriously undermined if it could be circumvented simply by formulating claims sufficiently widely to avoid express reference to an individual plant variety. On the other hand, the CPVO stated that they had no difficulty with the acceptance of claims in relation to plant material not in the fixed form of a plant variety which would admit the possibility of protecting a plant variety containing a patented invention"[323].

It is in this context that the Enlarged Board of Appeals declared that "a claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b), of the European Patent Convention (EPC) even though such claim may embrace plant varieties. The exception to patentability in Article 53(b), 1st half-sentence, EPC applies to plant varieties irrespective of the way in which they were produced. Therefore, plant varieties containing genes introduced into an ancestral plant by recombinant gene technology are excluded from patentability"[324].

This restrictive interpretation to potential claims, and arguably extensive yet "logical" approach to the exclusion of plant varieties from patentability was nonetheless seemingly cracked open by article 4§1 of the EU Biotech Directive, which states that "*plants and animals*" shall not be patentable, yet patents ought to be granted to inventions concerning plant and animals "*if the technical feasibility of the invention is not confined to a particular plant or animal variety*". (European Directive 98/44/EC, Art.4§1). This confinement criterion is defined as a "technical" one in the Preamble of the regulatory instrument, hinting at a considerably enlarged benchmark with the possibilities of genetic engineering and molecular biology. Furthermore, the Preamble specifies,

> "*a plant grouping which is characterised by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises new varieties of plants"* (European Directive 98/44/EC, Preamble, §31).

This approach potentially not only increases the scenarios of co-existence of patents and plant variety protection certificates on a specific plant grouping, but also increases the prospective overlaps between the two, as the former may be granted over specific genotypic information, and

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322 Enlarged Board of Appeals of the European Patent Office, *Transgenic plant/NOVARTIS II,* G-0001/98, 20.12.1999, p.3.
323 Ibidem, at p.13
324 Ibidem.

the second on the entire phenotype that arises from the expression of the whole genotype.

Essentially biological processes

Notwithstanding the tricky relationship between plant varieties and patents, the issue of patentable subject-matter is rendered even more complex since these inventions relates to living organisms and related processes, which are directly targeted by yet another formal exclusion from patentability. Non-biological and microbiological processes steadily constitute the “cornerstone of the biotechnology industry” and their referral in the formulation of the strong property paradigm provides “very broad scope for patent rights over biotechnological products and processes[325]. In this sense, it has also been argued that most if not all products developed through genetic engineering and microbiological processes are patentable[326], even though the reach of such statement has been re-assessed before the judiciary.

According to the EPO Guidelines, “biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature” can fall under patent protection, just as “plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety”, and also “a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety”[327]. Recent decisions of the Enlarged Board of Appeal have nonetheless proven the complexity of practical realities[328]. The issue especially arose with regards to molecular-assisted selection efforts that include complex and technical steps, which might be considered as non-microbiological and thus patentable processes[329]. The standard definition of the term "essentially biological process “within the meaning of Article 53(b) EPC 1973 was developed as a concept

> “to be judged on the basis of the essence of the invention taking into account the totality of human intervention and its impact on the result achieved”. It is the opinion of the Board that the necessity for human intervention alone is not yet a sufficient criterion for its not being "essentially biological". Human interference may only mean that the process is not a "purely biological" process, without contributing anything beyond a trivial level. It is further not a matter simply of whether such intervention is of a quantitative or qualitative character. […] In the present case, which presents a multistep process, each single step as such may be characterised as biological in a scientific sense but, as the Board stated, the facts clearly indicate that the claimed process for the preparation of hybrid plants represent an essential modification of known biological and classical breeders processes, and the efficiency and high yield associated with the product give evidence of technological

[325] AYKUT COBAN, "Caught between State-Sovereign Rights and Property Rights: Regulating Biodiversity," *Review of International Political Economy* 11, no. 4, 2004: pp.736-762 (at 746).
[326] WILLIAMS, 2000, p.73 (Life Patents, TRIPs and the International Political Economy of Biotechnology)
[327] OFFICE, "Guidelines for Examination in the European Patent Office."
[328] B. QUEST and F-Z. ZIMMER, "When Is a Process for the Production of Plants “Essentially Biological”? Decisions of the Enlarged Board of Appeal (G1/08 and G2/07)," *Biotechnology Law Report* 30, no. 4, 2011., and also MICHAEL BLAKENEY, "Patents and Plant Breeding: Implications for Food Security " *Amsterdam Law Forum* 3, no. 3, 2011.; both analysing the so-called Tomato and Broccli cases, Enlarged Board of Appeal G1/08 and G2/07.
[329] M. KOCK, "Essentially Biological Processes: The Interpretation of the Exception under Article 53(B) of the European Patent Convention," *Journal of Intellectual Property Law & Practice* 2, no. 5, 2007: pp.286-297.

> character[330]. The qualification of a process as 'essentially biological" would then be "on the basis of the essence of the invention, taking into account the totality of human intervention and its impact on the results achieved".

The so-called "Lubrizol principles" were confirmed and further refined by the Technical Board in the 1995 *Plant Genetic Systems* case[331], which favoured an intermediate approach where "a process involving at least one essential technical step which could not be carried out without human intervention and which had decisive impact on the final result would be patentable". As a result, a process claim was patentable because even though only the first steps used in the production of the plant were to be considered 'non-biological' (e.g. recombinant DNA). These nevertheless had to have a *decisive* impact *on the final result*, notwithstanding the subsequent 'biological' steps of regenerating and replicating the plants and seeds[332]. Two infamous and eagerly awaited cases since 2007 have shed a little more light on the issue. Cases G1/08[333] and G2/07[334], respectively opposing the State of Israel against Unilever with regards to a process involving crossing and selection of tomatoes, and opposing Syngenta, Limagrain against Plant BioSciences regarding a similar invention, were merged by the Enlarged Board of Appeals, which gave its verdict in 2010. The patents both concerned breeding methods, respectively breeding broccoli with anti-cancerogenic effects, and tomatoes with a trait that allowed the drying of fruits on the vine, allowing for substantial savings, and ignited twenty four amicus curiae submissons to the EPO. The conclusions of the Enlarged Board of Appeals went on to assert that:

> « 1. A non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants is in principle excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC.
>
> 2. Such a process does not escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants.
>
> 3. If, however, such a process contains within the steps of sexually crossing and selecting an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then the process is not excluded from patentability under Art 53(b) EPC[335].

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[330] Technical Board of Appeal of the European Patent Office, *Hybrid plant/LUBRIZOL*, 10 November 1988, T 320/87, Official Journal of the European Patent Office (1990), at 71.

[331] Technical Board of Appeal of the European Patent Office, *Plant Cells/PLANT GENETIC SYSTEMS*, 21 February 1995, T 356/93, Official Journal of the European Patent Office (1995), at 545.

[332] MICHELANGELO RP TEMMERMAN, "*The Patentability of Plant Genetic Inventions*", NCCR Trade Regulation Working Paper, 2006.

[333] Referral from Technical Board of Appeal of the European Patent Office, *Tomatoes II/STATE OF ISRAEL*, 3rd March 2004, T1242/06, Official Journal of the European Patent Office (2008), 523.; Enlarged Board of Appeal of the European Patent Office, *Tomatoes II/STATE OF ISRAEL,* 9 December 2010, G1/08, Official Journal of the European Patent Office (2013), 42.

[334] Referral from Technical Board of Appeal of the European Patent Office, *Broccoli/PLANT BIOSCIENCE*, T 83/05, Official Journal of the European Patent Office (2007), 644. ; Enlarged Board of Appeal of the European Patent Office, *Broccoli/PLANT BIOSCIENCE,* 9 December 2010, G2/07, Official Journal of the European Patent Office (2013), 42.

[335] Enlarged Board of Appeals of the European Patent Office, *Tomatoes II/STATE OF ISRAEL*, 9 December 2010, G1/08, and *Broccoli/PLANT BIOSCIENCE*, 9 December 2010, G2/07, Consolidated proceedings, Order.

The decisions adopted a surprisingly extensive interpretation of statutory exceptions, extending *de facto* their scope to all methods "which contain the steps of sexual crossing", and seem to limit the technical step measurement to those steps that do not enable or assist sexual crossing. This means that all molecular-marker assisted breeding processes will fail to escape the EPC 53(b) exclusion. However, the rulings also clearly state that the claims on the plants obtained through these methods remained valid, if, as aforementioned, the claim is not confined to as specific plant variety.

In the same lines, Article 4§1 of the Directive also formally excludes "***essentially biological processes*** *for the production of plants or animals*" from patent eligibility, defined as processes consisting "*entirely of natural phenomena such as crossing or selection*" (European Directive 98/44/EC, Art. 1§2).

Such exclusion nonetheless operates "*without prejudice to the patentability of inventions, which concern a microbiological, or other technical process or a product obtained by means of such a process*" (European Directive 98/44/EC, Article 4§3).

According to the Preamble of the European Directive, the patentable nature of a technical process may not necessarily extend to the product, since "*if an invention consists only in genetically modifying a particular plant variety, and if a new plant variety is bred, it will still be excluded from patentability even if the genetic modification is the result not of an essentially biological process but of a biotechnological process"* (European Directive 98/44/EC, Preamble, §32).

Even in the presence of detailed regulation, the definition of the exact contours of patentability exclusions has become an increasingly complex task. In molecular plant breeding, the patentability of a process isolating a substance already existing in nature seems to be generally accepted, even though recent case law before the European Patent Office has proven the complexity of practical realities[336]. For instance, innovative breeding processes or tools may retain a biological character yet constitute important technological leaps forward. This is especially true with regards to molecular selection efforts pertaining complex and technical steps, which might at first sight be considered as non-microbiological and thus patentable processes[337].

3.2.2. __Patent Width and the Bundle of Exclusive Rights__

"Mainstream Anglo-American legal philosophy" understands property as a "bundle of rights", combining Wesley Hohfeld's approach, where "any right *in rem* should be regarded as a myriad of personal rights between individuals", and A.M. Honoré's "description of the incidents of ownership"[338]. This conception adds supplementary layers to the classical approach to property rights as a defined individual's exclusive rights to exclude others from enjoying the tangible good falling under a deed or title. When beheld in the realm of intangibles, such bundle of rights theory

[336] QUEST and ZIMMER, "When Is a Process for the Production of Plants "Essentially Biological"? Decisions of the Enlarged Board of Appeal (G1/08 and G2/07)," *op.cit.*, and also BLAKENEY, "Patents and Plant Breeding: Implications for Food Security " *op.cit.*; both analysing the aforementioned Tomato and Broccoli cases, Enlarged Board of Appeal G1/08 and G2/07.
[337] KOCK, "Essentially Biological Processes: The Interpretation of the Exception under Article 53(B) of the European Patent Convention," *op.cit.*, pp.286-297.
[338] J.E. PENNER, "The "Bundle of Rights" Picture of Property," *UCLA Law Review* 43, no. 2, 1996: p.712.

ascribes one to consider the range of prerogatives that are granted to titleholders, especially those that may allow one to refuse access to protected knowledge, or allow one to condition its use to overbearing compensation from follow-on users.

Prerogatives awarded to right holders

Patents, once having passed the initial requirements set out by the aforementioned criteria, convey a number of prerogatives to the applicant. First and foremost, before delving into the extent of such prerogatives, one must assess the extent of protection granted on a given patent. There are diverging principles surrounding the determination of such extent of protection, as no real consensus exists on the interpretation of patent claims, even within the EPC legal order. Indeed, the TRIPS Agreement remains completely silent on the means through which literal infringements should be determined. While the United Kingdom has been known to interpret claims quite literaly, Germany tends to interpret them broadly, especially when determining the existence of literal infringement, even though a version of the US doctrine of equivalents has been seemingly adopted in the framework of the EPC. In light of such doctrine, the scope of a given claim can extend beyond literal wording, identifying the existence of infringement in cases where merely elements of the patented product or process are contained within a device or process. In any case, the EPC's more recent amendments have tried to set the record straight:

> "*The extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims*" (EPC, Article 69§1).

Most importantly, a parallel approach to the doctrine of equivalents was enshrined through the "Protocol on the Interpretation of Article 69 EPC", adopted in 2001 and which forms an integral part of the Convention states:

> *"Article 1: General principles*
> *Article 69 should not be interpreted as meaning that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Nor should it be taken to mean that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties.*
> *Article 2: Equivalents*
> *For the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims"* (Protocol on the Interpretation of Article 69 EPC).

Not only the interpretative and binding provisions clarify that the reality of claim interpretation lies between a literal reading and an unnecessarily broad one, it also hails that certain specific elements contained in the claim, but not forming its entirety, can be taken into account when determining potential infringements. Such non-literal and arguably broad approach aims to protect the patentee and its prerogatives, first against linguistic imperfections, and secondly against unforeseen technological advances as the full potential scope and impact of the invention may not be known at the time of filing[339]. By allowing for infringements to be noted only in presence of certain elements contained in the claim, it intends to reward an inventor who has made a significant contribution to the state of the art, and enlarges the scope of protection awarded by the exclusive titles.

Patent law has been generally described as not granting titleholders any rights to exploit the invention, but have rather been formulated as a negative right to exclude others from engaging in certain activities without their consent. This formulation might be misleading, in so far as the patent rights in effect "creates a zone of non-interference in which the patent holder may exercise the right by undertaking activities of commercial exploitation"[340]. In this sense, the right to exploit the invention is inherently encompassed in patent protection, which could rather be described as a bundle of rights awarded to right holders, describing their hold over the uses made of the invention by third parties.

In this sense, article 28 of TRIPS provides that product patents confer their owners the exclusive rights "*to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product*", while process patents encompass the rights "*to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process*".

Furthermore, §2 provides that "*patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts*" (TRIPS Agreement, Art.28).

The European Patent Convention understands the rights awarded by patents quite broadly, and leaves the effective contours to be designed by national laws. Indeed, the rights conferred by a European patent are as follows:

> *"1) A European patent shall, subject to the provisions of paragraph 2, confer on its proprietor from the date on which the mention of its grant is published in the European Patent Bulletin, in each Contracting State in respect of which it is granted, the same rights as would be conferred by a national patent granted in that State.*
> *(2) If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process.*
> *(3) Any infringement of a European patent shall be dealt with by national law"* (EPC 1973 and 2000, Art. 64).

The second indent of the article is the most interesting, as it embraces the extension of protection of process patents to products obtained through such process, quite impressively enlarging the rules of appropriation embedded in the law. The range of infringing acts does not widely differ from one legal order to the other, yet the trigger for infringement proceedings to be ignited may.

[339] RALSTON, William T. "Foreign Equivalents of the US Doctrine of Equivalents: We're Playing in the Same Key but It's Not Quite Harmony." *J. Intell. Prop.* 6 (2006): 177.
[340] DRAHOS, "Biotechnology Patents, Markets and Morality," *op.cit.*, p.445.

Indeed, in the United Kingdom for instance, the infringement of process patents depends on the knowledge of the alleged infringer, while such prerequisite is not sought after when facing product patents, where an "absolute liability" threshold has been favoured[341]. The reach of protection granted to products has as a result proven a tricky issue in the case of biotechnological inventions, especially product patents covering gene sequences.

> "It is generally accepted as a principle underlying the EPC that a patent which claims a physical entity *per se*, confers absolute protection upon such physical entity; that is, wherever it exists and whatever its context (and therefore for all uses of such physical entity, whether known or unknown). It follows that if it can be shown that such physical entity(e.g. a compound) is already in the state of the art (for example in the context of a particular activity), then a claim to the physical entity *per se* lacks novelty. It also follows that a claim to a particular use of a compound is in effect a claim to the physical entity (the compound) only when it is being used in the course of the particular physical activity (the use), this being an additional technical feature of the claim. Such a claim therefore confers less protection than a claim to the physical entity *per se*"[342].

Under traditional patent law principles, product claims extend to all instances where such product manifests itself, and would cover both recognised and potential uses of the product. This stance has however been alleviated in the field of biotechnology, where patent protection has been granted to "alternative uses of a particular compound", thereby restricting the wide-scoped reach of the aforementioned principle, all the while avoiding investment in further research into the patented compound with the goal of merely enhancing the value of the original or "first use" claim[343]. It should be noted here that in Europe, products-by-process claims are not accepted, i.e. the novelty of the process cannot normally be used to demonstrate the novelty of a product, even though the protection awarded to the process may extend to products obtained using such process, as shall be studied below. Faced with unclear case law, the European Patent Office, ruling on the so-called *Soybeans* case introduced by Monsanto[344], recently took a "clear standpoint in favour of purpose-bound product protection" to limit an extensive reach of prerogatives[345].

<u>Rights awarded to third-party users</u>

Intellectual property rights systems are designed as **coherent and efficient semi-commons**; and they therefore need to provide for limits in the scope of awarded monopolies, as a necessary part to the overall design[346]. In this sense, the copyright system provides for instance for the "fair use"

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341 As the European Patent Convention sets out the infringements proceedings to be dealt with under national law, it is Section 60(1)c of the 1977 Patents Act in the UK that establishes such implementing principle, see MACQUEEN et al., *Contemporary Intellectual Property: Law and Policy op.cit.*, Second edition, p.485.
342 Enlarged Board of Appeals of the European Patent Office, *Mobil Oil Corp v Chevron Research Co*, G-02/88, 1990, Official Journal EPO 93, p.15-16.
343 GREGORY ROSE, "International Regimes for the Conservation and Control of Plant Genetic Resources," in *International Law and the Conservation of Biodiversity*, ed. MICHAEL BOWMAN and CATHERINE REDGWELL, London: Kluwer Law, 1996, pp.186-187.
344 European Court of Justice, C-428/08, Monsanto Technology LLC v Cefetra BV, Cefetra Feed Service BV, Cefetra Futures BV, Alfred C. Toepfer International GmbH and, as intervener in support of the defendant, the Argentine State, 6th July 2010.
345 E GHIDINI AREZZO and GUSTAVO GHIDINI, *Biotechnology and Software Patent Law: A Comparative Review of New Developments*: Edward Elgar Publishing, 2011, pp.230-234.
346 FRISCHMANN and LEMLEY, "Spillovers," *op.cit.*, p.286.

defence against infringement claims, which "should not be considered a bizarre, occasionally tolerated departure from the grand conception of the copyright monopoly" but rather a critical element to its utilitarian efficiency and coherence[347]. All patent systems similarly provide for in-built boundaries to the exclusive rights granted to innovators, which are critical to the patent semi-commons' legitimacy and efficiency.

Quite straightforwardly, the first frontier stems from the limitation of these prerogatives in time. Indeed, although the term of protection tends to vary from one legal order to the next, all patent systems provide for such a limited term. The TRIPS Agreement states, in its Article 33, that the **minimum term of patent protection** "*shall not end before the expiration of a period of twenty years counted from the filing date*". When stringent regulatory approval mechanisms exist for products to be granted access to markets, so-called "Supplementary Protection Certificates" have been envisaged so as to ensure the full exploitation of patent terms. This option was for instance beheld in the case of medicinal and also plant protection products in the European Union[348]. Notwithstanding the inherent difficulties that have arisen when assessing the extent to which the protected invention and the product to be authorised are the same[349], such longer protection term has been advocated for by integrated biotechnology giants for genetically-engineered crops alongside plant protection products.

Inventions related to plant improvement that mostly rely on the use of living material have also raised an additional issue, which does not directly relate to the question of patentability itself, but rather concerns the **efficiency of disclosure** with regards to such material, and therefore to the need to ensure the sufficient balance of private reward and public interest. Indeed, one of the essential counterparts of granting such an important artificial monopoly to inventors is that the invention would be disclosed and not held as a trade secret. However, such disclosure had to be adapted in the case of living material so as to ensure that it operates "*in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art*", in accordance with Article 83 of the EPC. As a result,

> *(1) If an invention involves the use of or concerns biological material which is not available to the public and which cannot be described in the European patent application in such a manner as to enable the invention to be carried out by a person skilled in the art, the invention shall only be regarded as being disclosed as prescribed in Article 83 if:*
> *(a) a sample of the biological material has been deposited with a recognised depositary institution on the same terms as those laid down in the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure of 28 April 1977 not later than the date of filing of the application;*
> *(b) the application as filed gives such relevant information as is available to the applicant on the characteristics of the biological material;*
> *(c) the depositary institution and the accession number of the deposited biological material are stated in the application, and*

[347] LEVAL, "Toward a Fair Use Standard," *op.cit.*
[348] Supplementary protection certificates have been respectively granted through Regulations EEC no 1768/92, and 1610/96.
[349] MACQUEEN et al., *Contemporary Intellectual Property: Law and Policy op.cit.,* Second edition, p.473.

> *(d) where the biological material has been deposited by a person other than the applicant, the name and address of the depositor are stated in the application and a document is submitted to the European Patent Office providing evidence that the depositor has authorised the applicant to refer to the deposited biological material in the application and has given his unreserved and irrevocable consent to the deposited material being made available to the public in accordance with Rule 33*" (Implementing Regulations to the EPC, Rule 31, Deposit of biological material).

This specific requirement has however been interpreted quite narrowly so as to ensure that the incentive to apply for patents in living material remained intact. Indeed, no obligation to deposit material is triggered if the invention can be repeated on the basis of the written description, even if this should be a much more cumbersome way than by merely growing the deposited micro-organism[350], unless such "undue burden" is characterised by uncertainty of outcome and not just lengthiness[351]. The essential question is thus is this context to determine whether a notional skilled person is reliably able to replicate the same organism based on the information provided in the application, and to impose the material's deposit if such additional step is proven necessary.

However, ensuring the temporal limitation of the monopoly and the disclosure of its subject are not the only mechanisms used by the patent paradigm to balance the uncompetitively exclusive rights it grants. "The core unifying feature of the various limits which are imposed on the exercise of patent rights is our old friend, the public interest", urging action when the invention is not exploited or the technical details are kept out of the public domain[352]. As a result of such premise, Article 31 of TRIPS allows

> "***uses without the authorisation of the right holder***", where, according to national law, "*the subject matter of a patent [can be allowed to be used] without the authorisation of the right holder, including use by the government or third parties authorised by the government*", if a number of provisions are respected. (TRIPS Agreement, Art. 31)

The basic proviso is that such authorisation "*shall be considered on its individual merits*", making compulsory licensing negotiations mandatory and granted by the State on a case-by case basis, following unsuccessful efforts of the parties to reach a licensing agreements with "*reasonable commercial terms and conditions*". A waiver to such preliminary negotiation obligation is admitted in cases of "*national emergency or public non-commercial uses*". Furthermore, these "*non-exclusive*" and "*non-assignable*" licenses' "*scope and duration shall be limited to the purpose of which it was authorised*", while the rightholder "*shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation".*

Additional limits to the bundle of patent rights relate to the exploitation of the title in certain circumstances. Much like most IPR, patents are exploited through licenses and sub-licenses, under the belief that negotiations in the marketplace will result in the most efficient allocation of resources. However, a number of **specific actors or specific uses of the invention may be left**

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[350] Technical Board of the European Patent Office, *HIF Gamma/ Genentech*, T-223/92, 20th July 1993.

[351] Technical Board of the European Patent Office, *Erythropoietin/KIRIN-AMGEN*, T- 0412/93, 21.11.1994; *Monoclonal antibody* ,T-0418/89, 8.1.1991; and *Monoclonal antibody/AGEN*, T- 0431/96, 23.2.1999.

[352] MACQUEEN et al., *Contemporary Intellectual Property: Law and Policy op.cit.*, Second edition, p.475.

outside of the bundle of exclusive rights, or the license negotiation may be merely postponed, in the name of public interest. These mechanisms operate like liability rules, and are in effect statutorily defined opportunities that are awarded to those actors to use the invention without a license, as long as they remain within the limits set out by statutes or the judiciary. Article 30 of TRIPS allows Members to

> "*provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties*" (TRIPS Agreement, Art. 30).

In this context, exemptions for the use of proprietary material for **research purposes** are almost universally granted under all plant-related traditional intellectual property regimes, whether patents or plant breeders rights. Each national intellectual property system has its own voice on this particular subject, and positions remain patchy. In the United States, the research exemption is not even part of patent statutes, but has been rather restrictively carved by the judiciary. In the **European legal order,** the reach of the research exception seems to follow the precepts enacted in article 27 of the Community Patent Convention, even though the instrument has not been ratified[353]**.** Both the European Patent Convention and the EC Directive 98/44 on biotechnological inventions remain particularly silent on the subject, leaving the issue to be dealt with by the national legislator and judiciary. The experimental use defence is therefore "an area where there is considerable diversity of approach around the world, including within Europe", where for instance the German Supreme Court has exempted "all experimental acts as long as they serve to gain information and thus to carry out scientific research into the subject-matter of the invention, [even extending] to possible new uses hitherto unknown", while the English Patents Court rather considers "whether the immediate purpose of the transaction was to generate revenue or not"[354]. Belgium has then again opted for a much wider understanding of such exception, as the 2005 amendment of article 28§1(b) of the patents law has strayed away from "experimental use" vocabulary, stating rather that the bundle of patent rights does not extend to "acts accomplished for scientific purposes on and/or with the object of the patented invention"[355].

Last but not least, much alike plant variety protection, patent protection is also considered to be **exhausted** in certain legislative orders that apply the so-called "first sale doctrine", in accordance to which the monopoly rights cannot extend farther than the sale of products with the consent of the right holder. This doctrine is not tackled by the TRIPS Agreement, which leaves the issue to be determined at national level in its Article 6, just as the European Patent Convention, which is surprisingly silent on the issue. The possibility to *de facto* restrict the prerogatives of patent holders in the case of market release has in this regard been viewed as one of the flexibilities offered by the dominant patent paradigm. A flexibility that is commonly used in the United States,

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[353] In 1998, ten countries had already introduced the provision textually into their national legal orders, see WILLIAM R CORNISH, "Experimental Use of Patented Inventions in European Community States," *International Review of Industrial Property and Copyright Law* 29, no. 7 (1998).
[354] *Contemporary Intellectual Property: Law and Policy op.cit.,* Second edition, pp.502-503.
[355] Article 28§1(b) of the law on patents dated as of 28 March 1984, as modified by the law dated as of 28th April 2005, *M.B.*, 13th May 2005; see also GEERTRUI VAN OVERWALLE, "Van Groene Muizen Met Rode Oortjes: De Eu-Biotechnologierichtlijn En Het Belgisch Wetsontwerp Van 21 September 2004 " *I.R.D.I.* 4, 2004: pp.357-386.

but also in the United Kingdtom, Denmark, Germany, Ireland, Italy and the Netherlands, and is applied without much stir with regards to sales involving a single jurisdiction[356]. Belgium and France on the other hand, have recourse to the concept of a very limited "right of destination" in accordance to which supply of products can be surrounded by conditions on specific markets or users, without giving the ability to be used as an opposition to resale. The issue of parallel imports has caused much more headache, especially in view of the different types of approaches set out by national patent laws.

3.3. Other Intellectual Property Tools used in Plant Improvement

Alongside the more traditionally used instruments of intellectual property for the protection of plant-related innovations, namely plant variety rights and patents, a number of other **informational protection tools** have also growingly appeared in plant breeding research and development, such as trademarks, copyrights, and trade secrets, accordingly influencing the chains and costs of agrobiodiversity innovation. Within a sector that is largely knowledge and technology intensive such as the seed industry, there is still growing recourse to ***trademarks***, even though these instruments merely protect names and other symbols solely denoting products or technologies, and not the technologies themselves. Much of the widespread innovations are actually trademarked in practice, such as Keygene's AFLP markers or "Breeding by Design" model[357], a trademarked approach to plant breeding that encompasses ever-evolving prospects of selection and breeding methods. Trademark registrations primarily operate as a means to distinguish products from their competitors, but also as powerful communications tools, warranting product quality on account of a stronger brand image[358]. Within this growingly marketing oriented approach, a number of plant varieties have also been trademarked, such as Syngenta's brown tomatoes, where two specific varieties already protected under PVP have additionally been regrouped under the Kumato brand, visible to the very end consumer in its supermarket packaging. This increasingly prevalent practice exemplifies the novel marketing strategies favoured by companies wishing to push their products forward through brands, consequently enlarging their intellectual property portfolios.

Copyrights on the other hand, are another form of grants and reservations attributed to physical or moral persons over the literary, scientific or artistic creations of their mind without much formal administrative process, entailing a prohibition against copying rather than monopoly rights as such. While remaining a rarity, they are yet becoming important in the field of plant breeding on account of the growing recourse to databases holding genetic and phenotypic information. Even though these types of protection do not directly affect the trade of products that have been developed using the protected information, they still appear as an additional formal requirement to be taken into account in crop genetic improvement research costs.

Trade secrets protect "formulas, practices, processes, designs, instruments, patterns, or other compilations of information that can be used as competitive advantages in order to obtain artificial lead-time" through the secrecy and confidentiality surrounding them. Regulated at the national

[356] STOTHERS Christopher, "Patent Exhaustion: the UK Perspective", 16th Annual Conference on Intellectual Property Law and Policy Fordham University School of Law, 27-28 March 2008.
[357] J. D. PELEMAN and J. R. VAN DER VOORT, "Breeding by Design," *Trends Plant Sci* 8, no. 7, 2003.
[358] XU, *Molecular Plant Breeding*, *op.cit.*, p.523.

level, trade secret laws retain wide-ranging characteristics, and have often been used for the protection of inbred lines used in controlled hybridisation processes within the plant breeding industry, through the non-release of the hybrids' parents, even when these have been planted especially for field trials, as the secret does not commonly have to be absolute but be publicly unavailable[359]. This practice has propelled litigation alleging trade secret misappropriations with regards to parental hybrid lines, most notably the case having opposed Pioneer Hi-Bred and Holden Foundation Seeds, which did not assess whether genetic information could qualify as a trade secret, but rather showed that when such reality is undisputed for the parties concerned, this peculiar tool could effectively be used to protect breeding lines, side by side with patents and PVP[360]. Relying heavily on the physical security that may cover the companies' facilities, trade secrets may also cover new research programs or technologies under development, but also those aspects of plant biotechnology that cannot be detected in the final plant product, such as markers and regeneration methods, thereby avoiding the disclosure requirements entailed in PVP or patent protection[361]. The withholding of technical information undisclosed through the recourse to trade secrets may thus in truth not serve the public interest, even though society may still benefit from the commercialisation of the innovation itself, thereby reinforcing the case for strong disclosure-based intellectual property tools such as patents or PVP[362]. Trade secrets are particularly important for the newest agrobiodiversity innovators, since the regulatory data that is attached to plant protection products and genetically engineered crops is protected through this tool. Article 39§2 TRIPS provides that

> "*natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information (a) is secret, (b) has commercial value because it is secret; and (c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret*" (TRIPS Agreement, Art. 39§2).

Article 39§3 specifically addresses the submission of undisclosed test or other data for the market approval of pharmaceutical or agricultural chemical products, requiring from Member States

> "*to protect such data against unfair commercial use, [especially] against disclosure, except when necessary to protect the public*" (TRIPS Agreement, Art. 39§3).

So-called "regulatory data" holders are granted "exclusivity" for ten years both in the United States and the European Union, even though the former provides for fifteen years of data compensation, and the latter gives fives additional years of protection for new data. A quite recent but worryingly crucial feature of the molecular plant breeding property paradigm relates to the fate of the extremely complex and costly regulatory cultivation or import approval dossiers and the information contained therein, with regards to those transgenic traits and varieties that will fall within the public domain in the following years on account of their patents' expiry, for instance in 2014 for Roundup Ready formulations. The debates inherent to the development of so-called "generics" (or "biosimilars" in the pharmaceuticals industry) will heathen up especially with regards to the confidentiality and maintenance of national and foreign approval dossiers, as well as

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359 R. KJELGAARD and D. MARSH, "Intellectual Property Rights for Plants," *Plant Cell* 6, no. 11, 1994: pp.1524-1528.
360 BLAKENEY, *Intellectual Property Rights and Food Security*, *op.cit.*
361 XU, *Molecular Plant Breeding*, *op.cit.*, p.525.
362 GRAHAM DUTFIELD, *Intellectual Property Rights, Trade and Biodiversity* London: Earthscan, 2000, p.25.

the exact definition of "generic seeds" (especially with regards to the extent to which germplasm combinations could be altered).

Geographical indications may also be present within agrobiodiversity innovation chains. These peculiar instruments, which stand at the frail frontier between intellectual property rights and food quality policies, preserve a strong link with labelling requirements. Defined by WIPO as "signs used on goods that have a specific geographical origin and possess qualities, reputation or characteristics that are essentially attributable to that origin"[363], geographical indications (GI) take diverse forms. Even though there is a great disparity between legal frameworks protecting GIs, these instruments unanimously target products that have qualities linked to a specific territory. The link between quality and geography "varies according to the natural and cultural history of the resources and their transformation processes, as well as to the legal framework in which the GI develops"[364]. Appellations of origin are nonetheless aggregated at the international level in the context of the 1958 Lisbon Agreement, which defines this particular form of GI, as

> "*the geographical denomination of a country, region, or locality, which serves to designate a product originating therein, the quality or characteristics of which are due exclusively or essentially to the geographical environment, including natural and human factors" (*1958 Lisbon Agreement, Art.2)[365]

The TRIPS Agreement has also reified GI's to a certain extent, urging Member States in Article 22, to *"provide the legal means for interested parties to prevent: the use of any means in the designation or presentation of a good that indicates or suggests that the good in question originates in a geographical area other than the true place of origin in a manner which misleads the public as to the geographical origin of the good; [and also to prevent] any use which constitutes an act of unfair competition"* (TRIPS Agreement, Art. 22).

Without the need for a registration process, the minimal standard for geographical indication protection acts therefore as a tool against the misappropriation or misuse of geographical information to identify the origin, quality or reputation of product. Addressing more specifically the potential conflicts between trademarks and geographical indications, the TRIPS Agreement, mostly responding the pleas stemming from the European continent, also allows for greater room and protection scopes for GIs in international negotiations. Indeed, GI's are very much put forward within the European agricultural product quality policy, awarded on the basis of registration, in the form of "protected geographical indication" and "protected designation of origin", or even through "traditional specialities guaranteed"[366]. Aside from their product quality and consumer protection angles, geographical indications have also been put forward as means to protect, or at least

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[363] WIPO Geographical Indications Gateway, http://www.wipo.int/geo_indications/en/

[364] JORGE LARSON GUERRA, "*Geographical Indications, in Situ Conservation and Traditional Knowledge*", 2010.

[365] Article 2 of the Lisbon Agreement, which was adopted 31 October 1958, revised in 1967 and 1979, the full text can be found at http://www.wipo.int/lisbon/en/legal_texts/lisbon_agreement.html, as well as the international registrar that is maintained within the auspices of WIPO.

[366] In accordance with the TRIPS provisions specifically targeting wines and spirits, the European acquis on geographical indications operates a distinction between the aforementioned products and those agricultural foodstuffs, through the DOOR database maintained according to Council Regulation (EC) No 510/2006 (of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs, *OJ L* 93, 31.3.2006, p. 12–25) on one hand, and the specific E-Bacchus database based on bilateral agreements and Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) on the other.

recognise, both in situ conservation efforts undertaken by farmers, and also traditional knowledge[367].

CONCLUSION. The tangible balance of the strong property paradigm propelled by the world trade order

The contours of the TRIPS-propelled strong property paradigm have been carved around expansive and layered protection realities, which nonetheless carry the same overarching goals and outcomes, that of greater commercial exploitation of genetic resources. Indeed, plant breeders' rights and patents "are based on similar premises insofar as they both seek to give the private sector an incentive to enter a particular industry, as a stimulus for research and development of new varieties of plants"[368]. There is a greater prospect to see specific genetic compounds protected through separate yet closely interlinked angles, in terms of genetic material as a whole, and also at the level of the isolated and purified "useful" compound. The product-development oriented property paradigm has proclaimed the reign of plant variety rights awarded in accordance with the terms of the 1991 UPOV Conventions, as the prime specimen of an effective *sui generis* regime, which protects new, distinct, uniform and stable plant varieties' phenotypes, and extends its reach to both harvested material and varieties that are essentially derived from a protected initial variety. In parallel, patents, which had been drawn up for inanimate products, less sequential or incremental processes, and non-self-replicating technologies, have been growingly applied to biodiversity related innovation, challenging the definitions of invention, non-obviousness (or inventive step) and novelty. Stretching traditional understandings of patentable subjet-matter directly in the definition of scientific discoveries, the state of the art or of notional skilled persons, the products and processes involved in plant innovation have also been accompanied by extremely complex patentability exclusions, which have made the navigation of the patent system a byzantine challenge.

Aside from such layered and intensified protection, a relatively steady trend saw the triumph of negotiated third party uses against those statutorily determined exceptions. Opportunities for third parties to use innovations without the consent of the right holder have considerably shrunk in time, while the bundle of prerogatives awarded to the latter has extended, both in plant variety and patent protection.The parallel expansion of the realms of product protection has furthermore restrained the conditions designated for the lawful use of the plant-related innovation. It has effectively pushed for the development of iron-clawed licensing skills to be able to use improved agricultural biodiversity. Such premise, however justified, ought to be considered in light of the inherent balance of intellectual property rights, questioning whether the paradigmatic evolution has irrepressibly curbed the social compensation commanded by the grant of artificial lead-time to innovators. The double stretch in the strong property paradigm has resulted in a wince of the public domain, which remains crucial for follow-on innovation and arguably for food security in the case of agrobiodiversity innovation.

[367] LARSON GUERRA, *op.cit.*, 2010.
[368] CULLET, "Property-Rights Regimes over Biological Resources," *op.cit.*, p.654.

PART I CONCLUSIONS. Shrinking public domain against pronounced exclusivity in a formal seed market

The non-exhaustive nature of the products of crop genetic improvement, the emphasis put upon knowledge in this peculiarly complex research sphere, and finally the ease of reverse engineering possibilities have all set in motion the recognition of bundled intellectual property rights over the fruits of plant breeding research and to material attached thereto. These rights aim to regulate an innovator's hegemony over the access to the information linked to an innovative product or process. They also determine the conditions surrounding the product's subsequent uses. They try to address untraditional forms of innovation and attempt to allocate rights over the rather new yet ubiquitous information goods that are used and produced by various actors along the way. However, this allocation game faces important challenges, coming from the conceptual tradition of traditional knowledge, the divergent legal traditions involved, the changing structure of all involved actors, the accelerating pace of resource degradation and the new sustainability model of resource exploitation[369]. Any property undertaking needs to carefully settle adequate protection to fuel innovation on one hand, and diffusion sufficient enough to counter the social costs of monopoly. The equilibrium act that takes centre stage in agrobiodiversity innovation confronts in this context the inherent lack of innovative reward in seed development on the one hand, and its incremental nature and the close links it entertains with vital socio-economic rights on the other. It needs to have due regard to past contributors of knowledge and agro-biodiversity, as well as the future developers of incremental knowledge and new agro-biodiversity in the entire range of instruments affecting these peculiar innovation chains, but also to those who improve and grow the seeds that embody these invisible prerogatives.

Regulatory shifts in trade law have targeted both the tangible goods that are seeds, ensuring the quality, identity and purity of traded products, and their incorporeal features, ensuring that artificial lead-time would be awarded to innovators. However, the inherent balancing act of intellectual property protection, taking traditionally into account social welfare and the public interest next to private benefits, has been considerably shaken down by efficient forum-shopping and exclusivity-endowing practices. This movement came through the international reification, and the subsequent implementation and interpretation of the layered protection mechanisms entailed in the new intellectual property paradigm set by the TRIPS Agreement. Owing to the contentiously negotiated and imposed general characteristis of a **strong intellectual property paradigm**, those involved in plant innovation now need to navigate in a relatively unchained, or rather tortuously chained ocean of patents and plant variety rights. This new command also happens to occur in the background of a heavily controlled product market ensuring the delivery of quality seeds.

The TRIPS-impelled paradigm as a result holds multiple layers of proprietary instruments over the main inputs of food production, seeds. It aims to protect the new innovative products of biotechnology, and is thus centred on strong intellectual property rights protection carved around enhanced plant breeders' rights, lenient patentability requirements and wide bundles of patentee prerogatives. In OECD countries, **plant breeders' rights,** are granted under laws enacted in view

[369] THOMAS COTTIER, "The Protection of Genetic Resources and Traditional Knowledge: Towards More Specific Rights and Obligations in World Trade Law," *Journal of International Economic Law* 1, no. 4, 1998: pp.558-559.

of the different UPOV Conventions, mostly the 1991 text, in stand-alone national legislation. They confer a bundle of rights to a novel particular *combination* of genes manifested as a distinct, uniform and stable variety. They are closely and expressly linked to considerations of sequential innovators relying on access to improved germplasm on one hand, and of farming communities cultivating propagating material for their own consumption, to make ends meet, or as a viable commercial enterprise. The European Community Regulation 2100/94/EC reflects in this sense the general trend of the dominant paradigm, having notably extended the reach of breeders' prerogatives to harvested material and essentially derived varieties, while considerably narrowing the derogative privileges awarded to farmers who wish to save protected seeds. **Patents** on the other hand tentatively offer protection for big leaps in technological achievements[370], enabling the recovery of important research and development investment costs, while not completely obliterating technology transfer prospects. Provided the minimum protection standards of novelty, inventive step and industrial applicability are complied with, national statutory and jurisprudential decisions carve the patentability requirements and the range of prerogatives allowing right holders to exclude third parties to use protected inventions. *De lege rata* analysis shows that there are important differences from one legal tradition to the other, all the while demonstrating that patentability standards had to steadily be lowered or at least relaxed in order to accept most claims stemming from the world of green biotechnology within the realms of the patent paradigm[371]. The assessment of whether a product or process used in plant innovation constitutes a novel and non-obvious invention capable of industrial application has not been the only contentious challenge posed with regards to patentability in the European legal order defined by the European Patent Convention and the so-called Biotech Directive 98/44/EC. Specific questions as to the reach of expressly excluded subject-matter (i.e. plant varieties and essentially biological processes) have heightened the difficulties that accompany the determination of the public domain. The nebulosity surrounding the reach of third-party use rights allowed under the TRIPS standards so as to uphold the public interest has further tainted the dominant paradigm, which is for instance assorted by a legally uncertain research exception. Alongside these two more traditionally used instruments for plant-related innovations, **additional informational protection tools** also growingly carve research and development; such as trademarks, copyrights, and trade secrets, accordingly influencing the chains and costs of agrobiodiversity innovation. This web of intellectual property rights will mainly affect subsequent plant improvement efforts by apportioning rights and obligations around parent germplasm in its complete phenotypic sense through individual plant varieties, but also around germplasm constructs, i.e. input or output gene sequences, as well as enabling technologies and molecular research tools that allow improvers to gather information, or multiply and transform plants or plant cells.

Reified traditional intellectual property rights have slowly dismantled their inherent balance, favouring the development-centred generalised and pervasive contraction of artificial lead-time[372]. Indeed, "the effective life of the patent may be determined by the breadth of the right, rather than its statutory length"[373], a breadth that has been reified and magnified by TRIPS, but also been

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370 HELFER, "Intellectual Property Rights in Plant Varieties: An Overview with Options for National Governments."
371 ARTI K. RAI and JAMES BOYLE, "Synthetic Biology: Caught between Property Rights, the Public Domain and the Commons," *PLoS Biology* 5, no. 3, 2007.
372 RAI, "Regulating Scientific Research: Intellectual Property Rights and the Norms of Science," *op.cit.*
373 TED O'DONOGHUE, SUZANNE SCOTCHMER, and JACQUES-FRANÇOIS THISSE, "Patent Breadth, Patent Life, and the Pace of Technological Progress," *Journal of Economics & Management Strategy* 7, no. 1, 1998.

expanded through practice. This trend has strained the regulatory system to its breaking point, and weakenened the competitive ethos it remains based upon[374]. It therefore calls for an effective fine-tuning of the rules of appropriation and diffusion in order to maintain successfully innovative and equitable agricultural biodiversity use in competitive markets. The paradigm's shortcomings have been fiercely pushing for an equitable reassessment of the entire intangible protection system in light of the various actors involved in the diverse socio-technological context of agrobiodiversity innovation. The limits around biodiversity use, appropriation, production and re-use need in this context to be clearly re-defined in accordance with the effects of these artificial boundaries on the practices of the entire range of plant improvers.

[374] REICHMAN, "Legal Hybrids between the Patent and Copyright Paradigms," *op.cit.*

PART II ACTOR ANALYSIS: INNOVATION CONTEXTS, AGROBIODIVERSITY CONSERVATION AND USE GROUPS

In the backdrop of distinct property rights requisites, the law strives to build pioneering, efficient and equitable agrobiodiversity management opportunities. The dominant development oriented intellectual property paradigm seems nonetheless to have disrupted the inherent balance of between the grant of exclusive rights and the social compensation of exclusivity. It may have undermined the reach of the public domain that remains vital for the continuity of diverse plant improvement endeavours, and also for the sustainability of agricultural genetic diversity in the long run. We believe this is partially due to the fact that legislative action takes place out of the contexts it will be used in, and thereby does not sufficiently have regard to its **impacts on relevant users of agrobiodiversity.** In our case, the studied stakeholders embrace those actors engaged in plant improvement activities and agricultural cultivation, research and development efforts[375]. They may influence the collective management of agricultural biodiversity explicitly, setting up or acting as communities having the direct aim of conserving, using and improving PGRFA, but they may also do so implicitly, for instance by promoting their propagation and exchange[376]. They exist within socio-economic and technological contexts where genetic resources will effectively be conserved and used, within innovation systems that complement each other[377].

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[375] At the outset, the socio-technological contexts of plant improvement stem from scientific developments having influenced agricultural research. Agricultural research activities are traditionally categorised through a number of criteria relating either to the actors undertaking the activity or to the scope of the research. With regards to the actors, distinction is typically established between the private sector comprised of companies duly formed under commercial law, the public sector, comprised of experiment stations, universities or other research organisations falling generally under the realms of public and administrative law, and individuals whose rights are ensured either through human rights legislation or intellectual property rights. With regards to the scope of research, scholars distinguish extension, applied research and 'pure' or 'pre-invention' scientific research. The latter depends on scientific discoveries usually made in other fields than agriculture, and is intended to close the existing gaps between science and research potentials. Applied research designates what we most commonly think of when considering agricultural research, i.e. research aimed at increasing average yields and meeting our full research potential in terms of directly usable discoveries. Extension programs are designed to close the gaps between best practices and average yields, thus leading to speedier adoptions of new technology by farmers or more suitable orientations for research, answering the needs of the field. However, the lines between these research scopes have gotten increasingly blurrier, especially in complex technologies like molecular biology, where commercial applications are speedily easier to pinpoint. Furthermore, the rise of important public-private partnerships and a generalised decrease in public research expenditure make it harder to identify the actors involved in plant improvement in a classical sense. (see ROBERT E. EVENSON, "Economic Impacts of Agricultural Research and Extension " in *Handbook of Agricultural Economics*, ed. B. GARDNER and G. RAUSSER, New York: Elsevier Science, 2001, pp.583-590.; where the author not only identify these different categories, but also establishes links between their existence and successes and the stages of development witnessed by the State under study).

[376] EYZAGUİRRE and DENNİS, "The Impacts of Collective Action and Property Rights on Plant Genetic Resources," *op.cit.*, p.1491.

[377] Socio-technological contexts of plant improvement shall be viewed as "innovation systems", stepping beyond linear approaches to product or process development that have previously dominated science and technology studies. Innovation will be considered "in a more systemic, interactive and evolutionary way, whereby networks of organisations, together with the institutions and policies that affect their innovative behaviour and performance, bring new products and processes into economic and social use". WIETSE VROOM, *Reflexive Biotechnology Development: Studying Plant Breeding Technologies and Genomics for Agriculture in the Developing World* Wageningen: Wageningen Academic Publishers 2009, p.152. Prominent scholars of such an innovation systems approach include R.R. NELSON, "National Innovation Systems: A Retrospective on a Study," *Industrial and Corporate Change* 2, 1992.; B.A. LUNDVALL, *National Systems of Innovation: Toward a Theory of Innovation and Interactive Learning* London: Pinter Publishers, 1992., and CHARLES EDQUIST and B. JOHNSON, "Institutions and Organizations in Systems of Innovation," in *Systems of Innovation: Technologies, Institutions and Organizations*, ed. CHARLES EDQUIST, London: Pinter Publishers, 1997. This approach will be complemented by a "sociotechnical systems" stance that also takes into

In this context, the innovation system metaphor

> "may be defined as the network of agents whose interactions determine the innovative impact of knowledge interventions including those associated with scientific research. The concept is now used as a kind of shorthand for the network of inter-organisational linkages that apparently successful countries have built up as a support system for economic production across the board. In this sense, it has been explicitly recognised that economic creativity is actually about the quality of 'technology linkages' and 'knowledge flows' amongst and between economic agents. Where the interactions are dynamic and progressive great innovative strides are often made. Conversely where systemic components are compartmentalised and isolated from each other, the result is often that relevant research bodies are not at all productive. In extreme cases, they have ceased to provide any innovative output at all. Put another way, the key property of a system of innovation is therefore not so much its component parts, or nodes, but rather how it performs as a dynamic whole"[378].

Accordingly, the science behind the development and production of seeds has shaped divergent economic models that constitute the reality of the primary sector today. They can be understood through a **perspective inscribed in historical institutionalism,** embracing and analysing both formal and informal rules surrounding institutional change[379]. The incorporation of the historical and sociological dimensions of technical change[380] provides in this sense a toolkit to foster the

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account the social processes that influence the perception of technological strides; see BIJKER 1995 W.E. BIJKER, *Of Bicycles, Bakelites, and Bulbs: Toward a Theory of Sociotechnical Change* Cambridge: The MIT Press, 1995.
For a quick overview of the difficulties inherent to the study of organisational change vis-à-vis informational technology, see M.Lynne MARKUS and Daniel ROBEY, "Information Technology and Organisational Change: Causal Structure in Theory and Research", *Management Science,* 34:5 (1988), pp. 583-598. For an another example stemming from the pharmaceutical sector vis-à-vis the advances in molecular biology, i.e. those same technological breakthroughs having impacted PGRFA management as well, see REBECCA HENDERSON, LUIGI ORSENIGO, and GARY P. PISANO, "The Pharmaceutical Industry and the Revolution in Molecular Biology: Interactions among Scientific, Institutional and Organisational Change," in *Sources of Industrial Leadership: Studies of Seven Industries*, ed. DAVID C. MOWERY and RICHARD R. NELSON, New York: Cambridge University Press, 1999, 267-311.

[378] NORMAN CLARK, PAKKI REDDY, and ANDREW HALL, "Client-Driven Biotechnology Research for Poor Farmers: A Case from India," *International Journal of Technology Management and Sustainable Development* 5, no. 2, 2006., at p.129.

[379] Indeed, "institutional continuity and change (is) characterised by evolutionary processes in context-specific ways rather than by (linear) chains of independent events », WEISHAUPT, *From the Manpower Revolution to the Activation Paradigm: Explaining Institutional Continuity and Change in an Integrating Europe*, *op.cit.*, p.28.; see also STEINMO, "Historical Institutionalism," *op.cit.*

[380] The socio-technological contexts identified within this research draw not only from KUHN's scientific paradigms (KUHN, *The Structure of Scientific Revolutions*, *op.cit.*); but also from DOSI's technological paradigms (G. DOSI, "Technological Paradigms and Technological Trajectories: A Suggested Interpretations of the Determinants and Directions of Technical Change," *Research Policy* 11, no. 3, 1982.), but also to other seminal contributors such as RICHARD R. NELSON and SIDNEY G. WINTER, "In Search of Useful Theory of Innovation," ibid.6, no. 1, 1977.

regulatory shift that has been quite vocally advocated for in doctrinal thought[381] and by a plethora of civil movements[382].

Agriculture has witnessed numerous technological revolutions, from mechanisation, irrigation, greenhouses, to food storage and transportation possibilities. One might even say that every single human invention from fire to petrol has influenced our capacity to control and cultivate nature in order to spawn foodstuff. Our **ability to understand, cultivate and improve plant diversity** has yet played an unrivalled role in improving agricultural production patterns. The scrupulous command of genetic resources has affected agricultural production in terms of quantity and quality, altering the capacity, productivity, adaptability and sustainability of its patterns. Research directly involving agricultural genetic resources targets the introduction of new inputs within production schemes, seeds. An absolutely essential component along with soil, water and direct human nurturing, seeds can be considered the ultimate starting point of any agricultural ecosystem[383]. They have been exchanged, used, analysed and tested, first by farmers, then by scientists, and finally by private breeders. They have been used not only to provide foodstuff, but also to determine the best suitable varieties for cultivation in terms of environmental conditions or market demands. Throughout time, this particular research field has evolved from a brutal and wide search for important leads within a wide array of collected material, towards directed and focused activities, relying on scientific models pointing out the material showing greater promise before the undertaking of applied research *per se*.

All activities nonetheless possess a common ground, in that they also rely on the selection operated between and within plant species, which can mould crop varieties to satisfy human needs or adjust to environmental conditions. Differing degrees of genetic change occur in diverse fashion, on account of all the selections that are operated on fields (or in laboratories), with or without human intervention, incessantly creating and de-creating gene pools. Selection may in this context take place naturally, through mere survival, but also unconsciously, through the preservation of most valued crops based on the observation of production results on farm, through **mass selection**. It can also be carried out methodically, through a systematic modification of breeds according to predetermined standards[384]. The better understanding of genetic heredity allowed in this sense plant **breeders** to intentionally cross plant varieties to attain specific results in terms of size, colour or taste, and obtain high productivity rates at harvest[385]. Newfound uses of plant genetic resources have contributed to a striking escalation in yields and productivity. For

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[381] MERGES ROBERT, "Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents," *Tennessee Law Review* 62, 1994-1995; HELLER, "The Tragedy of the Anticommons: Property in the Transition from Marx to Markets," *op.cit*; AOKI, "Neocolonialism, Anticommons Property and Biopiracy in the (Not So Brave) New World Order of International Intellectual Property Protection," *op.cit*; BOYLE, "The Second Enclosure Movement and the Construction of the Public Domain " *op.cit.*; RAI and BOYLE, "Synthetic Biology: Caught between Property Rights, the Public Domain and the Commons," *op.cit.*; REICHMAN, "Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation," *op.cit.*

[382] Such as those targeting the patenting of life, advocating Access to Knowledge (A2K) or those movements more specifically targeted at defending farmers, such as the Crucible Group or Via Campesina.

[383] The title of the much-acclaimed and cited work of Jack KLOPPENBURG provides in this regard much guidance as to the role of *First, The Seed*, in agricultural production. See KLOPPENBURG, *First the Seed: The Political Economy of Plant Biotechnology 1492-2000*, *op.cit.*

[384] PAUL GEPTS, "Crop Domestication as a Long-Term Selection Experiment," in *Plant Breeding Reviews*, ed. J. JANICK, 2004, 24-25.

[385] For a comprehensive overview of these new possibilities, see BRUINS, "The Evolution and Contribution of Plant Breeding to Global Agriculture," 18-31.

instance, English wheat yields, which had only increased from zero point five to two metric tons per hectare in one thousand years, saw their results triple from 1960 onwards, reaching six metric tons on account of new plant varieties and the accompanying industrial agricultural model[386]. This escalation only took forty years, within a ground-breaking cycle twenty-five times shorter than the one characterised by un-methodical variety selection. The second agricultural quantum leap was achieved merely decades later, owing to the developments in **molecular biology and genomics science** of the late 1990's, adding incredible precision and foresight to the research process, shortening the cycle of product development, and generating the newest type of modern varieties, fruits of genetic modification[387]. Propelling and deriving almost exclusively from such new uses of genetic resources, the rates of return of research and development have cruised at considerably high levels in all agricultural commodities, especially with regards to field crops where mean rates reached as high as one hundred thirty five per cent, well privileged above the average of seventy five per cent for all agriculture[388].

Drawing from the recent theories on technological change having concentrated on the study of the parallel evolution of technology, public policy and institutions[389], we shall trace back the technology- induced shift in ownership and management of agricultural plant germplasm. This enterprise will first illustrate the **initial uses of agricultural biodiversity for cultivation purposes,** which have improved genetic variability through the selection of best-performing individuals (*Chapter 4).* The focus will thereon shift onto more recent **science-based and methodical plant improvement opportunities,** describing first the rise of conventional plant breeding (*Chapter 5*) and then the shift "from the Green to the Gene revolution" stemming from our knowledge of and experimentations with living organisms (*Chapter 6*). Accordingly, our analysis shall identify the institutions and actors that constitute the “Plant Genetic Resources System”[390], from indigenous communities of the genetically-rich “South”, to farmers, to public or private variety collectors and/or developers of the capital-rich “North”. This historical perspective shall lead to the identification of the different socio-technological contexts of agrobiodiversity innovation and the actors that navigate them; an identification that will guide our subsequent re-assessment of legal appropriation tools.

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[386] IFPRI, *Green Revolution: Curse or Blessing?* Washington D.C. : IFPRI, International Food Policy Research Institute, 2002. See also DEREK BYERLEE, "Modern Varieties, Productivity, and Sustainability: Recent Experience and Emerging Challenges," *World Development* 24, no. 4, 1996.

[387] PAUL GEPTS, "A Comparison between Crop Domestication, Classical Plant Breeding, and Genetic Engineering," *Crop Science* 42, 2002: 1780-1790.

[388] These rates have been assembled through the analysis of more than 292 published studies reporting estimates vis-à-vis rates of return of agricultural research and development under the auspices of IFPRI, see JULIAN M. ALSTON et al., *A Meta-Analysis of Rates of Return to Agricultural Research and Development: Ex Pede Herculem?* , ed. INTERNATIONAL FOOD POLICY RESEARCH INSTITUTE Washington: International Food Policy Research Institute, 2000, esp. at pp. 57-58.

[389] EDQUIST, *Systems of Innovation: Technologies, Institutions and Organisations*, *op.cit.*, and especially the article by Bo CARLSSON and Staffan JACOBSSON, "Diversity Creation and Technological Systems: A Technology Policy Perspective", where the authors analyse the case of genetic engineering both in the United States and Sweden.

For a quick overview of the difficulties inherent to the study of organisational change vis-à-vis informational technology, see M.Lynne MARKUS and Daniel ROBEY, "Information Technology and Organisational Change: Causal Structure in Theory and Research", *Management Science,* 34:5 (1988), pp. 583-598.

For an another example stemming from the pharmaceutical sector vis-à-vis the advances in molecular biology, i.e. those same technological breakthroughs having impacted PGRFA management as well, see HENDERSON, ORSENIGO, and PISANO, "The Pharmaceutical Industry and the Revolution in Molecular Biology: Interactions among Scientific, Institutional and Organisational Change," *op.cit.,* 267-311.

[390] CORREA, "In Situ Conservation and Intellectual Property Rights," *op.cit.,* 239-240.

4. CHAPTER 4: MASS SELECTION OF BEST PERFORMING INDIVUALS BUILDING ON INFORMAL SEED EXCHANGES

Up from the initial transformation of humankind from hunter-gatherers into farmers through the domestication of crops, agriculture has always tried to improve production results in fields. Within the more general Darwinian framework of survival of the fittest in the wild, agricultural practices have always exerted "an evolutionary pressure on plants"[391]. Individuals have always played a pivotal role in crop enhancement and have constantly sought to better cultivate, adapt and produce foodstuff. This role is traced back to ten thousand to twelve thousand years, when “wild progenitors gave rise to the first primitive varieties [that were] genetically quite narrow” and were gradually domesticated, starting the flow between the so-called crop wild relatives and cultivated species, generating landraces[392]. From the sixteenth to the eighteenth century, the individual landowner has grown beyond the depreciated “medieval husbandman closely following traditional practices” and working for his family on his land, towards a “**dynamic and experimental farmer-entrepreneur**”, using **cost-benefit analysis to choose between offered alternatives**[393].

Farmers, whether described as small-scale, subsistence-oriented, dynamic, or even professional, have continuously **selected their most efficient plants for sowing the following year**, in order to obtain better results in terms of yields. Even today a large proportion of the seed planted is either saved by farmers or exchanged on a farmer-to-farmer basis. In the mid-1980s farmer-saved seed accounted for an estimated thirty five per cent, or eighteen billion USD of the total estimated value of fifty billion USD for all agricultural seed used worldwide[394]. In developing countries, an estimated eighty per cent of the seed used in the early 1980s was farmer-saved seed[395]. Furthermore, the use of modern improved cultivars has not annihilated the recourse to farmers’ varieties in developed countries, as the many unregistered garden forms of dry bean that are still grown in The Netherlands show[396]. In this context, farm-based mass selection ought to be viewed as a stand-alone plant innovation chain, developing landraces or population varieties, based on informal and socio-cultural norms of exchange. This distinct system is still very much a present and indispensable reality of agrobiodiversity innovation. It is precisely these dynamic farmers’ selection endeavours that have been reinforced through precise scientific knowledge, obtaining more defined results through the crossing of different strains[397].

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[391] This distinction is used by Noel KINGSBURY in order to describe the mechanism through which humankind has substituted itself for the natural evolutionary process through crop domestication via selection and breeding efforts, see *Hybrid: The History and Science of Plant Breeding* Chicago: The University of Chicago Press, 2009, 3-5.

[392] KARL HAMMER and AXEL DIEDERICHSEN, "Evolution, Status and Perspectives for Landraces in Europe," in *European Landraces: On Farm Conservation, Management and Use*, ed. M. VETELAINEN, V. NEGRI, and N. MAXTED, Rome: Biodiversity International (IPGRI), 2009, pp.23-44.

[393] MURPHY, *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*, *op.cit.*, p.60.

[394] GROOSMAN, LINNEMANN, and WIEREMA, *Technology Development and Changing Seed Supply Systems: Seminar Proceedings, 22-23 June 1988*, *op.cit.*

[395] PRAY and RAMASWAMI, *A Framework for Seed Policy Analysis in Developing Countries*, *op.cit.*, p.4.

[396] ZEVEN, "Landraces: A Review of Definitions and Classifications," *op.cit.*, p.128.

[397] GEPTS, "Crop Domestication as a Long-Term Selection Experiment," *op.cit.*, 1-44.

4.1. A traditionally holistic approach to crop improvement

Mass selection could be defined as a **traditionally holistic approach to crop improvement based** on little-constrained seed exchanges, resulting in the development of local and non-uniform landraces. The key process of traditional farming systems relies on the repeated local reproduction of seed, where farmers influence such reproduction by choosing varieties and selecting interesting individuals[398]. In a context of great diversity and exchange, farmers repetitively select interesting or efficient plants for sowing the next year. This selection is based upon the observation of each variety's and each individual's performances on the field. The intensity and exact reach of the selection efforts operated on farm is impossible to determine with clarity at a global level, since there are merely a handful of case-studies recorded in comparison to the actual selections made on farms around the globe every day. Furthermore, this practice is used just as much in marginal systems within a low-input context relying on indigenous knowledge of farmers, as in developed countries such as Finland or the United Kingdom[399]. Major differences thus exist in the cultivation and improvement of landraces, as they might very well be cultivated through high-input and modern agronomic and agricultural techniques. However, a number of **general principles of operation** have been highlighted in the literature. Some commentators argue that farmers only carry out mild recurrent mass (or negative) selection between populations, while others tend to recognise the existence of conscious selection of traits in individual plants[400]. Others highlight the potential of retaining desirable characteristics in populations, despite the difficulty to qualify it as a breeding method *per se*[401]. Different phenomena and practices have been observed by commentators, such as seed replacement routines based upon the need to "revive tired cultivars" and thereby renew landrace seed stocks[402]. It is in this regard safe to say that the intensity and reach of variety selection will depend on a number of factors, including the experimental nature and interests or abilities of the farmer himself, but also the farm's geographical, agronomical and cultural surroundings.

Focused on the minimisation of risk, farmers traditionally plant a wide range of both species and varieties. Through a practice coined 'multiple cropping', they use a **mixture of species considered desirable** in terms of food or fibre production needs, or other socio-cultural or

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[398] CONNY J.M. ALMEKINDERS, NIELS LOUWAARS, and G.H. DE BRUIJN, "Local Seed Systems and Their Importance for an Improved Seed Supply in Developing Countries," *Euphytica* 78, 1994: p.208.

[399] V. NEGRI, N. MAXTED, and N. VETELAINEN, "European Landrace Conservation: An Introduction," in *European Landraces: On Farm Conservation, Management and Use*, ed. M. VETELAINEN, V. NEGRI, and N. MAXTED, Rome: Biodiversity International (IPGRI), 2009, p.7.

[400] JOHN GREGORY HAWKES, *The Diversity of Crop Plants,* Cambridge: Harvard University Press, 1983.

[401] Indeed, "mass selection has usually not been recommended as a breeding method to increase yield because heritability for spaced plant yields has usually been low" and therefore needs to be supplemented by a number of changes to become what has been coined "recurrent restricted phenotypic selection", a plant breeding method in its own right; see GLENN W. BURTON, "Enhancing Germplasm with Mass Selection," in *Advances in New Crops,* ed. J. JANICK and J.E. SIMON, Portland: Timber Press, 1990, pp.99-100. It should be noted that this breeding method based on recurrent selection and close to mass selection endeavours, has not been as extensively applied as other classical plant breeding methods and rather serves as an effective method when integrated to applied aspects of breeding, see ARNEL R. HALLAUER and LARRY L. DARRAH, "Compendium of Recurrent Selection Methods and Their Application," *Critical Reviews in Plant Sciences* 3, no. 1, 1985: pp.1-33.

[402] "Seed replacement could be defined as the replacement of home-grown (autochthonous) by fresh allochthonous seed, […] obtained from a neighbour or maybe obtained as well by exchange, from farther away, for instance a market or, when available from a breeder or variety maintainer, as a single person or as employee of a breeding/seed company." A.C. ZEVEN, "The Traditional Inexplicable Replacement of Seed and Seed Ware of Landraces and Cultivars: A Review," *Euphytica* 110, 1999: p.182.

religious community demands[403]. The variety of cultivated and selected varieties thus depends on the multi-criteria approach privileged by farmers in both production and selection**,** which may not merely focus on yield or other productivity-related aspects. Farmers seldom concentrate their efforts and production capacity on a single species. The decision to cultivate a traditional or an improved variety will be determined by the farmer's perception of the cultivar's or the landrace's ability to fulfil the household's requirements relative to alternative options. This decision will take into account the existence of markets and transaction costs, as well as the physical, economic, and cultural contexts of local agriculture[404]. Decisions to add or delete a specific variety or population are made in accordance with changes in the local biophysical or sociocultural environment and the consequent changes in the search for varietal traits, as certain characteristics might be less or more sought after due to internal or even external events, which may stretch as far as evangelisation[405]. Furthermore, these changing landscapes are heavily influenced by the availability of modern varieties that are similar to farmers' varieties or the availability of farmers varieties themselves, for instance through the presence of a local market with easy access to local seed stocks[406]. Selection methods based on plant characteristics have for instance been often described in the literature with regards to sorghum and pearl millet in Africa[407]. However, farmers do not only operate their selection on phenotypic characteristics. In the Mexican community of Cuzalapa for instance, seed selection does not operate on plants during cropping season or at harvest, but rather on piles of harvested maize ears[408]. These ears also constitute the farming household's grain stocks for personal consumption. Ear selection operates on the basis of multiple criteria, in the search for well-developed and well-filled ears without fungi or insect damage. Consequently, the objectives set out by mass selectors are not solely concerned with yield, but rather comprise of an **array of desirable characteristics**. Amongst these criteria lies the search for yield stability associated with diversity within and between cultivars. Farmers use observed yield as only one of several criteria to predict varietal performance in more stressed local environments[409]. Within the wide array of selection objectives pursued by farmers also lies the adaptation of species or varieties to local water and soil conditions or the availability of labour. These criteria are accompanied by general

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[403] CHARLES A. FRANCIS, "Biological Efficiencies in Multiple-Cropping Systems," in *Advances in Agronomy, Volume 42*, Academic Press, 1989, pp. 4-5.

[404] Heterogeneity of local agriculture promotes the maintenance of landraces; just as missing market sand high household transaction costs in the peasant sector may contribute to continued cultivation of landraces. STEPHEN BRUSH and E. MENG, "Farmers' Valuation and Conservation of Crop Genetic Resources," *Genetic Resources and Crop Evolution* 45, 1998: p.142.

[405] With regards to external causes determining the recourse to farmers' varieties for instance, the evangelisation of local populations has been pointed out as a main cause behind the decrease in use of local black and red maize varieties in Southern Belize due to the lack of interest in shamanist rituals where these varieties were heavily (and exclusively) used; see MICHAEL K. STEINBERG, "Maize Diversity and Cultural Change in a Maya Agroecological Landscape," *Journal of Ethnobiology* 19, no. 1, 1999.

[406] DAVID A. CLEVELAND, DANIELA SOLERI, and STEPHEN SMITH, "*Farmer Plant Breeding from a Biological Perspective: Implications for Collaborative Plant Breeding*", CIMMYT, Mexico, 1999.

[407] T. BERG, "The Science of Plant Breeding: Support or Alternative to Traditional Practices?," in *Cultivating Knowledge: Genetic Diversity, Farmer Experimentation and Crop Research*, ed. W. DE BOEF, K. AMANOR, and K. WELLARD, London Intermediate Technology Publications, 1993.; as well as T.A. MUSHITA, "Local Farmers Knowledge on the Management of Plant Genetic Resources in Communal Areas of Zimbabwe," in *Seminar on Local Knowledge and Agricultural Research* (28 Sept-2 Oct 1992, Zimbabwe: WAU/ENDA-Zimbabwe/CGN/GRAIN 1992)..

[408] D. LOUETTE and MELINDA SMALE, "Farmers' Seed Selection Practices and Traditional Maize Varieties in Cuzalapa, Mexico," *Euphytica* 113, 2000: p.28 and 32.

[409] MARK POLYAKOV and EUGENE GORYUNOV, "(Non) Obviousness of Claims to Genetic Sequences: Finding the Middle Ground," *Santa Clara Computer and High Technology Law Journal* 26, no. 1, 2009.

consumption objectives, whether having direct regard to taste, size or the use of varieties in traditional dishes, or through indirect uses, like the potential utilisation of products for animal feed or for roofing (in the case of sorghum for instance)[410].

The peculiar crop improvement mechanism that mass selection forms an **integral part of a more complex agricultural ecosystem**, which stretches beyond the cultivated field where farmers grow their crops, including adjacent land plots used for food supplements with social culinary value, or for organic fertilisers, within an intricately integrated system[411]. Even though it resonates more deeply with small-scale subsistence agriculture in contemporary times, mass selection nonetheless is not limited to what the "West" might assign to the agriculture of the developing world. It is still very much present in developed countries, as the aforementioned example of dry bean production in The Netherlands show[412]. It has also been taken on by a rather new trend in plant production, that of low-input and especially organic or bio-dynamic agriculture. Indeed, "organic or low-external-input systems in developed countries resemble farming systems in marginal environments of developing countries because environmental stress is heterogeneous, there are few varieties that meet the diverse needs of farmers in such systems and there is very little interest from the commercial seed sector"[413]. Indeed, the traits sought after by farmers in low-input environments, whether in organic agriculture or in small-scale subsistence agriculture, are considered to be too diverse to be adequately addressed by formal plant breeding programs[414]. Furthermore, the holistic approach to plant improvement also resonates more deeply with the value system that surrounds organic and low-input agriculture, favouring as a result techniques that work at the level of whole plant performance without breaking reproductive barriers between species, relying on the so-called *breeder's eye*[415].

The **products of mass selection efforts** operated under the aforementioned objectives and principles are coined **local, farmers' varieties or landraces**. These varieties are considered to provide high yield stability in marginal and relatively variable cultivation environments from years on end[416]. They have narrow geographical adaptation capabilities from one environment to the other. Contrary to those stable varieties that would be developed by plant breeders by the beginning of the 20th century, it is extremely difficult to define landraces as such. Indeed, they form plant groups or populations, rather than easily definable static varieties. Definitions have therefore attempted to highlight their inherent characteristics and the rationale behind their cultivation and development. Amongst other definitions, "an autochthonous landrace [has been

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410 ALMEKINDERS, LOUWAARS, and DE BRUIJN, "Local Seed Systems and Their Importance for an Improved Seed Supply in Developing Countries," *op.cit.*, pp.208-209.
411 ALTIERI, ANDERSON, and MERRICK, "Peasant Agriculture and the Conservation of Crop and Wild Plant Resources," *op.cit.*, p.50.
412 ZEVEN, "Landraces: A Review of Definitions and Classifications," *op.cit.*, p.128.
413 JULIE C DAWSON, KEVIN M MURPHY, and STEPHEN S JONES, "Decentralized Selection and Participatory Approaches in Plant Breeding for Low-Input Systems," ibid.160, no. 2, 2008.
414 Ibid.
415 The eye "can be developed to become a more consciously applied instrument for perceiving and assessing aspects of the wholeness or phenotypic integrity of a plant", in accordance with the holistic approach to cultivation in organic agriculture, along with the inherently intrinsic valuation of plants and the natural environment; see ET VAN BUEREN et al., "Concepts of Intrinsic Value and Integrity of Plants in Organic Plant Breeding and Propagation," *Crop Science* 43, no. 6, 2003..
416 CLEVELAND, SOLERI, and SMITH, *op.cit.*, 1999. , citing JACK .R. HARLAN, *Crops and Man (2nd Ed.)*, Madison: American Society of Agronomy, 1992.

viewed as] a variety with a high capacity to tolerate biotic and abiotic stress, resulting in a high yield stability and an intermediate yield level under a low input agricultural system"[417]; or as "a dynamic population(s) of a cultivated plant that has historical origin, distinct identity and lacks formal crop improvement, as well as often being genetically diverse, locally adapted and associated with traditional farming systems"[418]. In Sierra Leone, a study focusing on farmers' rice varieties has found that "there was consistency in the naming by farmers of traditional varieties, but inconsistency in the naming of newly acquired varieties and cultivars"[419], especially when one travelled outside the initial region. These findings nonetheless corroborated the difficulty of assessing landrace use and development with exactitude, in a context where variety names may be trumped by the farmers' seed exchange mechanisms, even though some populations had retained their "traditional credentials". Understanding and predicting the fate of farmers' varieties is indeed quite a complex task, both in terms of their creation and demise.

4.2. Mass selectors, reliance on seed exchange networks and socio-cultural norms

Today at least one and a half billion individuals still depend on small-scale farming for their livelihoods, living mostly from subsistence agriculture on less than two hectares of land[420]. In this context, traditional farming systems rely integrally on the farmers' interaction with the environment in its most general understanding, encompassing both domesticated and wild ecosystems. Their operations are generally carried out without or with very little access to external inputs, or capital, or precise scientific knowledge, but rather through the recourse to inventive self-reliance, experiential knowledge and locally available resources[421]. In this context, the web of unsanctioned and colloquial exchanges built around farmer mass selection have led to the unequivocal recognition, especially in social sciences, ethno-botany or geography, of a **farmer-based seed system, coined "informal".**

Whether treated as economic marginality or a social reality, the eldest yet vivacious agrobiodiversity innovation chain that is mass selection reveals the need to take into account a **wide range of external institutions**. Even though the development of local cultivars remains primordial for food security issues, the informal market's practice of "white untagged bags" cannot reliably communicate information on the seeds they contain on their own. These practices have thus unequivocally been accompanied by socio-cultural ties ensuring the flow of knowledge. In an effort to minimise risk and maintain high levels of security stocks, farmers do replace, modify or complete the stocks they keep for the same varieties through exchanges operating with other farmers. Farmers acquire seeds and information upon such seeds through a vast range of channels. They may do so through local, regional, national and even international farmers'

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[417] ZEVEN, "Landraces: A Review of Definitions and Classifications," *op.cit.*, p. 137.

[418] TANIA CAROLINA CAMACHO VILLA et al., "Defining and Identifying Crop Landraces," *Plant Genetic Resources* 3, no. 3, 2005., who highlight that, although these characteristics are commonly present in most landraces, they will not always be found in any individual landrace; as several crop-specific exceptions exist, especially with regards to the crop propagation method (sexual or asexual), or the length of formal crop improvement for instance.

[419] ROBERT CHAKANDA et al., "Analysis of Genetic Diversity in Farmers' Rice Varieties in Sierra Leone Using Morphological and Aflp® Markers," *Genetic Resources and Crop Evolution*, 2012.

[420] Agriculture is in this regard viewed as more than a simple economic activity but as a livelihood "for an estimated 86 per cent of rural people"; WORLD BANK, "*World Development Report 2008: Agriculture for Development* ", Washington, 2007.

[421] ALTIERI, ANDERSON, and MERRICK, "Peasant Agriculture and the Conservation of Crop and Wild Plant Resources," *op.cit.*, p.49.

organisations, weekly foodstuff markets and other personal or social networks. These exchanges can take place either inside or outside of their community, a practice that is for instance still pursued today in the Cuzalapa community located on the Pacific coast of Mexico[422]. Formal seed markets function on the basis of regulation pertaining to approval and promotion, with quality insurance and guarantee as to the identity of purchased seeds. In contrast, the informal material exchanges that mass selection activities rely upon are rather governed by **cultural norms and *ad hoc* rules determined solely by the participants to the exchange**, without regulatory intervention[423]. Indeed, the pool of genetic variation maintained by farmers does not solely depend on biophysical and agronomical factors, but is also determined by the existence and strength of social networks providing access to seeds, and the individual's status within these networks and the community in general[424]. Several case studies have highlighted that the decision to take part in the exchange or to accept an individual to the "free-handover of seed" is heavily influenced by the presence of relatives and socio-cultural ties between farmers[425]. Big farmers may indeed willingly exclude smaller ones from the network, as documented in Peru for potato seed ware[426]. New material may only be offered in "handfuls" to close friends or important neighbours outside of the local markets, as witnessed in Rwanda for beans[427].

While local farmers' markets carried out, and even intensified their exchange practices within small-scaled production units both in developing and developed countries, mass selection and its related seed exchange networks grew into new areas. In response to the forceful regulatory push towards a highly regulated and competitive formal seed market, networks solely concerned with seed saving and exchange were concomitantly constituted especially in developed countries in the 1990's. In parallel, organic farming and breeding was being developed as an alternative to industrial production, cultivating foodstuff in accordance with strict "cahier des charges" prescribing lesser recourse to farm inputs and a greater diversity in cultivated plant varieties[428]. Whether motivated by the "naturalness" of the produced food or by other values, organic farming and other non-certified types of low-input agriculture has become an undeniable reality of contemporary farming[429]. These models are all based on breeding methods close to mass selection efforts and revolve around strong-knit seed exchange and saving networks, and particularly suffer from the poor adaptation of modern cultivars to the conditions inherent to their unique agricultural

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422 LOUETTE and SMALE, "Farmers' Seed Selection Practices and Traditional Maize Varieties in Cuzalapa, Mexico," *op.cit.*, pp.26-27.

423 See notably LOUISE SPERLING, H.DAVID COOPER, and TOM REMINGTON, "Moving toward More Effective Seed Aid," *Journal of Development Studies* 44, no. 4, 2008: 586-612.; and also LESLIE LIPPER, C.LEIGH ANDERSON, and TIMOTHY J. DALTON, *Seed Trade in Rural Markets: Implications for Crop Diversity and Agricultural Development* London: Earthscan, 2009, pp.19-21.

424 For instance, shamans or certain women farmers have been known to maintain a greater number of farmers' varieties, with higher chances in igniting and participating to the exchange and the seed networks; CLEVELAND, SOLERI, and SMITH, *op.cit.*, 1999.

425 ZEVEN, "The Traditional Inexplicable Replacement of Seed and Seed Ware of Landraces and Cultivars: A Review," *op.cit.*, p.187.

426 CONNY J.M. ALMEKINDERS, NIELS LOUWAARS, and G.H. DE BRUIJN, "Local Seed Systems and Their Importance for an Improved Seed Supply in Developing Countries," ibid.78, 1994.

427 POLYAKOV and GORYUNOV, "(Non) Obviousness of Claims to Genetic Sequences: Finding the Middle Ground," *op.cit.*

428 BEATE HUBER, OTTO SCHMID, and LUKAS KILCHER, "Standards and Regulations," *The World of Organic Agriculture. Statistics and Emerging Trends*, 2010.

429 VAN BUEREN et al., "Concepts of Intrinsic Value and Integrity of Plants in Organic Plant Breeding and Propagation," *op.cit*; HENK VERHOOG et al., "The Role of the Concept of the Natural (Naturalness) in Organic Farming," *Journal of agricultural and environmental ethics* 16, no. 1, 2003.

ecosystems[430]. These contemporary networks tend to have **more institutionalised structures, bearing national, regional, or even international ambitions and reach**. In developed countries, seed exchange networks show the same characteristics as informal farmers' innovation, being also governed by cultural and *ad hoc* norms and articulated around "seed swaps". They nonetheless tend to be more institutionalised than those exchanges carried out by so-called "subsistence" or smaller farmers of developing but also developed nations. Indeed, most of these seed exchanges are organised around regulated networks, which either take the form of non-governmental organisations or of private clubs. They have been set up mainly in reaction to the State-sponsored, industry and productivity oriented formal seed markets. These coalitions usually set up "heirloom", "heritage" seeds catalogue and provide them to members for cultivation and saving, provided sometimes a portion of the saved seed is returned to them. Amongst many lies *Arche Noah*, an Austria based Central European Seed Savers Association set up in 1990 and which manages the largest private seed collection in Europe with six thousand plant varieties; the United States based *Seed Savers Exchange*, set up in 1975, and currently manages several different catalogues. All organisations do not however distribute seeds, some rather act as intermediaries between several smaller or more regional and local exchange networks, carrying out conservation projects, trainings and swap events at a larger scale, such as the French *Reseau Semences Paysannes* for instance, whose specific old heirloom vegetables projects brings together several local groups, which are active in mass selection activities (*Le Biau Germe, Germinance, Payzons ferme, Les Semailles, Le Potager d'un curieux, Graines del Païs, Jardin'envie*).

Farmers' innovation is based upon observations on farm and the selection of the best-performing individuals, not only in terms of yield but also on account of ecosystemic, social and economic considerations. Even though it is still uncertain whether or not farmers recognise a direct private value from genetic diversity as such, the private value of local crop populations is unequivocally accepted, as direct benefits derive from the production and consumption of landraces. This assumption is corroborated by the continuity of landrace farming practices even though alternative systems are proposed to farmers[431]. Heavily relying on social networks surrounding seed saving and exchanges, mass selectors, in both their traditional and more modern forms, develop and conserve landraces: non-uniform plant varieties that are particularly well adapted to local conditions. Notwithstanding their inherently heterogeneous and local focus, all seed exchange networks are based on the premise of an open innovation system. They do not seek to commercialise their seeds in the formal market, nor do they take steps to appropriate either the genetic resources they cultivate or the knowledge attached hereunto. This approach does not however fit well into the currently applicable legal tenets that surround seed systems. They have indeed been compelled to resituate themselves within the technological and regulatory environments that surround their activities, sustaining their production without infringing other actors' rights, and ensuring the survival of their biodiversity conservation and innovation model based on open access. Economic theory has predominantly hung on to the premise that informal seed systems should be treated as marginal or vestigial with regards to the economic development

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[430] KEVIN M MURPHY et al., "Evidence of Varietal Adaptation to Organic Farming Systems," *Field Crops Research* 102, no. 3, 2007.

[431] Indeed, the fact that landraces are still cultivated even though alternative systems are proposed to farmers, or the simple fact that variety selection still operates, shows that local varieties have direct private value for mass selectors. BRUSH and MENG, "Farmers' Valuation and Conservation of Crop Genetic Resources," *op.cit.*, pp.139-140.

process[432]. By the end of the 1990's, approximately three hundred million hectares of land were still considered to bear the hat of "subsistence agriculture" feeding two hundred and thirty million households or more than one billion people. These "marginal lands" are ignored by modern crop developers, and considered to be unproductive in their essence, heavily vulnerable to crop failure[433]. This latter approach needs however to bear the test of challenging contemporary times of food, financial and unemployment crisis, where returns to farming activities are generally witnessed, just as changes in consumption patterns, which have been pushing agricultural production towards invigorated lower-input systems[434]. While it is widely acknowledged that the social returns from research activities exceed the private returns of the particular developer[435], leading to the recognition of the public goods dimension of agricultural research, technological changes witnessed in past centuries may have very well transformed agricultural research into an impure public good, starting with the advent of science-based plant breeding.

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[432] LATHA NAGARAJAN and MELINDA SMALE, "Community Seed Systems and the Biodiversity of Millet Crops in Southern India," in *Valuing Crop Diversity: On Farm Genetic Resources and Economic Change*, ed. MELINDA SMALE, CAB International, 2006, p.212.

[433] EDWARD C. WOLF, "*Beyond the Green Revolution: New Approaches to Third World Agriculture*", WorldWatch Institute, Washington, 1986.

[434] Indeed, it is today widely acknowledged that a mere extension of modern breeding techniques into traditional systems will not successfully address the needs of food security, but rather needs creative new strategies to be developed; LAURA TANGLEY, "Beyond the Green Revolution: New Strategies Are Needed to Increase Food Production for More Than One Billion People Bypassed by Agricultural Technology," *BioScience* 37, no. 3, 1987.

[435] See for instance R. NELSON, "The simple economics of basic scientific research", *Journal of Political Economy,* 67 (1959), pp. 297-306; W. PETERSON, "Note on the Social returns to private research and development', *American Journal of Agricultural Economics,* 58 (1976), pp. 324-326; Joseph STIGLITZ, "Knowledge as a Public Good", *in* Inge KAUL et al., *Global Public Goods: International Cooperation in the 21st Century,* Oxford University Press, 1999, pp. 308-325.

5. CHAPTER 5: SCIENCE BASED PLANT BREEDING BUILDING ON INTERNATIONAL GERMPLASM FLOWS AND HEREDITY

Inherently local, at most regional genetic resources have attracted the interests of other actors than farmers. The appeal of exotic genetic resources for botanists and scientists was the first trigger that substantially altered the fate of biodiversity conservation and plant improvement. After having spent ten thousand years in the hands of farmers, the crown of seed control has steadily been altered on account of different technological revolutions. The Darwinian "evolutionary pressure"[436] on plants initially characterised by the selection of the most efficient plants by farmers in order to sow them the following year, highly intensified with the dawn of plant breeding. Its genesis metamorphosed crop improvement into a knowledge-intensive, extremely productive and fast-evolving research-and-development focused industry. The technological breakthroughs witnessed through the last decades of the 20th century have altered agricultural research and development activities with formidable speed, on account of our deepening knowledge of natural cycles, and more specifically of genetic heredity.

The development of science-based plant breeding has as a result propelled the development of farming inputs off-farm. It has ignited the distribution of improved and stable plant varieties by public research institutes or extension services, and progressively by private seed companies. Defeating fears related to the exponentially rising number of mouths to feed, while also driving commodity prices onto the lower side despite growing food demand, agricultural productivity gains attributed to our better understanding and use of genetic resources have been crucial to human and economic development. Since the domestication of plants epitomising the dawn of agriculture, it has taken ten to twelve thousand years for grain production to reach the impressive one billion tonnes mark in 1960, while the second billion tonnes mark was hit in merely forty years' time in 2000[437]. Such impressive development is not associated with industrialisation, but rather with crop genetic improvement and the development of professional plant breeding about two hundred years ago[438]. Plant breeding still undisputedly stands as an arena where returns on research investment remain "well above the returns attainable from alternative uses of funds"[439], whether from an international, public, or private perspective[440], even though the cycle of breeding remained a lengthy and tedious process whose success is never guaranteed.

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[436] KINGSBURY, *Hybrid: The History and Science of Plant Breeding*, *op.cit.*, p.4 but also pp. 618-621.; as well as MURPHY, *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*, *op.cit.*

[437] G.S. KHUSH, "Green Revolution: The Way Forward," *Nature Reviews Genetics* 2, 2001. (pp. 815-822)

[438] While high-yielding new plant varieties considerably raised yields on farm, the impressive figures of agricultural growth also benefitted from other technologies, such as nitrogen fertilisers or irrigation techniques; PAUL E. WAGGONER, "Agricultural Technology and Its Societal Implications," *Technology in Society* 26, 2004: p.126. In this context, the first comprehensive impact assessment of the introduction of high-yielding improved varieties, with a clear emphasis on those developed and distributed by public international research, highlight that crop varietal improvement "made it possible to meet the food grain demands of perhaps 500 million people", see J. ANDERSON, R. HERDT, and G.M. SCOBIE, *Science and Food: The Cgiar and Its Partners* Washington: World Bank, 1988, p.7.

[439] GARDNER, "Global Public Goods from the Cgiar: An Impact Assessment," *op.cit.* For more literature on rates of return on investment in crop varietal improvement, see also EVENSON, "Economic Impacts of Agricultural Research and Extension " *op.cit.*, 573-628.

[440] It is indeed extremely difficult to measure and determine with exactitude the contribution of international research centres, national agricultural research systems and the private sector to crop improvement. This feature exemplifies the specific construct of agricultural research and development, see ANDERSON, HERDT, and SCOBIE, *Science and Food: The Cgiar and Its Partners*, *op.cit.*

5.1. From crop selection to active plant breeding

The development of hybridisation techniques was achieved in timid steps, mostly on account of the re-discovery of principles governing genetic heredity. Reinforcing in reality farmers' selection endeavours through the infusion of precise scientific knowledge, breeders were able to obtain more defined results through the crossing of different strains[441]. Within this mind-set, it is the **shift from unconscious selection to methodically conscious rational attempts** that marks the development of science-based plant breeding. It is also precisely the strengthening of conscious, methodical and active variety selection activities that has historically impacted the perception and status of agricultural genetic diversity the most. The methodical scientific selection of genetic resources has indeed allowed plant breeders to intentionally cross varieties in order to attain specific results, such as size, colour or taste, and mostly obtain high productivity rates at harvest[442]. The evolutionary agricultural challenge of changing agronomic, environmental and human needs could effectively be resolved through the controlled enhancement of cultivated species, which provided the means to fit agricultural inputs to purpose. Throughout colonisation, sufficient working material to rise to such challenge had been accumulated and modestly studied within collection and characterisation efforts.

The introduction of new exotic crops, along with the growing complexity of rotation techniques and the divisions of land, resulted in the first Agricultural Revolution of the 18th and 19th centuries[443]. This revolution marked the **first attempts at "conscious active breeding"**. These undertakings first bore similarities to traditional farmer-like mass or individual selection operated mainly on species with asexual or vegetative reproduction, and evolved into timid attempts at methodical selection and variety crossing for a wider range of domesticated plants, including those with sexual reproduction, towards the beginning of the 20th century[444]. Crosses were still very tentative in nature, until the rediscovery of the infamous Moravian Gregor Mendel's 1865 *Experiments in Plant Hybridisation*, thirty-five years after its publication, after having only been cited three times until 1890. The rediscovery is indeed now considered an ultimate turning point for the future of plant breeding, exemplifying the "zeitgeist at work"[445]. Through his trials on peas, Mendel elaborated so-called "laws of inheritance", comprised of "segregation" and "independent assortment". Mendel's methodical phenotypic[446] observation was explicitly concerned with the expression of the plant's dominant alleles in the environment[447]. Practically, he identified the

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[441] GEPTS, "Crop Domestication as a Long-Term Selection Experiment," *op.cit.*

[442] BRUINS, "The Evolution and Contribution of Plant Breeding to Global Agriculture."

[443] See the definition of "revolution" by Ellen J. WILSON, and Peter H. REILL; *Encyclopedia of the Enlightment,* Facts on File, New York, 2nd edition, 2004, pp. 507-508.

[444] For an overview of the evolution from less understood empirical attempts to real scientific knowledge and understanding of the variety crossing process, as well as the role of the horticulture sector in such evolution, See R. OLBY, "Mendelism: From Hybrids and Trade to a Science," *Life Sciences* 323, 2000: 1043-1051.

[445] KINGSBURY, *Hybrid: The History and Science of Plant Breeding*, *op.cit.*, 142-143. The rediscovery was made independently by Hugo de Vries, Carl Correns and Erich von Tschermak-Seysenegg.

[446] Indeed, heredity tables show that in order to achieve the "Rr" (rough-stemmed) characteristic in the variety for sure, one needs to cross one "RR" and one "rr"; for when two "Rr" are crossed or planted again, their progeny might show different characteristics (such as "RR", "Rr" or "rr"); See *Hybrid: The History and Science of Plant Breeding*, *op.cit.*, 426-427 (esp. technical note n.418 "F421 and F422 Generations").

[447] A plant's phenotype can be defined as the expression of its genotype in the natural or cultivated environment, designating what may be observed of its characteristics through the naked eye, while a plant's genotype consists of the description of the actual physical material made up of DNA passed on at the organism's conception; see the *Stanford*

notion of "gene" as a unit, and carefully followed each generation of plants, coining the filial through the initial "F", the follow-up to a deliberate crossing "F_1", the following generation "F_2" and so forth. He determined and segregated the progeny's characteristics through a terminology that is still used by the industry today to identify generations of hybrid seeds. This enabled breeders to truly comprehend heredity, while also underlining the value of parental lines and their purity in the creation of new plant varieties, and especially in the rare but golden “hybrids”.

Drawing from enduring collection efforts of the past centuries, the so-called "Green revolution" of the 1960's quickly acquainted the world with new high-yielding modern varieties, which at times happened to be “hybrids”, i.e. hyper-performers that only showed such heterosis-bound performance only during the first sowing year. Indeed, in certain cases and for certain varieties, the products of plant breeding outperformed the parental lines used in their development, through the lesser-understood principle coined heterosis or hybrid vigour. Hybrids transformed plant breeding into a “lucrative science”[448], where the goals of research endeavours shifted from an effort of adapt exotic varieties into an effort to find specific traits ensuring disease resistance or higher yields[449]. As we shall see in the further course of this study, hybrids also present an additional advantage, in that their beneficial performance only presents itself during the first sowing year, yearning for a renewal of seed stocks by cultivators and therefore creating a study influx of income to seed developers. They have nonetheless not been developed for all crops and species, as they are usually present in maize and vegetables but not as easily operated in open-pollinated varieties, such as wheat, where hybridisation has proven more difficult than the development of “open” and thus re-sowable new varieties[450].

Whether faced with open-pollinated species or with hybrids, sexual crossing allows breeders to predict the crosses that are needed to stabilise a desired character, which responds to contemporary ecological, geographic, climatic and disease-related challenges faced by farmers. Relying on empirical "trial and error" techniques, breeders detect useful mutations and 'fixate' desired characteristics[451]. Breeders can, as a result, predict the occurrence of useful traits such as drought resistance or fungal tolerance as a result of deliberate crossing. The **lucrative promise of plant breeding** laid hence not only in greater yields but also in the possibilities to respond to farmer and consumer demands. The new uses bestowed upon these components of agricultural biodiversity have nonetheless mostly contributed to striking escalations in terms of yield, mostly due to the new varieties’ uniformity and stable physiological characteristics. Resulting yield gains are best

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Encyclopedia of Philosophy, available at http://plato.stanford.edu/entries/genotype-phenotype/ (accessed on December 2010).

[448] On the switch from traditional selection techniques to the manipulation of selected traits, see CARY FOWLER, *Unnatural Selection: Technology, Politics and Plant Evolution* Yverdon: Gordon and Breach Science Publishers, 1994, 118-120.

[449] See KEITH AOKI, *Seed Wars: Controversies and Cases on Plant Genetic Resources and Intellectual Property* Durham: Carolina Academic Press, 2008, 16-17.; and KLOPPENBURG, *First the Seed: The Political Economy of Plant Biotechnology 1492-2000*, *op.cit.*, 72-73.

[450] Hybrid wheat is at the time of writing still the subject of a “technology war” between the great seed giants, which have all set up research and development programs to achieve the “Graal” of plant breeding.

[451] MURPHY, *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*, *op.cit.*, 23-24. The first experimental manmade intergenic hybrids were produced by the middle of the 19th century and became quite common later on with the development of the private sector. Two elements have been said to have pushed the ability of breeders forward in terms of genetic manipulation, namely the new techniques of hybridisation that created very high yielding varieties, especially in maize, and the possibilities to deliberately produce genetic mutations, increasing the rate of mutagenesis by thousand-folds in a population to improve performance.

illustrated by the example of English wheat, for which yields had only increased from zero point five to two metric tons per hectare in one thousand years. Results triple from 1960 onwards, reaching six metric tons in just forty years' time, within a ground-breaking cycle twenty-five times shorter than the growth achieved by un-methodical variety selection[452]. The public International Rice Research Institute's IR8 rice variety, first introduced in the Philippines, produced for instance yields of nine point five to ten point five tons per hectare when average global rice yields were around two tons per hectare[453]. Yield increases up to a hundred per cent were witnessed on account of new plant breeding techniques and correlated genetic improvements[454]. These new varieties also fuelled a relentless cycle of necessary genetic improvement. The so-called "miracle IR 8 rice" is in this sense a truly comprehensive example, since it also illustrates the inherent need for constant research on the maintenance, further improvement and adaptation of these newly developed genetics. This variety indeed stands out through its inbuilt vulnerabilities against environmental conditions or the risks of genetic change[455].

While mass selection launched the pace of holistic agricultural development, deliberate crossing and hybridisation efforts relying on inheritance-focused methodical selection procured the flag of **intensified agricultural industrialisation**. The recourse to these improved varieties indeed not only significantly impacted agrobiodiversity management in itself, but also came about with a major reallocation of cultivation and food production schemes. Indeed, the Green Revolution presupposed not only the use of improved seeds, but also the recourse to external inputs such as fertilisers, nutrients, pesticides, irrigation techniques and modern farm equipment[456]. Past plant varieties put a lot of "energy into straw and foliage", having to rely on manure and water supply limits. Early high-yielding varieties of wheat and rice, fruits of the burgeoning plant breeding science, channelled in contrast "more energy into grain, benefited from fertilisers and flourished under irrigation"[457]. Breeding efforts were indeed accompanied by immense efforts in the conveyance of water to farms, and also presupposed the development and recourse to fertilisers,

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[452] IFPRI, *Green Revolution: Curse or Blessing?*, *op.cit.*; BYERLEE, "Modern Varieties, Productivity, and Sustainability: Recent Experience and Emerging Challenges," *op.cit.*

[453] See for instance S. YOSHIDA and F.T. PARAO, "Performance of Improved Rice Varieties in the Tropics with Special Reference to Tillering Capacity Crop Radiation Use Efficiency: A Review," *Crop Science* 29, 1972.; and also S. PENG et al., "Yield Potential Trends of Tropical Rice since the Release of Ir8 and the Challenge of Increasing Rice Yield Potential," ibid.39, 1999: 1552-1559.

[454] The estimation of yield gains awarded to crop genetic improvement remains a difficult and contentious task, on account of the myriad of factors influencing the estimation, such as the type of variety adoption taking place, all environmental conditions, the rate of varietal replacement and the role of improvement management techniques. However, yield increases of a hundred per cent or more have been acknowledged as a common reality, especially when modern varieties have been used in subsistence-orientated crop systems. See ROBERT E. EVENSON and DOUGLAS GOLLIN, *Crop Variety Improvement and Its Effect on Productivity: The Impact of International Agricultural Research* Oxon: CAB International, 2003., especially the results and conclusions related with regards to maize development in M. MORRIS, M. MEKURIA, and R. GERPACIO, "Impacts of Cimmyt Maize Breeding Research," in *Crop Variety Improvement and Its Effect on Productivity: The Impact of International Agricultural Research* ed. ROBERT E. EVENSON and D. GOLLIN, Oxon: CAB International 135-159. as well as other crop-specific articles.
In more general terms, see BYERLEE, "Modern Varieties, Productivity, and Sustainability: Recent Experience and Emerging Challenges," *op.cit.,* pp.697-718., for an assessment of the continuous contribution of modern varieties to human and sustainable development.

[455] PENG et al., "The Importance of Maintenance Breeding: A Case-Study of the First Miracle Rice Variety - Ir 8," *op.cit.,* 342-347.

[456] See SHIVA, *The Violence of the Green Revolution: Third World Agriculture, Ecology and Politics: Ecological Degradation and Political Conflict*, *op.cit*; KEITH B. GRIFFIN, *The Political Economy of Agrarian Change: An Essay on the Green Revolution* Massachussets: Harvard University Press, 1974.

[457] WAGGONER, "Agricultural Technology and Its Societal Implications," *op.cit.,* pp.125-126.

such as synthetic nitrogen for instance[458]. It thenceforth stirred the interest of a plethora of actors, from public sector researchers to the construction of a seed industry.

5.2. The renaissance of an actor: plant breeding as a commercial enterprise and the reign of seed companies

Even though biological material collection efforts matured in the hands of public botanical gardens or early research centres, plant improvement as such, and the development of new crop cultivation techniques, had interestingly remained the concern of much localised private ventures[459]. Agricultural innovation has emerged as an exclusively private institution, first in the hands of farmers, and then through the risks taken by venturesome, innovating and passionate individuals. The rediscovery and development of Mendelian genetics signalled the expansion of activities carried out by public institutes to include the development of new improved varieties. The first hybrids would indeed stem from the public sector, before the wheel turned again in the direction of the private sector, lured into plant improvement through its new productive and fecund promises.

5.2.1. From Public Hybrids…

Until the 19th century, plant improvement endeavours depended upon the interest, potency and innovativeness of individual landowners. Exotic material was collected throughout colonial expeditions, but these remained the property of individual scientists until the creation of a wider net of public collecting and disseminating agents[460]. Indeed, early-bird public experiment or satellite stations cultivated foodstuff to meet national needs but did not specifically target crop improvement or the development of best practices as such[461]. By the end of the 19th century, the public sector would however gradually take over and coordinate what had previously been almost exclusively private ventures, whether at the level of the landowner, farmer, collector or individual scientist[462]. It did so through the support of diverse institutions, such as clubs and societies dedicated to agricultural improvement. It also had recourse to calls for research made to the research community as a whole, with suitable incentives such as prizes or substantive financing. Food production and related crop improvement became part of a wider understanding, as a **national political tool** of primordial economic importance in terms of foreign dependence. In this context, the United States Department of Agriculture was founded in 1862, while state-run agricultural experiment units were established as early as the 1850’s in France and Germany[463]. Operating wide-ranging collection and screening programmes during the 1960's, State-funded agricultural and medicinal research institutes focused on concrete discoveries in the advancement of science and societal welfare in general. What is striking in this context is the fact that these new

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[458] This synthetic nitrogen was thereafter proven to deplete soil nitrogen because of its extremely invasive nature, yet 60 per cent of the Green Revolution’s crops were cultivated with its help; see DAVID TILMAN, "The Greening of the Green Revolution," *Nature* 396, 1998: pp.211-212.

[459] MURPHY, *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*, *op.cit.*, p. 63.

[460] These historical exchanges will be studied infra in order to retrace the origins of the public domain of PGRFA and the emphasis on the conservation and sustainable use of genetic diversity (Chapter 10.2).

[461] For instance, the Kew Gardens and the precursos botanical gardens were not really involved in plant improvement as such, BRONWYN PARRY, *Trading the Genome: Investigating the Commodification of Bio-Information* New York: Columbia University Press, 2004.

[462] MURPHY, *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*, *op.cit.*, pp. 59-82 (especially 60-63 where the author traces back the rise of public sector research in the United States).

[463] *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*, *op.cit.*, p.73.

actors also created networks of collecting agents, in similar fashion to the Banksian understanding of collection activities[464]. Modern prospecting activities were however granted a more institutional background as they were carried out on a contractual basis, as the State mandated botanical gardens to work with local associations in order to legitimise the collections[465].

Gargantuan public agricultural research programmes were gradually established, relocating in parallel crop development as an internationally strategic political and economic pursuit. Following what had already began in past decades, the end of the 19th and beginning of the 20th century saw an increase in State interest for undertaking biological collection expeditions and correlated research[466]. This trend notably intensified as the United States joined the race for exotic germplasm. Conscious of the limited range of endemic resources available within their borders, the well-endowed continents publicly funded colossal research programs to acquire specimens, mainly to be used for classification and analysis, but also for variety development. Much like their “imperial botaniser” predecessors, public research programmes “dispatched special agents overseas to search for new crop germplasm”[467]. Mark Carlton, a special agent of the United States Department of Agriculture, returned from instance from Russia in 1898 with several varieties of durum and hard red wheat, which proved to be extremely useful in fighting the Midwestern droughts and significantly increased production results[468]. On the other side of the Atlantic, Nikolai Ivanovich Vavilov and his colleagues adapted the “New World crops” they had collected to the agronomical conditions of the Soviet Union[469]. Bioprospecting efforts extended around the globe and throughout the 20th century. They were for instance conducted by Jack Harlan in Turkey during the 1940’s and onwards on behalf of the USDA’s “Division of Plant Exploration and Introduction”, unearthing wheat gene micro-centres[470]. These public institutions did not only carry out biological material collection endeavours; they also made use of _ arguably exponentially triggered _ technological developments in genetics, by developing and distributing improved and stable varieties[471]. The main goal of these State-funded programmes was to contribute to the **“advancement of science and the public good**”[472]. They indeed undertook public domain oriented characterisation and basic research. Especially in the United States, they also distributed

464 Joseph Banks accompanied James Cook during its travels in the Pacific was the owner of the first and greatest private collection of genetic resources in his personal home, he was later appointed as director to the national botanic Kew Gardens in London, see Chapter 10.2 of this study.

465 For a review of these subcontractual relationships and further development, see PARRY, *Trading the Genome: Investigating the Commodification of Bio-Information, op.cit.*, 109-112.

466 The creation of the United States Department of Agriculture in 1862, which took on responsibilities for the collection and dissemination of agricultural plant genetic resources, was indeed a turning point in the conception of control and use of germplasm. Coupled with the network of State Agricultural Experiment Stations, the USDA quickly established an efficient system to evaluate and introduce new varieties adapted to local conditions. See AOKI, *Seed Wars: Controversies and Cases on Plant Genetic Resources and Intellectual Property*, *op.cit.*, 14-16.

467 MURPHY, *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*, *op.cit.*, p.68.

468 Within five years of their introduction, these new varieties pushed annual production from 1600 tonnes to 550.000 tonnes; *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*, *op.cit.*, p.69.

469 HAMMER and DIEDERICHSEN, "Evolution, Status and Perspectives for Landraces in Europe," *op.cit.*

470 JACK R. HARLAN, "Anatomy of Gene Centers," *The American Naturalist* 85, no. 821, 1951.

471 It should however be noted that some European countries, such as the United Kingdom for instance, joined the public agricultural research bandwagon later in the 1960’s, having left the application of scientific developments in crop improvement to private entities that were nationalised or heavily subsidised; MURPHY, *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*, *op.cit.*, pp.74-81.

472 PARRY, *Trading the Genome: Investigating the Commodification of Bio-Information*, *op.cit.*, 38-39.

their new plant varieties for free and actively engaged in extension services designed to facilitate the uptake of agricultural improvements by farmers[473].

The global food crisis of the 1950's and 1960's saw a need to institutionalise the informal flows and free exchanges of biological material at the global level, in order to respond to the urgency of the Malthusian concerns related to shortages in food supply[474]. Within this mind-set, the national networks that dominated agricultural research and improvement during the early-twentieth century embraced a wider and more global societal conscientiousness. As a result, **internationally integrated *sui generis* institutions** were set up to accomplish the virtually unachievable goal of feeding the world, cementing the cornerstones of international agricultural research[475]. The main preventive response to apprehend potential food crises was to embed an international character to existing national nurseries and research networks. This move would enable them to efficiency gains and provide locally adapted plant varieties by having access to other nurseries' material and experiences. The first research centre to present an international structure focused on the development of wheat varieties resistant to stem rust disease. Indeed, in response to a stem rust epidemic that spread worryingly quickly, the USDA requested concerned nations to join forces in 1954. Wheat lines were tested by the "First International Stem Rust Trial"[476] based on efforts carried out in the "International Spring Wheat Rust Nursery", which formalised germplasm screening and related resource exchanges. This endeavour successfully brought the stem rust under control, and it did so in a context where all genetic resources and related information were "freely shared and made available to the co-operators and others who were interested"[477]. The project had an interesting active participant, the Office for Special Studies, an association between the Rockefeller foundation and the Mexican government. This office carried out transboundary experiments through off-site nurseries and engaged in international collaboration with national research centres. Under the leadership of the Nobel-prize winner plant breeder Norman Borlaug and with the financial support of the Ford and Rockefeller Foundations, the Latin American trials

[473] HALEY STEIN, "Intellectual Property and Genetically Modified Seeds: The United States, Trade, and the Developing World," *Northwestern Journal of Technology and Intellectual Property* 3, no. 2, 2004., at 162; The USDA's free seed distribution was shut down by Congress in 1924 after fifteen years of implementation. In general, the success of extension services that accompany such endeavours depends on the attractiveness of the invention, and the existence of personal contact between farmers and extension agents. BRIAN D. WRIGHT and TIFFANY M. SHIH, "Agricultural Innovation," in *NBER Working Papers Series*, ed. NATIONAL BUREAU OF ECONOMIC RESEARCH (Cambridge, MA2010)., at p. 33.

[474] Thomas Malthus' work in the 18th century indeed predicted that population growth would outweigh food production, which led to more recent academic conclusions that food and poverty aid should be limited to sustainable alternatives within countries able to attain self-sufficiency. These 'natural selection' population scholars include Paul EHRLICH and Garett HARDIN, the works of which have been heavily praised throughout time, but also equally criticised in contemporary doctrine not with regards to its diagnosis but rather the solutions that were brought forward to mitigate the unwarranted consequences of population growth and resource scarcity; see PAUL EHRLICH, "The Population Bomb," *New York Times*, 1970., PAUL R EHRLICH and ANNE H EHRLICH, "The Population Bomb Revisited," *The electronic journal of sustainable development* 1, no. 3, 2009. and GARRETT HARDIN, *The Ostrich Factor: Our Population Myopia* 1999.

[475] For a more in-depth overview of international agricultural research and its relation to the provision of global public goods, see DEREK E. TRIBE, *Feeding and Greening the World* Oxford: CAB International, 1995.; and DANA G DALRYMPLE, "International Agricultural Research as a Global Public Good: Concepts, the Cgiar Experience, and Policy Issues," *Journal of International Development* 20, 2008: 347-379.

[476] Approximately one thousand varietal lines were to be tested with the collaboration of Mexico, Columbia, Ecuador, Peru, Chile, Argentina and Canada; for an account of the genesis of this project and the first international nurseries, see http://apps.cimmyt.org/english/wps/obtain_seed/iwin/history.htm (accessed May 2012).

[477] H.J. DUBIN and JOHN P. BRENNAN, "*Combating Stem and Leaf Rust of Wheat: Historical Perspective, Impacts and Lessons Learned*", 2009.

and those developed in West Asia and North Africa were effectively merged into the "International Spring Wheat Yield Nursery"[478]. This new nursery and breeding programme saw formal inter-State collaboration in professional training, and provided breeding lines upon request. This evolution is considered to be the beginning of "the opening of the commons, a free germplasm exchange system and worldwide collaboration"[479]. The nursery later became the International Maize and Wheat Improvement Centre ("CIMMYT") in 1966. The internationalisation of biological collections and plant nurseries was effectively switched on. The second example of such phenomenon is the International Rice Research Institute ("IRRI") in the Philippines, founded in 1960 in the footsteps of the wheat-breeding programme, but with a stronger organisational structure. The success of these institutes created higher demand for their replication in other species and for other geographical conditions, underpinning the creation of a network of International Agricultural Research Centres ("IARC"), each focusing on the resolution of one or more specific problematic in food supply and cultivation, from livestock or forestry to tropical or semi-arid areas[480]. Further formalisation of PGRFA exchange and research continued at the international level throughout the middle of the 20th century and mostly during the 1970's. All IARC's were confederated under the single umbrella of the **Consultative Group for International Agricultural Research** ("CGIAR") in 1971. The Group maintained close links to both the World Bank and the United Nations, through the involvement of the Food and Agricultural Organisation ("FAO") and the United Nations Development Programme ("UNDP"). Even though this 'centralisation' movement was backed up by the aforementioned international organisations, the CGIAR kept an autonomous nature, being built around the principle of voluntary cooperation of the research centres involved. Established as an informal association, the aims of the Consultative Group were mainly to "examine the needs of developing countries for special effort in agricultural research at the international and regional levels in critical subject sectors unlikely otherwise to be adequately covered by existing research facilities and to consider how these needs could be met"[481].

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[478] For an account of the history of the International Spring Wheat Yield Nursery ("ISWYN"), considered as the first international nursery; see DEREK BYERLEE and HARVEY J. RUBIN, "Crop Improvement in the Cgiar as a Global Success Story of Open Access and International Collaboration," *International Journal of the Commons* 4, no. 1, 2010: 452-480 (at 454-455).

[479] DUBIN and BRENNAN, *op.cit.,* 2009.

[480] The IARC network counts within its realms the Africa Rice Centre (WARDA in Benin, founded 1971), the International Potato Centre (CIP in Peru, founded 1971), the International Institutes related to Tropical Agriculture (IITA in Nigeria, founded 1967 and CIAT in Colombia founded 1970), the International Centre for Agricultural Research in the Dry Areas (ICARDA in Syria founded 1972), the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT in India founded 1972), the Institutes concerned with Forestry Research (ICRAF in Kenya founded 1978; and CIFOR in Indonesia, founded 1993;), the International Livestock Research Institute (ILRI in Kenya founded 1994 through the merger of the International Livestock Centre for Africa and the International Laboratory for Research on Animal Diseases), the International Water Management Institute (IWMI in Sri Lanka founded in 1985), and the International Food Policy Research Institute (IFPRI in Washington DC founded in 1975).

[481] Founding Resolution of the Consultative Group for International Agricultural Research, Washington DC, May 1971, available at http://www.worldbank.org/html/cgiar/publications/founding.html (accessed August 2010).
The International Board for Plant Genetic Resources ("IBPGR") was created in 1991, subsequently named the International Plant Genetic Resources Institute ("IPGRI") and now Biodiversity International. This crosscutting institution, working under the auspices of the Consultative Group and with complex links to the United Nations System, further enhanced the globalisation of agricultural germplasm collections. It enabled the sounder international exchange of existing biological information. Initially managed by the FAO, the institution has been granted independent status and financing, for the history of the organisation, see http://www.bioversityinternational.org/about_us/ who_we_are.html#c619 (accessed September 2009). For an overview of the changing dynamics between the IARC's, the CGIAR and the FAO, see ROBIN PASTORIUS, *Scientists,*

Successors of the past centuries' botanical gardens, public agricultural research institutes were dramatically more result-oriented than their forefathers. They used biological collections to satisfy their global mission of plant improvement and food production. With a better-established structure and financial assistance, public research started **developing 'end products'**, i.e. seeds. Due to the uncertain nature of early breeding research results and thus imperfect profitable opportunities, crop improvement and seed distribution networks were traditionally instigated by the public sector, where research was understood as a public good[482]. Public structures gladly took over the challenge of becoming agricultural improvement hubs. By the 1950's, breeding centres had been established throughout industrialised countries and started to spread around the world through extension services[483]. Institutionalised agricultural research has nonethelles not been the sole feature of developed countries, even though the establishment of wide research programmes has occurred in these countries earlier in time vis-à-vis developing ones. While the former started to institutionalise agricultural research in the beginning of the 20th century, the latter delivered with a few decades' delay, by the middle of the same century, mostly through the regulatory and institutional push of development programmes established after the World War II[484]. The potential of methodical selection was quickly utilised by both the IARC's and national research institutes. Generating more than just pure material exchange, the work of these public entities was indeed mainly directed towards the development of high yielding new varieties. Combinations towards resistance to local stresses or threatening diseases were sought after, primarily through the recourse to semi-dwarf varieties, which showed increased yield results, up to forty per cent[485]. The scientists working under the CGIAR umbrella were in this context considered the catalysts of the Green Revolution, i.e., the introduction of these improved varieties in productivity-oriented agricultural production schemes. Together with the inherently cost-effective and interest-igniting characteristics of science-based plant breeding, the exemplary successes of publicly bred lines and the provision of characterised and open breeding material also thrust private sector re-involvement and expansion in plant improvement.

5.2.2. …To Private Crop Improvement

Public institutions, whether national or international, dominated the global institutional landscape of breeding research for most of the 20th century. However, the potential of scientific discoveries

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Plants and Politics: A History of the Plant Genetic Resources Movement Rome: International Plant Genetic resources Institute, 1997, pp. 48-68.

482 For an account of such viewpoint and the specific role played by the United States in the establishment of such public networks, see MURPHY, *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*, *op.cit.*, 61-65.

483 For an overview of extension services delivered by the public sector for better communication of scientific breakthroughs to the farmers, see *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*, *op.cit.*, 71-72 ; and EVENSON, "Economic Impacts of Agricultural Research and Extension " *op.cit.*, 573-628.

For the internationalisation of research networks and the CGIAR experience, see above, but also MURPHY, *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*, *op.cit.*, 83-97 and Chapter 86: Breeding goes global, the Green Revolution and beyond.

484 Robert E. EVENSON, "Economic Impacts of Agricultural Research and Extension", *in* Bruce L. GARDNER and GORDON C. RAUSSER (eds.), *Handbook of Agricultural Economics, Volume 1 Part 1 (Agricultural Production),* Elsevier Science, 2001, pp. 573-628.

485 See LENNARD BICKEL, *Facing Starvation: Norman Borlaug and the Fight against Hunger* New York Lennard Dutton, 1974., and K.M. QUINN, "Dr. Norman E. Borlaug: 20th Century Lessons for the 21st Century World," *Advances in Agronomy* 100, 2008: 1-13. For a more recent overview of the dwarfing genes used by the CGIAR network, see PETER HEDDEN, "The Genes of the Green Revolution," *Trends in Genetics* 19, no. 1, 2003: 5-9.

on selection methods and hybridisation techniques for the burgeoning 'industry' also gradually materialised. It really enfolded from the 1970's onwards, on account of **a newly developed viable and profitable business model.** This model significantly soared away from the traditional public good agricultural improvement paradigm, navigating towards a private research agenda. While the public sector harnessed and steered the way for future research and development, private entities showed flexibility in the adoption and advancement of technological change. State institutions were indeed never the sole actors furthering the opportunities of methodical plant breeding. Small-scale private corporations, either within the one-man-brand scheme or through the more classical commercial family enterprise, were also always present in the plant improvement landscape[486]. In terms of plant breeding, public supremacy in agricultural research was indeed mostly true within the "new continent", namely the United States, as private small-scale breeders were quite quick to grasp the impact of technological change and dominated hybridisation research throughout the European continent until the early 20th century[487]. However, in the early days of plant breeding, most private seed companies pursued commercial activity on the cleaning, treatment, storage, packaging, sale and distribution of improved seeds found in the public domain. They relied on genetic material developed by public institutions, with the relatively small exception of firms specialised in niche hybrids.

The private sector started to shyly be involved in the development of field crops, such as in maize or corn, where the first attempts at F1 hybridisation had been extremely efficient and lucrative, since farmers had to purchase the seed yearly to obtain the promised performances and had in fact done so[488]. From the 1970's onwards, the private seed sector sought to redefine itself in light of the new possibilities offered in terms of variety improvement. Consequently, it gradually expanded from the niche markets where it had been confined, such as the aforementioned hybrid maize sector, and slowly increased its global market share, becoming a proper industry[489]. The green lights glimmering over guaranteed productivity gains promised by the development of need-specific characteristic, the difficulties of product replication by competitors and the need for farmers to come back for purchase every year all contributed to the expansion of private research and development. Marketing a product with precise added value, responding to actual pleas coming from the field or shelves, became an increasingly viable basis for a financially lucrative business model. Furthermore, neither farmers nor other researchers could obtain direct knowledge of the parental inbred lines that were used to create hybrid varieties, or gain immediate access to those lines without several years of 'reverse selection'. These features highly enticed commercial interest, since it made hybrids inherently proprietary products[490]. Moreover, "hybridisation methods produced a one-generation 'heterosis' effect that [could not] be replicated in farmer-saved seed"[491]. Not only would the yields obtained during the subsequent years of hybrids' use be substantially lower, the characteristic segregated through crossing might also not be fully displayed by the following F_2 generation due to the crossed and 'impure' nature of its parental F_1

[486] KINGSBURY, *Hybrid: The History and Science of Plant Breeding*, *op.cit.*
[487] Small breeding companies were thus of high importance especially in the Netherlands and the United Kingdom, see *Hybrid: The History and Science of Plant Breeding*, *op.cit.*, 370-371.
[488] Ibidem *Hybrid: The History and Science of Plant Breeding*, *op.cit.*, pp. 372-373.
[489] MURPHY, *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*, *op.cit.*, 103-104.
[490] PATRICK MOONEY, *Seeds of the Earth: A Private or Public Resource?* Ottawa: Inter Pares, 1979, 62-63.
[491] ROBERT E. EVENSON, "Agricultural Research and Intellectual Property Rights," in *International Public Goods and Transfer of Technology, under a Globalised Intellectual Property Regime,*, ed. KEITH E. MASKUS and JEROME H. REICHMAN, Cambridge: Cambridge University Press, 2005, 192-193.

lines. Those desiring the exact same results derived from the hybrid seed had thus to purchase new F_1 lots the following sewing year. All biological barriers for private investment in germplasm research and product development had fallen[492].

The reasons behind the re-allocation of actors in agricultural research thus primarily relate to the technological opportunities created by the better understanding of plant science and the consequent development of "active breeding". This re-allocation was nonetheless also backed by the enactment of favourable liberal regulation worldwide. Indeed, the socio-economic landscape and political climate of the end of the 20th century, characterised by a stronger push for **deregulation and private innovation**, actively reinforced this institutional shift flared by technology**.** The enticement fed at the time by these technologically profitable opportunities was accompanied by a decline in economic growth, which led to significant decreases in government expenditure, along with a change of political ideology redefining the boundaries of State intervention. Public investment in agricultural research was to gradually lose its importance. Even though figures tend to vary, it has been said that public research only showed an annual increase between 0.2% and 1% during the 1990's, while this rate was 2.2% during the previous decade[493]. In the meantime, investment in private agricultural research showed annual increases up to 5.1%[494]. Within an asserted desire to balance the State budget and increase efficiency, plant research was slowly privatised, often through the use of the new concept of "near-market research" by policy-makers, coining the necessity to involve the private sector for innovation aimed at generating a specific product for the commercial market[495]. The official consecration of a new division of labour in agricultural research entailed the confinement of government-funded or owned institutions to concentrate on "pure or basic research" in genetics[496]. The degree of private involvement would be analysed on a case-by-case basis, but public institutions working on projects with potential commercial value were widely opened to "wholesale privatisation".[497]

Hand in hand with this accommodating re-definition of the role of the State in agricultural research, the private sector also benefited from regulatory changes in relation to the protection of the fruits of their research, in the form of more specific trade regulation and intellectual property

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[492] AOKI, *Seed Wars: Controversies and Cases on Plant Genetic Resources and Intellectual Property*, *op.cit.*, 19.

[493] P.G. PARDEY and N. BEINTEMA, *Slow Magic: Agricultural Research and Development a Century after Mendel* Washington: International Food Policy Research Institute, 2001 3-4. The authors also compare the public investment rates within the developing world in order to show the inequalities existing between and within resource-rich countries.

[494] JULIAN M. ALSTON, P.G. PARDEY, and J. ROSEBLOOM, "Financing Agricultural Research: International Investment Patterns and Policy Perspectives," *World Development* 26, 1998: 1057-1071.
See also the more recent study made by P.G. PARDEY et al., "*Agricultural Research: A Growing Global Divide?*", IFPRI (International Food Policy Research Institute) and ASTI (Agricultural Science and Technology Indicators Initiative), Washington, 2006. , where the authors also show that public spending in agricultural research shows major differences between the two hemispheres, the developing countries now constituting the largest region of public spending (pp.11-12).

[495] A.J. WEBSTER, "Privatization of Public Sector Research: The Case of a Plant Breeding Institute," *Science and Public Policy* 16, 1989: 224-232.

[496] This very strict division was famously defended by Henry A.Wallace in the 1920's, advocating that public entities should concentrate on 'pure or basic research', while private companies produced goods and farmers continued to use the product, see R. JR. PILKE, "In Retrospect: Science - the Endless Frontier," Nature, no. 466, 2010 (19 August): 922-923.

[497] For a review of this development through the eyes of an astonished public sector researcher and the interesting example of the Plant Breeding Institute ("PBI") in Cambridge, United Kingdom, see MURPHY, *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*, *op.cit.*, 127-133.

protection opportunities, whether through the aforementioned Bayh-Dole Act or the international reification of the strong property paradigm by the TRIPS Agreement. Within the 1980's context of extensive science-related privatisations, only fundamental research would be provided by public institutions, which also remained the main source of the raw and characterised biological material. The material's combination and the development or commercialisation of end products, i.e. varieties and seeds, would rather chiefly be carried out by private entities, acting as complementary institutions rather than competitive entities to public actors[498].

5.3. A new form of genetic diversity management prone to criticism

Significant changes operated both in terms of the possibilities offered by plant improvement science, and the actors involved in these endeavours. These shifts unsurprisingly also reshaped the values attached to genetic resources by altering their management, while igniting reticence over the creation of diverse private breeding pools in contrast to the uniform varieties found on fields, indifferent to socio-economic production contexts. The growing use of the Mendelian principles of heredity and segregation in agriculture dramatically changed collection and research activities related to biological material. It converted simple germplasm characterisation into an in-depth understanding and observation of selected phenotypic information, which would then be segregated and used in new varieties. Henceforth, with merely two key elements in their hands, i.e. a good degree of genetic variation between individuals and the means to identify and select the most suitable variants, breeders could produce a new population composed entirely of a selected and desired variety[499]. The opportunities offered by plant breeding thus set a **re-adjustment of the values attached to PGRFA** in motion, creating unfamiliar hierarchical distinctions between improved and wild genetic material. The weight granted to plant varieties and their inherent features substantively changed through the breeders' ability to methodically improve them. It also meant that genetic resources would be conserved and developed in breeding pools with sealed access. This new hierarchical agrobiodiversity management that took place "behind closed doors" did not receive unanimous praise. Albeit the Green Revolution's potential to create and conserve biodiversity, the characteristics of its products and the disruption of farmers' functions in agrobiodiversity management have tainted the delightful hopes of food security and sovereignty.

5.3.1. All New, All Improved, All Private Breeding Pools?

The new methodical approach to variety selection and improvement had significant impacts on the collection of biological material. Accordingly, not only was the 'renaissance' of the private sector going to influence the supply of end-products and the means through which agriculture was to be perceived, it was also going to influence the geographical and institutional distribution and flows of genetic resources. The newfound priorities of variety development and the prospects of commercialisation, coupled with races for market share and profits, created the outlook for the **return of confidential private collections**. Viewed this time as foundations for breeding pools within the realm of which new improvements could be developed, significant germplasm collections were established within private companies. Private breeders indeed screened and

[498] Public research thus moved away from the "commodity-form", i.e. the finished variety to become a complementary rather than a competitive industry with private research, which would choose the lines that could be commercialised. See AOKI, *Seed Wars: Controversies and Cases on Plant Genetic Resources and Intellectual Property*, *op.cit.*, 21-22.
[499] MURPHY, *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*, *op.cit.*, pp.12-13.

collected market successes, as well as benefiting from those genetic resources conserved within the auspices of international and national gene banks. They constitute heterogeneous pools and create new variations through their attempts at hybridisation and their success. Commercial research and development programmes established around new methodical and science-based breeding practices have, through their emphasis on plant improvement, furthermore altered the valuation of PGRFA in itself, through the internal composition of the breeding pools used in such programmes.

By using perfected techniques of crop hybridisation and the deliberate production of mutations, breeders fully exploit existing genetic variation to create new variation, within and between species[500]. The possibility to exploit genetic variation with pronounced preciseness has in this sense altered the conception of plant varieties and dramatically transformed the priorities and machinery of agrobiodiversity management. The selection of material found in biological collections has for instance changed drastically from a search for best results in individual samples to a **quest for specific traits and best combinations**. Breeding research is indeed primarily carried out on standardised and stable plant varieties, which are already known to breeders. Within the new agro-biodiversity management scheme of methodical plant breeding, the first two years of research programmes are used for the deliberate production of mutations and variety crosses. The subsequent 'lengthy and tedious' selection stage entails six to eight years devoted to examining the best recombination and stabilisation designs for the new variation[501]. Seeking to provide cultivars showing increased adaptation capability to differing agricultural environments, plant breeders thus not only made fresh use of existing collections, but they also altered genetic resource management in its general sense[502]. Certain species with absolutely no intrinsic value in the past due to poor overall results on farm became extremely interesting. These varieties bore direct yet concealed commercial value, as they possessed one or more desired characteristic that could be transmitted to new varieties, but could not have been identified without methodical breeding efforts[503].

The benefits of modern varieties rely on the constant input of new seeds, whether exotic or already improved genetic resources[504]. It is in this context widely acknowledged that commercialisation-oriented breeding programmes accordingly begin through an analysis of existing improved

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[500] A famous quote from the pioneer breeder Luther Burbank goes on to highlight "the close working partnership with Nature, helping her to produce for the benefit of mankind new… fruits in form, size, colour and flavour never before seen on this globe", a quote which has been attributed to a speech given in 1926 and has been become timeless since then *the New World Encyclopedia*, pages available at http://www.newworldencyclopedia.org/entry/Luther_Burbank; (accessed December 2010).

[501] ANKE VAN DEN HURK, "The Use of Genetic Resources in Plant Breeding," in *Responding to the Challenges of a Changing World: The Role of New Plant varieties and High Quality Seeds in Agriculture* (Proceedings of the Second World Seed Conference, held in Rome on September 8-10, 20092009), 62-69.

[502] J.S.C. SMITH and D.N. DUVICK, "Germplasm Collections and the Private Plant Breeder," in *The Use of Plant Genetic Resources*, ed. A.H.D. BROWN, et al., Cambridge: International Board for Plant Genetic Resources, Cambridge University Press, 1989, 17-31 (at 19).

[503] KINGSBURY, *Hybrid: The History and Science of Plant Breeding*, *op.cit.*, 370-372.

[504] For a good understanding of the composition of plant breeding programmes and their continuous reliance on the new input of seeds and genetic resources, whether landraces, exotic germplasm or improved varieties, see WILLIAM F. TRACY, "What Is Plant Breeding," in *Summit on Seeds and Breeds for 21st Century Agriculture, Rafi-USA*, ed. MICHAEL SLIGH and LAURA LAUFFER, available at http://www.rafiusa.org/pubs/Seeds%20and%20Breeds.pdf: 2004, 23-30.

For the determination of the degree of national dependence on genes from other areas of diversity, see XIMENA FLORES PALACIOS, "*Contribution to the Estimations of Countries' Interdependence in the Area of Plant Genetic Resources*", Rome 1997.

varieties, in an attempt to **further develop proven market successes**[505]. Then, exotic characters are incorporated in these foundations, in order to append the additional trait that would lead to an increase of productivity or efficiency in farming. Within this mind-set, it has been shown that wild genetic resources and landraces represented merely seven point nine per cent (7.9%) of the total germplasm used in breeding programmes[506], knowing that only two point four per cent (2.4%) of these had been conserved *in situ* by farmers all around the world. This impressively low figure has been mainly attributed to these resources' lesser quality and stability. Moreover, they require a greater amount of research to be efficiently used in variety improvement programmes, especially compared to those resources whose characteristics have already been established methodically. The low-level use of exotic genetic resources also finds rationale in the financial health of market-oriented breeding programmes. For instance, varietal development programmes for maize are considered to extend from six to eight years, with costs rocketing as high as seven million US dollars. However, the lifetime of developed varieties merely stretches from three to six years in terms of production and consumer demands[507]. This premise clarifies not only the search for specific favourable characteristics in collections, i.e. the look for commercially interesting traits, but also explains the main sources of raw material provision, i.e. the focus on stabilised and already tested market successes[508]. There is therefore a clear preference by private breeders to mostly manipulate elite germplasm, where perceived net values remain significantly higher compared to exotic resources. This preference accounts for the altered composition of these extended private gene pools, compared to those collections maintained by the public sector, whether at the national or international levels.

However, **exotic resources and landraces** still constitute a smaller yet often times vital part of these pools, as they are esteemed highly by variety developers in terms of long-term security[509]. Alongside the social, cultural and economic importance they carry for small farmers' livelihoods, landraces may indeed also be valued for their resistance to currently unknown or temporarily eradicated diseases. Indeed, however important the stress put upon the predictability of breeding programmes based on former market successes remains, it has also been demonstrated that researchers continued to rely, and in fact depended upon wild germplasm in order to ensure the long-term sustainability of their studies[510]. Figures indeed show that the agricultural industry could

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[505] SARAH LAIRD and R. WYNBERG, "*Access and Benefit-Sharing in Practice: Trends in Partnerships across Sectors*", Montreal, 2008. .

[506] Stemming further from the premise that biodiversity remains an ecological resource, the common belief of that our economies relied on biodiversity has been scientifically shown in a study dated as of 1996, whereby Timothy SWANSON demonstrated the role of such variability in nature with regards to research and development. The numbers mentioned here are drawn from a survey circulated within the private plant breeding sector by the World Conservation Monitoring Centre, which showed that commercial cultivars represented 81.5 percent of germplasm sources in breeding programmes; see SWANSON, "The Reliance of Northern Economies on Southern Biodiversity: Biodiversity as Information," *op.cit.*, 4-5., and WORLD CONSERVATION MONITORING CENTRE, "*Industrial Reliance Upon Biodiversity*", WCMC, Cambridge, 1996.

[507] Within the list of several factors limiting the use of exotic germplasm in US breeding programmes Michael LEE uses these figures to show that varietal development has become increasingly competitive and costly, see MICHAEL LEE, "Genome Projects and Gene Pools: New Germplasm for Plant Breeding? ," *Proceedings of the National Academy of Sciences of the United States of America* 95, no. 5, 1998: 2001-2004.

[508] KLOPPENBURG, *First the Seed: The Political Economy of Plant Biotechnology 1492-2000*, *op.cit.*, 79-80.

[509] DUTFIELD, *Intellectual Property Rights, Trade and Biodiversity*, *op.cit.*, 5-6.

[510] See the results of the study revealed by Timothy SWANSON (in SWANSON, *Global Action for Biodiversity, an International Framework for Implementing the Convention on Biological Diversity op.cit.*, 73-75., which showed that approximately eighty three percent of R&D was conducted on the basis of standardised varieties, while six point five percent focused on wild species and landraces.

and did indeed not rely on a static range of genetic material, which would not in itself provide the necessary variability to ensure the resistance of the new varieties. Breeders totally renewed their stocks every ten to fourtheen years, renewal for which natural diversity pools need to remain at their widest range. It should however be noted that the recourse and utility, and thus the presence of these resources within private breeding gene pools tend to vary from one crop to the other, in accordance with the specific needs of the cultivar[511].

5.3.2. New Genetic Diversity Put to its Own Test

Modern plant breeding activities present aspects of **biodiversity conservation and creation** that resonate deeply in the roles traditionally attributed to farmers in terms of on-farm agrobiodiversity maintenance. Breeders draw on past market successes and release new variants either through the use of known varieties and traits, or having recourse to wild germplasm (whether exotic material, wild relatives, or traditional landraces). They then create new genetic variation. Throughout the process, they actively contribute to the conservation of plant diversity. However, this newfound brilliance also ignited detrimental effects as a productivity-oriented agrobiodiversity management scheme, having propelled genetic uniformity and high-input agriculture to farmers unanimously, without having regard to their assimilation capacity. An all-encompassing paradigm change, the Green Revolution remains a double-edged sword, being attributed either extremely positive or extremely detrimental social effects, depending on the writers' perspective[512].

While the links between scientific genetic research and plant breeding became stronger day-by-day, the **relationship between farmers and breeders weakened considerably**. Farmers have been excluded from the "institutionalisation and professionalisation of breeding" activities, whether undergone within the public or burgeoning private sectors[513]. This rupture is nonetheless not as obvious as it would appear to us today, as most experiment stations and college administrators assumed at the time that farmers could and would produce their own hybrid seeds during the timid beginnings of plant breeding science[514]. This assumption became a reality for a short time-period. However, the power granted to technological breakthroughs instigated a different institutional organisation, weakening the ability of farmers to generate improved varieties. Not being able to keep up with the rapidly evolving know-how of hybridisation, farmers thus progressively lost an aspect of PGRFA management which had always been traditionally awarded to them, that of genetic enhancement. Any direct competition between landraces and

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[511] See for instance the differences between maize research and development, which tends to rely much more on landraces than sorghum, where variety development primarily revolves around exotic germplasm, see SMITH and DUVICK, "Germplasm Collections and the Private Plant Breeder," *op.cit.*, 17-31.

[512] In succinct terms, for objective evaluations of the Green Revolution, see ROBERT E. EVENSON and D. GOLLIN, "Assessing the Impact of the Green Revolution," *Science* 300, no. 5620, 2003., Abe GOLDMAN and Joyotee SMITH, "Agricultural Transformations in India and Northern Nigeria: Exploring the Nature of Green Revolutions", *World Development*, 23:2 (1995), pp. 243-263; R.B. SINGH, "Environmental Consequences of Agricultural Development: A Case Study from the Green revolution State of Haryana, India", *Agriculture, Ecosystems and Environment*, 82:1-3 (2000), pp. 97-103. A general overview of the Revolution's effects on equity and piracy allegations, including those negative reactions to the dissemination of modern varieties in the developing world, will be given in the further course of this study.

[513] KINGSBURY, *Hybrid: The History and Science of Plant Breeding*, *op.cit.*, 172-175., using the example of the Plant Breeding Institute of Cambridge University.

[514] Indeed, encouragement was given to decentralised "farmer enterprises", which were given parental seed stocks and developed hybrids; KLOPPENBURG, *First the Seed: The Political Economy of Plant Biotechnology 1492-2000*, *op.cit.*, 105-106.

hybrids bears in essence an unsustainable aspect, especially having regards to the extension of food distribution networks, the internationalisation and growth of food production demands, and concurrent demanding consumer requests. Modern varieties indeed bear much more universality and preciseness than farmers' varieties. The traditions of multiple cropping, the holistic approaches to crop cultivation and improvement, as well as the growing financial weight of modern agricultural tools and external inputs effectively pushed farmers outside of the active breeding realm. Farmers started to be considered as mere 'conservers' and 'cultivators', rather than active variety developers and genetic mass selectors. Due to the subsequent lack of distribution of inbred lines, 'breeders' emerged as stand-alone actors of genetic resource management, both in terms of their use and conservation, while commanding the driving seat of plant improvement from this moment forward.

Even though one cannot undertake an in-depth analysis of the social and economic consequences of the introduction of modern varieties within the scope of this study, it is still safe to say that the Green Revolution has been mostly welcomed in a negative fashion in the developing world where it introduced high-yielding varieties not adapted to the **socio-economic cultivation conditions**. The dissemination of high-yielding end-products of public research through the exploitation of 'heterosis' or hybrid vigour found within the crosses carried out at breeding institutes worldwide, was first condemned vis-à-vis its motivational impulses and its results on farmers of the developing world, a stance that has deepened further with the increased involvement of private companies in the development of modern varieties. In accordance with the national security focus of the international political scene of the 1950's, the spreading of F1 hybrids in the developing world by powerful nations such as the United States fuelled cynical foreign policy analysts to assert that the motivations lying therein was the elevation of developing countries to potential trading partners of the 'West', having fed their population and achieved economic growth[515]. It has been viewed as a change having fuelled inequality, caused evictions, reliance on inputs and mechanisation, while considering rural areas merely as spaces for food production destined to the industrialising urban populations. Indeed, this phenomenon has drawn in accurate critics over the social dislocations caused by the introduction of this new agricultural production scheme, but also over the increase of the costs of cultivation for farmers and the trade-offs witnessed between the promised yields and crop reliability. This highly pessimistic approach however needs to be alleviated. Indeed, it is generally accepted that these high-yielding varieties have successfully lowered the food prices for the regional consumer, and might have actually also had a positive effect on neighbouring rural economies through a "knock-on" effect[516]. High-yielding varieties have also had positive contributions in terms of productivity improvements and the modernisation of social structures around the world[517].

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[515] See KINGSBURY, *Hybrid: The History and Science of Plant Breeding*, *op.cit.*, pp.287-289.

[516] See HAZELL and RAMASAMY, *The Green Revolution Reconsidered: The Impact of High-Yielding Rice Varieties in South India*, ed. INTERNATIONAL FOOD POLICY RESEARCH INSTITUTE Baltimore: John Hopkins University Press, 1991., especially P. PINSTRUP-ANDERSEN and M. JARAMILLO, "The Impact of Technological Change in Rice Production on Food Consumption and Nutrition," in *The Green Revolution Reconsidered: The Impact of High-Yielding Rice Varieties in South India*, ed. HAZELL and RAMASAMY, Baltimore: John Hopkins University Press, 1991, pp.85-101.

[517] For positive evaluations of the impacts of the Green Revolution, see S. WORTMAN and R.W. CUMMINGS, *To Feed This World* Baltimore: John Hopkins University Press, 1978.; or more generally GERALD M. MEIER, *Leading Issues in Economic Development* New York: Oxford University Press, 1976, pp.560-562.

However, controlled plant improvement and its accompanying structural changes did not only impact farming communities and the economy in its overarching sense. The growingly privatised and input-oriented world of plant breeding also had effects on the **natural environment and the conservation of biological diversity**. Agricultural production has already in itself various detrimental effects on agro-biodiversity, amongst others the alteration or conversion of natural habitats. The intensification of agricultural practices is also considered to detrimentally affect biodiversity services, climaxing in species loss or changes in ecosystem stability and resilience[518]. The specialisation and homogenisation of agricultural production are also cited as causes of the genetic erosion witnessed with regards to agricultural plant diversity. This trend is shown through the well-known figures relating to the number of species actually used for human food consumption. Indeed, seven thousand out of two hundred and seventy thousand plant species known to science have never been used for food and merely nine species provide for seventy five per cent (75%) of human food worldwide[519], while only three crops provide sixty per cent (60%) of the calories we obtain from plants[520]. The introduction of modern varieties, fruit of plant breeding efforts, is often assumed to have led to the decrease of genetic diversity on farm, operating to the demise of locally adapted and inherently more gene-diverse farmers' varieties and populations. Such statement is indeed corroborated by numerous studies that have demonstrated that the infusion of new uniform varieties had a direct negative impact on the recourse to farmers' varieties[521]. Indeed, the area allocated to the cultivation of landraces did tend to decrease with the adoption of new modern varieties generally performing better in terms of yield and productivity[522]. Furthermore, modern plants developed new pest and disease resistances with devastating effects, such as the well-documented crisis and famines caused amongst others by the potato blight epidemic in Ireland in the 19th century or the corn leaf disease in the USA in the 1970s. Concerns have thereon been raised as to the role of plant breeding science in the reduction and uniformisation of crop genetic diversity[523]. In this regard, continuous selection efforts and crosses between genetically related cultivars may have very well led to a narrowing of the genetic base of cultivated crops[524]. Notwithstanding such erosion claims, the over-reliance on fertilisers and lack of regard for soil structure in the spread of the Green Revolution is also considered to have led to a general degradation of the environment. Studies from the Indian Punjab regions have in this regard attributed soil erosion, nutrient depletion, falling water tables and salinisation to the introduction of modern varieties' production scheme[525]. These findings do nonetheless need to be attenuated. Even though modern agriculture, especially monoculture and over-mechanisation, has been

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518 See STEFANO PAGIOLA et al., "*Mainstreaming Biodiversity in Agricultural Development - toward Good Practice*", Washington D.C, 1997. .

519 FOOD AND AGRICULTURE ORGANISATION, "*State of the World's Plant Genetic Resources for Food and Agriculture*", Rome, 1996. ; see also R. PRESCOTT-ALLEN and C. PRESCOTT-ALLEN, "How Many Plants Feed the World," *Conservation Biology* 4, 1990: 365-374. for an in-depth analysis of these figures.

520 HAROLD BROOKFIELD et al., *Cultivating Biodiversity: Understanding, Analysing and Using Agricultural Diversity* London: ITDG Publishing in collaboration with United Nations University, 2002.

521 For examples stemming from potato farmers in Peru, see STEPHEN BRUSH, J.R. TAYLOR, and M.R. BELLON, "Technology Adoption and Biological Diversity in Andean Potato Agriculture," *Journal of Development Economics* 39, 1992.

522 CLEVELAND, SOLERI, and SMITH, *op.cit.*, 1999.

523 PAUL GEPTS, "Plant Genetic Resources Conservation and Utilization: The Accomplishments and Future of a Societal Insurance Policy," *Crop Science* 46, no. 2278-2292, 2006., who underlines the creation of the C-8 Section of the Crop Science Society of America, focusing on Plant Genetic Resources, in 1990, in response to these genetic erosion concerns.

524 PLUCKNETT; DONALD L. et al., *Gene Banks and the World's Food* Princeton: Princeton University Press, 1987.

525 GORDON CONWAY, *The Doubly Green Revolution* London: Penguin, 1997.

mentioned as a major cause of extinction with regards to agricultural genetic diversity, the same modernisation, by reducing pressure on soil, has also been considered to have **helped the protection of biodiversity outside agricultural fields**[526]. Modern varieties can indeed contribute to such sustainability by propelling land-savings and reducing pesticide use by improving the resistance of varieties to biotic stresses[527]. Furthermore, certain studies have also shown that the fruits of plant breeding have actually maintained or even increased genetic diversity on farm, for instance in maize farms with field plots having diverse needs[528] or for the cultivation of wheat in general[529]. Research benefitting from molecular data has also shown that the decrease of diversity was undeniable during the period when landraces were replaced by modern cultivars, especially in the 1960's, but that genetic erosion has since then stopped, as new diversity had been created[530]. The issue might then very well lie not within the scope of genetic erosion *per se*, but on genetic replacement, and whether a complete substitution between farmers and modern varieties should be strived for. Crop-specific studies applied in defined socio-agronomical environments converge towards a globally moderate reduction of genetic diversity accompanied by a significant alteration of resource management with the introduction of science-based plant breeding[531].

CONCLUSIONS: Improving varieties, outsourcing informational inputs and reallocating actors

Mostly attributable to the growing use of quantitative genetics in modern agriculture, plant breeding was born again on the basis of the science-based phenotypic observation of plant varieties, including those genetic and environmental components, as well as their interactions. The selection and breeding of plant varieties was from then on overtaken by professionals, trained and educated towards this specific career, while farmers, whose unconscious selection had played an important role in the past, would only be seen as sowers of the seeds distributed through public or private networks. Furthermore, the necessities of Mendelian genetics and sexual hybridisation altered the design and provision of raw genetic material. Science-based breeding programmes did

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526 DETLEF VIRCHOW, *Conservation of Genetic Resources: Costs and Implications for a Sustainable Utilization of Plant Genetic Resources for Food and Agriculture* New York: Springer, 1999, 29-30.

527 BYERLEE, "Modern Varieties, Productivity, and Sustainability: Recent Experience and Emerging Challenges," *op.cit.*, 704-705., the author still stresses that the maintenance of a broad genetic base "provides insurance against losses from unexpected causes, such as new disease, and complement efforts to improve and maintain pest resistance".

528 The example comes here from Chiapas, Mexico, where farmers' varieties were preferred in those rocky, less fertile and tricky sloping field plots, whereas modern varieties were chosen in those flat field sites for their better performance; see M.R. BELLON, "The Ethnoecology of Maize Variety Management: A Case Study from Mexico," *Human Ecology* 19, 1991.

529 MARK VAN DE WOUW et al., "Genetic Diversity Trends in Twentieth Century Crop Cultivars: A Meta-Analysis," *Theory of Applied Genetics* 120, no. 6, 2010.

530 ROB VAN TREUREN et al., "*Genetic Erosion by Modern Plant Breeding? Fact or Fiction*", Wageningen University, Center for Genetic Resources, Wageningen, 2012. , where the authors operate a meta-analysis of molecular data from various publications, to show that only a 6 per cent decrease of diversity was observed in the 1960's.

531 Such moderate conclusion is corroborated by the more recent recourse to molecular biology to determine the impact of modern varieties upon genetic diversity, which have failed to point towards an unambiguous link between genetic erosion and uniform varieties; Y.B. FU, "Impact of Plant Breeding on Genetic Diversity of Agricultural Crops: Searching for Molecular Evidence," *Plant Genet Resour Charact Util.* 4, 2006.
See also VAN DE WOUW et al., "Genetic Diversity Trends in Twentieth Century Crop Cultivars: A Meta-Analysis," *op.cit.*, where the authors' meta-analysis leads to the conclusion that there are "No general trends pointing at a loss in regional genetic diversity as released by breeders in the last century […] However, this does not rule out the possibility of diversity loss for specific crops and regions."

not solely consist of exotic resources, but rather chiefly relied on existing improved germplasm and correlated parent inbred lines.

Backed by an encouraging political and regulatory climate, these developments led to the almost full conferral of commercial agricultural research and plant breeding activities into the hands of the private sector by the end of the 20th century. This new approach to PGRFA management focusing on specific traits and variety crossing possibilities was indeed bestowed upon small or medium-sized private companies, which would be crowned the new conservers and creators of genetic diversity. Plant breeders worked hard to create, expand and best exploit their private breeding pools mainly comprised of modern and stable cultivars with tested market value, but also by a small yet at times vital portion of landraces or wild relatives. An extremely lucrative industry based upon the use of agricultural genetic resources swiftly arose to reach soaring figures. Today's global seed market's value is estimated to reach fort two billion USD[532], a figure within which twelve billion USD is allotted to the United States' industry, while the European continent stands for seven billion EUR[533]. In this new socio-technological context, new stable and uniform plant varieties may be developed in eight to ten years (until their commercialisation), and cost around two to four million EUR.

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532 ISF, " *Estimated Value of the Domestic Seed Market in Selected Countries*", ISF, International Seed Federation, available at http://www.worldseed.org/isf/seed_statistics.html, 2011.
533 ESA, "*Facts and Figures: Representing the Seed Industry*", ESA, European Seed Association, available at http://www.euroseeds.org/who-we-are/esa-facts-figures/esa_10.0588.7/view 2010.

6. CHAPTER 6: MOLECULAR BIOLOGY AND BIOTECHNOLOGY BUILDING ON GENOMICS INTROSPECTION

The aforementioned major reversal in the landscape of participants to PGRFA management is attributed to the development of plant breeding. Yet plant improvement was to go through another transformation, fuelled by yet another scientific breakthrough in our understanding of plant biology. The extension of controlled plant improvement based on sexual hybridisation techniques into the world of molecular biology revolutionised genetic resource management once again. It at times reinforced the criticism voiced against the Green Revolution with even greater vehemence, and unquestionably pushed both farmers and conventional plant breeders to re-assess their place in agrobiodiversity innovation. Subsequently, with the development of genomics science, crop improvement has grown into a molecular and biotechnology-heavy industry, dramatically altering germplasm exchange opportunities. It has ignited a race for genetic trait royalties, and further broke links with farmers, who now face oligopolistic mega-structures[534].

By the end of the 20th century, with staggering speed, the “export of a gene sequence had become the equivalent to the export of the underlying organism”[535], converting the typical flows of germplasm and actual biological material into flows of genomic information. As our knowledge of a plant's anatomy and its inherent genetic sequences deepened, it was suggested that biotechnological advances would “be to the Green Revolution, what the Green Revolution was to traditional plant varieties and practices”[536]. Just as its predecessor, this latest change in research and development opportunities altered the organisational structure of plant improvement once again. Propelling and deriving almost exclusively from the new uses of genetic resources, the rates of return of research and development have cruised at considerably high levels in all agricultural commodities, especially with regards to field crops where Herculean mean rates reached as high as one hundred and thirty five per cent, well privileged above the average of seventy five per cent generally maintained in agriculture[537]. While the seed industry’s global value has doubled in less than thirty years’ time, its distribution within the sector has taken an even more remarkable turn. Indeed, while the highest company turnover was of seven hundred and thirty five million USD in the year 1985, the uppermost earnings reached as high as four thousand and twenty eight million USD in 2006, a figure that equalled the combination of the turnovers of the six biggest companies

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[534] SHARI L. BOYD, WILLIAM KERR, and NICHOLAS PERKIDIS, "Agricultural Biotechnology Innovations Versus Intellectual Property Rights Are Developing Countries at the Mercy of Multinationals," *The Journal of World Intellectual Property* 6, no. 2, 2003: 211-232., accounting the rise of seed multinationals, converted from the world of chemistry.

[535] JOHN BARTON, "The Biodiversity Convention and the Flow of Scientific Information," in *Global Genetic Resources: Access, Ownership and Intellectual Property Rights, the Beltsville Symposia in Agricultural Research*, ed. K.E. HOAGLAND and A. ROSSMAN, Washington D.C. : Association of Systematics Research Publishers, 1997, 55.

[536] F. BUTTEL, M. KENNEY, and JACK KLOPPENBURG, "From Green Revolution to Biorevolution: Some Observations on the Changing Technological Bases of Economic Transformation in the Third World," *Economic Development and Cultural Change* 34, no. 1, 1985: 31-55 (at 32).

[537] ALSTON et al., *A Meta-Analysis of Rates of Return to Agricultural Research and Development: Ex Pede Herculem?*, *op.cit.*

in 1996[538]. These figures are only one symptom of the altered seed industry structure and the new rules of the agrobiodiversity improvement game.

6.1. Molecular biology and biotechnology in agriculture

The science of genetics would witness incredible leaps forward through the middle of the 20th century. Brilliant minds such as Alfred Hershey, Martha Chase, James Watson and Francis Crick[539] notably unravelled the role and structure of deoxyribonucleic acid, more commonly known as DNA, a molecule discovered as early as 1869. The analysis of this molecule, which codifies all instructions related to living organisms from their growth to their reproduction and maintenance, opened the door to the excavation of genetic resources at a deeper level. On account of consecutive scientific breakthroughs, the term "biotechnology" became a recurrent term in exact and social science research alike, even though the general public, familiar with the term, has ordinarily no precise idea of its meaning[540]. A far-reaching idiom, "biotechnology" comprehensively refers to "the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services", in the prevalent wording of the Organisation for Economic Cooperation and Development ("OECD")[541]. Biotechnological innovations, which cover all kinds of innovations, including that of industrial fermentation and modern genetic engineering, have widened the spectrum of plant breeding. They have done so by developing very efficient novel screening tools and variety development techniques, new conservation and use possibilities. Accordingly, genomics science revolutionised the food industry in general[542] and breeding activities in particular, as scientists were now able to map and thus locate the genes responsible for specific features or diseases carried by plants. Distinctions were established within the organisms and between different traits on a cellular level, between simply inherited traits and complex polygenic ones, allowing greater control over the characteristics borned by plant varieties in the field or shelves[543]. Agricultural plant biotechnology is considered to have propelled revolution-like advances in three key areas, namely the isolation and replication of desirable traits through cell culture, the selection of genotypes and associated

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[538] These figures can be found in BERNARD LE BUANEC, "Evolution of the Seed Industry in the Past Three Decades," in *2007 ISTA congress* ed. 2007 ISTA NEWS BULLETIN (available at http://www.icarda.org/News/Seed Info/SeedInfo_35/NewsViews_35.htm)., and also in LOUWAARS, LE COENT, and OSBORN, *op.cit.*, 2010.

[539] Alfred Hershey and Martha Chase proved that DNA was genetic material, setting the scene for future scientists like James Watson and Francis Crick, who quite infamously identified the double helix structure of the DNA.

[540] ROBERT BUD, *The Uses of Life: A History of Biotechnology* New York: Cambridge University Press, 1994, 1-2.

[541] This definition has now been accepted as the most accurate general description of the phenomenon, OECD, *Biotechnology- International Trends and Perspectives,* Paris, 1982.

[542] For examples of the impact of genomics science on the food industry in general, see R.D. PRIDMORE et al., "Genomics, Molecular Genetics and the Food Industry," *Journal of Biotechnology* 78, 2000: 251-258.

[543] Simply inherited genes are being regulated or controlled by merely a few genes, generally within a region coined quantitative trait loci, "QTL", while the latter more complex trait depend upon the interaction of genes, a phenomenon coined epitasis. This distinction is particularly interesting in terms of modelling new crop improvement schemes, see M. COOPER et al., "Complexity, Quantitative Traits and Plant Breeding: A Role for Simulating Modelling in the Genetic Improvement of Crops," in *Quatitative Genetics, Genomics and Plant Breeding*, ed. MANJIT S. KANG, Oxon: CABI Publishing, 2002, 143-147.

For the contribution of genomics to the understanding of polygenic traits, see E.S. LANDER and N.J. SCHORK, "Genetic Dissection of Complex Traits," *Science* 265, no. 5181, 1994: 2037-2048., and RITSERT C. JANSON, "Complex Plant Traits: Time for Polygenic Analysis," *Trends in Plant Science* 1, no. 3, 1996.

phenotypes, and the creation of new transgenic organisms[544]. The changes brought about by genomics science to the field of plant breeding may thus be classified as those supplementing conventional selection and hybridisation methods on the one hand; and those offering new horizons to breeding by genetic modification and DNA recombination on the other.

6.1.1. Biotechnology in "Conventional" Plant Breeding

Exclusive of the possibilities offered by genetic manipulation *per se*, the general contributions of biotechnological innovation with regards to crop productivity and stability relate to tissue culture technologies on one hand, and to selection, screening or diagnostic tools and methods on the other. Both methods have brought in greater precision and considerable time gains in plant breeding endeavours. In terms of **tissue culture** technologies, biotechnological micro-propagation techniques have enabled the cloning of cells and their mass propagation. Botanists had attempted to cultivate plant cells starting from Gottlieb Haberlandt's successful experiments in the very early years of the 20th century[545]. Yet it was only on account of the subsequent advances in our understanding and processing of microorganisms that scientists and breeders were able to replicate plants on sterile media in a much more secure and efficient fashion. As a result, the conventional take on plant breeding that consisted of sexually reproducing the varieties that retained desired characteristics has evolved so as to include material generated through tissue and embryo culture. These possibilities allow not only a better control of the environment, but also enlarge the spectrum of crosses that can be accomplished. Using tissue culture, breeders are not only able to predict research results more accurately, but can thereon also cross species which would not naturally cross in nature. Unichromosomal "haploid" plants may now be consciously produced, putting aside the issue of unpredictable dominance, in favour of absolute certainty over the characteristic fuelled by the gene[546]. As a faster alternative to backcrossing efforts needed to obtain pure lines, haploids can be crossed to produce homogenous diploid plants where absolutely all undesirable traits have been eliminated[547]. While conventional breeding techniques require multiple generations of selection to stabilise desired traits; doubled haploids are genetically pure and produced in just one generation. Furthermore, the development of homogenous haploid cells has also opened the door to so-called "somatic" interspecies hybridisation[548], breaking a frontier that conventional plant breeders could not initially breach. Tissue culture techniques have

[544] ARIE ALTMAN, MEIRA ZIV, and S. IZHAR, "Plant Biotechnology and in Vitro Biology in the 21st Century" (paper presented at the 9th International Congress of the International Association of Plant Tissue Culture and Biotechnology, Jerusalem, Israel, 14-19 June 1988)., preface.

[545] His experiments during the very last years of the 19th century made Haberlandt the first scientist to culture isolated and fully differentiated cells in vitro on an artificial medium, research results that he presented as early as 1902; See SANT SARAN BHOJWANI and M.K. RAZDAN, *Plant Tissue Culture: Theory and Practice* Amsterdam: Elsevier, 1996., or JOHN H. DODDS and LORIN W. ROBERTS, *Experiments in Plant Tissue Culture* New York: Cambridge University Press, 1985.

[546] By forcing a double cell to expel half of its chromosomal constitution, haploidisation thus enables faster and more precise breeding, a potential that was identified very early in the history of biotechnology, see P.J. BOTTINO, "The Potential of Genetic Manipulation in Plant Cell Cultures for Plant Breeding," *Radiation Botany* 15, no. 1, 1975: 1-16.

[547] See NEI MATASOSHI, "The Efficiency of Haploid Method of Plant Breeding," *Heredity* 18, no. 1, 1963: 95-100., and Z. DHLAMINI, "*The Role of Non-Gm Biotechnology in Developing World Agriculture*", available at http://www.scidev.net 2006.

[548] MURPHY, *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*, *op.cit.*, 39-46., Roberta H. SMITH and Sung Hun PARK also include basic plant morphogenesis studies, germplasm preservation and transport and molecular farming to the list of contributions, see "Tissue Culture for Crop Improvement," in *Quantitative Genetics, Genomics and Plant Breeding*, ed. MANJIT S. KANG, Oxon: CABI Publishing, 2002, 189-196.

therefore allowed the development of new varieties through the combination of species outside each other's immediate gene pool and that would otherwise not interbreed[549]. Breeders can thus not only operate with greater adequacy, but can also make wide, perhaps even unlimited, variety crosses by using so-called “somaclones”[550].

Another extremely timesaving and accuracy-adding revolution brought to plant breeding by genomics science involves the development of **new screening and selection technologies**. Analysing plant varieties at the DNA level, tools such as molecular markers and immuno-diagnostics using molecular assays today assist the characterisation and management of plant genetic resources[551]. Through these analytical tools, breeders are currently able to process thousands of plants in great molecular detail during the course of a single day, while merely a few dozen samples could have been analysed in the past during the same time frame[552]. Molecular markers are short and identifiable DNA strips that indicate the presence of a desired trait within a plant's genome,. They contribute to the generation of genomics knowledge not only through 'fingerprinting', i.e. the characterisation of germplasm itself, but also through the dissection of desired traits and the identification of genetic regions or "quantitative trait loci's"[553]. These markers are incresingly included within crop improvement programmes through a new scheme coined "marker-assisted selection"[554]. This technique allows for selection to be operated concurrently on more than one trait for one plant[555] and allows for the efficient screening of characteristics that are difficult or time-consuming to predict through simple phenotypic analysis. Breeders can for instance screen disease resistance traits without need for pathogen exposal, or traits only found in mature plants without any need for maturing. Moreover, the segments of DNA identified through markers allow for the efficient follow-up of inheritance. They open the door for the transfer of desired traits to progeny or for the suppression of undesired ones, all the while having recourse to 'conventional' sexual hybridisation. Breeders today use a wide range of

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[549] See the definition of S. ARCIONI and F. PUPILLI, "Somatic Hybridisation," in *Encyclopedia of Applied Plant Sciences*, ed. B. THOMAS, DENIS J. MURPHY, and B. MURRAY, Oxford: Elsevier Academic Press, 2003, 1423-1431.

[550] Even if some reticence still exists vis-à-vis the use of clonal genetic variation due to the unpredictability and the risk of genetic instability of the somaclones, a number of new plant varieties have still been developed through the technique of somaclonal variation detection, and the possibilities offered by science shall very likely be further used in the future. See S. MOHAN JAIN, "Tissue Culture- Derived Variation in Crop Improvement," *Euphytica* 118, no. 153-166, 2001., and D.S. BRAR and S.M. JAIN, "Somaclonal Variation: Mechanism and Applications in Crop Improvement," in *Somaclonal Variation and Induced Mutations in Crop Improvement*, ed. S. MOHAN JAIN, D.S. BRAR, and B.S. AHLOOWALIA, Dordrecht: Kluwer, 1998, 15-38.

[551] DHLAMINI, *op.cit.*, 2006.

[552] STEVEN D. TANKSLEY, "Molecular Markers in Plant Breeding," *Plant Molecular Biology Reporter* 1, no. 1, 1983: 3-8.

[553] J.M. RIBAUT et al., "Use of Molecular Markers in Plant Breeding: Drought Tolerance Improvement in Tropical Maize," in *Quantitative Genetics, Genomics and Plant Breeding*, ed. MANJIT S. KANG, Oxon: CABI Publishing, 2002, 85-100.

[554] For an in-depth overview of possibilities offered by molecular markers in breeding and especially selection, see M. MOHAN et al., "Genome Mapping, Molecular Markers and Marker-Assisted Selection in Crop Plants," *Molecular Breeding* 3, 1997: 87-103.
Also see notably J.W. DUDLEY, "Molecular Markers in Plant Improvement: Manipulation of Genes Affecting Quantitative Traits," *Crop Science* 33, no. 4, 1993: 660-668.

[555] For an account of the advantages brought by molecular markers based analysis of given populations, over more classical trait-based analysis, see R.J. LEBOWITZ, M. SOLLER, and J.S. BECKMAN, "Trait-Based Analyses for the Detection of Linkage between Marker Loci and Quantitative Trait Loci in Crosses between Inbred Lines," *TAG Theoretical and Applied Genetics* 73, no. 4, 1987: 556-562.

molecular markers, which each present different advantages and constraints[556]. These markers first need to be identified, not only through sequencing efforts that may produce too much information and miss the important markers, but also by alternate detection techniques[557]. Diverse diagnostic tools exist, such as molecular assays and the more costly polymerase chain reaction ('PCR')-based DNA diagnostics, which may also identify viruses, disease-causing agents or suspected pathogens[558]. Besides their invaluable contribution to information and selection techniques, biotechnological breakthroughs may thus also play a major part in disease prevention and control.

Notwithstanding the institutional barriers surrounding the recourse to molecular biology tools, by the end of the 1990's, some of the shortcomings and flaws of the quantitative genetics' revolution had been levelled out. The new science of molecular plant breeding, with its enhanced knowledge of the desired traits' genetic architecture, literally allowed breeders to tailor-make specific new plant types to be highly productive in specific and more difficult growth environments, on account of DNA analysis and recombination[559]. Following in the footsteps of plant breeding, the second quantum leap of plant improvement was thus achieved, adding incredible precision and foresight to the research process, shortening the cycle of product development, while also generating the newest type of modern varieties, fruits of genetic modification[560]. IRRI's work on IR 8 has for instance incorporated this leap in order to obtain "Green Super Rice", in an effort to improve the grain quality initially obtained with sexual crosses operated on over two hundred and fifty varieties. This improvement is sought essentially after through the asexual incorporation of genes for targeted disease and insect resistance[561]. Molecular plant breeding, backed for instance by

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[556] They are mainly divided between those based on restriction fragment length polymorphism (RFLP) and those relying upon polymerase chain reaction (PCR). The latter form being less expensive, through an amplification of DNA segments without any need of DNA reproduction as such, it has been more widely used. Breeders also use microsatellites (simple sequence repeats SSR, short tandem repeats STR or sequence-tagged microsatellite sites STM), random amplified polymorphic DNAs, amplified fragment length polymorphism (the infamous AFLP markers) and also single nucleotide polymorphisms (SNP, the most common form of DNA sequence polymorphism and thus abundant enough for haplotype analysis). See notably V. MOHLER and G. SCHWARZ, "Genotyping Tools in Plant Breeding: From Restriction Fragment Length Polymorphisms to Single Nucleotide Polymorphisms," in *Molecular Marker Systems in Plant Breeding and Crop Improvement*, ed. HORST LORSZ and GERHARD WENZEL, Berlin: Springer, 2005.

[557] For example, SNP markers are identified through the lengthy yet widely used gel-based detection technique that is PCR-RFLP, also referred to as CAPS (cleaved amplified polymorphic sequence) analysis. These markers can also be detected through allele-specific primers or single-stranded conformation polymorphism analysis (SSCP). "Genotyping Tools in Plant Breeding: From Restriction Fragment Length Polymorphisms to Single Nucleotide Polymorphisms," in *Molecular Marker Systems in Plant Breeding and Crop Improvement*, ed. HORST LORSZ and GERHARD WENZEL, Berlin: Springer, 2005, pp.28-29.

[558] See ZEPHANIAH DHLAMINI et al., "*Status of Research and Application of Biotechnologies in Developing Countries*", FAO, Rome, available at http://www.fao.org/docrep/008/y5800e/Y5800E05.htm, 2005.
Also see NORMAN W. SCHAAD, JEFFREY B. JONES, and WESLEY CHUN, *Laboratory Guide for Identification of Plant Pathogenic Bacteria*: American Phytopathological Soecity Press
, 2001.

[559] S.P. MOOSE and R.H. MUNN, "Molecular Plant Breeding as the Foundation for 21st Century Crop Improvement," *Plant Physiology* 147 2008: 969-977.; or JACK C.M. DEKKERS and F. HOSPITAL, "Multifactorial Genetics: The Use of Molecular Genetics in the Improvement of Agricultural Populations," *Nature Reviews Genetics* 3, 2002: 22-32.

[560] GEPTS, "A Comparison between Crop Domestication, Classical Plant Breeding, and Genetic Engineering," *op.cit.*, pp.1780-1790.

[561] See GURDEV S. KHUSH, "New Technologies for Rice Production" (paper presented at the Rice is Life: Scientific Perspectives for the 21st Century; Proceedings of the World Rice Research Conference, Tsukuba, Japan, 2004), 6.; and RONALD P. CANTRELL and GENE P. HETTEL, "Research Strategy for Rice in the 21st Century" (ibid.), 26-37.; and also http://irri.org/news-events/media-releases/green-super-rice-is-coming.

marker-based selection or haploid technologies, has become an extremely precise breeding technique that nonetheless **relies on the access to a combination of complex technologies**. Diagnostic tools and molecular markers allow for substantive time gains if used efficiently, shortening the time frame for variety development by two to three years. However, they come at a price. With the exception of certain methods such as the simple sequence or microsatellite markers ("SSR markers") that are relatively cheap, the initial investment to build a stand-alone laboratory or a molecular unit within existing breeding programs is considerably high[562]. The tricky question that ought to be answered in terms of cost-effectiveness is therefore the trade-off between time gains and additional investment, which means that if "operating capital is constrained, the best breeding method will maximise the internal rate of return, i.e. conventional selection"[563]. This trade-off clearly shows the barriers that exist to enter the world of molecular biology.

6.1.2. Genetic Engineering and DNA recombination

Constantly deepening our knowledge of specific regions and markers responsible for certain traits within a plant's genome, genomics science soon extended to genetic recombination. Ever since Stanley Cohen and Herbert Boyer decided to join forces and proceed to DNA cloning experiments, providing results on the recombination of organisms in 1973, their ground-breaking discoveries have fuelled significant interest. The practical implications of their experiments heralded a new research and development field that was coined **'genetic engineering'**. Even though tissue culture techniques and molecular markers have speeded up the process of breeding and reduced unwanted gene transfers, conventional breeders were not able to neither control the exact degree of genetic change found in the new plant variety, nor totally eliminate all undesirable traits through mere sexual reproduction[564].

The language of molecular biology, solely considering cellular information, has thus been compared to a "**biological Esperanto common**",[565] whereby genetic instructions and functions showed no distinction between living organisms, as a universal language, which, when deciphered, unveiled a knowledge Eldorado in terms of plant variety improvement possibilities. Genetically engineered new varieties, presenting traits uncharacteristic to the very species they belong to, have thus demolished the walls of inherent genetic incompatibilities[566]. Building upon the developments in the field of molecular biology and genomics science, genetic engineering took the possibilities offered by genetic resources a step further, breaking the limits of reproduction past "mere" somaclonal hybrids. Through genetic engineering, it became possible to accomplish what evolution had not (yet) granted to certain plants, as it has been done in the development of C^4 photosynthesis rice. In this case, scientists granted the natural opportunity of photosynthesis to rice varieties that did not have this prospect, thereby significantly improving yields, water and nitrogen

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[562] BERTRAND COLLARD and DAVID MACKILL, "Marker-Assisted Selection: An Approach for Precision Plant Breeding in the 21st Century," *Philosophical Transactions of the Royal Society of Biological Sciences* 363, no. 1491, 2208: p.560.

[563] MICHAEL MORRIS et al., "Money Matters: Costs of Maize Inbred Line Conversion Schemes at Cimmyt Using Conventional and Marker-Assisted Selection," *Molecular Breeding* 11, no. 3, 2003.

[564] P.J. DALE, "Plants and Biotechnologies," in *The Economics of Managing Biotechnologies*, ed. TIMOTHY SWANSON, Dordrecht: Kluwer, 2001, 251-254.

[565] KLOPPENBURG, *First the Seed: The Political Economy of Plant Biotechnology 1492-2000, op.cit.*, 193.

[566] This phenomenon is witnessed in parallel to the interspecific somatic hybridisation prospects opened through the aforementioned plant cell and tissue culture methods.

use performances[567]. It is on account of recombination methods that modern agricultural genomics science has resolved the shortcoming of undesired genetic variation inherent to sexual mating. Indeed, through the recourse to transgenesis, namely the **insertion of exogenous gene into plants**, the recombination of DNA added to breeding in exactitude and time. Isolating one or two specific genes with pre-identified characteristics such as disease resistance within a donor organism, genetic engineers introduce these isolated genes within an external plant variety, creating a unique genetic modification and thus recombining the genome sequence of the recipient organism. The most common two techniques for transgene insertion are biolistics, using gold particles, and *Agrobacterium*-mediated gene insertion, whereby the organism is "infected" with DNA[568]. Molecular biology enables "changes in gene frequencies with a wholly unprecedented specificity, such recombinations [being] no longer limited to sexually compatible organisms"[569]. Genomics science, when applied to plant breeding, meant that the main barriers to new, stronger, more productive, resistant or adapted varieties had become the breeders' imagination, wiping out the frontiers of sexual reproduction, families or varieties in plants, bacteria or any other living organism. The availability of plant transformation techniques, either through the recourse to *Agrobacterium* or the development of biolistics, has tremendously extended the reach of plant breeding, by stretching it beyond the limitations imposed by sexual reproduction and cross-compatibility requirements, thereby making absolutely all organisms a potential material for plant transformation and new genetic diversity[570]. The limits rather now lied in the patience of the breeders and the financial means injected in their project, as the development of a single trait may cost more than one hundred million USD in a time span of twelve to thirteen years[571].

The "mere" infusion of biotechnological innovations to conventional breeding has mostly focused on the improvement of variety performance and breeding efficiency. On account of its open-ended barriers, the priorities of genetic modification have shown a wider range. In this context, distinction is generally made between genetic enhancement **directed towards the inputs of the variety or towards its output traits**, a difference highlighting whether the improved characteristics are uncovered respectively in the seed itself or on the harvested material[572]. In the former input-oriented research, transgenesis has accordingly attempted to directly improve biotic

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[567] C^4 Photosynthesis has indeed naturally arisen in different flowering plants in an independent fashion, but not in rice. C^4 rice thus needs a gene transfer for enzymes of the C^4pathway and leaf development, see PETER L. MITCHELL and J.E. SHEEHY, "Genetic Modification and Agriculture," in *Redesigning Rice Photosynthesis to Increase Yield*, ed. J.E. SHEEHY, BILL HARDY, and PETER L. MITCHELL, International Rice Research Institute, Elsevier, 2000, at 265-266.

[568] Biolistics refer to propelling small gold particles coated with exogenous DNA, while the second, more controlled method, refers to the use of a bacterial vector, such as Agrobacterium tumafaciens to insert DNA into a specific region of the plant: MURPHY, *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*, *op.cit.*, pp.46-47.

[569] KLOPPENBURG, *First the Seed: The Political Economy of Plant Biotechnology 1492-2000, op.cit.*, 192.

[570] GEPTS, "Plant Genetic Resources Conservation and Utilization: The Accomplishments and Future of a Societal Insurance Policy," *op.cit.*, p.2279.

[571] HAYES, LENCE, and GOGGI, "Impact of Intellectual Property Rights in the Seed Sector on Crop Yield Growth and Social Welfare: A Case Study Approach," *op.cit.*, and BELL and SHELMAN, "Monsanto: Realizing Biotech Value in Brazil (Harvard Business School Case 507-018)," *op.cit.*

[572] The distinction between the input and output traits within those being currently developed in the biotechnology sector is operated by Denis MURPHY, whereby the former expression designates those traits affecting the means through which the crop is grown without changing the nature of the harvested product, while the latter covers those traits that change the quality of the product itself; see MURPHY, *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*, *op.cit.*, 189-209., where the author makes a comprehensive description of each product category.

or abiotic stress resistances, just as conventional breeding efforts did, focusing on stresses related to viruses, bacteria and fungi, or to drought and other thermal stresses. Another major input trait developed by agricultural biotechnology relates to herbicide tolerance, one of the earliest transgenic traits to be developed commercially, and which is not found in conventional breeding methods[573]. With regards to those output traits improved through transgenesis, research has generated promising results in the enhancement of the harvested product's vitamins content, as well as in biofortification efforts against soil deficiency in essential minerals, or in the nutritional enhancement of oil crops. Both the development and spreading of these new genetically improved varieties have in this context been extremely impressive. The first billion of accumulated hectarage has taken ten years to be reached, starting from 1995, while the second billion was reached in merely three years, in 2008[574]. Not short of regulatory setbacks, the biotechnology revolution has been spreading much faster than conventional sexual hybridisation techniques in the world, in parallel to the head-turning speed through which technological advances continue to see the light of day. The latest of such advances is notably the generation of products combining 'stacked' transgenic traits, rooting for more performance in genetically modified crops projecting multiple benefits[575].

6.2. New actors of agrobiodiversity management: specialisations, acquisitions, and the dawn of an oligopolistic industry

Just as plant-breeding activities became conspicuously more reliant on laboratory work, "a **wholesale corporate takeover**" was coincidently taking place, whose rationale appeared to be this new dependence on genomics science[576]. Indeed, "the large and overwhelmingly public agricultural research effort of developing countries has, with a few notable exceptions, made relatively little progress in developing and commercialising agricultural biotechnology innovations"[577]. The clear shift from publicly-funded agricultural research into a private-sponsored one had been consecrated during the 1980's, the decades of plant breeders' reign[578]. With the development of molecular biology however, new actors got directly involved in PGRFA management. This pushed for a reallocation of the crown of seed control. Not only would cutting-edge laboratories take the lead while companies stemming from a chemical background entered

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573 *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*, *op.cit.*, 113-114., even though the early development of the herbicide tolerance trait is attributed to its readiness and easier nature (due to the fact that the traits were controlled by single genes that were available to scientists, without need for further research on characterisation or identification), the institutional impacts of this trait has been quite important (as the product developer was directly able to commercialise a double product package), an issue that we shall touch upon in the latter course of this study.

574 CLIVE JAMES, "*Global Status of Commercialised Transgenic Crops*", International Service for the Acquisition of Agri-Biotech Applications (ISAAA) Briefs no.39, Ithaca, New York, 2008. .

575 See the special case of 'stacked' GM crops in the 2009 study of the Joint Research Centers, a combination of traits which create additional conundrum in terms of regulatory issues, see ALEXANDER J. STEIN and EMILIO RODRIGUEZ-CEREZO, "*The Global Pipeline of New Gm Crops: Implications of Asynchronous Approval for International Trade*", European Commission, Sevilla, 2009. .

576 KINGSBURY, *Hybrid: The History and Science of Plant Breeding*, *op.cit.*, 378.

577 These notable exceptions include virus elimination using in vitro propagation, marker-assisted breeding, and use of genetic cultivar identification to improve the efficiency of germplasm conservation, which have been used for years in many countries. BRIAN D. WRIGHT and PHILIP PARDEY, "Changing Intellectual Property Regimes: Implications for Developing Country Agriculture," *Int. J. Technology and Globalisation* 2, no. 1-2, 2006: p.94.

578 BOYD, KERR, and PERKIDIS, "Agricultural Biotechnology Innovations Versus Intellectual Property Rights Are Developing Countries at the Mercy of Multinationals," *op.cit.*, 211-232., accounting the rise of seed multinationals, converted from the world of chemistry.

this lucrative market, the seed industry would also undergo impressive waves of mergers and acquisitions, resulting in an oligopoly of sizeable multinationals.

6.2.1. Cutting-edge Research Prospects Grabbed by New Corporate Actors

As one of the most knowledge-intensive industries in the world, agricultural or "green biotechnology" has proven to be a very efficient technological platform for **high-end, mostly public, research entities specialising in cutting-edge research.** Most of the initial efforts, especially those directly regarding the development of molecular research tools, were indeed carried out by the public sector, seen as "a key repository of up-to-date expertise in most of the cutting edge areas of new technologies, such as genomics, bioinformatics or molecular markers"[579]. Technological advances in plant genomics triggered the establishment of specialised early-stage public research laboratories or companies, less concerned with marketing issues *per se*, but developing products that would be infused into the marketplace later on by other actors. It has for instance been shown that in 1996, the "sales of products developed from inventions produced by academic research and licensed to industry amounted to twenty point six billion USD, [considering that] nearly two-thirds of these licenses were to small firms"[580]. Public and university initiatives were however not always designed to stay that way, and soon gained a private nature, even though the ties with their parent public institutions or universities would not be severed to the point of no return. The supremacy of the cutting-edge biotechnology start-up had began. One of the most striking aspects of this move has been its speed in reacting to the potential of the application of genomics science in agricultural plant biology. Indeed, the first company to exploit the DNA recombination technology was founded merely three years after its initial discovery[581]. Numerous technology licensing offices start-ups have been established in the field of biotechnology, financed mostly by venture capitalists[582]. Researchers of Cornell University set up their own start-up company, Biolistics, which developed the "Biolistic Particle Delivery System" gene gun technology. At the dawn of the 21st century, the knowledge-based biotechnology industry, defined in its largest sense, was thus predominantly composed of smaller-scale companies with strong ties to university scientists, whether official start-ups or entrepreneurial personal initiatives[583]. As a perhaps unforeseen result, the "intellectual centre of gravity" in biotechnological inventions was starting to move towards the private sector, especially through start-up firms in the likes of Mycogen or Calgene[584]. This has also for instance been the case of the infamous Genentech in the field of biomedicine, having started with the development of synthetic human insulin and has now grown in tremendous proportions.

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[579] MURPHY, *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*, *op.cit.*, p.240.

[580] STEVEN MCMILLAN, FRANCIS NARIN, and DAVID L. DEEDS, "An Analysis of the Critical Role of Public Science in Innovation: The Case of Biotechnology," *Research Policy* 29, 2000: p.2.

[581] CARY FOWLER et al., "The Laws of Life: Another Development and the New Biotechnologies," *Development Dialogue* 1-2, 1988: 179., coining the phenomenon "corporate takeover of the new biosciences".

[582] The importance of venture capital is especially true in biotechnology, a field where universities remain a major source of new technology; see L. ZUCKER, M. DARBY, and M. BREWER, "Intellectual Human Capital and the Birth of Us Biotechnology Enterprises," *American Economic Review* 88, no. 1, 1998.

[583] D.B. AUDRETSCH and P. STEPHAN, "Company-Scientist Locational Linkages: The Case of Biotechnology," ibid.86, 1996.

[584] JOHN BARTON, "Intellectual Property, Biotechnology and International Trade: Two Examples," in *Intellectual Property: Trade, Competition and Sustainable Development*, ed. THOMAS COTTIER and P. MAVROIDIS, University of Michigan Press, 2003, p.288.

In parallel to this specialisation and "entrepreneurial science" surge, the promises of "green biotechnology" and genetic engineering generated a great deal of **equity investment** stemming from major multinational firms active in remote fields[585]. Molecular science created a new biotechnology business model predominantly relying on molecular interactions and cellular manipulation. But this model's economic survival relied upon significant financial reserves and suitable high-end infrastructures to benefit from the genomic revolution. This dynamic and promising context, and the increasing cost-effectiveness attributed to breeding activities, swiftly tickled the interest of companies that had previously dominated the agricultural chemical sector. Indeed, at the dawn of the influential environmental movement, these agrochemicals 'giants' were under regulatory pressure to further regulate and reduce the use of pesticides, which had started to prove their detrimental effects on nature[586]. They thus had to find innovative ways for their activities' proliferation and could easily finance the expensive research and development tools required in the increasingly knowledge-intensive and laboratory-oriented world of plant biotechnology. Pharmaceutical companies accompanied this new extension, whether as parent entities (Pharmacia Upjohn for Monsanto for instance), or as inside divisions (G.D. Searle Company's green biotechnology division acquired by Monsanto in the 1980's)[587]. On the other hand, private conventional breeding and seed companies could not join the Gene Revolution with the same ease and speed. Indeed, "the type of scientific capacity required to mount a successful biotechnology research programme [was] fundamentally different from that needed for developing adapted crop varieties"[588]. The often times small or medium-scale seed enterprises maintained a sharp focus on phenotypic experimentation, field trials, the natural talent and intuition of individuals, while relying on the rapid uptake of the products of their research and uninterrupted cash flow[589]. The investment and know-how related to molecular biology had in this sense effectively triggered a shift away from seed companies specialised in delivering new plant varieties. A portion of agricultural input development and provision was as a result sliding away from the hands of those who could not take the leap of biotechnology.

6.2.2. "Acquiring" in the Name of Breeding Background and Market Control

Even though specialised entities were developing crucial molecular research tools and large chemicals originating multinationals were entering the plant innovation landscape, the initial basis of agricultural production and variety selection stayed very well in place. Conventional plant breeders were seemingly there to stay, even though there were fears of them becoming "a dying breed"[590]. This obituary was premature since genetic engineering could not survive without any

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[585] See BUTTEL, KENNEY, and KLOPPENBURG, "From Green Revolution to Biorevolution: Some Observations on the Changing Technological Bases of Economic Transformation in the Third World," *op.cit.*, 34-36., especially the tables describing the landscape of companies active in biotechnology in the middle of 1980's, showing the financial linkages of laboratories working on seed related technology to companies such as Kellogg, Johnson and Johnson or Hoffman-Laroche (p.35). This picture clearly demonstrates the interest of all influential companies within the entire food chain towards biotechnology, as well as the early signs of the "chemicals industry's reconversion".

[586] KINGSBURY, *Hybrid: The History and Science of Plant Breeding*, *op.cit.*, 377.

[587] MURPHY, *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*, *op.cit.*, pp.172-173.

[588] FUKUDA-PARR, "Emergence and Global Spread of Gm Crops: Explaining the Role of Institutional Change," *op.cit.*, 15-35., especially "Box 2.1. The Scientific Process for Generating GM Crop Varieties" by Greg TAXLER at p. 17.

[589] MURPHY, *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*, *op.cit.*, 103.

[590] JONATHAN KNIGHT, "Crop Improvement: A Dying Breed," *Nature* 421, no. 6 February 2003, 2003., where the author stresses the risks underlying the fact that molecular research is sexier and more exciting than conventional plant breeding, even for the public sector.

breeding background. Yet again, the collision of specialised laboratories, chemicals giants, and seed companies was inevitable, and it was a violently exterminating one, and on all sides. This collision's annihilating effects, unforeseen by certain actors, are best epitomised by the story of Calgene, one of the early-bird green biotechnology start-ups. Calgene was "a force of revolutionary change within the most traditional and backward of industries", agriculture, and arguably regrouped the most productive and innovative scientists working on green biotechnology[591]. These scientists dropped the so-called "antisense gene" (a gene constructed backwards that prevented the first sequence of DNA from achieving its purpose) into tomatoes, extending their shelf life considerably. The gene got the name of "Flavr Savr" and it became a new marketable product that would be very publicly pushed by the company in the name of its revolutionary nature, while other actors would continue their R&D more discretely. However, the company remained focused on molecular biology, and was not successful in understanding the needs of plant breeding, "thinking they could simply find a variety, splice in the gene and plant it"[592]. The molecular innovation model needed a complementary friend to survive the market and rise to the challenges of agricultural production. This need counts as one of the prime motivations lying behind the important re-structuring that would be witnessed in the molecular seed industry. Calgene ended up being gradually bought by Monsanto.

The collision tickled by the genomics revolution would indeed translate into a **radical movement of mergers and acquisitions,** also coupled with moderate restructuring trends such as strategic or research alliances and joint ventures. The motives behind this movement have been numerous and studied in depth throughout all academic disciplines[593]. They can nonetheless be essentially attributed to the need to supplement product pipelines, enhance research and development capability, and ultimately achieve wider market control. The evolution has in this context been two-fold in the seed sector, respectively through horizontal integration, by means of mergers operated within the same level of the production chain, and through the vertical integration of local small-scale seed companies providing for market-ready and geographically adapted varieties, ajar for biotechnological trait enhancement[594]. At the **horizontal level,** the main actors of the new seed industry started to rapidly acquire their competitors, in order to consolidate costs, extend their sphere of influence or even use this commercial strategy as a pre-emptive tool to defend their own valuable assets[595]. Studies have shown that the specificities of the agricultural biotechnology sector have opened the doors to this intensive take-overs race in their own right. Indeed, the high sunk costs, i.e those expenditures impossible to recoup, rendered market entry and exit extremely

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[591] DAN CHARLES, *Lords of the Harvest: Biotech, Big Money and the Future of Food*: Perseus, 2002, p.127 (as well as the entire chapter 110: "The Tomato That Ate Calgene").
[592] *Lords of the Harvest: Biotech, Big Money and the Future of Food*: Perseus, 2002, p.141.
[593] See for instance JEREMY RIFKIN, *The Biotech Century: Harnessing the Gene and Remaking the World* New York: Penguin, 1999., and J. OEHMKE et al., "Agricultural Biotech R&D Structure: Cyclical or Not?," in *The Regulation of Agricultural Biotechnology*, ed. ROBERT E. EVENSON and V. SANTANIELLO, Cambridge: CABI Publishing, 153-160.
[594] N. KALAITZANDONAKES and B. BJORNSON, "Vertical and Horizontal Coordination in the Agro-Biotechnology Industry: Evidence and Implications," *Journal of Agricultural and Applied Economics* 29, no. 1, 1997: 129-139.
[595] The horizontal dimension of the firm refers to the production scale in a single-product chain or its scope in itself; the desire to merge with competitors has been mainly attributed to the desire to exercise monopoly power, eliminating the dissipation of profits due to competing products. See JEAN TIROLE, *The Theory of Industrial Organisation*: Massachusetts Institute of Technology, 1988, 17-18. (translation of *Concurrence Imparfaite*); but also Oz SHY, *Industrial Organisation: Theory and Applications*, Massachusetts Institute of Technology, 1995.

costly for new players[596]. In parallel to such horizontal growth, a **wave of vertical absorptions of small-scale seed companies** concomitantly took place to the advantage of the newly formed giants. Vertical integration ensured that both the biotechnological capacity and the knowledge of the seed industry and process of breeding were combined in the same hands. As the demise of Calgene illustrated, the success of plant genetic engineering continued to depend upon an extremely solid base of conventional plant breeding. Breeders had to develop the stable and commercially successful varieties upon which the new technology was to be applied. Additional rationale has also been pinpointed to justify this phenomenon of vertical integration, namely the complementarity and substitutability of seeds and chemicals, making it more profitable for companies to enclose both production capacities[597]. The move was also corroborated to a certain extent by the regulatory changes regarding intellectual property protection, in order to constitute complete portfolios and avoid unsecure licensing deals[598]. Through this vertical integration movement, "trait developers have gained access to germplasm by acquiring seed companies with breeding programmes", while "historically, most germplasm developers [had been] independent from trait developers", to directly quote an industry giant, Dupont / Pioneer Hi-Bred International[599]. The core difference between the results of conventional plant breeding activities and so-called genetic engineering continued to lie within the premise that the former does not and cannot manipulate or alter the genetic integrity of organisms as the latter proposes to. However, the distinction between these two sectors was to become blurrier, as the commercial success of genetic engineering generally presupposed the existence of a successful cultivar obtained through conventional plant breeding, within which the biotechnology-derived trait enhancements would be incorporated[600].

Whichever the strategy or specific action path viewed fit to achieve higher market share, the final result of this changing industry structure has been the creation of an enormous 'life-sciences' complex, realising not only economies of scale but also that of scope, enclosing several product pipelines within its walls[601]. Even though the “life science” model is seemingly showing cracks today, as pharmaceutical giants have gradually divested themselves of their green biotechnology legs, both the **highly specialised and oligopolistic nature of the biotechnology market** are undeniably established. Whether reinforcing the oligopolistic structure resulting from the integration waves, or rather expanding them into the public realm, new external linkages are now

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[596] M. FULTON and K. GIANNAKAS, "Agricultural Biotechnology and Industry Structure," *AgBioForum* 4, no. 2, 2001: at 138 and 142-143.

[597] "Agricultural Biotechnology and Industry Structure," *AgBioForum* 4, no. 2, 2001: 144-145.

[598] It should however be noted that intellectual property rights have multiple effects on industry structure, depending on their scope and exploitation power. Indeed, well-defined intellectual property rights have shown to push for less vertical integration, favouring strategic alliances through licensing arrangements, with more flexible access to protected material. However, when rights have been found to be fuzzier or less clear-cut, companies have mostly preferred to buy companies as such rather than licensing material or technology to them; "Agricultural Biotechnology and Industry Structure," *op.cit.*, 145.

[599] "Comments of DuPont / Pioneer HiBred International Regarding Agriculture and Antitrust Enforcement Issues in Our 21st Century Economy", available http://www.pioneer.com/CMRoot/Pioneer/media_room/DuPont_DOJ_USDA_Comments.pdf (accessed January 2011), p.7.

[600] JORGE FERNANDEZ-CORNEJO, "*The Seed Industry in U.S. Agriculture: An Exploration of Data and Information on Crop Seed Markets, Regulation, Industry Structure and Research and Development*", United States Department of Agriculture, Economic Research Service, Washington D.C., 2004.

[601] "*The Seed Industry in U.S. Agriculture: An Exploration of Data and Information on Crop Seed Markets, Regulation, Industry Structure and Research and Development*", United States Department of Agriculture, Economic Research Service, Washington D.C., 2004.

emphasised by the biotechnology industry, favouring agreements with competitors, research agreements with universities, and investments in the capital stock of other biotechnology firms[602]. The industry consolidation of the industry has as a result without a doubt dramatically altered germplasm exchange opportunities. It consequently yielded a hefty impact on the deepening gulf between existing differences in stages of economic and human development, all the while contributing to the demise of the Gene Revolution's reach.

6.3. Opportunities for genetic diversity management veiled by concentration and distribution concerns

The biotechnology revolution holds much wider-reaching goals than plant improvement and productivity vis-à-vis agriculture. It comes across as a "broader technological transformation that is galvanising changes in the social organisation of all production processes in which organic substances or life forms play a significant role"[603]. Rightful or not, it has triggered messianic discourses as the sole solution to eradicate hunger and effectively feed our growing population under growingly more stressful cultivation conditions. Although the potential benefits of biotechnology science in terms of amplifying and conserving gene pools are almost unanimously flaunted, the actual reach of this development has been undermined by a variety of factors. These factors stem from ethical grounds, scientific knowledge itself, and also from the institutional organisation having surrounded the development of Gene Revolution and the distribution of its products[604].

6.3.1. *A Revolution of Unprecedented Environmental and Socio-economic Reach*

The product development possibilities offered by both molecular biology tools and genetic engineering demonstrate a major strength of the 'gene revolution': its potential contribution to biodiversity conservation, as well as its geographical and socio-economic reach. Classical quantitative phenotypic analysis continued to constitute the backbone of breeding programmes, as a framework upon which tools stemming from genotypic analysis have been appended[605]. However, biotechnology stretched characterisation efforts achieved by early collectors of biological material of the 19th century further away. It surpassed phenotypic observation experiments symbolising the 20th century and left almost no secret so as to the composition of germplasm. The advances witnessed in the field of plant molecular biology possess in this regard tremendous potential as to the **conservation of plant genetic resources**, through new storage methods and a greater understanding of biodiversity. By digging deeper into the organism, genomics science and the biotechnology revolution further informationalised genetic resources. Molecular biology has created a new kind of germplasm collector, focusing chiefly on the molecular level of genes, alleles, traits and their possible enhancement. The gene revolution has accordingly fully transformed genetic resources into sources of decipherate information, with

[602] ASHISH ARORA and ALFONSO GAMBARDELLA, "Complementarity and External Linkages: The Strategies of the Large Firm in Biotechnology," *The Journal of Industial Economics* 38, no. 4, 1990: pp.361-379.
[603] KLOPPENBURG, *First the Seed: The Political Economy of Plant Biotechnology 1492-2000, op.cit.*, 193.
[604] Indeed, neither are the genes behind valuable agronomic traits and their interaction not yet completely mastered today, nor are we able to accelerate the actual breeding process or increase the limited number of genes that can be dealt with per transformation event; see (Bingham, 1983; Gepts, 2002; Goodman, 2004).
[605] BRUCE WALSH, "Quantitative Genetics, Genomics and the Future of Plant Breeding," in *Quantitative Genetics, Genomics and Plant Breeding*, ed. MANJIT S. KANG, Oxon: CABI Publishing, 2002, 23-32.

simultaneously corporeal and informational compounds, striving away from a mere form of matter. Indeed, "what begins as a thick, messy whole organism (something unquestionably corporeal in form), [becomes…] progressively decorporealised, existing as a body of information"[606]. It is precisely the use of DNA sequencing or genetic marking technologies that have progressively led to such de-corporealisation, granting them both material and informational features[607], while also opening the door to new appropriation mechanisms. As a result of this new reign of information, resources shifted from traditionally observable phenotypes into abstract genotypes. Collection interests also extended deep to the level of microorganisms, especially crucial to the development of specialty enzymes. Genetic resource collections attributed to conventional sexual hybridisation techniques were mainly concerned with a variety in itself, seeing it as a whole organism, thus paying prime attention to those locally adapted, primitive and traditional landraces. Molecular biology re-shaped these collection endeavours so as to target individual genes, re-enlarging the focus of bioprospecting[608]. Bearing in mind the fact that a breeder's major objectives usually remain embedded within a single gene, allele or quantitative trait loci, conferring the plant with the sought-after tolerance or resistance to specific external or internal stresses, the emphasis of genetic material collections shifted towards those wild relatives, which could hold genes now able to show all their worth. Molecular researchers can indeed better take advantage of wild relatives' potential, especially when tackling issues like disease resistance and stress tolerance, just like rye's traditional tolerance to frost and cold, which researchers attempt to ultimately move to wheat varieties, who sensibly suffer in colder climates[609]. It is in this context that the biotechnology revolution has enabled researchers and breeders to understand and exploit genetic resources to the best of their abilities and potential, enlarging the opportunity for biodiversity creation and conservation, but also its extensive exploitation.

Besides its undeniable contribution to biodiversity conservation and the enhanced use of genetic variability, the Gene Revolution's product range also holds **great environmental, social and economic promises**. Biotechnology related innovations bear the promise of reducing the environmental pressure of agriculture through the products offered to farmers and consumers. Growing GMO's developed and commercialised today can for instance reduce the use of chemicals; even though there is tremendous unutilised potential to fight environmental risks such as desertification, soil erosion or salinisation[610]. The Gene Revolution may also actively be an essential component of food security and malnutrition related strategic actions, as epitomised by the research of the West African Rice Development Association ("WARDA") on a cross- breed

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[606] PARRY, *Trading the Genome: Investigating the Commodification of Bio-Information*, *op.cit.*, at 68.

[607] Through DNA sequencing for instance, the engineered sequence drawn from the examined genetic resource has simultaneously a corporeal and informational aspect. The sequence remains a form of matter (the nucleotides found in the gel) but is also a source of decipherable information that is converted into an archive of data and text, i.e. pure information. *Trading the Genome: Investigating the Commodification of Bio-Information*, *op.cit.*, 64-69.; where the author argues that technological advances such as portable cryogenic storage chambers, tissue-biopsy, digital imaging and DNA extraction, amplification and sequencing have completely transformed the collection, transportation and use of biological materials.

[608] W.J. PEACOCK, "Molecular Biology and Genetic Resources," in *The Use of Plant Genetic Resources*, ed. A.H.D. BROWN, et al., Cambridge International Board for Plant Genetic Resources, Cambridge University Press, 1989, pp. 363-376 (at 363-364).

[609] ANGELA LOVELL, "Researchers Are Discovering New Genes to Increase Tolerance to Disease and Environmental Stress," *Germination*, 2013.

[610] FUKUDA-PARR, "Emergence and Global Spread of Gm Crops: Explaining the Role of Institutional Change," *op.cit.*

easier to harvest by hand, set in motion through embryo rescue technology[611]. Furthermore, biotechnology does not necessarily rely on existing agricultural production schemes. It does not necessitate the same kind of knowledge vis-à-vis irrigation techniques or specific farm management training as for the cultivation of hybrids, but rather has the potential to adapt itself directly to challenging cultivation scenarios, such as extremely dry regions, potentially spreading even to the most remote areas of least-developing countries. Alongside the complex balancing discourse needs mainly attached to genetic engineering, biotechnology has also brought about uncontested positive progresses. Indeed, by shortening the life-cycle of breeding programs, molecular research tools also contribute actively to bringing socially, economically or environmentally interesting plant varieties into the market. The efficient recourse to haploid technology for instance shortens research time-span approximately by three to even four years, if used together with greenhouse and contra-season production[612]. Most of the pro-poor rhetoric used in favour of a positive correlation between the recourse to genetically engineered crops and poverty reduction do nonetheless favour a reductionist Malthusian argument that focuses on the need for more productive technologies to rise to the challenge. Even if this stance needs to be alleviated by recognising that hunger and poverty are much more complex notions that also are "an outcome of unequal entitlements to food", productivity growth still remains critical to achieve these goals[613]. The bottleneck lies here in assessing whether or not the products of the Gene Revolution are the sole responses for productivity, without falling into simplistic syllogisms.

6.3.2. <u>Tainted by Scientific and Institutional Shortcomings</u>

The grand promises of green biotechnology need to be alleviated, and "the messianic fervour of […] proselytes of transgenesis should strike a note of caution"[614]. The active choices in the development of genetically modified crops, with a clear emphasis on herbicide tolerance products, have received **acute criticism**. Notwithstanding the populist and ethical controversies over the final products of transgenesis, accusing "Frankenfoods" of "genetic pollution", and playing on inherent public reticence vis-à-vis obscure scientific experiments done behind the closed doors of underground laboratories[615], green biotechnology has in practice not lived to its real potential. Indeed, the range of possibilities offered by transgenesis do not reflect the reality of the research that is currently been undertaken and commercialised, since most of product development endeavours still tend to focus on herbicide tolerance[616], as well as pest and disease resistance[617].

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[611] DOMINIC GLOVER, "*Biotechnology for Africa? Democratising Biotechnology: Genetically Modified Crops in Developing Countries*", Institute of Development Studies, Brighton, available at http://www.ids.ac.uk/biotech 2003.
[612] LOVELL, "Researchers Are Discovering New Genes to Increase Tolerance to Disease and Environmental Stress," *op.cit.*
[613] BHARAT RAMASWAMI and CARL PRAY, "India: Confronting the Challenge - the Potential of Genetically Modified Crops for the Poor," in *Emergence and Global Spread of Gm Crops: Explaining the Role of Institutional Change*, ed. SAKIKO FUKUDA-PARR, London: Earthscan, 2007, p.158.
[614] MURPHY, *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*, *op.cit.*, p.159.
[615] We shall purposefully leave aside the ethical debate over the acceptable nature of transgenesis products aside, focusing rather on their socio-economic and technological contextualisation and the legal needs of its innovation chain; even though the social rejection of this technology undoubtfully has a major impact on its adoption and development; see notably RIFKIN, *The Biotech Century: Harnessing the Gene and Remaking the World*, *op.cit.*
[616] Indeed, herbicide tolerance has consistently been the dominant trait followed by insect resistance (biotic stress) from 1996 to 2003 in commercialised GM crop varieties; see CLIVE JAMES, "*Global Status of Commercialised Transgenic Crops:*" International Service for the Acquisition of Agri-Biotech Applications (ISAAA) Briefs no.30, Ithaca, New York, 2003. In 2004, over 70% of all hectares planted to GM crops included the herbicide resistant trait,

The reasons behind such narrow focus are manifold. First and foremost, they revolve around **scientific and technical shortcomings.** Indeed, it is inherently difficult to determine the sequences that should be moved in terms of utility and interest, and to operate the move swiftly within another organism, at the exact desired spot, even though all genes may theoretically be isolated and transferred into all organisms[618]. In oil crops for instance, the grand aspirations advocating the engineering of 'designer crops' capable of "producing any type of carbon-based product [ranging from pharmaceuticals, biodegradable plastics to vitamin-rich edible oils)…] have taken far longer than any of the [scientists] had imagined"[619]. The difficulty to transform the biotech potential into a concrete product responding to an actual plea for the fields or shelves considerably lowered the revolutionary reach of the Gene Revolution. Transgenesis' utility thus remains limited to those breeders that are not on a tight budget; work with well characterised material and on relatively simple traits regulated by a small number of genes, such as pest resistance[620]. Moreover, when commercialised, these products have had extremely virulent detrimental **social and economic consequences** on farmers, sowing the dramatical "seeds of suicide" on account of the sharp increase of seed prices, along with the undetachable agrochemicals to be sprayed to obtain the promised results[621]. These realities have triggered important national, regional and even global mobilisation against the products of transgenesis, shifting towards a wider debate on the politics, values and future of the agrarian society towards perhaps greater food sovereignty, in a context of farmer "indebtedness and increasing reliance on credit and loans from traders and seed companies"[622]. In this context, the development of Round-Up Ready soybeans in the United States is considered to have "nothing to do with improving the nutritional properties or commercial value of the bean […but] rather signals the increasingly monopolistic impetus of corporate efforts to enrol the seed into other product lines"[623]. This strategy of forced combination of both seeds and herbicide has been coined "accumulation by dispossession"[624], ringing alarm bells over the missed opportunity for biodiversity conservation or food security gains theoretically offered by the technology.

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according to an international study commissioned by the Secretariat of the Convention on Biological Diversity; see LAIRD and WYNBERG, *op.cit.*, 2008.

617 Such is the case in Europe; see for instance the study done by the Joint Research Centre of the European Commission within researchers operating in Europe, which shows that most researcher is done with regards to biotic and abiotic stress resistance (30 per cent of interviewees in applied research, while only 10 per cent focused on herbicide resistance); see M.VEGA and L. BONTOUX, "*Current Activities and Trends in Plant Biotechnology Research in Europe*", European Commission, Joint Research Centre, Luxembourg, 1998. .

618 KLOPPENBURG, *First the Seed: The Political Economy of Plant Biotechnology 1492-2000, op.cit.*, 298-299. pp. 298-299.

619 MURPHY, *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*, *op.cit.*, p.161.

620 *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*, *op.cit.*, p.48.

621 See for instance the virulent prose of VANDANA SHIVA et al., *Seeds of Suicide: The Ecological and Human Costs of Globalisation of Agriculture*: CAB International, 2000., exploring the suicide rates amongst farmers using Bt Cotton in the in Andhra Pradesh, Karnataka, Maharashtra, and Punjab regions of India.

622 IAN SCOONES, "Mobilizing against Gm Crops in India, South Africa and Brazil," *Journal of agrarian change* 8, no. 2-3, 2008., examining the movements born in India, Brazil and South Africa, along with the global linkages between these national initiatives in the backdrop of political and economic transition.

623 SARAH WHATMORE, *Hybrid Geographies: Nature, Cultures and Spaces* Thousand Oaks: Sage, 2002, p.130., cited in MICHAEL MASCARENHAS and LAWRENCE BUSCH, "Seeds of Change: Intellectual Property Rights, Genetically Modified Soybeans and Seed Saving in the United States," *Sociologica Ruralis* 46, no. 2, 2006: p.133.

624 HARVEY, *The New Imperialism, op.cit.*; the strategies of life sciences have in this regard also been analysed as an "empire-making" attitude striving to increase the power of "metropolitan centres of science and technology"; SHEILA JASANOFF, "Biotechnology and Empire: The Global Power of Seeds and Science," *OSIRIS* 21, 2006: pp. 273-292.

The **newly oligopolistic character of the agricultural input market** greatly contributed to the criticism waves plundering the Gene Revolution. Merely looking at the end of the 1990's to the beginning of the 21st century, the rate of integration and consolidation has been vertiginously swift, generating disturbing figures with regards to market control, fifty five per cent of which was in the hands of merely ten companies in 2008[625]. These figures have not only propelled hostile civil society movements and the instauration of 'watchdogs'[626]; they have also cost the industry's major players to be on many States' anti-trust red lists[627]. The potential censure of competition law against these structures is also heightened by anti-trust cases that have been filed by competitors, especially in the district of Saint Louis[628]. In parallel to the oligopolistic tendencies of the seed and agricultural biotechnology market, an even more radical concentration has indeed taken place in terms of **'trait ownership'.** This idiom would have been impossibly hard to fashion by Gregor Mendel. However surprising this trend may be, it was a natural and most often hidden consequence of the restructuring of the seed industry on the flow of germplasm, and the resulting artificial organic unity created between germplasm and trait developers. The concentration levels in the ownership of genes that contain enhancement traits are believed to actually be higher than those pertaining to the merger movement in terms of company and equity control. However, these levels remain extremely difficult to objectively quantify due to the commercial and private nature of the transactions. Information has nonetheless been made available by companies themselves, such as the undisputable leader in trait ownership, Monsanto, which confirmed its ninety eight per cent monopoly on herbicide tolerant soybean biotechnology seed traits in 2009, as well as its sky high shares in corn and other stacked traits[629]. It has also been shown that the market for biotechnology traits developed for cotton seeds was more concentrated that the cotton market itself, as merely three companies provided for traits, with extremely uneven distributional share between these top competitors, their leader maintaining more than ninety per cent of traits[630]. Most of the official data stems from patent ownership evaluation, which is easier to establish with exact certitude. Accordingly, the USDA has announced that the aforementioned mergers of the 1990's did in fact generate a heavy concentration of patent ownership in the agricultural biotechnology sector[631]. The 2003 study showed that the top ten patent assignees controlled over

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[625] LAIRD and WYNBERG, *op.cit.*, 2008.

[626] See for instance the Action Group on Erosion, Technology and Concentration, who have published a report in 2000, entitled "The Seed Giants: Who Owns Whom", TECHNOLOGY AND CONCENTRATION ACTION GROUP ON EROSION, "*The Seed Giants: Who Owns Whom*", available at http://www.etcgroup.com, 2000.

[627] Anti-trust cases have crowned newspapers' editorials as of 2003, see David Barboza's article for the New York Times, "Judge allows Antitrust case against seed producers", dated 24 September 2003, available at http://www.nytimes.com/2003/09/24/business/judge-allows-antitrust-case-against-seed-producers.html or Peter Whoriskey's on "Monsanto's dominance draws anti-trust inquiry", Washington Post of 29th November 2009, available at http://www.washingtonpost.com/wp-dyn/content/article/2009/11/28/AR2009112802471.html.

[628] Cases were indeed filed by Dupont and Monsanto in Saint Louis, and have interestingly been dropped in the context of a new licensing agreement in soybean technologies signed in march 2013 between these two competitors, see http://www2.dupont.com/media/en-us/news-events/corporate-news-releases.html

[629] Indeed, the company asserts that it possesses 86% share of herbicide tolerant corn traits and 83 % of stacked corn traits; see Monsanto, *Supplemental Toolkit for Investors*, June 2009, which had been available at http://www.monsanto.com/pdf/investors/supplemental_toolkit.pdf. The evolution of these figures is interestingly not found in the company's 2011 Investor Toolkit, which focuses on market share in terms of acreage, yield and product price.

[630] See the illustrations in B. FREESE, "Cotton Concentration Report: An Assessment of Monsanto's Proposed Acquisition of Delta and Pine Land," ed. INTERNATIONAL CENTRE FOR TECHNOLOGY ASSESSMENT CENTRE FOR FOOD SAFETY (Washington D.C2007), 8-9..

[631] JOHN KING and PAUL HEISEY, "*Data Feature : Ag Biotech Patents: Who Is Doing What*", http://webarchives.cdlib.org/sw1vh5dg3r/http://ers.usda.gov/Amberwaves/November03/DataFeature/, 2003

half of the patents that were issued before the year 2000. Tracking actual germplasm movements, as well as determining the actual extent of structural, organic and collaboration-based linkages between the different actors of the private industry became an incredibly difficult task. Figures do tend to corroborate the oligopolistic nature of the seed market and the near-monopolistic structure of the biotechnology traits market[632]. These figures have indeed impelled competition authorities to carry out more stringent analysis of gene ownership in merger applications, which has led to the conditional acceptance of certain acquisitions, whereby the availability of germplasm or genomics processes to competitors had to be ensured for specific periods of time[633]. Besides the civil society reaction impelled by these dominant positions, they have also created tensions within the private sector itself, between those conventional breeding- rooted companies and those derived from biotechnology enhancement trait development, but also within the latter companies themselves, anxious to the sight that one company is established "as the gatekeeper to future innovation in biotechnology and germplasm improvement, and as the sole arbiter of the new products that become available to farmers"[634].

Even though the concept of the 'life-sciences' company has started to show signs of slowing down and compartmentalisation vis-à-vis the agricultural production pipeline, the impacts of the high levels of both vertical and horizontal integration have been extremely detrimental. The institutional features of the Gene Revolution threaten the health of the sector in terms of competitivity, deteriorating the prospects of equity within the private sector itself, but also abate those prospects of equity with regards to farmers of both the developed and the developing world. The relationship between farmers and breeders, which had already been shaken up by Mendelian genetics, has received yet another wound through the increased recourse to plant genomics and the rise of impenetrable multinationals.

CONCLUSIONS: Recombining DNA, trading genetic traits and forming oligopolies

The infusion of molecular biology into plant improvement has ignited a new age of "gene hunting", next to the age-old specimen selection on farm on the one hand, and variety development through controlled crosses and field trials on the other. Even though all of these methods remain valid and efficient for crop innovation, they have been re-shaped by the advent of molecular research tools, offering preciseness and saving precious time, culminating in the even more complex reality of genetic engineering. Shortening the timeframe for the development of new varieties and adding much-acclaimed precision into the breeding process, biotechnological innovations have effectively revolutionised crop improvement. They have generated new genetic variation that could not be foreseen in the past, thanks to genetic engineering or somaclonal hybridisation methods. Molecular biology techniques have also indirectly expanded the universe

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(November). ; cited in MURPHY, *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture, op.cit.*, p.176.

[632] See for instance the graphic put forward by Philip H. HOWARD, whereby Monsanto finds itself in the centre of the cross-licensing agreement game, see PHILIP HOWARD, "Visualising Consolidation in the Global Seed Industry: 1996-2008," *Sustainability* 1, 2009: at 1279.

[633] Monsanto had thus to make corn germplasm available to other actors of the private sector after its acquisition of Holden in 1997, and make its plant transformation technology available to the University in California, see D. SCHIMMELPFENNIG, C. PRAY, and M. BRENNAN, "The Impact of Seed Industry Concentration on Innovation: A Study of Us Biotech Market Leaders," *Agricultural Economics* 30, 2004: at 159.

[634] "Comments of DuPont / Pioneer HiBred International Regarding Agriculture and Antitrust Enforcement Issues in Our 21st Century Economy", *op.cit.*, p.11-12.

of plant breeding on account of tissue culture opportunities, screening and diagnostic tools, or the support of molecular markers in conventional controlled plant improvement. Biotechnology has in this regard given breeders the possibility to develop new varieties faster, controlling the outcome of crosses with more acute precision through a deepened analysis of germplasm. The possibilities offered by molecular biology applied within conventional plant breeding efforts led to a race towards the development of molecular research tools, and not "solely" plant varieties or breeding techniques. While more "passive" molecular biology tools have been extremely useful in reducing the effects of unwanted genes, genetic engineering has increased the expression of desired traits in organisms that would not carry them.

These influxes have been accompanied by an important re-organisation of agricultural research and development, as well as crop production cycles, with grand promises and equally grand setbacks, whether at the level of the farm or within the seed industry itself. The expansion of our knowledge of organisms at the cellular level and the new horizons created through their manipulation has created a new institutional landscape. The symptoms of this new innovation context lie in the reign of specialised cutting-edge biotechnological research entities expanding from their initial public habitat into the world of agro-chemicals, and a consequent intensification of horizontal and vertical integration within the new private actors of the seed industry. Germplasm exchange opportunities between competitors were dramatically altered[635] in the face of oligopolistic mega-structures relying heavily on the new market for trait development rather than variety development[636]. The socio-economic and institutional features of green biotechnology thus bear fundamentally differences with conventional breeding activities. Indeed, there are today merely a few entities capable of investing billions into research programmes with uncertain outcomes, developing a viable and interesting product, getting its market approvals and then commercialising it. On the other hand, plant breeders who do wish to, and financially can take advantage of the "simpler" yet extremely effective tools offered by molecular biology are numerous and diversified around the world. The option of molecular breeding still presupposes the access to technology developed outside the traditional realm of plant breeding, obeying to other scientific norms and presupposing different skills, notably in terms of legal and commercial negotiation.

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[635] BOYD, KERR, and PERKIDIS, "Agricultural Biotechnology Innovations Versus Intellectual Property Rights Are Developing Countries at the Mercy of Multinationals," *op.cit.*, 211-232., accounting the rise of seed multinationals, converted from the world of chemistry.

[636] See the findings of LOUWAARS et al., *Breeding Business: The Future of Plant Breeding in the Light of Developments in Patent Rights and Plant Breeders' Rights*, *op.cit.*, who highlight the different income models in plant breeding, relying either on plant variety or trait royalties.

PART II CONCLUSIONS. The Five Categories of Actors of Agrobiodiversity Conservation, Use and Improvement

Undoubtedly creating new horizons for the selection and cultivation of foodstuff, **scientific progresses** have significantly altered farm management, cultivation and plant improvement practices. They have transformed the cycle of variety development, the priorities of agrobiodiversity management, and the actors involved in the provision of primary agricultural inputs. Farmers were the first users, conservers and creators of agricultural genetic resources, selecting best performing individuals in their fields for their own consumption or foodstuff trade. As colonial expeditions ignited tangled and international flows of biological material, genetic resources moved outside the realms of the traditional and informal seed exchange networks set up by farmer-selectors. The plant repertoire that had been domesticated for ten thousand years was thereafter taken on by public botanical gardens and their satellite stations, cultivating and studying exotic germplasm. Mastering heredity on account of scientific developments, these stations morphed into agricultural research centres, quickly engaging into the brave new world of plant breeding. Active breeding endeavours embedded in conscious sexual crossings efforts and phenotypic observations allowed the development of specific characteristics adapted to the desires of farmers or consumers**.** The stable and uniform plant varieties of the Green Revolution enabled farmers to reach astonishingly higher yield and productivity results, calming Malthusian concerns over growing population figures. However, the novel sharp race for industrial efficiency lit up criticism over the uniformisation of production and the socio-economic inadequacy of this Revolution to certain local conditions. Even so, the proficiency of science-based plant variety selection took another exponentially curve with the advent of molecular biology and the invisible world of genetics**.** Molecular research tools such as embryo rescue technology, molecular markers, and other screening or diagnostic tools were infused into plant breeding programmes. This progress caused a remarkable jump in terms of precision and control, and shortened the variety development cycle. In the meantime, the frontiers of sexual crossing and asexual reproduction were pushed further especially on account of genetic engineering. The Gene Revolution, by carving deeper into the genome, abolished (at least in theory) the species frontiers for crop improvement. Plant breeders and molecular research tool developers have been able to build resistances to biotic or abiotic stresses into varieties, all the while dramatically increasing productivity. Throughout these spectactular changes, mass selectors continued to cultivate and select locally adapted landraces, joined by the new generations of institutionalised seed exchange networks and selectors targeting low-input agriculture in the developed world. Methodically controlled crop improvement, and “molecular drilling" have however revised the list of actors involved within PGRFA management, whether at the level of agro-biodiversity use, conservation or dissemination. They redefined responsibilities within the pipelines of variety development, altering relationships within the PGRFA system, in a shaky balance between dependence, inspiration, trust and wariness. They have announced the age of the new agrobiodiversity users directly involved in agrobiodiversity-based innovation.

In this context, **mass selectors**, both in the form of **low-input farmers and gardeners,** observe best-performing specimens on farm and select these individuals for next harvest, and who maintain and develop landraces, i.e. farmers’ variety populations that are extremely well adapted to specific local conditions and for low-input agriculture such as organic farming. They do not solely follow a market-oriented approach, being influenced by social, anthropological or economic considerations, and rely on informal rules of seed exchange. Farmers traditionally reproduced their own means of production, but the revolution of science-based plant breeding propelled the development of farming inputs off-farm, making seeds external commodities. The age-old and locally adapted innovation model of mass selection was excluded from the institutionalisation and professionalisation of breeding activities in the name of productivity, uniformity and stability with a wider reach. The oldest seed controllers, after ten thousand years of variety selection on farm, have gradually become mere variety users and customers to both public and private breeders, and then to the green biotechnology industry, using a technology outside of their reach and control.

However, the reallocations of the crown of seed control did not only affect cultivators. Other actors also had to adapt to the new rules of the game. **Publicly funded conventional breeding or molecular research programmes,** which lied at the forefront of the two major technological strides, continued to develop new varieties and upstream molecular biology research tools mainly through non-market approaches of scientific progress and economic development. Propelled by an understanding of more open or at least less restrictive access opportunities, public research entities active in either plant breeding or molecular biology develop and aim to produce public goods by generating scientific knowledge. They therefore disseminate developed varieties and their research tools openly or with less restrictive appropriative stances, conforming to the informal norms of science. Furthermore, the lines between public good production oriented public research and commercially oriented product development attempts have been blurred by the Gene Revolution and the concomitant dawn of **molecular biology start-ups.** These often initially public entities build nonetheless their business model on the licensing of their often patented technology and research tools such as tissue culture, somatic hybridisation techniques, screening, sequencing and diagnostic tools. They have as a result broken from the traditions of public research concerned with more basic, uncertain and less lucrative knowledge and innovation.

The new molecular approach to crop improvement concomitantly created and altered the **seed industry** itself. In the brave new world of profit-maximisation driven crop improvement, **private conventional or molecular plant breeding entities** methodically observe specimens, consciously select them and deliberately reproduce desirable traits through sexual or asexual variety crosses, within small to medium seed companies. They traditionally rely on phenotypic observation and develop stable, uniform and improved varieties in an eight to ten years' time frame for an approximate cost of two to three million EUR. Private breeders develop stable and uniform varieties, and take integral part in the marketplace within a business plan of seeds and plant varieties' sale, complemented by eventual royalties on breeding material. If they have the capacity to find, license and integrate molecular technology within their own institutional organisation or their research agenda, they may at times rely on molecular research tools for the characterisation and use of genomic information, which are generally developed by highly specialised public entities or private start-ups. In the brave new world of molecular biology, breeders can now develop the same varieties in six to seven years with greater precision but with an increased initial cost of research, even though these expenses may become more cost-effective in the long run.

Entities can take advantage of this last technological stride only if their operating capital is high, or if they can integrate licensed technology. This is where a tear has operated between those entities able to genetically engineer new varieties and those merely licensing molecular research tools inherently designed to be applied within a conventional plant breeding programme, such as screening or diagnostic tools. Genetically engineered products, developed through the insertion of exogenous genes into plants, have to this day only been successfully developed within integrated structures encompassing both the dimensions of conventional breeding and molecular biology capacities, able to meet the extremely high sunk costs of market entry and able to invest more than one hundred million USD for the development of a single trait in a time span of twelve to thirteen years. **Integrated genetic engineering and molecular breeding companies** have been formed to acquire such capacity without having to license molecular technology from third parties. Relying on a market model based on the sale of seeds, but also of correlated products and technology, i.e. traits and techniques, these biotechnology giants collect royalties on both breeding material and molecular research tools.

ACTOR / USER	MASS SELECTORS	PUBLIC BREEDING AND MOLECULAR BIOLOGY RESEARCH	PRIVATE PLANT BREEDERS (SME's)	MOLECULAR BIOLOGY START-UPS	INTEGRATED BIOTECH GIANTS
SCIENTIFIC BACKGROUND	Observation of best-adapted individuals and selection for next harvest, based on multi-criteria analysis in ecosystemic approach	Controlled plant improvement Molecular biology research	Controlled plant improvement through conscious selection and deliberate reproduction of desirable traits (can rely on molecular research tools)	Molecular biology research aimed at the characterisation and more efficient use of genomic information	Widespread use of molecular research tools and insertion of exogenous genes within an existing genetic background
RESULTING PRODUCTS	Non-uniform farmers' varieties, landraces with high genetic variability and local adaptability	Stable and uniform plant varieties Molecular research tools	Stable and uniform varieties meeting producers and consumers' demands (sometimes heterosis, somaclones or haploids)	Molecular research tools (tissue culture, somatic hybridisation, screening, sequencing and diagnostic tools)	Stable and uniform varieties, GMO's or GM events "Traits"(stacked or not) and research tools
MOTIVATIONS	NON-MARKET: anthropo-social, environmental concerns, informal rules of seed exchange MARKET: farming income	NON-MARKET: public goods, economic development (free variety distribution, training), scientific knowledge MARKET? Bayh Dole	MARKET: sale of seeds and plant varieties (royalty on breeding material)	MARKET: sale and licensing of technology (royalty on tools)	MARKET: sale of seeds, traits and techniques: (royalty on breeding material and tools)

FIG.1: Socio-technological Contexts of Application for Innovation relying on the repeated use of Agrobiodiversity

Notwithstanding their positive contributions to the management of environmental stresses or food production and the institutional changes propelled by technological strides, both the revolutionary hybrids of the Green Revolution and the subsequent “pro-poor” biotechnology narratives have been equally tainted by **inherent shortcomings**. The growingly private and increasingly uniform and integrated structure of plant breeding encloses obstacles to the successful use of agrobiodiversity. Defined within the relatively more short-term goals of satisfying end markets or solving technical problems experienced by growers, the growing private nature of agricultural research and development generates numerous concerns. These relate to the fact that private actors have spread beyond the conduct of "near-market" applied research to reach long-term variety improvement, questioning the sustainability of the dominant industrial production model, and leaving crop development destined for population clusters with no market power to the sidelines. Indeed, "the private firm may only value the "monopoly rents that may be acquired from a technological innovation, while [discounting] any future stream of such rents with regard to the expectation of future technological or biological innovation"[637].

Even though the new structure of biodiversity management strikes through its capacity to generate new genetic variability and efficiently use existing diversity, it comes with a blatant lack of regard for *in situ* genetic resource conservation, as important breeding material is either found in the market embodying commercial success, or in gene banks, duly characterised for further research. Even though breeders using conventional or molecular tools do create new and performing genetic diversity, concerns have been voiced over the complete replacement of farmers’ varieties by these new improved models bred in private gene pools. Plant improvement relies on a constant input of agricultural biodiversity, whether it consists of farmers’ varieties exchanged in local markets, landraces accessed through gene banks, wild relatives actively prospected for hidden traits, or those improved varieties commercialised in the global marketplace. Not only these genetic resources need to remain diverse, but the various crop improvement opportunities need also to remain flexible and most importantly, viable, so as to provide this imperative diversity. New genetic diversity management models have also propelled fears of undermining farmers' sustainable livelihoods, while also kindling a growing anxiety over the technological land-locking of a science that had been open to researchers and breeders alike, even within the seed industry itself.

In essence, the (frequently vehement) critiques voiced over modern crop improvement chains clearly reveal that no unique technological responses may feed all existing socio-economic realities and the entire range of needs in national, regional or international agricultural production. Their role and place need to be adjusted according to local specificities, including agronomic considerations but also the level of education and training of farmers and breeders, the economic power of all actors involved, and aspects related to social organisation, regarding for instance feudal practices and land ownership figures. The detrimental impacts of technological breakthroughs in plant improvement, such as new high-yielding varieties or molecular biology tools have been commonly analysed through a political motivational lens, wounded by a much too recent colonial past, as well as the revolution’s technological shortcomings *per se*, and its impact over traditional community constructs. Studies focusing on human development today stress the

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[637] TIM GOESCHL and TIMOTHY SWANSON, "The Social Value of Biodiversity for Research and Development," *Environmental and Resource Economics* 22, 2002.

need to share existing technological knowledge with those countries lagging far behind the development wagon, while taking due account of the strengths and frailty of non-industrialised farmers. Attributing enough regulatory space for the dissemination of knowledge according to the specific needs of the different actors of agrobiodiversity innovation within the currently applicable strong property paradigm could perform this advocated shift more effectively.

PART III ACTOR DIAGNOSIS: IMPACTS OF ENCLOSURE ON AGROBIODIVERSITY CONSERVATION AND USE GROUPS

Agrobiodiversity innovation springs from different agrobiodiversity users, who navigate different socio-technological contexts and have diverging endogenous preferences. From a bird's eye viewpoint, all different agro-biodiversity innovation contexts remain an integral part of any successful use of agricultural biodiversity, and ought thus to be fostered through adequate policies and regulation. These frameworks cannot be uniform, yet rather need to acknowledge the specificities of each innovation context and its particular actors. All plant innovators manage agricultural biodiversity, all the while creating new genetic variability and conserving existing diversity. They do so efficiently in certain respects, and adversely in others. Such assessment would in essence look at the social and economical consequences of the adoption of a specific innovative product or more general agricultural production model. Yet any account of technological change also needs to take due account of the regulatory landscapes and legal environments within which these changes befall[638]. Private plant breeding activities may have kicked off with the dawn of the "hybrid", but they have predominantly intensified and strengthened with the grant of intellectual property rights over plant varieties and biological compounds.

In this context, anxiety has grown stronger over both the **technological and the regulatory land-locking of a science** that had been open to researchers and breeders alike. Studies on the impact of property regimes on research and development were gradually set off, highlighting certain detrimental effects of both science and law-based tools ensuring stronger levels of property and control over seeds[639]. Intellectual property protection has expanded from the market and product development oriented worlds of plant breeding and biotechnology into biodiversity conservation and traditional plant development endeavours[640]. The complex web of the strong property paradigm stands at two levels, first through prerogatives protecting innovators against the misappropriation of innovative products or processes, in the form of intellectual property rights, and secondly to a lesser extent through legislation determining the plant varieties' access to the market, in the form of seed certification schemes. Both mechanisms aim in economic terms to balance static and dynamic efficiency in the production and use of knowledge and correlated natural resources. In their legal transcription, they assign decision rights to an individual or a community, while also allowing for broader opportunities for other actors to use the resource[641].

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638 In contemporary economic theory focusing on systems of innovation, the "legal system" is viewed as a tool propelling or dragging innovation, but also as a factor enabling the complementarity of different sub-levels of innovation systems, whether national or sub-national (CHRIS FREEMAN, "Continental, National and Sub-National Innovation Systems- Complementarity and Economic Growth," *Research Policy* 31, no. 2, 2002. A policy analysis lens, allows on the contrary one to distinguish the effects of legal systems on innovation systems as such, whether the emphasis of regulation is put upon regulation or on litigation, analysing existing influences in terms of freedom of operation, predictability or enforcement of technology; see FRANS VAN WAARDEN, "Institutions and Innovation: The Legal Environment of Innovating Firms," *Organization Studies* 22, no. 5, 2001.

639 See for instance TIM GOESCHL and TIMOTHY SWANSON, "The Diffusion of Benefits from Biotechnological Developments: The Impact of Use Restrictions on the Distribution of Benefits," in *The Economics of Managing Biotechnologies*, ed. TIMOTHY SWANSON, London: Kluwer, 2002., and also LOUWAARS et al., *Breeding Business: The Future of Plant Breeding in the Light of Developments in Patent Rights and Plant Breeders' Rights*, *op.cit.*

640 SUSAN BRAGDON, "*International Law of Relevance to Plant Genetic Resources: A Practical Review for Scientists and Other Professionals Working with Pgr*", IPGRI, Institute for Plant Genetic Resources Rome, 2004.

641 Indeed, "the gain in dynamic efficiency from greater innovative activity [through the privatization of public goods such as knowledge attached to genetic resources] is intended to balance out the losses from static inefficiency from the

However, these mechanisms are flawed, especially when applied to certain actors of cumulative innovation chains such as agrobiodiversity improvement. Formal standards may fail to achieve what they were initially tailored for, i.e. the wide diffusion of technology in the public interest, as their considerable lack of flexibility cannot make room for all existing know-how and products[642]. In a similar fashion, private property rights over intangibles may not persistently make up for static inefficiency and "invite rent-seeking"[643]. If protection is too weak, it may result in "forgone innovation, and if it is too strong, it may sacrifice available benefits from consumer access, in "a poorly struck bargain [that] could slow economic growth to the extent that access to protected technologies is required to induce incremental innovations […], which is how the bulk of innovation occurs"[644].

Different **actors,** who tend to draw to different extents on the public domain, are affected by the enclosure of plant genetic diversity in different magnitudes. The "predominance of traditional intellectual property notions in discussions concerning biodiversity-related innovations has ensured that current regimes neither foster the sustainable management of these resources, nor offer adequate answers to the need to reward the multiple actors involved in their management"[645]. The design of alternative governance frameworks to promote the successful use of biodiversity in terms of efficiency, distribution and fairness, will therefore in our analysis stem from a central interrogation:

> **Does the prevailing property paradigm, characterised by lenient patentability requirements and enhanced plant variety rights protection, adequately cater for the needs of all categories of actors engaged in innovative and sustainable uses of agrobiodiversity?**

National choices in the implementation of the minimum standards set out by the TRIPS Agreement will not and have not been felt in a uniform fashion by all agrobiodiversity users. Both public research initiatives and farmers' innovation have been clearly put to the side-lines by the legal frameworks assigning control rights over genetic resources. Furthermore, the strong property paradigm has clearly favoured the private sector model able to develop or integrate molecular research tools, either in the form of private start-ups or biotechnology giants, pushing those primal seed companies that rather focus on the development of new and improved plant varieties into difficult corners. That is why our analysis will strive to identify with exactitude the adequacy, but also shortcomings and failures of the strong property paradigm on those agrobiodiversity users identified in the previous section as those actors relying on a broadly fenced public domain and the availability of biodiversity to improve upon. Acknowledging that the failures at the level of upstream research permeate to downstream innovation levels, we will as a result first tackle the paradigm's impacts on public research institutes focusing either on plant breeding or on upstream molecular biology research tools (*Chapter 7*). The analysis will thereon focus on private

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underutilization of the knowledge, the underproduction of the protected good" and also from thwarted competition; see JOSEPH STIGLITZ, "Knowledge as a Global Public Good " in *Global Public Goods: International Cooperation in the 21st Century*, ed. INGE KAUL, ISABELLE GRUNBERG, and MARC A. STERN, New York: Oxford University Press, 1999, at p.311.

642 R. HART and P. BUTTRICK, "Intellectual Property and Standards," *Patents World* 72, 1995: pp.26-28.

643 LEMLEY, "Property, Intellectual Property and Free Riding," *op.cit.*, p.1032.

644 MASKUS, *Intellectual Property Rights in the Global Economy*, *op.cit.*, pp.30-31.

645 CULLET, "Property-Rights Regimes over Biological Resources," *op.cit.*, p.658.

conventional or molecular breeding companies licensing improved plant varieties (*Chapter 8*), and then on the eldest yet primordial users and improvers of agrobiodiversity, mass selectors, (*Chapter 9*). Strong intellectual property rights, allowing for less statutory innovation use exception by third parties who wish to cultivate or improve the protected biological information, may indeed very well only respond to the needs of the most recent actors of agrobiodiversity innovation, i.e., integrated and transgenesis oriented large-scaled companies relying on seed and agro-chemical packages as well as technology royalty for their income, and specialised start-ups relying on the exploitation of a strong patent portfolio.

7. CHAPTER 7: PUBLIC RESEARCHERS IN PLANT BREEDING, MOLECULAR BIOLOGY OR BIOTECHNOLOGY

The implementation of the strong agrobiodiversity property paradigm greatly impacts publicly funded individuals and institutions engaged in plant-related research in all its range. It bears significant effects to those researchers active in national or international agricultural research institutes, focusing not only conventional but also molecular plant breeding, as well as those researchers active in universities or other institutes, focusing on the development of molecular research tools. Today, the numerous publicly funded institutions involved in plant improvement are growingly pushed to protect their research, just as they face the growing risks of infringing third party intellectual property rights. Corroborated by *ad hoc* legal regimes and an impetus to find alternative funding sources, public researchers are both confronted to strong property rights that might render the use of certain tools more difficult and costly, while also having recourse to these rights. The rather infamous case of the *Agrobacterium tumefaciens*- mediated or biolistic mediated gene transfer method resonates deeply in that regard. An absolutely crucial enabling transformation method of gene transfer to plant cells, it was developed by the public sector and "in hindsight had the IP rights been reserved for public-sector applications, […but was rather] committed on exclusive terms to commercial licenses"[646]. Public research has indeed also been impulsed to restrict the further uses of their own inventions. The strong property paradigm arguably spread to the public research sector first through the 1980 Bayh-Dole Act in the United States, which allowed public research institutions and universities to seek patent or other protection for innovations carried out under government grants. This trend gained remarkable momentum with the advent of molecular biology, as conventional plant breeding was being "dumped along the wayside as the unfashionable old cousin of genetic engineering"[647]. The direct funds for breeding oriented public agricultural research were drying up and universities replaced "retiring plant breeders with molecular geneticists more likely to produce high-profile journal article"[648], all the while securing royalty income for their institutions. As a result, public researchers encountered a dual stretch, not only having to face and license third party intellectual property rights, but also having to claim and license their own. "If the patent system works as we might presume it had been intended to work in some ideal moment of regulatory history, then techniques and technologies that otherwise might never have been developed will be stimulated and accelerated"[649]. There is unfortunately growling evidence that such premise does not hold true for all, even though certain aspects of the patent paradigm seem to correspond to the needs of public researchers, albeit partially.

The double evolution of being increasingly pushed to apply for patents while having to navigate existing rights does not echo well with the nature of molecular biology and plant breeding innovation, but also with the nature of publicly funded research and the informal norms and underlying objectives surrounding it. In this brave new world, severe shortcomings are

[646] A key patent for Agrobacterium was licensed to Ciba-Geigy (now Syngenta), and the biolistic technology was licensed exclusively to Dupont; see GREGORY D. GRAFF et al., "The Public-Private Structure of Intellectual Property Ownership in Agricultural Biotechnology," *Nature Biotechnology* 21, no. 9, 2003.
[647] KNIGHT, "Crop Improvement: A Dying Breed," *op.cit.*
[648] Ibid.
[649] MAY, "On the Border: Biotechnology, the Scope of Intellectual Property and the Dissemination of Scientific Knowledge," *op.cit.*, p.257.

experienced by all public breeders, whether those focusing on molecular biology, biotechnology or conventional plant breeding. They indeed all in essence first and foremost aim to produce public goods, and not to generate financial gain. Furthermore, they arguably do not entirely rely on past market successes. Nor do they strive to become sectoral leaders by responding to market dictated needs. That is why publicly funded basic and applied researchers have felt the impact of the development oriented patent paradigm on their activities more significantly. The strong product development oriented property paradigm first of all disregards the norms of science that guide public researchers, and which are built on communalism and the widespread and unpecuniary diffusion of innovation. It is also unsuited to address complex and incremental technologies like molecular or conventional plant breeding, as it becomes prone to the creation of patent anti-commons and encloses what should and could in essence not be enclosed too exclusively. In a similar fashion, it also fails to address the cumulative nature of agricultural plant improvement, which means that public researchers and downstream users are more likely to recycle public, common or traditional knowledge.

7.1. Disregard for Science Norms: Communalism and Non Market Valuation

Even though the development of molecular research tools might be seen as an innovation context fitted to strong intellectual property rights, just as much as integrated transgenesis, research endeavours surrounding these tools also bear elements of open innovation systems[650]. Indeed, these tools are still predominantly produced through publicly funded efforts, whether in universities or public agricultural research institutes. In parallel, the development of improved plant varieties or the mere conservation and characterisation efforts carried out by the latter institutes also remains attached to non-market values that do not fit well within a paradigm favouring concomitant or isolated quests for plant breeders' rights and patents. Both molecular biology and plant breeding efforts adopt an acute public goods production perspective, and are grounded on the communal norms of science, with a goal to distribute both knowledge and products as widely as possible.

7.1.1. Addressing communalism, cooperation and the public goods dimension of public agricultural research

Scientific inquisition is governed by several tenets. Norms of science have been identified by building on the major paradigm of the sociology of science and its ethos set up by Robert K. MERTON as an "affectively toned complex of values and norms which is held to be binding on

[650] The term's architect remains Henry CHESBROUGH, who understands innovation as the process of taking a given invention into the marketplace, which is considered open when ideas are able to both flow out of the organisation (whether a corporation or another social entity), and also flow into the organisation which ought to be flexible to new ideas, products and processes. The degree to which such flows operate cannot be equal, and is a delicate balance requiring ad hoc fine-tuning, but it still remains outside of a classical "closed innovation" understanding where success is traditionally understood as "control", and thus relies on an internally fused logic to bring new products on the market; see notably CHESBROUGH, Henry William. *Open innovation: The new imperative for creating and profiting from technology*. Harvard Business Press, 2003., (see notably his "Introduction" and the shift on innovation paradigms). A number of common elements of open innovation have later been developed, focusing on the desire to establish and manage "inter-organizational relationships with customers, competitors, suppliers, public and private research institutions or even seemingly unrelated businesses, with the aim of acquiring additional knowledge and skills for innovation processes, are increasingly seen as an important way for firms to augment their innovation capability", SARKAR, SOUMODIP, and ANA IA COSTA. "Dynamics of open innovation in the food industry." *Trends in Food Science & Technology* 19.11 (2008): 574-580.

the man of science"[651], as well as Michael POLANYI's view of a social system where "scientists, freely making their own choice of problems and pursuing them in light of their own personal judgment, are in fact cooperating as members of a closely knit organisation"[652]. Science tenets have in this context been notoriously codified as those of "cooperation, universalism, disinterestedness, openness and scepticism" by John ZIMAN[653]. These principles are found not only in publicly funded molecular research, but are also endorsed by scientists affiliated with international and national agricultural research institutes. They nonetheless have been considerably drawn aback by the strong property paradigm, and especially its component of patent protection. The actions of public researchers are today fenced by limitations imposed by IPR titles belonging to third parties, as well as the often gruellingly incentivised possibility to claim exclusive rights on their own inventions.

The main precept of publicly funded international and national agricultural research institutes, as well as universities or other public research organisations, remains the emphasis put on the **production of global public goods**. The national and international agricultural research centres having led the Green Revolution evolved in a world without informational property rights, using and distributing improved agricultural biodiversity in an unrestrained fashion. Both exotic and improved crop genetic resources were deemed to be shared by humankind in its most generous definition, and available for all to use for centuries of mass selection, as well as during most of the first steps of controlled hybridisation[654]. The Green Revolution's improved plant varieties produced by public research channels were distributed without proprietary claims, even under the growingly proprietary regulatory framework of first plant patent acts and the increasing number of plant variety protection systems[655]. This open practice also found evidence within the applicable regulatory system, as the wording of the 1983 International Undertaking on Plant Genetic Resources coined agricultural genetic resources the "common heritage of mankind", propelling a peculiar kind of legal appropriation rules[656]. Up until 1999, the fulfilment of food needs was not perceived as a primarily profit-making enterprise, especially by international agricultural research centres[657]. Due to the uncertain nature of early breeding research results and thus of unclear profitable opportunities, global crop improvement and seed distribution networks were still being instigated by the public sector, where research was understood as a public good. In order to

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[651] These norms are "expressed in the form of prescriptions, proscriptions, preferences, and permissions, and they are legitimatized in terms of institutional values" (at p.269); see ROBERT K. MERTON, *The Sociology of Science: Theoretical and Empirical Investigations* London: University of Chicago Press, 1973.

[652] MICHAEL POLANYI, "The Republic of Science: Its Political and Economic Theory," *Minerva* 1, no. 1, 1962: pp.53-74.

[653] JOHN ZIMAN, "Post-Academic Science: Constructing Knowledge with Networks and Norms," *Science Studies* 1, 1996: pp.67-80.

[654] CAROLINA ROA-RODRIGUEZ and THOM VAN DOOREN, "Shifting Common Spaces of Plant Genetic Resources in the International Regulation of Property," *The Journal of World Intellectual Property* 11, no. 3, 2008.

[655] These statues were enacted mostly in the developed world, home to early private commercial endeavours delivering improved varieties, see CARY FOWLER, "The Plant Patent Act of 1930: A Sociological History of Its Creation," *Journal of Patent and Trademarks Office Society* 82, no. 9, 2000., and K. SRINIVAS, "Intellectual Property Rights and Bio-Commons: Open Source and Beyond," *International Social Science Journal* 58, no. 188, 2006.

[656] This axiom has arguably led to the enactment of the broad public domain warranted by the ITPGRFA both for breeding and research, as well as the derogatory regime apportioned by the CBD system for non-commercial research efforts. For the exact reach of such regime, see CULLET, "Property-Rights Regimes over Biological Resources," *op.cit.*, p.655.and also Chapter 11 of this research.

[657] CGIAR, "*Cgiar Center Statements on Genetic Resources, Intellectual Property Rights and Biotechnology*", CGIAR, Consultative Group for International Agricultural Research, Washington, 1999.

improve agricultural productivity, they adapted exotic varieties to different geographies and local conditions, within the far-reaching goals of poverty alleviation and food security procurement[658]. Public programmes were at times also accompanied by free seed distribution schemes. The USDA has for instance distributed up to one point one billion seeds a year from the end of 19th century until the 1920's, free of charge[659]. In accordance with the public good orientation of national and international breeding activities, the distribution of these new varieties was mostly carried out without any proprietary claims until the 1980's. This approach enabled other researchers to work on these new products while allowing farmers to exchange or save interesting varieties[660]. Public agricultural research institutes acted as directors of both the discovery of pure knowledge and its application on the field. In the absence of coordinated state policy on the fate of publicly funded inventions, the ownership of scientific findings and the potential commercial products that may seldom arise from such discoveries indeed traditionally falls under public purview[661].

The technological stride of molecular biology nonetheless increased the commercial potential of basic research efforts. As a result, it warranted **regulatory action for the private appropriation** of research results; the prospect of which also spread to the world of publicly funded research and unsettled the traditional understanding of public good production. The impact of strong exclusive rights over the products or the conduct of public research sprung at the outset from an issue of finance. First the criticism of public expenditure in public agricultural research or even "science", and then its ominous decrease, significantly shaped the path of public researchers. It rapidly infused monopoly seeking into its primeval equation. Provocative stances in the economics of scientific research asserted that government support to scientific endeavours did not lead to economic growth by crowding out private sector research springing from marketplace opportunities[662]. Public funding for biomedical research and applied agricultural research was thereon reconsidered towards lower figures in order to balance the State budget and increase efficiency. As a result, the industry growingly got involved in the design of specific products for the commercial market[663], and increasingly funded research and development projects in universities[664]. The 1980 Bayh-Dole Act considerably contributed to such broadcast first in the United States, and then spread its influence across OECD countries. Designed to promote the widespread use of publicly funded research, the Act allowed universities to patent their inventions and commercialise them, using exclusive licenses if needed[665]. Seventeen years into the implementation of the statute, the total number of patents granted to universities in the United

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[658] For a concise summary of the achievements of public research, especially that of International Agricultural Research Centres (IARC's), See DEREK BYERLEE, GARY ALEX, and RUBEN ECHEVERRIA, "The Evolution of Public Research Systems in Developing Countries: Facing New Challenges," in *Agricultural Research Policy in an Era of Privatisation*, ed. DEREK BYERLEE and RUBEN ECHEVERRIA, Wallingford: CAB International Publishing, 2002, 19-34 (esp. at 25-26).

[659] KLOPPENBURG, *First the Seed: The Political Economy of Plant Biotechnology 1492-2000*, *op.cit.*, pp. 61-63.

[660] The only exception to the absence of ownership claims by IARC's in developing nations is Argentina, see BYERLEE and RUBIN, "Crop Improvement in the Cgiar as a Global Success Story of Open Access and International Collaboration," *op.cit.*, 462-463.

[661] REBECCA S. EISENBERG, "Public Research and Private Development: Patents and Technology Transfer in Government Sponsored Research," *Virginia Law Review* 82, 1996.

[662] TERENCE KEALEY, *The Economic Laws of Scientific Research* London: MacMillan, 1996.

[663] WEBSTER, "Privatization of Public Sector Research: The Case of a Plant Breeding Institute," *op.cit.*, 224-232.

[664] REBECCA S. EISENBERG, "Proprietary Rights and the Norms of Science in Biotechnology Research," *The Yale Law Journal*, 97, no. 2, 1987: at p.178.

[665] Royalties may then be shared with the individual inventors, as an incentive for scientists to seek patents and for industry collaborators to be re-assured when engaging in a research partnership.

States had been multiplied by ten, even though its share remained small compared to the private sector patenting activity[666]. "In 1997, Stanford University received over forty-three million USD from licensing the now-expired Boyer-Cohen patent claiming basic recombinant DNA technology, which represented over half of its total licensing income"[667]. European countries and universities unevenly followed suit through various policies and statutes. These disparate reactions nonetheless spurred a wide variety of extremely critical and poignant essays expressing concerns over the direction of pure scientific research and the increasing "lack of touch with its pure, public-spirited roots"[668].

Granting property rights over research discoveries has indeed been viewed as **anti-thetical to the norms of science,** "undermining a previously shared professional canon of promoting the dissemination of knowledge for the public welfare [on account of] the openness, the free exchange of ideas and information, the free exchange of strains of protein, [and] techniques"[669]. The clearly discernible disinclination to secure patents has a normative component, in that it is thought contrary to scientific norms, since making new observations available to the scientific community for evaluation and extension in further research is believed to facilitate the progress of science[670]. The publicly available nature of research tools has generally been seen as an important driver for innovation in upstream molecular-biology research. Indeed, both the unpatented sequencing technologies developed by Frederick SANGER and Walter GILBERT, and the early public molecular markers, such as RFLPs (restriction fragment length polymorphisms) have been central to "automated genomic research"[671]. Not only the potential uses of molecular biology instruments will most probably be unknown to the inventors, they also are often numerous, and will be developed outside the traditional actor boundaries of the patent system. For instance, RNA-mediated gene suppression mechanisms were successfully developed by multiple actors, and clearly drifted away from the clear and well-defined invention boundaries dictated by a strong patent system[672]. "Traditional scientific norms promote a public domain of freely available scientific information […based on] the view that scientific knowledge is ultimately a shared resource"; they rely on communalism[673].

Within a truly cumulative innovation chain such as plant breeding, the communalised nature of research and development innately surfaces even more virulently, as all agrobiodiversity improvement projects "benefit from the countless small-scale contributions to the prior art by individuals who draw from the public domain to make improvements, […] generating new

[666] BRAHY, "The Property Regime of Biodiversity and Traditional Knowledge: Institutions for Conservation and Innovation," *op.cit.,* p.58.
[667] CAROL NOTTENBURG, PHILLIP G PARDEY, and BRIAN D WRIGHT, "Accessing Other People's Technology for Non–Profit Research," *Australian Journal of Agricultural and Resource Economics* 46, no. 3, 2002., p.390
[668] ROBERT P. MERGES, "Property Rights Theory and the Commons: The Case of Scientific Research," *Social Philosophy and Policy* 13, no. 2, 1996.
[669] Hearings Before the Subcommitee on Investigations and Oversight and the Subcomm. on Science, Research and Technology of the House Commitee on Science and Technology, 97th Cong., 1st Sess. , *Commercialization of Academic Biomedical Research*, 1981. Cited in EISENBERG, "Proprietary Rights and the Norms of Science in Biotechnology Research," *op.cit.*
[670] "Proprietary Rights and the Norms of Science in Biotechnology Research," *op.cit.,* p.182.
[671] CARL PRAY and A. NASEEM, "Intellectual Property Rights on Research Tools: Incentives or Barriers to Innovation? Case Studies of Rice Genomics and Plant Transformation Technologies," *AgBioForum* 8, no. 2-3, 2005.
[672] C. CHI-HAM, K. CLARK, and A. BENNETT, "The Intellectual Property Landscape for Gene Suppression Technologies in Plants," *Nature Biotechnology* 28, no. 1, 2010: pp.32-36.
[673] RAI, "Regulating Scientific Research: Intellectual Property Rights and the Norms of Science," *op.cit.,* p.90.

information that others may exploit to their own advantage"[674]. The communalised nature of research also surfaces in the case of molecular breeding opportunities, which heavily rely on basic or pure research to elaborate new techniques allowing time, efficiency and precision gains in controlled hybridisation. Like the pressures and research needs which propelled the creation of the SNP Consortium in the sequencing of the Human Genome[675], crop improvement research has also relied on partially open institutions for the development of determinant molecular research tools[676]. Molecular biology research tools and isolated biological compounds perhaps best illustrate the challenges of appointing individual exclusive rights to "complex technologies" developed in a communalist perspective. Most, if not all technological breakthroughs in molecular biology have heavily relied upon "highly synergistic environments", drawing extensively from the public domain and from the contribution of numerous actors, knowledge and technologies. Further challenges also stem from the fact that public research organisations' engagement to obtain and exploit exclusive IPR is found to run against or at least weaken the correlated **norms of trust and cooperation** amongst researchers[677]. "Conflicts of interests amongst researchers and changes in the university research environment" were witnessed as early as the late 1990's, as the "patent and trade secret protection desired by industrial sponsors [was] in sharp conflict with the university's desire to maintain an open, academic, public-servant environment"[678]. Yet the new strong intellectual property paradigm has shifted the norms of cooperation in public research, leading to new difficulties in the negotiations and completion of joint projects on account of growingly un-communalised technology transfer offices and policies. While existing IPR titles have been shown useful in the negotiations of new research partnerships by "codifying the discrete quanta of technology that the partners license into the venture, making it easier to keep track of which partner contributed the technology"[679], negotiations have been getting seemingly more complex when public research institutions have been involved in the actual development of new technology. A multi-year and multi-faceted project focusing on the practice of United States-based companies showed that tensions arose more frequently in the negotiation of research joint ventures between commercial firms and universities, due to several issues, including "outrageous demands, the fact that IPR are viewed as significant source of income, that technology transfer offices are inexperienced"[680]. With striking consistency, all respondents to the survey found that universities had become "more aggressive and greedy" over the distribution of exclusive titles. In

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[674] JEROME H. REICHMAN, "Saving the Patent Law from Itself: Informal Remarks Concerning the Systemic Problems Afflicting Developed Intellectual Property Regimes," in *Perspectives on Properties of the Human Genome Project*, ed. F. SCOTT KIEF, Elsevier, 2003.

[675] Single nucleotide polymorphisms (SNPs), are DNA sequence variations that occur when a single nucleotide in the genome sequence is altered. SNP markers are considered useful for genetic mapping and genetic diversity applications in commercial plant varieties, especially with regard to wheat. See CHAO et al., "Analysis of gene-derived SNP marker polymorphism in US wheat cultivars", *Molecular Breeding* 23:1 (2009), pp. 23-33.

[676] A number of these initiatives will be studies in the latter course of this study, especially with regards to the sequencing of the Rice Genome.

[677] JASON OWEN-SMITH and WALTER W. POWELL, "Knowledge Networks as Channels and Conduits: The Effects of Spillovers in the Boston Biotechnology Community," *Organization Science* 15, no. 1, 2004: pp.5-21. The authors"argue that the spillovers that result from proprietary alliances are a function of the institutional commitments and practices of members of the network".

[678] DAVID E. KORN, "Patent and Trade Secret Protection in University Industry Research Relationships in Biotechnology," *Harvard Journal on Legislation* 24, no. 191-238, 1987.

[679] R.P. MERGES, "Intellectual Property and the Costs of Commercial Exchange: A Review Essay," *Michigan Law Review* 93, 1995.

[680] HENRY HERTZFELD, ALBERT LINK, and NICHOLAS VONORTAS, "Intellectual Property Mechanisms in Research Partnerships," *Research Policy* 35, no. 6, 1996.

parallel, similar conflicts over property rights have blocked projects between public research institutes themselves, whether in developed countries or in a North-South dynamic. A notable example of such collapse concerns the Andean strawberry research project led by the University of Davis in California[681]. These phenomena illustrate quite well the discordancy between the norms of science and the strong intellectual property paradigm, which, when upheld by public research organisations, negatively affects the social system of science, while also hampering the conduct and diffusion of research, especially far from the innovation frontier.

7.1.2. Warranting non market research and the dilemma of orphan crops

The traditional disinclination of publicly funded institutes to secure exclusive rights over their innovative plant varieties, products and processes, concurrently stems from another dimension of science norms, having this time regard to the goals of public research innovations and their diffusion. The public goods production perspective embraced by public researchers unquestionably bears a universal perspective. This aversion is not well catered for under the strong property paradigm, which remains dictated around market needs and the subsequent allocations of value. Actors whose research endeavours are fostered by the promise of strong exclusive property rights will solely cater innovation that bears social value in the market itself. As they deliberately and unavoidably rely on market mechanisms, they "exhibit a predictable bias for intellectual goods that generate the most appropriable value in consumer markets", and lead to the underproduction of various socially desirable intellectual goods such as basic research or products destined to smaller markets[682].

These roadblocks raise fundamental concerns, as technology transfers and innovation diffusion remains crucial for the global public goods that are food security and successful agrobiodiversity use. The availability of new improved varieties deriving from the modern biotechnological revolutions could for instance, according to the World Health Organisation, "not only have an important role in reducing hunger and increasing food security, but also have the potential to address some of the health problems of the world"[683]. The international agricultural community, joining the bandwagon, has recurrently rejoiced at the possible redress of Malthusian concerns through technology and classical or molecular biology-based plant breeding[684], pointing out that biotechnology remains a powerful tool in the fight against poverty if efficiently made available to poor farmers and consumers[685]. Notwithstanding the need to consider alternative production systems based for instance on agro-ecology[686], the significant economic development-related potential of biotechnology is at serious risk of realisation today. Such risk is mainly attributed to

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[681] PAUL A. DAVID, "Clearing Patways through the Thickets: Mitigating Anti-Commons Constraints on Exploratory R&D," in *Monte Verità Conference on THE ECONOMICS OF TECHNOLOGY POLICY* (Held in Ascona, Switzerland, June 17-22, 20072007).

[682] BRETT M. FRISCHMANN, *Infrastructure: The Social Value of Shared Resources* New York: Oxford University Press, 2012, pp.109-110.

[683] WORLD HEALTH ORGANIZATION WHO, "*Modern Food Biotechnology, Human Health and Development: An Evidence-Based Study*", World Health Organization, Food Safety Department, Geneva, 2005.

[684] E. DIAZ-BONILLA and S. ROBINSON, "Biotechnology, Trade and Hunger," (Washington D.C.: IFPRI, 2001).

[685] P. PINSTRUP-ANDERSEN and M.J. COHEN, "Modern Biotechnology for Food and Agriculture: Risks and Opportunities for the Poor," in *Agricultural Biotechnology and the Poor: Proceedings of an International Conference*, ed. G.J. PERSLEY and M.M. LANTIN (Washington, D.C., 21-22 October 1999: Consultative Group on International Agricultural Research, Washington D.C., 2000).

[686] DE SCHUTTER, *op.cit.*, 2011.

the property endowment systems that have been purposely built for the harshly competitive globalised seed market and the need to recoup seriously gigantic investments quickly, as well as to the nature itself of informational monopolies as they exist today. Notwithstanding the traditional institutional issues raised by geographic perspectives on the dissemination of technology in the developing world (having for instance regard to the crucial role of diffusion agencies), strong intellectual property rights do not indeed very well accommodate the **international developmental dimension of public research.** Such dimension concerns the conditions that enable the transfer of technology to those found in the margins of the lucrative seed markets, and a specific attention to the type of innovations that are produced.

Those "follower countries", poorest in terms of innovation capacity and neediest in terms of economic development, naturally disadvantaged vis-à-vis competition, are faced with reinforced external obstacles to growth in light of the "proliferation of legal monopolies and related entry barriers", which consign them within their disadvantages[687]. The strong intellectual property paradigm does not indeed trigger the **technology transfer opportunities** it should create in compensation of the artificial monopolies it creates. First, the mere publication of patents or plant variety rights certificates, viewed as a contribution of IPR to the social cost of monopoly rights, may in reality not encourage the diffusion of technical information, considering that this information ought first to be properly understood. Indeed, the stimulation of economic growth based on innovation is not only stimulated by the interaction effect through knowledge spillovers, but also through "learning by doing". Most IP systems broadly rely on tacit knowledge, and thus require that actors engage in more than literature or patent landscape reviews and rather possess "absorptive capacity"[688]. Without this active involvement and strategic prerequisite, the counterbalance of monopolisation will not really contribute and lead to technological progress by third parties. Codified information in IP certificates or even in variety catalogues will indeed not be translated into an exploitable technical advance by "unskilled workers with low absorptive capacity"[689] . The lack of diffusion of innovations far from the innovation frontier may also be a simple question of cost. An example of such phenomenon stems from the patent protection awarded to the biochemical reagent "Taq", an enzyme with heat-resisting properties upon which polymerase chain reaction ('PCR') relies. The fact that the patented Taq polymerase is now 'generic' has now substantially reduced the cost of PCR applications for both the developed and developing worlds, allowing for successful DNA diagnostics, and also identifying the presence of pathogens for further disease prevention or treatment. [690].

Next to the inherent needs to ensure the diffusion of produced innovations, the strong property paradigm also comes hand in hand with intrinsic shortcomings regarding the **production of innovations** itself. Indeed, in the current situation where artificial lead-time contraction has been extended to plant varieties and biological material or processes, "commercial viability, fuelled by financial reward or incentive, and market forces are the factors that determine which agricultural

[687] JEROME H. REICHMAN and KEITH MASKUS, "The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods," in *International Public Goods and Transfer of Technology, under a Globalised Intellectual Property Regime*, ed. KEITH MASKUS and JEROME H. REICHMAN, Cambridge: CUP, 2005.
[688] CHRISTINE GREENHALGH and MARK ROGERS, *Innovation, Intellectual Property and Economic Growth* New Jersey: Princeton University Press, 2010, pp.250-251.
[689] DINWOODIE and DREYFUSS, *A Neofederalist Vision of Trips: The Resilience of the International Intellectual Property Regime*, *op.cit.*, pp.43-44.
[690] DHLAMINI, *op.cit.*, 2006.

crops should be supported by research, and which others are not worthy of research and development effort"[691]. The blatant policy choice to let the private sector penetrate and reign over the once sacred realm of publicly controlled research leads to under-investment in certain types of crops or innovations, driven solely by market needs. "Since the 1930's, immense effort has been put into getting better hybrids, yet virtually no one has tried to improve open-pollinated varieties"[692]. Indeed, plant breeders' rights "generally do not encourage breeding related to minor crops in small markets"[693] or those crops with less substantive profit promises. Scholars have questioned whether it would be "reasonable to expect the research agenda to be geared towards the needs of individuals below the poverty line, as long as most of the research is carried out with a view to develop commercially valuable products"[694]. Under a strictly market-oriented paradigm, the contributions of research shall tend to be directed towards the needs of those close to the frontier of innovation. The goods responding to the needs of the unlucky many who keep (or are kept) far from the innovation frontier, quite dramatically coined "**orphan crops**", will indeed not be produced by the vertically integrated molecular plant breeding innovation chain, lacking proper markets to develop its activities[695]. Strong intellectual property rights may in this context be considered to "favour centralised crops breeding and the creation of uniform environmental conditions, [discouraging] agro-ecological research or local breeding tailored to local conditions"[696]. Innovation without patent pay-offs encloses a serious risk of drying up and undermining the conduct of research in those fields where the commercial or social value of innovation may not be as straightforward as others, such as tropical agriculture or poor regions where farmers lack the financial power to invest in expensive improved seeds. "The pursuit of patent-based monopolies only internalises one facet of reserve value, [that of the private valuation of biodiversity reserves by firms in intermediate good markets]", thereby underestimating by large margins the total social value of biodiversity reserves[697]. Indeed, within a "technological trajectory shaped by the imperatives of private property institutions", the results of research neglect a considerable portion of its objective, as new varieties are not developed to solve the social or environmental problems of those geographically remote and economically frail, like hunger or deforestation, but rather "mostly to increase shareholder values of companies that have invested heavily in R&D efforts in the biotechnology sector"[698]. An increasingly stringent and multilateral IPR system will thus not benefit all countries in an equal fashion, since it is rather the economic and technological levels of development in each country, and the size of its market, that will largely influence who gets to reap the benefits of innovation. This has for instance been the case of the biologically and legally difficult yet commercially attractive enough Asian rice market, which

691 CHIDI OGUAMANAM, "Beyond Theories: Intellectual Property Dynamics in the Global Knowledge Economy," *Wake Forest Intellectual Property Law Journal* 9, no. 2, 2008-2009: pp.33-34.
692 MURPHY, *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*, *op.cit.*, p.124.
693 UNCTAD and ICTSD, "*Intellectual Property Rights: Implications for Development*", UNCTAD-ICTSD, 2003.
694 CULLET, "Intellectual Property Rights and Food Security in the South," *op.cit.*, p.266.
695 SWANSON, *Biotechnology, Agriculture and the Developing World: The Distributional Impacts of Technological Change*, *op.cit.*
696 WALTER A. REID, "*Genetic Resources and Sustainable Agriculture: Creating Incentives for Local Innovation and Adaptation*", African centre for technology studies, Nairobi, 1992.
697 TIMOTHY SWANSON, "Why Is There a Biodiversity Convention? The International Interest in Centralized Development Planning," *International Affairs* 75, no. 2, 1997; "The Reliance of Northern Economies on Southern Biodiversity: Biodiversity as Information," *op.cit.*
698 G. PARAYIL, "Mapping Technological Trajectories of the Green Revolution and the Gene Revolution from Modernization to Globalization," *Research Policy* 32, no. 6, 2003: pp.981-982.

has been targeted by numerous innovative actors[699]. When the market imperative also takes public research hostage in view of income needs and prestige, those institutes, which would have traditionally invested time and money in the development of orphan crops, also "abandon" them. Monopoly-granting intellectual property rights on plant-related innovations have therefore been considered to lead to the misallocation of research expenditures, benefiting the developed world at the expense of those countries continuing their development process[700].

It is absolutely undeniable that the strong property paradigm has effectively permeated the daily life of public researchers in both molecular biology and plant breeding. Exclusive rights nonetheless enter into **stark contrast with the communal social organisation of public research,** oriented towards innovation diffusion and public good production. Current research and development strategies appear more inclined to serve public research institutions' crave of pre-eminence and finance, yearning to win the internal strife to become the best proprietary innovator, while also replacing shrinking public funding through license revenues[701]. Publicly-funded research institutes, which traditionally work towards finding solutions for the agricultural problems of resource-poor farmers in developing countries, have joined the patent race not to be left out from the world research pace[702]. They have been vehemently criticised in this process as "vassals of knowledge corporations, […] serfs of science", receiving meagre rewards for creativity from entities who come to own their ideas, as the new rewards for knowledge creation now convert from "keeping it secret and putting a price on it"[703].

7.2. Startling enclosure of incremental and cumulative inventions

Socially beneficial plant technologies have become increasingly lucrative but also expensive to develop due to scientific developments. They are yet self-replicating in nature and as a result call for regulatory action in order for their 'architect' to better control their fate and recoup the substantial financial investment in their development. This need was answered through intellectual property protection, which has been more or less extensively granted in different regions of the world under the tenets of a strong paradigm. In parallel to the first enclosure movement, identified by eminent commentators as the fencing off of common land, the possibilities offered by IPR to exclude others from using intangible information have been coined the "second enclosure movement"[704]. As aforementioned, this second enclosure transpired in plant improvement as a result of the emulation of need-specific plant variety protection regimes and the accretion of patent protection to cater the needs of biotechnology[705]. This double reality is nonetheless tainted by the inherent flaws of the development oriented patent paradigm to address incremental innovation. Inherently cumulative and incremental innovation such as plant improvement does not indeed produce major leaps forwards extremely often, and relies on a wide array of contributions, from

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[699] BARTON and BERGER, "Patenting Agriculture," *op.cit.*
[700] JIM M. DUNWELL, "Intellectual Property Aspects of Plant Transformation," *Plant Biotechnology Journal* 3, no. 4, 2005: pp.371-384.
[701] BARTON and BERGER, "Patenting Agriculture," *op.cit.*
[702] P.G. PARDEY, B.D. WRIGHT, and C. NOTTENBURG, "Are Intellectual Property Rights Stifling Agricultural Biotechnology in Developing Countries?," ed. INTERNATIONAL FOOD POLICY RESEARCH INSTITUTE (2001).
[703] PETER DRAHOS and JOHN BRAITHWAITE, *Information Feudalism: Who Owns the Knowledge Economy?* London: Earthscan, 2002, p.201 and 218.
[704] BOYLE, "The Second Enclosure Movement and the Construction of the Public Domain " *op.cit.*
[705] CORNISH, "The International Relations of Intellectual Property," *op.cit.*

biological material to processes or other products. Plant variety protection had in this regard been crafted as a “legal hybrid” taking such incrementality of agrobiodiversity improvement into account, even if precariously, while the traditional patent system has remained inherently flawed. The strong property paradigm therefore partially fails to address the allocation of control over sub-patentable innovations, stretching the gauge of ‘inventive step’ to its peripheral bounds. It also fails to address the inherent menace of recycling publicly available knowledge, in both of its dominant facets, i.e. patents and plant variety protection.

7.2.1. Protecting incremental and derivative contributions

New plant varieties, whether improved or traditional, as well as product or process innovations stemming from the application of molecular biology to plant breeding science, are remarkable examples of "deviant fields" in need of fresh paradigmatic legal hybrids[706]. Copyright-like protection fails to apply due to the fact that the protected object comprises of numerous elements that are all related to a specific function or application[707], especially for the various biotechnological tools used within the R&D cycle in the vein of processes or isolated traits. Proprietary rights in the form of patents have thus been seen as an answer to market failures in light of those innovations exposed to reverse engineering, begging for strong exclusivity over the product’s fate, stronger than those offered by the traditional copyright paradigm. However, in parallel with other industries based on complex technology, innovation chains that depend on **'incremental’ contributions rather than 'major leaps forward'** do not find neither sufficient protection, nor provide for adequate access vis-à-vis their research results in today's approach to intellectual property protection. They face inherent shortcomings linked to the overarching characteristics of agrobiodiversity innovation. Indeed, the development of new plant varieties is carried out in a common context of sub-patentable incremental innovation, produced in a cumulative fashion, relying on the work and knowledge of other actors, as well as on numerous research tools.

First and foremost, agricultural biotechnology builds on natural products. Leaps achieved in any steps of plant improvement therefore need to be **stretched to effectively qualify as "an inventive step" beyond existing "prior art"**, and correlatively open the door for exclusive control under the patent paradigm. For instance, bacteria and other expression "vehicles" that are used by biotechnology companies to produce purified versions of naturally occurring proteins will be subject to patents, claiming the purified versions of products that exist in nature.

> “In these cases, it can be argued that it is stretching the concept of inventing greatly to say that the patentee really invented the products. The true invention seems to be found in the method used to produce them in a desirable form. But because a product claim is typically broader than one simply focusing on a particular way of making that product, patentees seek -- and often obtain -- product patents”[708].

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[706] REICHMAN, "Legal Hybrids between the Patent and Copyright Paradigms," *op.cit.*
[707] RAI and BOYLE, "Synthetic Biology: Caught between Property Rights, the Public Domain and the Commons," *op.cit.*
[708] R.P. MERGES and R.R. NELSON, "On the Complex Economics of Patent Scope," *Columbia Law Review* 90, 1990.

The contentious content of the TRIPS Agreement and national legislation, as well as the correlated case-law efficiently demonstrate that patentability standards had to steadily be lowered or at least re-interpreted in order to accept biotechnology and biological research tools within the realms of the patent paradigm[709]. Technological strides with a growingly industrial focus, intensive lobbying and a clear political agenda have shifted the patentability line towards a pole dangerously closer to the fruits of basic research and discoveries, whether having recourse to the shaky notion of "technical step", or having to reconsider what constituted a "person skilled in the art"[710]. The requirement of non-obviousness or of the existence of an inventive step found in all national patent systems indeed theoretically prevents the patentability of living organisms as such, unless the criteria for such patentability are revised towards lower standards[711]. However, enzymes, polymerase or isolated genes have growingly been purified and fallen under patent protection in numerous jurisdictions. Even though the obvious character of most plant-related process innovations is frequently highlighted in the doctrine, the gene products of such methods seem to be treated as non-obvious in the patent paradigm developed rather for the purposes of inanimate and chemical rather than self-replicating biological inventions, creating extensive objections before competent Courts and Patent offices on the damaging spectre of broad biotechnology patents[712].

Furthermore, as is the case with synthetic biology, a sphere that draws inspiration from biotechnology, most of the innovations present in the conventional or molecular plant breeding innovation chains constitute in too many ways a novel recombination of already existing components or varieties to effectively be protected under the patent paradigm, or cover the use of a method that has become routine or widely known[713]. The inherently incremental nature of the controlled improvement of plant varieties leads to the assertion that major leap forwards should be witnessed much rarely than in other more classical fields, such as electrical engineering for instance. Agricultural biodiversity-related innovations are not just knowledge products, the use or acquisition of which not depriving the use of others, but they also first and foremost comprise of a combination of knowledge disseminated in a wide array of informational tools and products produced by other actors. Crop genetic improvement is essentially a **process of derivation**. It is a process where each incremental innovative contribution holds the potential of becoming a commercial product, whether it is realised through plant breeding on account of sexual or asexual crosses, or through various biotechnological techniques. Follow-on innovations or improvements directly derived from an underlying actual creation or invention are the cornerstone of any "cumulative innovation chain", raising critical interrogations as to their degree of appropriability

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[709] RAI and BOYLE, "Synthetic Biology: Caught between Property Rights, the Public Domain and the Commons," *op.cit.*

[710] MAY, "On the Border: Biotechnology, the Scope of Intellectual Property and the Dissemination of Scientific Knowledge," *op.cit.*, p.254.

[711] See for instance the aforementioned Genentech decision of the European Patent Office, where the Office opted for an imperatively restrictive approach to the determination of "notional skilled persons" that had to be gifted with a high degree of ingenuity in the knowledge intensive sector of biotechnology. See Technical Board of Appeal of the European Patent Office, *Polypeptide Expression/GENENTECH*, T 292/85, Official Journal of the European Patent Office 275 (1989)., and MACQUEEN et al., *Contemporary Intellectual Property: Law and Policy op.cit.*, Second edition.

[712] VAN WIJK J., "The Impact of Intellectual Property on Seed Supply," in *Linking Biodiversity and Agriculture: Challenges and Opportunities for Sustainable Food Security*, ed. L. THRUPP, Washington 1997.

[713] RAI and BOYLE, "Synthetic Biology: Caught between Property Rights, the Public Domain and the Commons," *op.cit.*

and control, and thus their optimal treatment[714]. The spreading and cumulative creation of information is duly captured by the example of hybrid corn, a primary innovation which creates directly related information on account of the partially appropriable improved variants of other corn hybrids, while also producing indirectly related and theoretically not appropriable public domain information as to the hybridisation process in itself[715]. This last type of information, coined *stimulative*, epitomises the inherent desire of information to be free, thereby showcasing the inadequacy of patent-like control over the course of cumulative innovation chains[716]. Both phenotypic and genotypic information can indeed be viewed either within the public domain as tools for further research, or as products in themselves[717]. Furthermore, so-called **submarine patents** accompanied by "reach-through provisions" have become increasingly common in the biotechnology industry. They allow for substantive rent extractions at subsequent innovation levels, thereby constituting roadblocks that innovators attempt to circumvent by "diverting scarce research resources from product development to 'reinventing the wheel"[718]. These provisions found in the patent system which enable monopoly owners to collect royalties on subsequent innovations created byusing the patented technology, have been vehemently compared to the eventuality of "a software company demanding royalties from a best-selling author who used its word-processing program"[719]. This trend has been heightened by the broadness of claims in the life sciences. Indeed, "frequently claims refer to nucleic acids or polynucleotides other than DNA—a broadening of language that will include other natural and synthetic polynucleotides that can carry the same information as the disclosed DNA »[720]. This assertion not only holds true for utility or product patents obtained on gene sequences, it also is valid for process patents awarded on foundational molecular research tools. An example of such "reach-through" royalty seeking strategy comes from the Cre-lox technology developed by Dupont, which enables scientists to mark a targeted gene in a DNA sequence, and then cut off said gene from the sequence using a specific enzyme. Instead of generally licensing the pure research tool, "Dupont asked the licensees for full-fledged reach-through rights on the scientific findings reached through experimentation with test animals that were genetically modified using the Cre-lox technique"[721].

All of these worrying realities make the crucial action of « inventing around the patent » essentially close to impossible. Not only is the expansion of IPR and its consolidation inadequate to address the inherently incremental nature of plant innovation, these phenomena are furthermore

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[714] MERGES and NELSON, "On the Complex Economics of Patent Scope," *op.cit.*, as well as MARK LEMLEY, "The Economics of Improvement in Intellectual Property," *Texas Law Review* 75, 1997: pp.1013-1023.

[715] CYNTHIA WAGNER, "The International Agricultural Research Centers: Poised for Change," *Technology in Society* 17, no. 4, 1995: pp.1006-1007.

[716] YOCHAI BENKLER, "Intellectual Property and the Organization of Information Production," *International Review of Law and Economics* 22, 2002: pp.81-107.

[717] YOCHAI BENKLER, *The Wealth of Networks: How Social Production Transforms Markets and Freedoms* New Haven.: Yale University Press, 2006.

[718] PRAY and NASEEM, "Intellectual Property Rights on Research Tools: Incentives or Barriers to Innovation? Case Studies of Rice Genomics and Plant Transformation Technologies," *op.cit.*, p.108.

[719] J. FORE, I. WIECHERS, and R.M. COOK-DEEGAN, "The Effects of Business Practices, Licensing and Intellectual Property on Development and Dissemination of the Polymerase Chain Reaction: Case Study," *Journal of Biomedical Discovery and Collaboration* 1, no. 7, 2006.

[720] JACKSON, "Innovation and Intellectual Property: The Case of Genomic Patenting," *op.cit.* p.11.

[721] Given the purely facilitative role of the technology in individual research, scientists have compared this approach to the "Steinway piano model"', where demands for compensation could be made for songs composed using that particular brand of piano; RICHARD LI-DAR WANG, "Biomedical Upstream Patenting and Scientific Research: The Case for Compulsory Licenses Bearing Reach-through Royalties," *Yale JL & Tech.* 10, 2007: at pp.299-300.

linked to "industries whose business models depend on the exploitation and reproduction of knowledge", rather singularities that have been promoted by innovators or authors[722]. In this context, the fence line between the ownerships of former and subsequent innovations finds itself determined rather by legal muscle than moral entitlement[723].

7.2.2. Recycling public knowledge

The growing private and upward corporate appropriation of genetic resources has been viewed as a reminiscence of the primeval "primitive accumulation" process of agricultural expropriation, especially from the perspective of developing nations and civil society[724]. First and foremost, the cumulative nature of plant improvement means that the knowledge or products developed by public researchers may and will be used by a plethora of other actors. Acting within the strong paradigm, these actors may enclose the fruits of public research, building on publicly available and unrestricted knowledge. Throughout time, most agrobiodiversity-related knowledge used by private plant breeders, molecular start-ups and integrated biotechnology giants has indeed always found thorough origins in the public domain fed by publicly funded projects or scientists. This assertion is especially true in light of the growing number of joint research projects carried out with institutions favouring less exclusive takes on the fruits of their research. The link of proprietary agrobiodiversity innovation and public science is well illustrated by the soaring proportion of citations originating solely in public science institutions universities, medical schools, and research institutes in screened biotechnology patents. In a study conducted in 2000, this proportion amounted to seventy one per cent, while twelve per cent of the patents cited joint efforts by public and private institutions, and only sixteen point five per cent of cited papers emanated entirely from private companies[725]. These figures corroborate the assertion that **publicly available knowledge is intensively used to develop patented technologies, especially in the field of biotechnology**. The university-industry knowledge complex has been considerably strengthened owing to the growing recourse to acute knowledge in molecular biology and plant sciences, crowning the dependence of the private sector upon basic research carried out by public institutions. This quite naturally urged calls for caution as to the possible "recycling of public knowledge for private reward"[726]. In other words, public researchers may be victims of misappropriation themselves, especially when patentability requirements are loosened up. They may find themselves having to negotiate licensing arrangements for the use of products or processes that only constitute minor improvements to their own research and discoveries, or even to those products that constitute no real improvements at all.

Notwithstanding such recycling, the cumulative nature of plant improvement also means that the knowledge or products developed by public researchers are also **always derived from other sources**, and are highly linked to other actors' contributions. These actors may include other public researchers, private breeders, but also may designate farming or indigenous communities.

[722] MAY, "The Denial of History: Reification, Intellectual Property Rights and the Lessons of the Past," *op.cit.*, p.48.
[723] DRAHOS and BRAITHWAITE, *Information Feudalism: Who Owns the Knowledge Economy?*, *op.cit.*, p.26.
[724] Critics of such deprival have been extremely vehement, see for instance HARVEY, *The New Imperialism*, *op.cit.*, and also JACK KLOPPENBURG, "Impeding Dispossession, Enabling Repossession: Biological Open Source and the Recovery of Seed Sovereignty," *Journal of Agriarian Change* 10, no. 3, 2010: pp.367-388.
[725] This study was conducted on 2334 biotechnology patents, which had 23,286 NPR on their front pages, see McMILLAN et al, 2000,
[726] DRAHOS and BRAITHWAITE, *Information Feudalism: Who Owns the Knowledge Economy?*, *op.cit.*, p.15.

Public researchers are therefore not immune to be perpetrators of biopiracy themselves, and the debates surrounding their onus have flourished with the recognition of "traditional knowledge" under the Convention on Biological Diversity[727]. Notwithstanding the wider reaching debate over the protection of such knowledge, agricultural innovation also stands the test of recognising farmers' contribution to the cumulatively observed characteristics attributed to particular plant varieties today. The caveats of establishing the reach of **prior art** in plant innovation is best epitomised by the aforementioned example of *Oryza longistaminata*, a wild rice variety from Mali[728]. This wild variety is resistant to bacterial rice blight, a trait that was not known by Malian farmers who considered it to be weed. However, a landless community had detailed knowledge of the resistance. Indian public researchers took on this interesting trait and transferred the variety to the International Rice Research Institute, who then developed varieties with blight resistance and distributed them in accordance with the CGIAR's public domain-oriented approach. The University of California in Davis then mapped the variety's gene responsible for the resistance trait, the Xa21 gene, which was patented in the United States in 1999. Acknowledging the complexity of prior art in this specific case, the University recognised the need for benefit sharing[729]. The history of blight resistance in rice shows the two contentious aspects of plant innovation monopolies, first with regards to the recycling of public knowledge, and second to the use of ethno-botanical indigenous knowledge, whether held in the hands of farmer communities or even remote landless groups. This tale vividly exemplifies the need to carefully assess the protection criteria of novelty, whether in patents or plant variety rights, respectively accounting for prior art and common knowledge. This finding is corroborated by several other cases which show that material obtained through international agricultural research was actually in itself recycled material from other sources. Indeed, freely distributed material was frequently found to have been enclosed by public institutions with little change or little additional breeding. The Rural Advancement Foundation International, now ETC Group, has for instance published a poignant account citing "147 Reasons to cancel the WTO's Requirements for Intellectual Property on Plant Varieties: the Biopiracy and Plant Patent Scandal of the Century", which recalls at least one hundred and seventy four cases of misappropriation[730]. Citing that "breeders' wrongs" take the form of systematic abuses where "plant patents are predatory on breeding work undertaken by farmers and indigenous peoples around the world", the report urges governments to take action against "intellectual kleptocracy". The report shows that public researchers have not only become unwilling intermediaries to the kleptocracy committed by private entities, but they have also at times been the perpetrators themselves. For instance, two Asian chickpea varieties held under the "in trust agreements of the CGIAR" and accessed by an Australian public institute went on to be claimed by the latter without any subsequent breeding work, and were thereafter "licensed to

[727] This particular aspect of public knowledge will also be tackled at bay in Chapter 9 of this study, since biopiracy cases often involve landraces and attached knowledge over which they have been granted certain rights by international environmental law; rights that are not well taken into account by the dominant property paradigm.

[728] This example is examined in BIBER-KLEMM et al., "Flanking Policies in National and International Law," *op.cit.*, pp.239-279 (at 241-232).. It also draws in from a detailed analysis made by UNEP and WIPO, *op.cit.*, 2002. (case study one – Mali).

[729] BLAKENEY, *Intellectual Property Rights and Food Security*, *op.cit.*, p.141.

[730] RURAL ADVANCEMENT FOUNDATION INTERNATIONAL, "Plant Breeders' Wrongs: 147 Reasons to Cancel the Wto's Requirements for Intellectual Property on Plant Varieties: The Biopiracy and Plant Patent Scandal of the Century," in *Rural News* (15 September 1998).

private companies for re-sale back to their region of origin"[731]. This last case epitomises how a public entity that has embraced the strong paradigm may blatantly undermine and disregard other public research actors but also farming communities' contribution to their "innovative" product or process.

The reification and reign of intellectual property rights have as a result been viewed as the novel forms of "accumulation by dispossession"; depriving communities from the commons they had traditionally contributed to. Nonetheless, piracy or title infringements only exist to the extent that exclusive or even collective protection titles are warranted over the innovation. Without patents, copyrights or plant variety rights, or other active regulatory action, the subsequent uses of the fruits of public research efforts cannot be controlled[732]. The reality of public knowledge recycling in plant improvement therefore warrants action to be taken in order to fence off the public domain, so as to allow compensation to occur when material or knowledge is used, copied or merely slightly modified to qualify for exclusive rights protection. Both the incremental and cumulative nature of plant improvement clearly emphasise the need for greater diligence in the assessment of protection standards and patentability requirements, whether assessing the inventiveness or novelty of the product or process under scrutiny.

7.3. Unpleasant encounter of research tools anti-commons and foundational patents in complex technologies

While the "second enclosure" idiom epitomises the pivotal role awarded to innovation, intangible information, and knowledge goods in our societies, it also highlights the inherent threat hanging over the very production of such goods. Monopoly rights awarded on "the intangibles commons of the mind" indeed greatly impact the production of innovative endeavours, especially in incrementally cumulative disciplines. They have raised howling concerns from public researchers facing a shrinking public domain, not only because of the need to preserve science norms or the difficulty of delineating exclusive protection in molecular biology and plant breeding, but also because of the detrimental impacts of foundational technology enclosure down the drain of complex technology development. Public researchers have felt these impacts prominently, being faced with patents howling over opportunities for molecular research[733]. In this context, overly exclusive and extensively scattered informational property rights may seriously risk slowing down vital "free-wheeling give and take" in the entire research chain[734]. Just as the absence of proprietary boundaries around natural resources may lead to free-riding and under-production in a tragic mind-set as to the fate of the commons[735], overly strict proprietary rights over resources,

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[731] "Plant Breeders' Wrongs: 147 Reasons to Cancel the Wto's Requirements for Intellectual Property on Plant Varieties: The Biopiracy and Plant Patent Scandal of the Century," in *Rural News* (15 September 1998), p.2.

[732] That is why this additional fencing off the public domain with regards to farmers shall be tackled in Chapter 11 of this study.

[733] As we shall elaborate in Chapter 8, private plant breeders also face the adverse effects of this new proprietary landscape.

[734] CAROL M. ROSE, "Several Futures of Property: Of Cyberspace and Folk Tales, Emission Trades and Ecosystems," *Minnessota Law Review* 89, 1998-1999: pp.154-155.

[735] HARDIN, "The Tragedy of the Commons," *op.cit.*

especially those of an informational nature, may in turn lead to excessive monopoly costs of intellectual property rights[736].

> "It is the ability of patents on genes to "reach beyond" the original utility included in their claims that gives them the potential to have such a significant influence on innovation. Rather than just controlling a specific invention, the control they seek over the gene's "information content" means that they produce a monopoly with considerably more leverage. This innovative leverage—whose effect could be positive or negative—is the most central characteristic of genome patents. As a result, in contrast to most discussions of gene patenting, the question is not whether these patents are valid under current law, but how the leverage they imply for current and subsequent innovation makes their issuance positive or negative from the perspective of society"[737].

This premise stands at the heart of the "control-criticism" literature established around the **anti-commons property rhetoric**, according to which the possession of restricting or blocking rights over a resource by too many individuals allows for upstream license stacking, thus resulting in the under-use and under-production of said resource[738]. So-called patent anti-commons can emerge when numerous property rights claims are appointed to separate building blocks for a particular product or a research cluster. They can also emerge on account of the "self-interested use of even just one patent – although lacking the encumbrances of multiple claimants characterising an 'anticommons' – [which] may impede innovation where a technology is cumulative (i.e., where invention proceeds largely by building on prior invention)"[739]. Public researchers' opportunities and costs to carry out their activities may be hindered not only by the fresh need to obtain mere knowledge of the radius of exclusive property claims, but also by the subsequent need to negotiate multiple access to multiple technologies required to carry on socially beneficial research. Legally sanctioned monopolies show their most gruesome side when the protected technology bears foundational aspects, which is even more enhanced given the incrementally cumulative but also complex nature of agrobiodiversity molecular research. This is especially true when patents are gruesomely enforced, in the likes of the PCR method patents, where Hoffmann-LaRoche "specifically named more than forty universities and government laboratories and more than two hundred scientists as directly infringing certain patents through their basic research"[740]. Rising transaction costs and direct impediments to research efforts have been as a result much debated in the particular context of molecular research tools in biodiversity related innovation.

7.3.1. Knowing about the multiple patents and their multiple owners

Anti-commons emerge within hostile innovation environments, characterised by the under-use and thus the under-production of innovative technologies, pushing legal scholarship to deplore the

[736] DRAHOS and BRAITHWAITE, *Information Feudalism: Who Owns the Knowledge Economy?*, *op.cit.*
[737] JACKSON, "Innovation and Intellectual Property: The Case of Genomic Patenting," *op.cit.*, p.12.
[738] HELLER, "The Tragedy of the Anticommons: Property in the Transition from Marx to Markets," *op.cit.*
[739] JOHN.P. WALSH, ASHISH ARORA, and WESLEY COHEN, "Effects of Reseach Tools Patents and Licensing on Biomedical Innovation," in *Patents in the Knowledge-Based Economy*, ed. WESLEY COHEN and STEPHEN MERRILL, Washington: National Research Council, 2003, p.287-288.
[740] R. FINN, "Ongoing Patent Dispute May Have Ramifications for Academic Researchers," *The Scientist* 10, 1996., cited in PETER CARROLL and DAVID CASIMIR, "Pcr Patent Issues," in *Methods in Molecular Biology: Vol. 226: Pcr Protocols*, ed. J.M.S. BARTLETT and D. STIRLING, Totwa: Humana Press, 2005, p.10.

inappropriateness of such restrictive approach to the grant of artificial lead-time through proprietary exclusiveness. Amongst the symptoms of anti-commons on research tools are patents thickets and royalty-stacking practices, even though evidence remains mixed on their existence and reach[741]. The "bewildering and overlapping array of exclusive property rights" that are ostensibly found in virtually all improved plant and genetic material upon which breeders or researchers base their activities upon nonetheless riskq to "discourage follow-on applications of routine technical know-how"[742].

The challenge does not only stem from the high number of patents in agricultural biotechnology, it also derives from the fact that "very fundamental methods and tools are patented", and that the "patents overlap in a way not found in the pharmaceutical industry"[743]. The proliferation of not only strong, but also of **broad foundational patents** that designate not only one technological application but rather encompass a range of claims, is as a result thought to impede the entire research community's range of action[744]. This gruesome reality potentially threatens an innovators' inherent right to build upon another innovators' creation, hampering with the intricate balance of IPR between the appropriation and the diffusion of protected products and processes. Patents in the field of green biotechnology are not only broader, they also bear the risk of covering basic research tools, as has been the case for instance in the genetic engineering of transgenic cotton plants and lines[745]. Opportunities to control so-called **enabling or platform technologies** have as a result been criticised for their anti-commons -akin detrimental effects. As specific sets of technological steps that can be utilised in various research areas, thereby leading to a wide range of subsequent innovations, platform technologies generally have no direct value for end-users, but represent a critical input for the development of commercial products[746]. The risks of awarding wide reaching control to upstream developers of platform technologies are numerous; yet always wander around their potential to stifle research and development[747]. What is worse, the controller might not even market the protected product or process as such, he might be what is pejoratively coined a "patent troll". Hiding behind a patent without contributing to any economic activity linked to production, these trolls hunt potential infringers down to make money from their patent portfolios. This practice is definitely hunted by public authorities, and both the judiciary and legislators are steadily taking tougher stances against it. Notwithstanding such unlawful practices, the grant of far-reaching exclusive rights to foundational innovations also causes inherent difficulties that are particularly heightened by the cumulative and contingent nature of plant

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[741] Comparing for instance the findings of MICHAEL A. HELLER and REBECCA S. EISENBERG, "Can Patents Deter Innovation? The Anticommons in Biomedical Research," *Science* 280, 1998., to those of WALSH, ARORA, and COHEN, "Effects of Reseach Tools Patents and Licensing on Biomedical Innovation," *op.cit.*, who find that the impediments of patenting are lower than expected, even though "delays associated with negotiating access to patented research tools, [are witnessed], and there are areas in which patents over targets limit access and where access to foundational discoveries can be restricted". (at p.286-7).

[742] REICHMAN and MASKUS, "The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods," *op.cit.*, pp.3-45.

[743] BARTON, "Intellectual Property, Biotechnology and International Trade: Two Examples," *op.cit.*, p.288.

[744] S. SALAZAR et al., "*Use of Proprietary Biotechnology Research Inputs at Selected Latin American and Asian Naros*", ISNAR, The Hague, 2000.

[745] JOHN BARTON, "Patents and Anti-Trust: A Rethinking in Light of Patent Breadth and Sequential Innovation," *Antitrust Law Journal* 65, no. 2, 1997.

[746] PRAY and NASEEM, "Intellectual Property Rights on Research Tools: Incentives or Barriers to Innovation? Case Studies of Rice Genomics and Plant Transformation Technologies," *op.cit.*

[747] HELLER and EISENBERG, "Can Patents Deter Innovation? The Anticommons in Biomedical Research," *op.cit.*, pp.698-701.

breeding innovation relying on molecular biology tools. In upstream hybrid research streams, the data produced for instance by sequencing consortiums and some selected research tools remains within the public domain. However, research efforts that aim to single out the exact utility of **molecular biology research tools** may lead to patent protection over what unvaryingly consists of platform technologies. These research tools constitute the new core of crop-genetic improvement, as an indispensable input for further research, side by side with both improved and exotic crop varieties that represent the operational background of crop-related research. Indeed, tools such as molecular markers, high-density genetic maps and structured mapping of populations provide breeders with the ability to "simultaneously define gene action and breeding value at hundreds of loci distributed relatively uniformly across entire genomes"[748]. The example of polymerase chain reaction (PCR) speaks volumes in this context, as a foundational technology used daily by all molecular biologists around the globe[749]. The method in effect amplifies small DNA pieces in vitro using a naturally occurring enzyme called DNA polymerase. Its invention can be traced back to 1983 and to a scientist, Kary Mullis, but was patented by Hoffman La Roche, first in the United States. However, the method was not the only patented element surrounding the technology, since the enzymes used in the process, as well as the machines such as the thermo-cycler, were also patented by Hoffman.

Public researchers are stung by the clearly **predominantly private and nearly monopolistic nature of patent ownership** in agricultural biotechnology and molecular plant breeding. There is mounting evidence that the plant genetics and genomics industry's concentration rate has been considerably heightened through the grant of patents on germplasm. Indeed, "half-dozen major firms […] hold substantial numbers of key patents […and] have coverage of the related enabling technologies"[750]. Not only have "trait development" activities created the contemporary notion of "traits market share", vis-à-vis biotechnology enhancement traits such as disease resistance or herbicide tolerance, it has consequently generated complex cross-licensing practices, where multinationals and small-scale companies alike find themselves more intricately linked to each other and to the market leader than in merger or acquisition situations. Indeed, in 2003, the "private sector accounted for seventy four per cent of the IP in [agricultural biotechnology], much of it aggregated into a few very large IP portfolios at major corporations, the top five of which control forty one per cent in the United States [while] the rest of the private sector, including independent biotechnology start-ups, holds thirty three per cent of agricultural biotechnology IP"[751]. The authors acknowledge that the percentage of private sector patent control may "likely be an underestimate, as a portion of the public-sector portfolio has also been licensed to companies in the private sector". In this context, research costs and benefits are assessed on account of the ability to capture a return on it through IP protection, judging "expected return on traits based on

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748 MOOSE and MUNN, "Molecular Plant Breeding as the Foundation for 21st Century Crop Improvement," *op.cit.*

749 GRAHAM DUTFIELD, *Intellectual Property Rights and the Life Sciences Industries: Past, Present and Future*: World Scientific, Second Edition, 2009, pp.27-29.

750 W.P. FALCON and C. FOWLER, "Carving up the Commons: Emergence of a New International Regime for Germplasm Development and Transfer," *Food Policy* 27, 2002: pp.204-205.

751 GRAFF et al., "The Public-Private Structure of Intellectual Property Ownership in Agricultural Biotechnology," *op.cit.*, where the authors analyse different clusters based on technology, such as plant enzymes, bacillus toxin, industrially important enwymes, metabolic pathways, disease resistance in rice, male-sterile seeds, viral proteins, herbicide resistance, product-quality traits, flowering control, pathogen resistance.

the ability of the company to charge a premium for that trait multiplied by the expected number of units sold containing that trait"[752].

Due to the complex and incremental nature of their fields, public researchers are not only affected by the licensing practices of technology-controlling giants, they are also further wounded by the need to access **multiple technologies before multiple actors,** significantly raising the costs attached to research and development endeavours. Indeed, the monopolistic nature of the global seed and trait market is also supplemented by another aforementioned trend, that of the proliferation of highly specialised molecular biology start-ups that are wired to develop a strong patent arsenal, albeit smaller, but as efficient, that the ones harboured by integrated giants. A "major challenge for management of public-sector IP is the high degree of fragmentation of technology ownership across numerous institutions, especially in light of the need for multiple technology components to provide freedom to operate in transgenic crops"[753]. For instance, promotors that are inserted into plants along with the new substantive genes have been patented, just as claims for the use of transgenic *Bacillus thuringiensis* (infamous Bt) maize have been awarded to multiple entities: the first firm to clone the gene, the first that put it in a plant, and the first to put it in a crop plant[754]. A study conducted by the Joint Research Centre of the European Commission on "new breeding techniques" such as the Oligonucleotide-directed mutagenesis (ODM) or the Zinc-Finger Nuclease (ZFN) technologies identified a total of eighty four patents on the seven new plant breeding techniques, amongst which seventy per cent were submitted by the private sector, twenty six by universities and four per cent by joint collaborations between private and public institutions[755]. The "proliferation of IP rights among multiple owners in agricultural biotechnology appears to have affected the rate and direction of innovation, a result of the so-called intellectual anti-commons"[756]. According to Paul DAVID[757], this phenomenon's anatomy first needs to be sought in the "search costs" associated to researchers' knowledge of patent landscapes around their innovation clusters. It is supplemented by the "transactions costs" that are associated to obtaining the license to actually use targeted technology. Faced with complex technologies, it is also enhanced by a phenomenon of "multiple marginalisation", where the "pricing of components ignores the pecuniary externalities on the demand for the project as a whole".

For the IP system to function effectively, **knowledge on protected products and processes remains the first key**. It is the primordial and tacit condition to achieve the inherent balance of exclusive rights with the innovation's disclosure. IPR navigation skills to access information about the mere existence of research tools and biological material are pretty straightforwardly crucial. They are not only crucial for fellow innovators, but also for patent examiners.

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[752] HAYES, LENCE, and GOGGI, "Impact of Intellectual Property Rights in the Seed Sector on Crop Yield Growth and Social Welfare: A Case Study Approach," *op.cit.*

[753] GRAFF et al., "The Public-Private Structure of Intellectual Property Ownership in Agricultural Biotechnology," *op.cit.,* p.995.

[754] Ibid.

[755] M. LUSSER et al., "*New Plant Breeding Techniques: State of the Art and Prospects for Commercial Development*", Publications Office of the European Union, Luxembourg, 2011.

[756] GRAFF et al., "The Public-Private Structure of Intellectual Property Ownership in Agricultural Biotechnology," *op.cit.*

[757] PAUL A. DAVID, "Securing the Knowledge Foundations of Innovation: Thinking About the Contractually Constructed Commons' Roles in the Era of Big Data," in *International Seminar of the PROPICE Project Property and Commons: New Issues of Shared Access and Innovatoin Association* (Paris, 25-26 April 20132013).

> "Since word meanings determine the precise boundaries of claims, a good deal of practice is required to draft claims in a patent, and a good deal more is required to understand what they say"[758].

Prohibitively high discovery costs may be rooted in the nature of innovations as such, whether these are easily defined and indexed in the mechanisms ensuring the disclosure of protected products and processes. Examining scaling within the patent system, the indexable or non-indexable nature of the patents and their correlated technology (i.e. our ability to place the items in a predictable order) has been demonstrated to play a key role in the mere knowledge of pre-existing exclusive rights on the new product that has been developed[759]. When innovations are indexed quite easily such as in the chemicals' sector, it is quite feasible to clearly determine whether patents exist on the molecules that are present in one's innovation. However, in non-indexable innovations such as software, or phenotypic and genotypic information for plant varieties, "the patent system scales so poorly that it's effectively impossible to know whether software you have written infringes other patents"[760]. With regards to 'complex technologies' such as molecular plant breeding or synthetic biology, intellectual property rights are often extremely hard to identify, as they remain fragmented across many owners and sometimes even cover broad sections or applications. This fragmentation significantly increases the known and unknown costs of research and development and undermines researchers' freedom to operate and navigate in the "patent thicket"[761]. Changing patent landscapes related to particular technologies not only create difficulties in the primary drawing of these landscapes in itself but also vis-à-vis its follow-up. This is especially valid for overlapping claims at both national and foreign offices, which "create a great deal of uncertainty in making product development and investment decisions that rely on a realistic "freedom to operate" assessment", both within the private and public sectors[762].

> There is a clear uncertainty attached to the value and quality of patents granted under currently applicable rules, « which is not an accident or a mistake. Rather, it is an inherent part of our patent system, an accommodation to the hundreds of thousands of applications filed each year, the inability of third parties to participate effectively in determining whether a patent should issue, and the fact that for the vast majority of issued patents, scope and validity are of little or no commercial significance »[763].

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758 THAMBISETTY, "Patents as Credence Goods," *op.cit.*, p.713.
759 CHRISTINA MULLIGAN and TIMOTHY B. LEE, "Scaling the Patent System," *NYU Annual Survey of American Law*, 2012., paper presented at the 12th Annual Intellectual Property Scholars Conference held in Stanford Law School, 9-10 August 2012.
760 The authors show that it would take two million patent attorneys working full time to determine whether software infringements existed vis-à-vis the patents issued on one year alone, since the searches cannot be reliably based on keyword alone and need to encompass all existing software patents. Ibid.
This premise might be less true in agrobiodiversity innovation, since certain keywords still can be activated for a number of innovations, for instance vis-à-vis specific plant species (if targeting a tomato rust resistance gene for instance); however, such searches are not always feasible due to the nature of innovation at hand, but also to the elements that can be entered within workable patent search engines.
761 J. HENKEL and S. MAURER, "Parts, Property and Sharing," *Nature Biotechnology* 27, 2009: pp.1095-1098.
762 C. CHI-HAM, K. CLARK, and A. BENNETT, "The Intellectual Property Landscape for Gene Suppression Technologies in Plants," ibid.28, no. 1, 2010.
763 MARK A LEMLEY and CARL SHAPIRO, "Patent Holdup and Royalty Stacking," *Tex. L. Rev.* 85, 2006., at p.95.

The consecration of the strong property paradigm implies as a result serious capacity-building efforts not only in national offices that grant titles, but also public research institutes, and all private actors, whether scientists or breeders.

7.3.2. Accessing patented tools despite blocking or delaying strategies

Not only do public molecular biologists and breeders need to identify if the material or techniques they are using are protected through patents or plant variety rights, they also need to be able to access the protected material or processes, and commercialise their own products developed on the basis of the latter. "National agricultural research systems and CGIAR institutions could jeopardise their funding if they systematically violated patents to develop useful applications of biotechnology"[764]. There is cumulative rationale and evidence pointing towards the hindrance of socially desirable research and development by the strong PGRFA property paradigm.

> « All patents restrict innovation. Privatising some part of technology-space unavoidably blocks the way for some later innovators. As a result, the fact that gene patents can block innovation is neither unusual nor unique. Due to a number of different characteristics, the potential for gene patents to restrict areas of innovation appears to be significantly greater than many other categories of patent monopolies »[765].

Amongst other phenomena lie the high number of patents, their concentration in the hands of small groups of enterprises and their alleged broad scope, but also the non-resilient licensing practices driving away the innovation's availability, as well as the fierce enforcement strategies characterising protection have raised concerns. Indeed, "if competing firms hold patents on different components of a complex technology, and they fail to cross-license them (which can happen for many causes, not all of them rational), development in an entire industry can be slowed down or even rendered impossible"[766]. Patents are considered to be inherently disadvantageous for complex technologies, as they stand for stimulus for research and development, but also find themselves used as a trading currency or bargaining chips[767], more often so than plant breeders' rights. Patents have in this context become a defensive means to prevent lockouts that could be formed through the denial to use an invention, in contrast to simple technologies such as chemicals for which patents remain an indispensable and less disputed tool[768]. Alongside the potential lockout that might be created within the private sector itself, "patent thickets" may impact public agricultural research and food security more widely, as exemplified by the case of pro-vitamin A-enriched 'Golden Rice'. Even though the patents were seemingly relinquished in favour of the poor in this particular case, the variety developed upon a public domain premise through the initiative of the Rockefeller Foundation, required permission with regards to about seventy patents in the United States alone, widening concerns for the sacrosanct "freedom to operate" in

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[764] MICHAEL R. TAYLOR and JERRY CAYFORD, "*The U.S. Patent System and Developing Country Access to Biotechnology: Does the Balance Need Adjusting?*", Resourcces for the Future, Washington, 2002.
[765] JACKSON, "Innovation and Intellectual Property: The Case of Genomic Patenting," *op.cit.*, p. 18.
[766] W. KINGSTON, "Innovation Needs Patent Reform," *Research Policy* 30, no. 3, 2001: p.408.
[767] B.H. HALL and R.H. ZIEDONIS, "The Patent Paradox Revisited: An Empirical Study of Patenting in the Us Semiconductor Industry 1979-1995," *RAND Journal of Economics* 32, 2001.
[768] MERGES and NELSON, "On the Complex Economics of Patent Scope," *op.cit.*; and KINGSTON, "Innovation Needs Patent Reform," *op.cit.*

biotechnology-backed plant breeding activities[769]. At this point emerges other critically condemned phenomena; regarding the exclusive **control of a single actor over foundational patents**, the issue of "blocking patents" on complementary technologies[770], and their concomitant impact on transaction costs associated with the growingly numerous licensing deals signed by public research institutes.

> Indeed, "patents are property rights but from a transaction perspective they are not like any other property right. The unclear metes and bounds of a patent make it an ill-defined entity with which to transact"[771].

When analysing the magnitude of the rewards that ought to be attained through innovation, especially within a cumulative cycle with few ground-breaking discoveries, it should be remembered that actors possessing restrictive monopoly rights have the ability to "choose the optimal level of output for the intermediate good embodying the patented technology"[772]. The position of molecular research tools and other foundational, enabling or platform technologies, as the groundwork of the innovation process in all modern agricultural biotechnology and plant breeding, elevates the conditions surrounding their appropriation and further use to an absolutely essential issue. Much like the largely cited example of the Human Genome and the uproar caused by the "Craig Venter" intellectual property protection strategy pattern, controversies have also surrounded research concerned with agricultural biotechnology oriented molecular biology strides. The aforementioned example of the polymerase chain reaction speaks volumes in this context, where the end of the protection term in March 2005 came as a relief for public and private researchers alike who "endured years of what many considered exorbitant prices for proprietary enzymes such as Taq PCR polymerase"[773]. The patent landscape surrounding the zinc finger nuclease also raises similar questions as to the tense relationship of private patent portfolios with the public domain. Indeed, with regards to ZFN, the "secrets of a cutting-edge technology that could transform gene therapy lie hidden in the IP vaults of a small biotechnology company". Sangamo BioSciences holds key patents and trade secrets "not only on the design of zinc fingers and zinc finger chimeric endonucleases, but also their uses in drug discovery and the regulation of gene expression"[774]. These key patents are nevertheless part of a larger patent estate, which also comprises of universities and public laboratories. However, even scientists "whose inventions are part of the patent estate instrumental to the company's fortunes are often not privy to key aspects of the technology"[775]. The company's extensive monopoly rights and its subsequent "catbird's seat" has led to growing unrest in the entire industry, as licensing deals have been known to be extremely difficult to negotiate, and have at times also been refused. The public case of a company who incidentally needed the technology for a sub-license, having secured a licensing deal with a

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[769] D. KRYDER, S.P. KOWALSI, and A.F. KRATTIGER, "*The Intellectual and Technical Property Components of Pro-Vitamin a Rice (Goldenrice™): A Preliminary Freedom-to-Operate Review*", Ithaca, New York, 2000.
[770] ROBERT MERGES, "Of Property Rules, Coase and Intellectual Property," *Columbia Law Review* 94, no. 8, 1994: pp.2655-2673.
[771] THAMBISETTY, "Patents as Credence Goods," *op.cit.* p.708.
[772] GOESCHL and SWANSON, *op.cit.*, 1999; GOESCHL and SWANSON, "The Social Value of Biodiversity for Research and Development," *op.cit.*
[773] MURPHY, *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*, *op.cit.*, p.283.
[774] CHRISTOPHER THOMAS SCOTT, "The Zinc Finger Nuclease Monopoly," *Nature Biotechnology* 23, no. 8, 2005: pp.23-28.
[775] Ibid., citing URNOV et al, *Nature* 435, 646-651, 2005.

university scientist for an invention that required the use of a Sangamo patent, which was ironically based on work carried out by another university scientist, speaks volumes. Faced with such facts, sarcasm might be as welcomed as deep unrest as to the creation of "patent empires" and the pressing need to creatively innovate around such artificial monopolies, which have derailed a great deal from their initial purpose.

Aside the challenging situation where a single actor obtains control over a foundational patent and decides to use it as a bargaining chip by rendering or refusing licenses unfairly, agricultural biotechnology also faces the issue of **"blocking patents" on complementary technologies**.

> Robert MERGES describes such situation as one where "one patentee has a broad patent on an invention and another has a narrower patent on some improved feature of that invention. The broad patent is said to "dominate" the narrower one. In such a situation, the holder of the narrower ("subservient") patent cannot practice the invention without a license from the holder of the dominant patent. At the same time, the holder of the dominant patent cannot practice the particular improved feature claimed in the narrower patent without a license"[776].

This blockage perceptibly arises when the prior art assessment shows that the subservient patent discloses an improved feature which meets the statutory tests of novelty and nonobviousness[777]. If research tools are diffused widely without restrictively appropriative stances, research efforts are not obstructed. However, the crude reality of public research sings a significantly different tune. The International Research Institute for Rice has for instance very publicly had trouble accessing licensed technology for the development of its Green Super Rice[778]. "This talk of violation indicates that the reach of US patents rights in the non-profit sector can extend well beyond the geographic bounds of their legal, if not their political, reality, and certainly beyond the scope of protection recognised by well-informed private firms"[779].

Access to patented technologies will be affected by their licensing terms and the corroborating practices such as high licensing fees, both also by refusals to license or the conditioning of license decisions to unacceptable terms. Low licensing fees are quite unsurprisingly linked to a potential wide distribution of the innovation, while a resulting decrease in profits deemed absolutely not inevitable, as the extremely lucrative example of the Cohen-Boyer patent on recombinant DNA has exposed[780]. On the other side of the spectrum, high license fee levels have in certain cases such as the polymerase chain reaction technology and the Taq polymerase, spurred heated controversies, not only because the "novel" character of the innovation was challenged before authorities, but also as fees for the use of such a crucial enzyme were deemed particularly

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[776] MERGES and NELSON, "On the Complex Economics of Patent Scope," *op.cit.*
[777] See, e.g., United States Federal District Court of Virginia, *Atlas Powder Co. v. E.I. Du Pont de Nemours & Co.,* 750 F.2d 1569, 1576.
[778] See KHUSH, *op.cit.,* 6.; and RONALD P. CANTRELL and GENE P. HETTEL, "Research Strategy for Rice in the 21st Century" (ibid.), 26-37.; and also http://irri.org/news-events/media-releases/green-super-rice-is-coming.
[779] WRIGHT and PARDEY, "Changing Intellectual Property Regimes: Implications for Developing Country Agriculture," *op.cit.,* p.95.
[780] EISENBERG, "Patenting Research Tools and the Law."

elevated[781]. However, studies conducted at the end of the patent protection term have shown that monopoly rights did not necessarily prevent the dissemination of the technological advance as it had sometimes been expected. Appropriate business practices could indeed guarantee the availability of the technology either through business partnerships, broad corporate licensing practices, adaptive licensing strategies or a sensible restraint in filing lawsuits against infringing researchers[782]. Such guarantee could even survive under an increasingly shrinking doctrine of experimental use in United States patent law[783]. The loosened licensing strategy from the technology holder, as for instance has been the case of PCR, also eased the past temptation of actors wishing to run the chain reactions to circumvent the intellectual property protection and find un-infringing approaches around the terms of the patent. Greater availability thus prevented the prominent inducement of free riding. Nonetheless, the cost of PCR applications for the developed and developing worlds was substantially reduced on account of the now 'generic' status of the Taq enzyme and the expiration of the core process patents on PCR technology[784], a development that might spread the use of the technology in fields neglected in the past or set off its entrance into new fields of research, such as tropical plant breeding. As aforementioned, another patent estate that is likely to resonate and impact the future of plant breeding deeply relates to the engineering and use of zinc-finger proteins[785]. This technology indeed enables scientists to virtually bind any DNA sequence of interest, and was initially owned by several different companies and academic institutions. This situation raised concerns as to the prohibitive costs faced by subsequent users and developers in the negotiation of multiple licenses.

It should be noted that the public research sector is not always the victim of patent anti-commons; they have, arguably less frequently, also **induced "patent monopolies",** or at least been accused of creating them. One example stems from the so-called "Axel patents", a string of extremely valuable inventions concerning notably gene-splicing technology. One of the patents, number 6,455,275 issued by the U.S. Patent and Trademark Office in 2002, held by Columbia University, was challenged in 2003 by several biotechnology companies, Biogen Inc, Genzyme Corp. and Abbott Bioresearch Center in a joint lawsuit. Many observers have asserted that the case remained "extremely unusual within the world of technology transfer, [and] was initiated because of the large sums of money the patent has generated"[786]. Issues have also arisen regarding the actual exploitation of public institutes' patented technology and the subsequent licensing strategies adopted by the licensees**.** Setbacks experienced by the relatively large-sized American Cyanamid (since then acquired by BASF) in product development due to the exclusive licensing agreement signed by the "Biolistic Particle Delivery System" gene gun technology developer, Cornell

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[781] FORE, WIECHERS, and COOK-DEEGAN, "The Effects of Business Practices, Licensing and Intellectual Property on Development and Dissemination of the Polymerase Chain Reaction: Case Study," *op.cit.*

[782] Indeed, Roche provided an impressive list enumerating PCR patent infringing researchers as evidence during an unrelated court case, a list within which prominent institutions such as the National Cancer Institute, MIT and Harvard University found their place. The patent holder expressly stated that it did not intend on prosecuting any of these researchers, thereby also renouncing to any claim for "reach-through" provisions it might have counted upon for income generation in the past; "The Effects of Business Practices, Licensing and Intellectual Property on Development and Dissemination of the Polymerase Chain Reaction: Case Study," *op.cit.*, p.10.

[783] C. WESCHLER, "The Informal Experimental Use Exception: University Research after Madey V. Duke University," *N.Y.U. Law Review* 79, 2004.

[784] DHLAMINI, *op.cit.*, 2006.

[785] S. CHANDRASEKHARAN et al., "Proprietary Science, Open Science and the Role of Patent Disclosure: The Case of Zinc-Finger Proteins," *Nature Biotechnology* 27, 2009.

[786] HOWARD KEN, "Biotechs Sue Columbia over Fourth Axel Patent," ibid.21, no. 9, 2003: pp.955-957.

University, towards the university researchers' own start-up company, Biolistics, bought by DuPont speaks volumes in this context. Negotiations between the two companies have indeed not succeeded, partially attributable to their competitor status in a different product market, which caused considerable delays in Cyanamid's alternate product development cycle[787]. The example of the infamous gene gun is further intriguing, since the innovation's initial developer, Cornell University, had failed to retain its own rights to use the gun for research and technology transfer purposes, while also falling short to separate certain philanthropic or humanitarian uses from the commercial license, thereby generating weighty problems for those "wishing to use the technology without having to abide by constraints imposed by DuPont and its sub licensees", as well as heavy criticism directed at the University[788]. Quite disturbingly, the actor who actually managed the intellectual property rights over the innovation was not its developer but merely its exclusive distributor. Commentators as a result asserted that monopoly rights had effectively become a mere instrument for maintaining lead-time over competitors, breaking the symbiotic link between the inventor and the innovation; even though such link continued to justify the award of exclusive rights over knowledge, due to the need to recoup research investments. In another disturbing scenario, researchers from the University of California Berkeley had developed transgenic wheat lines in 2003, shown to be less allergenic and obtained patent protection for their inventions. Yet they licensed their technology to a firm that did not pursue the development of hypoallergenic wheat, while the "sublicensing of rights back to the university, to allow product development of the hypoallergenic wheat to proceed, was delayed, hampering negotiations for further development with other firms that were potentially interested in this opportunity at that time"[789].

Even though strong patent protection may lead to a more rapid development of platform technologies themselves, the deterrent effect of such control over the wide-ranging stream of downstream innovations stands in dire need of further consideration and likely correction. The rising trend in patenting biological research tools has at first generally not been seen as a threat by the scientific community in itself, much to the contrary of civil society organisations focused on developmental divides or those vouching for more open source biotechnology research[790]. Consensus nonetheless emerged on the premise that the growing recourse to IPR tools considerably affected academic research, as the latter was altered by commercial concerns, competition and physical material allocation disputes[791]. Recent surveys conducted before academic agricultural biologists show that the major impediment actually relates to the institutional imperative that patenting and licensing strategies have become[792].

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787 PRAY and NASEEM, "Intellectual Property Rights on Research Tools: Incentives or Barriers to Innovation? Case Studies of Rice Genomics and Plant Transformation Technologies," *op.cit.*

788 RICHARD CAHOON, "Licensing Agreements in Agricultural Biotechnology," in *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*, ed. A. KRATTIGER, R.T. MAHONEY, and NELSEN L., MIHR: Oxford, U.K., and PIPRA: Davis, USA.: 2007.

789 J. COHEN, C. FALCONI, and J. KOMEN, "*Research Policy and Management Issues in Biotechnology for Developing-Country Agriculture: Problems and Opportunities,'*'", 1999.

790 These initiatives, which include amongst others BiOs and Cambia, will be studied in Chapter 12 of this study.

791 T. CAULFIELD et al., "Evidence and Anecdotes: Analysis of Human Gene Patenting Controversies " *Nature Biotechnology* 24, 2006.

792 Z. LEI, R. JUNEJA, and B. WRIGHT, "Patents Versus Patenting: Implications of Intellectual Property Protection for Biological Research," *Nature Biotehnology* 27, no. 1, 2009.

CONCLUSIONS. Public research and the strong IP paradigm

Public research, whether solely developing molecular research tools or developing improved plant varieties through a global public goods perspective, unmistakably bears elements of open or at least partially open innovation. These researchers act upon institutionalised norms of communalism, cooperation and diffusion that are ill-fitted to the market-oriented approach of the strong intellectual property paradigm. It has nonetheless very much become a gruelling reality for public researchers involved in applied plant breeding or molecular biology, and raises numerous challenges. The strong property paradigm, by permeating the social system where public researchers navigate from the inside and out, enters into vital conflict with the institutionalised norms that guide scientific endeavours and public agricultural research. In stark contrast with the communal and diffusion oriented nature of public research, private property rights have ignited solemn challenges as to the conduct and norms surrounding research projects, but also as to the diffusion of research products far from the innovation frontier.

The enclosure of an inherently incremental and cumulative innovation system such as plant improvement is also problematic on account of the overly restrictive and inadequately distributive nature of dominant informational monopoly rights. Not only may the race for exclusivity and the parallel growing enclosure pursuits fail to deliver the international public goods that researchers strive to produce, they may also create worrying cases of misappropriation; a phenomenon researchers may be both the perpetrators and the victims of.Enclosure, coupled with aggressive practices, may also worryingly prevent public researchers from carrying out or commercialising the socially beneficial products and processes they have developed. Despite their confidence in industry's rational tolerance for research infringement, public researchers are realistically sceptical as to the existence of any research exemption on their behalf. Academic or public research in agricultural biotechnology is indeed more compressed than the private actors which develop molecular biology research tools due to the inherently complex nature of licensing and material transfer agreement, unnecessarily raising transaction costs, not so much in terms of financial weight or technical difficulty, but rather in terms of delays in research, whether related to access to informational or physical compounds[793]. Difficulties linked to the strong agrobiodiversity property paradigm show only minor differences that can be attributed to the legal order or market segments they operate in, or to the personal history and approach of concerned public and/or commercial entities. All illustrative examples highlight “some features of a market for intellectual property that may impede agreement upon terms of exchange, including high transactions costs relative to likely gains for exchange, participation of heterogeneous institutions with different missions, complex and conflicting agendas of different agents within these institutions, and difficulties in evaluating present and future intellectual property rights when profits are speculative and remote”[794]. Challenging the seeming lack of problems deriving from the encouragement of patenting in upstream biological research tools, scientists henceforth contest the effects of exclusive rights on the supply of innovation.

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[793] LEI, JUNEJA, and WRIGHT, "Patents Versus Patenting: Implications of Intellectual Property Protection for Biological Research," *op.cit.*

[794] EISENBERG, "Bargaining over the Transfer of Proprietary Research Tools: Is This Market Failing or Emerging?," *op.cit.*

PARADIGM TRENDS	SHORTCOMINGS EXPERIENCED BY PUBLIC RESEARCHERS
Reign of exclusive individual rights: Protect or perish?	Disregard for communalism and openness in public research
	Lack of incentive for non or little market oriented research
Enclosure of cumulative innovation	Biopiracy risk vis-à-vis old users of biodiversity / knowledge (need to assess prior art / common knowledge)
	Recycling of public knowledge by third parties (need for proprietary boundaries)
Proliferation of patents with aggressive licensing practices: Anti-commons in molecular research tools	Raising search and transaction costs of socially beneficial research (information, negotiation)
	Use-blocking licensing: refusal – delays in research
	Uncertainty as to the legality of actions or possible exploitation of developed products

FIG.2: Shortcomings faced by public researchers in molecular biology and conventional plant breeding confronted to the strong PGRFA property paradigm

8. CHAPTER 8: CONVENTIONAL AND MOLECULAR PRIVATE PLANT BREEDERS DEVELOPING IMPROVED PLANT VARIETIES

Propelled by the TRIPS Agreement and new technological strides, the new property paradigm was carved around strong intellectual property rights protection characterised by enhanced plant breeders rights and lenient understandings of patentability requirements. While the conventional plant breeding based Green Revolution was anchored upon un-proprietary public processes for crop genetic improvement, gradually providing protection for the product of research efforts, the molecular biology-supported Gene Revolution did not rely on the same institutions. The actors involved in plant breeding continued to rely on the development and probable protection of their commercial product as such, i.e. plant varieties, even though they tried to keep up with new technological strides. Their success nonetheless also became contingent upon securing both the components (such as reagents) and the processes (such as molecular breeding techniques) that could be used along the way in order to gain precious time and precision in the breeding process. Most of the upstream agrobiodiversity innovation was however enclosed outside of the public domain, requiring considerable adjustments in private plant breeders' *modus operandi*. Meanwhile, the essence of plant breeding itself did not change. The relatively open approach inherent to plant breeding in terms of germplasm access perdured over time, all the while severely hitting the wall of hidden molecular enclosure prerogatives.

Current informational monopoly rights not only protect the plant variety, product of plant breeding programs as such, but may also cover the entire array of indispensable components and research tools that accompany the development of improved crops on account of the hefty re-definition of the rights and obligations surrounding PVP and patents. Breeding programmes have been heavily affected by its new, seemingly more efficient and profitable cousins of molecular biology and genetic engineering. They have also been affected by the concomitant strengthening of intellectual property rights, which assigned ever-growing limitations on the use of protected products, processes and varieties. The extremely high rates of consolidation in agrobiodiversity research and development activities have discouraged outsourcing for the benefit of internalisation, making it materially impossible for those companies with more moderate research capacity to fairly bargain for access to technology[795]. These companies operate as traditional breeding entities, relying upon the marketing and sales of propagating and planting material for their income-generation, either within a direct line of distribution or through a licensing model for propagation, usually based on plant breeders' rights, a choice determined according to product complexity and market size[796]. Their income is not generated by patented biotechnology research tools or process licenses, and they therefore continue to unreservedly rely on the accessible nature of both improved and exotic agricultural biodiversity. As conventional and molecular private plant breeders mainly rely on

[795] Willingly setting aside the issue related to the impact of consolidation on the amount of research itself, it has been demonstrated through transaction costs and evolutionary theories that the complexity of the the technical information exchanged between actors, as is the case of genomic information pertaining to agricultural germplasm, tends to increase the coordination costs of informational transfers, which in turn has been proven to discourage outsourcing for the benefit of an internalisation of research and development activities; KALAITZANDONAKES and BJORNSON, "Vertical and Horizontal Coordination in the Agro-Biotechnology Industry: Evidence and Implications," *op.cit.*

[796] LOUWAARS et al., *Breeding Business: The Future of Plant Breeding in the Light of Developments in Patent Rights and Plant Breeders' Rights*, *op.cit.*

improved varieties and proven market successes in their research and development programmes[797], they are for sure directly impacted by the restrictions stemming from plant variety rights (and arguably plant patents in the United States), which protect phenotypes as a whole. But they are also increasingly wedged by those "invisible" and unpredictable restrictions stemming from exclusive rights awarded to patent holders over products or processes, or those restrictions on the use of upstream biological material. This truth resonates in the growingly important place awarded to patents in different opinion papers published by industry organisations, whether at the international[798] or national[799] levels. Indeed, even though restrictions on the accessibility of improved genetic material may tentatively preserve the positive prospect of royalty income and foster innovation, it may also hamper the so-called sacrosanct "freedom to operate" that breeders long for, and therefore hamper innovation. The strong property paradigm fails as a result to meet the needs of non-integrated plant breeders on account of the seemingly less substantial weight of actual plant variety protection in light of the technological strides that have expedited bootlegging prospects, but also because of the disruptions in the breeders' access to upstream research tools and mounting complications attached to the use of exotic genetic material.

8.1. <u>Inadequacy of plant variety protection scope</u>

The *ratio legis* of plant variety protection, which had stood out as a better and fitter alternative to patents in agrobiodiversity innovation, has unfortunately not lived up to the expectations of effectively balancing private reward and public interest. At the outset, this legal hybrid was drawn up for the specific needs of the seed industry, especially those entities active in major field crops where hybrids were rare, such as wheat or soybean[800]. It nonetheless faced the difficulty of adapting to thrillingly fast evolving technologies in plant breeding science. Even though the cumulative nature of plant improvement still does take central stage in plant breeders' rights, these titles, including those awarded in accordance with the UPOV 1991 Convention provisos, have not been immune to deficiencies. They have on the one hand been hit by "obsolescence" claims stemming from the brave new world of genotype-based breeding, asking for more precise protection scope in light of easier reverse-engineering possibilities. On the other hand, they have also been hit by critics asserting the ever-shrinking freedom to operate awarded to subsequent breeders, and the growing need for legal training in essential derivation disputes.

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[797] B. WRIGHT, "Intellectual Property and Farmers' Rights," in *Agricultural Values of Plant Genetic Resources*, ed. ROBERT E. EVENSON, D. GOLLIN, and V. SANTANIELLO, Wallingford: FAO, 1998.

[798] The International Seed Federation's 2003 opinion on Intellectual Property only tackled the issue of "legal protection of biotechnological innovations and the co-existence of breeders' rights and patents" in merely two pages, while the 2012 opinion does entail a much more elaborate section on "patents for plant related inventions". See ISF, *op.cit.*, 2012; "*Isf View on Intellectual Property*", ISF, International Seed Federation, 2003.

[799] Numerous industry organisations have enacted complex opinions on intellectual property, having specific regards to the new landscapes of exclusive rights, for instance PLANTUM, "Position on Patent and Plant Breeders' Rights.", or UFS, *op.cit.*, 2011.

[800] Such concern played a particularly prominent role in the enactment of the 1970 Plant Variety Protection Act in the United States; JORGE FERNANDEZ-CORNEJO, "*The Seed Industry in Us Agriculture: An Exploration of Data and Information on Crop Seed Markets, Regulation, Industry Structure, and Research and Development*", United States Department of Agriculture, Economic Research Service, 2004.

8.1.1. Addressing the need to maintain the scope of plant variety protection

Scientific and technological developments in our understanding of heredity have had a tremendous impact on the seed market itself. But they have also widened the possibilities offered to plant breeders to use existing improved varieties, rewarding breeders with speedier and cheaper opportunities to dig into proven market successes. This development thus in turn requires a widespread assessment of the scope of plant variety protection. Indeed, the legal scope and inherent rationale of such *sui generis* protection mechanism may be significantly hampered and downgraded through the impact of new technological abilities. Not only has the scope of prerogatives granted been validly challenged, but the inherent difficulties to enforce one's exclusive rights over self-replicating technologies have also taken centerstage in recent debates concerned with plant breeders' rights. When effective premiums from the marketplace are not soundly available, whether because of a farmers' exemption with no boundaries or high transaction costs in the enforcement of IPR, private actors unvaryingly show a lack of interest in investing in related research programmes[801].

A central challenge to the plant variety protection has come to question the **validity of the industry-specific contours of protected subject-matter**, as well as the cogency of attached prerogatives in a rapidly changing innovation environment. While the main arguments were linked to a need to reinforce protection in order to better capture the benefits of plant varieties protected through plant breeders' rights, some challenges were also raised at foundational levels of the system's *raison d'etre* and its underpinning concepts. It has in this regard been rather successfully argued that the **notion of "plant variety" and the rubric of "DUS testing"** have rather become obsolete because of their intimate bond with underlying technological concepts that have been considerably altered by the shift from phenotypic observation to genotypic analysis and manipulation[802]. Even under the crown of the genotype, the notion of "plant variety" has remained fuzzily carved first around the criteria of homogeneity and stability and then through the taxonomic characterisation that is adjunct to the new more liberal stances of distinctness, uniformity and stability[803]. This approach has led commentators to understand the notion of variety as "a construct that developed as a pragmatic response to the marketplace, […] employed as a convenient legal construct to facilitate consensus on intellectual property rules [rather than] an inevitable consequence of biology"[804]. Furthermore, the merely legal and phenotype-oriented definition of a plant variety is carved around so-called DUS testing, deeply anchored into the analysis of morphological characteristics based on phenotypic observations. These tests nonetheless take a lot of precious time linked to the necessary passage from field trials. These trials may not only take away the competitive advantage of the breeder entering securely into the

[801] This is for instance the case of the United States wheat market, where IP protection is considered low by actors such as Pioneer, HAYES, LENCE, and GOGGI, "Impact of Intellectual Property Rights in the Seed Sector on Crop Yield Growth and Social Welfare: A Case Study Approach," *op.cit.*

[802] MARK D. JANIS and STEPHEN SMITH, "Technological Change and the Design of Plant Variety Protection Regimes," *Chicago-Kent Law Review* 82, 2007. The authors for instance argue that "PVP systems originated at a time when plant breeders conceptualised plants primarily in terms of observable characteristics (phenotype), but must operate today within a new paradigm of plant breeding in which plant breeders can characterise plants by molecular information (genotype)", at p.1561.

[803] BARRY GREENGRASS, "The 1991 Act of the Upov Convention," *European Intellectual Property Review* 13, 1991.

[804] JANIS and SMITH, "Technological Change and the Design of Plant Variety Protection Regimes," *op.cit.*, p.1572. The authors further state that the "variety concept was not an inevitable consequence of biology, but a predominantly commercial and even legal construct that can (and should) be discarded when circumstances change".

marketplace with a protection title at least six months after it could originally do so. These tests are likewise extremely costly, subjective, dependent on environmental interactions, and increasingly subtle as "marketplace pressures drive breeders towards incorporating very similar traits in phenotypically similar plants"[805]. They may as a result hinder the customers' and farmers' access to interesting, socially and environmentally useful new plant varieties. These findings have ignited cry outs asserting that plant variety protection was at a "critical juncture" pushing for its re-examination[806]. As a result, UPOV, as well as national testing centres have strived to incorporate molecular biology tools into their DUS protocols by adopting several intricate guidelines[807], in order to ensure time and efficiency gains. Such inclusion however fails to operate the necessary technological shift, not only because these criteria need to be adapted in accordance with the specific varieties to be testes, but also because most of the time researchers and analysts do not find adequately relevant significance between the data generated through molecular markers and morphological analysis[808]. These tools are as a result considered more as welcomed additions to the DUS testing protocols, but cannot by any means replace the time-consuming and costly phenotypic and subjective analysis on the field[809].

Technological strides have not solely shaken down the sturdiness of protection criteria and its accompanying definitions. They have also challenged the **effectiveness of the incentive lying at the foundation of plant variety protection**. Indeed, there has been mounting frustration at the potency of prerogatives granted to plant breeders. "Central to this dissatisfaction is the idea that the natural copying mechanism inherent in plants poses a major protective risk for those involved with developing new plant varieties"[810]. This protective risk has been considerably heightened on account of the precision and speed injected to plant breeding by molecular biology tools, which altered seed replacement cycles alongside the structural changes witnessed in the provision and creation of genetic diversity. Technological strides have considerably shrunk the commercially successful life of modern varieties, ranging from three up to seven years[811]. This dwindling and

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805 "Technological Change and the Design of Plant Variety Protection Regimes," *op.cit.*, p.1583.

806 In order to overcome its obsolence, JANIS and SMITH advocate that PVP system be remoulded closer to a system governed mostly by unfair competition rules. However, such solution has been validly questioned as a mere mitigation and not elimination of the obsolence problem, which could then be rather addressed by incremental reforms aimed at reducing the opportunities for industry capture, see LAURENCE R. HELFER, "The Demise and Rebirth of Plant Variety Protection: A Comment on Technological Change and the Design of Plant Variety Protection Regimes," ibid.: pp.1619-1626.

807 UPOV has for instance responded to such need through the so-called "BMT guidelines" adopted in 2010 and in 2011 the DUS testing guidelines; see UPOV, "Guidelines for DNA-Profiling: Molecular Marker Selection and Database Construction," in *UPOV Council, 44th ordinary session, UPOV/INF/17/1*, ed. UPOV (Geneva2010); "Possible Use of Molecular Markers in the Examination of Distinctness, Uniformity and Stability," in *UPOV Council, 45th ordinary session, UPOV/INF/18/1*, ed. UPOV (Geneva2011).

808 This has for instance been the case of the infamous SSR markers in pepper varieties, see YONG-SHAM KWON et al., "Use of Ssr Markers to Complement Tests of Distinctiveness, Uniformity, and Stability (Dus) of Pepper (Capsicum Annuum L.) Varieties," *Molecules and cells* 19, no. 3, 2005.

809 For grape varieties, researchers proved once again that there were no significant correlation between SSR and morphological data, but they also found that "genetic distances measured by SSRs were correlated to pedigree. These results suggested that SSRs could be used for pre-screening or grouping of existing and candidate varieties, allowing the number of varieties that need to be grown for comparison to be reduced". L TOMMASINI et al., "The Development of Multiplex Simple Sequence Repeat (Ssr) Markers to Complement Distinctness, Uniformity and Stability Testing of Rape (Brassica Napus L.) Varieties," *Theoretical and Applied Genetics* 106, no. 6, 2003.

810 JAY SANDERSON and KATHRYN ADAMS, "Are Plant Breeder's Rights Outdated - a Descriptive and Empirical Assessment of Plant Breeder's Rights in Australia, 1987-2007," *Melbourne University Law Review* 32, 2008: p.981.

811 P.W. HEISEY, "Accelerating the Transfer of Wheat Breeding Gains to Farmers: A Study of the Dynamics of Varietal Replacement in Pakistan," ed. CIMMYT RESEARCH REPORT NO.1 (Mexico1990)., but also LOUWAARS et al.,

limited time-span during which plant breeders are now required to amortise the costs of their research and development efforts has pushed them not only to increase the price of their seeds, but also to rethink and refocus their intellectual property rights approach towards **fuller enforcement, both vis-à-vis farmers and other breeders.** Several roads were taken in order to strengthen the title of plant variety protection, all of them targeted at raising the amount of potential royalties to be touched by the breeders, either from farmers or from fellow breeders protected material to develop and thereafter commercialise directly competing and worryingly similar products. Action has to that end been taking place in the legislative front, through direct amendments operated to the UPOV Conventions, accommodating the new needs of the changing plant breeding industry, but to limited avail. Two main amendments were brought in with the view of enhancing protection for plant breeders, both touching the prerogatives granted to the latter, either by mending the farmers' privilege, or by expanding the reach of the bundle of rights to so-called essentially derived varieties.

The gradual restriction of the farmers' exception in UPOV Conventions has indeed been advocated with a clear policy objective of enticing the private sector's interest in plant breeding, especially in market segments with strong farm saving opportunities and practices. However, it is incredibly difficult to monitor such farming practices and pursue infringers. The issue of farm saved seed royalties is much more important in cereals where exploitations tend to be larger in size, and the financial return from eventual farm-saved-seed royalties to breeders is estimated to amount to sixty five to seventy five million EUR per year[812]. In the absence of absolute permission rules, farmers decide in effect whether and to what extent they will make use of the farmers' privilege under plant variety protection. This means that "an incalculable number of plantings are undertaken each year, so that the holder or, as the case may be, the organisation representing him are not in a position to uncover by themselves cases of planting which entitle them to remuneration"[813].

Plant breeders had gradually been not only losing royalty income to farmers, but also increasingly to their direct competitors, on account of the self-replicating nature of plant innovations and the growingly less costly technological means to open up a stable variety's heredity. Indeed, owing to the new opportunities offered by molecular biology and the development of plant breeding science in general, the existence of the breeders' exception in plant variety protection also meant that an almost unfettered access would accompany the release of a carefully developed plant variety into the market. A product that took years to stabilise could directly end up in a competitors' gene pool, rapidly igniting research and development activities to improve the material through the natural and human resources at the breeders' disposal. Worse, the competitor could even commercialise and directly compete with one's own product relatively quickly, by operating only minor changes to the initially protected variety, having recourse to so-called "plagiaristic breeding". Technological strides digging deeper into applied molecular biology have considerably eased reverse breeding opportunities. This is particularly intriguing for breeders as the purification and thus use of parental lines has become much easier than before, opening competitors' gateway to

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Breeding Business: The Future of Plant Breeding in the Light of Developments in Patent Rights and Plant Breeders' Rights, *op.cit.*, p.12.

812 See the advocacy group: http://www.lafranceagricole.fr/actualite-agricole/semences-de-ferme-cov-l-esa-pour-un-systeme-harmonise-au-plan-europeen-69285.html

813 Commentary of *ECJ, Schulin v STV*, IPPT20030410, 2003, at p.5.

their sacred Grail. These tough realities propelled the need to better enforce the PVP system and provide more exclusivity through a tougher stance on “plagiaristic breeding”. It is to this end that the 1991 UPOV text has introduced a novel concept, that of **essential derivation**, which extended the range of acts requiring the initial breeder’s authorisation, as aforementioned. As aforementioned, the 1961 and 1978 acts were indeed deemed insufficient in light of the globalised industry’s new needs[814], and could not "prevent converted lines from infringing and pirating breeder's genetic material"[815]. As a result, Article 14(5) of the UPOV 1991 text now warrants the negotiation of a licensing agreement not only when the protected variety's use in a breeding programme leads to the commercialisation of a new variety that is not clearly distinguishable from the initial protected variety, but also when it leads to an "essentially derived variety". This expansion of protection was viewed as “the UPOV system’s most salient response to technological obsolescence”, drawing from “debates in patent law over non-literal infringement and in copyright law over the distinction between unauthorised derivate works and transformative fair uses”[816]. As aforementioned, this extension was also echoed in Article 13(1) and (2) of Council Regulation EC/2100/94, but both texts are worryingly silent on whether the differences that are sought after to assess essential derivation ought to be quantitative or qualitative.

The efforts to overcome the shortcomings of PVP protection on account of technological developments have as a result unsurprisingly **not really triggered the projected success**, mainly on account of the inherent difficulties to pursue legal action against potential infringers. Court decisions are indeed extremely rare in the case of EDV’s, as plant breeders prefer settling for arbitration with their direct competitors rather than entering into costly and lengthy trials. The first judicial interpretation of the notion came only in 2005, fourteen years after the enactment of the principle, from the District Court of The Hague in the Netherlands, in a case opposing Astée Flowers and Danziger 'Dan' Flower Farm[817]. The Court considered that 'a variety, even if it is to be regarded as deriving from another variety, may not differ significantly from the original variety',

> “The Court holds the opinion that it can be concluded from (the creation history of) the rules in both the UPOV Convention and the EU Regulation that a variety must not deviate considerably from the initial variety in order to consider it an EDV. First of all, the simple fact that the variety has been used at some point during the development of the new variety is not enough ground to consider the latter an EDV. To that end the Court points at the wording “essentially derived”, apparently to express the discrepancy between the EDV and the initial variety should not be too substantial […]. As a result of such analysis, the Court argued that “it was insufficiently motivated that and why that variety should be considered an EDV”, since “the differences were so substantial in number and significance”, and “it was insufficiently demonstrated how the large number of morphological differences could have been obtained with only relatively simple ‘acts of derivation”[818] (Astée Flowers vs Danziger 'Dan' Flower Farm, District Court of the Hague).

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[814] WENDT and IZQUIERDO, "Biotechnology and Development: A Balance between Ipr Protection and Benefit-Sharing," *op.cit.*
[815] ISF, *op.cit.*, 2005.
[816] JANIS and SMITH, "Technological Change and the Design of Plant Variety Protection Regimes," *op.cit.*, p.1592.
[817] District Court of the Hague, *Astée Flowers vs. Danziger 'Dan' Flower Farm*, 13th July 2005.
[818] Translation obtained through UPOV Newsletter no.99, September 2005, pp. 9-10.

This approach would preclude the launch of genetic comparison if faced with important morphological distinctions; an opinion not shared unanimously in the industry[819]. The claimant would indeed need to provide substantial evidence linking the small genetic differences to the carrying out of acts of derivation, i.e. that the initial protected variety had been used as a parent or grand-parent to the new variety. Such an approach, while maintaining the breeders' exception alive and well, may nonetheless considerably tone down the appeal of this new extension of prerogatives grounded on the greater ease of reverse engineering. The number of court cases addressing issues of plagiaristic breeding has arguably risen since then, but to too little or very limited avail. A major turning point was reached recently when an Italian judge from the Milano district court condemned Agriseeds to pay two hundred and five thousand EUR of damages (which covered all unjustified profits made with the sale of the copied variety, and an additional compensation for legal costs) to Rijk Zwaan in a case involving the international copying of a protected lettuce variety, which lasted seven long years to end in 2013[820]. Nevertheless, the relative simplicity of the case, which only involved the copying and identical reproduction of a protected variety, and its length of seven years compared to such straightforwardness, do push the commentator to raise the absence of effectiveness of plant variety protection. Company representatives from Rijk Zwaan conclude nonetheless that even though "cases like this are undoubtedly complicated and time-consuming, this example shows that fighting infringement in court can indeed be successful, [while they] hope that this positive outcome will motivate other seed companies to pursue infringement cases too"[821]. If the mere unlawful reproduction of protected plant varieties has to be fought for seven years, it becomes difficult to imagine how a traditional plant breeder can litigate disputes involving claims of essential derivation. Indeed, the EDV concept introduces numerous thresholds for triggering legal obligations for subsequent breeders. First of all, it relies on an overarching concern to establish the distinctness between the two concerned plant varieties, since if a subsequent plant variety is not distinct from the protected initial variety, the question of essential derivation should not even be addressed. Then it adds in the conditional layers of 'derivation' and the pursuit of 'conformity of the subsequent variety to the essential characteristics' of the initial variety. The concept of EDV has as a result failed to convince commentators because of the lack of precise thresholds and their inherent deficiencies to elucidate "the precise boundaries lines to define the scope of protected subject matter"[822].

At last, the UPOV 1991 text also relies on the principle of "limited dependence", which differentiates the cascade of derivation and that of legal dependence. According to such principle, a variety that is already considered to be essentially derived from another cannot be considered as an initial variety to another distinct plant variety, since "an initial variety cannot in any case be an EDV of some pre-existing protected variety"[823]. This limited dependence has been vehemently criticised in its inherent risk of overcompensating initial variety developers to the detriment of follow-on breeders of "intervening varieties" that may come in play further down the chain of

[819] Kiewiet, "Essentially Derived Varieties," *op.cit.*
[820] Casper Van Kempen, "Enforcement: Protection Is Only Half the Job," *Prophyta (Journal for breeders and producers of plant material)*, 2013., pp.28-31
[821] Press release of 05.12.2012, "Rijk Zwaan wins landmark case against illegal reproduction", available http://www.rijkzwaan.com.ua/wps/wcm/connect/rz+corporate/rijk+zwaan/news+and+events/news/news+items/rijk+zwaan+wins+landmark+case+against+illegal+reproduction(accessed May 2013).
[822] Janis and Smith, "Technological Change and the Design of Plant Variety Protection Regimes," *op.cit.*, pp. 1596-1598.
[823] "Technological Change and the Design of Plant Variety Protection Regimes," *op.cit.*, p.1594.

incremental plant improvement[824]. That is why the complexity of the "project to use EDVs to delineate [greater] scope of plant protection [has] become apparent […], as initial enthusiasm about EDV provisions is giving way to more sober reflections about the costs and challenges that they entail"[825]. The main legislative response to the lack of effective PVP protection in the molecular breeding age has therefore not solved the challenges experienced by non-integrated smaller-scaled private plant breeders. Not only has the notion of EDV further blurred the contours of protection for follow-on innovators, it has also failed to address the disconforts accompanying definitions of plant varieties and DUS testing operations.

8.1.2. Fronting the tragic fate of the breeders' exception

The breeders' exception is undoubtedly one of the cornerstones of the plant variety rights regime. It is the essence of this "legal hybrid", which allows for the continuous exchange and use of agricultural biodiversity between variety developers. It has in this sense been advocated very vocally as one of the main tools through which plant breeders continue to contribute not only to the overarching conservation and sustainable use goals of international environmental law, but also as a means to share the benefits deriving from the use of genetic resources. Indeed, the breeder's exemption and other exceptions to the breeder's right are viewed as "**inherent benefit-sharing principles**" found in the UPOV Convention[826]. Leaving improved varieties open for research undertaken on the material but also for the development of new and potentially competing plant varieties can indeed be likened to a form of technology transfer. Such transfer is vital for small and medium plant breeding companies, as it allows them to constitute and feed their gene pools without weighty costs. However, important tensions have arisen "between first generation breeders who have secured legal protection for new varieties and second generation breeders who seek to utilise those new varieties to develop more varieties"[827]. These tensions need to be duly addressed so as to continue to permit second generation innovators to engage in the production of public goods without the authorisation of first generation breeders, while also giving sufficient incentive for breeders to continue innovating and seek formal protection.

The breeders' exception has **seen its range considerably shrink** over time. Former industry players openly admit that

> "some major seed companies are loudly thinking about amendment of the breeder's exception, which is the cornerstone of the UPOV Convention. The idea is to delay access to protected plant varieties for breeding purposes for a number of years, whereby the delayed access might be different depending on the species"[828].

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824 W. LESSER and M.A. MUTSCHLER, "Balancing Investment Incentives and Social Benefits When Protecting Plant Varieties: Implementing Initial Variety Systems " *Crop Science* 44, 2004.
825 JANIS and SMITH, "Technological Change and the Design of Plant Variety Protection Regimes," *op.cit.*, p.1599.
826 UPOV, "Access to Genetic Resources and Benefit-Sharing: Reply of Upov to the Notification of June 26, 2003, from the Executive Secretary of the Convention on Biological Diversity (Cbd)," (Geneva: UPOV International Union for the Protection of New Varieties of Plants, 2003).
827 HELFER, "Intellectual Property Rights in Plant Varieties: An Overview with Options for National Governments."
828 WALTER SMOLDERS, "*Disclosure of Origin and Access and Benefit Sharing: The Special Case of Seeds for Food and Agriculture*", Quaker United Nations Office, Geneva, 2005.

This daunting prospect has nevertheless not yet seen the light of day, even though the breeders' exception has been considerably shred through amendments made to the UPOV Convention. Indeed, while under the 1961 and 1978 texts, this prerogative transpired like a true exemption, the 1991 version raised it to the rank of a "*compulsory exception*", through which certain actions would exceptionally not fall under the breadth of PVP protection. In all scenarios, licensing negotiations would emerge if the use of a protected variety in a breeding program had led to the commercialisation of a new variety that is not clearly distinguishable, or whose production required the repeated use of the protected variety. Under the latest Convention text however, the authorisation of the initial breeder will further be waived provided that its competitors' breeding programme does not produce an essentially derived variety. Even though "absolute permission rules" still delineate informational property titles (in accordance with which the permission of the monopoly-owner ought to be sought for using the protected information), liability rules (whereby the entitlement can be used without permission so long as adequate compensation is granted later), embody the specificity of cumulative plant-breeding innovation through the unequivocal breeders' exemption of PVP legislation[829]. The concept of essential derivation was not in essence designed to weaken such exemption, but rather to fight plagiarism. But it may have actually perhaps done so.

The main challenge faced by conventional plant breeders in this regard relates to the shrinking room for manoeuvre left for the use of protected material in breeding programmes. This shift has arguably converted plant breeders' prerogatives to use protected varieties to develop new biodiversity from a complete exemption from authorisation into an exception to the rights conferred to breeders. The aforementioned District Court decision of The Hague attempted to remedy such shift by stating:

> "The Court finds it important that the extension of the protection of initial varieties to EDV's can be considered an exception provision to the main rule of independence of distinguishable varieties. Being an exception, it should be interepreted in a limited manner" (Astée Flowers vs Danziger 'Dan' Flower Farm, District Court of the Hague).

Nonetheles, the wording of both the UPOV 1991 Convention and the EC Regulation remain very vague, and the interpretation it received in practice seemed to consider its reach as a tool to be used against all varieties tenuously resembling and thus directly competing with the "initial variety". These elements meant that the EDV concept bore the perilous risk of reducing the nature of statutory undeniable-use exemptions. Such an extension retains a disquieting potential to be used as a weapon to shut down or delay competitors possessing potentially better-performing yet dangerously similar products which would directly enter into competition with protected varieties, especially in relatively constrained markets such as the Mediterranean market for brown tomatoes for instance. Rather than trying to identify infringers, the extension of plant variety protection may create unnecessary and unproductive hostility within an innovation chain that is bound to create similarly derived products. That is why certain commentators take a restrictive interpretation to the notion of EDV, asserting that "the extension of breeders' rights to cover essentially derived varieties may be limited to varieties that take over virtually the whole of the genome of the

[829] MERGES, "Institutions for Intellectual Property Transactions: The Case of Patent Pools," *op.cit.*

protected variety"[830]. It seems nonetheless correct to assume that with little consensus over the genetic conformity threshold required to activate this extensive protection granted to cosmetic modifications, the EDV addition could be detrimental to small-scale breeders[831], especially those who do not have experience or training in legal proceedings. The current nebulous bundle of rights stemming from plant variety protection needs to be reforged into a fair and consistent system[832].

The essence itself of plant innovation, i.e. its self-replicating nature and its inherent link with cultivation, as well as technological developments in plant breeding science, have thus raised considerable challenges when it comes to ensure that plant variety protection's scope still remains interesting for breeders, without annihilating its inherent balance. These challenges are reflected in the shadows surrounding the criterion for protection, whether in its phenotypic focus or its newfound boundary of essential derivation. They are further enhanced by the substantial difficulties that detract from the enforceability of such protection titles, whether against farmers or fellow breeders. As a result, the new balance found in the international breeders' rights legislation is found to have **failed to grant breeders adequate and clear protection promises** that should warrant against an argued obsolescence and allow the full capture of fair benefits of an IP title faced with new imitation technologies. Instead, it has rather managed to overlook or at least curtail the role of liability rules embedded within the breeders' exception in the successful use of agrobiodiversity on farm and other small breeding programmes. Rather than addressing the arguably obsolescent failures of plant variety protection in terms of scope, the changing approach to the breeders' exception and the concept of essential derivation have exacerbated the drift away from a balanced public domain between initial and subsequent innovators.

8.2. Disruptive access to upstream research tools, patented products and processes

Today, the smallest portions of biological material may have a great impact over the entire plant breeding process. Researchers working on molecular breeding tools and breeders who wish to use them in their variety development program increasingly encounter numerous and fairly different intellectual property rights titles along the way, whether broad or restrictively defined. As a result, they face problems that highly resonate with those witnessed by public researchers, who are also faced with the plethora of legal entitlements that surround the research tools they need to in the cumulative chain of agrobiodiversity improvement. The issues appear nonetheless heightened in the case of plant breeders who encounter first-hand the great incrementality of their activity, and whose only sources of income stem from the marketplace. They are forced to adjust their practices to the co-existence of their old friend, plant variety protection, with other forms of legal entitlement attached to invisible and unimaginable portions of their gene pools. Encounters with patents are frequently problematic, requiring new assessments, strategies and thus training in order to be comprehended first, and dealt with later. Furthermore, the aforementioned example related to

[830] MICHAEL BLAKENEY, JOEL I COHEN, and STEPHEN CRESPI, "18 Intellectual Property Rights and Agricultural Biotechnology," *Managing agricultural biotechnology: addressing research program needs and policy implications*, no. 23, 1999.

[831] S. NARASIMHAN and D. ROBINSON, UNDP, UNITED NATIONS DEVELOPMENT PROGRAM, NEW YORK, 2008, P. 8. , "*Towards a Balanced 'Sui Generis' Plant Variety Regime: Guidelines to Establish a National Pvp Law and an Understanding of Trips-Plus Aspects of Plant Rights*",

[832] See for instance the opinion of the Secretary of the Committee for Novelty Protection of the International Association of Horticultural Products, MIA BUMA, "Essentially Derived Varieties and the Perspective of Growers," in *UPOV Seminar on Essentially Derived Varieties (October 22, 2013)* (Geneva2013).

the "Biolistic Particle Delivery System" gene gun technology has proven that adequate strategies may not always suffice to obtain authorisation to use patented technology. The example has further shown that refusals to license may at times also be anchored in unjustifiable rationale such as the potential licensee's competitor status in a different product market, hampering the production of socially beneficial goods[833].

8.2.1. <u>Issues of co-existence of patents and plant variety protection</u>

Even though patents tend to take centerstage in breeders' difficulties to access products or processes important for their research and development programs, other instruments may also be found on the path to accessing, developing or commercialising new socially desirable plant varieties. Relying heavily on the physical security that may cover the companies' facilities, trade secrets may also cover new research programs or technologies under development, but may also realte to aspects of plant biotechnology that cannot be detected in the final plant product, such as markers and regeneration methods, thereby avoiding the disclosure requirements entailed in PVP or patent protection[834]. The withholding of technical information undisclosed through the recourse to trade secrets does in truth not serve the public interest. This finding does reinforce the case for strong disclosure-based intellectual property tools such as patents or PVP, which at least allow for direct mechanisms to access protected technology[835].

Notwithstanding the even more invisible threat of trade secrets hidden within plant varieties, smaller-scaled private plant breeders are increasingly confronted with an unfamiliar and strong legal entitlement, i.e. patents. They are in this regard first confronted to a major feature of this strong entitlement, its **almost inexistent breeders' exemption**. Indeed, as aforementioned patents traditionally award relatively restricted room to follow-on use possibilities *vis-à-vis* protected innovations, especially in active breeding programmes. Patent legislation worldwide extremely rarely provides for exceptions to exclude third parties with specific respect to research conducted within the protection innovation, or to breeding. When both the patent and PVP systems are in interplay, "the highest level of protection afforded by patents for biotechnological inventions threatens the existence and weakens the functionality of the breeders' exemption, which is an essential feature of any *sui generis* PVP system"[836]. While the breeders' exemption that recognises immediate rights over protected material for further use in breeding programs, does remain the absolute foundation of plant variety rights protection worldwide, it is scarce in patent legislation. Indeed, under the tight-lipped TRIPS framework and the worryingly mute European Directive, merely a handful of national legal orders allow for breeding-specific research possibilities outside of negotiated licenses. In Germany, France and Switzerland (and probably soon in the Netherlands), the infamous PVP breeder's exemption has found its echo in patent legislation, where breeding programs could be initialised, even when the material contained patented traits, the consent of the patent holder needing to be sought at the commercialisation stage. The lack of consent from the right holder for carrying out active commercial research using the innovation

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[833] PRAY and NASEEM, "Intellectual Property Rights on Research Tools: Incentives or Barriers to Innovation? Case Studies of Rice Genomics and Plant Transformation Technologies," *op.cit.*
[834] XU, *Molecular Plant Breeding*, *op.cit.*
[835] DUTFIELD, *Intellectual Property Rights, Trade and Biodiversity*, *op.cit.*, p.25.
[836] CLAUDIO CHIAROLLA, "Commodifying Agricultural Biodiversity and Development- Related Issues," *9* 1, no. 25-60, 2006.

remains at first sight quite a positive departure from traditional patent protection, but its efficiency still needs to be tested[837], as early indicators show that such flexibility has in practice resulted in hostile reactions from competitors wishing to shut down on-going research activities[838].

In order not to diminish the incentive of patent protection, these options remain exceptional, and are awarded relatively restricted room. Licensing negotiations will thus largely triumph over the mandatory cavities that ensure less contrived further cumulative research or traditional seed saving practices for non-commercial purposes. However, companies that still generate their income from plant-variety licensing, sale or distribution, rather than patented biotechnology research tools or process licenses, continue to unreservedly rely on the accessible nature of both improved and exotic agricultural biodiversity[839]. The seed industry itself has quite vocally expressed its reserves to the inherent **risks of seeing patents and plant variety rights co-exist in the same genetic material**. Adopted in 2003, the International Seed Federation's view on Intellectual Property recalls that it is "strongly attached to the breeders' exception provided for in the UPOV Convention and is concerned that the extension of the protection of a gene sequence to the relevant plant variety could extinguish this exception"[840]. The 2003 Bangalore position paper, which mainly focused on plant variety protection and addressed patents and their co-existence in the last two of its total of fifteen pages, has been revised in 2012[841]. It now is thirty five pages long, and consecrates a greater deal of attention to patenting than before, epitomising the clear industry need to come up with common and workable solutions to the issue of co-existence of patents and plant variety rights, especially in a predominantly nationally regulated subject-matter that could have extremely damaging consequences for global seed trade.

8.2.2. Impact of ownership landscape and enforcement practices

Notwithstanding the new challenges of determining freedom to operate when faced with plant variety and patent protection on the same material, private plant breeders, just as public researchers, are also confronted to the **nearly monopolistic nature of patent ownership** in agricultural biotechnology and molecular plant breeding. Even when patents are favoured rather than trade secrets, companies with more moderate research capacity have been pushed in a really delicate bargaining position to gain access to technology. Both small and large actors of the private sector have been forced to negotiate licensing agreements with the "gene holders"[842], mainly on account of the legal exclusive rights granted upon the traits themselves. Just as public researchers, the challenges faced by plant breeders do not only stem from the high number of patents in agricultural biotechnology, they also derive from the enclosure of foundational or platform technologies, and the multitude of actors with multitudes of claims on complementary technologies or products[843]. The plant genetics and genomics industry's concentration rate has

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[837] BLAKENEY, "Patents and Plant Breeding: Implications for Food Security " *op.cit.*
[838] PLANTUM, "Position on Patent and Plant Breeders' Rights."
[839] LOUWAARS et al., *Breeding Business: The Future of Plant Breeding in the Light of Developments in Patent Rights and Plant Breeders' Rights, op.cit.*
[840] ISF, *op.cit.,* 2003.
[841] *op.cit.,* 2012.
[842] For a recent economic analysis of incentives at the hands of private companies vis-à-vis integration or licensing strategies depending on their position in the market, see GUANMING SHI, "Bundling and Licensing Genes in Agricultural Biotechnology," *American Journal of Agricultural Economics* 91, no. 1, 2009: 264-274.
[843] BARTON, "Intellectual Property, Biotechnology and International Trade: Two Examples," *op.cit.,* p.288.

been considerably heightened through the grant of patents on germplasm. As aforementioned, the contemporary notion of "traits market share" vis-à-vis biotechnology enhancement traits such as disease resistance or herbicide tolerance, has generated complex cross-licensing practices, where multinationals and small-scale companies alike find themselves more intricately linked to each other and to the market leader than in merger or acquisition situations. Again, in 2003, much of the IP in agricultural biotechnology was aggregated into a few very large IP portfolios held by major corporations, the top five of which controled forty one per cent in the United States[844]. Indeed, today “half-dozen major firms […] hold substantial numbers of key patents […and] have coverage of the related enabling technologies”[845].

The most bothersome aspect of wide control over agrobiodiversity research and development tools remains the unknown nature and range of existing patents or other intellectual property rights, combined with the possibility of a use-blocking license negotiation. Restrictive regulation, but also aggressive practives can in this context certainly increase the transaction costs involved in research and development activities. These characteristics have notably led to the crowning of the expression **“freedom to operate” in plant-related research**, as an incessant quest to ensure that the fruits of methodical selection or other developments can be commercialised in the long run, a freedom determined by the status of exclusive rights which may exist on the material and thus requiring continuous and prohibitively expensive surveillance[846]. A researcher who for instance wishes to transform plants using *Agrobacterium* related techniques, would not only need to seek the authorisation of the owner of the patents on the transformation methods themselves, but also cope with those possessing monopoly rights over the promoters, the marker genes and the actual gene of interest that is being introduced in to the plant[847]. The obstructive potential of licensing practices becomes especially frightening and genuine in light of a prospective obstruction in the commercialisation of socially useful innovations. Indeed, an innovation thought to be ready for the market might be completely blocked or inconveniently delayed through the upstream technology controller's decision. Breeders ought to make considerable yet often times insufficient efforts not to use proprietary transformation or fingerprinting techniques, to finally find that specific genes they were actively working on, or that simply found their way into the new combination, were protected by exclusive property rights, thereby requiring heavy licensing negotiations at the end of lengthy product development phases. These deals, occurring often times at the last stages of years-long research, when foundation seeds for distribution or cultivation may even be ready, have known to be quite ferocious. "Delay in obtaining access to a component of a complex technology is of course especially damaging to firms in technologies with a short life cycle, where the first firm to the market has every chance of setting the standards and even of locking the others out"[848]. This is especially true when patents are used as trading currencies rather than exclusive rights over

[844] GRAFF et al., "The Public-Private Structure of Intellectual Property Ownership in Agricultural Biotechnology," *op.cit.*, where the authors analyse different clusters based on technology, such as plant enzymes, bacillus toxin, industrially important enwymes, metabolic pathways, disease resistance in rice, male-sterile seeds, viral proteins, herbicide resistance, product-quality traits, flowering control, pathogen resistance.

[845] FALCON and FOWLER, "Carving up the Commons: Emergence of a New International Regime for Germplasm Development and Transfer," *op.cit.*, pp.204-205.

[846] JIM DUNWELL, "Patent and Intellectual Property Rights Issues," in *Transgenic Crop Plants*, ed. C. KOLE, et al., Springer, 2010, pp.411-433.

[847] PRAY and NASEEM, "Intellectual Property Rights on Research Tools: Incentives or Barriers to Innovation? Case Studies of Rice Genomics and Plant Transformation Technologies," *op.cit.*, pp.108-117.

[848] KINGSTON, "Innovation Needs Patent Reform," *op.cit.*, p.408.

a particular innovation. Maize breeders' practice raises serious concerns for the future of innovation in this regard, since they openly admit they would rather use their own gene pool rather than adventurously seeking new biological material, out of fear of falling against patent inquisitions aggressively operated in the United States[849]. Examples regarding delays in attaining research results, or simply conveying the difficulties to gain access to technologies are regrettably numerous. A blatant example of the linkage between strong IPR and the damage to the freedom to operate stems quite surprisingly from the cereals market. The flax breeding world has indeed been identified as relatively easy to navigate, on account of the market's relatively small dimension, the important presence of public sector initiatives and the limited use of biotechnology and molecular biology tools[850], compared for instance to the realities of the canola or soybean markets, where intellectual property rights have shrank breeders' freedom to operate. Another more specific example stems from the aforementioned polymerase chain reaction patent landscape, which remains central to molecular plant breeders, even though its reach has been wider in the biomedical sector. The technology, along with all associated components such as enzymes, but also all machinery and applications, has been at some point covered by six hundred patents claiming different aspects of PCR[851]. Most of the fundamental ones belonged to Hoffman – La Roche who capitalised all research applications linked to PCR by manufacturing the instruments and reagents needed for the process through joint ventures and licensors[852].

Just as public researchers, private plant breeders are the "middle men" of a cumulative cycle with few ground-breaking discoveries, where actors who possess restrictive monopoly rights upstream in the innovation chain have the ability to "choose the optimal level of output for the intermediate good embodying the patented technology"[853]. They face the extremely detrimental consequences of such weak position in the chain, trying to develop improved and stable new plant varieties which may unfortunately, knowingly, or unknowingly contain patented technology. Used to the legal hybrid of plant variety protection where the public domain is defined more loosely thanks to the breeders' exception, plant breeders have been taken aback by the risks of seeing their mareketable varieties blocked by the upstream technology controllers' decisions.

8.3. <u>Access and use of upstream biological material</u>

As aforementioned, most plant breeding programs rely predominantly on proven market successes, and are therefore impacted more greatly by intellectual property rights vested in such stabilised and improved germplasm. Yet they also depend upon the availability of landraces or wild relatives. Arguably, all improved germplasm also finds its origins in farmers' varieties, gene bank resources and wild germplasm; albeit having gone through an exponential number of crosses over breeding cycles. Furthermore, exotic resources and landraces still directly constitute a smaller yet

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[849] LOUWAARS et al., *Breeding Business: The Future of Plant Breeding in the Light of Developments in Patent Rights and Plant Breeders' Rights*, *op.cit.*

[850] VIKTORIYA GALUSHKO and CAMILLE RYAN, "Intellectual Property and Freedom to Operate in the Flax Breeding World: Canada in the Global Context," *International Journal of Technology and Globalisation* 6, no. 3, 2012: pp.171-187.

[851] CARROLL and CASIMIR, "Pcr Patent Issues," *op.cit.*, p.7.

[852] FORE, WIECHERS, and COOK-DEEGAN, "The Effects of Business Practices, Licensing and Intellectual Property on Development and Dissemination of the Polymerase Chain Reaction: Case Study," *op.cit.*

[853] GOESCHL and SWANSON, *op.cit.*, 1999; GOESCHL and SWANSON, "The Social Value of Biodiversity for Research and Development," *op.cit.*

vital part of private breeding pools, as they are esteemed highly by variety developers in terms of long-term security[854]. As aforementioned, breeders totally renew their stocks every ten to fourteen years, renewal for which natural diversity pools need to remain at their widest range[855]. It has in this sense been argued that "the worldwide community of breeders needs access to all forms of breeding material to sustain greatest progress in plant breeding and, thereby, to maximise the use of genetic resources for the benefit of society"[856].

The **opportunities to access exotic or local biological material, notably through international or national gene banks**, in order to feed or refresh their private collections has therefore an impact on the variety of resources that may be found in breeding pools. Private plant breeders thus feel the weight of public domain restrictions stemming from international environmental law[857]. If access to external resources is deemed difficult or overly costly, both financially and in terms of administrative burden, breeders would indeed spend greater effort in the maintenance of their exotic material. But they could also restrain from using exotic and local material as a whole, rather focusing on opportunities offered by improved material developed by their competitors around the globe for instance. The variability of breeding pools would inevitably suffer from such internal fall-back. The preservation but also the access to agricultural plant germplasm's wild relatives directly influences the future of agricultural research and development and concurrently agro-biodiversity as a whole[858]. Its natural basis cannot be reduced. In this regard, the importance of wide genetic diversity in plant breeding activities seems to counteract with the homogeneity found in the resulting new high-yielding varieties. Restraining the genetic pool available for both natural and human selection (by farmers and plant breeders alike) and narrowing the genetic base of agricultural crops may have extremely detrimental effects. It indeed increases the vulnerability of agricultural crops to sudden changes in climate, and to the appearance of new pests and diseases[859], an immense threat to future food production[860]. Enabling access to exotic material, but also, and more importantly, to characterised, halfway material or plant varieties and associated knowledge would contribute to the fight against homogenisation. It would as a result be conducive of more social welfare inducing agrobiodiversity uses.

Such access nonetheless needs to accommodate the **biopiracy concerns** that have been rightfully raised and consequently consecrated in the public domain fenced by international environmental

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[854] DUTFIELD, *Intellectual Property Rights, Trade and Biodiversity*, *op.cit.*, 5-6.
[855] See the results of the study revealed by Timothy SWANSON (in SWANSON, *Global Action for Biodiversity, an International Framework for Implementing the Convention on Biological Diversity op.cit.*, 73-75., whereby approximately 83 percent of R&D is conducted on the basis of standardised varieties, while 6,5 percent focuses on wild species and landraces.
[856] UPOV, "Access to Genetic Resources and Benefit-Sharing: Reply of Upov to the Notification of June 26, 2003, from the Executive Secretary of the Convention on Biological Diversity (Cbd)."
[857] A more detailed account of such restrictions shall be given in Part IV of this study, especially its Chapter 11.
[858] This reality has been further enhanced through technological developments whereby breeders increasingly use genetic material found in wild species which contain valuable alleles, while they focused on elite material, mainly found in genebanks, in the past; see JEREMY R. FRANKS, "In Situ Conservation of Plant Genetic Resources for Food and Agriculture: A Uk Perspective," *Land Use Policy* 16, 1999: 81-82.
[859] For a more detailed account of the consequences of genetic vulnerability, see STEPHEN GLIESSMAN, R. ERIC ENGLES, and ROBIN KRIEGER, *Agroecology: Ecological Processes in Sustainable Agriculture*: CRC Press, 1998, 205-206.
[860] See for instance PAUL R. EHRLICH, ANNE H. EHRLICH, and GRETCHEN C. DAILY, "Food Security, Population and Environment," *Population and Development Review* 19, no. 1, 1993: 1-32., HARLAN, *Crops and Man (2nd Ed.),*, *op.cit.*, HAWKES, *The Diversity of Crop Plants,*, *op.cit.*, and L. et al., *Gene Banks and the World's Food*, *op.cit.*

law. The caveats faced by public research in this regard included not only the novelty of plant varieties and the correlated determination of “common knowledge”, but also extended to prior art considerations. Private plant breeders who are solely concerned with obtaining exclusive rights over their new plant varieties through plant breeders’ rights are solely facing the former call for caution. Biopiracy cases have nonetheless equally targeted improved plant varieties developed by small-scaled plant breeders. The aforementioned RAFI study that highlighted “plant breeders’ wrongs” included biopiracy cases where plant variety protection was awarded to mostly public research institutes, on slightly modified landraces subject to little additional breeding[861]. They have been generally identified with regards to specific compounds or functions of biological material, rather than the complete phenotype. One main reason for this lies in the inherently non-uniform nature of landrace populations or wild relatives, which unmistakably need to be stabilised and further developed to qualify for plant breeders’ rights protection. In parallel, the Australian Heritage Seeds Curator's Association ('HSCA') has also “argued that at least one hundred and eighteen plant breeder's rights claims in Australia could be invalid because they had not been 'bred' and were not distinct”, arguing that “the threshold for breeding was too low”[862].

CONCLUSIONS. Private plant breeders and the strong IP paradigm

The *ratio legis* of plant breeding, as practiced by relatively small to medium, non-integrated private seed companies, needs to cope with several new ordeals stemming from the reification, development and implementation of the strong property paradigm. They face increasingly restrictive opportunities at the phenotypic level through plant variety rights, but also at the genotypic level through patents. These titles have indeed not been unreservedly considered as a vehicle to foster innovation, even within the world of market-oriented private plant breeding. Plant variety rights have been put to the test of technological strides of the genotype era, but also to the test of an enduring breeders’ exception. This *sui generis* instrument that accommodates the specificities of plant improvement indeed remains in dire need of further guidance for the full capture of innovation benefits, all the while maintaining its distinct approach to the public domain through a viable and inclusive scope. Technological strides have allowed quicker access to parental lines and enlarged the opportunities of plagiaristic breeding, pushing certain better-endowed actors to advocate wider protection scopes. Plant variety protection is thus faced by an inherent conundrum of maintaining the breeders’ exception alive and well (as its inherent feature adapted to the needs of cumulative agrobiodiversity innovation), while also ensuring that protection titles still generate revenue that is adequate enough to remain an actual incentive to innovate. Rather than addressing the arguably obsolescent failures of plant variety protection in terms of scope, the changing approach to the breeders’ exception and the concept of essential derivation have rather exacerbated the drift away from public domain principles enshrined in the initial balancing act of granting exclusive prerogatives over plant varieties.

Breeders have been concomitantly been put to the test of patents, often co-existing next to their familiar breeders’ rights protection. They naturally share a number of anxieties with public breeding institutes, especially with regards to the provisos surrounding upstream research tools or

[861] INTERNATIONAL, "Plant Breeders’ Wrongs: 147 Reasons to Cancel the Wto’s Requirements for Intellectual Property on Plant Varieties: The Biopiracy and Plant Patent Scandal of the Century."
[862] SANDERSON and ADAMS, "Are Plant Breeder's Rights Outdated - a Descriptive and Empirical Assessment of Plant Breeder's Rights in Australia, 1987-2007," *op.cit.,* p.990.

the recapture of publicly available knowledge, even though the private breeders' endeavours are quite naturally not assigned to non-monetary approaches, and are not governed by norms of science but rather by the rules of the market. Non-integrated actors of molecular and conventional plant breeding are nonetheless challenged by the high number of patents on upstream molecular research tools, with broad scopes, concentrated in the hands of small groups of enterprises. These companies, which resort to restrictive licensing practices, significantly drive away the innovation's availability to smaller-scaled plant breeders. Integrated competitors have furthermore pursued fierce enforcement strategies, which further increases the costs of research and development, all the while rescinding breeders' sacrosanct "freedom to operate". Moreover, both patents and plant variety rights also need to consider and accommodate restrictions that may surround the access to upstream biological material. They need to reclaim their built-in mechanisms that allow for social welfare enhancing uses of agricultural biodiversity, such as the farmers' and the breeders' exemptions. Private breeders nonetheless contribute to social welfare enhancing uses of agrobiodiversity by creating new genetic diversity that is adapted to regional or national needs, and by tapping on the inherent benefit-sharing opportunities provided by more relaxed intellectual property rights.

<table>
<tr><th>TRENDS IN THE STRONG PROPERTY PARADIGM</th><th>SHORTCOMINGS EXPERIENCED BY SMALL-SCALED PRIVATE PLANT BREEDERS</th></tr>
<tr><td rowspan="2">Speedy reverse-engineering and the reign of molecular breeding</td><td>Lack of adequate protection levels: is the incentive to innovate still present?</td></tr>
<tr><td>Insufficient royalty collection from breeders and farmers</td></tr>
<tr><td>Reign of exclusive individual rights in cumulative innovation</td><td>Biopiracy risk vis-à-vis old users of biodiversity / knowledge</td></tr>
<tr><td rowspan="3">Proliferation of patents with aggressive licensing practices</td><td>Uncertainty of freedom to operate: legality of actions when co-existence PVP-patents</td></tr>
<tr><td>Raising search and transaction costs of socially beneficial research (information, negotiation)</td></tr>
<tr><td>Use-blocking licensing: refusal – delays in research</td></tr>
</table>

FIG.3: Shortcomings faced by smaller-scaled private plant breeders in molecular and conventional plant breeding confronted to the strong PGRFA property paradigm

9. CHAPTER 9: MASS SELECTORS RELYING ON SEED EXCHANGE NETWORKS

The Green Revolution severely ruptured the relationship between farmers and agricultural researchers by excluding the former from the "institutionalisation and professionalisation of breeding" activities[863]. This rupture was not inexorable, as during the timid beginnings of plant breeding science, it was assumed that farmers could and would produce their own hybrid seeds[864]. However, the supremacy of the model favouring the peripheral and commercial provision of seeds with complex traits did settle on account of various technological strides and a favourable legislative framework. Farmers lost the genetic enhancement aspect of PGRFA management, to rather be considered as mere 'conservers' than variety developers today. Nevertheless, as aforementioned, mass selection, whether operated by farmers, gardeners or the rather new low-input breeders perdured. As aforemenetioned, farmer-saved seed did for instance still account for an estimated thirty five percent (or eighteen billion USD) of the total estimated value of fifty billion USD for all agricultural seed used worldwide in the mid-1980s[865], a proportion that culminated at the level of eighty percent in developing countries[866].

The regulatory landscape changes that accompanied both the Green and Gene revolutions did considerably weaken the ability of farmers to generate improved varieties. There are clear “distributive inequities” inherent to the TRIPS Agreement, and especially its Article 27§3b when analysed through the perspective of mass selection-based plant improvement. These preconceptions stem for the Agreement’s clear focus on end-producers and on those actors who developers knowledge or products with greater market value, purposefully setting aside other forms of knowledge that may present a more community-oriented and free-exchange-based outlook on innovation, especially with regards to agricultural or indigenous communities[867]. The property paradigm that derives from such focus concomitantly restricts public domain uses that the farmers’ innovation system relies upon. It does so through stringent certification schemes on the one hand, and obstructive intellectual property rights on the other. Neither do these two aspects of the property paradigm recognise mass selectors’ contributions to the entire chain of agrobiodiversity innovation, nor do they protect the products of their own innovation, landraces or low-input plant population, from misappropriation by leaving them outside of any property regime. Even though they are not “averse to the recognition of a plurality of right holders”, intellectual property rights “geared towards providing economic rewards to a single creator [seem to be] incapable of accommodating the contribution of communities of farmers”[868]. The property paradigm’s shrunk public domain and its extensive exclusive appropriation opportunities thus fail to accommodate the needs of farmers-selectors.

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863 KINGSBURY, *Hybrid: The History and Science of Plant Breeding*, *op.cit.*, 172-175., using the example of the Plant Breeding Institute of Cambridge University.

864 Indeed, encouragement was given to decentralised "farmer enterprises", which were given parental seed stocks and developed hybrids; KLOPPENBURG, *First the Seed: The Political Economy of Plant Biotechnology 1492-2000, op.cit.*, 105-106.

865 GROOSMAN, LINNEMANN, and WIEREMA, *Technology Development and Changing Seed Supply Systems: Seminar Proceedings, 22-23 June 1988*, *op.cit.*

866 PRAY and RAMASWAMI, *A Framework for Seed Policy Analysis in Developing Countries*, *op.cit.*

867 WEST, "Institutionalised Exclusion: The Political Economy of Benefit-Sharing and Intellectual Property," *op.cit.*, p.41.

868 CULLET, "Property-Rights Regimes over Biological Resources," *op.cit.*, p.653.

9.1. Forceful Illegality through Restrictive Seed Certification Schemes

First and foremost and in comparison with other socio-technological contexts of agrobiodiversity innovation, mass selection endeavours operated by farmers face a primeval and unique inadequacy in the strong property paradigm, that of stringent seed certification requirements. Indeed, modern seed laws have considerably restricted the actions of farmers-innovators both on the market and on their fields. Mass selectors have been forced to infringe upon market and certification rules, unwillingly creating unfair competition by using and exchanging their non-registered varieties because of the lack of adequate balance in applicable semi-proprietary legislation.

As aforementioned, seed marketing rules traditionally remain a "quality assurance process"[869] which attempts to resolve the inherent asymmetry in information flows[870], whereby public authorities control and inspect seeds intended for commercialisation. The desire to regulate seed markets and ensure their swift functioning finds its origins in the numerous prospects to cheat or adopt opportunistic behaviour in a market where the product sold cannot be identified at the moment of the sale or exchange. Nonetheless, it has also been openly argued that the issue was not merely one of quality but also reflected an active political choice espousing a particular agrobiodiversity innovation context, producing productivity and uniformity oriented improved plant varieties. As aforementioned, the proliferation of less uniform landraces could theoretically "wipe out the formal sector supply because they are priced lower and do not include licensing and other technology fees"[871]. Indeed, certification requirements have been traditionally more important in field crops, where numerous varieties have been released publicly released[872]. Backed by the first seed catalogues, which came to be the primary sources of gardening knowledge and germplasm for cultivators, seed merchants had to persuade their customers, used to saving seed free of charge, to return to them annually, and ''convince customers not to harvest seeds from their own gardens''[873].

In most developed countries, and increasingly in developing nations, seed distribution is only allowed after certification procedures based on the distinctness, uniformity and stability of plant varieties (so-called DUS testing), and the inclusion of either actors and/or varieties into official catalogues[874]. These instruments are best epitomised by the OECD Seed schemes, with its enlarged geopolitical influence outside the strict boundaries of the intergovernmental organisation, and which very much remain a perspective of a growingly industrialised seed sector**.** While farmers are protected against crooked seed distributors and impure seed lots by the establishment of official catalogues and clear insurance or liability regimes, the varieties they would perhaps want to cultivate for agronomical, environmental or cultural reasons fail to meet the requirements

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[869] DEVELOPMENT, *op.cit.*, 2012.
[870] ALBERSMEIER et al., "The Reliability of Third-Party Certification in the Food Chain: From Checklists to Risk-Oriented Auditing," *op.cit.*, p.930.
[871] FUKUDA-PARR, "Emergence and Global Spread of Gm Crops: Explaining the Role of Institutional Change," *op.cit.*, p.203.
[872] COPELAND and MCDONALD, "Seed Certification " *op.cit.*
[873] M. MOSKOWITZ, "Calendars and Clocks: Cycles of Horticultural Commerce in Nineteenth-Century America," in *Time, Consumption, and Everyday Life: Practice, Materiality, and Culture*, ed. ELIZABETH SHOVE, FRANK TRENTMANN TRENTMANN, and RICHARD R. WILK, Berg: Oxford, 2009, p.118., cited in PAUL ROBERT GILBERT, "Deskilling, Agrobiodiversity, and the Seed Trade: A View from Contemporary British Allotments," *Agriculture and Human Values* 30, 2013: p.109.
[874] TRIPP and LOUWAARS, "Seed Regulation: Choices on the Road to Reform," *op.cit.*

of the stringent marketing rules of distinctness, uniformity and stability. Furthermore, the focus of formal seed markets on approval and guarantees as to the identity, purity and performance of distributed seeds, cannot take into account the cultural norms that come in play within the informal seed exchanges and associated on-farm innovation attempts[875]. This reality challenges farmers, gardeners and organic plant breeders by restricting the choice of products circulating in the market, and also by restricting the range of action of seed exchange and improvement networks.

Marketing requirements in practice push informal seed exchange networks not only to the side-lines, but also at times force them in the **confines of illegality**.

> "Many [seed laws] are meant to organise the formal seed system but have effects that go well beyond. Many seed laws of the former Soviet Republics, for example, prescribe that all seed (that is used for planting) has to be certified, which in fact outlaws the saving of seed on-farm. More common, however, is the rule that only seed that is commercialised has to be registered and certified. This is the case in the seed laws of Cameroon, Niger, Senegal and many others. In most of these laws, however, the term 'commercialised' is not defined. The seed laws of South Africa and Malawi do specify that exchange and barter are included under the term 'sell'. This means that even the informal exchange of seed among farmers is illegal there"[876].

While intended to standardise crop names, protect consumers and foster investment in breeding, existing mainstream certification and informational protection legislation has had "the unintended consequence of drastically reducing the numbers of cultivars grown and impinging on the ability of farmers to grow older varieties or landraces not present on the list"[877]. The focus of formal seed markets on approval and guarantees as to the identity, purity and performance of distributed seeds, cannot indeed take into account the cultural norms that come in play within the informal seed exchanges and associated on-farm innovation attempts[878].

In this perspective, compulsory seed regulation and commercialisation have engendered "a process of **horticultural "deskilling",** in that the management of diversity has been completely delegated to commercial breeders and seedsmen, which in turn results in the erosion of the genetic heterogeneity due to commercial imperatives to produce new cultivar lines, combined with a narrowing genetic base of commercially bred vegetable species in the global North"[879]. This deskilling has been particularly felt in the South, where compulsory seed certification has gained incredible momentum in the aftermath of the Green Revolution.

> "Under the 'Green Revolution' approach, seeds and other inputs are subsidised in order to facilitate adoption of new varieties and associated technologies. Within this paradigm, centralised seed production units have been built in many countries as public institutions or

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[875] LIPPER, ANDERSON, and DALTON, *Seed Trade in Rural Markets: Implications for Crop Diversity and Agricultural Development, op.cit.*
[876] NIELS LOUWAARS, "Seed Laws: Biases and Bottlenecks," *Seedling*, no. July 2005, 2005.
[877] NEGRI, MAXTED, and VETELAINEN, "European Landrace Conservation: An Introduction," *op.cit.*
[878] LIPPER, ANDERSON, and DALTON, *Seed Trade in Rural Markets: Implications for Crop Diversity and Agricultural Development, op.cit.*
[879] GILBERT, "Deskilling, Agrobiodiversity, and the Seed Trade: A View from Contemporary British Allotments," *op.cit.*

enterprises to resemble the private European and North American seed industries. These formal seed systems subsequently developed specialised seed quality control institutions to create a quality-awareness with both seed producers and customers, and to safeguard the interests of farmers, similar to the official seed certification agencies in the North. In the era of privatisation of public institutions at the end of the 1980s, following structural adjustment policies, these seed quality control institutions became the driving force behind the development of seed legislation in the South. Such legislation was meant to provide these institutions with a legal backing, which was thought necessary to perform its police tasks especially with the new, private seed producers. As a result, many seed laws in the South strongly resemble those in the North. However, whereas in the North, the farmers' interest was often represented by a strong voice in the seed quality control systems, in several countries in the South this was not the case. The seed regulations were tacked onto existing bureaucratic structures and imposed upon both seed producers and users"[880].

The shortcomings of the highly regulated and compulsory approach to seed certification has not just altered seed supply in the South, it has also had detrimental consequences on the informal mass selection operating in the North as well. On the one hand, the networks that do not commercialise their material but yet become caught within the strongly appropriative and exclusive market they subsist in the margin of, will be "merely" disregarded by regulation. They will rather be viewed as trivial initiatives taking place outside of their scope, mostly considered in policies linked to environmental conservation or rural development schemes. The French network "AgroBio Périgord, Maison de la Semence" provides a good example of such **partial desperado collective action initiatives that exist in the dark confines of restrictive seed laws.** In order to conserve non-proprietary agricultural biodiversity, this network of two hundred and fifty growers located in Western France experiments on local populations or 'landraces', selecting those individuals presenting similar characteristics following two or three years of natural local adaptation, without ever falling under the range of six hundred individuals in order to avoid degeneration and maintaining so-called "security stocks" to minimise loss risks. They disseminate a technical book on the multiplication and selection of maize and sunflower on farm, based on the principles of mass selection. The experiment, which started in 2001 on a collective initiative, now receives support from regional institutions as an *in situ* biodiversity conservation project. The results of these conservation endeavours being not commercialised and therefore remaining outside of the regulated seed market, the products should in principle not face great difficulties within the currently applicable regulatory environments favouring high quality certification mechanisms. Indeed, market entry will generally not be sought within this kind of conservation-oriented exchange networks. Strict regulation will nonetheless forbid them to take their initiatives to another level and spread the products of their innovative endeavours more widely. Even though most farmers-selectors would in practice not be disrupted by seed marketing laws if they remain in their small informal sector and respect the customarily set limits of action, it has been shown that seed saving schemes that "attain relative success and reach a size that merits up-scaling, officials

[880] LOUWAARS, "Seed Laws: Biases and Bottlenecks," *op.cit.*, p.1-2.

or the locally established commercial seed companies may use the law to challenge such initiatives"[881].

Litigation has prospered with regards to those more contemporary networks, which, in an attempt to maintain genetic diversity and reach a wider range of customers, whether farmers or gardeners, sell their seeds. Conflicts have especially arisen over the **lack of equivalent certification requirements for the commercialisation of conservation varieties,** where the lack of registration of farmers' varieties in national catalogues has generally been ruled to be in violation of the formal seed market rules and has also raised suspicions over the creation of unfair competition. Indeed, in the absence of a "light catalogue" for farmers' varieties or a general exemption from certification, and thus in absence of a legal recognition of seed exchange platforms, litigation between formal and informal seed market actors has prospered and will continue to do so. This bitter reality is epitomised by the French case opposing *Kokopelli* to *Graines Baumaux*, which has been referenced by the Court of Nancy to the European Court of Justice in February 2011 (Case C-59/11)[882]. The latter was asked to assess whether seed catalogues violated principles of the *acquis communautaire* related to the liberty of trade, free movement of goods, proportionality, equality and non-discrimination, as well as the Union's obligations under international law, especially with regards to the Convention on Biological Diversity and the FAO International Treaty. The opinion of Attorney General Kokott, issued on 19th January 2012, seemed to indicate that the International Treaty did

> "not include any provisions which are unconditional and sufficiently precise as to challenge the validity of EU legislation on the marketing of seeds". However, in the light of the principle of proportionality, "the disadvantages of the marketing prohibition, [which include a negative impact on the freedom to conduct a business and agricultural biodiversity] manifestly outweigh its advantages" (ECJ, Kokopelli vs Graines Baumaux, Opinion Att.Gen. Kokott).

It was argued that this disadvantage was not sufficiently attenuated by the derogations carved out by Directive 2009/145. The Advocate General further contended that the conservation varieties Directive, by not giving "*sufficient consideration to the interests of economic operators and consumers"*, did not allow for sufficient scope *vis-à-vis* the use of old varieties and those products of mass selection, thereby concluding that

> "the prohibition on the sale of seed of varieties that are not demonstrably distinct, stable and sufficiently uniform […] is invalid as it infringes the principle of proportionality, the freedom to conduct a business […], the free movement of goods […] and the principle of equal treatment".

The judgment of the Court, issued on 12th July 2012, ran counter to the initial conclusions set out by Attorney Kokott, by taking a rather positivist approach to the principle of proportionality within the European *acquis communautaire*. In this regard, the Court assessed whether the exclusion of

[881] "Seed Regulations and Local Seed Systems," *Biotechnology and Development Monitor* 42, 2000., citing that the production of open-pollinated maize seed by the local Environment and Development Activities-Zimbabwe (ENDA) was for instance forbidden in the mid-1990s for these reasons.
[882] European Court of Justice, C-59/11, *Association Kokopelli vs. Graines Baumaux SAS*, 12 July 2012.

non-distinct, stable and uniform varieties from the formal seed market was appropriate for attaining the legitimate objectives pursued by official catalogue legislation. These objectives were identified as the increase of agricultural productivity and the reliability of the characteristics of the seed, which were adequately pursued by the litigious measures, setting the grounds of an efficient market without completely ruling out the marketing of old varieties. The Court ruled that:

> "the rules set out in Articles 3 to 5 of Directive 2002/55 are intended to secure improved productivity in vegetable cultivation in the European Union, the establishment of the internal market for vegetable seed by ensuring its free movement within the European Union, and the conservation of plant genetic resources, which are objectives of general interest. As is apparent from the grounds of the present judgment relating to the alleged breach of the principle of proportionality, those rules and the measures laid down by them are not inappropriate to the attainment of those objectives, and the obstacle to the freedom to pursue an economic activity which such measures represent cannot, in the light of the aims pursued, be regarded as disproportionately impairing the right to exercise that freedom" (ECJ, *Kokopelli vs Graines Baumaux*, para.79).

> "the acceptance regime laid down by Directives 2002/55 and 2009/145 contributes to improved productivity in vegetable cultivation in the European Union and to the establishment of the internal market for vegetable seed by ensuring the free movement of such seed within the European Union. Accordingly, the regime promotes, rather than restricts, the free movement of goods" (ECJ, *Kokopelli vs Graines Baumaux,* para.81).

The findings of the case have raised serious doubts as to the ability of conservation and innovation oriented seed exchange networks could continue to survive in the current European legislative environment. Since the facts pertaining to this specific case, the European Union has developed legislation on 'conservation and amateur varieties' for seed and seed potatoes in 2008[883], for vegetable seeds in 2009[884] and grass mixtures with wild plants in 2010[885]. In 2012, the Common plant variety catalogues contained six hundred and fifty-six conservation or amateur varieties, one hundred and fifty-eight agricultural and four hundred and ninety-eight vegetable species[886]. However, European seed legislation has undergone an extensive review process and the first proposed draft for a Regulation on the "production and making available on the market of plant reproductive material"[887] has considerably heightened concerns for the ability of associations like

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[883] Commission Directive 2008/62/EC of 20 June 2008 providing for certain derogations for acceptance of agricultural landraces and varieties which are naturally adapted to the local and regional conditions and threatened by genetic erosion and for marketing of seed and seed potatoes of those landraces and varieties, *OJL*, 162, 21.06.2008, pp.13-19.

[884] Commission Directive 2009/145/EC of 26 November 2009 providing for certain derogations, for acceptance of vegetable landraces and varieties which have been traditionally grown in particular localities and regions and are threatened by genetic erosion and of vegetable varieties with no intrinsic value for commercial crop production but developed for growing under particular conditions and for marketing of seed of those landraces and varieties, *OJL*, 312, 27.11.2009, pp. 44-55.

[885] Commission Directive 2010/60/EU of 30 August 2010 providing for certain derogations for marketing of fodder plant seed mixtures intended for use in the preservation of the natural environment, *OJL*, 228, 31.08.2010, pp.10-14.

[886] European Commission Report to the European Parliament, the Council and the European Economic and Social Committee, "Agricultural Genetic Resources- from conservation to sustainable use", COM (2013), 838 final, 28.11.2013.

[887] Proposal for a Regulation of the European Parliament and of the Council on the production and making available on the market of plant reproductive material, COM(2013), 262 Final (dated as of 6th May 2013).

Kokopelli to continue their operations. The revised 2013 draft, which is at the time of writing still being discussed before the European Parliament after an initial rejection, wishes to "adapt to the technical progress of plant breeding", but also to "reduce the cost and administrative burdens and support innovation", by overcoming the "uncertainties and discrepancies in the implementation" of existing complex and fragmented legislation, which create "an uneven playing field for professional operators on the single market"[888]. The replacement of twelve scattered Directives by one Regulation is an endeavour that can only be praised in the name of regulatory clarity and coherence; yet such enterprise has created civil society uproar in its failure to fully accommodate the needs of all plant innovation. Indeed, its main focus remains on the surface a strictly OECD approach oriented towards the productivity driven professional seed market and the facilitation of seed movement, even though it contains a number of provisos that accommodate the needs of "*farmer-breeders or gardener-breeders*"[889], while nonetheless confining such needs to so-called "*niche markets"* [890].

Besides stringent certification schemes that push mass selection to play dangerous games with the boundaries of lawfulness, **national strategies related to subsidisation** have also ignited quite fiery critiques, accusing them of falling into partisan choices by linking the used of certified seeds to the reception of direct payments[891]. This policy was notably used in the 1990's and resulted in impressive increases in certified seed use ratios in the European Union. Such was the case in Spain, where merely twelve point six per cent of the seed market comprised of certified seed at the beginning of the 1990's, and where such figure mounted up to seventy five per cent after the introduction of direct payments for certified seeds[892]. This policy, which is in itself not an inherently detrimental financial support to farmers who could not choose improved varieties by lack of means, has unfortunately not found its equivalent in supporting farmers or even conservation varieties, or only quite late in time in a number of countries. The European agri-environmental measures scheme takes the use of so-called conservation varieties into account for instance, while the Swiss use a fixed price mechanism for old varieties of spelt[893]. In countries like Turkey on the other hand, subsidies are still solely directed towards certified seed in an effort to boost transparency and quality, but also support the national seed industry. As much as subsidisation policies have contributed to acclaimed, and often times very much-needed, improvements in yield and productivity, their one-sidedness and limited range have failed to compensate the loss of genetic diversity that has resulted from the direct support of a single innovation chain for crop improvement.

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[888] Proposal context, p.2

[889] Both the content of such proposal, the opportunities offered by its inherent flexibilities, but also its shortcomings will be analysed in the further course of this study focusing on the emerging practices making room for mass selection efforts.

[890] This element of "niche market" has been indeed vehemently opposed by civil society movements, which view such confinement as a restriction of seed movement. Amongst associations that have been vocally against such proposal are the Soil Association but also the *ad hoc* advocacy campaign on "Seed Freedom", set out by Navdanya and the European Greens (http://seedfreddom.in). We shall delve into the exact critics that have been raised by these associations when analysing the solutions needed for the survival but also encouragement of mass selection based innovation.

[891] ALVARO TOLEDO, "Saving the Seed: Europe's Challenge," *Seedling* 2, no. 4, April 2002.

[892] Ibid.

[893] Ibid.

Stringent seed certification and marketing frameworks raise questions regarding the place left for farmers' innovation within a productivity-oriented seed market. They challenge commentators to determine whether mass selectors and their correlated seed exchange networks find adequate room to carry on their activities, which contribute equally to the conservation and generation of new genetic diversity. While rational and well-defined seed certification laws may definitely contribute to ensuring that a higher number of improved varieties do reach farmers, their partisan focus may very well lead to contradictory results. Not only would farmers' varieties not be able to reach their users any longer, their use and exchange might even be considered illegal. These institutional characteristics therefore lead to a systematic breakdown of the strong exclusive appropriation oriented paradigm with regards to the less technology-driven and more community-oriented mass selection innovation. This particular context does nonetheless continue to remain central not only to the conservation of agricultural biodiversity but it also constitutes the sole livelihood of small-scale farmers, urging therefore legislative and/or judiciary redress.

9.2. <u>Obstructive Intellectual Property Protection</u>

As we have seen, the seed certification element of the strong property paradigm pushes farmers' innovation into the confines of illegality by adopting a solely marketplace and productivity stance. The same phenomenon can also be witnessed in the paradigm's second tier. Indeed, its intellectual property component bestows an additional obstructive layer to the public domain that farmers heavily rely on to use and build new knowledge and landrace populations, even if they only concern a more limited number of plant varieties or related knowledge. As aforementioned, seed certification applies to the entire range of plant varieties made available on the market, while intellectual property rights need to be duly applied for by breeders and researchers and granted by patent or plant variety protection offices. Their range is thus more limited, answering stricter criteria set out in national legislation according to the minimum standards set out by the TRIPS Agreement. However, the reach of the bundled rights granted to right holders and the ensuing restrictions of public domain uses significantly impact farmers' range of action. Mass selectors who wish to build on existing knowledge and innovate collectively by relying on informal exchange networks cannot merely exist in the confines of intellectual property, and face ever-greater risks of infringing exclusive titles. Such risks have been impressively extended by legislative changes but also through tough judiciary stances, regarding both the shrinking farmers' exception and the fate of harvested material in patents and plant breeders' rights.

9.2.1. <u>From farmers' privilege to a strict exception</u>

The contours of the rules of diffusion that accompany patents or plant variety rights frame the possibilities for subsequent uses of protected material. Within such diffusion opportunities, the most striking aspect of intellectual property instruments targeting directly plant innovation has been the presence of strong liability rules operating as a "take now, pay later" understanding[894]. In the context of mass selection, a particular liability rule comes into play, that of the "farmers' privilege". Embedded in most PVP legislation, this privilege generally designates the specific actors that may benefit from the unlicensed use of the protection informational matter by farmers on account of national developmental specificities and the particular needs of the crop. This

[894] MERGES, "Institutions for Intellectual Property Transactions: The Case of Patent Pools," *op.cit.*

privilege enables farmers to save and exchange protected improved varieties, in light of ancestral traditions and socio-economic considerations as to their subsistence and their primordial role in the further *in situ* use and conservation of agrobiodiversity. Even though the strategic importance of these exemptions from protection retains the highest regard, their implementation has gained in complexity, in view of technological but also regulatory changes. The shrinking range of manoeuvre left to farmers for seed saving, using and exchanging within the strong IPR paradigm and a seemingly generalised lack of awareness or training in legal issues from the cultivators' side have led to mounting disagreements between variety developers and sowers, which are incresingly taken on by the judiciary.

The farmers' exemption, which allows farmers to sow protected seeds for the purposes of saving, using or exchanging them, remains a main feature of the **dominant *sui generis* plant variety protection** that is the UPOV system. Nonetheless, as aforementioned, its range and impact have considerably shrunk in time, especially in light of the fact that the privilege was full in the 1961 and 1978 Acts, where PVP protection did not reach acts perpetrated without any commercial purpose by third parties, including unmethodical selectors or farmers[895]. The 1978 Convention, being a minimal standards agreement, granted opportunities for the more precise design of the implicit rights' contours at the national level and thereby limit non-commercial uses. However, under the practice of so-called "brown-bagging" in accordance with this Act, farmers were even allowed to sell limited quantities of protected seeds for reproductive purposes[896]. Today, this privilege has become formally conditional to elements regarding national conditions, farm size or the necessity to use of the seed on the same farm, but it has also been surrounded by a licensing obligation[897], in accordance with the terms of article 15§2 of the 1991 UPOV Convention, and implementing national legislation. In the European Union, the contours of farm-saved seed have been dressed quite restrictively, conditioning the farmers' privilege to the payment of farm-saved-seed royalties, and limiting it to certain varieties in article 14§1 of EC Regulation 2100/94. While small farmers seemingly benefit from full exoneration, others ought to provide "*an equitable remuneration to the holder, which shall be sensibly lower than the amount charged for the licensed production of propagating material of the same variety in the same area; the actual level of this equitable remuneration may be subject to variation over time, taking into account the extent to which use will be made of the derogation provided for in paragraph 1 in respect of the variety concerned"* (EC Regulation 2100/94, Art. 14§3).

Having become an *optional* exception to the exclusive rights of breeders, rather than an array of acts considered outside the scope of the IP title in itself, the farmers' privilege has been "drowngraded" in the legislative context and judicial interpretations. Landmark cases on the other side of the Atlantic have reiterated that the farmers' exemption should be interpreted in a narrow fashion vis-à-vis the sale of the protected varieties' progeny, such as the ruling in *Asgrow vs. Winterboer* that secluded "brown-bagging" as a marketing practice violating United States'

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[895] DE CARVALHO, "Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patents Applications without Infringing the Trips Agreement: The Problem and the Solution," *op.cit.*, pp.371-401.
[896] HUIB GHIJSEN, "Plant Variety Protection in a Developing and Demanding World," *Biotechnology and Development Monitor* 36, 1998: pp.2-5.
[897] GRAHAM DUTFIELD, "Turning Plant Varieties into Intellectual Property: The Upov Convention," in *The Future Control of Food: A Guide to International Negotiations and Rules on Intellectual Property, Biodiversity and Food Security*, ed. GEOFF TANSEY and TASMINE RAJOTTE, London: Earthscan, 2008, pp.27-47.

legislation. In the European legal order, due attention has been given to the concept of a remuneration level that could be considered "sensibly lower" than the amount charges for the licensed production of propagating material. The European Court of Justice has for instance ruled that a flat rate of eighty per cent would not fall under such category[898], also mentioning that the rate applicable should be determined by taking into account "the varieties at issue and the area concerned", all the while confirming that a fixed and unnegotiable rate of fifty per cent of certified seed rate had been unequivocally imposed by the legislator[899]. The issue of farm saved seed royalties is much more important in cereals where exploitations tend to be larger in size, and the financial return from these royalties to breeders is estimated to amount to sixty five to seventy five million EUR per year, which, when divided into farming land, would not necessarily impose heavy burdens on the individual farmer[900]. In the current state of European Regulation, we should remind the reader that one of the most important cereal, i.e. maize, is not listed in the species to which the farmers' privilege is extended.

As a result, the move towards almost generalised royalty for seed saving was highly protested by farmers' organisations, which claimed that the amendment violated an ancestral right and a fundamental obligation that had both been recognised internationally[901]. Such attack should nonetheless be tempered, since the legislation does provide for an absolute exemption for so-called "small farmers", which nonetheless need to be determined with more detail, missing the opportunity for greater transparency vis-à-vis mass selectors, who will probably not be aware of their status, whether they met "*comparable appropriate criteria*" or not. In European national orders, French legislation has shown the strictest reaction to the privilege, establishing it solely with regards to wheat through a voluntary compulsory contribution system and considering all other farm saved seed as counterfeits, falling within the realms of the strict legislation 2007-1544 dated as of 30th October 2007. Under Australian law, "PBR owners who believe that farmer's privilege prevents them from obtaining a fair return on their investment in breeding can apply to have the exemption declared not available for specific taxa", even though none have done so[902].

The farmers' privilege has not only seen its reach shrink in plant variety protection legislation and correlated case law; it has also been shaken down by the **coexistence of patented elements next to protected plant varieties.** Indeed, farmers are absolutely prohibited to save, exchange, or re-use varieties that might be covered by a patent or might contain a patented element without authorization of the right-holder and negotiations on royalty payments. The inherent concern of the

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[898] European Court of Justice, reference for a preliminary ruling, joint C-7/05 and C-9/05, Saatgut-Treuhandverwaltungs GmbH vs. Ulrich Deppe, Hanne-Rose Deppe, Thomas Deppe, Matthias Deppe, Christine Urban (née Deppe) (C-7/05), Siegfried Hennings (C-8/05), Hartmut Lübbe (C-9/05), 8th June 2006.
[899] Ibidem, respectively at para 28 and 45-47.
[900] See the advocacy group: http://www.lafranceagricole.fr/actualite-agricole/semences-de-ferme-cov-l-esa-pour-un-systeme-harmonise-au-plan-europeen-69285.html « L'enjeu du COV (certificat d'obtention végétale) sur les semences de ferme, à l'échelle de l'Union européenne, est de l'ordre de 65 à 75 millions d'euros par an. Lorsque l'on sait que les surfaces de céréales, dans l'Union à 27, s'élèvent à 45 millions d'hectares, celles de colza à 6,5 millions d'hectares... le coût à l'hectare pour les agriculteurs est très minime».
[901] These demonstrations were notably held in France, specifically targeting the amendment of national plant variety legislation to conform to European norms in 2011, see http://www.lafranceagricole.fr/actualite-agricole/certificats-d-obtention-vegetale-semences-de-ferme-manifestations-d-agriculteurs-pour-demander-l-abrogation-de-la-loi-56484.html (accessed May 2012).
[902] ADVISORY COUNCIL ON INTELLECTUAL PROPERTY OF THE AUSTRALIAN GOVERNMENT, "*A Review of Enforcement of Plant Breeders' Rights*", Advisory Council on Intellectual Property of the Australian Government, Canberra, 2010.

PVP system vis-à-vis farmers is not omnipresent within patent laws as such, as these statutes tend to remain abstract in their nature, seeing that they are not designed to solely apply to agrobiodiversity-reliant innovations as PVP legislation is, with its inevitable links with the loftier issues of food security or environmental protection. This approach means that farmers should be "considered the licensees of a patented product"[903], as they are traditionally not granted any rights or prerogatives over the seeds they plant, if these are protected through a plant patent, or if they contain a patented product or process. Litigation has flourished over a range of infringements, from the possession of protected seed in itself to its re-use outside the scope of the legislation, without royalty collection or in larger farms than those targeted by applicable legislation for instance. In the United States, where the principle of independence between different IP systems did not warrant the adoption of specific rules addressing the co-existence of patents and plant variety rights, case law points towards the prevalence of patents. The legal challenge of multiple protection was epitomised by the wide array of enclosing instruments surrounding Round Up Ready canola, protected all at once through process and gene patents, plant variety rights, trademarks and the private contract that is the "Technology Use Agreement". In 1998, an infamous case opposed *Monsanto* to *Percy Schmeiser*[904], a Canadian canola farmer who replanted the seed he saved from batches of Round Up Ready canola seeds he had bought from the plaintiff. Although he argued that he was cultivating his own traditionally bred canola seeds, and that the batches were unknowingly contaminated with Monsanto's technology on account of cross field breeding by wind or insects, he was found to be infringing patents by using technology without a license[905]. An even more epinous challenge may arise when a mass selector is faced with a protected plant variety in accordance to which he could save and select protected seeds in certain circumstances, and within which a patented element may occur, such as a specific genetic sequence. Just as private plant breeders are faced with the challenge of making patent and plant variety protection coexist, farmers-selectors are confronted to the reality check new and unknown boundaries of the strong property paradigm. Their seed-saving and exchange practices may be further pushed into the realm of illegality not only through the evolution of plant variety protection, but also its concomitant implementation with patents.

9.2.2. <u>The twisted fate of harvested material</u>

In a parallel trend to the expansion of both breeders' rights and patent protection in their respective bundle of rights (an expansion that has awarded greater exclusion prerogatives to right holders) the scope of protection has also in parallel expanded in both instruments, through legislative amendments and judicial interpretation. Indeed, with regards to plant breeders' rights, protection has been extended to **harvested material** in the 1991 UPOV text. Such expansion is also present in the Community Plant Variety Organisation system, and has definitely reduced the margin of manoeuver that was formerly granted to farmers. While such expansion may be completely justifiable in view of the rising costs of developing new varieties and the losses generated by

[903] OLIVIER DE SCHUTTER, "*Seed Policies and the Right to Food: Enhancing Agrobiodiversity and Encouraging Innovation*", Report of the Special Rapporteur on the Right to Food, General Assembly of the United Nations, A/64/170, 2009.

[904] Supreme Court of Canada, *Monsanto vs. Schmeiser*, SCC 34, 21st May 2004, at 239; the first instance rulings had also found the patent valid and Mr. Schmeiser's acts to infringe on the title.

[905] CLAUDIO CHIAROLLA, *Intellectual Property, Agriculture and Global Food Security: The Privatization of Crop Diversity* Cheltenham: Edward Elgar, 2011, pp.96-97.and PHILIPPE CULLET, *Intellectual Property Protection and Sustainable Development* New Delhi: Lexis Nexis, 2005.

uncollected royalty payments for professional plant breeders, these rights still need to be put to balance with the necessity to ensure the continuity of farmer seed saving practices, as a biodiversity conservation tool and also as a mechanism fostering another viable and very much present innovation chain. That is most probably why the extension of the scope of protection to the harvested material (art. 14§2 UPOV 1991) or to the end product that has been derived from the harvested material (art. 14§3 UPOV 1991) has been carved around specific limitations. The prerogatives shall only be extended to such material under certain conditions, as the authorisation of the breeder shall be sought only if the material has been "*obtained through the unauthorised use of propagating material of the protected variety […], unless the breeder has had reasonable opportunity to exercise his right in relation to the said propagating material*". These conditions are cumulative, although their exact scope is not defined in the Convention text, and will need to be clarified either in national instruments or through judicial proceedings. In this specific regard, "there are significant concerns in the grains industry in relation to extended rights, [including the] uncertainty over what constitutes reasonable opportunity and whether crops grown from farm-saved seed are subject to extended rights"[906]. Breeders' concerns are particularly heightened in the horticultural sector where asexual propagating material (buds, cuttings or grafts) can not only be sold but also easily be used to grow another identical plant, which leads to very restrictive contractual clauses in order to ensure a return on breeding investment. These concerns were echoed in the 1991 UPOV Convention, which in effect introduced a "cascading right in which plant variety owners can, in certain circumstances, protect their harvested material", making it even more difficult to assess the effective scope of protection that is granted through plant breeders rights[907].

In general, governments have recommended that royalties may be obtained on harvested grain, which means that the farmers' rights to save and replant the seeds they have duly purchased are further limited. Furthermore, most plant breeders are increasingly making growers sign a so-called "**end-point-royalty" license** that foresees the provision of yearly information on the quantity of harvested material of protected plant varieties and the calculation of royalties due on account of sold or consumed harvested material. This system has the "benefits of reducing upfront seed costs for growers, overcoming loss of sales through farmer's privilege and sharing the risk of crop failure between growers and PBR owners"[908]. Indeed, "new forms of direct contracts with farmers, not with propagators, are now proliferating, because breeders find it more attractive to capture added value in a system based on licenses for harvested material. Such contracts include "licenses for producers or traders for harvested material" under which royalties are established on harvested material"[909]. Considering that the cost of research and development is already often included in the initial price of seeds (even though market prices may hinder such cost-meeting opportunity), additional contractual obligations pertaining to royalty payment can be viewed as unnecessary. For

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[906] GOVERNMENT, *op.cit.*, 2010.
[907] JAY SANDERSON, "Towards a (Limited) Cascading Right: What Is the Appropriate Scope of Protection for Plant Breeding," *UNSWLJ* 34, 2011.
[908] GOVERNMENT, *op.cit.*, 2010.
[909] Association of Plant Breeding for the benefit of society (APBREBES) Intervention to UPOV Explanatory Notes on Harvested Material, UPOV CAJ-AG on 25 October 2013, available at http://www.apbrebes.org/events/past. ABPREBES members include: Berne Declaration (Switzerland); Center for International Environmental Law (USA); Community Technology Development Trust (Zimbabwe); Development Fund (Norway); Local Initiatives for Biodiversity, Research and Development (Nepal); Searice – The Southeast Asia Regional Initiative for Community Empowerment (Philippines); and Third World Network (Malaysia).

instance, Monsanto is known to protect its research investments "by first obtaining intellectual property rights to its technologies and then "leasing" rather than selling, them to customers, [through a] lease agreement [that] obligates the purchasing farmer to a one time use and gives Monsanto the right to inspect the farmers fields for the next three years"[910]. Any assessment of the scope of PVP or patent protection in seed is thus intricately linked to the conditions that surround the sale of seeds to farmers; sale that is increasingly operating under extremely strict terms that act in effect as licensing agreements. Pioneer, one the integrated industry giants, uses the following wording on its bag tag license:

> "if the tag indicates this product or the parental lines used in producing this product are protected under one or more US patents, Purchaser agrees that it is granted a limited license thereunder only to produce forage, or grain for feeding or processing. Resale of this seed or supply of saved seed to anyone, including Purchaser, for planting is strictly prohibited under this license"[911].

In a parallel fashion, all industry giants with important intellectual property portfolios surround their sales with "technology agreements". For Roundup technology, farmers agree "to use the seed containing the Monsanto gene technologies for planting a commercial crop only in a single season. To not supply any of this seed to any other person or entity for planting, and to not save any crop produced from this seed for replanting, or supply saved seed to anyone for replanting. To not use [the] seed or provide it to anyone for crop breeding, research, generation of herbicide registration data or seed production".

The recourse to such contractual tools holds detrimental effects on growers, since the royalty collection extends as a result not only to propagators and seed producers, reaching further down the cultivation chain. The very active farmers' organisation Via Campesina indeed states that the "legal basis for contracts allowing for vertical integration in the supply chain is dubious and may not comply with the UPOV Convention, in particular with the **principle of exhaustion** of the breeder's right"[912]. In accordance with the principle of exhaustion, no further remuneration should be required following the consensual marketing of a protected plant variety. The minutes of the Diplomatic Conference of the 1991 UPOV Convention state that this requirement was implemented "because the breeder should exercise his right only once and receive a royalty only once and should do so at the earliest possible stage"[913]. However, it is still extremely uncertain whether such argument based on exhaustion could trump the initial rationale of plant breeders' rights protection, which is to recoup investment and allow for efficient royalty-collection. The judiciary seems to point towards this direction, highlighting the difficulties inherent to the collection of royalties in agriculture. The European Court of Justice has recently had to pronounce

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[910] DEBRA BLAIR, "Intellectual Property Protection and Its Impact on the Seed Industry," *Drake Journal of Agricultural Law* 4, 1999., p.326.
[911] MARK D JANIS and JAY P KESAN, "Intellectual Property Protection for Plant Innovation: Unresolved Issues after Jem V. Pioneer," *Nature Biotechnology* 20, no. 11, 2002.
[912] Paragraphs 14 and 15 of the UPOV, "*Report on the Seventh Session Held in Geneva*", UPOV, International Union for the Protection of Plant Varieties, Administrative and Legal Committee Advisory Group, available at : http://www.upov.int/edocs/mdocs/upov/en/caj_ag_12_7/caj_ag_12_7_7.pdf, October 29 and 30, 2012.
[913] ISF, *op.cit.*, 2012.

itself on a preliminary ruling introduced in a case opposing *Geistbeck v. Saatgut*[914], mostly on the amount that should be considered to constitute a "reasonable compensation"; compensation that ought to be played by farmers who have used propagated material of a protected variety. The European Court held that such "reasonable compensation" should be appropriately calculated on the basis of the amount of "*fees payable for the licensed production*" of the same quantity of material, rejecting that such compensation should mirror the lower threshold of "equitable remuneration" that is calculated in the exceptional case of authorised farm saved seed uses.

The same concern vis-à-vis the extension of protection scope to harvested material and cultivated foodstuff is also very much present in the case of patents. Indeed, the issue of patent exhaustion has been particularly contentious in presence of **self-replicating technologies**[915]. The particular issue of exhaustion has not been vehemently raised in all legal orders[916], and has been primarily addressed in the United States, where an important number of lawsuits have been brought against infringing farmers[917]. This trend is chiefly explained by the choice of regulation in this legal order, and the relatively smaller place occupied by plant variety protection as opposed to patents in agricultural plant innovation. Indeed, in the absence of fit-to-purpose plant variety protection accodomodating for the needs of farmers, the issue of the exhaustion of rights become absolutely crucial.

> "The patent-based policy set by the Federal Circuit is preferable to alternative legal regimes--such as trade secret and contract law--because it avoids disincentives to competition, innovation, and dissemination of new self-replicating technologies while reducing transaction costs inherent in their commercialisation. However, a categorical rule exempting them from patent exhaustion doctrine is unwarranted, [and…] should [rather] depend on the patentee's ability to charge supracompetitive prices in its primary market where consumers are able to substitute secondary-market embodiments"[918].

In a relatively short recent opinion, a unanimous Supreme Court seems to have corroborated the existence of such categorical rule, at least in the presence of stricter conditions of sale, even to subsequent generations of seeds. The Court in effect followed and widened the dominant jurisprudence that had already been established through cases such as *Pioneer Hi-Bred International, Inc. v. Ottawa Plant Food, Inc.*[919], which solidified the strength of "shrink-wrap licenses" under which all purchasers could agree to additional provisions written on the bag upon

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[914] European Court of Justice, C-509/10 *Josef Geistbeck and Thomas Geistbeck v Saatgut-Treuhandverwaltungs GmbH*, reference for a preliminary ruling from the German Bundesgerichtshof, 5th July 2012.
[915] This issue also concerns software, see notably JULIE E COHEN and MARK A LEMLEY, "Patent Scope and Innovation in the Software Industry," *California Law Review*, 2001.
[916] In the European Union for instance, patent exhaustion has been more fiercely debated with regards to the free circulation of goods intra European Union borders and therefore posed more at the moment of import of the goods, as dealt with in article 10 of the aforementioned Biotechnology Directive 98/44/EC. This provision contains in effect a standard exhaustion of rights provision, applying de facto the Silhouette/Davidoff ruling of the European Court of Justice; see H. NORMAN, *Intellectual Property Law Directions*: OUP Oxford, 2011, pp.428-430.
[917] In the year 2009, Monsanto was said to have filed at least 1200 infringement cases against farmers using and saving their patented technology; see JAY P KESAN, "Licensing Restrictions and Appropriating Market Benefits from Plant Innovation," *Fordham Intell. Prop. Media & Ent. LJ* 16, 2005.
[918] JEREMY N SHEFF, "Self-Replicating Technologies," *Stanford Technology Law Review*, 2013.
[919] United States Federal District Court of Iowa, *Pioneer Hi-Bred International, Inc. v. Ottawa Plant Food, Inc.*, 283 F. Supp. 2d 1018, 1031-33 (2003)

opening the products, including the absence of exhaustion. In *Monsanto Co. vs McFarling*[920], the main issue was to determine whether the royalty rate that was asked by Monsanto for seeds that had been saved by farmers was in effect reasonable, establishing that a low rate "would give infringers like McFarling an unfair advantage over farmers that complied with all of the provisions of the Monsanto license". Interestingly, the arguments put forward by the defendant stated that "prohibiting farmers from saving and replanting their own seed destroys a "secondary market," which would cause an artificially high price for Roundup Ready® seed". The rationale of the Court nonetheless did not focus exclusively on the economic position of the farmer. As Jason SAVICH argues,

> "had the Federal Circuit failed to protect subsequent generations of Monsanto's seed technology, innovators [would have been] pushed towards pursuing innovations that eliminated the self-replicating characteristics of this technology. As a result, inventors [would have had] sole control of the technologies and the resulting innovation will [would] be outside the regulation of patent laws"[921].

In a similar case, *Monsanto Co. vs Scruggs*[922], the "'first sale' doctrine of exhaustion of the patent right [was also considered not to be] implicated, as the new seeds grown from the original batch had never been sold", seeing as the sale was not unrestricted and that the use of seeds by growers was conditioned on obtaining a license. The United States judiciary has thus a clear history of siding with the "economic concerns that require protecting an inventor's right to subsequent generations of seed […] because every consumer turns into a potential producer"[923]. Even though the technology has finally been put in freezers, such self-policing has nonetheless proven to be conceivable through the development of the contentious "Genetic Use Restriction Technologies (GURTs)"[924]. These technologies "offered plant variety owners the technological means for

[920] United States Court of Appeals for the Federal Circuit, *Monsanto Co. v. McFarling*, Nos. 05-1570, -1598 (24th May 2007).

[921] SAVICH, "Monsanto V. Scruggs: The Negative Impact of Patent Exhaustion on Self-Replicating Technology," *op.cit.*, p.129.

[922] The US Court of Appeals ruled on the case which was brought against Mississipi farmers Mitchell and Eddie Scruggs, which were convicted to pay Monsanto Co. $6.3 million damages in 2010 (with prejudgment interest dating back to 2000 the amount increased to $8.9 million). United States Court of Appeals for the Federal Circuit, *Monsanto Co. vs Mitchell and Eddie Scruggs*, 04-1532, 05-1120 and 1121, 6th August 2006.

[923] SAVICH, "Monsanto V. Scruggs: The Negative Impact of Patent Exhaustion on Self-Replicating Technology," *op.cit.*Indeed, "an inventor must have sufficient legal and/or technological protections to allow her to make a return on her initial investment in research and development ("R & D") before competing against those who have not made that investment". The author does nonetheless state that such "incentive to invest, however, must be balanced with the diffusion of current innovations and promotion of future innovations to allow the greatest amount of innovation for the benefit of society".

[924] These so-called terminator technologies are defined as a range of molecular strategies designed to impede transgene movement. "Trait-GURTs regulate the expression of a specific transgenic trait in plants while enabling plants to remain fertile and set viable seeds. These methods reduce the amount of the product and, therefore, the level of exposure, but not the frequency of the transgene in subsequent generations. By contrast, Varietal GURTs impede transgene movement, either by rendering the plant unable to develop properly, or produce functional pollen or seed, or by preventing the transmission of the transgene. MELISSA J HILLS et al., "Genetic Use Restriction Technologies (Gurts): Strategies to Impede Transgene Movement," *Trends in plant science* 12, no. 4, 2007. The second type of GURTs may in effect act as a potential self-policing tool to enforce intellectual property rights titles; much like the digital rights management schemes that operate in the world of copyright. However, biotechnology patents are inherently attached to agricultural production and much broader issues of food security and social welfare. The effects of such self-policing are thus potentially much more worrying, TIMOTHY SWANSON and TIMO GOSCHL, "Genetic Use Restriction Technologies (Gurts): Impacts on Developing Countries," *International Journal of Biotechnology* 2, no. 1, 2000.

controlling the use of their products outside of the privileges afforded by the law"[925], outside the reach of institutions that aim to maintain the inherent balance of IPR laws.

Fed by a Federal Circuit that focuses on the need to recoup investment in self-replicating technology, the Supreme Court had to address the scope of the patent exhaustion doctrine, first in the field of microprocessors (*Quanta Computer Inc v. LG Electronics*[926]), and then specifically with regards to seeds. The former decision held that "the patentee had direct power through only the first level of the production and marketing process; [even though] if seed companies construct the sale of their seed such that the ultimate farmer is the first transaction in which title passes, then patent exhaustion will likely not apply"[927]. That is why the Court unsurprisingly held in 2013 that the doctrine of patent exhaustion with regards to biotechnology patents "does not permit a farmer to reproduce patented seeds through planting and harvesting without the patent holder's permission", siding with the plaintiff Monsanto against the defendant Mr. Hugh Bowman, an Indiana farmer[928].

As Justice Kagan holds, "under the doctrine of patent exhaustion, the authorised sale of a patented

> article gives the purchaser, or any subsequent owner, a right to use or resell that article. Such a sale, however, does not allow the purchaser to make new copies of the patented invention. The question in this case is whether a farmer who buys patented seeds may reproduce them through planting and harvesting without the patent holder's permission. We hold that he may not."

When using soybean that originated from prior harvests of other local farmers in the area regrouped in a grain elevator, Mr. Bowman could not *"'replicate' Monsanto's patented technology by planting it in the ground to create newly infringing genetic material, seeds, and plants*." In essence, the Court has developed a wide doctrine opposing patent exhaustion, which was traditionally set out to counterbalance the artificial lead-time and monopoly awarded to an innovator. The dominant opposing doctrine of conditional sale seems today to indicate that "a patentee may use an enforceable contract to restrict the rights of a buyer using a patented article, even after a subsequent sale"[929].

Only time will tell how the inherent need to allow for the diffusion of protection innovations, but also the socio-economic dimensions of agricultural cultivation on the one hand, and of high-end research and development will be addressed in this context of *ad hoc* patent exhaustion principles coupled with ever-widening contractual clauses. When read in combination with the evolutionary fate of the farmers' privilege or exception, it seems clear that the strong property paradigm does not primarily cater for the needs of mass selectors, it rather seems to obstruct their innovative activities by essentially viewing them as mere cultivators and customers. The paradigm's

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925 SAVICH, "Monsanto V. Scruggs: The Negative Impact of Patent Exhaustion on Self-Replicating Technology," *op.cit.*

926 Supreme Court of the United States, 06-937, *Quanta Computer, Inc. v. LG Electronics*, Inc., 553 U.S. 617 (2008), 9th June 2008.

927 JON SIEVERS, "Not So Fast My Friend: What the Patent Exhaustion Doctrine Means to the Seed Industry after Quanta V. Lg Electronics," *Drake J. Agric. L.* 14, 2009.

928 Supreme Court of the United States, 11-796, *Bowman v. Monsanto Company*, 569 U. S. (2013), 13th May 2013.

929 ADAM GARMEZY, "Patent Exhaustion and the Federal Circuit's Deviant Conditional Sale Doctrine: Bowman V. Monsanto," *Duke Journal of Constitutional Law & Public Policy Sidebar* 8, 2013.

boundaries could nonetheless accommodate the age-old, inherently collective and informal innovation chain of mass selection, keeping all the while in mind the need to foster more industrialised plant improvement models.

9.3. Misappropriation and lack of protection of farmers' traditional knowledge

Notwithstanding the relatively small contribution of wild relatives and indigenous knowledge to the development of new plant varieties or other related products and processes, "sustained legitimacy of IPRs protection for biotechnology cannot be achieved without effective and long-term protection of traditional knowledge and genetic resources"[930]. Mass selection produces not only material goods that shine through their sustainability and higher adaptability to the local climate, it also produces a wide range of associated knowledge, like any kind of grassroots innovation system, generating "an incredibly valuable diversity of knowledge and know-how for innovation for sustainability […], even if policies and markets only adapt and appropriate a part of it, or more frequently overlook it entirely"[931]. The currently applicable strong intellectual property paradigm falls short of such "fundamental amending and rebalancing" needed to "bring about sustainable development and equitable distribution of revenues and benefits of the technology"[932]. Such failure arises not only in the unavoidable consequence of knowledge misappropriation, but also in the lack of efficient protection and compensation mechanisms around farmers' knowledge.

The currently dominant intellectual property paradigm may not only be considered to have enclosed what is by definition not enclosable, but it has also failed to duly recognise all past contributions, small or big, of previous germplasm users and conservers. Several **litigated and confirmed cases of misappropriation** exist. The aforementioned case of the wild rice variety resistant to bacterial rice blight, the *Oryza longistaminata*, shines not only with regards to the contentious issue of recycling of publicly produced knowledge, but also with regards to the use of ethno-botanical indigenous knowledge, whether held in the hands of farmer communities or even remote landless groups. Indeed, the resistance trait that was later patented by the University of California in Davis was not known by Malian farmers but rather by a landless community[933]. Acknowledging the complexity of prior art in this specific case, the University recognised the need for benefit sharing.

Other infamous cases of 'biopiracy' relate to hoodia, neem, quinoa, enola bean, turmeric or basmati rice. The former case of hoodia was concerned with the development of a variety of drugs and products using the appetite suppressant characteristics of this plant that were known to the San people (living in the Kalahari desert of Southern Africa). This practice was first noticed by South African soldiers during the Namibian independence war and thereon passed on to the South African Council for Scientific and Industrial Research[934]. The latter filed for patent protection,

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[930] COTTIER, "The Protection of Genetic Resources and Traditional Knowledge: Towards More Specific Rights and Obligations in World Trade Law," *op.cit.,* p.563.
[931] ADRIAN SMITH and GILL SEYFANG, "Constructing Grassroots Innovations for Sustainability," *Global Environmental Change* 23, 2013: p.828.
[932] Ibid.
[933] This example is examined in BIBER-KLEMM et al., "Flanking Policies in National and International Law," *op.cit.*, pp.239-279 (at 241-232).. It also draws in from a detailed analysis made by UNEP and WIPO, *op.cit.*, 2002. (case study one – Mali).
[934] DUTFIELD, *Intellectual Property, Biogenetic Resources and Traditional Knowledge*, *op.cit.*, pp.52-53.

entered into licensing agreements with private sector actors such as the UK-based Phytopharm and then Pfizer, but was forced to negotiate the terms of an all-encompassing benefit-sharing agreement with the San following political pressure and intense media coverage of the shady affair[935]. The validity of the patents was not questioned in this particular case, but the tide had turned and opened the gateway for direct challenges. A patent on quinoa (*Chenopodium quinoa*), filed in 1994 in the United States covered the “cytoplasm conferring the property of male sterility derived from the Apelawa variety of quinoa”[936]. The application was dropped in 1998 following a strong campaign by RAFI and Bolivia’s National Association for Quinoa Producers, since the innovative property had actually been transferred naturally from a weed species in Colorado, making it possible to interpret the patent very broadly in ways that the inventors may not have intended[937]. Another case relates to a patent granted by the United States Patent Office in 1999 on an edible herbal mixture comprising karela, jamun, gurmar and brinjal, even though karela juice had long been used in India as an anti-diabetic mixture, as “documented in authoritative treatises such as Wealth of India and the Compendium of Indian Medicinal Plants”[938]. The plethora of patents granted on and around the neem tree (*azadirachta indica*) also caused international uproar and ended in challenges before both the United States and the European Patent Offices. In a similar vein, patents granted to the Texas-based RiceTec on rice varieties derived from Indian Basmati crossed with semi-dwarf varieties, including indica varieties, have been criticised as being “essentially derived from a farmers' variety, [that should therefore] not be treated as novel and the patent falsely claims a derivation as an invention”[939].

Even though traditional exclusion rights embedded in IP tools do not adequately fit the collective nature of innovation based on mass selection, the diverse and unstable, yet locally adapted varieties ought to be **protected against subsequent re-appropriation by either other farmers or the industry,** and compensation should be triggered, in case of re-appropriation for instance, at the commercialisation stage of new varieties incrementally developed by third parties. The ability of farmers to develop new varieties based on mass selection is regrettably still largely ignored by policy-makers. Regulators are confronted with a regulatory conundrum where protection should not only be granted to the conserved germplasm or created material, but also appreciate the farmers’ “dynamic and collective system of technology development and diffusion through every season”, based on skill sharing and seed exchange[940]. The strong protection paradigm’s focus has unfortunately solely remained the end-producer and developer of knowledge or products, purposefully setting aside other forms of knowledge that may present a more community-oriented

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[935] RACHAEL WYNBERG, "Hot Air over Hoodia," *Seedling, GRAIN* 13, 2010.

[936] The broad patent was not limited to a single hybrid or a variety, but covered any quinoa hybrid derived from "Apelawa", the male sterile cytoplasm found in Quinoa, including 36 traditional varieties; COMMITTEE ON ENVIRONMENTAL AUDIT, "Trade Related Intellectual Property Rights and Farmers' Rights : Appendix 7 to the Minutes of Evidence," ed. UNITED KINGDOM HOUSE OF COMMONS (http://www.publications.parliament.uk/pa/cm199900/cmselect/cmenvaud/45/45ap08.htm1999).

[937] DUTFIELD, *Intellectual Property, Biogenetic Resources and Traditional Knowledge*, *op.cit.*, p.54.

[938] While the particular patent was taken on the mixture of the above and not on the whole vegetable or fruit, it still raised serious concerns about the exploitation of indigenous and traditional Indian knowledge. AUDIT, "Trade Related Intellectual Property Rights and Farmers' Rights : Appendix 7 to the Minutes of Evidence."

[939] Ibid.

[940] PELEGRINA and SALAZAR, "Farmers’ Communities: A Reflection on the Treaty from Small Farmers’ Perspectives," *op.cit.*

and free-exchange-based outlook on innovation, especially with regards to agricultural or indigenous communities[941].

Within a truly cumulative innovation chain such as plant breeding, the communalised nature of research and development innately surfaces, as all agrobiodiversity improvement projects "benefit from the countless small-scale contributions to the prior art by individuals who draw from the public domain to make improvements, […] generating new information that other may exploit to their own advantage"[942]. The need for vigilance in enclosure indeed arises in view of the **cumulative and ancestral contributions** stemming from indigenous communities and all past innovators. All former contributors to plant improvement and conservation, whether fellow inventors or holders of traditional knowledge, and especially farmers in developing countries, have in a way "subsidised the commercial agricultural sector which appropriates most benefits deriving from [plant genetic] resources"[943]. The "ecological debt" of follow-on resource users is considered to be important in agriculture, even though it remains extremely difficult to quantify due to the interdependent nature of agricultural plant genetic resources, and also the incremental and cumulative nature of plant improvement. It has nonetheless been considered that in the year 1982 alone, the US wheat industry had been pushed forward of five hundred million USD a year through the use of the South's plant genetic resources[944]. Turkish wheat landraces, which have been developed and maintained through informal seed exchanges, have for instance supplied genes used for stem nematode, bunt and hessian fly resistance but also for stripe rust resistance. This last contribution was estimated to amount to fifty million USD a year to the United States seed industry[945]. The pleas for redistribution and compensation are better understood in light of these figures, even though their absolute accuracy may still be challenged with not too much trouble. The issue here lies in determining where one's invention ends to become another's, and how such contribution should be compensated for. Taking into account the incremental nature of plant innovation, the grant of IP titles carry additional cravings for vigilant consideration with regards to the pivotal notions of prior art, novelty and non-obviousness. It is complemented by a need to establish a trigger point for compensation, recognition or benefit-sharing when privately, publicly or collectively held information is used to develop a new variety, biological product or process. The need for vigilance arises with regards to the intricate relationship of crop improvement with the public domain of traditional knowledge, and the inherent considerations for the sharing of benefits arising from the use of genetic resources and associated knowledge.

The shrinking space for manoeuvre left to farmers for seed saving, using and exchanging within the strong IP paradigm, and a seemingly generalised lack of awareness or training in legal issues on the cultivators' side, have led to mounting disagreements between variety developers and sowers, leading to numerous court cases. Litigation has flourished over a range of IP infringements, from the possession of protected seed in itself, to its re-use outside the scope of the

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[941] WEST, "Institutionalised Exclusion: The Political Economy of Benefit-Sharing and Intellectual Property," *op.cit.*, p.41.
[942] REICHMAN, "Saving the Patent Law from Itself: Informal Remarks Concerning the Systemic Problems Afflicting Developed Intellectual Property Regimes," *op.cit.*
[943] CULLET, "Property-Rights Regimes over Biological Resources," *op.cit.*
[944] "World Interdependence: Maintaining Biological Diversity" *OECD Observer*, 115 (March 1982), pp. 42-44.
[945] KLOPPENBURG, *First the Seed: The Political Economy of Plant Biotechnology 1492-2000*, *op.cit.*, pp.167-168.

legislation, without royalty collection or in larger farms than those targeted by applicable legislation.

CONCLUSIONS. Farmers – Mass Selectors and the strong IP paradigm

Traditional exclusion rights embedded in intellectual property tools do not adequately fit the collective nature of innovation based on mass selection. The actors of mass selection, whether designating farmers, gardeners, or low-input breeders, are pushed to forcefully infringe third party proprietary interests or marketing rights, while the products of their own innovation are not protected against misappropriation.

Mass selectors have indeed been steadily pushed to the confines of illegality by seed legislation unapologetically oriented towards industrial agricultural production. Whether acting as partial desperado initiatives that exist in the dark confines of restrictive seed laws with a focus on landrace conservation and exchange, or trying to recoup the costs of selection and conservation efforts through commercialisation, the 21st century mass selectors and associated seed exchange networks have steadily hit the wall of unlawfulness. By trying to define themselves a place in a solely productivity oriented seed market, a place that has not always been granted to them, they have been accused of creating unfair competition by not complying with strict marketing rules. Mass selectors today also need to comply with additional obligations stemming from third party IPR, whether in the form of plant variety protection or patents. They need to reassess their selection efforts in light of increasingly restrictive farm-seed-saving opportunities. These restrictions arise as a result of shrinking farmers' privileges in IPR legislation. They also arise on account of regulatorily or contractually enhanced protection over harvested material and ad hoc approaches to the exhaustion of rights, calibrated to the needs of self-replicating technologies.

Furthermore and perhaps most startlingly, the contributions of the diverse and unstable, yet locally adapted varieties that stem from farmers' mass selection efforts and all associated knowledge ought to be taken into account in the incrementally cumulative agrobiodiversity innovation realm. These landraces should be protected against any subsequent re-appropriation that could be perpetrated either by other farmers or by the industry. Today no compensation is triggered at the commercialisation stage of new varieties incrementally developed by third parties on the basis of farmers' varieties. The ability of farmers to develop new varieties based on mass selection is regrettably still largely ignored by policy-makers, driven by the internationally reified property paradigm focused on the end-producer and developer of knowledge or products with high market value. The approach to the agrobiodiversity public domain as it stands today cannot adequately cater for the needs of mass selectors; thereby setting aside an important portion of socially and environmentally beneficial innovation that is dynamic and inherently collective.

TRENDS IN THE STRONG PROPERTY PARADIGM	SHORTCOMINGS EXPERIENCED BY MASS SELECTORS
Restrictive and productivity oriented seed legislation	Status of informal seed exchange networks as market actors?
	Illegality of landraces' cultivation, development and exchange
Proliferation and extension of patents and plant variety protection	Shrinking and nebulous farmers' privilege (uncertainty over reach of rights and obligations)
	Legislative and contractual extension of protection over harvested material: whither seed saving practices?
Reign of exclusive individual rights in cumulative innovation	Misappropriation of collective and traditional knowledge
	Lack of protection of landraces and associated knowledge

FIG.4: Shortcomings faced by mass selectors (farmers, gardeners and low-input plant breeders) confronted to the strong PGRFA property paradigm

PART III CONCLUSIONS Agrobiodiversity User Experiences and Contextualised Shortcomings of the Strong Intellectual Property paradigm

The strong IPR paradigm responds chiefly to the needs of integrated biotechnology giants that navigate the increasingly intricate, knowledge-intensive, and incrementally cumulative context of agrobiodiversity research and development using molecular plant breeding and DNA recombination. As a result, it operates to the detriment of other existing innovators, be it at community or farmer level, within both the public and private conventional breeding sectors, or with regards to the development of molecular research tools in publicly funded institutions. The reality of extensive and layered private property has had detrimental effects further down the chain of the sequential, cumulative and incremental innovation that is plant improvement. There is a greater prospect to see specific genetic compounds protected through two separate yet closely interlinked angles, first, in terms of genetic material, and second at the level of the isolated and purified "useful" compound[946]. Furthermore, the combined resort to plant variety rights and patents has spawned the brand new problematic of these two protection tools' co-existence, causing setbacks and an urging need for legal training within the public and private sectors alike. The expansion of the realms of product protection restrained the conditions designated for the lawful use of the plant-related innovation, pushing for the development of iron-clawed licensing skills to be able to use improved agricultural biodiversity. The range of manoeuvre left to researchers, breeders and farmers has been considerably slackened by the need to fuel private sector involvement in research and development and protect the products of its breeding efforts or molecular research. This need was notably propelled by technological developments allowing for speedier and more cost-effective copying of products that concomitantly are commercialised more extensively across national borders. It was impressively reinforced on account of the time-consuming, uncertain and difficult nature of title enforcement. The quite different statutory exemptions that pertain to breeding and farming share one commonality, related to their broad regulatory rationale and effect, since they initially remain constructs awarding an array of rights to members of society relying upon the use of agrobiodiversity, either for cultivation or for research, as a counterbalancing act vis-à-vis the grant of monopoly rights to a single actor who wishes to protect its own informational contribution to the field.

The increasing expansion of the rules of appropriation that characterise intellectual property rights regimes, coupled with the ever-shrinking rules of diffusion that originally stood as the balancing act ensuring the efficiency and equity of monopoly regimes, as a barrier against the drifts of over-protection, have triggered virulent societal and doctrinal criticism over the shortcomings of currently applicable intellectual property rights to effectively ensure and foster the innovatively successful use of agro-biodiversity. Prerogatives granted for the commercialisation or the subsequent use of new products or processes reward the often times colossal investments made for the development of plant varieties. They also intend to favour the diffusion of information and technology, through the marginal social return of avoiding trade secrecy. However, the very dual nature of plant improvement, which embodies both technology and information within the same physical object, whether in a plant variety or a gene sequence[947], turns this balancing act into an extremely difficult exercise. Furthermore, modern tools of informational innovation protection

[946] ROSE, "International Regimes for the Conservation and Control of Plant Genetic Resources," *op.cit.,* p.187.
[947] JACKSON, "Innovation and Intellectual Property: The Case of Genomic Patenting," *op.cit.,* pp. 5-25 (at p.27).

have failed their initial objective with the development of the "commerce of intellectual property", unfairly playing a knowledge game the foundations of which direly needs to be undisputedly strong for society to respond to all the future challenges that await us, especially with regards to agriculture facing the challenges of climate change and population growth. Mere exclusivity-seeking practices have weakened the primordial foundational link between the innovator and its innovation that still prevails as the legal rationale behind the grant of monopoly rights, through the excessive formalization of this link within a strategic portfolio, occasionally developed through research programs as such, but mainly achieved through the financial acquisition of the legal structure surrounding the innovator. There is profound discontent over the equity and sustainability of intellectual property protection within an incrementally cumulative innovation context such as plan improvement. Their suitability is contested as to their ability to protect the fruits of innovative efforts, but also to their capacity to ensure innovative products and processes are diffused. As a result, it is the strong agrobiodiversity paradigm's capacity to really foster socially and environmentally beneficial innovation that has been questioned.

This discontent has also not been felt in a uniform fashion by all actors of agrobiodiversity innovation. Certification regimes have for instance impacted mass selection more greatly[948], even more so when the latter has been completely disregarded by national or supranational legislation. While conventional plant breeders have rather been victims of the coexistence of plant variety rights and patents. Molecular breeding is on the other hand more vulnerable to the restrictions inherent to patent laws as such. Even though the tougher stance adopted in protection opportunities is viewed as a necessary encouragement of breeding efforts conducted on minor less commercially important crops, the new limits surrounding the statutory uses of plant-related innovations pose worrying threats to the economic survival of farmers relying on seed saving practices, smaller-scaled and non-integrated plant breeders, and public researchers relying on access to extensive gene pools and straightforward rewards for their contribution to agrobiodiversity[949]. By favouring "exploitation modes which focus mainly on the commercial potential of the resources, [the strong property paradigm] neglects their use to satisfy basic subsistence needs"[950]. Valid concerns of dispossession and unwarranted accumulation also raise legal interrogations as to the dominant paradigm's ability and capacity to recognise the cumulative and ancestral contributions stemming from the public domain, indigenous communities, or past innovators. Drawing on such concerns, the pivotal notions of prior art, common knowledge, novelty and non-obviousness carry additional cravings for vigilant consideration in the grant of IP titles and the extent of exclusive rights that accompany them. In the context of the TRIPS-propelled and internationally reified property paradigm, "an effective international system must permit States to gear their domestic laws to the

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[948] Accompanied by a complete ban on uncertified seeds and a lack of regard towards the latter products, seed certification mechanism indeed contributes greatly to the paradigm breakdown with regards to the protection and diffusion needs of the mass selection chain. See the aforementioned much turmoil-creating litigation which opposed Kokopelli, an organisation commercialising non-registered heirloom vegetable varieties and Graines Baumaux, a seed company taking full part in the formal seed system (European Court of Justice, *Kokopelli vs. Graines Baumaux*, Case C-59/11)

[949] DUTFIELD, "Turning Plant Varieties into Intellectual Property: The Upov Convention," *op.cit.*, pp.27-47.

[950] CULLET, "Property-Rights Regimes over Biological Resources," *op.cit.*, p.658.

needs of their local creative sectors and to deal with the distributive consequences of raising the cost of accessing the fruits of humankind's ingenuity"[951].

This customisation effort cannot however only take into account the strong intellectual property paradigm it proposes to redefine; it can be guided, but also needs to respect, the PGRFA public domain carved by international environmental law agreeements which focus on equity and sustainability rather than appropriability and innovation. These agreements nonetheless appoint distinct property rights and prerogatives, which can be viewed at times as solutions to identified paradigmatic shortcomings, but which can also lead to greater hinderance of cumulative plant improvement opportunities, as the "third enclosure" movement of biodiversity.

	PARADIGMATIC SHORTCOMINGS	**PATENTS**	**PLANT VARIETY PROTECTION**
PUBLIC RESEARCHERS	Disregard for science norms of communalism and trust Underproduction of non-market products, orphan crops and basic research Public knowledge recycled downward by private entities Misappropriation of traditional knowledge or other public domain goods by public researchers (prior art in patents and common knowledge in PVP)	Sub-patentable innovations: inventive step and novelty in natural products and processes Research tools and foundational patents: avoid hindrance and anti-commons	-
PRIVATE PLANT BREEDERS	Misappropriation of traditional knowledge or other public domain goods: prior art and common knowledge Ensure the consecration of the breeders' exception when faced with the co-existence of patents and plant variety rights	Research tools and foundational patents: avoid hindrance and anti-commons	Obsolescence in protection scope: need full capture of benefits to really stand as an incentive Need to adapt to the era of the genotype Legal certainty needed for the articulation of EDV and the breeders' exception
FARMERS	Forceful illegality through seed certification schemes not recognising seed exchange networks or overly restricting informal seed market Lack of consideration in enforcing and protecting farmers' knowledge and landraces	Almost inexistent farmers' exception Restrictive patent exhaustion doctrine for harvested material	Shrinking farmers' privilege, the era of royalties Enhancement of protection scope

FIG.5. Paradigmatic shortcomings faced by certain actors of plant improvement confronted to the strong PGRFA property paradigm

[951] DINWOODIE and DREYFUSS, *A Neofederalist Vision of Trips: The Resilience of the International Intellectual Property Regime*, *op.cit.*, Preface.

PART IV INSTITUTIONAL SHIFTS RESHAPING THE PUBLIC DOMAIN, TOWARDS SUSTAINABILITY AND EQUITY

The array of institutional and regulatory tools that today design the cumulative dominions over biodiversity stem primarily from property regimes that are assigned to improved plant varieties, specific components of, or processes linked to genetic resources. These regimes try to reward innovative human interventions built around genetic resources mainly outside of their natural habitats. This means that in the "life sciences industry, only the secondary stage of the research process is actually granted protection", while free access has been considered the rule for the primary traditional knowledge and information, as well as those tangible plant varieties that have populated fields for centuries[952]. Focused mostly on the conservation and sustainable use of biodiversity components, international environmental law agreements have nonetheless carved new understandings of control and appointed new collective rights over genetic resources. They have redefined the boundaries of the PGRFA public domain, at times broadening its scope so as to allow for facilitated access to genetic resources or for age-old seed saving practices, and at times restricting its reach, mainly in order to fight misappropriation of longstanding knowledge and usages by using the same weapons as the blight that they respond to, i.e. the exclusive enclosure of plant genetic resources. As a result, an additional layer of property regimes has been set out around tangible genetic resources that constitute the initial stage of all plant innovation research. Sovereign rights have been gradually recognised over resources deemed to be of "common concern" to humankind in environmental law, while agricultural genetic-resources have evolved from a common heritage understanding to a unique and specific, facilitated multilateral access mechanisms[953].

Several legal instruments were drafted around the need to halt the depletion of biodiversity, notably around sovereign rights over resources that came hand in hand with duties to conserve and use them rationally for the future generations, as embodied by Principle 2 of the 1972 UN Stockholm Declaration on the Human Environment[954]. In this conservationist perspective, the mechanism of compensation emerged as an incentive for the conservation of biodiversity in developing countries, enshrined in Principle 10 of the aforementioned 1972 UN Stockholm Declaration, which focuses on "adequate prices for raw commodities"[955]. However, the principles

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[952] SARR and SWANSON, "Economics of Intellectual Property Rights (Ipr) for Genetic Resources: North-South Cooperation in Sequential R and D," *op.cit.*

[953] Even though our analysis shall be concerned with the entire range of dominion built around the use of plant genetic resources, the main focus of this research will continue to lie within the study and re-definition of exclusive appropriation mechanisms, i.e. intellectual property rights, and to an extent, those rules pertaining to the marketing of seeds. Both the environmental law regime of access and benefit sharing, as well as the multilateral system established by the FAO International Treaty on PGRFA may have positive or detrimental impacts on agrobiodiversity-reliant research and innovation chains. However, we shall purposefully retain our focus on the exclusive use rights awarded to both the inputs and outputs of crop improvement, and on the public domain approaches favoured in both the CBD and ITPGRFA, hoping to further study the impact of other provisos, especially that of access and benefit-sharing, in the future.

[954] Declaration of the United Nations Conference on the Human Environment, 16th June 1972, Stockholm, Principle 2: "The natural resources of the earth, including the air, water, land, flora and fauna and especially representative samples of natural ecosystems, must be safeguarded for the benefit of present and future generations through careful planning or management, as appropriate."

[955] Principle 10 reads: "For the developing countries, stability of prices and adequate earnings for primary commodities and raw materials are essential to environmental management, since economic factors as well as ecological processes must be taken into account."

of benefit sharing and sovereignty were also seen by developing countries as important tools to ensure legal protection for resources found in their territory. Since developed countries had built up a strong system based on intellectual property rights to fully capture the benefits stemming from innovative endeavours and research programs, international environmental law would be the resource-rich South's forum to fight the misappropriation of genetic resources and all associated traditional knowledge. It would respond to the "biopiracy" operated by the grant of exclusive titles in developed countries without compensation for the holders of knowledge or the conservers of genetic resources. This dynamic stream drawing from the right to development has clearly dominated international environmental law making. It is upheld by the instruments linked to the 1992 Convention on Biological Diversity ("CBD"), especially the recently adopted Nagoya Protocol on the Access to Genetic Resources and the Sharing of Benefits Arising from their Utilisation. It is also enshrined in the *ad hoc* FAO instruments targeting plant genetic resources, whether the 1982 International Undertaking and 2001 International Treaty on Plant Genetic Resources for Food and Agriculture ("ITPGRFA"), which both consider benefit-sharing as an equitable compensation to the contribution of indigenous communities and farmers to innovation.

Examining first in a historical perspective the rationale and emergence of different international environmental and agricultural instruments *(Chapter 12)*, we shall thereafter delve into the delineation of property rights in instruments such as the CBD and the ITPGRFA *(Chapter 13)*. We believe that the illustration of the new public domain of agrobiodiversity constructed by international environmental law instruments may provide institutional tools to reclaim the inherent balance of property allocation; a balance that has been lost due to the stringently developmental practices that have been propelled by the dominant international trade and industrialised perspectives to PGRFA management and use. Emphasising the need to conserve agricultural biodiversity, international environmental law instruments nonetheless also mainly respond to pleas for equity and economic development.

10. CHAPTER 10: RATIONALE FOR THE INTERNATIONAL REGULATION OF AGRICULTURAL PLANT GENETIC RESOURCES

International standards and objectives for the prevention or mitigation of environmental harm have been established from the 1940's onwards[956]. The regulation of biological diversity first grew into a global priority with the international environmental negotiations back in the 1970's[957], supported both by conservationist pleas and requests for financial compensations deriving from the use of genetic resources[958]. In this context, the pivotal role of agricultural diversity to tackle the world's

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[956] International environmental agreements include purpose-specific conventions such as the 1946 International Convention for the Regulation of Whaling (ICRW); regional agreements such as the 1976 Barcelona Convention for Protection against Pollution in the Mediterranean Sea; and also cross-cutting agreements such as the 1973 CITES Convention on International Trade in Endangered Species of Wild Fauna and Flora; or the 1998 Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters.

[957] See PHILIPPE SANDS, *Principles of International Environmental Law*: Cambridge University Press, 2003 (second edition), 25-69.; for a thorough overview of the historical development of international environmental law and its intensification. The author identifies four distinct periods, from early fisheries conventions to the creation of the United Nations, to the Stockholm Conference (1945-72), the period between the Stockholm and Rio Conferences (1972-92), and the UN Conference on Environment and Development and beyond.

[958] The development of international environmental law concerned with biological resources can be seen as a "snapshot of environmental conservation movements" (SWANSON, "Why Is There a Biodiversity Convention? The International Interest in Centralized Development Planning," *op.cit.*), including those focused on protected areas or

biggest biotic and abiotic challenges in food production and food security was also widely recognised, in light of the world's bitter realities of hunger and malnutrition[959]. This focus was accompanied by concerns as to the sustainable but most of all equitable use of plant genetic diversity, igniting sovereignty and protectionist bilateralism-oriented rights and obligations for genetic resources providers and their users, including innovators. Before tackling the exact content of these rights and obligations and the reach of such property regime, we shall underline the rationale lying behind the push for international regulatory action in agrobiodiversity management, describing the ecological, historical and sociological causes of regulation, also propelled by the nature of the good itself, as both a private good producing tangible and informational public goods with both intergenerational and interregional dimensions[960].

10.1. The need to conserve agrobiodiversity in a sustainability perspective

Biological diversity has traditionally been understood as covering both the **variability of all ecosystems and the multiplicity of the species they contain, while being complemented by the genetic diversity found within these species**[961]. Diversity then does not only include the variety of life on Earth at all its levels, from genes to ecosystems, but also the ecological and evolutionary processes that help sustain such diversity[962]. Human actions impact particular levels of diversity, by threatening a specific ecosystem, species or a variety through over-use. They also profoundly alter ecological processes, through for instance extensive agricultural cultivation. Substantive literature is available on the loss of the world's biological diversity at all geographical and structural scales. They all underline the difficulty of establishing effective criteria to evaluate the impacts of human activities or natural phenomena on diversity. It is as a result an impossible task to precisely determine actual depletion rates[963]. Estimations of currently existing species also quite shockingly range from 3 million up to 50 million[964], while recent comprehensive conservation studies carried out by the World Conservation Union state that the best working estimate of the

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specific problems such as erosion. The pleas also include the desire to overcome the existing patchwork of regulation covering selected species or areas, mainly through an ecosystems approach, see BRAGDON, *op.cit.*, 2004. The anthropocentric aspect of the Convention, i.e. the use of biodiversity, stands behind the bio-prospecting movement and equity considerations.

[959] Target 2 of the first goal of the Millennium Development Goals (eradication of extreme poverty and hunger) emphasises the need to reduce by half the proportion of people who suffer from hunger by 2015. Linking biodiversity, food and nutrition has been accepted as a means to achieve such target by the Parties to the CBD and resulted in a cross-cutting initiative in 2006; EIGHTH CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY, "Decision Viii/23a " (2006).

[960] EYZAGUIRRE and DENNIS, "The Impacts of Collective Action and Property Rights on Plant Genetic Resources," *op.cit.*, p.1490.

[961] Biodiversity cannot in this sense be limited to the sum of all ecosystems, but rather needs to be understood as the representation of variability within and amongst species living in specific environments, as an "attribute of life rather than biological resources which are tangible biotic components of ecosystems", GLOWKA LYLE, *A Guide to the Convention on Biological Diversity*, Environmental Law and Policy Paper No.30: World Conservation Union's (IUCN), 1994, pp.19-24.

[962] KEVIN J. GASTON, "What Is Biodiversity?," in *Biodiversity: A Biology of Numbers and Difference*, ed. KEVIN J. GASTON, Blackwell Science, 1996, pp.1-12.

[963] As we shall develop further during the course of this research focusing on the situation in Turkey, the lack of species inventory and the inherent difficulties of such endeavours at the global scale is also to be seen as a major difficulty behind the exact determination of biodiversity loss.

[964] Renowned biologists Edward WILSON and Francis M. PETER stated that the best estimates laid between 5 and 30 million species, in *Biodiversity*: National Academies Press, 1988., p. 13-15.

number of species in 2008 lies between 8 and 14 million[965]. These difficulties and quite significant differences mainly strive from the multidimensional structure and definition of biodiversity favoured by scientists and law-makers alike, where loss is determined in terms of species richness within specific taxonomies, through their proportional and relative abundance[966]. Linear approaches are indeed seldom able to take the functional aspect of diversity into account. In addition, plants have not been inventoried as well as mammals or birds and therefore their extinction rates estimates tend to be based on models, rather than reported and documented extinction figures[967]. This raises considerable uncertainties and leads to diverging predictions. Quantitative studies thus differ widely, while the sole common feature of the doctrine, also reflected in the Millennium Ecosystem Assessments, is to assert that "virtually all of Earth's ecosystems have now been dramatically transformed through human actions" and show alarming signs of deterioration[968]. The Global Biodiversity Outlooks prepared by the Secretariat to the 1992 Convention of Biological Diversity confirmed such premise[969][970].

Human interaction with natural ecosystems is particularly complex in agriculture. As admitted by the Conference of Parties of the Convention on Biological Diversity, "far more understanding is needed of the multiple goods and services provided by the different levels and functions of **agricultural biodiversity**, […] such as the relationship between diversity, resilience and production in agro-ecosystems, […in light of] the traditional and newer practices and technologies used in agriculture, which utilise, or impact on, agricultural biodiversity in different ways."[971] Biodiversity has been shown to perform ecosystem services beyond food or income production, mainly biological renewal processes such as the regulation of the abundance of undesirable organisms or detoxification, crucially important in agriculture[972]. Agricultural ecosystems display

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965 The IUCN Red List of Endangered Species, 2008 update (see also the Factsheet on the State of the World's Species), whereby within the 44,838 species under study, 869 (2%) are Extinct or Extinct the Wild; 6,928 (38%) are threatened with extinction (with 3,246 Critically Endangered, 4,770 Endangered and 8,912 Vulnerable); 3,513 (8%) are Near Threatened; while 5,570 (12%) have insufficient information to determine their threat status (Data Deficient).

966 The traditional ecological indices through which species diversity are measured include the Margalef index taking species richness into account, the Berger-Parker index of dominance (or relative abundance), and the Shannon index taking both richness and relative abundance into account, and at last species evenness or proportional abundance calculations. See MELINDA SMALE and A. KING, "*Genetic Resource Policies: What Is Diversity Worth to Farmers? On-Farm Genetic Resources and Economic Change*", International Plant Genetic resources Institute Rome 2005. pp. 4-5.

967 VIRCHOW, *Conservation of Genetic Resources: Costs and Implications for a Sustainable Utilization of Plant Genetic Resources for Food and Agriculture*, *op.cit.* pp. 17-18.

968 WORLD RESOURCE INSTITUTE, "*Millenium Ecosystems Assessment, Ecosystems and Human Beings: Biodiversity Synthesis*", Washington D.C, 2005. pp. 12-15.

969 CBD SECRETARIAT, "Global Biodiversity Outlook," (Montreal2001). and for the recent re-assessment of the figures see "Global Biodiversity Outlook 2," (Montreal2006).; both respectively available at http://www.cbd.int/gbo1/ and http://www.cbd.int/gbo2/) see sections focusing on the study of current trends regarding the goal of reducing the rate of loss of the components of biodiversity, the maintenance of ecosystems integrity and the identification of major threats to biodiversity.

970 For a comprehensive overviews of the causes lagging behind biodiversity loss, see EDWARD B. BARBIER, JOANNE C. BURGESS, and CARL FOLKE, *Paradise Lost? The Ecological Economics of Biodiversity* London: Earthscan, 1994, Chapter 4: "Driving Forces for Biodiversity Loss", pp. 60-87.; where the authors emphasise on proximate and underlying causes of the loss, such as population pressure, erroneous uses of economic incentives leading to market and policy failures, inadequacy of institutional frameworks and the shortcomings of our cultural and ethical approaches to biodiversity conservation.

971 FIFTH CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY, "Appendix of Decision V/5 " (15-26 May 2000)., where the Parties identified the distinctive features of agrobiodiversity and set up a particular plan of action in this regard, as we shall touch upon in the second chapter of this study.

972 MIGUEL A. ALTIERI, *Biodiversity and Pest Management in Agroecosystems* New York: Haworth Press, 1994, 5-9.

one fundamental material difference vis-à-vis natural ecosystems, as they comprise of domesticated plant or animal species and their associated genetic resources, intended for the sole purpose of food and agricultural production. The notion of species with regards to agricultural plant biodiversity covers a relatively small amount of crop species and is traditionally outnumbered by the **varieties** found within a given crop species. These varieties include landraces, farmer-selected cultivar types, their crop wild relatives, as well as advanced cultivars, resulting from genetic or genomic improvement efforts generated by scientific and technological achievements. The genetic material contained within traditional varieties, modern cultivars, and their wild relatives is considered to be the biological basis of world food security by directly or indirectly supporting the livelihoods of every person on earth[973]. As components of the fundamental structural level of agrobiodiversity, they are treated as the key feature of food production[974], serving as a "repository of genetic adaptability and thus a safety net in the event of environmental change"[975].

The relationship between agriculture, especially modern agricultural practices, and the preservation of natural biodiversity on the one hand and the **efficient management of agro-biodiversity** on the other, is nothing but a simple matter. Modern agriculture, especially monoculture and over-mechanisation, has been mentioned as a major cause of extinction with regards to agricultural genetic diversity. Yet the same modernisation, by reducing pressure on soil, has also been considered to help the protection of biodiversity outside agricultural fields[976]. Modern varieties can contribute to such sustainability by for instance propelling land-savings and reducing pesticide use by improving the resistance of varieties to biotic stresses[977]. However, the intensification of agricultural practices may also detrimentally affect biodiversity services, by causing species loss or altering ecosystem stability and resilience[978]. The specialisation and homogenisation of agricultural production permeates in the infamous figures relating to the number of species actually used for human food consumption. Indeed, seven thousand out of two hundred and seventy thousand plant species known to science have never been used for food, merely nine species provide for seventy five per cent of human food worldwide[979], while only three crops provide sixty per cent of the calories we obtain from plants[980]. Such homogenisation is cited as a major cause of genetic erosion witnessed in agricultural plant diversity.

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[973] Genetic erosion indeed threatens good security, increases risks of diseases by diminishing resilience, and prevents future discoveries by narrowing the genetic base of agricultural research; for an account of the role of agricultural biological diversity in the achievement of food security and the threats surrounding such achievement, see LORI ANN THRUPP, "Linking Agricultural Biodiversity and Food Security: The Valuable Role of Agrobiodiversity for Sustainable Agriculture," *International Affairs* 76, no. 2, 2000: pp.265-281.

[974] See for instance J.R. HARLAN, "Our Vanishing Genetic Resources," *Science* 188, no. 4188, 1975: 618-621., where the author more specifically underlines the importance of landraces' genetic integrity and diverse nature, which, as balanced populations, are the basic resources upon which future plant breeding depend.

[975] PALACIOS, *op.cit.*, 1997.

[976] VIRCHOW, *Conservation of Genetic Resources: Costs and Implications for a Sustainable Utilization of Plant Genetic Resources for Food and Agriculture*, *op.cit.*, 29-30.

[977] BYERLEE, "Modern Varieties, Productivity, and Sustainability: Recent Experience and Emerging Challenges," *op.cit.*, 704-705., the author still stresses that the maintenance of a broad genetic base "provides insurance against losses from unexpected causes, such as new disease, and complement efforts to improve and maintain pest resistance".

[978] See PAGIOLA et al., *op.cit.*, 1997. .

[979] ORGANISATION, *op.cit.*, 1996. ; see also PRESCOTT-ALLEN and PRESCOTT-ALLEN, "How Many Plants Feed the World," *op.cit.*, 365-374. for an in-depth analysis of these figures.

[980] BROOKFIELD et al., *Cultivating Biodiversity: Understanding, Analysing and Using Agricultural Diversity*, *op.cit.*

Interestingly enough, this pressuring force suffers greatly from the detrimental effects of its pressure on nature, since the primary agricultural inputs, i.e. seeds, continue to be based upon nature and depend on the maintenance of natural genetic diversity. Biological diversity continues to provide the **foundation for all plants and animals used for agricultural purposes,** considering that all domestic crops worldwide are derived from wild species that have either been modified through domestication, selective or methodical breeding, controlled hybridisation or genetic engineering[981]. Even though commercial research and development is generally carried out on standardised and stable plant varieties, which are already known to breeders, it has been demonstrated that researchers continued to rely, and in fact depended upon wild germplasm in order to ensure the long-term sustainability of their studies. Aforementioned figures revealed by Timothy SWANSON[982] showed that eighty three per cent of agricultural crop improvement research and development was conducted on the basis of standardised varieties, while six point five per cent focused on wild species and landraces. The agricultural industry could therefore and did indeed not rely on a static range of genetic material, which would not provide the necessary variability to ensure the resistance of the new varieties, and totally renewed its stocks every ten to fourteen years, renewal for which natural diversity pools need to remain at their widest range. The preservation of agricultural plant germplasm, both in its improved form or in its wild relatives, thus directly influences the future of agricultural research and development and concurrently agro-biodiversity, which will not overthrow homogenisation if its natural basis is reduced[983]. Researchers and variety developers ought to continue to be able to take full advantage of the library of successful survival and resistance strategies provided by evolution, whether at the phenotype or genotype level[984].

The rather novel and unmistakably uncertain act of branding “biodiversity” can be viewed as “a response given to a concrete situation that is certainly preoccupying but which goes well beyond the scientific domain”[985]. Notwithstanding the science that illustrates the numerous ecosystem services provided by the diversity of life, the relatively new commitment of doctrinal discourse towards such variety “anchors a discourse that articulates a new relation between nature and society in global contexts of science, cultures and economies”[986]. It is exactly this discourse that was translated into a legal obligation to conserve and use plant genetic resources sustainably, as a crucial component of agricultural biodiversity, as the primary inputs of cultivation and crop improvement, and finally as the providers of various public goods.

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[981] MIGUEL A. ALTIERI, "The Ecological Role of Biodiversity in Ecosystems," *Agriculture, Ecosystems and Environment* 74, 1999: 19.

[982] The results of the study are found in *Global Action for Biodiversity, an International Framework for Implementing the Convention on Biological Diversity op.cit.*, 73-75. The author goes on to conclude that agriculture, along with the pharmaceutical industry in fact constitute living defence systems for the maintenance of their biological foundation, rather than static industries.

[983] This reality has been further enhanced through technological developments whereby breeders increasingly use genetic material found in wild species which contain valuable alleles, while they focused on elite material, mainly found in gene banks in the past; see FRANKS, "In Situ Conservation of Plant Genetic Resources for Food and Agriculture: A Uk Perspective," *op.cit.*, 81-82.

[984] SWANSON, *Global Action for Biodiversity, an International Framework for Implementing the Convention on Biological Diversity op.cit.*, p.74.

[985] ARTURO ESCOBAR, "Whose Knowledge, Whose Nature? Biodiversity, Conservation and the Political Ecology of Social Movements," *Journal of Political Ecology* 5, 1998: p.55.

[986] "Whose Knowledge, Whose Nature? Biodiversity, Conservation and the Political Ecology of Social Movements," *Journal of Political Ecology* 5, 1998.

10.2. The need to address the property regime of agrobiodiversity

Taking into account the broad foundation of the new biodiversity discourse, international agreements have not only focused on purely biological aspects and affiliated socio-economic impacts. They have also rather uniquely set up an internationally agreed property regime over genetic resources, appointing great control but also numerous obligations to Member States' institutions. This second tier of international biodiversity conservation law stems not only from a purely ecological prospect, but also from a **developmental perspective,** which is embedded in a desire to remedy longstanding socio-economic inequities. The need to address the property regime of agricultural plant genetic resources find its roots in the history of biological prospecting, starting from colonial times. The collection of genetic resources, understood in purely scientific fashion, pertains to the physical gathering of natural material on the field. It relates to the quest and appropriation of "exotic" objects, i.e., objects that cannot be naturally found in the territory where the legal entities pursue their research[987]. Mere resource collection activities thenceforth shift into "**bioprospecting**" through the inclusion of anthropocentric "commercial viability" and "potential human use" objectives in research endeavours[988]. The market potential attached to prospecting push collecting efforts to be viewed as a "process that enables individuals or groups to alienate particular bodies of material for their exclusive use"[989]. Collection and characterisation activities taking place upstream significantly shape the appropriation regimes that will gradually ensue up to the very end of a genetic resource's cycle of use. From their genesis to their gradual institutionalisation, the patterns and actors of germplasm collections efforts illustrate the changes in our perception as to the functions and ownership of nature. The historical contextualisation of genetic material exchanges may thus qualify to understand the claims of biological piracy or misappropriation, as well as the struggle for a public domain fenced anew. Struggles for equity and compensation indeed lay at the heart of principles regulating the legal status of plant genetic resources in international environmental law.

10.2.1. History of PGRFA Exchanges: Quest for exotic genetics and the dawn of biological collections

Exotic and rare resources have always nursed research interests, since the dawn of biology and life sciences in general. Such interest was already present in the earliest of human civilisations, presented first hand as a need to ensure the specific society's survival, and later as a necessary process to maintain its welfare conditions. In light of the ever-increasing population numbers and the parallel industrialisation process, "no society seemed to have **enough ecological assets at**

[987] Biological prospecting that stems from these collection activities is then defined as "the systematic search for genes, natural compounds and whole organisms in wildlife with a potential for product development", see N. MATEO, W. NADER, and G. TAAYO, *Encyclopedia of Biodiversity, Vol.1* New York: Academic Press, 2001, 471.
[988] All definitions of bioprospecting indeed put the emphasis on such anthropocentric approach, as a "search for genes […] *with a potential for product development*", (NOEL CASTREE, "Bioprospecting: From Theory to Practice," *Transactions of the Institute of British Geographers* 28, no. 1, 2003: 36.) or an "exploration of biodiversity for *commercially valuable* genetic and biochemical resources", a "search for wild species, genes and their products *with actual and potential use to humans*" (emphasis added): See WALTER A. REID et al., *Biodiversity Prospecting: Using Genetic Resources for Sustainable Development* Washington D.C: World Resources Institute, 1993.
[989] PARRY, *Trading the Genome: Investigating the Commodification of Bio-Information, op.cit.*, 14., also see KATHLEEN MCAFEE, "Selling Nature to Save It? Biodiversity and Green Developmentalism," *Environment and Planning* 17, 1999: 133-154.

home to manage the quantum jump"[990]. It thus became apparent that the exploitation of ecological resources outside one's sovereign territory would be extremely beneficial for those countries in wish of growth and expansion. Even though the collection of rare raw materials has been a praised leisure pursuit dating back to late medieval kingdoms, it is widely considered that the natural world was truly opened to investigation during the 18th century[991]. Collectors of the time were indeed ordered to gather species of agricultural or medicinal value in the name of the "Empire" and bring them back home. These instructions initiated the **'tangled flows' of both wild and domesticated plants** throughout the world, acquainting eager consumers with exotic foodstuff and setting the foundations of what has been coined agricultural germplasm interdependence[992]. The journey of tomato, originating in Mexico as a small yellow 'tomato', epitomises the vividness of these international exchanges and their agronomical and societal impacts. The tomato indeed travelled within South America and then to Europe through Spanish colonial expeditions, where it became the 'love apple', slowly turning red before heading back to the North American continent with French settlers[993].

Thoroughly organised collecting expeditions and the subsequent intensification of commodity flows primarily enabled naturalists to grab a better understanding of the materials collected, and thus of nature itself. The **physical accumulation of biological material** came hand in hand with the **concentration of knowledge** within the hands of a lucky few. The colonial collections of the 18th and 19th centuries were indeed aimed at the consolidation of economic power through the potential use of the collected material in the service of agriculture and industry. They also served the greater objective of imperial expansion, in terms of both geography and cultural or scientific excellence[994]. Natural historians who accompanied the discovery expeditions carried out during this prosperous era indeed continue to represent grandeur and academic eminence in our 21st century psyche. The name of Charles Darwin today for instance still echoes with ethology and revolutionary scientific ideas[995]. This opening period put the emphasis on the **individual carrying out the collecting activities** as such, even though the initial impetus behind the resource flows were of national dimension. Indeed, colonial expeditions were by their nature state-funded and controlled by the State. However, quite interestingly, while all genetic resources found in the "discovered lands" were deemed to be freely appropriable, botanists accompanying these expeditions were carrying collection activities in a private capacity. Such individual-oriented approach enabled them to demand further expenditure from the State or other botanical gardens

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[990] A.W. CROSBY, *The Columbian Exchange: Biological and Cultural Consequences of 1492, 30th Anniversary Edition.* London: Praeger, 2003, Preface. See also Chapter 7, 'Weeds' (pp.145-216) for an account of the differing influences of European agriculture and plants over the range of colonised territories.

[991] PARRY, *Trading the Genome: Investigating the Commodification of Bio-Information*, *op.cit.*, 12-13., where the author attempts to define the process of "collection" of biological information by tracing its roots back in history, from medieval times to its intensification during 18th and 19th centuries.

[992] For an account of this web of flows, see E. PAWSON, "Plants, Mobilities and Landscapes: Environmental Histories of Botanical Exchange," *Geography Compass* 2, no. 5, 2008: 1464-1477.

[993] "Plants, Mobilities and Landscapes: Environmental Histories of Botanical Exchange," *Geography Compass* 2, no. 5, 2008: esp. at 1467.

[994] PARRY, *Trading the Genome: Investigating the Commodification of Bio-Information*, *op.cit.*, pp. 33-37.

[995] Charles Darwin indeed took part in such expeditions, aboard the H.M.S. Beagle, collecting diverse specimens for study, as related in Charles DARWIN and Janet BROWNE (ed.), *The Voyage of the Beagle: Charles Darwin's Journal of Researches*, Penguin Classics, London, 1989; and CROSBY, *The Columbian Exchange: Biological and Cultural Consequences of 1492, 30th Anniversary Edition.*, *op.cit.*

that desired to hold the material in their archives[996]. The example of Joseph Banks, who accompanied James Cook on its travels in the Pacific, stands out in this particular matter. All the specimens collected during the expeditions he took part in, whether they had been physically collected by him or not, were to remain under his direct control, in his personal home[997]. This understanding led to the establishment of one the greatest privately domiciled collections in England. From an international standpoint, the collections were thus made on biological material that could be considered *res nullius* as such, while they were coined the private property of the "individual gatherer" once isolated from their natural habitats.

In the **early-19th century,** materials collected during colonial expeditions fell **under public ownership** through the grant of **public scientific or botanical garden status** to institutions formerly controlled by private persons. The State could thereby exclude anyone from using the gathered biological resources and maintained control over them. The Kew Gardens were for instance transferred from the control of the Crown to the State's authority in 1840, transforming a "privately funded pleasure garden into a publicly funded scientific research institute"[998]. These European public colonial gardens did not merely collect material in the "new world". They also carried out **empirical characterisation** activities and established plantations according to the alimentary needs of their population, including those living overseas[999]. To this end, colonial powers slowly established wide networks for their botanical gardens. They opened "satellite stations" in the colonised and biologically-rich world, where the collected germplasm would be **actively used for cultivation** purposes. The stations remained under the management of the botanical gardens of the North, who continued to control the flow of genetic resources as power hubs or "centres of calculation"[1000]. These extended networks created the first modern agricultural experiment stations, concretely using the collected materials on field. However, such practices concomitantly exacerbated the high concentration of knowledge in the hands of a few colonial powers presenting no diversity centre within their boundaries. For instance, the United Kingdom possessed sixty-one botanical gardens without having any centre of biodiversity within its territory. Greece or Turkey on the hand lacked (and arguably still do lack) the institutional capacity to make use of the numerous diversity centres found within their sovereign borders[1001]. Endemic or threatened resources were therefore often not protected in their own botanic gardens, but rather needed to be transferred to skilled institutes elsewhere.

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[996] See LUCILE BROCKWAY, *Science and Colonial Expansion: The Role of the British Royal Botanic Gardens*: Yale University Press, 2002., and D. MACKAY, "Agents of Empire: The Banksian Collectors and Evaluation of New Lands," in *Visions of Empire: Voyages, Botany and Representations of Empire*, ed. D. MILLER and P. REILL, Cambridge: Cambridge University Press, 1996.

[997] See DAVID MILLER, "Joseph Banks, Empire, and the Centres of Calculation in Late Hanoverian London," ibid., ed. D. MILLER and P. REILL, 24., (cited in PARRY, *Trading the Genome: Investigating the Commodification of Bio-Information*, *op.cit.*p. 34).

[998] *Trading the Genome: Investigating the Commodification of Bio-Information*, *op.cit.*, 35.

[999] For instance, tea, originally from China and thus quite an expensive good to import, found itself being cultivated in East and South East Asia (most notably Ceylon) and also East Africa in order to meet the growing demand of the product in Great Britain, see *Trading the Genome: Investigating the Commodification of Bio-Information*, *op.cit.*, 36-37., and the figures exposed by KLOPPENBURG, *First the Seed: The Political Economy of Plant Biotechnology 1492-2000*, *op.cit.*, 155.

[1000] The concept of "centre of calculation" is drawn from actor-network theory and describes points that operate from afar within the created network of mobility.

[1001] See MIKE MAUNDER, SARAH HIGGENS, and ALASTAIR CULHAM, "The Effectiveness of Botanic Garden Collections in Supporting Plant Conservation: A European Case Study," *Biodiversity and Conservation* 10, 2001: 385.

Due to the national appropriation strategies that prevailed, collection and cultivation endeavours paved the way for the North-South unrest vis-à-vis the **dichotomy between the availability of biological resources on the ground and the capacity to use them**. Germplasm movements may nonetheless also be viewed in a wider and more enthusiastic perspective, not only encompassing linear material transfers from 'Southern' colonies to European centres of calculation, but also including movements between colonial territories. Indeed, the undesirably unilateral character attached to germplasm exchanges under the colonial era needs to be slightly tempered by evidence of movements within and between Southern areas[1002]. Examples of such "transoceanic movements' include the sugar cane, initially collected by the French in Tahiti and disseminated in the East Indies and the Caribbean[1003]. These transoceanic movements have been further reinforced by the strong connections that existed between European botanical gardens themselves, and the subsequent human-induced exchanges between eager botanists. Within this landscape of extended resource exchange, most of the intentional flow and redistribution of biological material remains nonetheless attributable to the Northern botanical gardens and their affiliated Banksian network of collectors. The contribution of indigenous communities to these exchanges has indeed not been recorded extensively, except from a number of recent studies[1004]. Then again, the Banksian network of collectors warranted some interaction and cooperation with local populations. These communities' contribution was generally welcomed quite sceptically by the expeditions, due to the lack scientific categorisation of genetic resources and the geographical variations in their characterisation[1005]. Attempts to quantify the contribution of native communities to the accumulation of biological resources and associated knowledge have awakened demands for the re-examination of ownership issues attached to the genetic resources accumulated and studied during "the reign" of botanical gardens.

The movement of biological material had become significantly institutionalised in the hands of botanical gardens, which gradually retrieved genetic resources themselves, and all information attached therein. However, the informational goods imported and studied by colonial powers were not viewed as commodities as such. Indeed, the emphasis of trade and research was clearly put on **end products.** For instance, the rubber obtained from a tree was viewed as a commodity by the Kew Gardens, while the genotype of that same rubber was considered freely appropriable. Indeed, no real property titles or other ownership claims were recognised on the information linked to the genetic resources collected and characterised during this period, even that of the gathering power or of the collector, in contrast with the end products of the plants these varieties related to[1006]. While plant varieties' end products were considered to be the national property of the State

[1002] STEPHEN BRUSH, "Indigenous Knowledge of Biological Resources and Intellectual Property Rights: The Role of Anthropology," *American Anthropologist* 95, no. 3, 1993: 653-671 (esp. at 657-658).

[1003] See PAWSON, "Plants, Mobilities and Landscapes: Environmental Histories of Botanical Exchange," *op.cit.*, 1469., for these examples, and WILLIAM BEINART and KAREN MIDDLETON, "Plant Transfers in Historical Perspective: A Review Article," *Environment and History* 10, no. 1, 2004: 3-29., for a more comprehensive criticism of the "one-sided imperalist" approach to Columbian exchanges of plants and other resources.

[1004] The use of idioms such as "brokers of international knowledge" has for instance been coined vis-à-vis such collectors, see L. SCHIEBINGER, *Plants and Empire: Colonial Bioprospecting in the Atlantic World* New York: Harvard University Press, 2007, 23-100.

[1005] For a historical perspective focusing on the role of indigenous people in material collection with specific regards to medicinal uses, see RICHARD H. GROVE, *Green Imperialism: Colonial Expansion, Tropical Island Edens and the Origins of Environmentalism, 1600-1860* Cambridge: Cambridge University Press, 1995, at p. 540, also see Chapter 542 on indigenous knowledge (pp.573-594).

[1006] See BROCKWAY, *Science and Colonial Expansion: The Role of the British Royal Botanic Gardens*, *op.cit.*, 42-45.

harbouring or financing the collections, their **genotypes and the correlated information** were not. This approach reached even further. The "botanical chess game"[1007] through which colonial powers appropriated exotic plant germplasm indeed considered exotic and non-institutionalised genetic resources as a freely appropriable good. They therefore attached no costs to biological prospecting activities but those related to the maintenance of the collections[1008]. However, they also found it unnecessary to constrain the future uses of these goods. The genetic raw material collected by botanical gardens or other national institutions was also considered to be in the public domain, with little or no conditions surrounding consequent uses by third parties. States, through centres of calculation and satellite stations, were the only major actors of an inherently tangled international exchange of biological material. The concentration of both resources and knowledge in the same expansionist hands forecasted the divide between the technologically rich 'North' versus biologically rich 'South', a divide that has dominated recent international negotiations. While end products were deemed appropriable, the information attached thereto was not.

Operating wide-ranging collection and screening programmes during the 1960's, public research institutes focused on concrete discoveries in the advancement of science and societal welfare. They similarly created networks of collecting agents, in similar fashion to the Banksian understanding of collection activities[1009]. Modern prospecting activities were however granted a more institutional background as they were carried out on a contractual basis, as the State mandated botanical gardens to work with local associations in order to legitimise the collections[1010]. Gargantuan public agricultural research programmes were gradually established, relocating in parallel crop development as an internationally strategic political and economic pursuit. Following what had already began in past decades, the end of the 19th and beginning of the 20th century saw an increase in State interest for undertaking biological collection expeditions and correlated research[1011]. The global food crisis of the 1950's and 1960's saw a need to institutionalise the informal flows and free exchanges of biological material at the global level, in order to respond to the urgency of the Malthusian concerns related to shortages in food supply[1012]. The total number of genetic resources that can be accessed through the international agricultural

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1007 The metaphor that has become widely used can be first found in MOONEY, *Seeds of the Earth: A Private or Public Resource?*, *op.cit.*, 85.; where the author studies the dynamics of this chess game and the accompanying geographical shift of resource availability.
1008 KLOPPENBURG, *First the Seed: The Political Economy of Plant Biotechnology 1492-2000*, *op.cit.*, pp.152-153.
1009 Joseph Banks accompanied James Cook during its travels in the Pacific was the owner of the first and greatest private collection of genetic resources in his personal home, he was later appointed as director to the national botanic Kew Gardens in London, see Chapter 10.2 of this study.
1010 For a review of these subcontractual relationships and further development, see PARRY, *Trading the Genome: Investigating the Commodification of Bio-Information, op.cit.*, 109-112.
1011 The creation of the United States Department of Agriculture in 1862, which took on responsibilities for the collection and dissemination of agricultural plant genetic resources, was indeed a turning point in the conception of control and use of germplasm. Coupled with the network of State Agricultural Experiment Stations, the USDA quickly established an efficient system to evaluate and introduce new varieties adapted to local conditions. See AOKI, *Seed Wars: Controversies and Cases on Plant Genetic Resources and Intellectual Property*, *op.cit.*, 14-16.
1012 Thomas Malthus' work in the 18th century indeed predicted that population growth would outweigh food production, which led to more recent academic conclusions that food and poverty aid should be limited to sustainable alternatives within countries able to attain self-sufficiency. These 'natural selection' population scholars include Paul EHRLICH and Garett HARDIN, the works of which have been heavily praised throughout time, but also equally criticised in contemporary doctrine not with regards to its diagnosis but rather the solutions that were brought forward to mitigate the unwarranted consequences of population growth and resource scarcity; see EHRLICH, "The Population Bomb," *op.cit.*, EHRLICH and EHRLICH, "The Population Bomb Revisited," *op.cit.* and HARDIN, *The Ostrich Factor: Our Population Myopia*, *op.cit.*

research centres network amounts to six hundred thousand specimens today[1013], rendering the Consultative Group for International Agricultural Research indispensable in the *ex situ* preservation of agricultural biodiversity worldwide. However, numerous uncertainties remained as to the legal status of their germplasm collections, whether they presented an international or national character, or were to be considered in the public domain or not. These uncertainties were also present within the Consultative Group itself, which ordered a study that revealed "a general lack of provisions for the ownership of genetic material or for its devolution in the event where an International Agricultural Research Centre ceased to operate. […] In general, however, the consultants [considered] that the germplasm collections would not pass automatically to the host government"[1014], in accordance with the trustee role the Group wanted to endorse. The actual management of the genetic resources found within their auspices has in this sense been compared to a 'classic open source system for crop improvement'. It was based on a collaborative model where the original material was freely exchanged and distributed, information fully shared, participation opened in a non-discriminatory fashion and further research not prevented by intellectual property rights[1015]. The actual legal status of collections remained nonetheless blurry. The centres and their collections were to hit the wall of ownership reservations and biopiracy allegations raised at the end of the 20th century, confronted to the new actors of agricultural input provision, and the new rules of the plant improvement and conservation game[1016].

10.2.2. Sowing the "seeds of discontent"

Natural biodiversity provides the foundation for all plants used for agricultural purposes, whether to form wild relatives, landraces, stable, improved or genetically engineered varieties. Technological developments carving deeper into genetic resources transformed them not only into informational goods, but also propelled them as strategic economic and industrial development tools. Even though commercial research and development is generally carried out on standardised and stable plant varieties, researchers continue to rely on wild germplasm, and are growingly doing so on account of molecular biology tools[1017]. Numerous estimations have been made as to the contribution of exotic germplasm to the wealth generated by the industrial countries' seed industry, a contribution that reached billions of US dollars[1018]. As aforementioned, it has for instance been shown that Turkish wheat landraces supplied genes used for stem nematode, bunt and hessian fly resistance but also for stripe rust resistance, this last contribution having been estimated to amount to fifty million USD a year to the United States seed industry[1019]. The

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[1013] It should be noted that all CGIAR centres do not possess germplasm collections.

[1014] WOLFGANG E. SIEBECK and JOHN BARTON, "*The Legal Status of Cgiar Germplasm Collections and Related Issues*", Agenda Document, TAC 57, 1991.

[1015] BYERLEE and RUBIN, "Crop Improvement in the Cgiar as a Global Success Story of Open Access and International Collaboration," *op.cit.*, 453 and 457-463.; the authors use the example of wheat breeding programmes and the CIMMYT to illustrate their premise.

[1016] MICHAEL BLAKENEY, "Agricultural Research: Intellectual Property and the Cgiar System," in *Global Intellectual Property Rights: Knowledge, Access and Development*, ed. PETER DRAHOS and R. MAYNE, New York: Oxfam and Palgrave Mac Millan, 2002, 110-111.

[1017] See Chapter 7.3 for a detailed account of the uses of exotic material within conventional breeding programs, and Chapter 9.3. for those uses allowed by molecular breeding techniques.

[1018] In 1982, merely to US wheat industry was estimated to have been pushed forward of 500 million $ a year through the use of the South's plant genetic resources, "World Interdependence: Maintaining Biological Diversity" *OECD Observer*, 115 (March 1982), pp. 42-44.

[1019] KLOPPENBURG, *First the Seed: The Political Economy of Plant Biotechnology 1492-2000*, *op.cit.*, pp.167-168.

realisation by germplasm-providing countries of the actual value of the resources they freely shared with public research institutions under the belief of their 'common heritage' status, but especially the limited re-distribution of this wealth to germplasm donor countries (or the lack thereof), spurred feelings of discontent and theft; a theft that would be labelled **"bio-piracy"**. Critics were also growingly concerned by the private sector's consecutive uses of the germplasm collections that international research centres harboured; especially in light of the proprietary claims made by several companies over the 'by-products' obtained through freely exchanged material[1020]. The dismantlement of colonial regimes and the expansion of intellectual property tools in the Northern hemisphere transformed genetic resources into "politically salient resources", announcing the return of the normative principle of national sovereignty against proprietarian intellectual property rights[1021].

The **material and intellectual appropriation efforts of the West** overthrew all research or commercial aspiration that less-endowed nations might have had over genetic resources. Public agricultural research programmes were grounded on a "common heritage of mankind" understanding of genetic resources ownership, while those private endeavours were based on the maximum extent of enclosure one could ensure, whether in secrecy or under strong intellectual property rights. Next to such understanding, what was perceived to be "Green gold" had not brought any reward to the States sheltering used natural components or to those individuals having invested time and effort to conserve genetic resources for centuries. "The concern of developing countries focused on the free flow of genetic resources along a predominantly developing country pathway, with no flow of benefits back to developing countries", especially when research led to commercialised products[1022]. International crop improvement efforts were also accompanied by biological piracy and misappropriation allegations, mostly directed towards the private sector. However, public agricultural research and their correlated germplasm collections could not escape the vigorous reactions of the main providers of genetic resources and centres of diversity[1023]. The CGIAR system has indeed been viewed as the "modern successor to the 18th and 19th century botanical gardens that served as conduits for the transmission of plant genetic information from the colonies to the imperial powers"[1024], thereby formally endorsing bio-piracy. The fact that merely fifteen per cent of collected samples were stored in the developing world, against the eighty-five per cent that found their way to the safer and readier gene banks of developed nations sparked

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[1020] See BLAKENEY, "Agricultural Research: Intellectual Property and the Cgiar System," *op.cit.*, pp.111-112., for a short review of the biopiracy allegations made against CGIAR research centres; or the work carried by Rural Advancement Foundation International against cases of biopiracy, see the Editorial of the *New Scientist* dated as of February 1992 with the title "Lest we starve: Rich Nations have to get Tough with Raiders of the World's Gene Banks", available at http://www.newscientist.com/article/mg15721210.100-editorial--lest-we-starve--rich-nations-have-to-get-tough-with-raiders-of-the-worlds-gene-banks.html

[1021] ANTHONY J. STENSON and TIM S. GRAY, *The Politics of Genetic Resource Control* New York: St Martin's Press, 1999.

[1022] SUSAN BRAGDON, KATHRYN GARFORTH, and JOHN HAAPALA, "Safeguarding Biodiversity: The Convention on Biological Diversity," in *The Future Control of Food: A Guide to International Negotiations and Rules on Intellectual Property, Biodiversity and Food Security*, ed. GEOFF TANSEY and TASMIN RAJOTTE, London: Earthscan, 2008, p.83.

[1023] BLAKENEY, "Agricultural Research: Intellectual Property and the Cgiar System," *op.cit.*, p.111.

[1024] KLOPPENBURG, *First the Seed: The Political Economy of Plant Biotechnology 1492-2000*, *op.cit.*, p.161.

criticism over the loss of control of the South in favour of the North, allegedly serving private interests once again[1025].

The technological strides that generated new innovation models heavily based on genomics science and informational components **spawned strengthened regulation** a**round the access and use conditions** of genetic resources. Scientists manipulating and depending upon plant genetic resources had to face the fact that "the past collegial system of free exchange among researchers (was) breaking down", requiring the emergence of compensation mechanisms[1026]. These elements bore witness to the proclamation of the "dawn of 20th century biological colonialism and imperialism", salvaging the South's genetic resources through continuous practices of unearned appropriation and enclosure[1027]. The world's "gene centres", as identified by Dr. Nikolai Vavilov, would convert into fortresses, shielding the gold of a new genetic "El Dorado" against those rich in technology but poor in genetic resources[1028]. While the well-anchored principle pertaining to the free access to genetic resources continued to prevail well until the end of the 20th century, most States established a **permit system requiring scientists to ask for permission to collect material** from national authorities[1029]. These systems were mainly launched to control germplasm flow, but the lack of subsequent verification by State authorities or efficient tracking rendered the permits nearly useless for regulating genetic resources' outflow[1030]. Another development in the practice of genetic resource collection was the emergence of so-called **'bioprospecting contracts',** through which the benefits from the use of biological material could be returned to the stewards of these resources. Inserting the notion of compensation into the framework governing the access to genetic resources, these contracts were also changing the definition of collection activities. This approach addresses the "inequity implied in the disparity between [economically poor but biologically affluent] communities and others with opposite attributes, […], transforming common heritage into a stream of compensation"[1031]. In this sense, it upholds the understanding that biological resources constitute a form of property that nonetheless ought to be used sustainably and appropriated equitably. In a similar mind-set, discussions arose on the use of 'material collection or transfer agreements' in relation to biological resources to address the imbalances between their providers and users. The rules of access would undergo substantial changes from the 1990's onwards not only regulating access but also triggering a return stream of benefits, whether

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[1025] The designation of storing gene banks is made by the International Board for Plant Genetic Resources and the geographical dichotomy can mainly be attributed to the lack of institutional capacity.CARY FOWLER and PATRICK MOONEY, *Shattering: Food, Politics and the Loss of Genetic Diversity* Tucson: University of Arizona Press, 1990, pp.182-193., as well as FOWLER, *Unnatural Selection: Technology, Politics and Plant Evolution*, *op.cit.*, pp.184-185.

[1026] ARMINEH ZOHRABIAN et al., "Valuing Pre-Commercial Genetic Resources: A Maximum Entropy Approach," *American Journal of Agricultural Economics* 85, no. 2, 2003: at p.429.; where the authors attempt to estimate the marginal value of poorly characterised materials, showing that the benefits deriving from pest susceptibility improvement using the specific genetic material remain higher than the costs of conservation attached to the resource.

[1027] For the most vehement critics of new genetic resource collection techniques and their links to old colonial practices, see VANDANA SHIVA, *Monocultures of the Mind: Perspectives on Biodiversity and Biotechnology* Penang: Third World Network, 1993.; or from the same author, *Biopiracy: The Plunder of Nature and Knowledge* Cambridge MA: South End Press, 1997.

[1028] HEINRICH VON LOESCH, "Gene Wars: The Double Helix Is a Hot Potato," *CERES* 131, no. 23, September-October 1991: pp.39-44.

[1029] Such permit system was established for instance in Turkey through the Decree on the Collection, Conservation and Use of Plant Genetic Resources dated as of 15.08.1992, *Resmi Gazete no.21316*.

[1030] PARRY, *Trading the Genome: Investigating the Commodification of Bio-Information, op.cit.*, pp.204-206.; where the author narrates the testimony of field researchers struggling with administrative hurdles to get national permits and not being faced with any official control at State borders.

[1031] STEPHEN BRUSH, "Bioprospecting the Public Domain," *Cultural Anthropology* 14, no. 4, 1999. at p.537.

monetary or not, in the likes of technology transfer. This double feature aimed to sooth accusations of biological theft, and burn down the frustration of genetic resource-providing countries unable to see any real distribution of the wealth created by the use of material initially found on their soil.

CONCLUSION. Greater Biodiversity in a Broad yet Equitable Public Domain

Agricultural genetic variability is used, created, depleted and improved in a strategic context of global biodiversity loss. This reality has prompted pleas for biodiversity conservation and for the sustainable use of resources, which not only provide the foodstuff and income of farming communities, but also ensure the longevity of living processes and the efficiency of research endeavours. The collection of genetic resources, whether endemic, local or exotic, chiefly through colonial expeditions and then wide-scaled public research and extension programmes of the North, has concomitantly prompted compensation pleas. These pleas are grounded in the historical struggle for equitable rights to development in light of disparate and outwardly unfair socio-economic realities. Tangled and constant international germplasm exchanges have indeed regrettably been accompanied by the concentration of knowledge and improved resources in the hands of a lucky few developed States.

Concern as to the legal status of the genetic resources that were accumulated, used and developed throughout colonial times as a result also significantly shaped the spirit of international environmental negotiations, anchoring the greatest North-South divide to date. Personal and private appropriation has remained undoubtedly exceptional, heralding conceptions of common heritage and distributional equity. The unequal exchange patterns between the biologically-rich countries and technologically-apt entities nonetheless sufficed to sow the 'seeds of discontent' and set off the demands for concrete regulatory approaches to distributional justice pleas. The history of biological collections unmistakeably elucidates the foundation of genetic commoditisation, the buzzword status of biopiracy, the struggle of communalist international research efforts and the subsequent unhinged private control over surplus value. It corroborates the pleas for the return to public custody through perceptions of global genetic legacy, grounded on a broadly fenced public domain, which provides sufficient room to compensate the “ecological debt” of industrial nations over biodiverse countries.

11. CHAPTER 11: WEIGHING THE PUBLIC DOMAIN IN INTERNATIONAL BIODIVERSITY CONSERVATION LAW

Reactions to the "gene drain, […] siphoning off the Third World's germplasm to 'gene banks' and breeding programmes of the North, [which have been] patenting the offshoots of this common heritage"[1032] led to significant regulatory changes operating towards sustainability and equity. Major international agreements were as a result enacted primarily to support practices that conserve and use biodiversity in a sustainable fashion; all the while having regards to environmental justice and equity claims. In addition, and this is the specific concern of this thesis, they also contain important public domain and intellectual property governance principles that aim to foster both biodiversity use and research, while also preserving traditional knowledge and farmers' livelihoods. By formally raising genetic resources to the rank of commodities, available, exploitable and officially tradable on markets, international biodiversity law has shaped a new economic space for biological material[1033].

Before the initiation of global environmental governance in the 1970's, the international regulation of biological resources had long remained an untamed and singular creature. Indeed, most of the environmental regulation had formerly been concerned with "truly" global resources, such as air for example, where "joint international strategies for their use, conservation and development have to be agreed"[1034]. As such and in their material form, biological resources are linked to land. They are thus domestic in nature, as public or private tangible goods, subject to the property regime set out in national laws. However, information found within these resources' genotypes possesses global public goods qualities[1035]. Genetic resources do not conform to the traditional definition of global resources in international environmental law making. It is important to note that in the first international environmental instruments, natural resources were only consider as tangible goods, raw materials. Therefore, the aspect that was the target of regulation was the quantitative transaction for the economic exploitation of the resources, as knowledge on genetic resources was scarce in the 1950s and 1960s. It has nonetheless been argued that genetic resources would have been included in the claim for sovereign rights over natural resources[1036]. The 1949 United Nations Scientific Conference on the Conservation and Utilisation of Resources[1037], made up of technical experts, focused on specific groups of natural resources such as land, water, forests,

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1032 PATRICK MOONEY, "The Law of the Seed: Another Development and Plant Genetic Resources," *Development Dialogue* 1, no. 2, 1983. at p. 3.

1033 Indeed, the introduction of international agreements such as the CBD or TRIPS has been referred to as a construction and formal constitution of genetic resources as industrial commodities available to be engineered, patented and exploited in ethical, just and sustainable ways for the greater good of their preservation. PARRY, *Trading the Genome: Investigating the Commodification of Bio-Information*, *op.cit.*, 125.

1034 As for instance the regulation of the ozone layer and its 1985 Vienna Convention and 1987 Montreal Protocol on Substances that Deplete the Ozone Layer; SWANSON, "Why Is There a Biodiversity Convention? The International Interest in Centralized Development Planning," *op.cit.*, pp.307-308.

1035 JOSEPH STRAUS, "The Rio Biodiversity Convention and Intellectual Property," *International Review of Industrial Property and Copyright Law* 24, no. 5, 1993: pp.602-603.

1036 UN Resolution 1803 refers to "natural wealth and resources": according to the analysis of Nico Schrijver, the definition of natural resources is no longer as clear cut as it used to be: until recently, it tended to be economically oriented, focusing on the use to be made of it by humankind, thus neglecting the intrinsic value of natural resources and the integrity of ecological systems; NICO J SCHRIJVER, *The Evolution of Sustainable Development in International Law: Inception, Meaning and Status*, vol. 2: Martinus Nijhoff Publishers, 2008.

1037 The United Nations scientific Conference on the Conservation and Utilisation of Resources – United Nations Educational Scientifique and Cultural Organization, NS/URN/1, 10 November 1948.

fuels, minerals, and wild life, included a session on land natural resources, which also included chemurgy, food yeasts, and microorganisms. The conference concentrated on the shortage of resources due to population increase and parallel demand, rather than the importance of the still unknown research information contained within microorganisms. No or little consideration was given to resources as objects of research, neither to what was then identified as the information contained in genetic material.

The introduction of regulatory instruments dealing directly or indirectly with biological material at the international level created a new economic space for genetic material and formally raised them to the rank of commodities, available, exploitable and officially tradable on markets[1038]. The international law of biodiversity, targeting either all life forms or specifically addressing the needs of agricultural production, elevates sustainability and environmental justice to normative principles. These two aspects are notably found in the 1992 Convention on Biological Diversity and the 2004 International Treaty for Plant Genetic Resources in Food and Agriculture. In this context, their core concerns reside in the conservation and sustainable use of genetic resources. However, they also address equity and property allocation issues by ensuring compensation and benefit-sharing on the one hand, and participation on the other. The latter element of justice has been driven by "a strategy of regime-shifting to modify the principles, norms, rules and decision-making procedures of intellectual property protection"[1039].

11.1. <u>The Convention on biological diversity and related instruments</u>

While the idea of sustainable development is generally attributed to the infamous 1987 Brundtland Commission report "Our Common Future" as "*a development that meets the needs of the present without compromising the ability of future generations to meet their own needs*", the origins of "environmental justice" are usually traced back to the 1960's civil liberties movement. Arguably building on such heritage, international regulatory instruments were directed towards the conservation and sustainable use of biological diversity, and more specifically genetic resources. They have in this regard given international normative stance to environmental justice, in both distributive and participatory terms, in an effort to break the cycle of biological piracy, pushing further than classical conservation instruments by addressing property rights issues. Indeed the principles of environmental law not only include the conservation and the sustainable use of its components, but also encompass justice and equity prospects that address the legal status of genetic resources and their relation to the public domain. These principles have been formulated for the first time in the Stockholm Declaration and are key concepts in international regimes governing the climate or biodiversity, finding echo in the CBD, and its most recent Nagoya Protocol.

[1038] Indeed, the introduction of international agreements such as the CBD or TRIPS has been referred to as a construction and formal constitution of genetic resources as industrial commodities available to be engineered, patented and exploited in ethical, just and sustainable ways for the greater good of their preservation. Bronwyn PARRY, *op.cit.*, pp. 125.

[1039] HELFER, "Regime Shifting: The Trips Agreement and New Dynamics of Intellectual Property Lawmaking," *op.cit.*, pp.54-55.

11.1.1. Principles of biodiversity conservation, sustainable use, and environmental justice

As aformenetioned, genetic resources do not conform to the traditional definition of global resources in international environmental law making, due to their inherently dual nature, both as domestic tangible goods and informational public goods. Biodiversity depletion concerns were however gradually recognised on account of a "confluence of international dialogues that have existed for several decades", including but not limited to debates focusing on protected areas, the sustainable use of natural resources or environmental funding[1040]. Amongst other endeavours, a soft-law instrument acknowledging mankind's responsibility for all species inhabiting the Earth saw the light of day through United Nations General Assembly Resolution 37/7 in 1982, commonly referred to as the "World Charter for Nature"[1041]. The Charter asserted that

> "*the degradation of natural systems owing to excessive consumption and misuse of natural resources […], leads to the breakdown of the economic, social and political framework of civilization*". (World Charter for Nature, UN/GA/37/7)

Building on such initiative, the official advent of biodiversity came about during the 1992 United Nations Conference on Environment and Development[1042], otherwise known as the "**Rio Earth Summit**" and the adoption of the Convention on Biological Diversity ("CBD")[1043]. It is interesting to note that the CBD is both an international treaty as such, and thereby constitutes a formal source of public international law, but it also represents an institutional framework for the continuous development of the law and practice of biodiversity conservation, through both legal and scientific initiatives[1044]. The Parties to the Convention meet regularly during "Conferences" (commonly coined COP) with extensive decision-making powers. They also cooperate through different subsidiary bodies focusing on specific topics such as the Ad Hoc Open Ended Working Groups on Biosafety or on Access and Benefit-sharing. These initiatives have respectively led to the adoption of the 1999 Cartagena Protocol on Biosafety and recently the 2012 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation.

Contracting Parties to the Convention unite their forces in the face of different streams. They are:

[1040] SWANSON, "Why Is There a Biodiversity Convention? The International Interest in Centralized Development Planning," *op.cit.*, p.307 and 309.; where the author cites various movements and motivations lying behind the development of the CBD: debt for nature, environmental fund, sustainable use, farmers' rights and bio-prospecting movements.

[1041] World Charter for Nature, United Nations General Assembly Resolution 37/7, 1982.

[1042] The first stages of the adoption of the CBD can be traced back to a 1981Resolution adopted by the World Conservation Union's General Assembly, requesting further analysis on a potential international agreement on the conservation, accessibility and use of biological resources; see REGINE ANDERSEN, *Governing Agrobiodiversity*, Global Environmental Governance Aldershot: Ashgate, 2008, pp.117-119., citing C. DE KLEMM, "Conservation of Species: The Need for a New Approach," *Environmental Policy and Law* 9, no. 4, 1982: pp.118-128. For a background of the international negotiations having officially started in 1988, see PATRICIA W. BIRNIE and ALAN E. BOYLE, *International Law and the Environment* Oxford: Oxford University Press, 2002, pp.568-571.; *The World Conservation Strategy* (1980) prepared by the IUCN, UNEP and WWF with the collaboration of the FAO and UNESCO; and FIONA MCCONNELL, *The Biodiversity Convention: A Negotiating History, a Personal Account of Negotiating the United Nations Convention on Biological Diversity-and After*: Aspen Publishing, 1996.

[1043] Opened for signature on 5th June 1992, the CBD entered into force on 29th December 1993.

[1044] TEN KATE and LAIRD, *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing*, *op.cit.*, p.13.

> *"Conscious of the intrinsic value of biological diversity and of the ecological, genetic, social, economic, scientific, educational, cultural, recreational and aesthetic values of biological diversity and its components,*
> *Conscious also of the importance of biological diversity for evolution and for maintaining life sustaining systems of the biosphere"* (CBD, Preamble),

In this context, the CBD's primary aim is set as the **comprehensive preservation of biodiversity**, along with the "*sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources*" (CBD, Article 1).

This imperative builds on a precautionary approach to halt the depletion of resources. Indeed, Contracting Parties are

> *"Aware of the general lack of information and knowledge regarding biological diversity and of the urgent need to develop scientific, technical and institutional capacities to provide the basic understanding upon which to plan and implement appropriate measures,*
> *Noting that it is vital to anticipate, prevent and attack the causes of significant reduction or loss of biological diversity at source,*
> *Noting also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat"* (CBD, Preamble).

The methods through which ecosystems' and species' diversity and their genetic variability can be conserved are numerous and include the constitution of protected areas, of listings of protected species, the adoption of recovery measures of threatened species, or the restoration of ecosystems from a strictly conservationist point of view[1045]. Although their efficiency and adequacy are being discussed[1046], the two major conservation techniques commonly used by experts are traditionally identified with regards to the location of preservation endeavours, on and off their natural habitats. *Ex situ* conservation of the structural components of biodiversity refers to the management and collection of species or varieties outside their traditional natural ecosystems, being kept in institutions and environments solely managed by humankind. The establishment of culture collections such as botanic gardens or zoos exemplifies the conservation of natural biodiversity off site[1047]. On the other side of the spectrum lies *in situ* conservation, where all components are conserved and managed in their natural habitats. In situ management is best illustrated by the protected areas or parks institution, which, despite their shortcomings, has generally managed to

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[1045] We acknowledge that conservation efforts need to be coupled with adequate general-scoped resource management schemes, but shall not develop such aspect with great depth due to the scope of this chapter. For an argumentaire for non-renewable resource management, see Carol A. HOFFMAN; and Ronald C. CARROLL; "Can we sustain the biological basis of agriculture?", *Annu. Rev. Ecol. Syst.* 26 (1995), pp. 69-92

[1046] The adequacy of preservation, defined as a negotiating tool for the "transition from past to future in such a way as to secure the transfer of maximum significance" shall not be developed further here but some discussions may be found in Alan HOLLAND and Kate RAWLES; "Values in Conservation", *Ecos.*, 14:1 (1993), pp 14-19; and Kate RAWLES; "Biological Diversity and Conservation Policy", in Markku OKSANEN; and Juhani PIETARINEN, *Philosophy and Biodiversity,* Cambridge University Press, Cambridge, 2004, pp. 199-216 (esp. 208-212), where the author establishes the primary link between valuation and conservation objectives, subject we shall touch upon further in the course of this research.

[1047] Ex situ conservation has raised more debate with regards to natural biodiversity than for agriculture, especially with regards to the ethics of holding animals in captivity but also for the relative nature of its costs and benefits; and has thus been generally considered as a secondary measure of biodiversity preservation; see KEVIN J. GASTON and JOHN I. SPICER, *Biodiversity: An Introduction* Blackwell: Oxford, 2004. pp. 152-153.

rise as an obligation under international agreements[1048]. Both methods' shortcomings have led the international community to declare the two approaches as opposite sides of the overall spectrum required for effective conservation[1049].

To this end, the CBD's article 8 urges Member States to ensure that biodiversity is conserved *in situ,* notably through, inter alia, the establishment of a

> *"system of protected areas, the regulation or management of biological resources important for the conservation of biological diversity whether within or outside protected areas, with a view to ensuring their conservation and sustainable use; the protection of ecosystems, natural habitats and the maintenance of viable populations of species in natural surroundings; [and also of] threatened species and populations"* (CBD, Art.8),

> "*For the purpose of complementing these in situ measures*", Article 9 of the Convention also addresses the *"ex situ conservation of components of biological diversity, preferably in the country of origin of such components",* urging States to *"establish and maintain facilities for ex-situ conservation of and research on plants, animals and micro- organisms, preferably in the country of origin of genetic resources".*

The CBD is also an agreement of its time, and does also address the inherently utilitarian attitude through which biological material has been viewed in history. The **sustainable use** of biodiversity advocated for by Article 10 of the CBD highlights amongst other measures, the need to

> "*protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements; [and] support local populations to develop and implement remedial action in degraded areas where biological diversity has been reduced*" (CBD, Art.10),

The actual regulatory content and characteristics of such sustainable use have remained purposefully fuzzy since the sole criterion is one of "*avoidance or minimisation of adverse impacts on biological diversity*", yet it undoubtedly recognises the need to ensure local populations' participation in all biodiversity related policies. The CBD system has come up with fourteen operational principles, the "Addis Ababa Principles and Guidelines for the Sustainable use of Biodiversity", which largely put emphasis on the ecological and socio-economic scales of biodiversity use and its impact.

The CBD system also makes room for specific forums assigned to the study of the particular needs of **agricultural genetic diversity,** even though the Convention does not contain an agrobiodiversity-specific provision. The Nairobi Final Act, through which the CBD was formally adopted, contains a specific resolution recognising the linkages of the Convention with sustainable agriculture, paving the way for future COP considerations regarding agrobiodiversity. Even

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[1048] For the shortcomings of the protected areas movement, including the creation of 'paper parks', due to the lacks of commitment to the protected resource itself and to appropriate development policies surrounding the designations; see SWANSON, "Why Is There a Biodiversity Convention? The International Interest in Centralized Development Planning," *op.cit.* pp. 310-312.
[1049] JEFFREY MC NEELY, *The Role of Protected Areas for Conservation and Sustainable Use of Plant Genetic Resources for Food and Agriculture* Rome: IPGRI, 1996.

though most of the subsequent work relates to the relationship of the CBD with the FAO Global System on PGRFA[1050], an *ad hoc* thematic programme on agricultural genetic resources was also set up as early as the third conference of the Parties and formally adopted two years later[1051]. It focuses on different areas, including land and water resources, farm inputs, traditional knowledge and plant, animal and microbial genetic resources.

11.1.2. Public Domain and Intellectual Property Rights in the CBD

State sovereignty over natural and genetic resources

Negotiated under the auspices of the United Nations Environment Programme, the Convention's foundation is the reiteration of "national sovereignty" over genetic resources that are the "common concern of humankind". Contracting Parties indeed *"Affirm that the conservation of biological diversity is a common concern of humankind,* [and] *Reaffirm that States have sovereign rights over their own biological resources"* (CBD, Preamble)

The common concern perception highlights the importance of biodiversity, as an issue where all nations should have standing, and also underlines the duty to cooperate for efficient conservation and management policies, yet does not make any statements on its property regime, in contrast to prior "common heritage" approaches[1052]. Through this move, the CBD effectively upholds the long-existing **principle of State sovereignty**, which had already been distended to cover natural resources in 1962 through the General Assembly Resolution 1803 on Permanent Sovereignty over natural resources[1053]. This Resolution indeed recognised "*the inalienable right of all States freely to dispose of their natural wealth and resources in accordance with their national interests*"[1054].

This principle emerged as an instrument of international economic law in the post-war era from two main concerns of the United Nations: economic development and self-determination of colonial people[1055]. In the 1950s, developing countries advocated this principle to secure the benefit arising from the exploitation of natural resources and to provide newly independent states

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[1050] The linkage with the FAO Global System, which would come to include the International Treaty on PGRFA, has been strongly highlighted by several COP Decisions, starting already from 1994 onwards through decision I/9 and especially Decision VI/6, which recognised the synergy between the two legal instruments, see BRAGDON, GARFORTH, and HAAPALA, "Safeguarding Biodiversity: The Convention on Biological Diversity," *op.cit.* "Safeguarding Biodiversity: The Convention on Biological Diversity," *op.cit.*, p.95.
[1051] See Decision III/11, also mentioning case studies on pollinators and soil micro-organisms, based upon Recommendation II/7 of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA), and Decision V/5, which formally adopts the multi-year thematic programme on agrobiodiversity, specifically mentioning pollinators and also genetic use restriction technologies.
[1052] CULLET, "Property-Rights Regimes over Biological Resources," *op.cit.*, pp.654-655.
[1053] DUTFIELD, *Intellectual Property, Biogenetic Resources and Traditional Knowledge*, *op.cit.*, p.5.
[1054] General Assembly Resolution 1803 (XVII) of 14 December 1962 "Permanent sovereignty over natural resources: the UNGA created in 1958 the Commission on Permanent Sovereignty over Natural Resources 'to conduct a full survey of this basic constituent of the right to self- determination, with recommendations, where necessary, for its strengthening' and the work of the Commission resulted in the adoption of the Declaration on Permanent Sovereignty over Natural Resources in UNGA Resolution 1803. It is important to underline that Resolution 1803 of 1962 can be considered a binding Resolution, apart from the strong political force every General Assembly Resolution has, because principle 7 clarifies that the violation of the rights of peoples and nations to sovereignty over their natural wealth and resources is contrary to the spirit and principles of the Charter of the United Nations.
[1055] SCHRIJVER, *The Evolution of Sustainable Development in International Law: Inception, Meaning and Status*, *op.cit.*, 2.

with legal tools to defend their economic sovereignty against property and contractual rights claimed by foreign states and companies. By the beginning of 1952, the United Nations General Assembly had already underlined that the use of natural resources by under developed countries was a pre-requisite to foster economic development "in accordance with their national interests". Resolution 523 on "integrated economic development and commercial agreements" underlined the root of globalised market's market, where the contractual power of less developed/newly independent states in selling raw materials and resources was not proportionate to those buying developed states.

> The Resolution recalled that a necessary requisite for "*economic development plans in under developed countries is the creation of conditions under which these countries could more readily acquire machinery, equipment and industrial raw materials for the goods and services exported by them*" (Resolution UN/GA/523, Preamble).

Commercial agreements should as a result facilitate the movement of machinery, equipment and industrial raw material for the development and improvement of standards of living in under-developed or less developed countries.

> Moreover it is "*recommended"* that such agreements should "*not contain economic or political conditions violating the sovereign rights of the under-developed countries, including their rights to determine their own plans for economic development"* (Resolution UN/GA/523, Para.1).

Ever since its first mention by the United Nations General Assembly, the right to use and control national resources has thus been strongly linked to the right to development. Indeed, the General Assembly went back to these principles in Resolution 626 on the "Right to exploit freely natural wealth and resources"[1056], adopted following the nationalisation by Iran of the Anglo-Iranian Oil Company by the end of 1952. The Resolution referred to the good faith and balance within the economic exchange of natural resources: it encouraged member States

> "*to have due regard, consistently with their sovereignty, to the need for maintaining the flow of capital in conditions of security, mutual confidence and economic cooperation among nations*" (Resolution UN/GA/626).

States thus an arguably light obligation to keep a balance and avoid disproportionate flow of capital in economic transactions with developing states, within the use and exploitation of natural resources. These arguably weak but first contractual safeguards granted to countries selling natural resources can be seen as the root of the principles of access and benefit-sharing codified later by the Convention on Biological Diversity. Another step forward a toothed legal oligation was taken ten years later, with Resolution 1803 of 1962[1057].

1056 United Nations General Assembly Resolution 626 (VII) on the '*Right to Exploit Freely Natural Wealth and Resources*', 21 December 1952.

[1057] United Nations General Assembly Resolution 1803 (XVII) on the "Permanent Sovereignty over Natural Resources", 14 December 1962.

> This text underlined that "*economic and financial agreements between the developed and the developing countries must be based on the principles of equality and of the right of peoples and nations to self-determination*" (Resolution UN/GA/1803, Preamble).

International soft law is here interfering with national commercial practices in favour again of an economic balance in the exchange of natural resources. The Resolution goes even further by stating that in case where an authorisation for activities of exploration, development and disposition of national natural resources is granted by a state to a foreigner, the profits arising from such activity

> "*must be shared in the portions freely agreed upon, in each case, between investors and the recipient state*". It also added that "*due care being taken to ensure that there is no impairment, for any reason, of that State's sovereignty over its natural wealth and resources*" (Resolution UN/GA/1803, Para 3).

The sovereignty approach in effect bounds the public domain, especially at the national level, segmenting it international environmental law[1058], protecting the tangible and intangible inputs to innovation by opting for a property rule and upholding traditional knowledge. Indeed, even if sovereignty merely implies the lack of superior authority that of the state at the international level, it does consign private-property rights- akin effects in domestic spheres, as "the state is the repository of sovereign rights"[1059]. Even though it is not directly concerned with the grant of intellectual property rights *per se*, the CBD regime fences the public domain upstream of innovation, which inevitably bears considerable consequences to the distribution of resources in an economics perspective, but also, and this is the focus of our analysis, advocates regime-shifting or legal change to the downstream fencing of the public domain linked to the products of innovation, i.e. intellectual property rights.

Procedural justice: access and benefit-sharing regimes

Building on the practical consequences of the customary principle of sovereignty over natural resources, the groundwork of the **procedural and distributive environmental justice** and property rights angle of the 1992 CBD lies in its article 15, which states that

> "*the **sovereign rights of States** over their natural resources, [is recognised and] the authority to **determine access** to genetic resources [is considered to rest] with the national governments and is subject to national legislation*" (CBD, Article 15§1, emphasis added by author).
>
> Even though "*conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties [should be created] and restrictions that run counter to the objectives of this Convention not be imposed]*" (CBD, 15§2).

[1058] JONATHAN CURCI, *The Protection of Biodiversity and Traditional Knowledge in International Law of Intellectual Property* Cambridge: Cambridge University Press, 2010, p.295.
[1059] CULLET, "Property-Rights Regimes over Biological Resources," *op.cit.*

Genetic resources therefore do not lie within a straightforward public domain. The latter is indeed contingent on and determined by **national access and benefit sharing** ("ABS") regimes, where a liability system may operate to share the benefits of the resources' use. It has been argued that the grounding of benefit-sharing and collection authorisation requirements upon the territorial foundation of germplasm was deliberately procedural, avoiding the controversies that would have fuelled the multiple political divergences over an equitable distribution argument[1060]. Access regulations were viewed as a victory by developing country negotiators, since they amplify the simpler market and negotiations-based flexible and unbureaucratic "bioprospecting contracts" regime favoured by bioresource user nations, but still facilitate bargaining between suppliers (governments) and users (companies or other institutions) and ensure the greater capture of benefits[1061]. The compensation provisos stem from the obligations penned in articles 15§4 and 15§5, which set the grounds for the principle of access to genetic resources

> "*on mutually agreed terms*", "*subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party*" (CBD, Art.15§§4-5).

The provisions of the CBD, even if they don't address the property regime of genetic resources as such, do break with the formerly unfettered access approach to genetic resources, based on the exercise of sovereign rights of States. The Convention does not only grant States the right to withhold access to the resources at their will, it also grants them the rights to receive compensation from the use of such resources. The public domain constructed by the CBD does as a result not grant free access to genetic resources, but rather fences the public domain around the new **principles of prior informed consent and mutually agreed terms**. It is in this sense a public domain accompanied by a bilateral liability mechanism that ensures *ex ante* that the benefits arising from the use of genetic resources have been shared and that the determined monetary or non-monetary compensation has been awarded to the sovereign right-holding State and the traditional knowledge holder communities. This new fencing has radically impacted the activities of public researchers and institutions, like gene banks for instance, which witnessed significant drops in accessions just after the signature of the CBD due to legal uncertainty and fear of infringing reproclaimed sovereign rights[1062]. Within the CBD system, all genetic resource uses are however not created equal. Indeed, the Convention has an intricately complex regard to those resources and uses which ensure that their products remain in the public domain, for instance when no commercial intent can be found at the time of access[1063]. This "special treatment" can be attributed to the reflection of the permanent sovereignty principle in the CBD, which allows states to "determine access to genetic resources within their boundaries, with a duty to facilitate access to those resources for environmentally sound uses"[1064]. The **non-binding 2002 Bonn Guidelines**[1065]

[1060] See Kristin S. SHRADER-FRECHETTE, "Agriculture, Ethics and Restrictions on Property Rights", *Journal of Agricultural Ethics*, 1 (1988), pp. 21-40.
[1061] DUTFIELD, *Intellectual Property, Biogenetic Resources and Traditional Knowledge*, *op.cit.*, p.6.
[1062] MICHAEL HALEWOOD, "Governing the Management and Use of Pooled Microbial Genetic Resources: Lessons from the Global Crop Commons," *International Journal of the Commons* 4, 2010.
[1063] MATTHIAS BUCK and CLAIRE HAMILTON, "The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation," *RECIEL* 20, no. 59, 2011: p.59.
[1064] CULLET, "Property-Rights Regimes over Biological Resources," *op.cit.*, p.656.
[1065] Bonn Guidelines on access to genetic resources and the fair and equitable sharing of the benefits arising from their utilisation, adopted by the 6th Conference of the Parties in 2002 through decision VI/26, UNEP/CBD/COP/6/20, Annex 1, Decision VI/24A, pp. 253-269.

were an important milestone to establish the direction that would be taken in a binding international regime that would really bring out the aforementioned salvation[1066]. However, in light of the unsolved issues in the interpretation of Article 15 of the CBD[1067], as well as the non-binding nature of the Guidelines, their adoption have not majorly altered the behaviour and commitment of biodiversity and traditional knowledge users to seek prior informed consent and mutually agreed terms[1068]. The Nagoya Protocol, which has at the time of writing not yet entered into force, will, as a binding multilateral instrument, make both concepts a reality, and trigger extensive law-making for the realisation of benefit-sharing transactions, whether financial or not[1069].

By including a prerogative to ensure the **"*fair and equitable sharing of the benefits*** *arising out of the utilisation of genetic resources*", the CBD strives away from the "classical conservationist design"[1070], incorporating a wider range of socio-economics concerns, and a desire to use these resources for developmental purposes[1071]. This feature has been justified by the desire of biodiversity rich developing countries to counterbalance the global trade and linked intellectual property negotiations that were going on under the leadership of a wealthy few[1072]. In this context, a "fair and equitable" access and benefit-sharing regime based on sovereignty prerequisites has been viewed as the salvation to the phenomenon of bio-piracy[1073], as a cornerstone of the CBD regime[1074]. The meaning and operational content of such **"fair and equitable"** terms is not as straightforward as one would have hoped, yet several dimensions have been highlighted, including but not limited to the enabling of the level-playing field,

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1066 The Guidelines provided opportunities to assess the efficiency of adopted measures that aimed to "ensure that scientific and commercial values" derived from the use of genetic resources be transformed into a positive force for both economic development and environmental conservation. They allowed for practical room for improvement, provided the success and failures of such measures would be properly assessed.

1067 Indeed, a number of issues remained unsolved in the Guidelines' text, such as definitions of communities, the CBD-TRIPS relationship, the protection of traditional knowledge and the extent of benefit-sharing (whether it should be individually, regionally or nationally determined), or the adoption of model transfer agreements; which should all be addressed in the CBD's "evolutionary process", viewing the Guidelines as "a useful first step" towards a coherent, efficient and fair ABS framework; STEPHEN TULLY, "The Bonn Guidelines on Access to Genetic Resources and Benefit Sharing " *RECIEL* 12, no. 1, 2003: pp.97-98.

1068 EVANSON CHEGE KAMAU, BEVIS FEDDER, and GERD WINTER, "The Nagoya Protocol on Access to Genetic Resources and Benefit-Sharing: What Is New and What Are the Implications for Provider and User Countries and the Scientific Community?," *Law, Environment and Development Journal* 6, no. 3, 2010.

1069 It should be noted here that the Protocol makes room for "specialised ABS agreements", such as the agrobiodiversity-specific ITPGRFA.

1070 ANDERSEN, *Governing Agrobiodiversity*, *op.cit.*, p.120.

1071 BRAGDON, GARFORTH, and HAAPALA, "Safeguarding Biodiversity: The Convention on Biological Diversity," *op.cit.*, pp.84-85.

1072 D.M. MCGRAW, "The Story of the Biodiversity Convention: From Negotiation to Implementation," in *Governing Global Biodiversity: The Evolution and Implementation of the Convention on Biological Diversity*, ed. P.G. LE PRESTRE, Burlington: Ashgate, 2002, pp.14-15.

1073 Rules ensuring that scientific communities "gave back" to indigenous communities have indeed triggered in language focused on "facilitated access" and "fair and equitable benefit sharing"; see KABIR BAVIKATTE and DANIEL F. ROBINSON, "Towards a People's History of the Law: Biocultural Jurisprudence and the Nagoya Protocol on Access and Benefit-Sharing," *Law, Environment and Development Journal* 7, no. 1, 2011.

1074 Responding to concerns of the G-77 on the neglect vis-à-vis the benefit-sharing dimension of the CBD, COP-2 had to re-affirm that the Convention was based upon prior informed consent, mutual reliance and the equitable sharing of benefit deriving from the use of genetic resources, CBD, Report of the second meeting of the COP to the CBD, Un Doc. UNEP/CBD/COP/2/19, 1995, paragraph 107; as well as the Jakarta Ministerial Statement on the Implementation of the CBD, which is actually more known for its mandate on the protection of marine biodiversity. See also TULLY, "The Bonn Guidelines on Access to Genetic Resources and Benefit Sharing " *op.cit.*, p.85.

> "respect for human rights, value and legal systems across cultural borders, […allowing] democratic and meaningful participation in policy decisions and contracts negotiation by all stakeholders, […and] not unnecessarily restricting access to non-rival goods and resources"[1075].

In its most generic meaning, equity refers to 'fairness, impartiality and even-handed dealing', according to the Oxford Dictionary. With regards to legal theory, the concept has been traditionally linked to the administration of justice and thus directly to the scope of judicial review, both at the national and international levels, as a means to resolve disputes in fairness. Indeed, the term equity retains a strong connection with the praetor-inspired flexibility of the jurisprudential system witnessed in common law traditions[1076]. It is thus no surprise that equity has traditionally been established within the doctrine as a concept to be applied by courts of law outside the scope of legal provisions in force, in a judicial system making room for such flexibility[1077]. Within the international legal order, equity is now widely considered as a material source of law, alongside treaties and custom, within the category coined 'general principles of law'[1078], by both the international courts[1079] and the doctrine[1080]. The use of equity cannot thus be limited to the opportunities it brings with regards to individualised justice. Indeed, the concept also entails the prospect of introducing considerations of fairness or good faith within general provisions, by offering standards for the allocation and sharing of resources and benefits or achieving distributive justice[1081]. The appeal of equity is easily understood in international environmental law, which has to deal with very wide-ranging time conundrums in attempts to minimise our actions' impacts on future generations, but also very disparate signatories, representing highly unequal stages of wealth, welfare and priorities. That is why one of the most significant references to equity is still to this day found within biodiversity conservation law[1082]. The difficulty arising from such reference concerns the understanding of equity, since the wording might only refer to *infra legem* equity, interpreting principles to be found within the realms of international law, or could very

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[1075] DUTFIELD, *Intellectual Property, Biogenetic Resources and Traditional Knowledge*, *op.cit.*, pp.45-47.

[1076] See for instance Stephen N. SUBRIN, "How Equity Conquered Common Law: The Federal Rules of Civil Procedure in Historical Perspective", *University of Pennsylvania Law Review*, Vol. 135, No. 4 (Apr., 1987), pp. 909-1002, for a perspective on the development of equity procedures in the United States.

[1077] It is generally understood however, that the absence of express authorisation to apply equity within disputes brought before the court, does not entail a prohibition to use it.

[1078] See Bin CHENG, *General Principles of Law as Applied by International Courts and Tribunals*, Cambridge University Press, New York, 2006, pp. 7-20; for a historical account of the *travaux preparatoires* that led to the adoption of 'general principles of law' as a source of international law, along with the dissenting opinions that were expressed during the discussions over what would become article 38(1) of the Statute of the International Court of Justice.

[1079] In his 'individual' opinion to the judgment of the Permanent Court of Justice on *The Diversion of Water From Meuse (Netherlands vs, Belgium)*, Judge Manley Hudson states that "The Court has not been expressly authorizes by its Statute to apply equity as distinguished from law. […] Under article 38 of the Stature, if not independently of that Article, the Court has some freedom to consider principles of equity as part of the international law which it must apply", at pp. 75-77.

[1080] Proponents of such viewpoint include prominent scholars such as Wolfgang FRIEDMANN (in *The Changing Structure of International Law*, Columbia University Press, New York, 1964, pp. 197-200), and Charles DE VISSCHER ("Contribution a l'etude des sources du droit international", *Revue de droit international et de droit compare*, 60 (1933), pp.395-420).

[1081] These uses have been identified by C.G. WEERAMANTRY, *Universalising International Law*, see especially the Chapter 9 "General Principles of Law: Equity in a Global Context", pp. 240-

[1082] Articles 1, 8 (j), 15 (7) and 19 (2) of the Convention on Biological Diversity, opened to signature in Rio on 5th June 1992 and entered into force on 29th December 1993.

well encompass a broader understanding, as an independent and autonomous source of principles that ought to inspire contractual arrangements deriving from the use of biodiversity[1083].

Whither scientific and technologic development? The CBD system and intellectual property rights

The importance to **support the development of scientific capabilities** in developing countries had already been highlighted in the 1972 Stockholm Declaration. Science and technology are given a very noble role of contributor to economic and social development and their application is called to solve environmental problems "*for the common good of mankind*" in Principle 18 of the Declaration.

> As a result, "*Scientific research and development in the context of environmental problems must be promoted in all countries; especially the developing countries and the free flow of up-to-date scientific information and transfer of experience must be supported and assisted. Environmental technologies should be made available to developing countries on terms which would encourage their wide dissemination without constituting an economic burden on the developing countries*" (Stockholm Declaration, Principle 20).

The importance of developing scientific and technical capabilities emerged in the preparatory discussions organised before the United Nations Environmental Programme (UNEP) leading to the infamous **1987 Brutland Commission Report**. An entire portion of the document is dedicated to "broadening the technological base", in a focusing rather on international relations, rather than sovereignty. 'Our Common Future' focuses on "*institutional* imperatives in addressing sustainable development issues, including political, economic, social and administrative systems. [It] explicitly addresses the matter of production and technological systems, but without anchoring the discussion in the realities of the patchy, embryonic state of global science and technology cooperation"[1084]. Scientific collaboration and technology transfer is nonetheless considerd a core element of sustainable development, as

> *"The procedures and policies that influence [the international exchanges of technology] must stimulate innovation and ensure ready and widespread access to environmentally sound technologies*" (Brundtland Report, Paragraph 65).

In this context, the emerging property paradigm and also the shift in actors involved in innovation directly linked to sustainable development such as plant improvement is assessed critically.

> "*Developing countries paid about $2 billion in 1980 by way of* ***royalties and fees****, mainly to industrial countries. The gap in scientific and technological capabilities is particularly wide in areas of direct relevance to the objectives of sustainable development, including biotechnology and genetic engineering, new energy sources, new materials and substitutes, and low-waste and non-polluting technologies*" (Brundtland Report, Paragraph 67, emphasis added).

1083 Francesco FRANCIONI, *Equity in International Law*, Max Planck Encyclopedia of Public International Law, pp. 7.

1084 ALLAM AHMED and JOSEPHINE ANNE STEIN, "Science, Technology and Sustainable Development: A World Review," *World Review of Science, Technology and Sustainable Development* 1, no. 1, 2004: at p.7.

> *The principal policy issue as regards the impact of payments is the impact of patents and proprietary rights. In 1980, industrialised market economies accounted for sixty-five per cent of the world total of patents granted, and the socialist countries of Eastern Europe held twenty-nine per cent. Developing countries held only six per cent, and most of these had been granted to non-residents. Proprietary rights are a key element in the commercial development of technology. But their application in certain areas may hamper the diffusion of environmentally sound technologies and may increase inequalities.* (Brundtland Report, Paragraph 68).
>
> *In the past. publicly funded research provided new technology to small producers, particularly farmers, on a full or subsidized basis. The situation is not very different now, and in areas such as* ***new seed varieties there is some reason to believe proprietary rights could act as a major barrier to developing countries' acquisition of new technologies****. International cooperation is essential to maintain the flow of genetic material and to ensure an equitable sharing of gains.* (Brundtland Report, Paragraph 69, emphasis added).

Agricultural innovation thus receives particular consideration in the Report, as an area crucial for sustainable development, but also as an area where wide-scoped proprietary rights could have considerable detrimental impacts. As a result, the influential document also called for developing countries to narrow the gap in technological capabilities especially in the area of biotechnology and provide for the equitable sharing and widespread diffusion of the technologies developed." This idea is still present in the **1992 Rio Declaration on Environment and Development** where Principle 9 called for states

> "*to cooperate to strengthen endogenous capacity-building for sustainable development by improving scientific understanding through exchanges of scientific and technological knowledge, and by enhancing the development, adaptation, diffusion and transfer of technologies, including new and innovative technologies*", (Rio Declaration, Principle 9).

However, these considerations did not survive the negotiation of the **Convention on Biological Diversity** in their wide form, and the language of the Convention bears a very different tone from the one favoured by the Rio Declaration.

> Article 12 of the Convention requires signatories to "*promote and encourage research which contributes to the conservation and sustainable use of biological diversity*".
>
> Through its Article 16, dedicated to the "Access to and Transfer of Technology" States further commit themselves to "*provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity*" (CBD, Art. 16).

Notwithstanding the restriction of the obligation to transfer technologies that contribute to conservation and sustainable use, the focus is only on transfer of and access to technology, and not more on development of technology and endogenous capacity building for sustainable development. The Brutland Report's idea of adding value to natural resources has become entirely marginalised in favour of an approach to natural resources as "*in situ*" resources to be conserved. The interface of science, technology and sustainable development for all genetic resources has only re-appeared in the **Nagoya Protocol**[1085]. The Protocol contains specific “provisions that address the global organization of scientific collaboration at the non-commercial stages of the research cycle”, in its Annex citing various non-monetary benefit-sharing measures in the upstream dimensions of research, and especially in its article 8, 10 and 11, which explicitly address the status of non-commercial research[1086]. In this context, article 8a of the Nagoya Protocol urges signatories to

> “*create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research*.” (Nagoya Protocol, Art 8a)

The public domain conditions that surround the implementation of these derogatory provisions depend upon the definition of “non-commercial research purposes”, which is no easy task. Such notion could either include all “activities that are in the exploratory phase of research, i.e. not involving the sale of a genetic resource, its components or derivates for profit-making purposes; and whose research results remain in the public domain”, or it could rather merely point at activities “at the stage of basic research, which would generate no monetary benefits for profit or personal gain, and whose research results remain in the public domain”[1087]. While the first approach operates with greater flexibility by envisaging *ex post* re-negotiation of mutually agreed terms for accessing genetic resources, the second seemingly tries to get the most benefits possible *ex ante*, outside of a liability rules scheme.

The Nagoya Protocol also provides for possible future scenarios for collaboration and benefit-sharing in its articles 10 and 11, which might possibly also apply to some areas of activities of the research communities. The Protocol in this regard compels parties to consider the need for, and modalities of, a

> “***global multilateral benefit-sharing mechanism*** *to address the fair and equitable sharing of benefits derived from the utilisation of genetic resources and associated traditional knowledge that occur in transboundary situations, or for which it is not possible to grant or obtain prior informed consent*” (Nagoya Protocol, Art 10).

Moreover, its article 11 prescribes an obligation to collaborate in cases where the same genetic resources are found *in situ* within the territory of more than one party, with a view to implementing the obligations set out by the Protocol. The language of these references to the

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[1085] UNEP, CBD, Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity, opened to signature on 29th October 2010.

[1086] TOM DEDEURWAERDERE, ARIANNA BROGGIATO, and DIMITRA MANOU, "Global Scientific Research Commons under the Nagoya Protocol: Governing Pools of Microbial Genetic Resoures," ed. GERD WINTER and EVANSON CHEGE KAMAU, 2013.

[1087] TOM DEDEURWAERDERE et al., "Governing Global Scientific Research Commons under the Nagoya Protocol," in *The 2010 Nagoya Protocol on Access and Benefit-Sharing in Perspective: Implications for International Law and Implementation Challenges*, ed. ELISA MORGERA, MATTHIAS BUCK, and ELSA TSIOUMANI, Leiden: Martinus Nijhoff, 2013, pp.414-415.; the first approach acknowledges the unpredicatability of scientific research, allowing for benefit-sharing agreements to take form at later stages of the process, “once results are clearer and potential value is easier to evaluate”.

global multilateral benefit-sharing mechanism remains nonetheless extremely vague and reflects the result of an achingly difficult compromise, which led to a procedural obligation to merely consider the opportunity of such a mechanism[1088]. The scope of the provision can be interpreted narrowly or extensively. In the wider sense, it might re-open the issue of the temporal or geographical scope of the Protocol, covering perhaps materials in *ex-situ* collections that were collected prior to the entry into force of the CBD; whereas in the narrow sense, it would merely address the status of genetic resources that are found in user countries' jurisdiction but are of unknown origin or legal status[1089]. It is important to underline that the benefits shared through this mechanism must be used to support the conservation of biodiversity and the sustainable use of its components globally. This means that the benefit-sharing is not going to the provider or providers. This could represent a disincentive for countries to build up such a mechanism; an assertion that has proven to this day true[1090].

Notwithstanding the inherently sovereign nature of genetic resources and the accommodating nature of non-commercial access, the CBD also carves the public domain through its direct approach to **intellectual property rights**. Indeed, the Convention urges Member States to concomitantly recognise that IPR might also carve into their legal status. First of all, the Parties to the Convention,

> "*recognising that patents and other intellectual property rights may have an influence on the implementation of this Convention , shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives"* (CBD, Art 16§5).

It nonetheless leaves the space open as to the real practical impact of sovereign rights in intellectual property rights application. Several references are rather made to IPR in the associated yet non-binding Bonn Guidelines. According to Paragraph 16(d), Parties should consider taking

> "*measures to encourage the **disclosure of the country of origin** of the genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights*" (Bonn Guidelines, Paragraph 16(d))

Even though nothing in the binding Convention text or in the Nagoya Protocol refers to such opportunity of both disclosure and prior informed consent disclosures, a number of subsequent COP decisions have tried to give substance, or at least nourish the debate as a means to ensure the respect of mutually agreed terms. The aforementioned decision VI/24, to which the Bonn Guidelines were annexed, for instance called for the gathering of future information, inter alia, on the "*feasibility of an international recognised certification of origin system as evidence of prior*

1088 BUCK and HAMILTON, "The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation," *op.cit.,* p.59.

1089 Ibid., p.60.

1090 The first reflections on this mechanism in 2011 did not lead to any consensus on two basic questions: whether the mechanism was needed and how it would be articulated. However, a consistent opinion was expressed in favour of a step-by-step approach to build up a flexible instrument. Participants generally recognised that the mechanism was meant to be complementary to the system based on prior informed consent and mutually agreed terms – not an alternative to it. See MORTEN WALLØE TVEDT, "*A Report from the First Reflection Meeting on the Global Multilateral Benefit-Sharing Mechanism*", Fridtjof Nansen Institute, Oslo, 2011.

informed consent and mutually agreed terms, [as well as] the role of oral evidence of prior art in the examination, granting and maintenance of intellectual property rights"[1091].

Decision VII/19 directly requested WIPO and UNCTAD to conduct analysis on "*options for model provisions on proposed disclosure requirements, practical options for intellectual property application procedures with regard to the triggers of disclosure requirements*"[1092].

This has led both institutions to produce substantial documents on the disclosure of origin, pushing also WIPO to establish an "Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore" at its General Assembly's 25th Session in 2000[1093]. However to this date, the work of the Committee has not been able to set out an internationally agreed threshold regarding disclosure requirements in IPR applications. Furthermore and most importantly, the Committee is attempting to give legal substance to a form of collective rights acknowledged with the CBD. The Convention has indeed also appraised the protection of so-called **traditional knowledge** attached to genetic resources. In order to achieve the *in situ* conservation of biodiversity, article 8(j) of the Convention states that

> *"each contracting Party shall, as far as possible and as appropriate: subject to national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity"*(CBD, Art.8j)

The exact extent and nature of protection to be granted to such knowledge remains to be determined, since nothing in the Convention defines it in complete proprietary terms, pursuing instead the "aim of free flow of plant germplasm based upon public funding"[1094]. Indeed, the Convention does not apportion exclusive rights over genetic resources or their components as such. It does not determine who is the "owner" of specific resources or knowledge attached thereof. Nor does it determine the exact extent of prerogatives that accompany the recognition of sovereign rights or traditional knowledge. Nevertheless, "its principles – prior informed consent and benefit sharing with countries of origin and local communities – are based on the assumption that there are "providers" and "recipients" of genetic resources, and that they must establish, contractually, the conditions for access and benefit-sharing"[1095]. The CBD has a result been considered to drive its approach extensively from the holistic concept of "Traditional Resources Rights", which bring together "bundles of rights which are held to be widely accepted in legally and non-legally binding instruments, ranging from human rights, land rights, culture for

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[1091] Decision VI/24 of the Sixth Conference of the Parties to the Convention on Biological Diversity, "Access and benefit-sharing as related to genetic resources", adopted *the Hague, Netherlands*, 7 - 19 April 2002, UNEP/CBD/COP/6/INF/24.

[1092] Decision VII/19 of the Seventh Conference of the Parties to the Convention on Biological Diversity, Annex, Terms of Reference for the Ad Hoc Open-Ended Working Group on Access and benefit-sharing, adopted in Kuala Lumpur, Malaysia 9 - 20 February 2004, UNEP/CBD/COP/7/INF/19.

[1093] For an account of the different decisions that preceded, but also succeeded the establishment of this Committee, both within the auspices of the WIPO or the CBD COP meetings, see GRAHAM DUTFIELD and UMA SUTHERSANEN, *Global Intellectual Property Law*: Edward Elgar Publishing, 2008., pp.338-343.

[1094] CURCI, *The Protection of Biodiversity and Traditional Knowledge in International Law of Intellectual Property*, *op.cit.*, p.292.

[1095] JULIANA SANTILLI, *Agrobiodiversity and the Law: Regulating Genetic Resources, Food Security and Cultural Diversity* London: Earthscan, 2012, at p.117.

indigenous and local communities"[1096]. The legal basis of traditional knowledge protection has been subject to much criticism, especially due to the lack of equivalency and retaliatory force which makes it merely "conditional and subservient obligations attached to conventional intellectual property rights"[1097]. Legislative endeavours have nonetheless been going strong before the World Intellectual Property Organisation's aforementioned "Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore", which negotiates a binding international agreement on the extent of such knowledge and its relationship to existing property regimes. Notwithstanding its rickety international reification, the consecration of traditional knowledge does delineate the public domain carved out by the CBD system. Such delineation can be viewed either in a more restrictive fashion inscribed in the exclusivity of traditional IPR and the subsequent withdrawal of traditional knowledge from the public domain. Or it can be analysed through a wider construct comparable to a "paying public domain" where knowledge holders would be entitled to "a right to compensation" for follow-on uses, without the prerogative to block them and thereby keeping the knowledge within the boundaries of an accessible yet conditional public domain, a legally defined and temporary semi-commons[1098].

Neither the sustainability, nor the equity angles advocated by the rather unique system of the CBD have **been welcomed with unanimous praise**. Indeed, the choices made by the international community to regulate and conserve biodiversity have been conveyed as an unnecessary and ineffective "neoliberalisation of nature", putting a price and trading nature in order to save it, in the name of "green developmentalism"[1099]. The relationship of the CBD and its Nagoya Protocol with other international agreements, especially those related to the regulation of trade, also gives rise to conflicting commentary. ABS requirements are in this sense either viewed as a potential for complementary synergy and deterrence of misappropriation[1100], or through the lens of a vicarious push as a regulatory response to an unsolicited commodification of genetic resources upstream in innovation chains[1101]. The lack of equivalency and retaliatory force in the sovereign and

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[1096] COTTIER, "The Protection of Genetic Resources and Traditional Knowledge: Towards More Specific Rights and Obligations in World Trade Law," *op.cit.,* p.565. Notably referring to UNEP view that even though it is still inadequate because enshrined in a mixture of legally binding and non-binding instruments, the concept of TRR "can grow as additional rights accrue and is adapted through the development of national and international legislation", UNEP, Convention on Biodiversity, Traditional Knowledge: Critical Linkages, UNEP/CBD/TKBD/1/2, 1997.

[1097] WEST, "Institutionalised Exclusion: The Political Economy of Benefit-Sharing and Intellectual Property," *op.cit.,* p.21.; where the author explains his hypothesis that the Nagoya protocol actually assists in the reification of intellectual property rights and fails to achieve the objectives initially set out in the Convention and the Protocol itself.

[1098] This approach is notably advocated by Jerome REICHMAN, REICHMAN, "Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation," *op.cit.* And JEROME H. REICHMAN and TRACEY LEWIS, "Using Liability Rules to Stimulate Local Innovation in Developing Countries: Application to Traditional Knowledge," in *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime*, ed. KEITH MASKUS and JEROME H. REICHMAN, Cambridge: CUP, 2005.

[1099] Bioprospecting is, in this sense, the most controversial conservation strategy ever adopted in environmental policy, serving only those "establishment environmentalists"; notably see CASTREE, "Bioprospecting: From Theory to Practice," *op.cit.,* p.36., and MCAFEE, "Selling Nature to Save It? Biodiversity and Green Developmentalism," *op.cit.,* pp.133-135.

[1100] CBD, *The CBD and the Agreement on Trade-related Intellectual Property Rights (TRIPS): Relationships and Synergies,* UN Doc., UNEP/CBD/COP/3/23, 1996 or LI ENHENG, "Promotion for a Mutually Supportive and Complimentary Relationship between Trips Agreement and Cbd -the Essential Role of Wto in Conservation of Biological Diversity and Protection of Tk," in *WIPO/ESCAP High-level Policy Forum on Intellectual Property Rights and Trade, 23-25 July 2007* (Macao, China2007).

[1101] In this viewpoint, the Nagoya Protocol emerges from a reactionary regime-shifting process; see WEST, "Institutionalised Exclusion: The Political Economy of Benefit-Sharing and Intellectual Property," *op.cit.,* interpreting the work of Laurence HELFER on the general interactions of the TRIPS Agreement with the CBD, and the indigenous rights recognised under the CBD system has led commentators to deplore the creation of merely "conditional and subservient obligations attached to conventional intellectual property rights", which continue to benefit from extreme legal dependency[1102]. The equity angle of the CBD has nonetheless produced political pressure for the disclosure of origin or evidence of prior informed consent before intellectual property offices[1103], without unanimous triumph. Aside from unwarranted and moderately successful commodification, the CBD carries inherent shortcomings[1104]; these features also appear to be quite ill fitted for agricultural genetic resources, especially plants, in view of their historical flows and their current use patterns in cultivation or research and development. Indeed, "the mercantile approach adopted by the CBD does not take into consideration agricultural species of great local and regional importance for food security, which are not commodities, and, therefore, of little commercial interest"[1105]. Furthermore, the national implementation of CBD obligations seldom identify food security neither as a priority nor as a concern, just as it rarely provides for a wide-scope experimental use exception, hence creating a significant hurdle of crucial importance to PGRFA, especially in cases where the State in question is not a signatory of the International Treaty on plant genetic resources for food and agriculture, and therefore does not exclude those crops listed in its Annex I from the scope of their stringent access and benefit-sharing laws[1106].

11.2. <u>The International Treaty on plant genetic resources for food and agriculture</u>

Regardless of socio-technological innovation contexts, agricultural plant genetic resources remain highly interdependent at the international level. This is not only attributed to the tangled flows impelled by the colonial era, but also to the intertwined nature of all varieties in non-methodical or science-based plant breeding, notably due to the processes of variety selection. International crop conservation efforts have in this context mainly been assigned to the "belief that the genetic legacy of our ancestors is threatened by modern conditions, especially record high populations, technological change, and infrastructural development"[1107]. While it is widely acknowledged that the social returns from research activities exceed the private returns of the particular developer, leading to the recognition of the public goods dimension of agricultural research[1108], technological

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exploitation of other spheres of law-making on account of the expansion of the list of international venues, "Regime Shifting: The Trips Agreement and New Dynamics of Intellectual Property Lawmaking," *op.cit.,* pp.1-83.

1102 "Institutionalised Exclusion: The Political Economy of Benefit-Sharing and Intellectual Property," *op.cit.,* p.21.; where the author explains his hypothesis that the Nagoya protocol actually assists in the reification of intellectual property rights and fails to achieve the objectives initially set out in the Convention and the Protocol itself.

1103 Amongst the prolific literature on this subject, see BRAGDON, GARFORTH, and HAAPALA, "Safeguarding Biodiversity: The Convention on Biological Diversity," *op.cit.,* p.98.; for a swift overview of the issue.

1104 Notwithstanding the fact that the sovereignty-reliant and mainly bilateralism-prone features of sustainability and equity principles make their implementation extremely dependent on national capacities and compliance control powers, favouring once again States with greater institutional capacity, even with help from the Global Environmental Facility.

1105 SANTILLI, *Agrobiodiversity and the Law: Regulating Genetic Resources, Food Security and Cultural Diversity*, *op.cit.*, at p.117.

1106 GURDİAL SİNGH NİJAR, "Food Security and Access and Benefit Sharing Laws Relating to Genetic Resources: Promoting Synergies in National and International Governance," *International Environmental Agreements: Politics, Law and Economics* 11, no. 2, 2011.

1107 O.H. FRANKEL, "Genetic Conservation in Perspective," in *Genetic Resources in Plants – Their Exploration and Conservation*, ed. O.H. FRANKEL and E. BENNETT, Owford: Blackwell Scientific Pubs, 1970.; *cited in* BRUSH and MENG, "Farmers' Valuation and Conservation of Crop Genetic Resources," *op.cit.,* p.141.

1108 See for instance R. NELSON, "The simple economics of basic scientific research", *Journal of Political Economy,* 67 (1959), pp. 297-306; W. PETERSON, "Note on the Social returns to private research and development', *American* changes witnessed in past centuries have transformed agricultural research. The interdependence of PGRFA has become rather precarious and ominous in view of the asymmetrical uses of genetic resources, which fail to balance exclusive appropriation and distributive aspects. The need to design an *ad hoc* instrument for the conservation, but also the sustainable and equitable use of PGRFA while ensuring the widest possible access to germplasm for research and development was espoused by the international community as early as the 1980's, ultimately leading to the enactment of the the International Undertaking for Plant Genetic Resources in 1983. Its precepts nonetheless had to be reviewed in light of the bilateralism and sovereignty oriented CBD regime. In view of the specificity of agrobiodiversity, but also in view of the growing web of enclosure-oriented international instruments favouring bilateralism, these considerations ultimately lead to the adoption of a binding treaty constituting an arguably more extensive public domain that the CBD, for a limited number of crops, following lengthy negotiations. This *ad hoc* regime attempts to rebuild the agrobiodiversity public domain in view of the specificities of plant improvement and the socio-economic dimensions of agricultural production.

11.2.1. Principles of agrobiodiversity conservation, sustainable use, and environmental justice

The concoction of an international regime governing expressly plant genetic resources for food and agriculture and addressing the specificity of agrobiodiversity conservation and its inescapable use was bequeathed into the hands of the Food and Agricultural Organisation of the United Nations. Policy discussions on the international management and status of PGRFA started in the 1970's, much like environmental dialogue. They led to the adoption of the FAO Global System for the Conservation and Utilisation of PGRFA in 1983**.** This package addressed both *in situ* and *ex situ* agrobiodiversity management, and comprised of a non-binding yet promising international agreement, the **International Undertaking for Plant Genetic Resources ("IU")**[1109]. The International Network of *ex situ* Collections was established along with the Commission on Plant Genetic Resources for Food and Agriculture, the first permanent intergovernmental body specifically dedicated to PGRFA[1110]. The Undertaking, adopted at the twenty-second session of the FAO Conference held in Rome professed its goals to include the exploration, preservation, evaluation and availability of PGRFA for plant breeding and scientific purposes. The FAO Conference's resolution 8/83[1111] in this regard recognised that

> *"(a) plant genetic resources are a heritage of mankind to be preserved, and to be freely available for use, for the benefit of present and future generations;*
> *(b) full advantage can be derived from plant genetic resources through an effective programme of plant breeding, and that, while most such resources in the form of wild*

Journal of Agricultural Economics, 58 (1976), pp. 324-326; Joseph STIGLITZ, "Knowledge as a Public Good", *in* Inge KAUL et al., *Global Public Goods: International Cooperation in the 21st Century*, Oxford University Press, 1999, pp. 308-325.

1109 UN Food and Agriculture Organisation (FAO), International Undertaking on Plant Genetic Resources, adopted by Conference Resolution 8/83 of the FAO at Rome on 23rd November 1982.

1110 The Commission also monitored the implementation of the Undertaking; FAO Conference resolution 9/83; as well as FOOD AND AGRICULTURAL ORGANISATION FAO, "About the Commission on Genetic Resources for Food and Agriculture," (Rome: http://www.fao.org/nr/cgrfa/cgrfa-about/cgrfa-history/en/).; which includes a regularly updated table on the historic milestones of the CGRFA history and its evolving mandate.

1111 Twenty-Second Session Of The FAO Conference, Rome, 5-23 November 1983, Resolution 8/83, which adopted the International Undertaking.

> *plants and old land races are to be found in developing countries, training and facilities for plant survey and identification and plant breeding are insufficient or even not available in many of those countries;*
> *(c) plant genetic resources are indispensable for the genetic improvement of cultivated plants, but have been insufficiently explored and are in danger of erosion and loss"*(Resolution 8/83, FAO Conference)

However, the international legal climate was shifting. The CBD got adopted in 1992, followed by the international minimum IP protection standards of the TRIPS Agreement two years later. These developments urged for an adaptation of the international agricultural community to the new legal landscape. Not only did the IU's provisions need adaptation, but the insufficiency of a non-binding international text to ensure the facilitated flow of agricultural germplasm also created a "constructive unison" between both developed and developing countries, the seed industry and non-governmental organisations[1112].

On account of these postulates and the need for regulatory action, the Commission on Genetic Resources for Food and Agriculture ignited the re-negotiation of the legal component of the FAO Global System. This re-negotiation took "six and a half arduous years, from the First Extraordinary Session of November 1994 to its Sixth Extraordinary Session in June 2001", mostly because of the polarisation between developed and developing countries[1113]. The debates initiated before the UN Food and Agriculture Organisation came about as "heavily politicised, with concerns about intellectual property rights and national germplasm embargoes" that were set up through other international instruments[1114]. Adopted by the Conference in November 2001, the **International Treaty on Plant Genetic Resources for Food and Agriculture ("ITPGRFA")** came into force in June 2004[1115].

> The objectives of the Treaty "*are the **conservation and sustainable use** of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security*" (ITPGRFA, Art. 1§1).

In its conservation angle, it advocates an "***integrated approach** to the exploration, conservation and sustainable use*" of agrobiodiversity, where both *in situ* and *ex situ* efforts are equally acknowledged (article 5§1). Applied to agricultural biodiversity and especially crop genetic variability, the terminology and conservation techniques involve additional dynamics. *Ex situ*

1112 CHRISTINE FRISON, FRANCISCO LOPEZ, and JOSE ESQUINAS-ALCAZAR, *Plant Genetic Resources and Food Security: Stakeholder Perspectives on the International Treaty of Plant Genetic Resources for Food and Agriculture* London Earthscan, 2011.; Introduction, p.9.

1113 MICHAEL HALEWOOD and KENT NNADOZIE, "Giving Priority to the Commons: The International Treaty on Plant Genetic Resources for Food and Agriculture," in *The Future Control of Food: A Guide to International Negotiations and Rules on Intellectual Property, Biodiversity and Food Security*, ed. GEOFF TANSEY and TASMIN RAJOTTE, London: Earthscan, 2008, p.120.

1114 BRAGDON, GARFORTH, and HAAPALA, "Safeguarding Biodiversity: The Convention on Biological Diversity," *op.cit.*, citing MOONEY, "The Law of the Seed: Another Development and Plant Genetic Resources," *op.cit.*

1115 UN FAO, International Treaty on Plant Genetic Resources for Food and Agriculture, adopted by Conference Resolution 3/01 of the FAO at Rome on 3rd November 2001. The Treaty entered into force ninety days after the deposit of the fortieth instrument of ratification, in accordance with its Article 28; as of 2012, it counts a total of 127 Contracting Parties and the European Union.

conservation of agricultural plant genetic resources is realised through what is referred to as gene banks, following different techniques focusing either on the storage of dried seeds, or on the management of crops in fields as living collections or concerned at last with in vitro conservation under slow growth conditions[1116]. While the importance to preserve genetic diversity in living collections cannot be questioned, their activities have not been sufficient to neither ensure better productivity, nor provide for wider genetic bases within varieties used in modern agriculture[1117]. Nonetheless, the steady development of crop germplasm preservation in gene banks since their launch in the 1920's with N.I. Vavilov's efforts may also have undermined the pivotal role of farming systems producing the initial germplasm used by institutional breeders. Because *ex situ* centres have put greater emphasis on major crops, tending to neglect those having localised importance, they have been at times accused to further expand genetic uniformity worldwide[1118]. That is why *in situ* conservation, designating the management of varietal and genetic diversity on farm, has been granted mounting importance. This approach targets the management of biodiversity used in agricultural cultivation or as sources of genes directly in habitats where they arose and continue to grow[1119]. By allowing plants to dynamically adapt to their environment, on-farm diversity management allows for the gene exchanges necessary for the enrichment of crop varieties[1120]. Farmers themselves depend on the survival of local genetic diversity in order to fully meet their ecological needs and to protect their cultural traditions, while modern agriculture also depends (even if to a lesser extent) on the existence of what has been called 'exotic germplasm', whether found in cultivated fields or in the wild[1121]. However, *in situ* conservation also has shortcomings, as domesticated plants may neither possess natural habitats as such but the farm, nor survive in cohabitation with their wild relatives[1122]. Furthermore, suspicions on the reliability of on-farm management, the impracticability of returning to primitive agriculture[1123] and the availability of the diversity thereby created for plant breeders and users[1124] corroborates the need for an all-encompassing approach to agrobiodiversity conservation.

[1116] For an account of these ex situ techniques and the shortcomings of gene banks in terms of distinguishing between base and active collections, see VIRCHOW, *Conservation of Genetic Resources: Costs and Implications for a Sustainable Utilization of Plant Genetic Resources for Food and Agriculture*, *op.cit.* pp. 35-36.

[1117] Looking at the institution of gene banks through a slightly utilitarian perspective, Steven TANKSLEY and Susan McCOUCH argue that the new strategies for both the evaluation and efficient utilisation of the germplasm they collect need to be developed, stating that these shortcomings might stand behind the narrow genetic base used with respect to the development of modern crop varieties; see S.D. TANKSLEY and S.R. MCCOUCH, "Seed Banks and Molecular Maps: Unlocking Genetic Potential from the Wild," *Science* 277, no. 5329, 1997. pp. 1063-1066.

[1118] STEPHEN BRUSH, "Rethinking Crop Genetic Resource Conservation," *Conservation Biology* 3, no. 1, 1989.

[1119] A.H.D. BROWN, "The Genetic Structure of Crop Landraces and the Challenge to Conserve Them in Situ," ed. STEPHEN BRUSH, 2000. pp. 29–50.

[1120] For a thorough analysis of the advantages of in situ conservation put forward by scientists, see ALTIERI, ANDERSON, and MERRICK, "Peasant Agriculture and the Conservation of Crop and Wild Plant Resources," *op.cit.*; pp. 55-56.

[1121]HOPE SHAND, *Human Nature, Agricultural Biodiversity and Farm-Based Food Security, 1997*, Study Prepared by the Rural Advancement Foundation International for the Fao Ottawa: Rural Advancement Foundation International, 1997., pp. 22-24.

[1122]VIRCHOW, *Conservation of Genetic Resources: Costs and Implications for a Sustainable Utilization of Plant Genetic Resources for Food and Agriculture*, *op.cit.* pp. 34-35 and 38-41.

[1123] See the arguments put forward by OTTO H. FRANKEL and MICHAEL E. SOULE, *Conservation and Evolution* Cambridge: CUP, 1981.

[1124] See CARY FOWLER and TOBY HODGKIN, "Plant Genetic Resources for Food and Agriculture: Assessing Global Availability," *Annual Review of Environment and Resources* 29, 2004: pp.165-166.

That is why Article 5 of the ITPGRFA relates to both, by urging Member States to

> "(c) *Promote or support, as appropriate, farmers and local communities' efforts to manage and conserve on-farm their plant genetic resources for food and agriculture*;
> (d) *promote in situ conservation of wild crop relatives and wild plants for food production, including in protected areas, by supporting, inter alia, the efforts of indigenous and local communities;*
> [and also to] (e) *cooperate to promote the development of an efficient and sustainable system of ex situ conservation, giving due attention to the need for adequate documentation, characterization, regeneration and evaluation, and promote the development and transfer of appropriate technologies for this purpose with a view to improving the sustainable use of plant genetic resources for food and agriculture*" (ITPGRFA, Art. 5).

This double feature is complemented by a requirement to **use diversity in a sustainable fashion,** enshrined in the Treaty's Article 6, which notably promotes policies

> "(a) *pursuing fair agricultural policies that promote, as appropriate, the development and maintenance of diverse farming systems,*
> (b) *strengthening research […] for the benefit of farmers, especially those who generate and use their own varieties and apply ecological principles in maintaining soil fertility and in combating diseases, weeds and pests*;
> (c) *promoting, as appropriate, plant breeding efforts which, with the participation of farmers, particularly in developing countries, strengthen the capacity to develop varieties particularly adapted to social, economic and ecological conditions, including in marginal areas*;
> (d) *broadening the genetic base of crops and increasing the range of genetic diversity available to farmers*;
> (e) *promoting, as appropriate, the expanded use of local and locally adapted crops, varieties and underutilized species*" (ITPGRFA, Art.6).

These measures unmistakably highlight the broad understanding of "biodiversity" beyond that of biological material, by putting social, cultural and economic considerations at the central stage of the "sustainable use" notion. They also put great emphasis on the actors of PRGFA conservation and use, advocating the unequivocal recognition of their distinctive contributions to agrobiodiversity management, the need for greater participation, and the active promotion of conservation-oriented endeavours, especially that of farmers. Indeed, "the "sustainable use of agricultural biodiversity" is most simply thought of as all uses of agricultural biodiversity that contribute to its conservation and continued availability as an input to agriculture", according to Biodiversity International[1125].

11.2.2. Public Domain and Intellectual Property Rights in the ITPGRFA

Both the International Undertaking and the subsequent ITPGRFA have a very specific approach to property rights surrounding agrobiodiversity, especially agricultural plant genetic resources. The broader common heritage understanding of the former has had to be replaced by a more

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1125 BIODIVERSITY INTERNATIONAL, *Agriculture, Agricultural Biodiversity and Sustainability* Rome: Biodiversity International, 2010.

constrained view taken into account not only the proliferation of exclusive individual rights but also of sovereign rights over these resources. Both approaches nonetheless embody a clear commitment to ensure the greatest rate of availability of plant biodiversity.

Common heritage understanding of the International Undertaking

The clearly instrumentalist and anthropocentric approach focusing on the potential uses of agrobiodiversity of **the International Undertaking** was built upon

> "*the universally accepted principle that plant genetic resources are a* ***heritage of mankind and consequently should be available without restriction***" (International Undertaking, Art. 1)[1126].

According to Philippe CULLET, it is the "common ownership or common management of a given resource is referred to as common heritage of mankind […], which implies that all states have equal access to the resources but also that all states should benefit from the exploitation of a given 'common resource', whether they actually participate in the exploitation or not". The negotiations however showed that proponents of strong intellectual property heavily contested that such "universal status" be given to all plant varieties or their components, including improved germplasm[1127]. This stance was echoed in the non-binding nature of the text and the important reservations made with regards to its content. The Undertaking, signed by one hundred and thirteen States, was still considered "a partial victory for the developing countries"[1128]. Three interpretative resolutions to the International Undertaking were adopted in 1989 and 1991 in order to level out overarching concerns and reservations voiced by signatory parties, while also trying to attract outsider core industrial States. The first resolution recognised the consistency of plant breeders' rights with the provisos of the Undertaking in order to re-assure breeders that their prerogatives would not be waived by the "common heritage" status. The second, adopted concomitantly, set the groundwork for the recognition of "farmers' rights" to participate in the benefits derived from improved PGRFA. The Undertaking thus also addressed equity concerns raised by the sentiment that, while breeders were compensated through royalty payments stemming from intellectual property titles, farmers, viewed as the initial germplasm providers, were not[1129]. By re-affirming the prospect of exclusive intellectual property rights within a "heritage" understanding, these two resolutions were considered by the Conference as foundation-layers for a lasting equitable global system for sharing the costs and benefits attached to agricultural biodiversity, on a background of unhampered access to genetic resources[1130]. The Undertaking is a non-binding system that attempts to carve principles around the access and use of agricultural plant genetic resources. It strives to make sure these resources are made available for "*for the purposes of scientific research, plant breeding or genetic resource conservation",* but that

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[1126] Aside from the legal qualification of PGRFA, the Undertaking mainly put the emphasis upon the evaluation and documentation of genetic resources, opening debates which for instance led to the adoption of an International Code of Conduct for Plant Germplasm Collecting and Transfer in 1993, see HALEWOOD and NNADOZIE, "Giving Priority to the Commons: The International Treaty on Plant Genetic Resources for Food and Agriculture," *op.cit.,* pp.120-121.

[1127] FOWLER, *Unnatural Selection: Technology, Politics and Plant Evolution*, *op.cit.*, pp.187-190.

[1128] ANDERSEN, *Governing Agrobiodiversity*, *op.cit.*, p.91.

[1129] LEE ANN JACKSON, "Agricultural Biotechnology and the Privatization of Genetic Information: Implications for Innovation and Equity," *The Journal of World Intellectual Property* 3, 2000: p.16.

[1130] ANDERSEN, *Governing Agrobiodiversity*, *op.cit.*, p.95.

they are also exchanged in an unrestricted fashion, to corroborate the international dependency of agrobiodiversity flows.

> In this context, "*Governments and institutions having plant genetic resources under their control to* ***allow access*** *to samples of such resources, and to permit their export, where the resources have been requested for the purposes of scientific research, plant breeding or genetic resource conservation. The samples will be made available free of charge, on the basis of mutual exchange or on mutually agreed terms*." (IU, Article 5)

> An internationally coordinated network of national, regional and international centres was to be created "*under the auspices or the jurisdiction of FAO, that have assumed the responsibility to hold, for the benefit of the international community and on the principle of* ***unrestricted exchange****, base or active collections of the plant genetic resources of particular plant species*" (IU, Art. 7).

In an attempt to bring clarity to the nebulous legal web and to give substance to the aforementioned principle of "unrestricted exchange", the CGIAR centres signed the so-called "**in-trust agreements**" with the FAO in 1994, reaffirming the place of their gene collections within the IU's "international network of ex situ collections"[1131]. The centres had to ensure that recipients of their material did not claim any ownership over exchanged genetic resources, while hazily pondering on the extent of (or lack thereof) prerogatives for all further uses and improvements on their material. To this end, they reiterated the 'common heritage' status of resources held within their auspices and adopted guidelines trying to ensure these resources remained in the public domain[1132]. The materialising practice nonetheless failed short of effectively acknowledging the specificity of agricultural biodiversity in a context of commodity-oriented international legal landscape.

<u>The multilateral access and benefit-sharing mechanism of the International Treaty</u>

While its predecessor, the 1983 International Undertaking, considered agricultural plant genetic resources as a "heritage of mankind available without restriction", the **2004 ITPGRFA** has had to adopt its approach to the precepts of international trade and environmental law. The Treaty's first articles are noticeably silent about the legal status of agricultural plant genetic resources. The issue is rather addressed indirectly, since its article 10§1 goes on to state that Contracting Parties

> "*recognise the sovereign rights of States over their own plant genetic resources for food and agriculture, including that the authority to determine access to those resources rests with national governments and is subject to national legislation"* (ITPGRFA, Article 10§1).

[1131] GERALD MOORE and EMILE FRISON, "International Research Centres: The Cgiar and the Itpgrfa," in *Plant Genetic Resources and Food Security: Stakeholder Perspectives on the International Treaty of Plant Genetic Resources for Food and Agriculture*, ed. CHRISTINE FRISON, FRANCISCO LOPEZ, and JOSE ESQUINAS-ALCAZAR, London: Earthscan, 2011, pp.154-155.

[1132] CGIAR reaction dates from 1998, when an IPR moratorium was announced "to ensure that the materials in the CGIAR remain in the public domain", CGIAR Press Release, "CGIAR Urges Halt to Granting of Intellectual Property Rights for Designated Plant Germplasm", 11th February 1998.

Gone is therefore the "common heritage" understanding from the vaults of the FAO legislative tools, to be replaced by the overarchingly binding recognition of State sovereignty over natural resources, and also exclusive individual rights over innovation products and processes. It is by exercising such sovereign rights that the ITPGRFA signatories do nonetheless espouse the idea of a **multilateral system for access and benefit sharing ("MLS"),** as an

> "*efficient, effective, and transparent, both to facilitate access to plant genetic resources for food and agriculture, and to share, in a fair and equitable way, the benefits arising from the utilisation of these resources, on a complementary and mutually reinforcing basis"* (ITPGRFA, Article 10§2).

This proviso acts as the cornerstone through which a genetic resources commons is established[1133]. Consensus was almost spontaneously reached on the specificity of agricultural plant genetic resources, and the impracticality of CBD-like bilateral mechanisms for agricultural germplasm. Compared to other fields of biodiversity use like pharmaceuticals for instance, the bargaining positions of developing countries was indeed weaker for resources used for agricultural purposes. Not only did they "lack the scientific and technological capacity to capture the benefits of agrobiodiversity themselves, [but it was also impossible or unfeasible to apportion] benefits fairly"[1134]. It was unquestionably accepted that bilateral negotiations would infuse heavy burdens into the initial stages of research and development, as crop improvement remained inherently incremental in nature[1135]. Furthermore, it was also extremely difficult, maybe even impossible to trace back the origin of agricultural plant genetic material, due to the inherently international interdependency and intertwined resource exchange patterns. This characteristic was successfully put forward during the negotiations, especially on account of efforts undertaken by the FAO and the Commission on Genetic Resources for Foof and Agriculture[1136]. Studies regarding the patterns of accessions in gene banks corroborated the finding of interdependency, showing for instance that more than eighty per cent of accessions requested by Uganda and Kenya before the CGIAR network between 1980 and 2004 were mostly collected in other continents[1137]. Another study revealed that the network did create a so-called "multiplier effect" that did not solely consist of South to North exchanges but rather enjoyed a multi-tiered nature[1138]. Another crucial element related to the difficulty to determine the country of origin of agricultural plant genetic resources

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1133 HALEWOOD and NNADOZIE, "Giving Priority to the Commons: The International Treaty on Plant Genetic Resources for Food and Agriculture," *op.cit.*

1134 DUTFIELD, *Intellectual Property, Biogenetic Resources and Traditional Knowledge*, *op.cit.*, p.6.

1135 CARY FOWLER, MELINDA SMALE, and S. GAIJI, "Unequal Exchange? Recent Transfers of Agricultural Resources and Their Implications for Developing Countries," *Development Policy Review* 19, no. 2, 2001.; ANDERSEN, *Governing Agrobiodiversity*, *op.cit.*, p.97.

1136 Perhaps the most cited of CGRFA Background studies remains to this day Ximena PALACIOS' study published in 1998; PALACIOS, *op.cit.*, 1997. ; where no country or region was ranked as even close to self-sufficiency in their reliance to plant agrobiodiversity.

1137 MICHAEL HALEWOOD, S. GAIJI, and H.D. UPADHYAYA, "*Germplasm Flows in and out of Kenya and Uganda through the Cgiar: A Case Study of Patterns of Exchange in Developing National Policies*", http://www2.merid.org/bellagio/4E-Kenya_Uganda_Germplasm_Flows.pdf, 2005. ; cited in HALEWOOD and NNADOZIE, "Giving Priority to the Commons: The International Treaty on Plant Genetic Resources for Food and Agriculture," *op.cit.*, p.118-119.

1138 The abundant literature on this subject is reprised in SGRP: SYSTEM-WIDE PROGRAMME ON GENETIC RESOURCES, "*Annotated Bibliography Addressing the International Pedigrees and Flows of Plant Genetic Resources for Food and Agriculture*", IPGRI, Rome, 2006. , including JACK KLOPPENBURG and DANIEL KLEINMAN, "The Plant Germplasm Controversy," *BioScience* 37, no. 3, 1987.

beyond those Vavilovian centres of genetic origin (viewed often times as being overly simplistic[1139]). This difficulty was heightened on account of the complex genealogical trees of improved plant varieties', attributed to the multiple crosses made by farmers and breeders to develop them[1140]. The analysis of new varieties' pedigrees, such as the Sonalika wheat, a product of the Green Revolution, showed that modern crop improvement was a product of the combination of genetic resources from all over the world and did not rely on a limited number of raw materials[1141].

Addressing biopiracy issues was therefore not the main urge for regulation, trumped by the specificity of agricultural research and development. The main perspective revolved around the **need to maintain a widest possible public domain**, used to promote social welfare enhancing PGRFA uses, all the while permeating such domain with equity considerations and recognising thereby the ancestral contributions to agrobiodiversity conservation and knowledge. In spite of valid biopiracy claims, the dissemination of knowledge and technology from CGIAR centres and the inherent features of agricultural production heavily attenuated the issue of biodiversity misappropriation. Knowledge dissemination indeed stemmed not only from the essence of the living and reproduction-based plant breeding science as such, but also due to the role and approach of agricultural scientists to questions of access and ownership. Scholars pointed out in this regard that the practice of international research programs may have held the acquisitive aspect of biological collections, but did not hold the exploitative side attached to their colonial roots[1142]. Evidence for this argument stems from the analysis of germplasm flows from the CGIAR centres to the developing world, suggesting that international gene banks actively contribute to agricultural development in these countries by providing them the breeding lines of the wild genetic diversity collected by the centres. These transfers enhance agricultural research in these "resource-rich and cash-poor" countries by reducing the cost of national crop development programmes (that would otherwise need to invest to identify the exact gene pool and the parents of these genetic resources).

Even with such consensus and seemingly less-tensed negotiating standpoints, intense debates lingered on the materials that would be subject to the MLS set in motion, the extent to which intellectual property rights could condition material obtained from the MLS, and the reach of farmers' rights that would be exported from the IU's interpretative resolution as a counterpart to

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1139 HARLAN, *Crops and Man (2nd Ed.),, op.cit.*

1140 CARY FOWLER, "Protecting Farmer Innovation: The Convention on Biological Diversity and the Question of Origin," *Jurimetrics: The Journal of Law, Science and Technology* 41, 2001., as well as for a more general outlook on bread wheat pedigrees see MELINDA SMALE, "*Understanding Global Trends in the Use of Wheat Diversity and International Flows of Wheat Genetic Resources*", CIMMYT, http://www.cimmyt.org/english/docs/eco_wpaper/ewp96_02.pdf, 1996.

1141 Sanjaya RAJARAM, "The Human Right to Food and Livelihoods: The Role of Global Wheat Research", paper presented at "Building on Past Achievements to Advance the Future Direction of Australian Agriculture," ATSE Crawford Fund and Australian Institute of Agricultural Science and Technology, University House, Canberra, 12 September 2001, available at http://www.crawfordfund.org/assets/files/publications/derektribeaward010.pdf

1142 See the results of research conducted by FOWLER, SMALE, and GAIJI, "Unequal Exchange? Recent Transfers of Agricultural Resources and Their Implications for Developing Countries," *op.cit.,* pp.181-204.; and IPGRI, "The Demand for Crop Genetic Resources from International Collections," (Rome: IPGRI, 2003).; on account of which the recent flows of germplasm dating from 1972 to 1991 show that the movements from the CGIAR gene banks to less-developed countries were four times higher than the number of samples provided by these countries (approximately 125.000 samples provided by LDC's to 530.000 provided by the CGIAR banks) for all exchanged agricultural crops (cereals, roots and tubers, legumes and pulses, vegetables and forage crops).

the recognition of potential IPR titles[1143]. The basic tenets of the"Multilateral System of Facilitated access and Benefit Sharing for using and conserving the listed major food crops within **the public domain for research, breeding and training**" was espoused in Articles 10 to 13 of the Treaty. In this context, the first hurdle was to determine the material that would be infused in such system. As a result of tedious and complex negotiations, the pool of genetic material falling within the MLS is determined extremely unstraightforwardly.

> The MLS "*covers the plant genetic resources for food and agriculture listed in Annex I, established according to criteria of food security and interdependence*" (ITPGRFA, Article 11§1), but "*includes all plant genetic resources for food and agriculture listed in Annex I that are under the management and control of the Contracting Parties and in the public domain*" (11§2), those material "*held in the ex situ collections of the International Agricultural Research Centres of the CGIAR*" (11§5) while "*Contracting Parties also agree to take appropriate measures to encourage natural and legal persons within their jurisdiction*" (11§3) who hold potential MLS material to put it within the system[1144].

The pool of genetic material falling within the MLS covers thirty five crop species and twenty nine forage species upon which the world is interdependent and which are critical to food security, and are mostly held by governments and the International Agricultural Research Centres of the Consultative Group on International Agricultural Research. Indeed, the latter have signed so-called "Article 15 Agreements" with the Treaty Secretariat in order to make all their germplasm available under the MLS[1145]. The restrictions of the MLS to only those crops listed in Annex I, which was set up on political grounds rather than scientific rationale, has effectively side-lined major crops such as soy bean, strategic vegetables such as tomato or pepper, and other cash crops like agroforestry or ornamentals[1146]. It has been widely and quite vocally criticised as undermining the reach of the system. The total number of accessions secured under the MLS represents "is close to the twenty three per cent of the almost five million accessions of Annex I crops" worldwide, and is mostly attributed to international gene banks' and to national contributions, such as the Canadian Department of Agriculture[1147]. Notwithstanding its inherent limits, by facilitating access to a

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[1143] For a lengthy and comprehensive view of the negotiations and specific stakeholder perspective on the process and its results (including the different perspectives all present during negotiations, ranging from the African, Asian, European, Latin American and Caribbean Regional Groups), see FRISON, LOPEZ, and ESQUINAS-ALCAZAR, *Plant Genetic Resources and Food Security: Stakeholder Perspectives on the International Treaty of Plant Genetic Resources for Food and Agriculture*, *op.cit.*; for a national perspective from the UK, see STUART COUPE and ROGER LEWINS, *Negotiating the Seed Treaty* Warwickshire: Practical Action Publishing, 2007.

[1144] The extent of MLS material made available by Member States or natural and legal persons is made available at http://www.planttreaty.org/inclusions

[1145] Indeed, article 15 of the International Treaty "calls upon the IARCs to sign agreements with the Governing Body with regard to such *ex situ* collections, in accordance with [a number of] terms and conditions, [which include, inter alia, that] plant genetic resources for food and agriculture listed in Annex I of this Treaty and held by the IARCs shall be made available in accordance with the provisions set out in Part IV of this Treaty".

[1146] BERT VISSER, "The Moving Scope of Annex 1: The List of Crops Covered under the Multilateral System," in *Crop Genetic Resources as a Global Commons: Challenges in International Law and Governance*, ed. MICHAEL HALEWOOD, ISABEL LOPEZ NORIEGA, and SELIM LOUAFI, London: Earthscan, 2013.

[1147] ISABEL LOPEZ NORIEGA, PETERSON WAMBUGU, and ALEJANDRO MEJIAS, "Assessment of Progress to Make the Multilateral System Functional: Incentives and Challenges at the Country Level," ibid., pp.205-206.

number of genetic resources, the MLS does still attempt to create a genetic resources commons[1148], as a "core norm" of the ITPGRFA[1149].

Notwithstanding its inherent interpretative limitations, the MLS renders any *ad hoc* bilateral negotiations between providers and recipients irrelevant[1150] for a total of sixty-four species listed in Annex I of the ITPGRFA, and triggers (at least in theory) benefit sharing through the provisions of the standard Material Transfer Agreement[1151] (sMTA) to be used at the entry to the MLS and throughout its navigation.

> Access to MLS material, which should be "*provided solely for the purpose of utilisation and conservation for research, breeding and training for food and agriculture, [… and most of all should be] accorded expeditiously, without the need to track individual accessions and free of charge, or when a fee is charged, it shall not exceed the minimal cost involved*" (ITPGRFA, Article 12§3).

Such access is nonetheless conditional to a number of rights and obligations set out by the sMTA. These obligations evidently aim to implement the ITPGRFA provisos, especially with regards to **benefit-sharing,** which should be executed

> "*fairly and equitably through the following mechanisms: the exchange of information, access to and transfer of technology, capacity-building, and the sharing of the benefits arising from commercialisation*" (ITPGRFA, article 13§2).

The latter benefits are shared through a designated trust mechanism, to which the recipients contribute in the event that products are commercialised while incorporating material "in the form received"[1152] and being "available *with* restriction".

> Product-based commercial benefit-sharing is triggered "*in the case that the recipient commercialises a product that is a plant genetic resource for food and agriculture and that incorporates material as referred to in article 3 of this agreement, and where such product is not* ***available without restriction*** *to others for further research and breeding, the recipient shall pay a fixed percentage of [0.77 per cent of] the sales of the commercialised product into the mechanism established by the Governing Body for this purpose"* (sMTA, article 6§7).

To be "available without restriction, a product should be

> "*available for research and breeding without any legal or contractual obligations, or technological restrictions, that would preclude using it in the manner specified in the Treaty"* (sMTA, Article 2), which designates the event of patent protection over the commercialised product or its components.

[1148] HALEWOOD and NNADOZIE, "Giving Priority to the Commons: The International Treaty on Plant Genetic Resources for Food and Agriculture," *op.cit.*

[1149] ANDERSEN, *Governing Agrobiodiversity*, *op.cit.*, p.106.

[1150] CHIAROLLA, *Intellectual Property, Agriculture and Global Food Security: The Privatization of Crop Diversity*, *op.cit.*, pp.18-19.

[1151] The standard Material Transfer Agreement was adopted by the Treaty's Governing Body at its First Session, through Resolution 2/2006.

[1152] The recipient has the obligation to abstain from claiming "any intellectual property or other rights that limit the facilitated access to the Material provided under this Agreement, or its genetic parts or components, in the form received from the Multilateral System", in accordance with article 6.2 of the sMTA, igniting the obligation of Article 12§3d of the Treaty.

Notwithstanding the extremely conditional nature of such trigger, as well as the time needed for it to show its tangible effects in long breeding cycles, the principle of benefit-sharing under the ITPGRFA presents numerous additional flaw. Indeed, the mere reality that most countries do not allow for the patentability of plant varieties, and rather have recourse to plant variety rights, just as the additional sour reality that "larger 'crop life' companies are avoiding, whenever possible, accessing material through the multilateral system"[1153], seriously puts the efficiency of this equity-minded angle in jeopardy. This avoidance is also attributed to the very disparate interpretations that could be given to the notion of "availability without restriction". Indeed, industry players tend to argue that only patents which do not include neither a breeders, nor a farmers' exception would trigger such mandatory benefit-sharing, leaving the *sui generis* plant variety rights outside of this scope, even the titles awarded under the 1991 UPOV Text. Interestingly, the public sector also is of a similar view, arguing that patents, technological restrictions and contractual or license restrictions may trigger mandatory benefit-sharing, but plant breeders' rights would not[1154]. However, certain commentators have argued that not only should patent protection be presumed to restrict access for research and breeding, but such premise should also include UPOV 1991-type plant variety protection, since these "impede informal exchange and sale of seeds, [reducing] opportunities for on-farm breeding, varietal improvement and selection by farmers" just as other technical means in the like of hybrids or genetic-use-restriction technologies should also trigger mandatory benefit-sharing under the sMTA[1155]. It is nonetheless extremely unlikely that the development of hybrids or even the grant of plant variety protection may be considered such a trigger in reality, seeing the already undeniable reticence of the industry and national research institutes in that regard.

Other means of benefit-sharing are also provided for, namely the solution of "voluntary payments" (sMTA article 6§8), and more interestingly, the so-called African proposal of "crop-related payments under the sMTA" (sMTA article 6§11), triggering the payment obligation "as soon as the recipient sells any product of the respective crop", without regard as to whether it incorporates material received from the MLS[1156].

> Voluntary payments stem from the fact that "*In the case that the Recipient commercializes a Product that is a Plant Genetic Resource for Food and Agriculture and that incorporates Material as referred to in Article 3 of this Agreement and where that Product is available without restriction to others for further research and breeding, the Recipient is encouraged*

[1153] MICHAEL HALEWOOD, ISABEL LOPEZ NORIEGA, and SELIM LOUAFI, "The Global Crop Commons and Access and Benefit-Sharing Laws: Examining the Limits of International Policy Support for the Collective Pooling and Management of Plant Genetic Resources," in *Crop Genetic Resources as a Global Commons: Challenges in International Law and Governance*, ed. MICHAEL HALEWOOD, ISABEL LOPEZ NORIEGA, and SELIM LOUAFI, London: Earthscan, 2013, at p.24.

[1154] This view has been for instance argued by Masa IWANAGA, Director General of the CGIAR CIMMYT Centre, see "ITPRGRFA and sMTA: CIMMYT perspectives and experiences", speaking at the APSA seed congress.

[1155] CLAUDIO CHIAROLLA and STEFAN JUNGCURT, "*Outstanding Issues on Access and Benefit Sharing under the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture*", Der Erklärung von Bern, Development Fund, 2011. This opinion is also shared by SANTILLI, *Agrobiodiversity and the Law: Regulating Genetic Resources, Food Security and Cultural Diversity*, *op.cit.*, pp.144-145.

[1156] CARLOS CORREA, "An Innovative Option for Benefit-Sharing Payment under the Itpgrfa: Implementing Article 6.11 Crop Related Modality of the Standart Material Transfer Agreement," in *Plant Genetic Resources and Food Security: Stakeholder Perspectives on the International Treaty of Plant Genetic Resources for Food and Agriculture*, ed. CHRISTINE FRISON, FRANCISCO LOPEZ, and JOSE T. ESQUINAS-ALCAZAR, London: Earthscan, 2011, pp.250-251.

to make voluntary payments into the mechanism established by the Governing Body for this purpose in accordance with Annex 2 to this Agreement" (sMTA, Art.6.8).

Whereas the alternative option to mandatory payments stems from the assertion that

"The Recipient may opt as per Annex 4, as an alternative to payments under Article 6.7, for the following system of payments:

a) The Recipient shall make payments at a discounted rate during the period of validity of the option;

b) The period of validity of the option shall be ten years renewable in accordance with Annex 3 to this Agreement;

c) The payments shall be based on the Sales of any Products and of the sales of any other products that are Plant Genetic Resources for Food and Agriculture belonging to the same crop, as set out in Annex 1 to the Treaty, to which the Material referred to in Annex 1 to this Agreement belongs;

d) The payments to be made are independent of whether or not the Product is available without restriction;

e) The rates of payment and other terms and conditions applicable to this option, including the discounted rates are set out in Annex 3 to this Agreement;

f) The Recipient shall be relieved of any obligation to make payments under Article 6.7 of this Agreement or any previous or subsequent Standard Material Transfer Agreements entered into in respect of the same crop;

g) After the end of the period of validity of this option the Recipient shall make payments on any Products that incorporate Material received during the period in which this Article was in force, and where such Products are not available without restriction. These payments will be calculated at the same rate as in paragraph (a) above;

h) The Recipient shall notify the Governing Body that he has opted for this modality of payment. If no notification is provided the alternative modality of payment specified in Article 6.7 will apply" (sMTA, art.6.11).

This article establishes a 'crop-based' modality of payment, as the recipient pays its contribution on the basis of the sales of products that constitute plant genetic resources that belong to the same crop of the MLS sample received and used.

> "Article 6.11 was proposed by the African Group during the negotiations leading to the adoption of the SMTA, as a result of its concern about the long period that would be normally necessary to develop new varieties that eventually incorporate materials from the MLS and the limited circumstances in which the obligation to pay might arise out under article 6.7 of the SMTA"[1157].

To this day, no money has come to fuel the Benefit-Sharing Fund of the Treaty from any of these options. Irrespective of the innovative benefit-sharing approach of the ITPGRFA, it also contractually bounds subsequent users through the viral license established by article 12§4, which commands that

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[1157] "*Itpgrfa: Options to Promote the Wider Application of Article 6.11 of the Smta and to Enhance Benefit-Sharing*", Berne Declaration and Development Fund, 2013.

> "*the provision that the recipient of the plant genetic resources for food and agriculture shall require that the conditions of the MTA shall apply to the transfer of plant genetic resources for food and agriculture to another person or entity, as well as to any subsequent transfers of those plant genetic resources for food and agriculture*". (sMTA, Article 12§4).

Nonetheless "nothing in the text of the ITPGRFA and the SMTA [suggests] that their drafters intended to limit the freedom of the subsequent recipient to opt for any of the payment modalities"; the latter could thus "opt for article 6.11 of the SMTA even if the provider had opted for article 6.7, and vice-versa"[1158]. Epinous questions quickly arose at to the status of MLS materials transferred through the sMTA. The first one related to the fate of material "under development", determining whether it could be possible to put restrictions on the further transfer of such material to a third party.

> "***Plant Genetic Resources for Food and Agriculture under Development****" means material derived from the Material, and hence distinct from it, that is not yet ready for commercialization and which the developer intends to further develop or to transfer to another person or entity for further development. The period of development for the PGRFA under Development shall be deemed to have ceased when those resources are commercialised as a Product",* (sMTA, Art 3).

Both the Treaty and the sMTA establish as a principle that

> "*Access to plant genetic resources for food and agriculture under development, including material being developed by farmers, shall be at the discretion of its developer, during the period of its development"* (ITPGRA, Art. 12.3e, and sMTA, Art. 5c).
>
> In this context, the Provider is granted greater discretion, as he may also establish additional conditions, within *"the right of the parties to attach additional conditions, relating to further product development",* including inter alia, the right to exclude others from using said material[1159].

The second challenge faced by the reach of the MLS was to determine whether material developed by the CG centres having signed agreements under the Treaty, or any other MLS user could be made available to farmers for **direct use for cultivation** with or without a sMTA[1160].

1158 "*Itpgrfa: Options to Promote the Wider Application of Article 6.11 of the Smta and to Enhance Benefit-Sharing*", Berne Declaration and Development Fund, 2013.

1159 This prerogative is made clear in article 6.6 of the sMTA, while it is considered that nothing in the IT or sMTA text, nor in commercial practice, precludes the provider from assorting a number of additional conditions, including the right to exclude others from using the material; see Secretariat Working Document, "Restrictions on further transfer of PGRFA under development" Second Meeting of the Ad Hoc Technical Advisory Committee on the Standard Transfer Agreement and the Multilateral System, Brasilia, Brazil, July 2010, IT/AC-SMTA-MLS 2/10/5.

1160 This question was resolved through the interpretation of Treaty text and negotiating history, distinguishing between those materials that have been acquired by IARC's through an sMTA or without one. The latter scenario is less complex than the first, where different options have been sought out by the Governing Body. The use of material for cultivation should in this respect perhaps require the user to "request the express permission of the provider to make the material available to farmers for direct use for cultivation", provided that the provider does have legal authority to grant such permission, and provided that the often times blurry lines between use for cultivation or for research is clarified in the specifics of the Case. See the document prepared to facilitate discussions: Secretariat Working Document, "Transfer" and "Use" of Plant Genetic Resources for Food and Agriculture under the sMTA – Transfer to Farmers for Direct Use for Cultivation", Second Meeting of the Ad Hoc Technical Advisory Committee on the Standard Transfer Agreement and the Multilateral System, Brasilia, Brazil, July 2010, IT/AC-SMTA-MLS 2/10/7.

> It has in this regard been "considered an accepted practice of the CG Centres, not altering the integrity of the Multilateral System, and a right of Contracting Parties, to make improved material they have developed from material acquired from the Multilateral System available to farmers for direct use. This is indeed a fundamental objective of the Multilateral System".

Intellectual property rights, the material from the MLS and plant innovation actors

The system does display "characteristics of a global public good, in so far as Article 12 establishes that Parties to the Treaty are to provide access to those PGRFA held within the joint pool, to other parties and to legal and natural persons under the jurisdiction of any party" to the Treaty[1161]. The public domain fenced by the ITPGRFA in this regard also stems from its **approach to intellectual property rights**.

> Indeed, "*recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their **genetic parts or components**, **in the form received** from the Multilateral System*" (ITPGRFA, Article 12§3d).

In light of such a primordial yet purposely vague provision that represents "a careful compromise among the delegations"[1162], there is nonetheless an urgent need to better define the scope of "genetic parts and components", just as the notion of "in the form received"[1163]. Indeed, the divergent interpretations of negotiators and signatories on the exact reach of such restraint over private appropriation and the lack of subsequent agreement on the subject in the Treaty's Governing Body meetings have considerably blurred the boundaries of the agrobiodiversity public domain. While developed country breeders tend to argue that the form of a variety received from the MLS is altered through deliberate crossings and especially biotechnological tools, "the donors of landraces and wild forms, […] argue that the operated transformation, even by biotechnological means, is of minor importance", making them staples of the MLS[1164]. Numerous countries, including the European Union, have in this regard enacted interpretative declarations stating that "PGRFA or their parts or components having undergone innovation may be subject to IP protection"[1165]. The industry has also come up with its own interpretation of the provision, stating that

[1161] COSIMA HUFLER and RENE LEFEBER, "Our Heritage Is Our Future: Humankind's Responsibility for Food Security," in *Plant Genetic Resources and Food Security: Stakeholder Perspectives on the International Treaty of Plant Genetic Resources for Food and Agriculture*, ed. CHRISTINE FRISON, FRANCISCO LOPEZ, and JOSE ESQUINAS-ALCAZAR, London: Earthscan, 2011, p.243.
[1162] HALEWOOD and NNADOZIE, "Giving Priority to the Commons: The International Treaty on Plant Genetic Resources for Food and Agriculture," *op.cit.*
[1163] FRISON, LOPEZ, and ESQUINAS-ALCAZAR, *Plant Genetic Resources and Food Security: Stakeholder Perspectives on the International Treaty of Plant Genetic Resources for Food and Agriculture*, *op.cit.*, Conclusions.
[1164] JOSE CUBERO, "Plant Breeders: The Point of View of a Plant Breeder in the Itpgrfa," in *Plant Genetic Resources and Food Security: Stakeholder Perspectives on the International Treaty of Plant Genetic Resources for Food and Agriculture*, ed. CHRISTINE FRISON, FRANCISCO LOPEZ, and JOSE ESQUINAS-ALCAZAR, London: Earthscan, 2011, at p.205.
[1165] These declarations have mainly stemmed from European countries, including Belgium. See SANTILLI, *Agrobiodiversity and the Law: Regulating Genetic Resources, Food Security and Cultural Diversity*, *op.cit.*, at p. 140.

> "It is possible to claim intellectual property or other rights that limit access to the genetic parts or components isolated or inherited from the material received, provided of course that the patentability criteria are fulfilled and in particular the utility one in case of patent. A genetic sequence as such, without proved industrial activity, should not be patentable. However, the rights granted should in no case limit access to the initial genetic material"[1166].

The threshold of "formal identity" between the material acquired through the MLS and the material where intellectual property protection is sought after could in this sense be "interpreted as allowing IP once significant, inventive manipulation has occurred"[1167]. But it cannot in any case be interpreted as preventing or curtailing the grant of exclusive titles on products or processes obtained by using genetic resources obtained through the ITPGRFA system.

> "Whether this provision means that no IPRs of any sort can be claimed or that IPRs could be obtained as long as those rights do not limit the facilitated access is still uncertain – an uncertainty that has carried over into the SMTA. There is further uncertainty as to what 'parts and components' mean in practice and the extent to which IPRs may be claimed over them. Different parties have differing takes on what this provision means. Most developed countries interpret it as meaning that IPRs can be taken out on a product if some improvement or modification has been made, in other words if it is not 'in the form received' from the Multilateral System. However, most developing countries take the view that 'parts and components' implies that products containing parts and components of resources received from the Multilateral System, as well as derivatives, are covered by this provision and that it therefore prohibits IPRs over them. Parties fully recognise and admit these differences in interpretation and, it is hoped that the Governing Body of the Treaty will at some point in the future address the issue and give a definitive interpretation consistent with the spirit of the Treaty"[1168].

Furthermore, the contractual commons set out by the ITPGRFA is set out in a viral license-like fashion with regards to the obligation of sharing the benefits arising from the use of MLS material that is not made available without restriction for further research or breeding.

> "*A Recipient who obtains intellectual property rights on any Products developed from the Material or its components, obtained from the Multilateral System, and assigns such intellectual property rights to a third party, shall transfer the benefit-sharing obligations of this Agreement to that third party*". (sMTA, Article 6.10)

This objective is not only the conservation and sustainable use of agricultural plant genetic diversity as such, but also echoes to an additional aspect of the ITPGRFA that addresses the property regime of agrobiodiversity, i.e. the appraisal of **farmers' rights**. The Treaty proclaims the so-called farmers' rights in its Article 9, as a bundle of socio-economic rights including those

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[1166] ISF, "*Interpretation of Article 12.3(D) of the International Treaty on Plant Genetic Resources for Food and Agriculture*", ISF, International Seed Federation, 2005.

[1167] STEPHEN BRUSH, "The Demise of 'Common Heritage'and Protection for Traditional Agricultural Knowledge," in *Biodiversity and the Law: Intellectual Property, Biotechnology and Traditional Knowledge*, ed. CHARLES R MCMANIS, London: Earthscan, 2007, at p.305.

[1168] HALEWOOD and NNADOZIE, "Giving Priority to the Commons: The International Treaty on Plant Genetic Resources for Food and Agriculture," *op.cit.*

related to seeds, as, amongst other rationales, a response to the evolution of the farmers' privilege to save and exchange protected seeds into a clear exception to the exclusive rights of breeders, rather than an array of acts considered outside the scope of the IP title in itself[1169]. The substantial content of such farmers' rights is not straightforwardly defined. A number of measures are nonetheless listed in order to protect and promote these rights, but their scope shall be defined within national legal orders.

> *"The Contracting Parties agree that the responsibility for realising Farmers's Rights, as they relate to plant genetic resources for food and agriculture, rests with national governments. In accordance with their needs and priorities, each Contracting Party should, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers's Rights, including:*
>
> - *The protection of traditional knowledge relevant to plant genetic resources for food and agriculture;*
> - *The right to equitably participate in sharing benefits arising from the utilisation of plant genetic resources for food and agriculture; and*
> - *The right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture"* (ITPGRFA, Art.9.2).

Linking the protection of farmers' rights to traditional knowledge and insisting on the participatory aspects that accompany this bundle of rights, article 9 seems to further condition farmers' rights to save or exchange seeds to national law and the "appropriateness" of the measures. Indeed,

> "*nothing in this Article shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate*" (ITPGRFA, Art.9.3).

The Treaty Secretariat combines the "Submissions of Views and Experiences on the Implementation of Farmers' Rights Submitted by Contracting Parties and Relevant Organisations", to which unfortunately only three countries have contributed, namely Madagascar, Norway and Poland, while no less than ten non-governmental organisations have made submissions between 2012 and 2013[1170]. As the notion of farmers' rights is solely addressed in the international arena through article 9 of the ITPGRFA, which clearly states that the substantial content of such notion shall be granted by national law-makers, the exact extent of prerogatives that could potentially impact the PGRFA public domain remains unclear. It is nonetheless generally understood that its scope goes beyond the farmers' privilege enshrined as an exception to plant variety (or even patent) protection in certain legal for a, since the main rationale is to "ensure sufficient legal space for farmers to continue saving, using, exchanging and selling farm-saved-

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[1169] PELEGRINA and SALAZAR, "Farmers' Communities: A Reflection on the Treaty from Small Farmers' Perspectives," *op.cit.*, pp.175-182.

[1170] These submissions are compiled at http://www.planttreaty.org/content/farmers-rights-submissions, amongst the ten organisations are the Berne Declaration, the Via Campesina, the Development Fund, Biowatch, but also the European Seed Association, and the latest contributor, the GREEN Foundation.

seed and other propagating material" through all means necessary[1171]. Farmers' rights may thus impact traditional IP regimes but also seed marketing laws, as well as subsidisation policies.

CONCLUSION Principles of International Environmental Law: public domain and intellectual property rights

National sovereignty claims were first declared at the level of the Untied Nations General Assembly, and then subsequently consecrated through global environmental conferences, in order to balance the ineffective and uneven distribution stemming from historical free access and exchange patterns[1172]. The developmental and biopiracy narrative was translated into a restriction of the biodiversity public domain through access and benefit-sharing obligations, coupled with parallel conservation objectives. The Convention on Biological Diversity builds a public domain that is restricted by a bilateral liability mechanism attached to the access to sovereign resources, which triggers *ex ante* or *ex post* benefit sharing. The International Treaty on Plant Genetic Resources for Food and Agriculture builds on the other hand an enlarged public domain that is only restricted through a conditional multilateral liability mechanism triggered either *ex post* from the award of titles restricting the availability of resources listed in the Treaty's Annex I or *ex ante* through the so-called "African Proposal".

Faced with more interdependent and tangled genetic resources, negotiations were indeed carried out within the FAO mainly in order to address the property regime applicable to the public and common heritage held notably within CGIAR collections. These two sets of regulatory instruments have acquainted the international community with the principles of national sovereignty, benefit-sharing, traditional knowledge and farmers' rights. Striving to conserve biological diversity and ensure the sustainable and equitable use of its components, international environmental instruments have further contributed to the commodification of biodiversity, advocating a regime shift in property rights, and a newly defined agrobiodiversity public domain. Just as the ITPGRFA grants facilitated access to germplasm for use "in training and research" in the multilateral system, the CBD, and most importantly the Nagoya Protocol recognises the specificity of non-commercial research. Furthermore, both instruments acknowledge the contributions of indigenous and farming communities, in terms of the knowledge attached genetic resources and their role in the conservation of biodiversity on site. The public domain of agrobiodiversity is also assorted by further bundles of rights pertaining to the protection of traditional knowledge and the recognition of farmers' rights. International environmental law thus shapes the so-called "Plant Genetic Resources System" and reserves different rights and obligations to its stakeholders, fencing the public domain of upstream biological material.

[1171] SANTILLI, *Agrobiodiversity and the Law: Regulating Genetic Resources, Food Security and Cultural Diversity*, *op.cit.*, pp.202-203.
[1172] Jack KLOPPENBURG, and Daniel L. KLEINMAN; "The Plant Germplasm Controversy", *Bioscience*, 37:3 (1987), pp. 190-198.

PART IV CONCLUSIONS. Salvaging international trade and environmental law through the public domain

Since its inception, the international law of biodiversity, whether in its most general understanding or its specific agricultural leg, has been guided by a desire to ensure the conservation and sustainable use of natural and therefore also genetic resources. All entitlements awarded through these instruments should therefore in principle be viewed in such environmental lens. In this approach, sovereign rights, access regulations and benefit-sharing obligations have all been drafted through a conservation objective. However, the international legal regime's reality is much more complex than such assertion, as most of its measures have also been adopted following economic and developmental considerations, including distributive justice appeals. Indeed, the conservation of biodiversity remains very much linked to biodiversity's economic value and associated ecosystem services in international law. In this context, first the CBD and then arguably to a lesser extent the ITPGRFA have both hallowed the monetisation and the enclosure of biodiversity within a sovereignty-bound property approach, following the re-affirmation of developing countries' right to development. The CBD system remains built around national sovereignty claims which aim to balance the ineffective and uneven socio-economic welfare distribution stemming from free access and exchange patterns, advocating both benefit-sharing and conservation obligations. Negotiations carried out within the FAO rather aimed to preserve the public and common heritage held notably within CGIAR collections, taking due account of the characteristics of intertwined agricultural germplasm flows and of the sequential nature of agrobiodiversity use.

Notwithstanding their notional differences, these two sets of regulatory instruments have acquainted the international community with shared principles of national sovereignty, benefit-sharing, traditional knowledge and farmers' rights. Both agreements have contributed to an understanding of genetic resources as commodities, available, exploitable and officially tradable on markets, just as much as the international and national prerogatives which have carved the strong intellectual property paradigm. The principles of international environmental law have indeed built additional and equally solid fences around the PGRFA public domain. The reach of these instruments theoretically solely limit the status of genetic resources upstream, mainly on account of the sovereign rights that herald the obligation to share the benefits arising from the use of genetic resources. It also in parallel concedes terrain to collective rights attached to farmers and to traditional knowledge, while acknowledging the specific nature of scientific research or breeding efforts. In this sense, the new biodiversity public domain is not only affected by the extent of intellectual property prerogatives, its new boundaries depend upon a number of factors.

The new public domain depends on the exercise of each Provider State's **sovereign rights** to determine the conditions that surround the access to genetic resources and the modalities that have been set out in order to share the benefits deriving from their use. In accordance with the provisions of the ***Nagoya Protocol or as CBD compliant legislation***, States need to establish whether they will seek out "prior informed consent" for those resources under their control. If they seek out such consent, a number of principles need to accompany the contractual framework of "mutually agreed terms", triggering *ex ante* or *ex post* compensation for the use of genetic resources. Compliance mechanisms need to be put in place to ensure that such consent and terms have been sought for and respected by genetic resource users. States may sovereignly ***decide to take part in the ITPGRFA system***, designating those Annex I crops that will be accessed under the terms of the "Multilateral System", and the benefits of which shall be collected and shared under the terms of the "standard Material Transfer Agreement". Benefit-sharing would be triggered in the event the material is not made available for further research or breeding or through an *ex ante* crop-specific lump sum payment.Furthermore, no intellectual property right could cover the material "in the form received" from the Multilateral system, thus restricting the reach of the intellectual property paradigm in signatory countries. The new agrobiodiversity public domain will also depend on the national implementation of new **collective rights enshrined** at the international arena. The CBD obligation of States to "respect, preserve and maintain ***traditional knowledge"***, and the ITPGRFA obligation of States to "realise, protect and promote ***farmers' rights"***.

The adjustments operated to the agrobiodiversity public domain by international environmental law have not solely infused equity and sustainability into the management of plant genetic resources; they have at times also hampered the realisation of the distributive justice objectives they were set out for. Indeed, the bilateral approach of the CBD, through restrictive national stances to grant access to sovereign resources, or hardy negotiations over *ex ante* or *ex post* benefit sharing, has been accused of contributing to the creation of **yet another "tragedy of the anti-commons**". This time, the anti-commons effect is concerned with raw plant genetic resources, the access to which is completely depended upon the sovereign decisions of provider States, not even the users or maintainers of genetic resources. Nor are the sovereign prerogatives accompanied by requirements that may help carve a public domain, such as those related to the time limits, disclosure or liability rules that traditionally come hand in hand with intellectual property rights. Furthermore, the sovereignty-oriented access and benefit sharing debate is serving extremely diverging and inherently conflicting approaches, as for instance the desire to ensure the benefits of research and development are shared while restricting access to resource use in order to prevent biological piracy[1173]. In this sense, the regime established by the ITPGRFA considerably differs from the CBD approach, even though it is mandatorily based upon customary sovereign rights. The Treaty indeed is constructed as an enlarged public domain that is only restricted through the multilateral liability mechanism that sovereign States have decided to set up for a number of crops. Furthermore, in practice, the trade-bound legal instruments that regulate the formal seed market have in effect outplayed those instruments regulating the conditions of access to genetic resources and the sharing of benefits deriving from their use. The principles enshrined in international environmental law seem difficult to apply faced with a public domain that is growingly restrictively fenced in light of the new needs of agrobiodiversity innovation.

However, and notwithstanding its inherent potentially hazardous anti-commons effects, international biodiversity law also presents vital tools that attempt to redress certain failures of the strong property paradigm vis-à-vis specific actors of plant improvement. In our view, the reassessment that such finding entails does not necessarily require the obliteration of the strong property paradigm as a whole, but can rather be found within its lines. Having due regard to the incorporeal nature of relevant innovations, the ease of reverse-engineering and the colossal investments required for their development, systems drawing from completely open source models or from such understanding would in our view fail to deliver significant portions of socially, agronomically or environmentally meaningful innovations. The recognition of intellectual property rights, even in their strongest forms, remains a beneficial and necessary tool for the development of easily replicated innovations that are neither incremental nor foundational. Instruments

[1173] BRAM DE JONGE and NIELS LOUWAARS, "The Diversity of Principles Underlying the Concept of Benefit Sharing," in *Genetic Resources, Traditional Knowledge and the Law: Solutions for Access and Benefit Sharing*, ed. EVANSON CHEGE KAMAU and GERD WINTER, London: Earthscan, 2009.

developed by the biotechnology-heavy plant variety improvement chain would require and benefit from such restrictive approach. However, the dominant bundle of rights may need to be revised and adapted to the needs and practices of other agrobiodiversity users, especially those "who produce information without intending to sell their output as a good […] such as universities, public interest organisations and individuals who communicate with each other either as "amateurs" or as professionals driven by internal motivations not by a profit motive"[1174].

These actors include public plant breeders and molecular biologists who strive towards the production of public goods, as well as farmers and gardeners who conserve and develop landrace populations". Less obviously, it also includes commercial organisations and individual professionals that operate on a service model that provides free access to information around which the service is rendered, rather than the sale of information as product"[1175], which arguably covers conventional plant breeders deeply attached to the breeders' exception and plant variety rights.

[1174] BENKLER, "Through the Looking Glass: Alice and the Constitutional Foundations of the Public Domain," *op.cit.*, p.181.
[1175] Ibid.

PART V ADJUSTMENTS AND SOLUTIONS TO THE PROPERTY PARADIGM BUILDING ON SOCIAL ORGANISATIONAL INNOVATION

Intellectual property schemes have failed to achieve what they were initially tailored for in all agrobiodiversity improvement chains, i.e. fostering and supporting innovative endeavours. Dichotomies in economic development and excessively restrictive appropriation and diffusion rules have precluded certain actors of plant improvement from using the growth opportunities others have benefited from. Partly as a result of such developmental opportunity dichotomies and the uniformisation of plant improvement, the strong property paradigm has been permeated by both sustainability and equity pleas found in the much more disparate prerogatives of international biodiversity conservation law. Developing countries, and a number of industrialised nations, have embraced the opportunity to shift back the dominant trade regime so as to integrate the principles, norms and rules found in hard or soft law instruments governing natural and agricultural biodiversity[1176]. Both biodiversity provider nations and advocacy groups have pushed for a revision of the strong IP paradigm towards harmonisation with the CBD and ITPGRFA, and the accommodation of ABS rules, recognising traditional knowledge and farmers' rights[1177]. Not only has the interface between the international rules of trade and environmental law been the focus of the revision of Article 27§3b of TRIPS, they have also been specifically coined "outstanding implementation issues [which would] be an integral part of the Work Programme" by the subsequent Doha Ministerial Declaration[1178]. These considerations led to a serious questioning of the TRIPS provisions, calling for its replacement by "alternate intellectual property paradigms", or less intrusively calling to modify its interpretation or implementation[1179].

We will experiment with the in-built flexibilities of the global IP paradigm, to ensure that sustainability and equity pleas are addressed, and particularly to ensure that the needs of all plant improvement users and all socio-technological contexts of innovation are addressed in the national implementation of plant-related intellectual property rights. Critics and practice have both highlighted the genuine insufficiencies of the strong IPR regime in various areas, such as the disregard for *in situ* agrobiodiversity conservation, the tricky coexistence of patents and plant breeders' rights, the difficult access to platform technologies, research tools or to private pools of improved seed varieties, the lack of protection of collective informal innovation or the little regard with regards to the misappropriation of public or traditional knowledge. However, due to their piecemeal nature, these critics have not yet produced a major shift in the paradigm. Nor have the proposed alternative solutions been able to impose themselves as valid and viable institutional mechanisms. What is missing in such piecemeal approaches to the institutional effectiveness and/or defects of the protection of agrobiodiversity-related intangibles, in our view, is the fact that

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1176 HELFER, "Regime Shifting: The Trips Agreement and New Dynamics of Intellectual Property Lawmaking," *op.cit.*, pp.63-71., where the author highlights evidence towards such an "integrationist regime shifting strategy".

1177 Notably see the advocacy paper of GRAIN, "*For a Full Review of Trips 27.3(B): An Update on Where Developing Countries Stand with the Push to Patent Life at Wto*", http://www.grain.org/article/entries/39-for-a-full-review-of-trips-27-3-b, 2000.

1178 The revision of article 27§3, ignited in 1998, was taken on by the Seattle Ministerial Conference of December 1999, were no agreement was reached, arguably rendering developing countries' efforts to amend the provision even more assertive and detailed (HELFER, *Ibid*., p.64). The outstanding implementation issues are mentioned in Paragraph 12 of the Declaration of the Fourth Ministerial Conference held in Doha, Qatar, on the 14th November 2001, WT/MIN(01)/DEC/1.

1179 UNITED NATIONS DEVELOPMENT PROGRAM, "*Making Global Trade Work for People*", Nairobi, 2003. pp.221-222.

solutions have not been grounded on the emerging and normative practices of relevant agrobiodiversity users. This fresh approach draws in from a systematic analysis of the impacts of the institutional paradigm of strong intellectual property rights on each of these groups. In this context, tailor-made innovative solutions can and should be used to overcome the deadlocks in implementing the general property principles of both the CBD and the ITPGRFA next to the need to provide artificial lead-time to worthy innovators. This exercise will assist policy-makers, but also stakeholders in reclaiming a PGRFA public domain that is sustainable, equitable and efficient, fostering both formal and informal innovation, accounting clear compensation for all knowledge contributors, while also preserving biodiversity for present and future generations. Furthermore, in the specific case of innovation based on natural resources that embodies inherent sustainability concerns, the need to draw on new modes of operations brought by novel configurations of actors, institutions and practices has increasingly been recognised, in innovation or transition studies alike[1180].

All the solutions that will be investigated in this study will rest within or around existing intellectual property rights instruments or management tools. They will however not be found within the development and prospectively extensive protection paradigm. They will rather reclaim the historical balance between monopoly rights and the public domain that was illustrated in the first chapter of this research. They will do so by incorporating the emerging social actor practices that make room for the principles of sustainability and environmental justice stemming from international environmental law. Our current intellectual property system can indeed provide sufficient flexibility so as to set up an equitable knowledge-based economy, accommodating the rights and needs of all actors involved in agrobiodiversity innovation, from the farmers to the public or private breeders, producers, microbiologists and consumers. Unfortunately, as acknowledged by the Crucible Group,

> "there has been a distressing lack of inventiveness in encouraging innovation. It is possible for a country, for example, to develop a *sui generis* IP system that varies the years of protection depending upon the species involved (as UPOV does), or excludes certain species (for example, some or all basic food crops). *Sui generis* national laws could vary the scope of protection for different biomaterial categories such as medicinal plants and food crops. The application criteria could also be adjustable depending upon the purpose of the invention or even its origin. It might also be possible to establish unique rules covering national treatment, national working, licencing provisions (compulsory or automatic licences), or a system that discriminates in its fee structure on the basis of nation of origin"[1181].

Acknowledging that no perfect trade-off between protection, access and diffusion can exist, those rights, privileges and use conditions inherent to the current patent and PVP paradigms could be adequately distributed into a coherent regulatory framework which would better address the needs

[1180] This approach is advocated by transition scholars who highlight the deficiencies of innovation systems approaches that "fall short of addressing the process of transformation of the socio-technological systems needed for the transition to strong sustainability", see K. M. WEBER and H.. ROHRACHER, "Legitimizing Research, Technology and Innovation Policies for Transformative Change: Combining Insights from Innovation Systems and Multi-Level Perspective in a Comprehensive 'Failures' Framework.," *Research Policy* 41, no. 6, 2012; TOM DEDEURWAERDERE, "*Sustainability Science for Stronger Sustainability* ", 2013.
[1181] THE CRUCIBLE GROUP, *People, Plants and Patents: The Impact of Intellectual Property on Biodiversiy, Conservation, Trade and Rural Society* Ottawa: International Development Research Centre, 1994.

of all contexts of agrobiodiversity-reliant innovation. The adoption of an entirely novel intellectual property paradigm seems indeed at this point rather unlikely and perhaps not necessary. This reality holds true especially in view of the colossal task of reconciling widely differing actors' often conflicting interests and diverging research and development priorities. It is indeed national priorities that should drive any decision as to what, or if, IP systems are required in support of innovation. We therefore believe the task at hand hinges on experimenting in a more consistent manner with various models and emerging agrobiodiversity user practices that build partially open innovation systems grounded on the flexibility of informational property regulation. Stemming from one general premise; that IPR regimes "moderate their exclusionary principles with limitations and exceptions [that are] in part designed to construct a public domain of resources [and in part support uses that generate socially beneficial spillovers]"[1182]; what will be understood as flexibility in this research shall bear a multi-faceted dimension. It will first refer to the flexibility granted to Member States for the national implementation of international minimal standard of intellectual property rights, especially those deriving from the TRIPS Agreement. But it will also address the boundaries and accommodations provided for by international, supranational or national legal instruments to the benefit of actors concerned with and using protected plant innovations (innovators, researchers, licensees, farmers); whether these boundaries concern the protection scope, the extent of prerogatives awarded to right-holders, or the reach of sanctioned exceptional uses by third parties. At last, it will also investigate the institutional arrangements that may provide solutions for both the providers and users of protected innovations, as alternative and additional flexibility tools.

The **first type of flexibility** is quite straightforward. It implies that international intellectual property rights conventions[1183], and more particularly the TRIPS Agreement, are to be seen as prescriptive instruments without direct effect in national legal orders, indifferent to monist or dualist approaches to international law, but rather requiring (or permitting) the signatories States to adopt legislation[1184]. International conventions constitute in this context "minimum standards agreements", or more subtly "backbones" of prescriptions addressed to Member States[1185]. This holds especially true in the internationally reified intellectual property paradigm. Indeed, none of the UPOV Conventions prevents their signatories from adopting more stringent legislation, as long as their tenets remain complied with. Just as article 8§2 of the TRIPS Agreement states that

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[1182] MADISON, FRISCHMANN, and STRANDBURG, "Constructing Commons in the Cultural Environment," *op.cit.*, pp.668-669.

[1183] Such as the 1883 Paris Convention for the Protection of Industrial Property or the 1978 Patent Cooperation Treaty in terms of industrial property, or the 1886 Berne Convention for the Protection of Literary and Artistic Works in terms of creative property.

[1184] DENIS BORGES BARBOSA, "Minimum Standards Vs. Harmonisation in the Trips Context: The Nature of Obligations under Trips and Modes of Implementation at the National Level in Monist and Dualist Systems," in *Research Handbook on the Protection of Intellectual Property under Wto Rules: Intellectual Property in the Wto*, ed. CARLOS CORREA, Cheltenham: Edward Elgar, 2010, pp.67-69.

[1185] JEROME H. REICHMAN, "Universal Minimum Standards of Intellectual Property Protection under the Trips Component of the Wto Agreement," *International Lawyer* 29, 1995.; LAURENCE R. HELFER, "Adjudicating Copyright Claims under the Trips Agreement: The Case for a European Human Right Analogy," *Harvard International Law Journal* 39, 1998.

Even though a general consensus on such "minimum standards" approach does exist, a number of TRIPS requirements have been viewed as "maximum standard prescription", where more intensive protection cannot be foreseen by Member States, including the principle of "global protection of users' rights" developed by HENNING G. RUSE-KHAN, "Time for a Paradigm Shift? Exploring Maximum Standards in International Intellectual Property Protection," *Trade, Law and Development* 1, no. 1, 2009: pp.56-102.

> "*appropriate measures ... may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology*" (TRIPS Agreement, Art.8.2).

In the specific context of plant-related international intellectual property rights, the international agreements also offer considerable **flexibilities directly linked to the content and extent of prerogatives awarded to right holders and users.** For instance, both "optional subject-matter exceptions" from patentability and the definitions of the relevant terms[1186], such as the "non-biological and microbiological processes" are referred to in article 27§3 of TRIPS. This flexibility allows for a multitude of choices in the optimal regulation and implementation of exclusive rights. As a result, the extent and reach of IPR may be limited. Just as national or actor-specific needs may also be accommodated through tools such as compulsory licensing and exceptions surrounding the possible negotiation-free use of the protected innovation. The **last flexibility concerns institutional arrangements** that could be developed by either the right-holders themselves (as in patent pools), or the end-users themselves (through technology transfer clauses), or through a combination of both (through enhanced participatory plant breeding for instance). These schemes allow actors to navigate within the IPR landscape. They provide *ad hoc* solutions to the obstacles set out by the strong IPR paradigm, which may preclude the initial development or subsequent use of market or social successes. Based on the idea that "community production" might be the best-suited solution to the free-rider problem of public goods production, these tools nonetheless bear the risk of becoming a "one-size-fits-all panacea approach in rivalry with privatisation, public subsidy and the public domain"[1187]. Exploring all rooms for manoeuvre between suffocatingly restrictive exclusivity and the insecurely spineless public domain should alleviate such danger.

In order to efficiently address all coping strategies and emerging practices by experimenting with the flexibilities of intellectual property rights, we will, for each category of actors, illustrate and analyse practices of social organisational innovation coming either from the agrobiodiversity users themselves, or from external actors such as the judiciary or even to a certain extent policy-makers. This analysis will allow us to thereon discuss the legal and institutional propositions that could uphold these practices. The groundwork will eventually also break the obstacles stemming from "the inflexibilities of the flexibilities" of the TRIPS Agreement, which have been criticised as having been designed to make their use rather difficult[1188].

[1186] GRAHAM DUTFIELD, LOIS MURAGURI, and FLORIAN LEFERVE, "Exploring the Flexibilities of Trips to Promote Biotechnology in Developing Countries," in *Research Handbook on the Protection of Intellectual Property under Wto Rules: Intellectual Property in the Wto*, ed. CARLOS CORREA, Cheltenham Edward Elgar, 2010, p.541.
[1187] MADISON, FRISCHMANN, and STRANDBURG, "Constructing Commons in the Cultural Environment," *op.cit.*, 670., referring to the notable examples of community production advocated by Yochai BENKLER, *The Wealth of Networks: How Social Production Transforms Markets and Freedoms*, *op.cit.*
[1188] STIGLITZ, "Economic Foundations of Intellectual Property Rights," *op.cit.*, p.1717.

12. CHAPTER 12: ADJUSTMENTS FOR PUBLIC RESEARCHERS

The future of plant improvement still largely depends upon the products of basic and strategic research, which, because of their long-run, uncertain payoffs and the difficulty of appropriating benefits, have more traditionally continued to be developed by the public sector[1189]. Furthermore, even if the entirety of genetic variability may not be accessible through gene banks, plant breeders still prefer to have recourse to these institutions, in order to not only gain access to the corporeal organism, but also to the primordial associated information stemming from characterisation and evaluation activities, making this agrobiodiversity source a much easier, quicker and less costly source than those collected on farms or natural habitats themselves[1190]. Public plant improvement is also more likely to develop so-called orphan crops, which will naturally be neglected by solely market-oriented choices of lucrativity and productivity, even though these crops feed more people than industrial agriculture[1191]. Hence strong public support for research, especially vis-à-vis basic and strategic research should be considered as one of the major stimulants to private investment in R&D, and thus to the successful use of agricultural biodiversity. Public researchers' activities have nonetheless been considerably distraught by the strong agrobiodiversity property paradigm. The developmental approach to intellectual property and correlated practices has made access to interesting technologies and material impossible or considerably more costly or difficult. It also pushed public domain oriented institutes outside of their traditional open access oriented innovation schemes, all the while making them more vulnerable to commit biopiracy or be the victim of misappropriation themselves.

The norms of communalism and independence, and the heavy appraisal of the public domain have nonetheless "continued to operate even as the science of molecular biology matured and the ease with which commercial products could be derived from the underlying science increased"[1192]. The partial breakdown or restricted access to research tools has in this sense been alleviated "because firms and universities have been able to develop "working solutions" that have allowed their research to proceed, [including] taking licenses, inventing around patents, infringement (often informally invoking a research exemption), developing and using public tools, and challenging patents in court"[1193]. These practices have been at times corroborated, supported or even triggered by adequate policy responses or through the practice of external actors, such as the judiciary. Indeed, "changes in the institutional environment, particularly new U.S. Patent and Trademark Office (USPTO) guidelines, and active intervention by the National Institutes of Health (NIH), and some shift in the courts' views toward research tool patents"[1194], appear to have further reduced the threat of breakdown and access restrictions, although the environment remains uncertain. The jurisprudential turns taken by the EPO Board of Appeals, as well as the gradual guidance given in the EPC Implementing Rules have also contributed to to ease the stresses felt by public researchers. As these stresses have almost exclusively felt within the more limited scope of the

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1189 BYERLEE, "Modern Varieties, Productivity, and Sustainability: Recent Experience and Emerging Challenges," *op.cit.*
1190 TEN KATE and LAIRD, *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing*, *op.cit.*
1191 DE SCHUTTER, *op.cit.*, 2009. , 2009.
1192 RAI, "Regulating Scientific Research: Intellectual Property Rights and the Norms of Science," *op.cit.*, p.93.
1193 WALSH, ARORA, and COHEN, "Effects of Reseach Tools Patents and Licensing on Biomedical Innovation," *op.cit.*, p.286.
1194 Ibid.

lenient patent system, social organisation has mostly been active in this particular front of the property paradigm, and not necessarily on plant variety protection[1195]. In this context, we shall describe the struggles and solutions brought up around the world of plant biotechnology and public plant breeding in a gradual fashion, according to their reach and also feasibility. Straightforward and more classical solutions indeed tend to reclaim the level playing field awarded in patentability and protection scope, including liability rules such as the research exception. More elaborate, and therefore trickier to reach consensus upon without encroaching competititon law principles, are those solutions playing with licensing mechanisms as such, whether aiming towards humanitarian uses or standardisation. A last type of adjustment requires even more favourable conditions in order to bloom and operate, as it involves setting up *ad hoc* institutional collaborations retaining a hybrid and semi-open nature, potentially leading to clearing-houses and patent pooling.

12.1. Acting on IPR elligibility and protection scope

The scope of intellectual property rights protection has considerably been enlarged with the implementation of the strong property paradigm, just as the criteria triggering protection, especially that of patents, have been loosely interpreted in order to foster innovation in the highly lucrative burgeoning green biotechnology industry. As a result of such trends, it is the cradle of all inadequacies, i.e. the reach of patent protection, which has predominantly challenged public researchers involved in molecular biology or plant breeding. In this context, the reach of patent protection is characterised by both the delineation of patentability, i.e. patent eligibility, and also the extent of prerogatives awarded to right-holders, predominantly to control the subsequent uses of protected inventions. In this context, both public researchers, acting directly by challenging broad claims or advocating legislative change, and external actors such as the judiciary or patent offices, have been trying to recalibrate the extensive reach of artificial monopolies. They have done so to address a few shortcomings at a time, namely to avoid biopiracy claims, just as to ensure that public results are not misappropriated, and also to warrant that patented technologies can be accessed and used by public research entities without considerable hurdles. These adjustments mainly address the shortcomings caused by a single trend of the strong property paradigm, the enclosure of cumulatively incremental innovation. They thus try to better delineate the boundaries between original and subsequent innovators, providing for adequate compensation, yet also enough manoeuvre for inspiration, building on the shoulders of giants.

12.1.1. Patent eligibility for plant varieties and "non essentially biological products of nature": inventive step, novelty and exclusions

As aforementioned, research in the life sciences is closely linked to the realm of scientific discoveries regarding the genetic basis of various biological functions [1196]. The patentability lines of novelty, utility and non-obviousness have therefore been actively shifted towards a pole dangerously close to the fruits of basic research and discoveries in this field so as to provide

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[1195] Even though public plant breeders, in the likes of those working under the auspices of the CGIAR, have also been challenged by the shrinking scope of the breeders' exception in plant variety protection, this particular shortcoming of the strong property paradigm shall be studied more in depth in Chapter 13 of this study, focusing on private plant breeders.

[1196] MAY, "On the Border: Biotechnology, the Scope of Intellectual Property and the Dissemination of Scientific Knowledge," *op.cit.*, p.254. DRAHOS, "Biotechnology Patents, Markets and Morality," *op.cit.*, pp.441-449 (at 444).

artificial lead time to industry players investing heavily in most generally uncertain products. This shift has mainly operated under the impetus of the developed world in order to boost private sector involvement in the field of biotechnology, where products self-replicate and are thus easily reverse-engineered, and where sunk costs remain very high. Notwithstanding the need to provide enough incentives for private actors to innovate in this peculiar field, there is nonetheless an equally pressing need to address other consequences linked to the nature of cumulative innovation. Contrary to the trend that has lowered patentability requirements in order to include biotechnology related innovations within the scope of patent protection; the need to allow public sector agrobiodiversity innovation advocates **stricter patentability requirements** to be set up, in order to avoid anti-commons landscapes in molecular research tools. Especially with regards to the essential assessments of novelty, inventive step and utility criteria, a rigorous approach to patentability could avoid broad formulations or reach-through claims detrimental for future innovative prospects, and prevent the protection of subpatentable innovations. Numerous professional organisations have openly and quite vocally been opposed to broad patents in the life sciences, such as the Biological Innovation for Open Society, the American College of Medical Genetics and the College of American Pathologists in the biomedical field. This wide-ranging inquisition has as a result impacted public researchers active in molecular biology, green biotechnology or public breeding, first indirectly, but also directly, as they have often grabbed the chance to advocate higher standards of patenting in their own fields. This debate has even pushed the large pharmaceutical firm Merck to argue against "locking up the basic structural and descriptive elements of the genome by narrowly held patent protections"[1197]. The approach of applied biotechnology firms has nonetheless remained in the defense of patentability « in the context of producing things », as opposed to those entities with business models mainly focused on DNA sequencing and patenting, such as dedicated start-ups.

Novel, "real" and non-essentially biological inventions

Notwithstanding the challenges posed by the brave wide world of green biotechnology and genomics in terms of inventiveness and industrial application, patentability assessements have step upon the trick of **novelty** in this inherently cumulative and incremental innovation context. The novelty threshold is indeed tricky to properly assess, as it essentially requires one to determine whether follow-on innovations are worthy of protection, despite the fact that they will almost inescapably constitute an incremental contribution to the initial invention. This particular issue echoes at different levels when it comes to patents covering molecular research tools and living organisms. It refers to the need to rigorously establish the existence of **prior art** vis-à-vis previous discoveries or inventions stemming from both the private and public sectors, while also addressing the issue of biological piracy or the appropriation of products of nature or naturally occurring products or processes. In cumulative innovation chains such as biotechnology, the number of forward citations, i.e. the citations received by subsequent patents, just as the number of backwards citations, i.e. those references to patents significantly raise the rate of opposition to

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[1197] More "genomics" oriented private entities indeed are much more moderate in their approach than "biotechnology firms", to which the ownership of a gene is absolutely central in their business plans, see JACKSON, "Innovation and Intellectual Property: The Case of Genomic Patenting," *op.cit.*, p. 14, citing notably ARTHUR L CAPLAN and JON MERZ, "Patenting Gene Sequences," *BMJ: British Medical Journal* 312, no. 7036, 1996. Editorial: Patenting gene sequences. *British Medical Journal*, 312(7036), 926. Available at: http://www.bmj.com/cgi/content/full/312/7036/926. Accessed August 25, 2002.

patents, at least according to a study operated before the European Patent Office[1198]. That is why the criterion of prior art has to be broadly yet meticulously assessed in all legal orders. This evolution is based on the premise that when widely available yet never published knowledge comes to be patented, the monopoly rights granted to titleholders are considered to not "generate research or advance knowledge in any way, [but rather] impose a societal cost, without any corresponding benefit"[1199].

The threshold of novelty has also been quite controversial in biotechnology related patents, because its compounds and processes are, as aforementioned, quite close to **natural phenomena**. That is why lack of novelty has often been brought before opposition procedures in patent offices or in judicial proceedings, arguing that claimed compounds occurred naturally and therefore neither novel nor constitute a non-obvious invention in the sense of patentability requirements. Even though the products of nature doctrine remained an essential milestone of patent protection, the United States judiciary, especially the "Court of Appeals for the Federal Circuit began shaping the law in a manner that allowed patents on naturally occurring phenomena as long as the applicant included the phrase 'isolated and purified' in the specification"[1200]. This shift has ignited a recalibration of the product of nature doctrine, which lost its echo in the criteria of "**invention**", rather than novelty in patents related to living organisms or processes[1201], as the new product ough to to have a different function than the natural product it derived from in order to fall under the "high-water mark" of patentability[1202]. The debate over the stretch of the western understanding of an "invention" faced with living organisms has struck an age-old cord in the discussions over patent eligible subject matter, which rules out in principle the protection of abstract ideas, laws or products of nature, as well as naturally occurring things[1203]. Its traditional definition seems to suffer when confronted to living material, urging legislators to try to shape its contours more precisely.

Faced with the difficult task of transposing European Directive 98/44/EC on the protection of biotechnological inventions, the Belgian legislator attempted to define an invention as

> "*clearly distinguishable from the pure discovery of an element, which exists independent of human intervention, and which can take different shapes, more specifically: a new application, a new method for the creation or isolation of something new or existing, a new product, a new combination of new or known means, and which serves as a guideline to act*

[1198] The study found that the" group of patents receiving more than nine forward citations is in fact attacked in 44.5% of all cases, nearly twice as often as the group of patents which is referenced seven to nine times", DIETMAR HARHOFF et al., "Citation Frequency and the Value of Patented Inventions," *Review of Economics and statistics* 81, no. 3, 1999.

[1199] STIGLITZ, "Economic Foundations of Intellectual Property Rights," *op.cit.*, p.1709, citing the example of the turmeric patent. .

[1200] DEMAINE and FELLMETH, "Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent," *op.cit.*, p. 357.

[1201] Indeed, in biotechnological inventions, it is extremely difficult to operate a distinction between the assessments of the different patentability criteria, a difficulty that is found in judicial decisions, which tend as a result to refer to the three keys as an undivided whole, Ibid.

[1202] REBECCA S EISENBERG, "Patenting the Human Genome," *Emory Lj* 39, 1990., at 725.

[1203] ANDREW BECKERMAN-RODAU, "The Problem with Intellectual Property Rights: Subject-Matter Expansion," *Yale Journal of Law and Technology* 13, 2010., p. 56.

in a certain way by the direct use of controllable natural phenomena to achieve the result that is predictable out of the causes"[1204].

The definition was rejected in the text that was finally adopted, following the advice of the High Council for Industrial Property and the Council of State, as it strayed away from a literal transposition of the Directive and probably disallowed the flexible interpretation that could prevail before the European Patent Office[1205]. As a result of this clear reticence to define the boundaries of patent eligible inventions in statutes, the essential criterion of "invention" itself has been rather put to the dissection table of patent offices and the judiciary faced with biotechnology patents, as aforementioned. The "law of nature" exception has been thoroughly used in cases regarding green biotechnology patents before the judiciary. A prominent case before the United States Supreme Court was asked to consider "*a composition patent that claimed a mixture of naturally occurring strains of bacteria that helped leguminous plants take nitrogen from the air and fix it in the soil*"[1206]. The ability of the bacteria to fix nitrogen was well known, but it could not be used in all crops. The patent applicant combined several nitrogen-fixing bacteria that did not inhibit each other into a single inoculant and obtained a patent. The Court held that the compositionwas not patent eligible because "there was *"no way in which we could call [the bacteria mixture a product of invention] unless we borrowed invention from the discovery of the natural principle itself* "[1207]

The line that has been crossed by the currently applicable patent paradigm between discoveries and inventions is showing even more cracks with regards to isolated and purified nucleotide sequences, even in the United States, more lenient towards the technical nature of patentable inventions. The aforementioned *Myriad Genetics* ruling of the United States Supreme Court[1208], read togather with *Mayo vs. Prometheus,* show the ongoing re-assessment of broad claims that are dangerously close of natural laws and phenomena. The Promotheus ruling was concerned with a process patent, a method that optimised drug dosage, while Myriad's claims covered the "isolated sequences of the relevant gene along with isolated subsections" and "cDNA", which does not normally exist in the body but are rather naturally created through retroviruses. Adopting a parallel reasoning, the Court ruled that the claims involved in these product patents could simply not be viewed as inventions. The initial questions asked in the petition introduced by the Association of Molecular Pathology were indeed whether "*humans genes [were] patentable?*"[1209]. Petitioners did introduce their action because Myriad was granted "a monopoly on clinical testing of ITS genes, which was then blocking avenues of scientific inquiry and creating barriers to scientific progress

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[1204] Draft proposal to modify the Act of 28th March 1984 on Invention Patents, with regard to the patentability of biotechnological inventions, Council of State Report, *Parl. Doc.,* Chamber, 2001-2002, no.50-1886/001, pp.30-73. Translation provided for by VAN OVERWALLE, "Implementation of the Biotechnology Directive in Belgium and Its after-Effects," *op.cit.* pp.892-893.

[1205] Ibid.

[1206] United States Supreme Court, *Funk Brothers Seed Co.v. Kalo Inoculant Co.*, 333 U. S. 127 (1948), at 128-129.

[1207] Ibid, at 132.

[1208] United States Supreme Court, *Association for Molecular Pathology v. Myriad Genetics, Inc*. No. 12–398, June 13, 2013; This case has a long judicial history, having been first heard in 2010 before the Federal District Court in Manhattan, which invalidated the patents on account of the products of nature doctrine. The Court of Appeals then reversed the judgment, only to be brought before the Supreme Court, which on 15th July 2013, sided partly with the petitioners.

[1209] The question also made direct reference to the Mayo ruling, asking whether "the court of appeals err in upholding a method claim by Myriad that is irreconcilable with this Court's ruling in Mayo Collaborative Services. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012)?; *Association for Molecular Pathology v. Myriad Genetics, Inc* , Petition for a writ of certiorari filed on September 25, 2012.

and medical care"[1210]. Already in its dissent to the Court of Appeals judgment, Judge William Bryson had raised concern that "*broad claims to genetic material*" like those of Myriad could become "a *significant obstacle to the next generation of innovation in genetic medicine*". Considering the merits of the case, and

> Considering that *"the central dispute among the panel members was whether the act of isolating DNA—separating a specific gene or sequence of nucleotides from the rest of the chromosome—is an inventive act that entitles the individual who first isolates it to a patent*; the Court "*merely holds that genes and the information they encode are not patent eligible under §101 simply because they have been isolated from the surrounding genetic material"*[1211].

The aforementioned *Myriad* ruling, read in combination with the *Mayo* stance, clearly show the new critical approach of the highest United States judiciary to the question of patent eligible subject matter in innovation heavily relying on living organisms or biological processes, to the dismay of more traditional patent commentators and practitioners[1212].

In a parallel fashion, the **lack of inventive step or non-obvisousness** has also been successfully advocated in different judicial fora. This particular gauge was especially put to good use with regards to the infamous case of Taq polymerase. While the Australian patent office invalidated all claims related to such polymerase, as well as all DNA polymerases from any other *Thermus* species that would act as thermal re-agent in the PCR process, the European Patent Office followed suit and recognised the lack of "inventive step" for the claims held in the similar thermostable enzyme patent[1213]. Both reactions based their findings on previous publications by scientists over the properties of such enzyme[1214]. In the United States, the issue of "non-obviousness" in nucleotide sequences has been challenging the USPTO as early as 1988, where the Federal Circuit asserted that the question remained to determine whether an invention was 'obvious to try' i.e. that it resolved to "explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it"[1215]. The test of non-obvisousness, and especially the role played by the content of prior art was later re-clarified by the District Court, which asserted that if such prior art only suggested an infinite number of possible nucleotide

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[1210] "Are Human genes patentable", Editorial of the New York Times, April 14th, 2013.

[1211] United States Supreme Court, *Association for Molecular Pathology v. Myriad Genetics, Inc*., No. 12–398, June 13, 2013, Opinion of the Court.

[1212] Critcism heavily arose on the nebulous interpretation of §§101, 102 and 103 of the patent act by the Supreme Court, as it "specifically ignored the Government's objective, reasonable and until today correct assertion that any step beyond a statement of a law of nature transforms the claim into one that displays patent eligible subject matter, with issues of whether those steps are known to be properly resolved by 102 and 103", see GENE QUINN, "Killing Industry: The Supreme Court Blows Mayo V. Prometheus," *IP Watchdog* 2012..

[1213] CARROLL and CASIMIR, "Pcr Patent Issues," *op.cit.,* p.12.

[1214] The publications mentioned in the decisions belonged to Russian public scientists KALEDIN, SLIUSARENKO, GORODETSKII, "Isolation and properties of DNA polymerase from extreme thermophylic bacteria Thermus aquaticus YT-1", *Biokhimiia*, 45 (1980), pp.644-651; which built upon the work of CHIEN, EDGAR and TRELA, "Deoxyribonucleic acid polymerase from the extreme thermophile Thermus Aquaticus", *J. Bacteriol.*, 127 (1976), pp.1550-1557.

[1215] United States Court of Appeals for the Federal Circuit, *In Re O'Farrell*, 853 F.2d 894, 898 (1988); but also POLYAKOV and GORYUNOV, "(Non) Obviousness of Claims to Genetic Sequences: Finding the Middle Ground," *op.cit.*, pp. 7-8.

sequences, the claimed gene sequences could not be obvious[1216]. In 2009, the U.S. Patent and Trademark Office decision to reject the claims to cDNA encoding the human "Natural Killer Cell Activation Inducing Ligand" (NAIL) protein, which was grounded on obviousness based on the combined teaching of an existing patent and an academic publication, was challenged before the US Distrct Court[1217]. The judiciary confirmed the Patent Office's approach, which had asserted that the DNA and protein sequences could be obtained by conventional methodologies known to one of skill in the art, and it found that obviousness required a "reasonable expectation of success from previous teachings". The gauge of the inventive step was also put forward in the *Myriad* case. Indeed, the first plaintiff Institut Curie claimed that the gene sequence that was patented was partly based on information from public genome databases, and it would therefore not fill the shoes of an inventive step[1218]. These rulings clearly show the critical shift taken by the judiciary of developed and biotechnology-savvy countries faced with the tricky task of qualifying patent claims relying on living organisms or biological processes as inventions.

The extent to which an invention relying on or consisting of biological material can be considered patentable has not only been addressed through the "positive" patentability requirements as such, but also in the assessment of the ***ad hoc* exclusions from patentability** that have for instance been carved in the European legal order. Determining the real extent of these exclusions has been at times more arduous than others, but their existence has been generally considered to provide an additional safeguard against the wrongful appropriation of discoveries and unjust provision of artificial lead time. These exclusions have at times been quite wide-scoped, extending to the entire range of plant improvement, as the strong paradigm merely dictates that plant varieties be protected through an efficient *sui generis* regime and that microbiological processes befall under patent protection. The Indian legislative order for instance foresees patent protection to processes including substances intended for use as food, medicine or drugs, all the while rejecting the patentability of the substances themselves, and also reducing the duration of the terms of protection in matters related to food, medicine or drugs[1219]. Other national legislators have activated the flexibility of TRIPS article 27§3(b) to exclude plants from patent protection altogether, such as the Andean Pact Countries. The Integration Agreement indeed stipulates that "*the entirety or part of living beings as encountered in nature, natural biological processes, biological material existing in nature or which may be isolated, including the genome or germplasm of any natural living being*"[1220] shall not be considered inventions.

These exclusions need to be carefully drafted in order to stey within the realms of TRIPS minimum standards. Indeed, denying patent protection to plant materials can only be compatible with the TRIPS Agreement provided that the exclusion does not extend to plants with modified or

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1216 United States Court of Appeals for the Federal Circuit, *In Re Bell*, 991 F.2d 781, 783 (1993).
1217 United States Court of Appeals for the Federal Circuit, *In Re Kubin*, 561 F.3d 1351 (2009).
1218 LORI B ANDREWS, "Genes and Patent Policy: Rethinking Intellectual Property Rights," *Nature Reviews Genetics* 3, no. 10, 2002: at p.806.
1219 PHILIPPE CULLET, "Revision of the Trips Agreement Concerning the Protection of Plant Varieties: Lessons from India Concerning the Development of a Sui Generis System " *The Journal of World Intellectual Property* 2, no. 4, 1999.
1220 Andean Community, Subregional Integration Agreement of the Andean Community (Cartagena Agreement), Decision 486 – Common Provisions On Industrial Property, 14th September 2000, Article 15 (b), translation provided by GEERTRUI VAN OVERWALLE, "*Patents in Agricultural Biotechnology and the Right to Food*", Report A/64/170 Seed policies and the right to food: Enhancing agrobiodiversity, encouraging innovation, 2009.

artificial plant gene sequences, which often significantly vary from naturally occurring substances and thus are properly classified as inventions[1221]. They have been primarily used in order to address the dilemma of orphan crops, where the absence of aggressive intellectual property portfolios may ease research and development costs involved in these forgotten acreages. However, the efficiency of such measure, without any additional formal incentive to invest time and effort in overlooked research fields, remains questionable. Indeed, the absence of exclusive rights over products or processes will not on their own trigger active investment in research and development, but it will rather merely contribute to easing the burden of actors that are already inclined to do so, such as public researchers, but also farmers themselves, as we shall tackle in the further course of this study.

In regions with greater biotechnology industry presence, the main interrogation with regards to negative patent eligibility has been the exclusion of "**essentially biological processes**" from protected subject-matter. Especially in the European legal order, the challenge has been to determine whether so-called "native traits" were patentable. This trickier question has shed light on the necessity to grant a stricter interpretation of obviousness and those "essentially biological processes", in order to avoid that the results of a mere screening of wild germplasm carried out at the stage of "pure basic research" be subject to patent protection. In line with the flexibilities offered by the IPR paradigm, "essentially biological processes" indeed fall outside the scope of patent protection both in the European Patent Convention and the EC Directive 98/44, as aforementioned. According to the EPO Guidelines, "biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature" can fall under patent protection, just as "plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety", and also "a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety"[1222]. Recent decisions of the Enlarged Board of Appeal have nonetheless proven the complexity of practical realities[1223]. The issue especially arose with regards to molecular-assisted selection efforts that include complex and technical steps, which might be considered as non-microbiological and thus patentable processes[1224]. The standard definition of the term "essentially biological process stems from the so-called Lubrizol principles studied in Chapter 3 of this study, which views the qualification of a process as 'essentially biological" *on the basis of the essence of the invention, taking into account the totality of human intervention and its impact on the results achieved*"[1225]. These principles were confirmed and further refined by the Technical Board in the 1995 *Plant Genetic Systems* case[1226], which favoured an intermediate approach where "*a process*

[1221] These sequences are indeed significantly different from naturally occurring substances, and would need to be warranted the quality of "inventions", see (LESKIEN and FLITNER, "Intellectual Property Rights and Plant Genetic Resources: Options for a Sui Generis System.", 1997, p. 9).
[1222] OFFICE, "Guidelines for Examination in the European Patent Office."
[1223] QUEST and ZIMMER, "When Is a Process for the Production of Plants "Essentially Biological"? Decisions of the Enlarged Board of Appeal (G1/08 and G2/07)," *op.cit.*, and also BLAKENEY, "Patents and Plant Breeding: Implications for Food Security " *op.cit.*; both analysing the so-called Tomato and Broccoli cases, Enlarged Board of Appeal G1/08 and G2/07.
[1224] KOCK, "Essentially Biological Processes: The Interpretation of the Exception under Article 53(B) of the European Patent Convention," *op.cit.*, pp.286-297.
[1225] Technical Board of Appeal of the European Patent Office, *Hybrid plant/LUBRIZOL*, 10 November 1988, T 320/87, Official Journal of the European Patent Office (1990), at 71.
[1226] Technical Board of Appeal of the European Patent Office, *Plant Cells/PLANT GENETIC SYSTEMS*, 21 February 1995, T 356/93, Official Journal of the European Patent Office (1995), at 545.

involving at least one essential technical step which could not be carried out without human intervention and which had decisive impact on the final result would be patentable". As a result, "a process claim was patentable because even though only the first steps in the production of the plant were to be considered 'non-biological' (e.g. recombinant DNA) these nevertheless had a *decisive* impact *on the final result*, notwithstanding the subsequent 'biological' steps of regenerating and replicating the plants and seeds"[1227]. The two infamous and eagerly awaited cases of "Broccoli and Tomato"[1228][1229] both concerned breeding methods, respectively breeding broccoli with anti-cancerogenic effects, and tomatoes with a trait that allowed the drying of fruits on the vine, allowing for substantial savings, and ignited twenty four amicus curiae submissons to the EPO. The decisions adopted a surprisingly extensive interpretation of statutory exceptions, extending *de facto* their scope to all methods "which contain the steps of sexual crossing", and seem to limit the technical step measurement to those steps that do not enable or assist sexual crossing. This means that all molecular-marker assisted breeding processes will fail to escape the EPC 53(b) exclusion. However, the rulings also clearly state that the claims on the plants obtained through these methods remained valid, if, as aforementioned, the claim is not confined to as specific plant variety. Urged by these rulings and growing discontent over the nebulous approach of the Biotech Directive taking its roots on the interpretative rule 23b(5) of the European Patent Convention, the European Parliament welcomed these decisions and adopted a resolution in May 2012, calling on "the EPO to exclude from patenting products derived from conventional breeding and all conventional breeding methods, including SMART breeding (precision breeding) and breeding material used for conventional breeding"[1230]. It should however be noted that most national legislative orders are still heavily bound by the terms of Article 2.2. of the aforementioned Directive, which ambigiously states that "a process is *essentially* biological if it consists *entirely* of natural phenomena such as crossing or selection". The recent Enlarged Board of Appeals' approach to the European Patent Convention's article 53 (b) seems to indicate that the second gauge of entirety should not prevail over the former. Such an interpretation would definitely immensely contribute to maintain a wider public domain in breeding techniques that are predominantly non-molecular and mostly rely on biological processes with few twists.

Against broad and "undisclosed" claims

Another challenge faced by public researchers relates to the risk of meeting **broad patents in their freedom to operate assessments.** They have in this regard highly benefited from the fact that when the uses of technologies are unknown**,** both legislators and the judiciary have recognised the urging need "to limit the scope of property rights to ensure the necessary balance between

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[1227] TEMMERMAN, *op.cit.*, 2006.

[1228] Referral from Technical Board of Appeal of the European Patent Office, *Tomatoes II/STATE OF ISRAEL*, 3rd March 2004, T1242/06, Official Journal of the European Patent Office (2008), 523.; Enlarged Board of Appeal of the European Patent Office, *Tomatoes II/STATE OF ISRAEL*, 9 December 2010, G1/08, Official Journal of the European Patent Office (2013), 42.

[1229] Referral from Technical Board of Appeal of the European Patent Office, *Broccoli/PLANT BIOSCIENCE*, T 83/05, Official Journal of the European Patent Office (2007), 644. ; Enlarged Board of Appeal of the European Patent Office, *Broccoli/PLANT BIOSCIENCE*, 9 December 2010, G2/07, Official Journal of the European Patent Office (2013), 42.

[1230] European Parliament resolution of 10 May 2012 on the patenting of essential biological processes (2012/2623(RSP)), P7_TA(2012)0202.

seeking to maximise the benefit to society while minimising the amount of property protection necessary to be an adequate incentives to creators"[1231].

In the United States, even though the statutory definition of patentable subject matter in section 101 was considered in its broadest sense to include "everything under the sun", the Supreme Court has nonetheless been generally reluctant towards patents awarded for inventions without known uses or too broadly defined **utility**. As early as in 1966, in *Brenner vs. Manson*, patent protection was denied to a working chemical process patent since the compound produced by such process had no known uses, acknowledging that protection would "confer power to block off whole areas of scientific development, without compensating benefit to the public"[1232]. The reticence over the patentability of inventions with little identified uses has been very much a global reality, leading to a strict approach to the patentability criteria of "utility" or "industrial applicability". The main concerns over the threshold of utility in molecular biology related to the claim covering expressed sequence tags, even though it is extremely difficult to get a clear picture of the potential anti-commons created by stacked patent rights[1233], urging patent offices to adopt clearer guidelines with regards to DNA-related patents. The United States Patent office has in this regard renewed its utility guidelines in 2001, stipulating that the alleged use of the invention ought to be "substantial"[1234]. In a parallel yet a little more intricate fashion, the European Patent Office's guidelines expressly state that

> *"In relation to certain biotechnological inventions, i.e. sequences and partial sequences of genes, the industrial application is not self-evident. The industrial application of such sequences must be disclosed in the patent application"* (European Patent Office Guidelines for Examination, The European Patent Application, Section 4.9, reprised in EPO Implementing Rule 29§3).

These elements show the existence of a seemingly convinced trend that may slowly be inching its way towards the recalibration of standards for granting patents in biotechnology related fields. It is also being reinforced by a reflection on the notion and efficiency of "**disclosure**" in a field such as biotechnology where the person 'notionally skilled in the art' is granted tremendous weight in both assessing the inventiveness and novelty of proposed subject matter. There is indeed inherent uncertainty in molecular biology related patent applications and claims, as their drafting does not necessarily preclude the efficient disclosure of protected inventions.

> "The jurisprudence of the EPO shows that […] in cases where the breadth of the claims exceeds the invention disclosed, the court may apply a broader approach to '**enabled disclosure**', seeking to include an equitable or 'fairness' standard, [within its reading of art.83 and 84 of the EPC]"[1235].

[1231] BECKERMAN-RODAU, "The Problem with Intellectual Property Rights: Subject-Matter Expansion," *op.cit.,* p.49.
[1232] United States Supreme Court, *Brenner vs. Manson*, 383 U.S. 519 (1966)
[1233] Indeed, expressed sequence tags are generally "defined by the way in which the materials are obtained, not by their substance or structure, patent applications rarely use the word EST", making them extremely difficult to identify and track down. It is however certain than over one million applications claiming one or more EST have been filed with the United States PTO in 2000; see WANG, "Biomedical Upstream Patenting and Scientific Research: The Case for Compulsory Licenses Bearing Reach-through Royalties," *op.cit.,* at pp.288-289. And also MARTIN ENSERINK, "Patent Office May Raise the Bar on Gene Claims," *Science* 287, no. 5456, 2000.
[1234] United States Patent Office, Utility Examination Guidelines, 66 Fed. Reg. 1092, 5th January 2001.
[1235] THAMBISETTY, "Patents as Credence Goods," *op.cit.*, pp.716-717.

However, these shifts in patent office practices have their own limitations, notwithstanding the diverging viewpoints on the need and extent to which patentability standards ought to be revised. Patent offices, cannot be asked to "second-guess technology trends" in order to accommodate the standards to the improvements of the technology[1236]. Even when one reflects upon patentability standards in order to adjust them to the needs of public researchers, this questioning fails to address the **information deficit** that is inherent to the patent system as a whole; a deficit that is particularly heightened when faced with complex and rapidly evolving technologies such as biotechnology. The diagnosis was harshened by findings that highlighted that the United States Patent office had "reengineered itself so as to declare its mission to be 'to help its customers get patents'[1237]. The bias, even if only in appearance, had to be redressed; just as the inherent information deficit and high uncertainty that characterise certain technologies, such as biotechnology, where there are high transaction costs involved in gathering information about patent applications and filing oppositions if need be. In this context, an interesting partial market and agrobiodiversity user-oriented solution has been to discuss the opportunity of "peer to patent projects"[1238]. This initiative acts as a community patent review mechanism, and has been the inspiration of the online pre-grant review process that is actively promoted by the USPTO, in order to sthrenghten the quality and validity of claims.

> « The proposal for open patent examination (nicknamed « peer-to-patent ») separates scientific from legal decision-making. By means of an online network, the scientific community provides what it knows best – scientific information relevant to determining the novelty and non-obviousness of a patent application. With her deep knowledge of the pertinent statutory standards, the patent examiner then uses that input to make a legal determination of patentability. In this model, the patent examiner remains the ultimate arbiter »[1239].

This enterprise is an active attempt to levy out the the detrimental consequences stemming from the legal fiction of the person having ordinary skills in the art, assessed in the isolated bureaucracy of patent offices, instead of expert 'academical' input, bringing the best of both worlds. It nonetheless has inherent shortcomings.

> Indeed, « inventors have to consent to review and anyone can be a 'peer-reviewer'. Patent offices unlike top journals with respect to publications are in the business of making it easier for inventors to get patents. Competitors or the public do not bring the same 'self correcting' tensions that reviewers in science are expected to bring. It is therefore questionable whether lessons learnt from journals on removing conflicts of interest can be carefully mapped onto this new process »[1240].

Patent offices can nonetheless try to be attentive to the critical situation of the life sciences, without necessarily taking the mostly favourable but equally uncertain leap of peer patent review.

[1236] CUKIER, "Navigating the Future (S) of Biotech Intellectual Property," *op.cit.*
[1237] MARK A LEMLEY, "Rational Ignorance at the Patent Office," *Nw. UL Rev.* 95, 2000.
[1238] THAMBISETTY, "Patents as Credence Goods," *op.cit.*, p.735.
[1239] BETH SIMONE NOVECK, "Peer to Patent: Collective Intelligence, Open Review, and Patent Reform," *Harv. JL & Tech.* 20, 2006.
[1240] THAMBISETTY, "Patents as Credence Goods," *op.cit.*, p.735.

This cautious approach has been favoured by the European Patent Office, through its policy of "Raising the Bar", which gave particular attention to the standard of the "inventive step". Even though the initiative "may give the impression of an intention to raise patentability standards, […its] intention is, in implementing the Rule changes to the EPC of 1st April 2010, to achieve greater clarity as to the subject matter for which patent protection is sought at the earliest appropriate stage of the procedure in order to improve the focus of the search"[1241].

The burdens of further research on patented compounds seem to be generally alleviated when strict approaches are adopted to assess the qualification of the product or process as an "invention" or to determine prior art, while alternative uses of compounds are considered to comply with patentability requirements so as to foster due investment in costly research but avoid reach-through monopoly rights. However, the legal demarcations concerning the artificial allocation of rights taking into account both initial and follow-on innovative efforts have not been and cannot ever be a linear and straightforward affair limited to the issue of patentability. Considering the inherent difficulties regarding the amendment or merely the strict application of patentability requirements in the life sciences, there may be "one reform where the public sector, academia and industry ought to be able to find common ground: establishing a research exemption from infringement on gene-related patents"[1242].

*12.1.2. **<u>Bundle of fair patent rights: patent width and the research exception</u>***

The most contentious issue that was raised by public scientists involved in biodiversity-related innovation, but also by private plant breeders, relates to the scope of protection and the bundle of rights that come with the grant of patents on research tools. Indeed, as aforementioned, if the scope of prerogatives and claims are too wide and all encompassing, there is a clear risk of creating anti-commons effects on subsequent sequential innovation. The boundaries set out by the TRIPS Agreement nonetheless seem to leave enough manoeuvre margin to attenuate undesirable effects of enclosure in public green biotechnology and plant breeding.

<u>Protecting the claim, and only the claim</u>

A central challenge relating to the broadness of claims stems from the diverging principles surrounding the **interpretation of patent claims** itself. While the United Kingdom has been known to interpret claims quite literaly, Germany tends to interpret claims broadly especially when determining the existence of literal infringement, against the background of a flexible EPC doctrine of equivalents adopted through the "Protocol on the Interpretation of Article 69 of the EPC". When a broad doctrine of equivalents is withheld, the balance of the patent paradigm shifts from the public interest to the protection of the inventor against subsequent alternative uses of his or her invention. That is why countries such as the United Kingdom have for instance developed a reading of the EPC favouring the latter public interest, through a formula of "purposive construction" that seeks all the elements of the claim in the alleged infringing product[1243]. In the United States, the Federal Circuits court unanimously recognised the validity of a reverse

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[1241] JOHN BEATTY, "The European Patent Office 'Raising the Bar' Initiative," *World Patent Information* 33, no. 4, 2011.
[1242] CUKIER, "Navigating the Future (S) of Biotech Intellectual Property," *op.cit.,* p.251.
[1243] Ralston, William T. "Foreign Equivalents of the US Doctrine of Equivalents: We're Playing in the Same Key but It's Not Quite Harmony." *J. Intell. Prop.* 6 (2006): 177., at 183.

equivalents defence against literal infringement allegations. This interpretation stems from the traditional doctrine of equivalents, which in essence states that if the patented invention and the alleged infringing one are nearly identical, patentability requirements would not be met. In this context, “an innovation may infringe a patented invention if the innovation performs substantially the same function as the patented invention in substantially the same way to obtain the same result”[1244].

> Drawing from such precept, “the law acknowledges that one may only appear to have appropriated the patented contribution, when a product precisely described in a patent claim is in fact '*so far changed in principle*' that it performs in a '*substantially different way*' and is not therefore an appropriation”[1245], upholding to the doctrine of reverse equivalents.

This doctrine has been used to justify the white flag granted to an allegedly infringing DNA sequence that was “so far changed” from the patented sequence that it performed the function (whether the same or a similar one) “in a substantially different way”[1246]. Even though this construct allows improvements to be patented, it would nonetheless not affect the original patentee’s rights, who may use the patent as a “holdup right”, in order to “garner as much value as possible”[1247]. The doctrine of reverse equivalents stands on “an economic rationale for improvement patents [that] stresses their tendency to encourage bargaining between improvers and original patentees, [who would cross-license their technologies], to gain access to the improved [and cost-saving] technology”[1248]. The stretch of the doctrine with regards to the threshold of novelty in biotechnology patents is quite straightforward for follow-on users. The line that is been walked on is nonetheless quite a delicate one here, and relies heavily on claim interpretation and the role of equity in common law jurisdictions.

In this context, the doctrine of **patent misuse** has a longstanding history, especially in common law traditions. It is generally accepted to occur when « the patentee has impermissibly broadened the physical and temporal scope of the patent grant with anti-competitive effect »[1249]. According to this doctrine set out first in 1964 in the United States[1250], practices that extend the royalty term beyond the patent’s expiration do constitute *per se* misuse.

> « There has been a long-standing debate over whether the misuse defense should be available only in circumstances in which the patentee has violated anti-trust laws. Patent

[1244] LINDA J DEMAINE and AARON XAVIER FELLMETH, "Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent," *Stanford Law Review*, 2002., p. 453.

[1245] United States Court of Appeals for the Federal Circuit, *SRI International v. Matsushita Electric Corp. of America*, 775 F.2d at 1123, 227 U.S.P.Q. (1985)., at 587.

[1246] United States Court of Appeals for the Federal Circuit, *Scripps Clinic & Res.Found v Genentech*, 927 F.2d 1565 (1991).

[1247] MERGES and NELSON, "On the Complex Economics of Patent Scope," *op.cit.*

[1248] Ibid.

[1249] MAUREEN A O'ROURKE, "Toward a Doctrine of Fair Use in Patent Law," *Columbia Law Review*, 2000., p. 1195.

[1250] United States Supreme Court, *Brulotte v. Thys Co.*, 379 U.S. 29, 32 (1964). The Court ruled that « a patent empowers the owner to exact royalties as high as he can negotiate with the leverage of that monopoly. But to use that leverage to project those royalty payments beyond the life of the patent is analogous to an effort to enlarge the monopoly of the patent by tieing the sale or use of the patented article to the purchase or use of unpatented ones”.

misuse case-law is largely, but not entirely, co-extensive with anti-trust doctrine ; certain conduct can constitute patent misuse but does not violate the antitrusr laws »[1251].

A number of lawsuits have been filed against Monsanto for "patent misuse," but to date these legal claims have been unsuccessful, just as they have rather been concerned with allegations made by farmers and not public researchers or direct competitors, leaving the issue to be debated in the ethical realm [1252]. Trying to limit rather than annihilate "reach-through" royalty seeking mechansisms, a number of countries have rather more straightforwardly provided for a **purpose-bound restricted protection** to biodiversity-linked patents, especially that of genetic sequences. This response has been cast in statutes in Europe, where the *ad hoc* legislative framework has shifted to define the scope of enforceable rights by adjusting in effect the definition of protected subject-matter in patents covering living or replicating organisms. A report prepared by the European Commission in 2005 with the assistance of an expert group addressed the epinous

> "*question of whether patents on gene sequences (DNA sequences) should be allowed according to the classical model of patent claim, whereby a first inventor can claim an invention which covers possible future uses of that sequence, or whether the patent should be restricted so that only the specific use disclosed in the patent application can be claimed ("purpose-bound protection")*"[1253].

Indeed, the text of the European Biotech Directive seemed to operate a distinction in its article 9 for gene patents, since

> "*the protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product in incorporated and in which the genetic information is contained and performs its function*".

On this particular subject the Commission remained cautious, stating that even though valid arguments for a purpose-bound protection may be put forward in the name of the freedom of research,

> "*it may be questionable whether attempting to further refine the scope of protection of gene sequence patents in the light of divergences between national legislations will have any significant effect on actors in the field*"[1254].

The issue of purpose-bound protection was put to its widest stretch in a recent dispute opposing Monsanto and the Argentinian government with respect to round-up ready (RR) soybean, which was not protected under a patent in the Argentinian legal order but in the European Union and the United States. In a move that has been coined "a handbook case of the so-called 'strategic litigation"[1255], the company argued that the import of RR soymeal, even if not intended for cultivation, was infringing upon its exclusive artificial monopoly in the EU market since the

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[1251] MARK A. LEMLEY, "Beyond Preemption: The Law and Policy of Intellectual Property Licensing," *California Law Review* 87, 1999., p.152.

[1252] GARY E. MARCHANT, "Genomics, Ethics and Intellectual Property," in *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*, ed. A. KRATTIGER, R.T. MAHONEY, and NELSEN L., MIHR: Oxford, U.K., and PIPRA: Davis, USA.: 2007., p. 35.; referring to United States Court of Appeals for the Federal Circuit, *Monsanto Co. vs Mitchell and Eddie Scruggs*, 04-1532, 05-1120 and 1121, (2006).

[1253] Report from the Commission to the Council and the European Parliament - Development and implications of patent law in the field of biotechnology and genetic engineering (SEC(2005) 943), COM/2005/0312 final, point 2.1.

[1254] Ibid.

[1255] CARLOS CORREA, "The Monsanto Vs. Argentina Dispute on Gm Soybean," *Third World Resurgence* 203, 2007.

soymeal contained the DNA sequence that was the object of its patent claim. As the case was brought before the European Court of Justice, Attorney General Medozzi argued that

> "It seems irrefutable that Article 9 of Directive 98/44 is a rule for the extension of patent protection. That provision is based on the assumption that the patented DNA is protected as such, and extends that protection to cover also, in certain circumstances, the 'material' in which the DNA sequence is contained, provided that the DNA information is performing its function. Since it is common ground that, being only a residue, the patented DNA sequence does not perform any function within the soy meal, the additional protection under Article 9 cannot be relied on in the present case."[1256]

The Court followed suit, stating that *"Article 9 of Directive 98/44 on the legal protection of biotechnological inventions is to be interpreted as not conferring patent right protection in circumstances such as those of the case in the main proceedings, in which the patented product is contained in the soy meal, where it does not perform the function for which it is patented, but did perform that function previously in the soy plant, of which the meal is a processed product, or would possibly again be able to perform that function after it had been extracted from the soy meal and inserted into the cell of a living organism. That interpretation is supported by the wording of Article 9 of the Directive, which makes the protection it provides for subject to the condition that the patented DNA sequence performs its function in the material in which it is incorporated."*[1257]

Drawing from the drafting history of the Directive, authors have approached this reading of Article 9 quite critically, since the extension of patentability was set out in order to "avoid exhaustion of the patentee's rights by first-sale exhaustion, the legislator needed to clarify that the patent protection should extend as long as the characteristics caused by the invention existed"[1258]. The Judgment also raised concern as "an accused infringer may deny infringement by simply asserting that the patented sequence does not perform its function at the time of alleged infringement because many geens are only temporarily functional or only functional in certain tissues or organs"[1259]. As a result of such approach, "the enforceability of patent claims directed to isolated nucleotides used as reagents, such as reagents in diagnostic methods, are also put at significant risk by the ECJ's opinion"[1260]. The author believes that such shift towards a purpose-bound protection does on the contrary counterbalances and prevents the vertiginous extension of patent protection scope in the strong paradigm. It may allow public researchers (but also private plant breeders) to develop new products or processes that could inadvertedly contain patented gene sequences without making active use of the patented function. The judgment has in this regard been praised as to its positive effects on Brazilian and Argentinian agriculture, questioning the licensing

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[1256] European Court of Justice, *Monsanto Technology LLC v Cefetra BV and others*, Case C-428/08, Opinion of Attorney General Mengozzi of 9th March 2010, para 27.

[1257] European Court of Justice, *Monsanto Technology LLC v Cefetra BV and others,* C-428/08, Judgment, 6th July 2010, para 46 to 50.

[1258] MICHAEL A KOCK, "Purpose-Bound Protection for DNA Sequences: In through the Back Door?," *Journal of Intellectual Property Law & Practice* 5, no. 7, 2010.

[1259] VID MOHAN-RAM, RICHARD PEET, and PHILIPPE VLAEMMINCK, "Biotech Patent Infringement in Europe: The Functionality Gatekeeper," *J. Marshall Rev. Intell. Prop. L.* 10, 2010.

[1260] Ibid, p.551.

agreements that were imposed by Monsanto on a technology that was not protected by a patent, changing "the balance of power between national and international actors"[1261].

However, the actual reach of these adjustments focusing on claim interpretation and purpose-bound protectional boundaries can easily be circumvented through new tactiques in the management of intellectual property portfolio, and proficient claim drafting techniques. Their impact can also be questioned in absence of a sound research or experimental use exception that would allow third party researchers to actually use the invention in their research and development programs in the first place.

The experimental use or research exception

One of the main and strongest defences that could be and has been used by public researchers to avoid infringing third party intellectual property in their endeavours indeed lies in the so-called **research or experimental use exception**. In legal frameworks where the research exception is absent from statutes or very strictly defined by the judiciary, follow-on innovators, or even scientists who wish to better understand the underlying mechanisms, or who wish to build mere knowledge upon protected inventions, can be completely stripped of latitude in their everyday actions. This has very infamously been the case the patents held by Myriad Genetics on the BRCA1 and BRCA2 compounds used in genetic tests and cancer therapy, as all testing on and with the inventions were disallowed, except for those conducted Myriad's own laboratories[1262]. Uncertainties over the existence and exact reach of research exceptions remain extremely worrying in green biotechnology, since the essence of genomics science itself does not allow follow-on users and innovators to "work-around" the protected invention. Indeed, it is inherently impossible to find substitutes to compounds and even to a certain extents processes in biotechnology.

> "Exceptions are in their nature limitations on rights and so, one would have thought, replacing exclusions with exceptions involves replacing a rights-free environment with one in which rights are granted but are limited. Conceptually, that involves a necessary diminution of the public domain. Not surprisingly, therefore, advocates of the public domain in science have typically argued for exclusions"[1263].

That is why the adjusments warranted by public researchers have not only operated on the patentability exclusions as such, but also on the exceptions to the rights conferred. In this context, the opportunity to provide for either an *ad hoc* or a general research exception in the bundle of exclusive patent rights follows suit from Article 30 of TRIPS, which allows Member States to

> "*provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and*

1261 MARCELO DIAS VARELLA, PINTO MARINHO, and MARIA EDELVAEY, "Contesting Monsanto's Patents on Life: Transnational Juridical Dialogue and the Influence of the European Court of Justice on Soybean-Exporting Countries," *Tulane Journal of Technology & Intellectual Property* 16, 2013.

1262 WANG, "Biomedical Upstream Patenting and Scientific Research: The Case for Compulsory Licenses Bearing Reach-through Royalties," *op.cit.,* p.295.and also MATTHEW RIMMER, "Myriad Genetics: Patent Law and Genetic Testing," *European Intellectual Property Review* 25, 2003.

1263 LIONEL BENTLY, "Exclusions from Patentability and Exceptions to Patentees' Right: Taking Exceptions Seriously," *Current Legal Problems* 64, 2011.

do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties" (TRIPS, Article 30).

It should be noted that Article 30 exceptions should not result in "a substantial curtailment" of the patent owner's exclusive rights[1264]. This strict interpretation has led scholars to conclude "the commercial acts allowed under a traditional breeders' exemption would "conflict with a normal exploitation of the patent"[1265] and would thus be inconsistent with article 30. As aforementioned, each national intellectual property system has its own voice on this particular subject, and positions remain patchy, even in Europe, where national laws have been considerably unified through the European Patent Convention and the late attempts to create a Unitary patent. In the United States, the research exemption is not even part of patent statutes, but has been rather restrictively carved by the judiciary. Arguably, this type of common law exception is also prevalent in Australia, where the 1990 Patents Act does not expressly provide for a general infringement defense for experimental uses[1266].

The existence and reach of the research exception is defined **statutorily** in certain legal orders. For instance, article 53 of the Andean Pact limits the scope of patent rights by leaving certain acts outside of the patentee's monopoly, such as those

"*carried out in a private circle or for non-commercial purposes, exclusively to experiment with the subject matter of the patented invention, [and finally those carried out] exclusively for the purposes of teaching or scientific or academic research*"[1267].

As for the European legal order, the reach of the research exception seems to follow the precepts enacted in article 27 of the Community Patent Convention, even though the instrument has not been ratified[1268]**.** Both the European Patent Convention and the EC Directive 98/44 on biotechnological inventions remain particularly silent on the subject, leaving the issue to be dealt with by the national legislator and judiciary. However, such civil-law-akin approaches to regulation have not in any shape or form prevented vigorous debates over the exact reach and strength of such exception.

1264 World Trade Organisation Dispute Settlement Body, *Canada - Patent Protection of Pharmaceutical Products (Generic Medicines)*, WT/DS114/R, 17 March 2000, para. 7.36. The case was brought by the European Communities against provisions of Canadian patent law, which were designed to ensure the swift commercialisation of generic medicine at the end of patent protection terms. As a result, the statutes established a so-called "regulatory review exception", which allowed the use of patented pharmaceuticals in order to obtain authorisation before the expiry of the patent term. This particular exception was considered to be in conformity with TRIPS minimum standards, whereas the "stockpiling exception", which allowed competitors to manufacture and stockpile patented goods during a certain period before the patent expires, "substantially curtailed the exclusionary rights required to be granted to patent owners under Article 28.1 to such an extent that it could not be considered to be a limited exception within the meaning of Article 30 of the TRIPS Agreement".

1265 HELFER, "Intellectual Property Rights in Plant Varieties: An Overview with Options for National Governments.", section 2.3.2.6. *Exceptions and limitations*

1266 NOTTENBURG, PARDEY, and WRIGHT, "Accessing Other People's Technology for Non–Profit Research," *op.cit.*, p.395.

1267 Andean Community, Subregional Integration Agreement of the Andean Community (Cartagena Agreement), Decision 486 – Common Provisions on Industrial Property, 14 September 2000, Article 53.

1268 In 1998, ten countries had already introduced the provision textually into their national legal orders, see CORNISH, "Experimental Use of Patented Inventions in European Community States," *op.cit.*

Even though there is seemingly "a general consensus that the exemption applies irrespective of the way the patented subject matter has been put into operation and the place of the experiment, be it a public laboratory, hospital or a private company, […] doubts arise about the scale, nature (experiments 'on' versus experiments 'with' the patented subject matter) and final purpose of the experiment (commercial versus non-commercial)"[1269].

A number of public science organisations have raised alarm bells as to the lack of certainty concerning the extent of the research exception, such as the Royal Society, a self-governing fellowship based in the United Kingdom, which urged governments "to consider clarifying and harmonising the existing exemptions for 'private and non-commercial' and 'experimental' use"[1270]. The reach of the exception is indeed extremely varied from one Member State to another. Belgium has for instance opted for a much wider understanding of such exception, as the 2005 amendment of article 28§1(b) of the patents law has strayed away from "experimental use" vocabulary, stating rather that the bundle of patent rights does not extend to "*acts accomplished for scientific purposes on and/or with the object of the patented invention*"[1271]. This move came after an initial condemnation of the country by the European Court of Justice for failing to implement the so-called Biotech Directive, in an attempt "to regulate and curtail the (far reaching and possibly negative) effects of [biotech] patents, through the introduction of two additional measures which exceed the strict finality of the Directive[1272]. In Germany, the research exemption is provided for by Section 11 No. 2 of the Patent Act, which reads "*the effects of the patent shall not extend to […] acts done for experimental purposes which are related to the subject matter of the invention*". The German Supreme Court has on another scale exempted "all experimental acts as long as they serve to gain information and thus to carry out scientific research into the subject-matter of the invention, [even extending] to possible new uses hitherto unknown"[1273]. This approach focuses on the notion of "subject-matter of the invention", and even though it is seemingly extended, it also highlights that the product or process may not be solely used as a tool, as these acts would not lead to dependent patents. In this reading, all uses that would fail to trigger another border of control and compensation for the initial patentee need to be left outside the scope of the research exception.

On another note, the English Patents Court rather considers "whether the immediate purpose of the transaction was to generate revenue or not"[1274]. In light of "evidence from the United States that one out of six research projects is stopped or never started because of intellectual property rights", but also because of the unclear nature of the research exception in national United Kingdom statutes, and the fact that such exception is "not widely used and in need of reform"; a consultation was launched in 2008 by the Intellectual Property Office[1275]. One of the models proposed was drawn from Switzerland, "which promotes the pursuit of knowledge about the object of an

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[1269] VAN OVERWALLE et al., "Models for Facilitating Access to Patents on Genetic Inventions," *op.cit.,* (at p.143).
[1270] The Royal Society, "Keeping Science Open: the Effects of Intellectual Property Policy on the Conduct of Science", London, April 2003.
[1271] Article 28§1(b) of the law on patents dated as of 28 March 1984, as modified by the law dated as of 28th April 2005, *M.B.,* 13th May 2005; see also VAN OVERWALLE, "Van Groene Muizen Met Rode Oortjes: De Eu-Biotechnologierichtlijn En Het Belgisch Wetsontwerp Van 21 September 2004 " *op.cit.,* pp.357-386.
[1272] "Implementation of the Biotechnology Directive in Belgium and Its after-Effects," *op.cit.,* at p.890.
[1273] MACQUEEN et al., *Contemporary Intellectual Property: Law and Policy op.cit.,* Second edition, pp.502-503.
[1274] Ibid.
[1275] *Contemporary Intellectual Property: Law and Policy op.cit.,* Second edition, pp.503-504.

invention, exempts only non-commercial purposes and specifically allows the use of the invention for teaching purposes"[1276]. A quite recent case before the High Court of England *CoreValve Inc v Edwards and Lifesciences*[1277] appears to have broadened the research exception by permitting the unlicensed use of the subject matter of the patent until the breaking point of revenue generation[1278].

There seems to be a general European trend to enshrine a relatively broad research exception under national patent laws. However, the recently signed Unified Patent Court Agreement[1279] has seemingly limited research exemptions narrowly to those required by EU Directives.

The Agreement's article 27 indeed deals with those "limitations of the effects of a patent":

> *"The rights conferred by a patent shall not extend to any of the following:*
> *(a) acts done privately and for non-commercial purposes;*
> *(b) acts done for experimental purposes relating to the subject-matter of the patented invention;*
> *(c) the use of biological material for the purpose of breeding, or discovering and developing other plant varieties*" (Unified Patent Court Agreement, Art.27).

This approach may lead to wider exemptions for national patents, as well as for European Patents that are not opted out of the Unified Patents Court when it comes into effect. Nonetheless, the third indent of the disposition does hint at a European-wide consensus on the need for a broader exception when faced patents in green biotechnology. This is especially good news for public researchers involved in plant breeding, even though the Agreement's wording does not provide more legal certainty or clarity to public researchers active in molecular biology or genomics. The derogatory regime established for plant breeding extends to all product patents, since it is the exclusive right conferred by such patent that should not extend to the use of biological material for breeding new varieties. Therefore, patents on isolated genetic sequences or expressed sequences tags would not warrant royalties to its innovator at the stage of breeding. With regards to the more classical research exception, the gauge of experimentation "relating to the subject-matter" of the invention is maintained, together with its ambiguous yet also convenient boundaries.

Other legal orders, generally those inscrive in common law traditions, prescribe a **judicial exception** as a defense mechanism against infringement. On the other side of the Atlantic, the position of the United States judiciary has been drastically reviewed to its lowest possible denominator in 2002, "reducing the effectiveness of the [experimental use] defence to next to nothing"[1280]. The Appellate Court has in *Madey vs. Duke* considerably limited the scope of the research exception to uses for "amusement, to satisfy idle curiosity, or for strictly philosophical

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[1276] Ibid.

[1277] High Court of England, *Corevalve Inc v Edwards Lifesciences AG & Ano*r, Court of Appeal - Patents Court, January 09, 2009, [2009] EWHC 6 (Pat)

[1278] YAHONG LI, "Intellectual Property and Public Health: Two Side of the Same Coin," *Asian Journal of WTO & International Health Law & Policy* 6, no. 2, 2011. And also EVANS MISATI and KIYOSHI ADACHI, "*The Research and Experimentation Exceptions in Patent Law: Jurisdictional Variations and the Wipo Development Agenda*", 2010.

[1279] Council Agreement on a Unified Patent Court, *OJC*, 20th June 2013, 175/01, 2013.

[1280] MACQUEEN et al., *Contemporary Intellectual Property: Law and Policy op.cit.*, Second edition, p.503.

inquiry"[1281] which would be the only acts falling under the realm of the 35 USC statutory exceptions. The Court furthermore not only reversed the burden of proof of such experimental use, to be viewed as an "affirmative defence" where elements should be brought forward by the defendant, but it also considered that the "intent" element could not be solely satisfied through the non-profit status of the defendant[1282]. Evidence of the uses made with the patented invention and the subsequent gains ought thus to be considered when assessing the existence of infringement. The US Federal District's restrictive approach to the two hundred years old judicially created exception has as a result been criticised in its characterisation of university research as "driven by business interest in competing for prestige, students and research grants"[1283]. The rule of "business furtherance" supported by the *Madey* decision in effect means that "scientists working in any institute that embraces a purpose for advancing the progress of even basic science will be expelled from the realm of experimental use"[1284]. In fields where no statutory exception such as the so-called Bolar exception on early-on upstream research exists, this restrictive judiciary understanding means that an initial discoverer has the ability to control the entire stream of research and development down the patent line[1285]. It is nonetheless difficult to assess the exact reach of the experimental use defense when it is solely carved in judicial decisions.

> "Since experimental use becomes an issue only in infringement actions, judicial pronouncements on its reach address situations where patentees have found a defendant's activities sufficiently annoying to be worth the trouble of pursuing a lawsuit. The factor has undoubtedly skewed the universe of experimental use decisions towards cases that implicate commercial interests. Within this universe, the experimental use defense is frequently raised and rarely sustained"[1286].

In light of the extremely narrow and also uncertain nature of this judicially created exception and its unavailability in most practical circumstances, some commentators have urged for its **replacement by "a legislative exemption** that carefully balances the competing policies behind the patent system"[1287]. They have urged Congress to overrule this threat to scientific progress by

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[1281] United States Court of Appeals for the Federal Circuit, *Madey vs. Duke*, 307 F.3d 1351 (2002). The Trial Court had taken a wider stance, relying on the "commercial purpose" criteria that had been favoured beforehand. Madey would have indeed needed to establish that the University was using the patent for "definite, cognizable, and not insubstantial commercial purposes."

[1282] "Regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative".

[1283] SAUNDERS, "Renting Space on the Shoulders of Giants: Madey and the Future of the Experimental Use Doctrine," *op.cit.*

[1284] WANG, "Biomedical Upstream Patenting and Scientific Research: The Case for Compulsory Licenses Bearing Reach-through Royalties," *op.cit.*, at p.263.

[1285] The so-called Bolar or regulatory exception exonerates "studies and trials with a view to satisfying the abbreviated regulatory approval process for generic medicines" from the authorisation of rightholders, and is found on numerous different legal order, see WILLIAM RODOLPH CORNISH, *Intellectual Property: Omnipresent, Distracting, Irrelevant?* : Oxford University Press, 2004, at p.30., but also WIPO, *op.cit.*, 2011 (18th March). , Annex I, TRIPS flexibilities, pp. 273-284.

[1286] EISENBERG, "Proprietary Rights and the Norms of Science in Biotechnology Research," *op.cit.*, pp.219-220.

[1287] DEFRANCO, LEVY, and POGACH, "The Experimental Use Exception: Looking Towards a Legislative Alternative," *op.cit.*

amending patent statutes with a viable exception for academic and non-profit institutions[1288]. The National Academy of Sciences (NAS) has followed suit by recommending that Congress amend the patent statute to permit experimental uses of patented inventions in limited circumstances[1289], a proposal that was also supported by the American Intellectual Property Law Association[1290]. The NAS report went on to state that

> "in view of the academic research community's belief in the existence of such an [experimental use] exemption, and behaviour accordingly, there should be some level of protection for non-commercial uses of patented inventions. Congress should consider appropriately narrow legislation, but if progress is slow or delayed the Office of Management and Budget and the federal government agencies sponsoring research should consider extending "authorization and consent" to grantees as well as contractors, provided that such rights are strictly limited to research and do not extend to any resulting commercial products or services. Either legislation or administrative action could help ensure preservation of the "commons" required for scientific and technological progress"[1291].

This stance was supported by legal professionals, who "endorsed legislation which would serve to exempt from infringement research that is directed to any of the following activities: (1) evaluating the validity of the patent and the scope of protection afforded under the patent; (2) understanding features, properties, inherent characteristics or advantages of the patented subject matter; (3) finding other methods of making or using the patented subject matter; and (4) finding alternatives to the patented subject matter, improvements thereto or substitutes therefor"[1292.]

In view of the vulnerability ignited by the current operation of the patent system when faced with a lack of potential of work-around possibilities, "providing a research exemption is in everyone's interests – and is a low impact solution to a high impact problem"[1293]. The Congress, through the so-called Hatch-Waxman Act, provided for such a statutory research exemption in 1984, but limited its scope to research for the purposes of drug development, even though its scope has been viewed as quite broadly by the judiciary, stretching its range to the use of patented inventions in preclinical research the results of which are not included in an official submission[1294]. The reluctance of the United States Congress to draft a broader research exception similar to those recognised on the Old Continent is rooted in arguments raising against a wider interpretation of the judicial exception itself, and therefore against a statutorily carved right for follow-on users. These criticisms are not limited to such common law traditions, and have to a certain extent also resulted in a more global suspicious probe over the detrimental effect of the existence of a research

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[1288] SEWELL, "Rescuing Science from the Courts: An Appeal for Amending the Patent Code to Protect Academic Research in the Wake of Madey V. Duke University," *op.cit.*

[1289] SCIENCES, *op.cit.*, 2004.

[1290] The rationale for the Association's support for the NAS proposal is stated as follows: "failing to have a definitive provision in the patent law exempting experimentation can create many potential adverse consequences, including threatened patent litigation, complicated licensing negotiations, efforts to secure compensation based upon the fruits of any experimentation (including "reach-through" royalties), royalty stacking, and delays in starting experiments until patent issues can be resolved"; see ASSOCIATION, *op.cit.*, 2004.

[1291] SCIENCES, *op.cit.*, 2004.

[1292] ASSOCIATION, *op.cit.*, 2004.

[1293] CUKIER, "Navigating the Future (S) of Biotech Intellectual Property," *op.cit.*

[1294] VAN OVERWALLE et al., "Models for Facilitating Access to Patents on Genetic Inventions," *op.cit.*, p.144.

exception itself. Some commentators assert "because academic institutions are increasingly benefiting from the patent system, they should also be held accountable when they infringe the patents of others"[1295]. But the main argument set forward by opponents of a broad research exception lie in the fact that such enlarged unlicensed use opportunity might diminish the incentive function of exclusivity granted to innovators who lack natural lead-time in the competitive marketplace. Reducing the incentive value of patents would then result in a decrease in innovation or a shift away from the disclosure of inventions, with greater resort to trade secrecy[1296]. This particular aspect is heightened by the fact the discernement of infringement with regards to research tools is particularly high, since these will not necessarily be present at the moment of commercialisation or in the final outcomes of research, unless the end products of scientific publications make express reference to the protected tools[1297].

Commentators have argued that a broad research exception should be accepted, except when the tools could be readily available on the market, whether sold through a catalogue or through other means allowing the transaction to occur in all anonymity, which as a result levy the obstacles raised vis-à-vis the access to protected tools[1298]. This approach would really highlight that the main rationale for the recognition of a broad experimental use exception lies in the acknowledged risk of anti-commons in an overly restrictive and aggressive patent landscape in complex, cumulative and incremental technologies. Other adjustments have also been advocated in order to counterbalance the disincentive occasioned by divesting a patent owner's injunctive remedy, notably by creating the opportunity for a sufficiently generous after-the-fact monetary award, as in the case of **liability rules** with reach-through provisions[1299]. Jerome REICHMAN designs an improved and rational set of liability rules, which would overcome the long-term disutilities that result from the progressive inability of ancillary liability rules to duly foster innovation by restoring the “historical buffer zone between IPR and free competition”[1300]. Such challenge would be managed according to the author by providing sufficient artificial lead time to the innovator, as well as allowing for the conditional reverse engineering of the innovation to develop socially desirable new products based upon former human advancement. Correcting the failures of traditional trade secret principles, these new rationalised liability rules would reward and stimulate innovators by overcoming the lack of natural lead-time available to them through a "limited, non-exclusionary form of relief", enabling second-comers to use sub-patentable inventions to develop innovations of their own, "on the condition that they contribute directly or indirectly, to the first innovators' research and development costs"[1301]. The author believes that a carefully and clearly

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[1295] DEFRANCO, LEVY, and POGACH, "The Experimental Use Exception: Looking Towards a Legislative Alternative," *op.cit.*

[1296] JORDAN P KARP, "Experimental Use as Patent Infringement: The Impropriety of a Broad Exception," *Yale LJ* 100, 1990.

[1297] WANG, "Biomedical Upstream Patenting and Scientific Research: The Case for Compulsory Licenses Bearing Reach-through Royalties," *op.cit.*, p.303.

[1298] OFER TUR-SINAI, "Cumulative Innovation in Patent Law: Making Sense of Incentives," *Idea* 50, 2009: at 577-578.

[1299] JANICE M MUELLER, "No Dilettante Affair: Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools," *Wash. L. Rev.* 76, 2001: p.41.

[1300] REICHMAN, "Legal Hybrids between the Patent and Copyright Paradigms," *op.cit.*, but also REICHMAN, "Saving the Patent Law from Itself: Informal Remarks Concerning the Systemic Problems Afflicting Developed Intellectual Property Regimes," *op.cit.*, and REICHMAN and MASKUS, "The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods," *op.cit.*

[1301] REICHMAN, "Legal Hybrids between the Patent and Copyright Paradigms," *op.cit.*

drafted statutory research exception would achieve the same result, if designed to trigger a truly equitable and transparent liability rule mechanism.

As aforementioned, acting both on the patentability of certain products or processes, while also addressing the issue of infringement linked to patent breadth, are both necessary when it comes to plant innovation, where the innovation environment and the implementation of intellectual property rights have proven detrimental for researchers carrying out their activities in a publicly-funded environment. However, both these actions possess important shortcomings to address the "intertemporal externality of cumulative innovation where the first invention stems from basic research and constitutes a so-called research tool that is not directly of interest to final users"[1302]. These lacunas have been mainly demonstrated by economic analysis of IPR regimes[1303], and have urged both legal commentators and policymakers to consider alternatives, such as compulsory licensing mechanisms or liability rules systems. Indeed, an internationally recognised wide-reaching academic research exemption for biological research tools might not, according to certain commentators, properly discourage universities' institutional administrators from pursuing strong exclusive rights and licensing strategies[1304]. Strategies should therefore be envisaged on several fronts, ranging from more traditional legislative amendments to intellectual property rights legislation to indirect attempts on actors' practices to enlarge the public domain, and having perhaps also recourse to more institutional solutions to the same end.

12.2. <u>Acting on licensing practices to facilitate access to patented technology and disseminate research results</u>

The award of monopoly rights does not in itself prevent the dissemination of technological advances at all. They are on the contrary designed to ensure that inventive solutions are disclosed and most of all, used by many, all the while compensating the innovator for its productive and socially beneficial ideas and investment. Reflexive practices can therefore guarantee the availability of the technology either through business partnerships, broad corporate licensing practices, adaptive licensing strategies or a sensible restraint in filing lawsuits against infringing researchers. Such guarantee could even survive under an increasingly shrinking or at least extremely uncertain doctrine of experimental use in patent laws in the United States, the European Union, or elsewhere[1305]. This reality reinforces the premise that it is mostly the aggressive practices of rightholders, along with the defensive proliferation of exclusive titles, which have led to the breakdown of the agrobiodiversity property paradigm for certain agrobiodiversity actors. The inherent balance of intellectual property rights may thus be reclaimed through licensing practices, and various actors have indeed cultivated such open-minded strategies. Notwithstanding its inherent limitations, the need for action on licensing relies on the shared sentiment that the commitment to exclusive licenses in foundational research tools such as transformation methods, selectable markers and constitutive promoters greatly impairs the constitution of a "public sector

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[1302] GIANCARLO MOSCHINI and OLEG YEROKHIN, "Patents, Research Exemption, and the Incentive for Sequential Innovation," *Journal of Economics & Management Strategy* 17, no. 2, 2008.
[1303] JERRY R GREEN and SUZANNE SCOTCHMER, "On the Division of Profit in Sequential Innovation," *The RAND Journal of Economics*, 1995.
[1304] LEI, JUNEJA, and WRIGHT, "Patents Versus Patenting: Implications of Intellectual Property Protection for Biological Research," *op.cit.*
[1305] WESCHLER, "The Informal Experimental Use Exception: University Research after Madey V. Duke University," *op.cit.*

tool box of enabling technologies"[1306]. United States public institutions that hold numerous gene patents have in this context for instance evolve towards less exclusive licensing in the past ten years[1307]. Facing a considerable anti-commons landscape in upstream research tools in light of strengthened IPR monopoly rights and subject-matter expansions, efforts have been put forward by social actors to "bring conceptual unity in a re-evaluation of the public domain or intellectual commons"[1308], leading to the creative commons and open-source biotechnology movements. These movements have been triggered and corroborated by emerging agrobiodiversity user practices, doctrinal commentary, and legislative changes all reclaiming a broader or simply differently constructed public domain with regards to the availability of protected inventions to third parties.

12.2.1. Compulsory and humanitarian licensing

The first prospect of broadened licensing agreements stems from an opportunity directly provided for in the TRIPS Agreement. **Compulsory licensing,** a mechanism provided for in Article 31, affirms that the subject matter of a patent may be used without the authorisation of the right holder in certain circumstances, according to national law, "*including use by the government or third parties authorised by the government*". This particular liability rule that may allow the broader use of protected inventions therefore requires the express action of public authorites. The basic proviso is that such State-led authorisation "*shall be considered on its individual merits*", where public authorities themselves will negotiate the conditions of compulsory licensing on a case-by case basis with the rightholder. This negotiation may occur following unsuccessful efforts of the parties to reach a licensing agreements with "*reasonable commercial terms and conditions*", usually in cases of dependency. However, a waiver to the obligation to enter into preliminary negotiations is admitted in cases of "*national emergency or public non-commercial uses*". These "*non-exclusive*" and "*non-assignable*" licenses' "*scope and duration shall be limited to the purpose of which it was authorised*", while the rightholder "*shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation"* (TRIPS, Art.31).The same opportunities do also, as aforementioned in Chapter 3, exist within plant variety protection laws, surrounded by similar boundaries, and could thus be triggered to address the dilemma of orphan crop distribution, although this issue has been less challenging in light of adequately funded strong international public agricultural plant breeding efforts.

Compulsory licensing opportunities are considered by some commentators to be "preferable to a wide-ranging statutory exemption in order to ensure that the uses of biotechnology research tools remain reasonable and do not encroach too much on the innovators' expected returns on costly investments"[1309]. Even though the need for wider public domain approaches such as the one

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[1306] GRAFF et al., "The Public-Private Structure of Intellectual Property Ownership in Agricultural Biotechnology," *op.cit.*, p.992.
[1307] ASHLEY STEVENS, FRANCES TONEGUZZO, and DANA BOSTROM, "Autm Us Licensing Survey: Fy 2004 Survey Summary," 2005., cited in CUKIER, "Navigating the Future (S) of Biotech Intellectual Property," *op.cit.*
[1308] CURCI, *The Protection of Biodiversity and Traditional Knowledge in International Law of Intellectual Property*, *op.cit.*, p.287.
[1309] See DeFranco, Levy, and Pogach, "The Experimental Use Exception: Looking Towards a Legislative Alternative", *op.cit;* referring to RUTH E FREEBURG, "No Safe Harbor and No Experimental Use: Is It Time for Compulsory Licensing of Biotech Tools," *Buff. L. Rev.* 53, 2005; DEFRANCO, LEVY, and POGACH, "The Experimental Use

offered by compulsory licensing is greatly expressed in public upstream molecular research, there has been relatively little recourse to this peculiar antidote to the shortcomings of the patent system[1310]. This lacuna can perhaps be attributed to the fact that the products of green biotechnology protected by patents have been controversial in their own right, and have not been viewed as a straightforward answer to the issue of food security as is the access to clinically proven drugs to combat a specific disease. It has also been attributed to the wording and scoping of this liability rule in the TRIPS Agreement, which would have been shaped differently, if the initial goal of the agreement were to really make sure access to generic medicines, or any other product of biotechnology, became a reality[1311]. The limited recourse to this tool can furthermore also be explained by the lack of centralised authority and therefore of clarity and legal certainty, and the perception that the recourse to or the threat of having recourse to this peculiar tool may inevitably act as a disincentive to innovation[1312].

The recourse to compulsory licensing remains nonetheless interesting to address the bumpy scenario where access to a particular protected product or process is denied by a rightholder to a competitor having developed a derived product. A few examples exist with regards to health policies and have been mostly implemented for the purchase or local production of antiretroviral medicine following the Doha Declaration, respectively in 2002 in Zimbabwe following to the urgency of the AIDS epidemic in the country, and in 2004 in Mozambique and Zambia[1313]. In the field of public health, the United Nations Development Programme, in its Human Development report, has recommended that independent and semi-judiciary administrative systems be established in order to assess the need to grant compulsory licenses and ensure their negotiations and tracking[1314]. A number of alternative or hybrid systems have been also advocated, such as a “compulsory licensing mechanism with reach-through royalties”; where the monetary contribution would be calibrated on account of the contribution of patented subject matter to the final research result, taking as a result their actual value in consideration[1315]. This option would arguably be more tempting for patentees who tend to regard compulsory licensing schemes with little conceived mistrust, since it seemingly provides greater royalty collection opportunities. The mechanism nonetheless opens the door to other potentially contentious issues, common to compulsory licensing as a whole, that of determining the exact extent of the contribution of one innovation to the development of another, as well as the intervention of public authorities in the sphere of contractual autonomy.

Exception: Looking Towards a Legislative Alternative," *op.cit.* And MELANIE K KITZAN HAINFIELD, "Is the Experimental Use Exemption for Patent Infringement Still Needed," *J. Marshall Rev. Intell. Prop. L.* 3, 2003.

[1310] CARLOS CORREA, "Public Health and Intellectual Property Rights," *Global Social Policy* 2, no. 3, 2002.

[1311] STIGLITZ, "Economic Foundations of Intellectual Property Rights," *op.cit.*

[1312] COLLEEN CHIEN, "Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?," *Berkeley Technology Law Journal* 18, no. 3, 2003., p. 856.

[1313] CECILIA OH, "Compulsory Licences: Recent Experiences in Developing Countries," *International Journal of Intellectual Property Management* 1, no. 1, 2006.

[1314] UNITED NATIONS DEVELOPMENT PROGRAMME, "*Human Development Report: Making New Technologies Work for Development*", UNDP, New York, 2001. The report highlights that compulsory licenses “are already in use from Canada and Japan to the United Kingdom and the United States for products including pharmaceuticals, computers and tow trucks. They are used particularly as antitrust measures to prevent reduced competition and higher prices. But so far these provisions have not been used south of the equator. Developing countries, like other countries, should be able to do in practice what TRIPS allows them to do in theory” (at p.8).

[1315] This peculiar type of compulsory licensing is proposed by WANG, "Biomedical Upstream Patenting and Scientific Research: The Case for Compulsory Licenses Bearing Reach-through Royalties," *op.cit.*

Given the resolved unlikeliness of seeing compulsory licensing schemes activated by national authorities in the field of green biotechnology, upstream molecular biology tools have rather been subject to a plethora of **voluntary public releases of information and IPR donations.** This trend is especially noticeable in the case of molecular markers, which are extremely lucrative since absolutely necessary to the development of molecular plant breeding. Indeed, as aforementioned, "the opportunity to tag a fast mutating – repetitive – sequence motif as a simple polymerase chain reaction marker represents the ideal resource for the development of a valuable, if not the most important, marker class to be applied in practical plant breeding, particularly in species otherwise characterised by low levels of genetic diversity"[1316]. Simple sequence or microsatellite markers (SSR markers) are also "particularly useful for gene mapping and marker-based selection since they are amenable to high-throughput analysis and are informative in many types of genetic crosses", especially in programs using "a genetically narrow gene pool" such as rice[1317]. An important number of these SSR markers for rice were first made available by Monsanto in 2001 through a public release of six thousand six hundred and fifty-five SSR-containing DNA sequences, which allowed thereafter the development and release of two thousand two hundred and forty new SSR markers for rice by the joint contributions of nine international research groups to the so-called "International Rice Microsatellite Research Initiative"[1318].

There are other "well-publicised news stories of donations of intellectual property rights for technologies patented in the Europe, the USA and other rich countries, such as Golden Rice, and virus-resistant potatoes, sweet potatoes and yams for use by poor farmers in developing countries"[1319]. In the case of pro-vitamin A-enriched 'Golden Rice', the seventy patents were as aforementioned seemingly relinquished to allow the variety to find its way towards farmers[1320].

> "Although they could be used in the laboratory under the so- called "experimental use" exemption to patent exclusivity, once the rice left the lab, the force of all the IP rights came into play. Paying to license each technology would make the rice far too expensive for its target market. Although some firms have waived their rights or negotiated reasonable agreements, even one holdout could stop the use of the rice"[1321].

The said freedom to operate was actively attained in 2001 in this particular project, as a private-public partnership between the inventors and the agrichemicals company Syngenta was formalised, thereby "facilitating access to a number of key technologies held by multiple private actors through the signature of material transfer agreements"[1322]. "After much negotiation and

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[1316] MOHLER and SCHWARZ, "Genotyping Tools in Plant Breeding: From Restriction Fragment Length Polymorphisms to Single Nucleotide Polymorphisms," *op.cit.*, p.25.
[1317] SUSAN R MCCOUCH et al., "Development and Mapping of 2240 New Ssr Markers for Rice (Oryza Sativa L.)," *DNA research* 9, no. 6, 2002.
[1318] The International Rice Microsatellite Research Initiative joins together both public and private researchers from the USDA Agricultural Research Service and Cornell University, see ibid..
[1319] WRIGHT and PARDEY, "Changing Intellectual Property Regimes: Implications for Developing Country Agriculture," *op.cit.*
[1320] KRYDER, KOWALSI, and KRATTIGER, *op.cit.*, 2000.
[1321] JACKSON, "Innovation and Intellectual Property: The Case of Genomic Patenting," *op.cit.*, p. 20, citing EISENBERG, "Patenting Research Tools and the Law." andJ. GILLIS, "Monsanto Offers Patent Waiver," *Washington Post* http://washingtonpost.com/wp-dyn/articles/A33142-2000Aug3.html, 2000, August..
[1322] The history of the project is detailed on their website: http://www.goldenrice.org/Content1-Who/who2_history.html

high-profile media attention, all the license holders agreed to grant free use of their intellectual property for distributing the rice to farmers who will earn less than ten thousand USD from growing it"[1323].

IPR donations have not always been absolute, invoking the full public release of information or inventions themselves. They have also been borne **moderate** characteristics. Examples range from the reticence of prosecuting public researchers for fear of public image backlash or fear of straining indispensable good relationships between scientists, and relaxed licensing strategies for a particular technology. The mere **loosened licensing strategy** from the PCR technology holder has for instance infamously helped ease the past temptation of actors wishing to run the chain reactions to circumvent the intellectual property protection and find un-infringing approaches around the terms of the patent. Greater availability thus prevented the prominent inducement of free riding. The example of another enabling technology, "constitutive promoters, i.e. genetic regulatory elements required to drive the expression of selectable marker genes and specific transgenes" [1324], the patents of which were **not fiercely prosecuted** by right-holders, also shows that only partial or moderate humanitarian stances may at times also be very efficient. It also highlights the vulnerability of an approach solely relying on the voluntary release of information. The said promoter fell under patents that defined the sequence regulating gene expression in a functional manner in the hands of Monsanto Company in the United States and Japan "directed to chimeric genes containing the 35S or the 19S promoter controlling a heterologous gene", and also the Rockefeller University in the United States, "directed to the DNA sequences of the individual subdomains of the 35S promoter, combinations of them, and the use of B subdomains in particular to form tissue-specific promoters"[1325.]. Even though "the most common constructs using the cauliflower mosaic virus (CaMV) 35S promoter derived from a viral genome is owned by Monsanto, many alternative promoters that confer constitutive gene expression were developed in public sector organisations and are either in the public domain or can be licensed for nominal fees"[1326]. This development was made possible mainly because patent owners have generally not shown interest in prosecuting academic users of the promoter, even though injunctions were sought after private actors[1327]. Restraint in prosecuting public researchers for patent infringement has a result also been considered beneficial for plant improvement advances in general, yet the shaky nature of such practice is not difficult to grasp.

[1323] PROGRAMME, *op.cit.*, 2001.

[1324] GRAFF et al., "The Public-Private Structure of Intellectual Property Ownership in Agricultural Biotechnology," *op.cit.*

[1325] This information is made available by the Patent Lens set up by CAMBIA-Bios, Technology Landscapes, Promoters Used to Regulate Gene Expression, Plant Pathogen Promotors, the CaMV 35S promotor, available at http://www.patentlens.net/daisy/promoters/242/g1/250.html

[1326] These alternatives include a dicot ubiquitin promoter, a figwort mosaic virus (FMV) 34S promoter, mannopine/octopine synthase or the FMV and peanut chlorotic streak caulimovirus full-length transcript (FLt) promoters. The FMV 34S promoter has been used to drive constitutive gene expression and is reported to be essentially equivalent to the CaMV 35S promoter, but has not been widely distributed to the public-sector research community; see GRAFF et al., "The Public-Private Structure of Intellectual Property Ownership in Agricultural Biotechnology," *op.cit.*

[1327] For instance, the DNA Plant Technology Corporation had to acknowledge the infringement of one of Monsanto's patent, along with others, and entered into a confidential legal settlement agreement for compensation of the patent owner, see http://www.patentlens.net/daisy/promoters/768/242/g1/250/1511.html

The reach of such occasional leaps of generosity can only go so far in a competitive market environment, without completely undermining the ethos of awarding artificial lead time to deserving innovators. Not only do they depend on the "individual idiosyncrasies, whims and caprices"[1328] of States and companies, they can also "lead to an unduly sanguine assessment of corporate generosity with respect to IPR"[1329]. Experimenting with innovative or loosened licensing schemes may therefore address the shortcomings related to the anti-commons landscape created in molecular research tools or other foundational technologies, as well as the distributional dilemma in technology transfer rebuttals, but it may not address all of them with the same efficiency. For instance, the cost of PCR applications for the developed and developing worlds was substantially reduced on account of the 'generic' status of the Taq enzyme and the expiration of the core process patents on PCR technology[1330]. The new prices will probably help spread the use of the technology in fields neglected in the past or set off its entrance into new fields of research, such as tropical plant breeding.

12.2.2. Model or standard contracts with emphasis on the public domain

The dilemma of addressing the communal nature of public research, the disregard of orphan crops, or the use-blocking licensing practices cannot be all addressed through actor-led humanitarian attitude or State-led unblocking intervention. That is why IPR flexibilities bearing subtler interventions in contractual autonomy have been also used, rather attempting to play on the **content of licensing terms themselves, or by drawing up standard material transfer agreements**. Several actors have as a result been trying to come up with a sound and more open IP management strategy as a whole. In order to do so, they have drafted model licensing agreements attached to their own protected technology so as to make enough room for the norms of science and the proviso of public goods production. They have also drawn material transfer agreements or model clauses fit for their own understanding of exclusive rights and innovation distribution for unprotected technology and the transfer of tangible research material as such. A number of standard terms have been enacted, drawing at times from the world of information technologies, but also from the public domain set out in the ITPGRFA, with the hidden or little conceived objective of creating new agrobiodiversity commons and related institutions.

In order to overcome the hurdles of the strong property paradigm on public research, doctrinal commentary has been unanimous in recommending the establishment of "model license templates to facilitate agreements on mutually-beneficial terms and obviate the need for difficult and protracted negotiations on a case-by case basis, or, indeed, the need to revert to compulsory licenses at all"[1331]. Legislators have advocated this approach as well. In the United Kingdom, the Intellectual Property Office has for instance published informal and little interfering guidelines on "How Licensing Intellectual Property can help your Business" in July 2008 in order to protect the licensor and ensure that socially beneficial inventions were actually licensed on reasonable

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[1328] ENOCK MANDIZADZA and GORDON CHAVUNDUKA, "Traditional Medicine and Hiv and Aids Treatment: Challenges, Prospects and Lessons for Zimbabwe," *Antiretroviral Treatment in Sub-Saharan Africa. Challenges and Prospects*, 2013.
[1329] NOTTENBURG, PARDEY, and WRIGHT, "Accessing Other People's Technology for Non–Profit Research," *op.cit.*, p. 408
[1330] DHLAMINI, *op.cit.*, 2006.
[1331] MACQUEEN et al., *Contemporary Intellectual Property: Law and Policy op.cit.*, Second edition, p.475.; citing the Gowers Review of Intellectual Property.

terms[1332]. The OECD, following the findings of its 2002 report on "Genetic Inventions, Intellectual Property Rights and Licensing Practices"[1333], has come up with "Recommendations on Licensing Genetic Inventions" in 2006[1334]. Although limited to the licensing of genetic inventions used in human health care, these guidelines' state that licensing practices should

> *"1. A […] foster innovation in the development of new genetic inventions related to human healthcare and should ensure that therapeutics, diagnostics and other products and services employing genetic inventions are made readily available on a reasonable basis.*
> *1. B […] encourage the rapid dissemination of information concerning genetic inventions.*
> *1. C […] should provide an opportunity for licensors and licensees to obtain returns from their investment with respect to genetic inventions".* (OECD 2006 Guidelines for the Licensing of Genetic Inventions, Principe 1).

Furthermore *"The Best Practices also suggest that, to ensure a strong research base and as a supplement to competition law, licensors should consider licensing those genetic inventions that comprise base or platform technologies broadly. Mechanisms such as patent pools, patent clearinghouses or standard contractual provisions may be of assistance in implementing this best practice. Once again, licensors and licensees must be aware of limitations on such arrangements contained within competition law".* (OECD 2006 Guidelines, Principle 47).

Indeed, competition law imposes sound boundaries to the establishment of standard contractual provisions (and also with regards to the institutional solutions that shall be tackled in the next section of this Chapter)[1335]. It is nonetheless useful to say at this point that "new anti-trust policies may have reversed an antipathy to licensing that had long given strength to antitrust defences against patent infringement actions"[1336].

A number of **"open-source" licensing practices** have tried to draw from the experience in the world of information technologies, which has "overcome strict IP laws by harnessing aspects of the system itself – a jiu-jitsu manoeuvre of the law, whereby the opponents' strength is used against him"[1337]. There are numerous examples of open-source licenses, mostly stemming from the software world. Notwithstanding their inate differences as to the "extent to which they allow public-domain property to be mixed with private property rights", they share "the fundamental

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[1332] United Kingdom Intellectual Property Office, "Licensing IP: Health Check 1, How Licensing Intellectual Property can help your Business, July 2008.
[1333] ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT OECD, "*Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies*", Paris, 2002.
[1334] OECD, "*Recommendations on the Licensing Genetic Inventions*", Paris, 2006. , adopted by Council of the OECD on February 23rd, 2006 (see C(2005)149/Rev1). Even though OCED Council decisions are non-binding documents, they do represent an important political commitment from the Member States.
[1335] We shall not delve in too much detail into these boundaries within the scope of this particular research, leaving rather the task to the concluding remarks of our study, where we shall attempt to bridge gaps with other legal disciplines, but also perhaps fill the gaps that are inherent to a study limited to the property regime of agrobiodiversity.
[1336] BARTON, "Patents and Anti-Trust: A Rethinking in Light of Patent Breadth and Sequential Innovation," *op.cit.*, p. 449, citing JAMES B KOBAK, "Running the Gauntlet: Antitrust and Intellectual Property Pitfalls on the Two Sides of the Atlantic," ibid., 1996.
[1337] CUKIER, "Navigating the Future (S) of Biotech Intellectual Property," *op.cit.*, at p.250.

trait that their use is placed in the public domain"[1338]. The first license of this kind is the infamous General Public License, implemented through the "Free Software Foundation" as a "copyleft license" where users can rightfully copy the software[1339]. However, open source biotechnology is "a model for open source patenting or free biotechnology [which] presents a constellation of legal issues not typically found in previous open source licensing"[1340]. Attempts at using patent protection somewhat counterintuitevely have nevertheless seen the light of day. Even though comprehensive open-source licensing schemes, as understood within the realms of copyright, have not been set up in the world of green biotechnology patents, a number of standard licenses and model contracts have nevertheless been trying to reclaim the inherent balance of IPR, all the while having regards to the newfound obligations stemming from international biodiversity law.

When faced with the need and will to draft **licenses allowing for greater research operational freedom**, the actual cost of using patented technology will be determined on account of the license agreements' terms, especially those relating to the new crosses or variants that may be developed by the licensee or its sublicense, if faced with an indirect sublicense. The choice in this regard usually stands between upfront paid-up licenses or royalty-bearing licenses on each sale, or can also warrant the re-negotiation of the license when research shifts to display a commercial stance. The inherent struggle to distinguish experimental and commercial research endeavours resonates here once more, echoing the need for clear identification in the terms of the licensing agreement. In the particular example of the "gene gun incident", the **University of Cornell** was pushed to reconsider its practices and drafted a clearer IP policy. It preferably opted for non-exclusive licensing deals, spelling all the while out specific provisions regarding the philanthropic use of the inventions within all contracts, ensuring the "diligent use and development of Cornell technologies for any and all crops in any geographical region"[1341]. The licensing agreement preffered to set up a hybrid system of lump-sum payments, owed by the licensee at certain milestones (such as trials, approvals, first sale), the amount and time of disbursement of which are predetermined in the license agreement[1342].

In the same vein, but stretching the open-source approach a step further, the Australia-based **CAMBIA** (Centre for the Application of Molecular Biology to International Agriculture) grants non-commercial researchers in non-profit settings a cost-free licence on the basis of its exclusive rights to b-glucuronidase (GUS). As a result, this enabling research tool was "widely used by researchers in non-profit organisations who ultimately moved to corporations and continued using GUS", at which point fees have been charged for using the technology in commercial research[1343]. This move was not only preempted, but also taken into account to build an effective scenario of limited commons, since the license agreement drew the boundaries of appropriation clearly at the moment of access. Indeed, under the BiOS license, patents that are awarded on improvements to

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[1338] BRUCE KOGUT and ANCA METIU, "Open-Source Software Development and Distributed Innovation," *Oxford Review of Economic Policy* 17, no. 2, 2001: at p.254.
[1339] See notably LERNER, Scope of open source, WU, open-source software.
[1340] SARA BOETTIGER and DAN L BURK, "Open Source Patenting," *Journal of International Biotechnology Law* 1, no. 6, 2004.
[1341] CAHOON, "Licensing Agreements in Agricultural Biotechnology," *op.cit.*
[1342] Ibid.
[1343] NOTTENBURG, PARDEY, and WRIGHT, "Accessing Other People's Technology for Non–Profit Research," *op.cit.*, p.396.

the technology to create transgenic plants need to be "granted back" and have to be made available to other users of the commons. Indeed, article 3 of the BiOS license states:

> "In partial consideration for the rights granted to BiOS LICENSEE, BiOS LICENSEE grants to CAMBIA, a worldwide, non-exclusive, royalty-free, fully-paid license, with the right to sublicense to other BiOS Licensee, under the Improvement Patents, for use which is within the scope of the Licensed Patents, and a worldwide, non-exclusive, royalty-free, fully-paid license, with the right to sublicense to other BiOS Licensee, to any Improvements not protected under the Improvement Patents, any Technology Data and any Improvement Material provided by BiOS LICENSEE to CAMBIA and necessary to practice Improvements"[1344].

Standard contracts have also at times taken the form of **material transfer agreements (**MTA), which generally operate when tangible material is exchanged next to an **adjunct (and generally viral) license to be negotiated further down the line**. Just like licensing clauses, these standard clauses may be utilised to prevent the dilemma of public knowledge recycling, all the while upholding the traditional norms of science in the strong appropriation environment. Many examples of such a meticulous approach exist, and most of them do not rely on a standardised license, but build the boundaries of material and innovation sharing at the exchange of material, through viral contracts that open licensing negotiations at a defined threshold of product development.

An example, amongst many others, of model clauses bearing a more open stance relates to the **Commonwealth Scientific and Industrial Research Organisation** (CSIRO) standard terms and Guidelines that have been set up with regards to the MTA for biological material comprising gene-silencing vectors. CSIRO scientists have discovered an important research tool in green biotechnology, elaborating a method to silence gene expression in plants using RNA interference, publishing their research in 1998. "CSIRO has embarked on a broad licensing strategy to provide access to this powerful technology"[1345]. The MTA for the vectors is available online but "only for the transfer of the material to educational and research organisations for internal research purposes", as material contain GatewayTM recombination sites that are Invitrogen's proprietary technology[1346]. If the recipient does not qualify for such criteria, a license needs to be negotiated with Invitrogen. In the case of public researchers, this easy-to-use ad hoc research MTA facilitates greatly the access and use of proprietary technology that has been developed hand in hand by public and private actors, even though the interpretation of the terms "internal research purposes" may put freedom to operate in jeopardy for institutes with more astute hybrid structures.

[1344] CAMBIA BiOS License for Plant Enabling Technology, para.3; available at www.cambia.org/daisy/PELicense/751/1169.html

[1345] CSIRO, Enabling the Gene Silencing Revolution, "Commercial Opportunity", http://www.csiro.au/Organisation-Structure/Divisions/Plant-Industry/Enabling-the-gene-silencing-revolution.aspx (accessed March 2014).

[1346] The standard terms indeed expreslly state that "CSIRO only has permission to distribute these vectors to educational and research organisations for research purposes", http://www.csiro.au/Organisation-Structure/Divisions/Plant-Industry/RNAi/Gene-Silencing-Vectors---Terms-and-Conditions.aspx

The most notorious standardised material transfer agreement in plant improvement remains the sMTA, which constructs the "limited compensatory liability regime"[1347] set up by the 2004 **International Treaty on Plant Genetic Resources for Food and Agriculture.** As aforementioned, the sMTA remains a private contract between the provider and the recipient of germplasm (as a fixed plant variety a landrace, or material in development), which settles a compensatory liability that enters into play at specified moments. Compensation can either be ignited when the recipient commercialises a PGRFA product that incorporates the material that has been transferred while not making it available for further research and breeding (in accordance with article 6.7 of the sMTA), or it can take the shape of a lump-sum payment negotatied under the terms of article 6.11 of the sMTA). This internationally reified standard contract is mainly used by gene banks, and especially by the Consultative Group on International Agricultural Research, which also extends its reach outside of crops listed in Annex I of the ITPGRFA. The CGIAR, having faced the strong paradigm's sour sword upon their shoulders with the Golden Rice incident, was nonetheless pushed to adopt a new stance on intellectual property and reflect further on the use of the sMTA. Even faced with the crude realities of the Bayh-Dole Act, only a handful of the sixteen CGIAR centres have sought patent protection for their inventions[1348]. This means that the only real bargaining chips in the hands of the CGIAR remain its "goodwill, access to local institutions involved in the generation and transfer of technologies, and non-designated germplasm, in the form of breeding lines"[1349]. But its cross-licensing opportunities and bargaining power has been considerably altered with the enactment of the 2004 ITPGRFA public domain. That is why the Consultative Group has had to radically rethink its approach to agrobiodiversity related intellectual property rights. The **CGIAR Principles on the Management of Intellectual Property Assets** were adopted in February 2012, reiterating a "vision to reduce poverty and hunger, improve human health and nutrition, and enhance ecosystem resilience", while "intended to be consistent with both the ITPGRFA and the CBD"[1350]. Restating that "the CGIAR regards the results of its research and development activities as international public goods" and therefore adopting the "prompt dissemination of research results" as a rule, the Principles do nonetheless acknowledge that in certain limited cases, more restrictive licensing agreements may see the light of day. Restrictions on global "free access" can as a result be restricted through limited exclusivity agreements, restricted use agreements and IPR applications. This might seem at first sight as a step back from the traditional public domain oriented approach of the CGIAR and the precepts of the sMTA, but in reality these ostensible restrictions have been drawn up in order to avoid that the products of the IARC's research be misappropriated by complete enclosure oriented parties.

> Indeed, "multinationals pick up Center technologies, traits, varieties etc. freely, package them in proprietary combinations, charge what they want ("what the market will bear") and

[1347] V HENSON-APOLLONIO, "Case 10. The International Treaty on Plant Genetic Resources for Food and Agriculture: The Standard Material Transfer Agreement as Implementation of a Limited Compensatory Liability Regime," in *Gene Patents and Collaborative Licensing Models*, ed. GEERTRUI VAN OVERWALLE, Cambridg: Cambridge University Press, 2009., p. 289.

[1348] ERAN BINENBAUM, PHILIP G PARDEY, and BRIAN D WRIGHT, "Public-Private Research Relationships: The Consultative Group on International Agricultural Research," *American Journal of Agricultural Economics*, 2001.pp. 748–753

[1349] NOTTENBURG, PARDEY, and WRIGHT, "Accessing Other People's Technology for Non–Profit Research," *op.cit.*, p 403.

[1350] CGIAR, "*Principles on the Management of Intellectual Assets*", CGIAR, Consultative Group for International Agricultural Research 2012.

> effectively restrict access. […] In addition, as National Systems are under increasing budget pressure, they are licensing to multinationals materials they receive "freely" from Centers with no benefit returning to the originating Centers »[1351].

As a result, the Principles seem to indicate that, in very exceptional conditions, CGIAR centres may protect their own varieties or technologies through intellectual property rights, just as they may need to restrict their use because of other considerations, if they for instance wish to restrict their use by third party private distributors, or if they need to incorporate proprietary third party technology in their products. In this context,

> "*The Centers shall carefully consider whether to register/ apply for (or allow third parties to register/apply for) patents and/or plant variety protection over the Centers" respective Intellectual Assets. As a general principle, such IP Applications shall not be made unless they are necessary for the further improvement of such Intellectual Assets or to enhance the scale or scope of impact on target beneficiaries, in furtherance of the CGIAR Vision*" (CGIAR Principles on Intellectual Assets, Art. 6.4.2).

Furthermore, limited exclusivity agreements can be signed by CGIAR centres in accordance with article 6.2 of the Principles states that such limit has to be

> "*Necessary for the further improvement of such Intellectual Assets or to enhance the scale or scope of impact on target beneficiaries, in furtherance of the CGIAR Vision*", and also be "*as limited as possible in duration, territory and/or field of use".* Furthermore, the agreements need to ensure that the technology is available, i.e. that is accessible "*free of charge (except for actual costs or reasonable processing fees) or at a reasonable cost)*" within both a "research" and an "emergency" exception. While the former extends to "*non-commercial research carried out by public sector organisations, i.e. government entities, such as national governments, national agricultural research institutions, publicly funded international agriculture research centers, and publicly funded educational institutions*", the latter is triggered by a "*food security emergency declared by a national government or a multilateral and internationally recognised institution based on generally accepted benchmarks of the Integrated Food Security Phase Classification*" (CGIAR Principles on Intellectual Assets, Art. 6.2).

The Principles have also been set up so as to allow the centre to use proprietary third-party technology that are indispensable to produce socially beneficial and relevant plant varieties. In this scenario, the centres may enter in "restricted use agreements" in accordance with the terms of article 6.3, if

> "*They are, to the best of their knowledge, unable to acquire equivalent Intellectual Assets from other sources under no or less restrictive conditions, […and] the Consortium and/or the Centers shall use their best efforts to ensure that such third party Intellectual Assets are only used in relation to, or incorporated into, such intended products/service*" (CGIAR Principles on Intellectual Assets, Art. 6.3).

[1351] CGIAR Consortium Office, "*Examples of Restrictions to Global Access to Maximize Impact*", CGIAR, Consultative Group for International Agricultural Research, 6th March 2012, 2012.

Furthermore, one can also imagine that the standard material transfer agreement operates next to a predetermined license. This option has been hailed and developed within the auspices of the infamous Creative Commons initiative, which has set up a "Model Patent License", "intended to provide a simple standard model license to make patents that are being held for defensive purposes available for other uses—outside of those for which they are being maintained for defensive uses—on reasonable and non-discriminatory terms: preferably free of charge and without unnecessary field limitations"[1352]. Even though "there is currently no legal equivalent that can act alongside the patent system for protecting inventions to ensure that they are opened up, […] an offshoot of Creative Commons called **Science Commons** was designed to try to devise just such a mechanism"[1353]. The main impetus behind this project was to reduce transaction costs involved in accessing proprietary or non-proprietary technology through the creation of "a voluntary and scalable infrastructure for rights representation and contracting representied by use standard agreements, web-based meta data and 'human-readable deeds'"[1354]. The organisation has actually come up with a flexible range of options, all the while adhering to the core principles articulated by the National Institute of Health and its 1995 "Uniform Biological Material Transfer Agreement" and the shorter "Simple Letter Agreement"[1355]. The Science Commons team acted on a simple premise:

> "Discussions with stakeholders reveal a number of recurring problems. Supposedly uniform agreements are actually "customised" in time-consuming negotiations, although all players would benefit if they could bind themselves to restrict choices to a more limited set of standard options. Even the "short form" version agreements are perceived as too long and too complex. The agreements themselves are hard to interpret and scientists often find them mystifying, (or ignore them altogether as a result.) Finally, there is no connection between efforts to streamline the legal process for clearing materials, and efforts to streamline the practical process of actually fabricating and transferring the materials themselves"[1356].

In the Science Commons material transfer agreements, the user is generally free to "use the materials for research that [he/she] supervises, allow others under [her/his] supervision to use the materials, publish the results of [his/her] research", but may do so under the following conditions: "the use of the materials is restricted by fields of use, [he/she] may not use the materials for clinical purposes, and [he/she] may not use the materials in connections with the sale of a product or service. The organisation's revolutionary idea was to not only come up with a agrobiodiversity user-ignited consensus on contractual terms, but also to link the legal documents to the metadata of biological material. This process would allow, "in some areas at least, […] to click right from the description in the literature of an experiment using a DNA sequence, to a cheap "print out" of that sequence ordered online from a low cost intermediary, applying the terms of the standard

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[1352] Model Patent License, "How to use this Model Patent License Agreement, available at http://wiki.creativecommons.org/Model_Patent_License (accessed March 2014).
[1353] CUKIER, "Navigating the Future (S) of Biotech Intellectual Property," *op.cit.*, at p.250.
[1354] T NGUYEN, "Case 6. The Science Commons Material Transfer Agreement Project. A Standard License Clearinghouse?," in *Gene Patents and Collaborative Licensing Models*, ed. GEERTRUI VAN OVERWALLE, Cambrigde: Cambridge University Press, 2009., p.146.
[1355] Ibid., p.147.
[1356] JOHN WILBANKS and JAMES BOYLE, "Introduction to Science Commons," *Science Commons* 3, 2006., p.9.

MTA"[1357]. A pilot project was launched within the iBridge Network, but since then the Science Commons project has been re-integrated within the Creative Commons organisation and seems to have dried down from 2011 onwards.

Designed to pursue the double benefit of protecting the results of public research against its misappropriation without compensation, all the while ensuring the dissemination of inventions, especially for the advancement of science, model and standard licensing agreements and material transfer agreements have been extensively used to levy out the strong property paradigm's shortcomings faced with public good oriented research. The move from the CGIAR, long committed to the goals and precepts of the ITPGRFA and the sMTA, towards even partial restrictive stances is one of the many social practices that show how much standardisation efforts towards a PGRFA commons are a long and bumpy road. This is especially true in the reality of molecular plant breeding, which needs to actively incorporate agrobiodiversity users that strive in the strong property paradigm. The great dependency that continues to exist reciprocally between public researchers and private molecular developers, whether integrated giants or patent oriented start-ups, makes the resort to one (or a few)-sizes-fits-all licensing approaches difficult to achieve in green biotechnology.

Along with compulsory licensing schemes warranting State intervention and voluntary humanitarian IP donations, licensing standardisation efforts operate within the flexibilities of the TRIPS propelled paradigm. They do try to act on the problematic of enclosing cumulative innovation as such, and do so to arguable success. They also try to levy out the inadequacies of the paradigm with regards to less-endowned nations and individuals, all the while allowing for facilitated access to protected inventions. However, these licenses generally possess a static structure where the distinctions between public and private domain are determined *ex ante*, which may not always suit the needs of complex inventions where improvements and uses may lead in diverse and unanticipated directions[1358]. The design of clear and careful provisions is key; yet again they ought also to provide enough flexibility to users so as to attract a wide array of actors. Standard contracts are as a result in dire risk of setting the ground for ever greater re-negotiations between parties, which at the end of the day, will prevent them from achieving what they were tailored for, i.e. facilitating the access to patented information or to non-proprietary biological material.

12.3. Building institutions to facilitate access to innovation

Challenges experienced by public researchers with regards to the proliferation of patents, increasingly aggressive licensing strategies, along with the more metaphysical shortcomings of the strong IP paradigm regarding the norms of communalism and cooperation in public research, cannot solely be addressed through licensing schemes. That is why public researchers have attempted to build truly "open and collaborative research" architectures, emphasising rather "the organisation of production and what is done with the results of production, rather than details of licenses"[1359]. The shortcomings of the strong property paradigm could in this sense be, and have at

[1357] Ibid., p.10.
[1358] ARTI K. RAI, "Critical Commentary on "Open Source" in the Life Sciences," in *Gene Patents and Collaborative Licensing Models*, ed. GEERTRUI VAN OVERWALLE, Cambridge: Cambridge University Press, 2009., p.216.
[1359] Ibid., at p.214.

times been, remedied through **institutional mechanisms that facilitate the licensing, sharing and production of knowledge and innovative products or processes**. Different models target collaboration either within the public or private realms, or within a hybrid public-private configuration. They can either be based on the economic principles of an 'intellectual property clearinghouse', including data sharing and patent pooling at the edge of product development, still dependent on pre-existing exclusive titles, or can be more concerned with research architecture as such, in the form of partially open collaborative research partnerships at the outset of research endeavours. An important number of institutions have been committed to building a financially secure public domain, combining both public and private actors. The latter generally view monetary or non-monetary contributions to the public domain as « property pre-empting investments », made to counteract the strength and reach of competitors' property rights. When such investments are combined with strictly non-profite ventures, they can constitute, in Robert MERGES' view, partial 'self-correcting' mechanisms of intellectual property rights[1360]. These mechanisms are crucial since they rely on private action and not just government policy to address the excesses of intellectual property law much more effectively[1361].

12.3.1. <u>Accessing Patented Innovation through clearing houses and cooperative pooling</u>

Walking the thin red line very similar to standardised licensing mechanisms, a number of solutions have attempted to bridge the gap between proprietary technology and its users by building cooperative institutions, either gathering information about patent-holders, or bringing them together. These efforts resonate with what has been advocated by eminent innovation economics scholars such as Paul DAVID on the reconstruction of scientific research commons through "cooperative pooling and open-access cross licensing of research tool-sets"; providing an "institutional remedy for the harms that can result from the expanded use of IPR protections and the market as a means to promoting the production of international public goods that take the form of scientific and technical information"[1362]. These institutional remedies may take very different forms, but generally all remain difficult to ignite at first, as most of them "may emerge only when upstream patents pose a keen threat to the core interest of a class of businesses, thus making a collective defense desirable"[1363]. It is also difficult to successfully run them, as stringent boundaries are established through competition law requirements, just as all involved agrobiodiversity improvement actors need to continuingly share aligned goals and interests. Amongst technology access and/or transfer systems, clearing-houses (although finding their origins in banking law) are used to describe mechanisms that try to pair up developers and users of technology or biological resources[1364]. Some may 'merely' provide information with regards to the patent landscape that ascends before researchers; others may operate to ease access to technology, whether in the aftermath of a standard license negotiation or on a basis of open access[1365], complemented by

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[1360] ROBERT P MERGES, "A New Dynamism in the Public Domain," *The University of Chicago Law Review*, 2004.
[1361] THAMBISETTY, "Patents as Credence Goods," *op.cit.*, p.739.
[1362] DAVID, "Clearing Patways through the Thickets: Mitigating Anti-Commons Constraints on Exploratory R&D."
[1363] WANG, "Biomedical Upstream Patenting and Scientific Research: The Case for Compulsory Licenses Bearing Reach-through Royalties," *op.cit.*, p.307.
[1364] ANATOLE F KRATTIGER, "Financing the Bioindustry and Facilitating Biotechnology Transfer," *IP Strategy Today* 1, 2004., p.20
[1365] This distinction has been withheld by ESTHER VAN ZIMMEREN, "Clearinghouse Mechanisms in Genetic Diagnostics. Conceptual Framework," in *Gene Patents and Collaborative Licensing Models: Patent Pools,*

different mechanisms such as “honest-brokerage”, royalty collection mechanisms or patent pools. Within this landscape, institutions can either operate between patent holders themselves, or rather be set up as an independent, usually State-led or charity-led mechanism[1366].

Information clearing-houses

Amongst the institutional solutions that may help navigate patent landscapes that public researchers are confronted to, the most basic and perhaps equally elemental remains those striving to gather **information on such landscapes.** Without attempting to negotiate access to the technology itself, these initiatives can be nevertheless extremely useful to assess the reach of claims to which rightholders have been warranted a temporary monopoly. Some may even provide for explanatory notes next to claims, allowing the innovator to grasp a better understanding of what has been indeed invented, as well as valuing the actions that he or she would be allowed to do with the material or process with and without the rightholder’s authorisation. As aforementioned, a major hurdle of the strong property paradigm relates to the nebulous and costly nature of information costs in the first baby steps taken to determine one’s freedom to operate in a particular research area.

> “For non-legal professionals, a problem common to all the existing databases is the interface, which caters to individuals with expertise in intellectual property. Another issue is the limited number of searchable fields. Unlike the indexed scientific literature at the National Library of Medicine, patent publications are not indexed, forcing a text-based search. While many would not be put off by the need for a text-based search strategy, the language used in writing patents is very stylistic and to some extent codified by the drafters. A patent title may bear faint resemblance to the subject matter. For example, many published patent applications lodged at the World Intellectual Property Organisation (WIPO) office bear the title Secreted human proteins”[1367].

In order to respond to this epinous challenge, numerous mechanisms have been put at play. Amongst others is the **Convention on Biodiversity’s Clearinghouse Mechanism** set up to promote technical and scientific cooperation, as well as facilitate the exchange of scientific, technical and legal information regarding biodiversity, in accordance with article 18.3 of the CBD. The mechanism functions as a network of national public focal points and authorities, but does not extend to proprietary information, and most of the links provided on the website solely concern the biodiversity conservation strategies or projects; some links are no longer attributed[1368]. Other more patent oriented databases exist as well, such as the European Patent Office’s **Espacenet**, which nonetheless does require at least a certain amount of familiarity with IPR language, Google Patent Search, and other fee-based databases like Delphion, Dialog or Micropatent[1369].

Clearinghouses, Open Source Models and Liability Regimes, ed. GEERTRUI VAN OVERWALLE, Cambridge: Cambridge University Press, 2009., at p.69.

[1366] This particular distinction is studied in more detail by REIKO AOKI and AARON SCHIFF, "Promoting Access to Intellectual Property: Patent Pools, Copyright Collectives, and Clearinghouses," *R&D Management* 38, no. 2, 2008.

[1367] NOTTENBURG, PARDEY, and WRIGHT, "Accessing Other People’s Technology for Non–Profit Research," *op.cit.*, pp. 401-2.

[1368] This is for instance the case for the Belgian CHM link (http://be.chm-cbd.net , tried to access Debriary 2014).

[1369] VAN ZIMMEREN, "Clearinghouse Mechanisms in Genetic Diagnostics. Conceptual Framework," *op.cit.*, p. 71.

Completely **independent information clearing-houses** exist as well. The **Global Biodiversity Information Facility** is in this context an initiative triggered by debates in the OECD's Global Science Forum, but set out as an independent international organisation in the form of a "federated data repository"[1370], indexing information on species and specimens, allowing users to search all the data at once[1371]. The approach of the flexible GBIF Memorandum of Understanding to intellectual property is quite straightforward, as all data that is gathered by the Facility is openly accessible, while data providers maintain their exclusive rights on the information, and can as a result impose use restrictions both to GBIF itself, and to those accessing and using the data through the Facility as well[1372]. This iniative's success can be attributed to several characteristics, which in parallel make it difficult to apply to a gene patent clearing-house *per se*. Indeed, the data gathered by the Facility is of little commercial value. Just as the clearing-house, it does not try to link material users and providers, nor does it stand on strongly enforceable legal ground. Indeed, compliance is based on a non-binding and therefore flexible Memorandum of Understanding, which "may not be sufficient in the highly charged area of gene patents", just as it is grounded on "moral suasion common to scientific endeavours, to enforce its data-use and data-provider agreements"[1373].

In the specific field of biotechnology patents, a solution has been drawn by the aforementioned non-profit CAMBIA organisation, which has set up a completely text searchable engine, coined the "**Patent Lens**", pulling together information from ninety different jurisdictions. A completely independent initiative, the Lens also gives a number of explanations for most patents that are included in the database, as well as granting some background assistance for the "naïve user". "Powered by eight busy software engineers, and funded by a patchwork of foundations and the Queensland University of Technology in Brisbane, Australia, […] it will work best when it has cultivated a wiki-style following of users willing to take the time to annotate content, develop tools and share analyses"[1374].

> In light of the fact that "data sets, standards compliance and analytical tools must be improved—in particular, data sets and analytical tools must be made openly accessible—in order to provide a basis for effective decision making and policy setting to support biological innovation. [The Lens acts as] a web-based platform that allows such data aggregation, analysis and visualization in an open, shareable facility. Within 'The Biological Lens' facility, the sequence database currently holds 147,565,858 million nucleotide and amino-acid sequences disclosed in 323,721 global patent documents comprising both applications and grants. Of these sequences, 67% are repeated at least once in the corpus. Some level of redundancy is to be expected, as the same sequence may be either referenced in a single patent document for different purposes or mentioned in

[1370] JEROME H REICHMAN and PAUL F UHLIR, "A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment," *Law and Contemporary Problems*, 2003., p.315-462.
[1371] The data that is gathered in GBIF stems from different sources, including specimens held in natural history museums and other research institutions, observations without bio-collection activities, and information on species names, both past and current.
[1372] JAMES L. EDWARDS, "Case 3. The Global Biodiversity Information Facility (Gbif). An Example of an Information Clearinghouse," in *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Regimes*, ed. GEERTRUI VAN OVERWALLE, Cambridge: Cambridge University Press, 2009.p.122.
[1373] Ibid, p. 123.
[1374] X, "The Patent Bargain: An Open-Source Patent Database Highlights the Need for More Transparency Worldwide.," *Nature* 504, 2013.

> many related or unrelated patent documents. Although a majority of patent documents list only one or a few sequences, a substantial number list thousands or even millions of sequences. For example, US Pat. No. 7,777,022 discloses 4.2 million sequences. As millions more sequences become available, patent offices face a difficult challenge to render that information accessible to and useable by the public"[1375].

This enterprise will not only allow officer from patent offices in jurisdictions with limited budgetary capacity or limited experience with intellectual property rights on living organisms to gather information in a less costly and perhaps even more efficient manner, raising as a result the quality of patents awarded worldwide. It will also be of tremendous use to those researchers facing "entry barriers that disadvantage small-to-medium enterprises (SMEs) and innovation-focused and impact-driven public sector and philanthropy"[1376]. The organisation has also undertaken the colossal task of building patent landscapes for numerous technologies related to green biotechnology, namely with regards to the *Agrobacterim*-mediated transformation of plants, to the promoters used to regulate gene expression, the antibiotic resistance genes and their uses in plant genetic transformation, the resistance to phosphinotricin, positive seletion, and bioindicators[1377]. The organisation's efforts have been praised as a means "to return to the bargain at the root of the patent system, and to use the computational and social-media tools at our disposal to publicise inventions, rather than obscure them"[1378].

<u>Technology-exchange clearing-houses</u>

Going further than the precept of data mining and knowledge sharing, **intellectual property and technology exchange clearing houses** could be imagined as a step smoothing the navigation of complex patent landscape and the so-called "patent thicket". Institutions have indeed been designed to not only make information regarding exclusive informational rights owned by public research institutes, including universities, available to researchers around the world, but also theoretically them smoother access to protected inventions[1379]. The idea of brokerage needs to be present in these institutional solutions, really bringing together the users and providers of protected inventions, even though effective access to the technology will not be granted by the clearing-house itself but through either the *ad hoc* or the standardised licensing agreement entered into between the licensor and licensee[1380]. These strategies will be particularly "important in the future for sharing access to key enabling technologies, to enable innovators to develop and deploy the trait technology projects of the public sector"[1381]. Already in 2001, the UNDP Human

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[1375] OSMAT A JEFFERSON et al., "Transparency Tools in Gene Patenting for Informing Policy and Practice," *Nature biotechnology* 31, no. 12, 2013.
[1376] Ibid.
[1377] These landscapes are available for all to see, study, access, print and download at http://www.patentlens.net/daisy/patentlens/landscapes-tools/explore-landscapes.html, even though the authors do warn of their potential outdated nature, as landscapes may change quite rapidly and are as a result difficult and costly to update.
[1378] X, "The Patent Bargain: An Open-Source Patent Database Highlights the Need for More Transparency Worldwide.," *op.cit.*
[1379] R. HERDT, G. TOENNIESSEN, and J. O'TOOLE, "Plant Biotechnology for Developing Countries," in *Handbook of Agricultural Economics, Vol. 3: Agricultural Development, Farmers, Farm Production and Farm Markets,*, ed. ROBERT E. EVENSON and R. PINGALI, Amsterdam: 2007.
[1380] VAN ZIMMEREN, "Clearinghouse Mechanisms in Genetic Diagnostics. Conceptual Framework," *op.cit.*, p. 73.
[1381] GRAFF et al., "The Public-Private Structure of Intellectual Property Ownership in Agricultural Biotechnology," *op.cit.*, p.995.

Development Report directly refered to a potential intellectual property clearing-house as a viable and efficient solution to the developmental divide created on account of the TRIPS-propelled strong property paradigm:

> "Identifying and accessing individual patent claims for research in agricultural biotechnology is complex. A fairer and more efficient global trade in patented genetic materials, germplasm and applied technologies would be made possible through a clearinghouse. By identifying all relevant intellectual property for a given technology, indicating what is available for use and how, establishing a pricing scheme and monitoring and enforcing contracts, the clearinghouse could be an important step towards solving the collective problem of agricultural research"[1382].

Technology-exchange clearing-houses should thus be seen as facilitators, with different degrees of congegration and access facilitation. They have been designed either to provide open access to protected inventions, or to warrant access through standardised licenses.

> "Agricultural biotechnology IP clearinghouses could bundle together sets of complementary patents from different patent holders into complete biotechnology or agronomic systems contracts (thus providing upstream technology aggregation). Through active pursuit of such syndication strategies it would be possible to create customised licenses that could greatly increase the use of inventors' technologies and make multi-patent technology systems readily available and affordable to researchers"[1383].

Several efforts have tried to establish actual technology exchange clearing houses in the field of agricultural biotechnology, unfortunately to no global avail and limited success. Perhaps the most infamous of all such endeavours is the **Public Intellectual Property Resource for Agriculture** (PIPRA), designed in 2004 to integrate fragmented IP portfolios held by public institutions through collaborative management and a standard license[1384]. The independent organisation was set up as a consortium of universities and public research institutes, regrouping forty-six institutions from thirteen countries, but mostly from the United States, "accounting for approximately fifty per cent of the public/non-profit patented agricultural technologies"[1385]. Mildly ambitiously, but to great success, PIPRA was also involved in more "classical" capacity building exercices, building a much needed integrated structure of "scientific and legal skills [to provide] expertise, talent and resources that enable the delivery of a wide range of services"[1386]. Together with the Oxford-based

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[1382] PROGRAMME, *op.cit.,* 2001.

[1383] NOTTENBURG, PARDEY, and WRIGHT, "Accessing Other People's Technology for Non–Profit Research," *op.cit.*, p. 411.

[1384] ALAN B. BENNETT and SARA BOETTIGER, "Case 5. The Public Intellectual Property Resource for Agriculture (Pipra). A Standard License Public Sector Clearinghouse for Agricultural Ip," in *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Regimes*, ed. GEERTRUI VAN OVERWALLE, Cambridge: Cambridge University Press, 2009., SARAH VANUXEM, "Pipra: Un Commun Contrarié Sur Les Technologies Agricoles" (paper presented at the Séminaire international,'Propriété et communs. Les nouveaux enjeux de l'accès et de l'innovation partagée', 2013)., and CHIAROLLA, *Intellectual Property, Agriculture and Global Food Security: The Privatization of Crop Diversity*, *op.cit.*, at p.100.

[1385] BENNETT and BOETTIGER, "Case 5. The Public Intellectual Property Resource for Agriculture (Pipra). A Standard License Public Sector Clearinghouse for Agricultural Ip," *op.cit.*, p.139.

[1386] SARA BOETTIGER and KAREL SCHUBERT, "Agricultural Biotechnology and Developing Countries: The Public Intellectual Property Resource for Agriculture (Pipra)," in *Biodiversity and the Law:" Intellectual Property, Biotechnology and Traditional Knowledge"*, ed. CHARLES R MCMANIS, London: Earthscan, 2012.

Centre for Intellectual Property Management in Health Research (MIHR), which is designed as a non-profit IP management organisation with a developmental focus, PIPRA has also developed an extensive handbook on best practices in licensing, available online free of charge with great practitioner's insight and advice for all involved actors[1387]. More innovatively, challenged by the Rockefeller Foundation, the initiative "bundled public sector institutions' licensed and unlicensed technologies in "shared technology packages", in an attempt to make them more readily available to member institutions for commercial licensing or for designated humanitarian or special use"[1388]. The attempt was also quite unique in the fact that PIPRA actively maintained "collaborative working relationships with the owners of displayed technologies", and went as far as to develop a pilot project on "Enabling Technologies for Plant Transformation", acquiring and testing "complementary technologies required for the transfer of foreign genes into plant cells" in a made-for-purpose laboratory[1389]. Trying to establish easier freedom to operate paths for gene transfer with different promoters, PIPRA explored the possibility of consolidating the patent rights to the enabling technologies it had identified in a convenient one-stop shop system[1390]. This evolution slowly turned PIPRA into a timid patent pool.

> "Technology providers agreed that all component technologies would be valued equally, as the patents, collectively, were more valuable than any individual patent and any commercial revenues would be shared among the technology providers in proportion to the number of technology components they provided. To decrease transaction costs, technology providers strongly supported the administration of the patent pool through a single entity which had proscribed permissions to sublicense third-party patent rights. Since PIPRA is not a legal entity, the University of California, serving as the host institution, manages and licenses the technology pool on behalf of PIPRA-member universities"[1391].

Very similar in institutional organisation and also unfortunately in fate is the **Public Intellectual Property for Agricultural Biotechnologies** (EPIPAGRI) initiative, which also had governmental support from the European Commission. Aimed at encouraging public intitutes to collaborate in the management and promotion of their IP portfolios, the project's aim were very ambitious

> "EPIPAGRI will result in an information system composed of a database over agricultural biotechnologies patents and know-how, including histories and statuses, and a software package designed to help technology transfer experts in collecting, extracting, and analysing IP information. The second outcome from EPIPAGRI consists of patent pools ready to be proposed to internal and external PROs for joint management and industrial partners for technology transfer and commercialisation EPIPAGRI will also bring proposals of intellectual policy measures to national and European policy-makers aiming at preserving

[1387] A KRATTIGER et al., "Executive Guide to Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices," *MIHR/PIPRA/bioDevelopments-International Institute Available online at www. ipHandbook. org*, 2007., which is available online free of charge, http://www.iphandbook.org
[1388] KRATTIGER, "Financing the Bioindustry and Facilitating Biotechnology Transfer," *op.cit.*, p.22.
[1389] BENNETT and BOETTIGER, "Case 5. The Public Intellectual Property Resource for Agriculture (Pipra). A Standard License Public Sector Clearinghouse for Agricultural Ip," *op.cit.*, p.140-1.
[1390] RICHARD ATKINSON et al., "Public Sector Collaboration for Agricultural Ip Management," 2003.
[1391] CECILIA L CHI-HAM et al., "An Intellectual Property Sharing Initiative in Agricultural Biotechnology: Development of Broadly Accessible Technologies for Plant Transformation," *Plant biotechnology journal* 10, no. 5, 2012., p. 507.

the rights for academic research to utilize public research results and facilitating access of industry, in particular SMEs, and developing countries to biotechnological innovations" [1392].

Needless to say, no **patent pools** have emerged from these initiatives, in that the clearing-houses have not really morphed into such cooperative pooling. These pools have been formed for more than 150 years, especially in the United States, "either voluntarily or with the involvement of the USA Government to affect and shape industries"[1393]. They constitute « a voluntary agreement between two or more patent owners to license one or more of their patents to one another or third parties »[1394]. As a result, they are considered to be "the aggregation of intellectual property rights which are the subject of cross-licensing, whether they are transferred directly by patentee to the licensee or through some medium, such as a joint venture, set up specifically to administer the patent pool"[1395]. This particular construct is viewed as highly beneficial when faced with « truly *complementary* patents, [which makes] the patent pool desirable and procompetitive, but assembly of *substitute or rival* patents in a pool can eliminate competition and lead to elevated license fees »[1396]. Notable examples include the DVD or MPEG pools[1397]. Patent pooling examples are nonetheless extremely hard to find in the world of green biotechnology, except for those aforementioned examples of the PIPRA enabling technology FTO roadmap, and the CAMBIA BiOS, which, when stretched to their outer limits, may be considered as patent pools. Indeed, as standard setting is not really an issue in biotechnology, the recourse to patent pools has not been necessary for industry to commercialise products and unlock tricky situations[1398], while also making it difficult to assess which patents ought to be viewed as essential or complementary[1399]. Patent pools are furthermore extremely difficult to envisage in the world of green biotechnology and molecular plant breeding, because of these innovation chains inherent cumulative nature, as products developed upstream will not be well defined downstream[1400]. This premise is exacerbated by the fact that patents are more important in biotechnology than in other research fields, making participation to pools that may limit financial (through greater royalty rates) and technological (through cross-licensing and bargaining opportunities) gains less probable[1401].

Other attempts have, less comprehensively than traditional technology exchange clearing-houses or patent pools, all the while retaining an immense utility, set up **brokerage institutions** to access

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1392 European Commission, "EPIPAGRI - Towards European Collective Management of Public Intellectual Property for Agricultural Biotechnologies", 2006.

1393 NOTTENBURG, PARDEY, and WRIGHT, "Accessing Other People's Technology for Non–Profit Research," *op.cit*; ibid., p.410.

1394 KRATTIGER, "Financing the Bioindustry and Facilitating Biotechnology Transfer," *op.cit.*, p.28.

1395 Joel KLEIN, cited in DAVID SERAFINO, "*Survey of Patent Pools Demonstrates Variety of Purposes and Management Structures*", 2007.

1396 SHAPIRO CARL, "Navigating the Patent Thicket: Cross Licenses, Patent Pools and Standard Setting," *Innovation Policy and the Economy* 1, 2001., p.134.

1397 See J. CLARK et al., " Patent Pools: A Solution to the Problem of Access in Biotechnology Patents, White Paper ", ed. UNITED STATES PATENT AND TRADEMARK OFFICE (available at www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf 2000). CARL, "Navigating the Patent Thicket: Cross Licenses, Patent Pools and Standard Setting," *op.cit.*, pp. 134-136, or CLARK,

1398 KRATTIGER, "Financing the Bioindustry and Facilitating Biotechnology Transfer," *op.cit.*, p. 29.

1399 CARMEN CORREA, "Case 2. The Sars Case. Ip Fragmentation and Patent Pools," in *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Regimes*, ed. GEERTRUI VAN OVERWALLE, Cambridge: Cambridge University Press, 2009., p.48.

1400 VANUXEM, *op.cit.*, p.19. citing the fact that the USPTO paper advocating the creation of patent pools in the field of agricultural biotechnology has not ignited any movement from stakeholders, even ten years after its publication.

1401 HELLER and EISENBERG, "Can Patents Deter Innovation? The Anticommons in Biomedical Research," *op.cit.*

technology, especially with a view to address to developmental divide. The International Service for the Acquisition of Agri-biotech Applications (ISAAA) for instance exemplifies one facet of institutional developments towards a facilitated university-industrial collaborative knowledge complex. This service negotiates the terms of access to private sector technologies for the improvement of subsistence crops and/or the transfer of technology and know-how. It has successfully acted as a broker of technology-transfer for a research project aimed at the development of maize streak virus-resistant varieties in Africa[1402].

> «ISAAA operates primarily as a facilitator, matching available technologies to meet identified needs, brokering technologies, and building capacity by transferring knowledge and know-how between companies in developed countries and the public sector in developing countries. ISAAA also addresses other constraints in biotechnology transfer, such as regulatory and public perception issues »[1403].

The other more recent and equally successful brokerage example of the Rockefeller Foundation led African Agricultural Technology Foundation (AATF) reinforces arguments for the creation of less extensive but more collaborative clearing-house mechanisms. The AATF is furthermore quite unique in the sense that « it is prepared to in-license technologies from the private sector, which it then sub-licenses to its partners in Africa, and more importantly it strongly focuses on downstream activities, including the creation of local, national and regional markets for the products pro- duced from transferred technologies »[1404]. The AATF was particularly built with transgenesis products in mind, which include additional regulatory aspects and therefore require stewardship efforts that can be more easily performed by a non-proft intermediary, better endowed to endorse civil liability, in comparison to less experienced and trained institutes. Amongst other projects, they have successfully negotiated "through a royalty-free patent license, a gene conferring resistance to the *maruca* pod borer in cowpea, and is facilitating strict bio-safety regulatory compliance for its development and deployment in West Africa", with the aim of developing disease resistant cowpea varieties that would not require expensive pesticide use[1405].

Our analysis shows that information clearing-houses are vital for the navigation of complex patent landscapes, and are quite easy, yet costly to set up and maintain up to date. Independent initiative like the CAMBIA Patent lens should receive greater support, in order to continue ensuring the level-playing field in information gathering. Capacity-building initiatives with greater emphasis on the educational voids are also primordial and effective, just as brokerage insitutions with firm emphasis on human and economic development. More encroaching open access or managed technology clearing-houses may be effective in certain very "well-defined niches", especially for developmental use and technology transfer to less endowned nations, but is still rather costly to develop, with very limited applicability[1406]. Even though it seems difficult to establish a technology exchange clearing-house or even patent pools in its most extensive sense in public agricultural plant improvement, agrobiodiversity user practice seems to indicate that steps are being taken to build similar systems.

[1402] F. WAMBUGU, "Why Africa Needs Agricultural Biotech," *Nature* 400, 1999 (1st July).
[1403] KRATTIGER, "Financing the Bioindustry and Facilitating Biotechnology Transfer," *op.cit.*, p. 23.
[1404] Ibid., p.24.
[1405] WIPO Magazine, « Fighting Africa's food deficit », 2/2011, available at http://www.wipo.int/wipo_magazine/en/2011/02/article_0002.html (accessed April 2014).
[1406] Ibid., p.22.

12.3.2. Developing partially open collaborative research partnerships and triple helixes

Cooperation in the field of molecular biology and plant improvement has not only been attempted in a landscape where exclusive titles had already been granted. Given the tremendously difficult task of bringing together agrobiodiversity use actors, either solely public, or both public and private, at the closing stages of research endeavours, collaboration have intuitively tried to build bridges at their outset, to great success. The fairly novel research tools that have arisen on account of the infusion of molecular biology into plant breeding science constitute the new core of crop genetic improvement, as an indispensable input for further research, side by side with both improved and exotic crop varieties that represent the operational background of crop research. Indeed, tools such as molecular markers, high-density genetic maps and structured mapping populations provide breeders with the ability to "simultaneously define gene action and breeding value at hundreds of loci distributed relatively uniformly across entire genomes"[1407]. These tools' position at the groundwork of the innovation process in modern biotechnology, whether applied to conventional plant breeding or to transgenesis, elevates the conditions surrounding their appropriation and further use as an essential issue in shaping agrobiodiversity research. The existence of partially open collaborative research partnerships, joint ventures or other institutions is therefore has in this sense been crucial for follow-on or fellow innovators trying to pursue their research and development efforts more publicly within an aggressive property paradigm.

Open or partially open upstream research collaborations

Examples of **public-private collaborations that emphasise openness** are numerous in the world of green biotechnology. Non-market actors focusing on fundamental research, such as public sector research programs or universities continue to play an essential role in the development of upstream molecular research tools. They have become privileged partners offering pre-competitive research and also for applied research in cluster fields with little private sector presence. With regards to applied transgenesis trials, the public sector has been shown to focus on those less-commercial crops, targeting "commodities that are relatively neglected by the private sector but important to the mission of the public sector institution"[1408], focusing on biotechnological innovations useful in specific agricultural landscapes, solving ecosystem problems related to both biotic and abiotic stresses[1409]. As for pre-competitive collaborative research models, the Seed Biotechnology Centre of the University of California in Davis for instance conducts numerous collaborative research programs for the development of breeding tools *per se*, together with consortiums of companies, for instance in terms of whole genome mapping in pepper and lettuce or the constitution of a genome database in carrots. Providing "fee-for-service work" for both academics and industry, or collaborating within more structural agreements, these public entities' inherent strategy remains to guarantee "that the results of [their] research consumers, by actively seeking to grant licenses for patented inventions"[1410], instead of using these licenses as powerful

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[1407] MOOSE and MUNN, "Molecular Plant Breeding as the Foundation for 21st Century Crop Improvement," *op.cit.*
[1408] OEHMKE, 2001 J. OEHMKE, "Biotechnology R&D Races, Industry Structure, and Public and Private Sector Research Orientation," *AgBioForum* 4, no. 2, 2001.
[1409] D. FRISIO et al., "Public Vs. Private Agbiotech Research in the United States and European Union," ibid.13, no. 4, 2010.
[1410] Description of licensing opportunities offered by the Flanders Institute of Biotechnology (VIB), at http://www.vib.be/en/business-opportunities/Pages/default.aspx

commercial credence. Straightforwardly, this role is far more crucial for the traditional business model, which relies on seed sales and licenses obtained on the basis of plant breeders rights for income, and does not have sufficient biotechnological capacity to keep up with the international pace. However, the second business model encompassing such capacity within its realms is no exception to the new rule of collaboration, often availing itself of non-market actors through close partnership agreements. For instance, the publicly-funded Flanders Institute for Biotechnology ("VIB") has many research and development partners within the private sector, including a project carried out together with the University of Ghent and BASF Plant Science for the prediction of gene functions through novel bioinformatics tools, in order to find yield enhancing genes for corn and rice. This cooperation stems from the recent acquisition of Crop Design, a VIB spin-off focusing on trait discovery, by BASF in 2006. "Although much has been written about the possibilities for public-private collaborations in agricultural biotechnology research, [study results conducted in 2003] indicate that only a relatively small proportion (2.8%) of patents in this area have been jointly invented by collaborating private and public-sector researchers"[1411]. More and more, '**interactive innovative processes"** are being established in the field of molecular biology**,** where society profits from the existence of a rich innovation structure where institutional learning is routine[1412]. These processes include the concept of entrepreneurial university model[1413] and the promotion of the so-called "triple helix" of interaction between industry, government and universities as a key feature of the knowledge economy[1414]. The example of the North Carolina Biotechnology Centre might in this regard be interesting. As an independent and financially self-sufficient organisation, it indeed acts as co-ordinator between industry, government, universities, financial institutions and even the media. This successful recipe was taken over by the United Kingdom's national biotechnology innovation system[1415]. This has also arguably been the case of the Egyptian Agricultural Genetic Engineering Research Institute (AGERI), which has developed molecular tools but also transgenic plants[1416].

Grand-scale research projects and partially open partnerships between actors that should in all likelihood not have deviated too far from the strong property paradigm are particularly representative of the desire of public researchers to affirm the communal nature of foundational research in biology. Much like the largely cited example of the Human Genome and the uproar caused by the "Craig Venter" intellectual property protection strategy pattern, controversies have surrounded research focusing on crop variety genome mapping. The particularly interesting research collaboration that is the International Rice Genome Sequencing project (as well as other international attempts at sequencing) demonstrates that socially useful innovation may not only be achieved and sufficiently incentivised through partially-open information systems, but that it

[1411] GRAFF et al., "The Public-Private Structure of Intellectual Property Ownership in Agricultural Biotechnology," *op.cit.*

[1412] PHILIP COOKE, "Regional Innovation Systems: General Findings and Some Evidence from Biotechnology Clusters," *Journal of Technology Transfer* 27, 2002.

[1413] R. SMILOR, G. DIETRICH, and D. GIBSON, "The Entrepreneurial University: The Role of Higher Education in the United States in Technology Commercialisation and Economic Development," *International Social Science Journal* 45, 1993.

[1414] H. ETKOWITZ and L. LEYDESDORFF, *Universities and the Global Knowledge Economy* London: Pinter, 1997.

[1415] COOKE, "Regional Innovation Systems: General Findings and Some Evidence from Biotechnology Clusters," *op.cit.*, p.138.

[1416] SEIFE AYELE, "Biotechnology Generation, Delivery and Adoption: The Case of Bt Biopesticide in Egypt," *International Journal of Technology Management and Sustainable Development* 4, no. 2, 2005.

actually also heavily relies on such partial open mechanisms. A condition for the success of such endeavours lies in the fact that all parties do recognise the role played by unpatented sequencing technology and access to other research teams' provisional research results in achieving the final research objective. Sequencing efforts are remarkable since the direct raw output of research activities is not subject to patent protection *per se*, as the technical step and non-obvious nature of the invention ought to be expanded in order to do so. However, their potential impact on further research remains immense, especially with regards to the rice genome, viewed as the "Rosetta stone of cereals", able to procure greater insight into the genetics of grasses and also all major cereals, such as maize, barley or wheat, sizable commercial markets compared to the seemingly less lucrative rice market in itself[1417]. Map-based sequence information grants knowledge over the location of all the genes in a genome, thereby extending the usefulness of molecular-marking technology, gaining in both accuracy and efficiency[1418], while also providing greatly improved estimates for gene action controlling traits of interest[1419]. Sequence information therefore constitutes an absolutely essential instrument for preliminary mandatory research in molecular plant breeding and transgenesis. However, without further research aimed at their isolation and better understanding, as well as strong arguments as to their precise utility and their precise linkage to important crop traits, monopoly rights would typically not be granted over a simply mapped pair of gene sequences[1420].

Mapping efforts focusing on different rice genomes were undertaken around the same periods of time through a plethora of both public and private actors that were able to drive up the initial capital cost required to enter the sequencing business, costs mainly represented by trained personnel, royalty-bundling prices of laboratory instruments, specialised software, and licenses for the use of patented enzymes. The public actors involved represented powerful nations who could invest in such a gargantuan project, while also having a great social interest in doing so: igniting the race was Japan, with its "Rice Genome Research Program" dated as early as 1991, following in its footsteps was the current Beijing Genomics Institute in 1993 which boldly had further recourse to Craig Venter's time-efficient whole genome shotgun sequencing technology, and finally emerging was a consortium of publicly funded laboratories regrouped within the "International Rice Genome Sequencing Project", under Japanese leadership and a commitment on the release of research results into openly accessible databases[1421]. On the other side of the spectrum, two private agrobiotechnology giants initiated sequencing projects focusing on the same genomes examined by the public initiatives, with a commitment for proprietary mapping, even a prospect for the sale of resulting information to other biotech and seed firms[1422]. While Monsanto funded piece-by-piece research conducted in the University of Washington in Seattle, Syngenta signed with Myriad Genetics, a high-end specialized laboratory, and the Clemson University of South Carolina, using the Venter shotgun technology. The dichotomy between the public and private approaches to

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[1417] D. NORMILE and E. PENNISI, "Rice: Boiled Down to Bare Essentials," *Science* 296, 2002.
[1418] T. SASAKI and B. BURR, "International Rice Genome Sequencing Project: The Effort to Completely Sequence the Rice Genome," *Current Opinion in Plant Biology* 3, 2000.
[1419] MOOSE and MUNN, "Molecular Plant Breeding as the Foundation for 21st Century Crop Improvement," *op.cit.*
[1420] PRAY and NASEEM, "Intellectual Property Rights on Research Tools: Incentives or Barriers to Innovation? Case Studies of Rice Genomics and Plant Transformation Technologies," *op.cit.*
[1421] SASAKI and BURR, "International Rice Genome Sequencing Project: The Effort to Completely Sequence the Rice Genome," *op.cit.*
[1422] PRAY and NASEEM, "Intellectual Property Rights on Research Tools: Incentives or Barriers to Innovation? Case Studies of Rice Genomics and Plant Transformation Technologies," *op.cit.*

sequencing led to controversies at the publication of the draft sequences in 2002 by both teams having used whole genome shotgun approaches. Indeed, the private sponsored research results were not made available on public databases, but rather through the companies' own websites. For the sake of "the public benefit of bringing this important science out of trade secret status", an agreement was reached with *Science*, the scientific journal having published the provisional Syngenta results in 2002, setting up common conditions for the future use of "a gene's worth of data" in the partially assembled draft raw genome sequence for the purposes of research without need for negotiation, while large data requests or commercial applications required ad hoc conditional concession from the company[1423]. Even though criticism burgeoned[1424], most researchers acknowledged that sequencing data was in reality being shared quite openly through all fronts, first by Monsanto through its strong University link in the project and the creation of a specific website allowing publicly funded researchers access to draft sequences, and then by Syngenta as well. Indeed, all private sponsored research results winded up in the international public consortium databases, either because demand for proprietary information remained too low, or through collaborations with public institutes who shared their sequences on GenBank[1425]. Specific contractual agreements were drafted in this regard, as the Member Institution Registration Agreement enlisted before WIPO and signed between Genoscope (the "Principal Investigator", representing the French consortium within the IRGSP) and Pharmacia Corporation, (representing Monsanto) shows. Information related to the draft genome sequences identified by the private sector-sponsored research division thus always remained of a partially open nature, further driving innovation. The complete rice genome sequence was made available through the NCBI database in December 2004, leading to the completion of the full map-based sequences for all examined rice varieties in August 2005. A similarly structured consortium, focusing on the post-sequencing field of "functional genomics", was set up in 2003, building an International Rice Functional Genomics Working Group, hoping this time to characterize more than half of the gene functions of the already sequenced genome. Along the same lines as the rice initiative, an "International Wheat Genome Sequencing Consortium" was established in 2005, including the traditional members of the scientific academic community and representatives of the public research institutes, but also those of the private sector, with companies such as Monsanto, Syngenta, KWS or Biogemma within their list of coordinating members. The consortium was created in an effort to facilitate international cooperation and thus advocate for the completion of complete mapped sequencing of the wheat genome, but it is also interestingly "committed to ensuring that the sequence of the wheat genome and the resulting DNA-based tools are available for all to use without restriction", exemplifying the instigating potential of partially open innovation systems in upstream research. More recently, the exclusively public "Potato Genome Sequencing Consortium" has published the entire genome sequence of two different potatoes, the highlight of which has been the identification of more than 800 disease-resistance genes having each the potential to be used in the fight against agronomically and socially devastating diseases such as the potato cyst nematode and the potato blight pathogen *Phytophthora infestans*, famous for causing the Irish potato famine of the 1840s.

[1423] E. MARSHALL, "A Deal for the Rice Genome," *Science* 296, 2002.
[1424] DECAN BUTLER, "Geneticists Get Steamed up over Public Access to Rice Genome," *Nature* 416, 2002.
[1425] PRAY and NASEEM, "Intellectual Property Rights on Research Tools: Incentives or Barriers to Innovation? Case Studies of Rice Genomics and Plant Transformation Technologies," *op.cit.*

The **value of open access to sequence data produced by the public sector** has been embodied as an instrument putting considerable pressure on private organisations to release their sequence data (in the pharmaceutical sector, also pressuring all health agencies to release other information such as metadata about strains[1426]). Map-based sequence information grants knowledge over the location of all the genes in a genome, and thereby extends the usefulness of molecular-marking technology, gaining in both accuracy and efficiency[1427]. It also provides greatly improved estimates for gene action controlling traits of interest[1428], and thus constitutes an essential instrument for preliminary mandatory research in molecular plant breeding. However, without further research aimed at their isolation and better understanding, as well as strong arguments as to their precise utility and their precise linkage to important crop traits, monopoly rights would typically not be granted over a simply mapped pair of gene sequences[1429]. The absence of intellectual property rights at the immediate end of the research and development chain did nevertheless not impede private investment for the map sequencing of the rice genome. The patent landscape completed by CAMBIA with regards to the United States legal order indeed shows that only zero point twenty-six per cent of the rice genome and less than 1 per cent of the coding sequence has actually been claimed in the one hundred and eighty-two patents granted by the USPTO, even though eighty-three per cent of these patents' explicitly claim genome sequences. Patents have within this exemplary framework mostly enabled time gains, thrusting inquisitive minds to question the actual extent monopoly rights should continue to bear for the sole objective of providing lead time in an increasingly competitive market. The genesis and culmination of rice genome mapping thereby exposes that partially open information represents a prerequisite for further research and innovation within the world of high sunk cost bound specialized biotechnology research. Within the framework of hybrid upstream research streams, while the data produced by the consortium remains within the public domain, research efforts that achieve to single out the exact utility may nonetheless lead to patent protection over what shall unvaryingly consist of platform technologies, to which a solid door of access shall be maintained. Furthermore, the potential disregard or overlook for adequate rules of diffusion below the fence of raw research data still ought to be carefully considered. This assessment is nonetheless extremely difficult, since science commons are not organised through a strict differentiation between commercial and non-commercial intent, but rather encompass activities that are "conducted under public domain-like conditions (without any ownership claims that would restrict access and use of the research results and basic research material)"[1430].

Meanwhile, and certainly building on the heritage of both the Human and Rice Genome projects, **publicly available databases,** especially those with a wide approach to data availability, have played an important role in the development of molecular plant breeding. For instance, PLEXdb (Plant Expression Database), an initiative of the US government, "is a unified gene expression resource for plants and plant pathogens. PLEXdb is a genotype to phenotype, hypothesis building

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[1426] J.A. EISEN and C.J. MACCALLUM, "Genomics of Emerging Infectious Disease: A Plos Collection," *PLoS Biology* 7, no. 10, 2009.
[1427] SASAKI and BURR, "International Rice Genome Sequencing Project: The Effort to Completely Sequence the Rice Genome," *op.cit.*
[1428] MOOSE and MUNN, "Molecular Plant Breeding as the Foundation for 21st Century Crop Improvement," *op.cit.*
[1429] PRAY and NASEEM, "Intellectual Property Rights on Research Tools: Incentives or Barriers to Innovation? Case Studies of Rice Genomics and Plant Transformation Technologies," *op.cit.*
[1430] DEDEURWAERDERE et al., "Governing Global Scientific Research Commons under the Nagoya Protocol," *op.cit.*, p.419.

information warehouse, leveraging highly parallel expression data with seamless portals to related genetic, physical, and pathway data."[1431] In the world of foundational molecular research tools, the SNP Consortium also stands out through its very open approach to intellectual property. The Consortium brings together a "group of thirteen firms searching for single nucleotide polymorphisms (single base changes in the genome associated with diseases), which is not only publishing its discoveries but is also filing official paperwork with the PTO disclaiming rights to its "inventions"[1432]. "In facing a menace to their common goals and interests, competing pharmaceutical companies overcame high costs and created a public data pool to preclude SNP patents and to facilitate the exchange of scientific findings"[1433]. This organisation goes one step further than bringing together data sets and making them available to the public, and we shall try to underline the conditions needed to reach such higher level of aggregation in cooperative pooling in green biotechnology. There is nonetheless mounting evidence that **sound and completely open biology movements** are gaining importance. Such is the case of the "do-it-yourself biology" community, which is "emerging as a movement that fosters open access to resources permitting modern molecular biology, and synthetic biology among others. It promises in particular to be a source of cheaper and simpler solutions for environmental monitoring, personal diagnostic and the use of biomaterials"[1434]. This movement builds upon the 2003 registry of standard biological parts, through which more than three thousand and four hundred genetic building blocks were made publicly available. In 2010, "open-PCR DNA", a kickstarter funded self-assembly machine capable of copying DNA. The previously mostly United States based community now has a European hub, which has been brought together through a website and advocates a completely open approach to molecular biology research tool development.

Warranting actor participation in agricultural research

Notwithstanding the importance of new open and collaborative research architectures to increase access to data or to research tools, these institutional structures may not always target and therefore not lead to the **increased development of targeted innovation for developing countries**[1435]. They will therefore come short of addressing the dilemma of orphan crops in public research playing the strong property game. There have in this regard been specific attempts to bring biotechnology more directly within the ambit of civil society in general and of resource-poor farmers in particular. A prominent example includes the Andhra Pradesh Netherlands Biotechnology Programme (APNLBP)[1436]. The Programme was an initiative funded by the Dutch government from 1995 forward and its approach was radically different from previous dissemination strategies, where remote research and development laboratories traditionally developed "a raft of new technologies" to distribute to developing world farmers, trying to solve the problems they were facing. These problems were however diagnosed in the ivory towers of

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[1431] http://www.plexdb.org/index.php

[1432] JACKSON, "Innovation and Intellectual Property: The Case of Genomic Patenting," *op.cit.*, pp.13-14.

[1433] WANG, "Biomedical Upstream Patenting and Scientific Research: The Case for Compulsory Licenses Bearing Reach-through Royalties," *op.cit.*, p.312.

[1434] THOMAS LANDRAIN et al., "Do-It-Yourself Biology: Challenges and Promises for an Open Science and Technology Movement," *Systems and synthetic biology* 7, no. 3, 2013.

[1435] ALAN G. ISAAC and WALTER G. PARK, "Open Development : Is the 'Open Source' Analogy Relevant to Biotechnology," in *The Role of Intellectual Property Rights in Biotechnology Innovation*, ed. DAVID CASTLE, Cheltenham: Edward Elgar, 2009.

[1436] CLARK, REDDY, and HALL, "Client-Driven Biotechnology Research for Poor Farmers: A Case from India," *op.cit.*

national or international research institutes or universities. In the APNLBP model, "the emphasis was put on direct interaction with farmers and related actor groups such as non-governmental organisations", in order to overcome the age-old understanding of technology development and transfer rooted on "a faith in the scientific method as the main source of improved technological practices for the poorest of the poor, relatively little attention paid to the tacit knowledge and local preferences of other groups including the farmers themselves"[1437].

> The APNLBP model "followed an 'interactive bottom up (IBU)' approach, based on the principles of participatory technology development (PTD). All projects were to be formulated on the basis of local needs assessment and priority setting, to which end users, researchers, policymakers, government and NGOs should all be involved. In addition a central principle was to be constant interaction between farming communities and scientists in the process of technology development and adaptation. These interactions would be used to combine indigenous knowledge of people with both tacit stakeholder and modern scientific knowledge. […] Ownership is entrusted to a multi-stakeholder steering committee called the Biotechnology Programme Committee (BPC). The Committee consists of representatives from grassroot level NGOs, heads of developmental departments of the state government, representatives of the Department of Biotechnology (DBT) and the Indian Council of Agricultural Research (ICAR), Government of India (GOI) and scientists of national and international repute. [… Some project tracks were] isolating native genes by approaches of functional genomics, molecular mapping and wide hybridisations".

The success of the endeavour relied on a steady flow of information across agrobiodiversity user groups, including NGO's, exemplify the benefits of thinking about agricultural plant improvement through a metaphor of innovation systems. It also exemplifies a desire from public researchers to break with traditional isolation behaviour and cooperate not only with each other, but also those using the produced public goods.This desire has been prominently felt in the CGIAR led IARC's, which have supported the new era of "participatory plant breeding" (PPB) arguably since the beginning of the 21st century[1438]. This rather recent approach to plant breeding involves scientists and farmers, but can also include consumers, vendors, industry or rural cooperatives in plant breeding research. Scholars generally operate a distinction between formal and farmer-led participatory plant breeding, where the former resonates more appropriately as an adjustment led by public researchers faced with the shortcomings of plant improvement research. It should be noted here that PPB does not solely respond to the shortcomings induced by the reification of the strong property paradigm, it has also appeared following critics regarding the lack of efficiency of public agricultural research, and also the aforementioned uniformisation critics directed at the Green Revolution[1439]. In this context, former-led PPB designates those programs where farmers

[1437] Ibid.

[1438] The Consultative Group has indeed set up a Program on Participatory Research and Gender Analysis for Technology Development and Institutional Innovation, which maintains detailed documentation on different participatory plant breeding programs and projects.

[1439] Indeed, the development of PPB reflects a more profound reshifting of the roadmap of agricultural research, recognising the pitfalls of the conventionally linear research and development scheme that had prevailed until the 1990's. DEREK BYERLEE, "The Search for a New Paradigm for the Development of National Agricultural Research Systems " *World Development* 26, no. 6, 1998., DEREK BYERLEE and G ALEX, "National Agricultural Systems: Recent Developments and Key Challenges," *Note prepared for the Interim Science Council of the Consultative Group on International Agricultural Research (CGIAR)*, 2003., and also MARK LUNDY, MARÍA VERÓNICA GOTTRET, and "merely" join in programs that are initiated, pursued and finalised by public research institutes[1440]. These can be of larger or smaller scale, covering different geographical locations, or just few sites, with different decision units to manage the project, where either the region or the local community may take the reign.

Within its "Feed the Future" Global Hunger and Food Security Initiative, the United States Government has for instance set up "innovation labs" in a designated set of nineteen countries, with a common knowledge management program, the "Digest Project". The intiative has for instance carried out a program with the lead contribution of Michigan State University, Cornell University and national agricultural research centres, a project "combining conventional, molecular and farmer participatory breeding approaches to improve Andeans beans for resistance to biotic and abiotic stresses in Ecuador and Rwanda"[1441]. Another example of collaborative research through a coalition approach relates to sorghum poultry in Andhra Pradesh India[1442]. In this particular example, a 'network' is established as participants voluntarily enter into the coalition to carry out mutual and joint activities, while remaining part of autonomous organisations.

> "Sorghum poultry coalition grew out of a long-standing partnership between International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) and the private sector. ICRISAT played a nurturing role, often through informal networks, to the emerging private seed industry and relied, in turn, on them to ensure that the new material they developed reached farmers. In 2000, ICRISAT signed an agreement with eight private sector seed companies to develop sorghum hybrids whereby each company makes a grant to ICRISAT and the scientists then make their results available to all the companies in the consortium"[1443].

Although not completely vested in property rights concerns, these examples show that open and collaborative partnerships, even those including enclosure-oriented private actors, can still be and have been developed in order to overcome the pitfalls of growingly market-oriented plant improvement research. These endeavours, whether situated at the very end of the bargaining chain by incorporating developing country actors, or found rather at the very top of 21st century plant improvement, i.e. in the production of molecular data; both need strict conditions to come about. Indeed, involved actors need common goals and concerns; they also arguably need to have had informal contacts with one another before the coalition or consortium's genesis.

JACQUELINE ASHBY, *Learning Alliances: An Approach for Building Multi-Stakeholder Innovation Systems*: Institutional learning and change (ILAC), 2005.

[1440] On the other side of the spectrum lies farmer-led PPB, when scientists seek to support farmers own systems of breeding, varietal selection and seed maintenance, which we shall tackle in more depth in Chapter 14 of this study, LOUISE SPERLING et al., "A Framework for Analyzing Participatory Plant Breeding Approaches and Results," *Euphytica* 122, no. 3, 2001.

[1441] The project website is http://crsps.net/resource/combining-conventional-molecular-and-farmer-participatory-breeding-approaches-to-improve-andean-beans-for-resistance-to-biotic-and-abiotic-stresses-in-ecuador-and-rwanda/ (accessed March 2014).

[1442] The main impetus behind the coalition formation was the need to "overcome the apprehensions on the use of rainy season sorghum in poultry feed rations and creation of sustainable marketing linkages between sorghum growers and the poultry industry through innovative institutional systems assume importance for ensuring continuous sorghum grain supply to industry and assured incomes to poor sorghum growing farmers". REDDY GURAVA et al., "Enhancing Technology Generation and Transfer through Coalition Approach: A Case of Sorghum Poultry Coalition, Andhra Pradesh, India," *International Journal of Technology Management and Sustainable Development* 5, no. 2, 2006.

[1443] ibid., p.149.

CONCLUSIONS. Possible adjustments for public sector plant improvement and upstream research tool development

Public researchers involved in molecular biology but also plant breeding face a number of backlashes stemming mostly from the patent component of the strong property paradigm reified under the TRIPS Agreement. Aggressive licensing practices, used as bargaining chips against public actors who seldomly possess strong negotiating powers, just as very constraining exclusive distribution agreements have both been experienced and seen as symptoms of an altered order of protection and production of knowledge goods by public researchers. The setbacks they have faced have nonetheless been addressed through several means, whether found in pure self-regulatory actions requiring social organisation efforts within their own cluster, or stepping further away than such cluster, by warranting regulatory action from third parties, mostly national or European legislators. All of these adjustments, whether confined to self-regulation or not, attempt to respond to the shortcomings of the strong property paradigm vis-à-vis their own informal norms and needs, which yearn for a slice of partially open innovation, and build and rely on a wider public domain. These adjustments have taken advantage of the inherent flexibilities of the property paradigm, allowing for eased access, development and dissemeination of increasingly crucial molecular research tools. They all face their own difficulties, whether in terms of realistic fulfilment, if for instance they require important legislative amendments, or rely on the exercice of contractual autonomy in unison so as to set up patent pools or other technology clearing-houses, or in terms of legal certainty and enforceability, when they for instance rely on third parties' reluctance to prosecute infringements, or set up informal institutions that exist on the sidelines of the property paradigm.

All of these adjustments do not address the same issues either, and a unique solution to the entire array of shortcomings experienced by public researchers cannot be vented like a magic wand, even though certain strategies may help ease a couple of issues at the same time. In order to include the norms of science within the equation of the patent age for instance, the majority of documented practice has targeted the licensing practices of all technology developers, whether entirely or partially waiving rights over certain products *ex ante* (at times within wide-scaled collaborative projects), or by pushing for developmental or humanitarian use terms, or setting up standardised contracts to perhaps even manage to form institutions like clearing-houses or pools. The setbacks stemming from aggressive licensing strategies have been addressed by these measures as well, but with an additional stress on more classical liability rules that act as compulsory licensing schemes with the active involvement of the State, acting as a broker between entities that have failed to reach an agreement on the use of inventions linked by dependent patents. The success of these initiatives rely nonetheless on the on the whims and caprices of individual companies. To address the inherent challenges stemming from the enclosure of products of cumulative and incremental innovation in itself, and not just aggressive licensing, action has generally required to go beyond mere self-regulation, as the latter has only gone so far as to "raise the patent bar" or ensure peer review systems in patent examinations to assess prior art. Public researchers have thereby tried to build on the eligibility of molecular inventions for patent protection, unvaryingly highlighting the need for extremely careful consideration in the qualification of the product or process as an invention, or in the assessment of the criteria of non-obvisousness, novelty and utility. The same kind of action has been concerned with backing literal claim interpretations and purpose-bound patent protection so as to avoir reach-through practices that allow initial discoverers to control the entire stream of downward innovation, especially in gene sequence patents. In order to counter the profileration of broad patents in plant improvement related technologies, public researchers have also preached for other regulatory mechanisms that award enough space for fellow innovators to use protected inventions in the early, or even arguably later, stages of their research programmes; the main one being concerned with an experimental use or research exception that would be broad and legally certain enough to accommodate their needs. The loss of royalties that would be experienced by patent holders in this scenario will have nonetheless need to be assessed, even though this impact can be kept to a minimum if for instance an *ex post* liability scheme is clearly established so as to be triggered at the commercialisation stage. The deviance of the strong property paradigm has also been addressed by acting directly on licensing terms, establishing a clear preference for non-exclusive licensing, clearer terms for subsequent use through up-front payments, or much more open systems on the margins of strong exclusive rights. Most of agrobiodiversity user action and practice has focused around the end to navigate the new waters of enclosed cumulative innovation components, even though certain adjustments have also been enacted to address the issue of biopiracy, so as to avoid the misappropriation of sovereign biological material and traditional knowledge by public researchers. These adjustments have mainly concerned the re-evaluation of the notions of common knowledge or prior art in IPR applications, and also include institutional solutions, such as the integration of a wider array of actors within the research process, namely farmers and local communities.

The account of social innovation propelled and guided by public researchers involved in plant improvement against the difficulties they have been growingly facing due to the strong property paradigm do show that solutions to these challenges can be found within the latter's boundaries. However, as aforementioned, all of these solutions do not address the same challenges, and most of them require strong will-power and unity, either within the specific actor category concerned, or within the domestic or regional legal order these actors navigate in. Points of convergence and divergence ought thus to be assessed within the different strategies, and then ought to be weighed against the interests of all other actors of plant improvement.

<table>
<tr><th rowspan="2">TRENDS</th><th rowspan="2">SHORT-COMINGS</th><th colspan="2">SOCIAL INNOVATION, EMERGING PRACTICES AND COPING STRATEGIES</th></tr>
<tr><th>Self-regulation</th><th>Beyond self-regulation</th></tr>
<tr><td>Protect or perish?</td><td>Commu-nalism
Orphan crops</td><td>Ex ante waiver of property rights
Humanitarian and developmental licensing schemes
Comprehensive partially open joint research projects, including participatory plant breeding
Clearing houses and cooperative pooling</td><td>Exceptions to patentability in certain crops
Legal certainty for compulsory licensing opportunities and developmental licenses
Alternative mechanisms to foster innovation (direct subsidies or project support)</td></tr>
<tr><td rowspan="2">Enclosing cumulative innovation products</td><td>Recycling of public knowledge
Information deficit</td><td>“Peer-to-patent” open application review system
“Raise the patent bar” in complex technologies</td><td>Fight lenient patentability for products of nature: strict approach to invention, non-obviousness and novelty</td></tr>
<tr><td>Biopiracy risk</td><td>Participatory plant breeding and ex ante waiver of rights</td><td>Strict prior art assessment
Disclosure of origin in patent applications</td></tr>
<tr><td>Patent proliferation</td><td>Research costs -
Legal uncertainty</td><td>Assistance / capacity-building in patent landscape assessment
Information and technology exchange clearing-houses</td><td>Fighting lenient patentability for discoveries / products of nature
Sharp and Sound Research Exception (legal certainty)</td></tr>
<tr><td>Aggressive licensing - ABS</td><td>Refusal – delays in research</td><td>Standard licenses and MTAs
Clearing houses and cooperative pooling
Comprehensive partially open joint research projects</td><td>Ad hoc compulsory licensing for research tools and foundational patents</td></tr>
</table>

FIG.6: Adjustments responding to the shortcomings faced by public researchers in molecular biology and conventional plant breeding confronted to the strong PGRFA property paradigm

13. CHAPTER 13: ADJUSTMENTS FOR PRIVATE PLANT BREEDERS

The development of science-based plant breeding is marked by the shift from unconscious mass selection towards conscious rational attempts at varietal adaptation, characterised by the use of the Mendelian heredity and segregation principles, and the recourse to controlled hybridisation, as an inheritance-focused selection method based on the phenotypic observation of plant varieties[1444]. Smaller-scaled private plant breeders, as entities trusting on variety licensing for their income, in this context rely on the widest access to both improved and wild genetic resources pools, and increasingly to patented molecular biology tools[1445]. Breeding programmes have been heavily affected by the strengthening of intellectual property rights. The resurgence of strong and broad patents, as well as the parallel extension of protection scopes have both put ever-growing limitations on plant breeders' ability to use protected products, processes or varieties in their research programmes. The restrictions stemming from strong rules of appropriation with regard to the accessibility of improved genetic material, despite preserving the positive prospect of royalty income, have hampered the sacrosanct "freedom to operate" that breeders long for.

However, the breakdowns created by the restricted access to proprietary yet fundamental research tools has been alleviated "because firms and universities have been able to develop "working solutions" that have allowed their research to proceed, [including] taking licenses, inventing around patents, infringement (often informally invoking a research exemption), developing and using public tools, and challenging patents in court"[1446]. Private plant breeders have also in parallel taken action to ensure that the exclusive prerogatives granted to them in order to recoup their initial investment and also reward their risky and innovative endeavours. The turmoil created by the Europe-wide support given to the recognition of a breeders' exemption within patent laws, reaching at times as far as demanding an extensive interpretation of the existing exemption under UPOV-like plant-variety protection at the commercialisation stage[1447], coupled with the calls for better defined and balanced public/private research partnerships and other institutional solutions, all show the existing disquiet about the future of agricultural research and development within smaller-scaled private structures as well. Involved in a thorny conundrum, breeders have strived to establish a working balance between the reach of their own exclusive rights and the correlated promise of royalty income to recoup investment on the one hand, and need to control the transaction costs involved in the necessary use of genetic material and linked processes.

13.1. Acting on the Patent and PVP scope

Practical experiences have shown that smaller or medium scaled private entities that develop improved plant varieties are much less accustomed to the reality of patents than of plant variety protection, with the perhaps notable exception of those established in the United States, where

[1444] P. BOWLER, *The Mendelian Revolution: The Emergence of Hereditarian Concepts in Modern Science and Society* Cambridge: Cambridge University Press, 1989.

[1445] LOUWAARS et al., *Breeding Business: The Future of Plant Breeding in the Light of Developments in Patent Rights and Plant Breeders' Rights*, *op.cit.*

[1446] WALSH, ARORA, and COHEN, "Effects of Reseach Tools Patents and Licensing on Biomedical Innovation," *op.cit.*, p.286.

[1447] Such extensive stretch has notably been advocated by industry associations in the Netherlands, see INTERNATIONAL ASSOCIATION FOR HORTCIULTURAL PRODUCERS, "*Aiph Position on Patent and Plant Breeders' Rights*", AIPH, 2010; PLANTUM, "Position on Patent and Plant Breeders' Rights."

plant patents have been granted since 1930. Indeed, the American Seed Trade Association has not published detailed position papers on the subject, concentrating rather on the expiration of biotechnology patents and the need to prepare the future of so-called "regulatory dossiers" and stewardship obligations for GM events[1448]. In other regions of the world, the trigger and reach of patent protection at the interface between these two protection tools have received more detailed attention from private plant breeders. The main objective here lies in ensuring legal certainty. It also focuses on the freedom to operate when constituting gene pools for breeding programmes, whether these are taken from the market of improved varieties, or prospected in the wild or in the gene banks. Breeders respectively face the conundrum of intellectual property rights navigation, and access and benefit-sharing legislation with its accompanying biopiracy claims.

13.1.1. Patent eligibility and other protection requirements

Plant breeders also face the adverse consequences of patent thickets present in molecular research tools and nucleotice sequences, just as much as public researchers, even if they may be more accustomed to negotiating licenses or playing on cross-licensing opportunities, while being generally less concerned with the dilemma of orphan crops or the issue of exclusiveness in itself. That is why much of what has been said in the previous section on possible adjustments on patentability requirements for and by public researchers will also serve the interests of private plant breeders. The confrontation with patents has nonetheless pushed the latter to re-assess the reach of patentable subject matter in their own terms, in an effort to limit its boundaries with regards to the strong biological link of all breeding activities and the existence of plant variety protection.

Patentability requirements

Numerous seed associations have vocally been advocating **high patentability standards** in agricultural biotechnology, influencing and welcoming the practices of patent offices and judicial authorities. The relatively newly formed French UFS, Union Francaise des Semenciers, has issued warnings against "**broad claims**", wishing

> "claims be granted up to a limited extent only, so that other breeders are not unduly restricted in their capacity for innovation. This question is closely linked to the state of knowledge at the time of the submission of the application and also to the evaluation of the criterion of inventiveness. UFS would like to avoid any possible blocking or restriction to genetic variability"[1449].

In 2003, noting the need greater speed and quality in patent examinations, the ISF welcomed a number of trends, which mainly stood in line with the dominant property paradigm, safe for certain reserves:

[1448] Under the heading of "key issues in IPR", the ASTA has indeed come up with a membership-led frameword called "the Accord", negotiated from 2010 onwards in order to provide the necessary transition of regulatory and stewardship responsibilities for biotechnology events. To do so, two different agreeements have been drafted, establishing in effect a pyramidal authorisation procedure, the Generic Event Marketability and Access Agreement (GEMAA) and the Data Use and Compensation Agreement (DUCA). For more information see http://www.agaccord.org/ (accessed November 2013).

[1449]UFS, *op.cit.*, 2011. , p.3.

> « Sequences or partial sequences of genes are subject to the same criteria of patentability as in all other areas of technology (novelty, inventive step and industrial application) such that the industrial application (utility) must be disclosed in the patent application as filed. In other words, it is accepted that a mere DNA sequence or nucleotide without indication of a function does not contain any technical information and is not a patentable invention. It is accepted that a **utility** must be specific to the subject matter claimed, that it must be credible for a person of ordinary skill and be practical, meaning attributing a real world value to the claimed invention »[1450].

Private plant breeders, in their individual capacity, have been quite active in filing oppositions contending the lack of **novelty** of certain biotechnology patents, notably those related to nucleotide sequences or breeding methods, as aforementioned. However, along with all traditional patentability requirements, it seems that common consensus has been difficult to reach to interpret such criteria. Private plant breeders have been additionally quite concerned with the **potential disclosure of origin** requirements that may be infused into patent and PVP applications, much more so than public researchers. This common concern has led to the adoption of official industry positions. The apprehension of plant improvers vis-à-vis disclosure has generally not been voiced against its feasibility, but has been rather directed at the additional financial burdens and the desire to perceive this requirement outside of the strict scope of IPR regulations, as a parallel civil liability stream. One of the challenges of disclosure in plant improvement lies in the fact that the less rigorous "novelty" criterion that opens the door to plant variety protection is solely a market definition that does neither entail biological property nor a prior art search. It might as a result be difficult to oversee such search in PVP applications, which are generally handled by more technical oriented entities, generally found under the auspices of Agriculture Ministries. However, as aforementioned, "the lack of commercial potential for landraces and their immediate derivatives [means] this is not a significant concern"[1451], even though the notion of "common knowledge" can be recalibrated in order to recognise the contributions of mass selectors, an approach that we shall tackle in the next section of this research. In the private plant breeders' perspective, the issue has as a result mostly been raised with regards to patent protection. Contrary to integrated biotechnology giants and "big pharma"; private plant breeders have never been completely against the disclosure of available information on accessed genetic resources. However, due to the specificities of agricultural plant improvement and the historically tangled and interdependent germplasm exchanges, they have rather insisted on a principle of "**declaration of source**", rather than origin[1452]. As "seed companies cannot run the risk of using material they have not legally accessed – it may cost them a fortune –breeders have to write down in their notebooks what material they used. Disclosure of origin (in the sense of source) is not an extra burden for seed companies"[1453]. Indeed, imposing the disclosure of the source of the material, i.e., "that the applicant should be obliged to say from where the genetic resource was obtained » is a reality private plant breeders are willing to do.

[1450] ISF, *op.cit.*, 2003. p. 14.
[1451] DUTFIELD, *Intellectual Property, Biogenetic Resources and Traditional Knowledge*, *op.cit.*, pp.55-56.
[1452] ISF, "*Isf Paper on Disclosure of Origin*", ISF, International Seed Federation, 2003.
[1453] SMOLDERS, *op.cit.*, 2005. , p.5

> Indeed, « normally the applicant knows and is allowed to indicate this with the following possible exception: In the breeding community, one reason why the "source" could not be known is that the genetic material is a historical part of the breeder's nursery and that there is no record of the original source »[1454].

Nonetheless, linking such disclosure to IPR protection requirements continues to create unrest amongst breeders. For instance, while UPOV "encourages information on the origin of the plant material, used in the breeding of the variety, to be provided where this facilitates the examination", it "could not accept this as an additional condition of protection [as] in certain cases, for technical reasons, applicants may find it difficult, or impossible, to identify the exact geographic origin of all the material used for breeding purposes"[1455]. The International Seed Federation insists for instance that such disclosure be defined as follows:

> "ISF believes that if origin has the meaning of "country of origin" in the sense of the CBD, the disclosure of origin would be impractical and very often not possible. Indeed, it is extremely difficult and in most cases impossible to trace the origin of a biological resource. Moreover, it is also very difficult to determine when and where biological materials, in the form received, have developed these distinctive properties. ISF proposes to solve this problem by providing information on the "source" of the biological material, i.e. that the applicant should be obliged to say from where he/she obtained the material. Normally he/she knows and is allowed to indicate this with possible exceptions:
> In the breeding community, one reason why the source could not be known is that the biological material comes from the breeder's nursery and that there is no record of the original source;
> Sometimes the biological resource has been received in the frame of a confidential contract and the disclosure of the origin would be a breach of that contract »[1456].

In this context, industry associations have advocated the potential disclosure requirements that may be infused into patent and PVP applications to be drafted as a declaration of source, the **non-compliance of which should befall in civil or crimimal law**, and could be followed through a clearing-house mechanism. The ISF for instance provides that compliance with CBD legislation cannot be drafted as a « universal requirement to demonstrate Prior Informed Consent in intellectual property protection applications »[1457]. The European Seed Association has in this regard a more comprehensive opinion:

> « The disclosure of the "source" should be an administrative requirement only and thus, the failure to disclose, could not invalidate the title of protection. (The disclosure of the "source" would not be a criterion of protection). Non-compliance or fraud should be sanctioned by civil and/or criminal law measures. Misappropriation should be prosecuted by the provider country. To facilitate the disclosure process, ESA suggests a central clearing house process which would allow applicants with a single, standardized

[1454] ESA, "*Position Paper on Plant Ip Protection and Biodiversity*", ESA, European Seed Association, Brussels, 2011.
[1455] UPOV, "Access to Genetic Resources and Benefit-Sharing: Reply of Upov to the Notification of June 26, 2003, from the Executive Secretary of the Convention on Biological Diversity (Cbd)," p.3.
[1456] ISF, *op.cit.*, 2003.
[1457] Ibid.

> declaration (similar to the declaration for biomaterial deposits under the Budapest Treaty) to satisfy the legal requirements for all countries. Ideally such clearinghouse should be associated to the WIPO ».

Subject-matter exclusions

Subject-matter exclusions from patentability reflect national and also regional specificities at their most contentious level. Indeed, North America has generally been more prone to warrant patent protection to plant varieties as a whole, whereas the Old European Continent has been reluctant to forego or diminish the hybrid protection offered by plant breeders' rights on a particular variety's phenotype. This distinction is not only present in pertinent legislation, it is also reflected in the viewpoints of industry associations. Private plant breeders have indeed showed greater reluctance towards patent enclosure possibilities in Europe, than in Canada, for instance, where it is considered:

> "Plant cell patents (also called plant variety and variety improvement patents) can be an important component of the Canadian IP toolbox. The protection afforded by these types of patents can encourage investments in locally adapted germplasm and can help move Canada further into a position of global agricultural leadership. In the absence of plant variety patents, companies may be more likely to focus on trait development without the complementary effort of germplasm/variety improvement"[1458].

This approach is not only explained by the fact that plant variety protection in Canada is considered to be weaker by plant breeders, following the precepts of the 1978 UPOV Convention, but also by the landscape of actors active in the country, which is reflected in the association's membership[1459]. The European Seed Association, which regroups a much higher number of SME structures, has on the contrary been continuously supporting the **subject matter exclusions** provided for by European legislation in plant-related inventions. The French Seed Association UFS has also directly tackled patent claims covering nucleotide sequences, proclaiming an undisguised aversion to the patenting of "native traits".

> "UFS calls native traits all characteristics (phenotypes) of a given plant, conferred by one or more genetic elements which is itself/are themselves:
>
> > a) naturally present (i.e. exist in the nature, in one individual of the species or a very close species) and recombined in the given plant by a sexual combination (with or without use of DNA markers) or
> >
> > b) obtained by a traditional selection method (which include and are not limited to random mutagenesis using chemical agents or ionizing beams, "tilling" methods).
>
> To avoid uncertainty about the concept of "native feature", UFS considers that it does not apply when:

[1458] Canadian Seed Trade Association, "*Moving the Needle: Making Canadian Farmers More Competitive, the Role of Intellectual Property Protection. The Vision for the Future*", Canadian Seed Trade Association Policy, 2013. p. 5.

[1459] The entire list of CSTA members is indeed available on their website, regrouping less than a hundred companies in total, which is very far from the number of SME's that are for instance active in the European Union.

> a) genetic diversity has been created by biotechnological means including, but not limited to, directed mutagenesis, or cisgenesis,
> b) introgression in the plant by means of sexual crossing only is not possible and needs to be facilitated by other means such as protoplast fusion, transformation, deletion enzymes.
>
> UFS considers that native traits and related native genes have to be excluded from patentability in order to preserve the use of genetic variability, and this with regard to the specificity of the profession, the basis of which is the recombination of native traits"[1460].

The UFS position is quite unique, in that it reflects on the need to better frame patents on genetic sequences, either within the inventive step gauge or in the assessment of essentially biological products if need be. There seems to be a lack of consensus on this particular issue within the International Seed Federation, whose position paper needs to reflect the views of the seed industry as a whole, including those integrated transgenesis giants that navigate and use the strong property paradigm without suffering its impediments, as smaller-scaled plant breeders do.

The 2012 position paper of the International Seed Federation reflects the diverging routes and consequent lack of consensus within its wider membership, as its section on patentability openly recognises ongoing debates over the criteria triggering protection with regards to biotechnological inventions :

> « ISF believes that inventions relating to traits made by humans (generally described as traits introduced or modified in the genome by human actions such as human-made mutant traits or GM traits) and modern technologies should be eligible for patent protection.
> ISF is cognizant of the fact that the patentability of traits based on naturally occurring genetics assembled in the target plant by crossing and selection ("native traits") and traditional breeding processes is currently debated.
> ISF firmly believes that, when addressing the question of patentability, solutions need to be found which maximize the innovation potential both for new varieties and patentable inventions. Solutions must recognize the specific needs of national or regional seed industries and their respective legislative systems and they must also reflect the need for global movement of seed »[1461].

The Federation does not delve into the shaky territory of analysing inherently national or regional patentability requirements. However, the consensus does reflect underlying tensions within its membership and associated differences of opinions. The European Seed Association, which also represents a wider range of seed industry actors, yet possesses a great proportion of SME's within its ranks, has not been able to tackle the issue of patentability as such either, focusing rather on the scope of protection awarded through patents, by advocating purpose-bound protection and a clear breeders' exception, where membership consensus seems to exist. Nonetheless, in its comprehensive 2012 position paper on intellectual property protection, ESA reiterated that

[1460] Ibid.p.4.
[1461] Ibid., p. 24.

> « both the European Patent Convention (EPC) of 1973 and Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions clearly stipulate that plant varieties as such as well as essentially biological processes for the production of plants are excluded from patentability. ESA fully supports these exclusions »[1462].

With regards to the scope of such exclusions, ESA has maintained that

> « Breeding processes based on crossing and selection (i.e. essentially biological processes) are excluded from patentability. This principle must also be applied to biological material resulting from the application of such "essentially biological processes".
>
> The effect of any product patent on biological material must not extend to any biological material which has the same properties, but has been produced by means of an "essentially biological process" and independently, i.e. without using the patented material »[1463].

ESA has also stated that the exclusion of essentially biological processes of Article 53(b) of the European Patent Convention should also extend to the products directly obtained by such process.

> "ESA is of the view that a claim directed to plants obtained by a *non* essentially biological process, such as, a process consisting of genetic modification, technically induced mutagenesis, protoplast fusion or another technical process not based on crossing and selection, is allowable even if the same plants could be obtained by an essentially biological process. However the effect of the patent protection granted on such plants should not extend to biological material obtained by an essentially biological process excluded under Article 53(b) EPC. Otherwise such exclusion would be meaningless"[1464].

The subject-matter exclusion should be viewed as a whole, and not be approached too restrictively, in order to maintain coherence in legislative drive and spirit. However, "plant varieties that are the result of a non-essentially biological process that is patentable, and each of the following generation of plants that possesses the same characteristics, will thus be patentable"[1465].

To a lesser extent, a number of actors have also attempted to **correct the inadequacies of PVP** protection in light of biotechnological advances. The most active in this respect has been CIOPORA, which, as aforementioned regroups members of the seed industry most prone to quick copying. It is in this context that they have been advocating

> "Some internationally accepted standards of "minimum distances" must be gradually implemented, species by species, by the UPOV Technical Committee if the *sui generis* system of protection instituted by UPOV is to be effective enough. Such standards should

[1462] ESA, *op.cit.*, 2011.
[1463] "*Position on Ip Protection for Plant-Related Inventions in Europe*", ESA, European Seed Association, Brussels, 2012.
[1464] "*Written Statement in Respect of Case G 2/13*", ESA, European Seed Association, Brussels, 2013.
[1465] TEMMERMAN, *op.cit.*, 2006.

> be applicable in all member countries of the Convention and should provide that every protected variety commands a certain "perimeter" of protection within which other candidate varieties cannot obtain a separate protection"[1466].

Interestingly, the new ISF view on intellectual property does not delve into the criteria opening up plant variety protection, but rather limits its analysis to the testing of distinctness, uniformity and stability. This seems to indicate that, except for a uniform approach to the possibility of disclosing the source of genetic material used to come up with improved plant varieties or patentable products and processes, there is little general consensus, or a least overall prudence amongst private plant breeders in advocating particular patentability requirements. Nonetheless, they are obvisouly influenced, and at times also directly influence, the debates over these requirements that are happening before the judiciary and also in patent offices. These stakeholders' active involvement is however much more prominent when it comes to examining the bundle of rights that accompany temporary exclusive rights.

13.1.2. ***Bundle of exclusive rights: essentially derived varieties under an evident breeders' exception***

In parallel to the newfound reach in PVP legislation, conventional breeders increasingly began to be confronted with an unfamiliar and strong legal entitlement, i.e. patents, where relatively restricted room has traditionally been awarded to follow-on use possibilities *vis-à-vis* protected innovations, especially in active breeding programmes. Indeed, patent legislation worldwide extremely rarely provides for exceptions to exclude third parties with specific respect to research conducted within the protection innovation, or to breeding. As aforementioned, when both the patent and PVP systems are in interplay, "the highest level of protection afforded by patents for biotechnological inventions threatens the existence and weakens the functionality of the breeders' exemption, which is an essential feature of any *sui generis* PVP system"[1467]. Non-integrated conventional plant breeders who rely on the sale of plant varieties for income have thus increasingly felt the urge to reclaim the breeders' exception, all the while mitigating the reach of essentially derived varieties. In this context, they have been pushed to assess the contribution and opportunity of a breeders' exemption in patent regulation, while also determining the extent of the threat in PVP systems should be carefully addressed, notably in light of the essentially derived varieties ("EDV") concept, and also of the inevitable co-existence of PVP with patents on the same material or within the product development chain as a whole.

Lifting the veil of essentially derived varieties

As aforementioned, there is an urgent need in plant variety protection to reassess the existing the need to maintain the incentive of protection in the era of the fast-paced genotype quest on the one hand, without resulting in an unwarranted upheaval of the breeders' exception, which would dangerously hamper the operations of plant breeders on the other. It is perhaps interesting to note at this early stage of investigation that the concept of essential derivation has been maintained in

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[1466]CIOPORA, "*Green Paper on Intellectual Property*", CIOPORA, International Community of breeders of asexually reproduced ornamental and fruit-tree varieties, 2003. , p.27.
[1467]CHIAROLLA, "Commodifying Agricultural Biodiversity and Development- Related Issues," *op.cit.*

the **Indian legislation,** even though its general level of protection has not been viewed stringent enough to adhere into any UPOV Conventions. The 2001 statute provides for a bundle of rights similar to that of UPOV 1991, and likewise extends breeders' prerogatives to essentially derived varieties, that are defined in the same language than UPOV 1991 and listed in a separate registrar[1468]. The statute, allowing for the protection of farmers' varieties in the first place, does in parallel also consider the situation where an EDV would be derived from such a landrace, and triggers benefit-sharing obligations with non-governmental organisations or individuals acting on behalf of a village or local community[1469].

The approach to the issue of EDV in the European Union, where our positive law analysis was rooted, has borne more traditional aspects, in parallel to other OECD countries, where the need to elaborate on the exact extent and definition of essential derivation in legislative texts has been unequivocally addressed, reinforced by self-regulatory social organisation initiatives taken by breeders' organisations. Canadian Seed Trade Association, where the legislative framework is compliant with the 1978 UPOV terms, for instance advocates

> "Amendments to Canada's Plant Breeders' Rights Act to incorporate language around essentially derived varieties are important to provide a balance between access to and protection of initial originators of germplasm"[1470].

Some industry organisations have even gone so far as to acknowledge the limits put upon the breeder's exception by the concept of the EDV, seeing such consequence as a sectoral need. This has been mostly the case of those entities active in the ornamentals industry, which are more prone to plagiaristic breeding than other fields. CIOPORA indeed considers "the EDV-concept does not constitute a limitation of the free access to germplasm, but it constitutes a temporary limitation of the exploitation of varieties, if they are EDV"[1471]. Acting with a legal framework complying with the 1991 UPOV terms, the European Seed Association more watchfully states,

> « The extension of the scope of breeders' rights from a protected initial plant variety to such essentially derived plant varieties forestalls both the unrightful appropriation of the intellectual property of the breeder of the initial variety and the misuse of the breeder's exemption, i.e. the free access to protected varieties for breeding purposes and the possibility to obtain plant variety protection for the resulting new plant varieties. Therefore ESA supports the EDV concept as an instrument for addressing the problem of plagiarism (or me-too varieties) and an important tool for ensuring not only a balanced, but also an efficient protection of plant variety rights »[1472].

Breeders have also felt the need to address the complexity surrounding the EDV notion, highlighting the absolute necessity to ensure legal certainty in a breeders' determination of his freedom to operate for the continuity of their activities. As aforementioned, the EDV concept

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[1468] VILAS TONAPI, M. ELANGOVAN, and N SEETHARAMA, "Essential Derivation of Varieties and the Imminent Challenges to Indian Plant Breeders," *Electronic Journal of Plant Breeding* 1, no. 4, 2010.

[1469] DHAR, *op.cit.*, 2002.

[1470] ASSOCIATION, *op.cit.*, 2013. , p.3.

[1471] CIOPORA, "*Position on Essentially Derived Varieties*", CIOPORA, International Community of breeders of asexually reproduced ornamental and fruit-tree varieties, 2008.

[1472]ESA, "*Esa Position on the Concept of Edv*", ESA, European Seed Association, Brussels, 2014.

indeed introduces numerous yet equally nebulous **thresholds triggering compensatory obligations** for subsequent breeders. Relying not only on the overarching concern to establish distinctness between plant varieties, EDV assessments adds in the conditional layers of 'derivation' and the pursuit of 'conformity of the subsequent variety to the essential characteristics' of the initial variety. The latter criterion has proven particularly troublesome, and has been the central focus of both self-regulatory endeavours and judicial courts, based on a quite natural quantitative enquiry of the variety's characteristics. Indeed, its definition in the 1991 Convention text is unclear and "the enforcement of EDV policies requires standardised protocols to be applied in an internationally agreed framework"[1473]. The overarching condition of distinctness, as the subsequent tests of conformity and derivation, just as the additional consideration of limited dependence all need to be clarified either through straightforward legislation or interpretative acts. The diplomatic conference establishing the 1991 version of the UPOV Convention required that UPOV develop **guidelines to assess EDVs**, which are still in progress. The work on these guidelines started in 1991 and was put to a halt in 1993, where it was decided that further work was premature[1474]. Responding to a growing industry need, an explanatory note was prepared in 2009[1475], following six years of technical work, but important elements were still open to discussion, since the guidelines did not give proper guidance on the number of difference to be considered in EDV assessments, or on the relationship between the notions of "dependency, derivation and conformity". The reach of essential derivation has not only been discussed by policy-makers, it has also, even if to a lesser extent, been interpreted by the **judiciary**. The aforementioned 2005 ruling of the District Court of The Hague has for instance adopted an interpretation of EDV favourable to the continuity of the breeders' exception, but plant breeders who wished to ensure the capture of full benefits from their research programmes welcomed it with more prudence.

Faced with a nebulous legislative and judicial context, **industry associations** have advocated **eased conflict resolution solutions**, in the likes of arbitration and the reversal of the burden of proof linked to an EDV presumption. They have tried to lead the way in determining species-specific thresholds that would indicate a high probability of essential derivation between two plant varieties, establishing said presumption. The problem faced by breeders is that in the absence of specific tresholds, the determination of "predominant derivation" will prove to be a battle fought by legal muscle (which most SME's lack), rather than objective assessment of innovative breeding practices:

> "With regard to me-too-varieties it is unclear, in what case a variety, which results from crossing and selecting, is predominantly derived from one of its parents. This question has to be answered on the basis of the genome of the varieties in dispute and it is up to the breeders of the specific species to determine a threshold, above which predominant derivation exists in these cases. As long as no such thresholds exist, the parties involved in

[1473] FIONA LEIGH et al., "A Comparison of Molecular Markers and Statistical Tools for Diversity and Edv Assessments," in *In the Wake of the Double Helix: From the Green Revolution to the Gene Revolution: Proceedings of an International Congress Held in Bologna, May 27-31, 2003*, ed. R. TUBEROSA, R.L. PHILLIPS, and M. GALE, Bologna: Avenue Media, 2005, p.349.
[1474] UPOV, Administrative and Legal Committee, CAJ/32 and Technical Committee TC/29, both having met in April 1993.
[1475] UPOV, "*Upov Explanatory Note on Edv, Upov/Exn/Edv/1*", UPOV, International Union for the Protection of New Varieties of Plants, Geneva, 2009.

> a dispute have to find solutions on their own or, if they fail to do so, the courts have to decide on the basis of expert opinions"[1476].

For instance, the ISF, in the vicinity of which an alternative dispute resolution system has been established through ISF rules on arbitration, spends considerable amount of time on the notion of essential derivation in its position paper on intellectual property. Most importantly, the Federation has also teamed up in order to come up with species-specific science-based technical thresholds and methodologies to establish distinctness between varieties and as a result help determine essential derivation.

> "The approach pursued in one of the protocols adopted by ISF, the one for perennial ryegrass, is that, if there is any doubt as to whether a new variety is an EDV of another variety (initial variety) - doubt based on the fact that the new variety 'presents the essential characteristics of that initial variety' - the genetic distance between the two varieties (the squared Euclidian distance) will have to be measured. If the distance is 7 or less, then there are grounds for seeking arbitration, where it is possible that the burden of proof may be reversed; the grower of the alleged derived variety would have to demonstrate that he did not derive that variety. In such cases, the breeding history would have to be tabled. Here, therefore, we see that the trigger point is that two varieties display the same essential characteristics. Whilst not stated explicitly, logic takes along that we are talking about phenotypical correlations. The genetic comparison is the next step. […] In the ISF Guidelines for 'EDV in Lettuce', there is a description of a method for genetic comparison of lettuce varieties. Probably also here phenotypical correlations form the trigger point for this comparison. While the principles behind this type of code is widely supported, it does not seem to be easy to reach agreement on acceptable codes for all the parties involved in relation to the most important species. ISF has adopted only a limited number of codes"[1477].

These protocols have been supplemented by interpretative resolutions trying to shed light on the reach of UPOV and national provisions extending the scope of PVP protection to essentially derived plant varieties. Associations have for instance attempted to clarify the notion of **« essential » characteristics**, highlighting that

> « The term "essential characteristics" in Art 14 (5) b) i) and iii) must not be limited to characteristics relevant for the marketing of the variety. Any such limitation would give rise to a very subjective evaluation and thus legal uncertainty. In the UPOV 1991 Convention the adjectives essential, important and relevant in relation to variety characteristics are to be regarded as synonyms. »[1478].

Furthermore, numerous organisations have also advocated the **reversal of the burden of proof** faced with highly similar varieties, including the European Seed Association, which

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[1476] CIOPORA, *op.cit.*, 2008. p.3.

[1477] BART KIETWIET, "*Essentially Derived Varieties*", European Union Community Plant Variety Office, available at http://www.cpvo.europa.eu/documents/articles/EDV_presentation_PlantumNL_March_2006_BK.pdf (accessed November 2013). , 2006.

[1478] ESA, *op.cit.*, 2014. , basing its analysis on an interpretation of "the discussions reflected in paragraphs 516 - 525 and 545 - 547 including the relevant proposals DC/91/56 and DC/91/57 as mentioned in the minutes of the Diplomatic Conference".

> "Supports the reversal of the burden of proof in favour of the holder of the plant breeders' right of the initial variety once a certain degree of genotypic similarity between the initial variety and a suspected essentially derived variety is reached. A scientific threshold triggering such reversal of the burden of proof needs to be determined for each species or group of species. Furthermore, such thresholds should not be set at too low a level in order to avoid that derivation is deemed too easily. Thresholds set at a too low level will lead to an increased number of unjustified edv court cases. Breeders taken to court would of course still have the chance to prove that they have not used the protected initial variety. But still these breeders would have to take time and cost to defend themselves in court. This could lead to greater reluctance of breeders in the use of germplasm of their competitors' varieties and thereby to a factual limitation of the breeders' exemption. The validity of the scientific thresholds for individual species or groups of species should be regularly reviewed in the light of the most recent technical developments and if necessary be revised »[1479].

Responding to the numerous position papers drawn by industry organisations, but also to the scientific and technical work that allowed the adoption of different protocols before the ISF, **UPOV authorities** have reacted to at least consider working on more precise guidelines on the assessment of EDV. A seminar specifically dedicated to the concept of essential derivation was held in Geneva in October 2013, where the closing remarks from the UPOV Council President announced future work in this area.

> « Guidelines that embrace a broad spectrum of stakeholders and interests may be more credible and persuasive for the Courts. The international standing of UPOV may help in the use of guidelines by Courts. Alternative Dispute Resolution (ADR) mechanisms (Mediation, Arbitration and/or Expert Determination) could be useful tools for EDV. Publication of an anonymized summary of ADR outcomes could offer guidance and could lead to harmonisation"[1480].

Private plant breeders, mostly those activein the European continent, probably because of their historical attachment to plant variety protection, have welcomed the new trigger of essential derivation for collecting royalties on the basis of a new, uniform and stable plant variety rather positively. They have nonetheless attempted to resolve the resulting uncertainties and reticence to use improved germplasm, while also trying to correct aggressive commercial practices that have threatened legal action against competitors with similar yet not essentially derived plant varieties. In this context, they have advocated scientific thresholds to be established either to reverse the burden of proof or to determine the existence of essential derivation, while establishing specific arbitration rules for the smooth resolution of conflicts. It is yet to be seen how these informal thresholds will be used in the courts and plant variety protection offices, perhaps guided by the commentary of UPOV authorities, which would be most welcomed at this stage.

[1479] Ibid.

[1480] KITISRI SUKHAPINDA, "Closing Remarks," in *UPOV/SEM/GE/13/PPT/17, UPOV Seminar on Essentially Derived Varieties* (Geneva, 22nd October 2013: UPOV, 2013).

Reinforcing the breeders' exception in plant-related IPR

In parallel to the efforts to ensure legal certainty as to the actual scope of protection vis-à-vis essentially derived plant varieties, debates have concomitantly focused on the core of the issue of innovation diffusion, i.e. on **the contours of the breeders' exception.** The breeders' exemption, which stands out as an efficient liability rule operating under a "take now, pay later" understanding[1481] has been seen as an efficient response to the shortcomings of the strong IPR paradigm to address the needs of molecular and conventional plant breeding, as chains producing inventions whose truly non-obvious and discontinuous character does not stand out as clearly as in "pure biotechnology"[1482]. These debates have not only taken place within the circles of plant variety protection itself, advocating at times an extension of the existing exemption under UPOV-like plant-variety protection to the commercialisation stage, but it has mostly been highly debated in patent 'circles'. Private plant breeders have nonetheless expressed great concern over the fact that the patent research exception does not specifically provide a viable defence against infringement when these breeders wish to use plant varieties containing patented genetic sequences[1483]. The contribution and **opportunity of a breeders' exemption in patent regulation** has as a result been increasingly assessed in the light of the characteristics of product development in plant breeding.

It is interesting to note in this regard that the existence of the breeders' exception in PVP legislation, and the demands for its inclusion in patent laws, has not only been rooted in the cumulative nature of plant breeding, but it has also been rooted in compliance with international biodiversity law. Indeed, the fact that the phenotype of improved plant varieties is open for further research and even breeding has been advocated as a **benefit-sharing mechanism** in itself. The International Seed Federation has for instance affirmed its support for "a single international regime to govern the development of rules and regulations concerning access to all genetic resources for plant breeding", where "the breeders' exception would be recognised as benefit-sharing"[1484]. Some organisations have gone as far as stating that the mere existence of the breeders' exception as a benefit-sharing mechanism prevents the need to enact additional compensation mechanisms. CIOPORA, the International Community of Breeders of Asexually Reproduced Ornamental and Fruit Varieties, for instance states that

> "The free access to protected varieties for breeding purposes is a very important form of benefit-sharing and this approach is unique for the sector of plant breeding, no other industry knows this form of benefit-sharing institutionalized by law. Different from and as an advantage to simple monetary benefit-sharing it provides the potential to creating additional value. But the breeder's exemption also reflects and acknowledges that unrestricted access to any kind of genetic resources as breeding material is essential to

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[1481] MERGES, "Institutions for Intellectual Property Transactions: The Case of Patent Pools," *op.cit.*

[1482] REICHMAN, "Saving the Patent Law from Itself: Informal Remarks Concerning the Systemic Problems Afflicting Developed Intellectual Property Regimes," *op.cit.*

[1483] The Royal Society of Plant Breeders has for instance expressed such concern directly during a consultation by the United Kingdom Department of Trade and Industry in 2004, "Patents for Genetic Sequences: the Competitiveness of Current UK law and practice".

[1484] ISF, "*Isf Communication "Support for a Single International Regime to Govern the Development of Rules and Regulations Concerning Access to All Genetic Resources for Plant Breeding'*"", ISF, International Seed Federation, 2012.

> ensure future progress in breeding, which, again, is to the benefit of the society as whole. By additional ABS rules the strange situation would be created, that protected varieties (in which a lot of R & D has been invested) are freely accessible for breeding, but wild varieties would be not. For all these reasons CIOPORA agrees with UPOV that no additional ABS-regulations are necessary; otherwise additional barriers to progress and utilisation of genetic resources will be established"[1485].

While the author cannot be fully on point with such a restrictive approach to the compensatory legal obligations stemming from the new agrobiodiversity public domain of international environmental law, which would for instance disregard other technology transfer opportunities but also to a certain extent the recognition of farmers' rights, the existence of a broad breeding exception as a means of benefit-sharing could be fully recognised as one means to uphold the new PGRFA public domain. While those breeders' exemptions recognising immediate rights over protected material for further use in breeding programmes remain the absolute foundation of plant-variety-rights protection worldwide, these remain scarce in **patent legislation.** The TRIPS framework remains indeed tight-lipped and yet a handful of national legal orders allow for breeding-specific research possibilities outside negotiated licenses. In Germany, France and Switzerland[1486] (and probably soon in the Netherlands), the PVP breeder's exemption has found its echo in patent legislation, where breeding programmes could be initialised, even when the material contained patented traits, the consent of the patent holder needing to be sought at the commercialisation stage. As early as 2003, when commenting on the initial political consensus reached within the Council of the European Union on the reach of the "Community Patent", the European Seed Association had already expressed concern over the limited reach of the research exception in patent legislation.

> The breeders' exception "is crucial for plant breeding where using existing plant genetic resources, even in the form of protected commercial plant varieties, is an indispensable precondition to further genetic progress. The recent history of plant breeding has clearly shown the scientific and economic importance of this exception. It has enabled major and continuous progress in modern agriculture, e.g. the improvement of yields, strengthening resistances to diseases or adapting specific production to specific markets and climates. The fact that there is no equivalent provision under the patent system to the breeder's exception under the UPOV system creates an ambiguous situation when a plant as such is protected via a patent as the research exception in the patent proposal is too restrictive for plant breeding purposes"[1487].

[1485] CIOPORA, "*Positions of Ciopora Regarding an Access-and-Benefit-Sharing-Regime under the Convention of Biological Diversity* ", CIOPORA, International Community of breeders of asexually reproduced ornamental and fruit-tree varieties, Campinas, Brazil, 2009. p.3.

[1486] In France, Article 613-5-3 of the Code of Intellectual Property defines the "exclusive rights of exploitation", including those acts undertaken for the creation, discovery and development of plant varieties. A similar approach is found in Switzerland, in Article 9(e) of the federal law on patents, as well as in the German patent law's Article 11(2a).

[1487] ESA, "*Esa Position Paper on the Proposal for a Council Regulation on the Community Patent (Com/2000/412)*", ESA, European Seed Association, Brussels, 2003.

This position has also been quite vocally advocated by national associations, such as Plantum, the Dutch Plant Breeders' Association, which has been very active in this field. Drafted in 2009, their position paper on intellectual property goes as far as ascertaining:

> "As far as plant material is concerned, the publication of an invention or a deposit does not contribute in any way to the stimulation of innovation, and therefore represents no added value for society as a whole, if the protected material itself may not be made freely disposed of for the purpose of the development of new varieties.
> [To remedy this,] It is not sufficient to allow patented varieties to be used freely for plant breeding purposes whilst the trading in new varieties still requires a licence. As long as there is no guarantee that a licence will be obtained, it would be irresponsible to invest several millions in a plant breeding programme which may end up having to be abandoned. Therefore, no plant breeding takes place with patented material until the licence negotiations are complete. By the time it becomes clear whether a licence will or will not be granted, and hence whether further breeding will be possible, the patent holder has been able to completely monopolise the crop or the trait concerned. In view of the very long development period, it is no longer possible at that point to set up a competitive breeding programme »[1488].

The Association has in this sense been advocating an extended breeders' exception, which would continue to operate at the time of the new plant variety's commercialisation, at which point a system of "compulsory licensing" would enter into play. The Plantum wording has been taken on by the AIPH, the International Association for Horticultural Producers in 2010, concluding "the breeders exemption in its full reach should be maintained also when a patent right is included"[1489]. In 2011, the French "Union Francaise des Semenciers" followed suit, coming up with a similar, yet a little more restrained approach to a breeders' exception in patent legislation.

> "UFS is strongly attached to the possibility of maintaining access to the genetic material of a variety containing a patented element. UFS supports the disposition introduced into the French and German implementation of the European directive on biotechnological inventions, which allows the breeder to use any variety containing patented elements free of duties on sale if in the end, the new variety obtained no longer contains these patented elements"[1490].

The issues highlighted by small and medium sized breeders seem to have found **echo before the European legislator**. Indeed, in its aforementioned strict stance over the patentability of essentially biological processes, the European Parliament has reiterated the critical importance of conventional breeding methods to modern plant and animal breeding, but it has also mainly highlighted that:

> "It is a fundamental principle of the international system of plant variety rights based upon the UPOV Convention, and of the EU system based upon Regulation (EC) No 2100/94,

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[1488] PLANTUM, "Position on Patent and Plant Breeders' Rights."
[1489] PRODUCERS, *op.cit.*, 2010.
[1490] UFS, *op.cit.*, 2011. p.5.

that the holder of a plant variety cannot prevent others from using the protected plant to promote use of protected varieties for further breeding activities […] it is important that a similar privilege should exist within patent law throughout the European Union"[1491].

These considerations have been taken up by the recent European Agreement on a Unified Patent Corurt, which in its article 27, deals with those "limitations of the effects of a patent":

"The rights conferred by a patent shall not extend to any of the following:
(a) acts done privately and for non-commercial purposes;
(b) acts done for experimental purposes relating to the subject-matter of the patented invention;
*(c) the use of biological material for the **purpose of breeding, or discovering and developing other plant varieties**"*. (Unified Patent Court Agreement, Art.27, emphasis added by the author).

This important move from the European Union, one of greatest players of the seed industry, will probably find positive echo in other legislative for a, especially in developing countries with wider SME presence. The lack of consent from the rightholders for carrying out active commercial research using the innovation is at first sight quite a positive departure from traditional patent protection, and its efficiency still needs to be tested[1492]. Early indicators show that such flexibility has, in practice, resulted in hostile reactions from competitors wishing to shut down on-going research activities. There are also extremely heated discussions on the extent that the breeders' exception should have in practice, and the trigger point where licensing negotiations would need to be undertaken, if the patented element should still be present at the stage of commercialisation or not. The mechanism has been criticised due its discount of contractual freedom to license protected products or processes, based on a belief that transactional bottlenecks are likely to be overcome by so-called "repeat players" that frequently need to exchange rights[1493].

13.2. Acting on the enforcement of prerogatives

The objective here lies in the full capture of prerogatives that come with plant variety protection. As aforementioned, plant breeders who rely on sales and royalty income from their stable and improved plant varieties are in dire need of fully capturing the benefits of plant variety protection. This need is inherent to the nature itself of plant innovation, which remains indissociable from cultivation. It also stems from the self-replicating disposition of the developed product, by farmers, researchers and competitors. But it has also been particularly exacerbated by the brave new world of molecular breeding, which allows competitors' to speedily discover marketed varieties' innermost riddles. In order to ensure that third parties duly respect the complete prerogatives of exclusive intellectual property titles, especially in light of the rapidly evolving opportunities offered by molecular technology, several options have been put forward by the community of

[1491] European Parliament resolution of 10 May 2012 on the patenting of essential biological processes (2012/2623(RSP)), P7_TA(2012)0202.
[1492] BLAKENEY, "Patents and Plant Breeding: Implications for Food Security " *op.cit.*
[1493] MERGES, "Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations " *op.cit.*

plant breeders and the State, if and when needed. Some measures target the use of protected varieties by farmers, and other initiatives are rather directed towards other plant breeders.

They are all based upon an initial consideration, that

> "By loosing turnover and growing costs, also the calculated return on investment shrinks. In a worst case scenario this might force a company out of business, especially since it are often small and medium sized, family owned businesses, which are involved in breeding. But even without such a final consequence, a breeder who needs to calculate on a low (if any) return on investment due to improper IP-protection will not be encouraged to develop new varieties"[1494].

Acting on legislative flexibilities and opportunities

One of the strategies put forward by breeders in order to protect their gene pools has been the recourse to **trade secrecy,** which obviously hampers the public domain in a considerable fashion. This solution has been particularly relevant for parental lines, which are crucial to the breeding business. Challenges were raised vis-à-vis the protection of parental lines of hybrid varieties way before the dawn of molecular science, and have been subject of much debate. These lines are indeed generally covered by trade secrets, and are not available in the market as such. Their protection has been vehemently fought for in courts, epitomised by the 1992 lawsuit brought by Pioneer to Holden Foundation Seeds, where the latter had to pay forty six million USD of damages[1495]. The judiciary did not assess whether genetic information could qualify as a trade secret, but rather showed that when such reality is undisputed for the parties concerned, this peculiar tool could effectively be used to protect breeding lines, side by side with patents and PVP.

Trade secrets can be avoided through adequate incentivisation in national instruments carving out the protection of plant varieties, especially those with a **clear and direct legal entitlement to act upon the detection of infringements**. These entitlements are generally not only found in intellectual property rights legislation as such, but also in customs regulations as well. An example of the former action comes from Spain where "rural police are engaged in monitoring and inspecting growers and plant raisers to check on infringements"[1496]. In Italy, the legislation further provides for a reversal of the burden of proof with regards to harvested material obtained through the use of the protected variety's propagating material, which are presumed to be illegal in the absence of proof to the contrary[1497]. With regards to customs action, the Europen Union has acted to strengthen potential actions that could be taken when faced with infringing goods[1498].

[1494] CIOPORA, "*Ciopora Strategy Paper on the Negative Effects of Infringements of Plant Variety Rights*", CIOPORA, International Community of breeders of asexually reproduced ornamental and fruit-tree varieties, 2007. , p.3.

[1495] BLAKENEY, *Intellectual Property Rights and Food Security*, *op.cit.*

[1496] VAN KEMPEN, "Enforcement: Protection Is Only Half the Job," *op.cit.*pp. 28-29.

[1497] Article 107(2) of the Italian Intellectual Property code (D.lgs.n 30/2005).

[1498] Directive 2004/48/EC on the enforcement of intellectual property rights and the Council Regulation (EC) No 1383/2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights, *OJL* 195, 2nd June 2004, pp. 16-25 ; as well as Council Regulation (EC) No. 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights, which has been repealed by the new Council Regulation (EU) no 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights, *OJL* 181, 29.6.2013, A number of other legislative actions have been pleaded for by industry organisations, such as « One competent EU court, possibly linked to the future EU Patent Court, or one per Member State for infringement cases regarding EU Plant Breeders' Rights in order to create more expertise in the field of EU Plant Breeders' Rights within courts; Similarly, one competent court per Member State for infringement cases regarding national plant breeders' rights; In infringement cases where an expert opinion on variety identity and/or (lack of) distinctness is required a possibility for holders of plant breeders' rights to apply for such an expert opinion to be carried out by CPVO examination offices »[1499].

Notwithstanding their usefulness in protecting innovative breeders against infringements, these solutions do not respond to the aforementioned issues regarding the need to collect the full range of royalties that would act as a **sufficient trigger to foster greater investment** in plant breeding. Action has to that end also been taking place in the legislative front, advocating the gradual restriction of the farmers' exception in UPOV Conventions with a clear policy objective of enticing the private sector's interest in plant breeding, especially in market segments with strong farm saving opportunities and practices. The issue of farm saved seed royalties is much more important in cereals where exploitations tend to be larger in size, and the financial return from eventual farm-saved-seed royalties to breeders is estimated to amount to sixty five to seventy five million EUR per year[1500]. First and foremost, this issue has been dealt with through direct legislative amendments. As aforementioned, the EU acquis was amended so as to condition the use of farm-saved-seed to a reasonable royalty rate. Indeed, under article 14 of Council Regulation 2100/94, farmers are given the right to grow protected seed, but this right is subject to the payment of royalties to be determined by national authorities. In Australia, plant variety protection laws were amended in 1994 with a clear desire to foster private investment in wheat breeding, as the former 1987 statutes did not regulate farm-saved seed as strictly as breeders would have wanted, and especially did not condition its re-use to royalty payments[1501].

Institutional solutions to enforce IP rights

Nonetheless, even with such legislative amendments, the problem of compliance and enforcement remained a persistent challenge. These challenges led up to interesting examples of institutional design and social innovation from plant breeders. It has for instance led up to the launch of "Operation Plant Breeders' Rights" in Australia in 2004 "in an attempt to catch seed pirates who were […] costing the Australian seed industry three hundred million AUSD per year"[1502]. The submissions collected during this initiative largely "lamented the problem of enforcement, particularly as plant breeder's rights relate to self-replicating biological material and the difficulties of relying on small farming communities for evidence". In the absence of absolute permission rules, farmers decide in effect whether and to what extent they will make use of the farmers'

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pp.15-34, where the early release of goods said to infringe plant variety protection has been tightened, now possible if no precautionary measures have been adopted by the competent authority (article 24).

1499 ESA, "*Esa Position on the Enforcement of Plant Breeders' Rights*", ESA, European Seed Association, Brussels, 2011.

1500 See the advocacy group: http://www.lafranceagricole.fr/actualite-agricole/semences-de-ferme-cov-l-esa-pour-un-systeme-harmonise-au-plan-europeen-69285.html

1501 THOMSON, "The Yield of Plant Variety Protection," p.5.

1502 SANDERSON and ADAMS, "Are Plant Breeder's Rights Outdated - a Descriptive and Empirical Assessment of Plant Breeder's Rights in Australia, 1987-2007," *op.cit.*

privilege under plant variety protection. This means that "an incalculable number of plantings are undertaken each year, so that the holder or, as the case may be, the organisation representing him are not in a position to uncover by themselves cases of planting which entitle them to remuneration"[1503].

When legal entitlements and compliance mechanisms are not clear enough or cannot be efficiently pursued, breeders have resorted to self-regulation. They have done so by putting their interests together and set up **specialised entities** to enforce their titles. That is how associations like the Anti-Infringement Bureau set up in 2011 have seen the light of day. This Brussels-based organisation is actively involved in fighting and pursing infringement cases in courts, either through "pilot enforcement projects", as the one ignited in Italy in 2012, where its members were given legal and technical support to take legal action, or by directly representing them and taking appropriate action on their behalf. The same entity is also considering taking its actions one step farther, contemplating the possibility to set up a "collective European Union trademark for use by plant raisers who commit to respect production guidelines ensuring the traceability from seeds to plants"[1504]. This trademark would act as an "assurance that the plants delivered correspond to the variety ordered and are produced lawfully". Even if industry peak bodies and licensing associations do exist in certain segments of the plant breeding industry, they are affected by the fragmented nature of the industry itself and may thus serve the benefit of wider scoped entities that possess greater financial interest and budgets to enforce titles. Agrobiodiversity users have in this instance "supported a central coordinating organisation which could represent breeders' interests or provide independent investigation and specialist enforcement skills"[1505]. However, in Australia at least, where such stakeholder consultation was conducted, government action was not favoured, at least "unless sectors of the plant breeding industry come to an agreement on the structure and function of a central body and seek the Government's assistance"[1506].

In order to fully capture the value of their protection inventions, breeders do not only have to fight infringements, they also need to **collect the royalties** that are triggered by the use of their products, especially in light of the new expansion of farm-saved-seed royalties and harvested material.

> "In the UK, the agency developed to organise and encourage these payments is known as Fair Play. This group was developed as a joint initiative between the British Society of Plant Breeders (BSPB) and the major farming unions in the UK in order to "combat farm-saved seed evasion." Farmers can pay these fees in two ways. If they purchase seed, the payment is included in the invoice sent by the seed dealer and these payments are then forwarded to the seed company. If the farmer saves seed, then the farmer must pay the fee directly to the BSPB. The system is not perfect, and some farmers avoid paying fees by claiming that they are planting non-protected varieties. However, an estimated 90% of the royalties are collected, in part because farmers who do not pay are in violation of British law. […] Breeders in the United States can, in theory, collect this premium when a farmer sells protected varieties but not when a farmer uses the protected variety himself. In the

[1503] Commentary of *ECJ, Schulin v STV*, IPPT20030410, 2003, at p.5.
[1504] VAN KEMPEN, "Enforcement: Protection Is Only Half the Job," *op.cit.*, p.29.
[1505] GOVERNMENT, *op.cit.*, 2010.
[1506] Ibid.

United States, the responsibility for collection lies with the owner of the IP right, and there is a perception among seed company executives that the costs associated with collection, both legal and reputational, are likely greater than the benefits"[1507].

Other collection agencies exist as well, but the British Society of Plant Breeders' example proves interesting in the means through which the financial compensation system was established. The Society indeed set up a "Fairplay" campaign in 2005, where "plant breeders and the farming unions [worked] together to safeguard future innovation in plant breeding by tackling the gap in unpaid royalties on farm-saved seed". Joining forces with the major farmers' union, the BSPB has negotiated an efficient scheme to collect royalties either on tonnage or at a hectarage rate, in a unique formula that has been agreed upon between stakeholders. However, certain agrobiodiversity users do not consider this quite efficient royalty collection mechanism wide and proficient enough. **Contract-based farm-saved seed royalty enforcement** has become the norm and increasingly apparent. For instance, a UK-based company focused on cereals, Senova, acting on the premise that applicable legislation was insufficient in the European Union, has set up a contractual approach to better IP enforcement, through the concept of "Royalty Area Collection"[1508]. The institution's actions are grounded upon the "structured contract approach", based on the conditions of sale that surround the seeds of improved and protected varieties. The scheme acts under a unified royalty rate in each area, with guarantees of transparency and traceability, since the contract provide for a flat rate per hectare for each variety sown, the means of collection, and an obligation on growers to maintain sound records of seed usage, assorted with a right to inspect and audit. These contractual obligations go far beyond the prerogatives awarded under plant variety protection in the European Union, as the right to information on farm saved seed hectarage is not unequivocal in applicable laws. For instance, in Belgium, it is generally considered that information on farm-saved seed ought to be obtained through or with the consent of the growers[1509], whereas the German legal order looks into an array of evidence that may indicate that royalty payment is due, whether as a reasonable compensation in cases of PVP infringement, or an equitable remuneration in cases of farmers' derogational uses[1510].

13.3. Facilitating access to research tools and patented foundational technologies

In order not to be outstripped in an increasingly competitive market, plant breeding companies have had no choice but to include the biotechnological revolution within their innovation chain. They merely faced two options to do so, either develop their own applied research capacity with a reliance on public sector initiatives for fundamental research, or obtain licenses or contracts with companies which either specialise in biotechnology research or possess large strategic biotechnological capacity. Acting on the same rationale and solutions as public researchers, private plant breeders have for this purpose also entered into complex licensing but also other cooperation

[1507] HAYES, LENCE, and GOGGI, "Impact of Intellectual Property Rights in the Seed Sector on Crop Yield Growth and Social Welfare: A Case Study Approach," *op.cit.*

[1508] Chris GREEN, "Royalty Area Collection: a contract-based approach to better IP management", presentation at the UPOV Symposium on Contracts in relation to Plant Breeders' Rights, held in Geneva, 31st October 2008, available at http://www.upov.int/export/sites/upov/news/en/2008/8_Green.pdf. (accessed February 2014).

[1509] Comm. Huy (réf.) 18 May 2004, *I.R.D.I.*, 2005, liv. 2, p. 163, note VAN OVERWALLE, G., "Over kwekers, boeren en trieerders: driehoeksverhoudingen in het kwekersrecht onder de loep", pp. 168-169.

[1510] Higher Regional Court of Düsseldorf ("OLG Düsseldorf"), Case 4a O 191/08, 18th July 2013, I-2 U 145/09.

agreements aiming to facilitate their access to molecular research tools and to patented foundational technologies. The molecular plant breeding innovation chain retains certain particularities that are difficult to surround by traditional IP tools, since there are often times multiple types of protection surrounding a single product, whether at the actual physical level of possession, or at the informational level of trademarked breeding methods or molecular markers, patented genetic construct components such as promoters, plant breeders' rights protected plant varieties or even trade secrets. The navigation of the so-called "patent thicket" that ought perhaps to be re-baptised the "control thicket" in plant breeding, is further challenged by issues regarding the freedom to operate upon which all agricultural crop genetic improvement remains based, a freedom that may seriously be jeopardised before the menace of royalty-stacking. Indeed, if the numerous right-holders over the different "components" of the final plant variety that a company wishes to commercialise state important up-front or sales-volume linked royalty payments, such commercialisation may quite realistically never take place, as it may cost more than it would bring in.

Licensing solutions: cross-compulsory schemes and pro-rata protocols

Royalty stacking undoubtedly threatens the development and commercialisation of new varieties by plant breeders in need of accessing molecular research tools, whether in the form of molecular markers, sequence tags, or non-essentially biological processes like haploid technology that may all allow for time and precision gains in their research programmes. The difficulties experienced even by the arguably strongest and most experienced private breeders, even those with integrated biotechnology capacity, enhance the need for such action. The argument that had long opposed Syngenta International AG and Monsanto Company on proprietary *Agrobacterium*-mediated transformation technology has for instance been resolved through a **cross-licensing agreement**. This particular solution nonetheless warrants the opposing entities to possess significant economic strength, an existing patent portfolio that is of interest to the other party, and an established legal expertise.

Acting in specific regard to the negotiated uses of patented molecular research tools, the navigation of licensing practices could be facilitated and universalised through **pro-rata protocols** including provisions against royalty stacking or even prefabricated licensing provisions encompassing ex post compensatory liability rules. The adjustment of existing rights and obligations between technology developers, holders and users, but also of the necessity to foster innovation all the while maintaining access to information and scientific progress, indeed calls for a swift and equitable tailoring of license terms. A solution against the threat of royalty stacking and the difficulty of having mere recourse to traditional licensing or cross-licensing solutions could therefore lie within the development of such "pro rata sharing protocols", which may self-adjust as the mosaic of involved actors evolves. As to the content of such license protocols, in practice, the buzz worthy "**fair, reasonable and non-discriminatory" (FRAND)** terms mainly used by a number of knowledge-intensive and competition-savvy industries for product compatibility could for instance be looked at, based on fixed fees payments, which could then combined with an added-value calculation pattern modifying the initial amount in accordance with existing repayments, trademark use or other incentives. The recourse to FRAND license terms has been specifically recommended for instance by the European Seed Association, which has "called upon holders of patent rights to follow FRAND (fair, reasonable and non- discriminatory) conditions in their licensing policies »[1511]. Other pathways for a solution might involve the recourse to shrink-wrap licenses or bag labels in seeds, with a common denominator established for instance through the submission of **model agreements** to those institutions governing applicable international treaties, such as the CBD's COP or the ITPGRFA's Governing Body. Just like the aforementioned examples of standard licenses in the case of public researchers, the recourse to such model terms nonetheless presents inherent difficulties, including the wall of competition law, a necessary uniform motivational impetus from all active actors, and arguably also training for all.

A number of prominent actors have in the meantime come up with **facilitated licensing mechanisms,** such as Syngenta's electronic licensing platform, where theoretically even the toughest competitors will not meet refusals to access patented technology. The online platform brings together a number of technologies, from promotors regulating gene expression to techniques of plant transformation, where the user can find technology categorised either as a "native trait" or as an "enabling technology", not shying away from contentious wording[1512]. The technology pages thereafter provide detailed information on the product or process, as well as patent information and financial terms attached to the license, usually fixed at a flat rate or a signature fee that will rise depending on the company size, including compensation for associated trademark licenses when applicable. The type of product of processes covered by patents is an important element to assess the feasibility and interest in facilitated online access, whether such access is provided directly by a single right-holder, or by several ones through an alternative institutional solution:

> "Two relatively rare types of patents, however, do have qualities that should make them more conducive to online promotion. The first are those few patents that cover highly important general-purpose research methods, for which a winning marketing strategy would be to grant as many routine nonexclusive licenses as possible throughout the entire industry (which was the licensing strategy for the famous Cohen-Boyer patents of UC-San Francisco and Stanford). Holders of such general-purpose patents would benefit greatly from the low transaction costs of online promotion and distribution. Second, more numerous patents protecting highly specific and well-defined incremental improvements to familiar downstream products or processes could also be distributed online. These kinds of inventions are often most valuable when exclusively sold or licensed to the one specific potential user who values that innovation the most. Holders of these patents would benefit from the ease of finding and notifying a potential buyer and from the low transaction costs for executing a routine transaction. Finally, however, the bulk of patents that fall somewhere in between these two examples, either in terms of importance or in terms of

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[1511] ESA, *op.cit.*, 2012.
[1512] Syngenta E-licensing homepage, http://www3.syngenta.com/global/e-licensing/en/e-licensing/Pages/home.aspx (accessed February 2014).

generality of application, will likely be difficult assets to transact in the online exchange environment"[1513].

Moving aside from pure self-regulation, licensing has been used as a formal tool to overcome lethal shortcomings linked to the co-existence of PVP and patent titles. The bottleneck regarding the implementation of the breeders' and the farmers' exception was for instance solved in the European Union through a formal mechanism providing for **cross-compulsory licensing** in certain blocking scenarios. Article 12 of the Biotechnology Directive 98/44 indeed allows breeders to obtain a license for the use of a patented biotechnological invention, if the acquisition or exploitation of plant variety right is not possible without infringement. According to the criteria of Article 31 TRIPS, such licensing should trigger appropriate royalties and be conditional to the demonstration of an unsuccessful application for contractual license. Interestingly, the criteria stemming from patent law, which requires the plant variety to constitute "a significant technical progress of considerable economic interest" was also taken over in the European Union's scheme for plant variety protection. In the past, EC Regulation 2100/94 only considered compulsory licensing in the case of public interest, and has now enlarged its scope to allow patent holders to use plant varieties that contain patented component.

> "*On application, a compulsory licence for the non-exclusive use of a protected plant variety pursuant to Article 12(2) of Directive 98/44/EC shall be granted to the holder of a patent for a biotechnological invention, subject to payment of an appropriate royalty as equitable remuneration, provided that the patent holder demonstrates that (i) he/she has applied unsuccessfully to the holder of the plant variety right to obtain a contractual licence; and (ii) the invention constitutes significant technical progress of considerable economic interest compared with the protected plant variety.*
>
> *Where, in order to enable him/her to acquire or exploit his/her plant variety right, a holder has been granted a compulsory licence in accordance with Article 12(1) of Directive 98/44/EC for the non- exclusive use of a patented invention, a non-exclusive cross-licence on reasonable terms to exploit the variety shall be granted, on application, to the holder of the patent for that invention,*
>
> *The territorial scope of the licence or cross-licence referred to in this paragraph shall be limited to the part or parts of the Community covered by the patent*" (EC Regulation 2100/94, new Article 29 as amended by EC Regulation 873/2004).

Such a double cross-licensing efforts creates legal certainty for breeders who are worried about their freedom to operate, albeit through a complex administrative system whose efficiency still ought to be tested. Notwithstanding the inherent difficulties to assess when technical progress may be significant enough to trigger it, enlarged cross-licensing possibilities like the European solution do not address the issue of legitimacy of accessing protected genetic material during the

[1513] GREGORY D. GRAFF and DAVID ZILBERMAN, "Towards an Intellectual Property Clearing-House for Agricultural Biotechnology," in *Agricultural Biodiversity and Biotechnology in Economic Development*, ed. JOSEPH COOPER, LESLIE LIPPER, and DAVID ZILBERMAN, Springer, 2006., pp.394-395.

development cycles of breeding programmes[1514]. Since such licensing schemes only provide for partial solutions when a new plant variety is developed enough to qualify for protection and has a determined value, they do not address the uncertainty braving around the initial stages of breeding programmes. This uncertainty could not be waivered without the inclusion of appropriate research exemptions into all patent systems[1515].

Any action solely affecting individual licensing practices, whether with the intervention of the legislator, or in a solely self-regulatory stance, in order to allow access to technology through cross-compulsory or fairer schemes, or facilitating diffusion through online platforms, bears inherent limits. They may quite easily not only hit the wall of self-interest, but also competition law. This type of adjusments will furthermore solely operate with regards to certain types of inventions, whether these are linked to a specific actor's material, or possess characteristics that make more relaxed access opportunities more profitable and interesting for right-holders; pushing as a result for wider and potentially more global and durable collective solutions.

Institutional solutions to affect information and transaction costs in the access to upstream tools

Considering the high costs of developing a comprehensive biotechnology laboratory, **cooperation agreements** have emerged not just between private and public entities, but also within the private sector itself, as the successful business endeavour that owns the AFLP fingerprinting technology, Keygene, exemplifies, with its four strategic shareholders (Enza Zaden, Rijk Zwaan, Vilmorin and Takii, which are all within the top ten best-performing companies in the vegetables seed sector) who wished "to create synergy and higher efficiency in their molecular genetic research programs and thus improve their breeding efforts"[1516]. Next to this collaborative model stand specialised laboratories, often times start-ups having emerged from within academic entities, selling extremely high-end biotechnological tools. Extensive collaboration agreements and research partnerships also do exist vis-à-vis these specialised independent entities, as the extensive patent-holder Mendel Biotechnology exemplifies, an applied biotechnology research market actor with associative endeavours with both Monsanto, which possesses exclusive royalty-bearing licenses to Mendel technology in certain crops, as well as with Bayer Cropscience, aiming at the development of further chemical products that regulate plant stress tolerance[1517]. In this specific regard, solutions have also been envisaged in order to encourage the recourse to formal agreements between breeding institutions based upon partially open innovation systems, discouraging the patenting of research tools while fostering their common development and use.

[1514] CHIAROLLA, *Intellectual Property, Agriculture and Global Food Security: The Privatization of Crop Diversity*, *op.cit.*, p.103.
[1515] Ibid*Intellectual Property, Agriculture and Global Food Security: The Privatization of Crop Diversity*, *op.cit.*, p.102.citing Ralph JORDENS, "Legal and Technological Developments Leading to the Symposium: UPOV's Perspective", paper presented at the WIPO-UPOV Symposium on the co-existence of patents and plant breeders' rights in the promotion of biotechnological developments, 25 October 2002.
[1516] Description of Keygene's strategic shareholders: available at http://www.keygene.com/about/business_profile.php (accessed July 2011).
[1517] Both multinationals are coined "strategic partners" by Mendel Biotechnology, a company that was within the top 10 patent application filers before the European Patent Office (between the years 2003 and 2007), see http://www.mendelbio.com/ strategicpartners/index.php, and LOUWAARS et al., 2009, p.36.

Just as the dilemmas faced by public researchers with regards to licensing-based solutions to the nebulous patent clouds in agricultural biotechnology, private plant breeders, who are even less prone to using standardised terms, have also attempted to come up with independent and actor-led institutional solutions to anti-commons scenarios. The UFS for instance highlighted that **information clearing-houses** may be of primordial value to private plant breeders navigating the complex patent landscape of agricultural biotechnology.

> "Transparency concerning the link variety – patent(s) is therefore essential for the use of genetic variability, as it is needed in breeding. In order to move towards more transparency about the status of varieties, and also to clarify certain legal questions, UFS declares itself in favour of a public information policy:
>
> The creation of a database containing, for each variety put on the market, the link to publicized applications for patents and to any relevant granted patents the breeder knows of.
>
> This data should be consultable on a website where each breeder can view the situation of any variety marketed, if concerned by the presence of any patented elements"[1518].

It is in this context that, in 2012, « in order to improve transparency of patent information ESA proposes the setting up of a web- based database allowing breeders better information and thus a more informed decision regarding the material they use. Therefore, ESA calls upon patent holders to put information on the patented status of their varieties in a public database available on their own company websites at the moment when the relevant patent application is published. Furthermore, ESA proposes and will actively support the creation of a portal containing links to all relevant company websites for facilitating access to information to breeders »[1519]**.**

The notable **ESA patent database, coined PINTO** (Patent Information and Transparency On-line), is continuously being shaped, being updated every six months, and has begun to operate on a simple and free registration-based website.

> "ESA's unique project provides the link between a plant variety and a patent, information which is currently not available elsewhere. The primary goal of PINTO is to allow breeders to make a more informed choice when deciding on the varieties to be used in a breeding program. Nevertheless, PINTO can prove to be a useful and valuable tool also in the daily work of farmers, growers, researchers or any other interested party. The main feature of PINTO is the search tool function which allows users to look through the content of the database on the basis of a number of search criteria such as variety denomination, species, patent number, patent holder or keyword"[1520].

Social innovation stemming from plant breeders themselves has not to this day yet produced further-reaching institutional arrangements, thrusting us to conclude that the conditions to go

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[1518] UFS, *op.cit.*, 2011. p.4.
[1519] ESA, *op.cit.*, 2012.
[1520] PINTO home page, http://pinto.azurewebsites.net/ (accessed February 2014).

beyond information clearing-houses, such as patent pooling, are so far not met in the sector, even more so than in the field of public plant improvement related research. This could be explained by a very strong attachment to the breeders' exception, a mechanism that inherently diminishes transaction costs linked to access to protected technology, and thus by the fact that the main concerns concern the informational transaction costs related to the patent landscape navigation.

CONCLUSIONS. Possible adjustments for non-integrated private conventional plant breeders

The needs of "conventional plant breeding", in a small-scaled private yet cumulatively incremental innovation context comprised of a multitude of breeders of different size and assortment, are not completely catered for by the strong intellectual property paradigm. Faced with the growing threat of easy reverse-engineering possibilities that the multiple scientific breakthroughs today offer their competitors, private plant breeders have attempted to rebuild enough protection and ensure that their exclusive rights are dutifully enforced. At the same time, they have fought hard to maintain their sacro-sanct freedom to operate, acknowledging the peculiar nature of plant improvement, even when it is as knowledge intensive and profit and productivity-oriented as it has become today. A number of initiatives have also attempted to respond to the rules embedded in the PGRFA public domain by international biodiversity law, addressing issues regarding prior art assessment and advocating the recourse to a "declaration of source" obligation triggering if need be, civil or criminal proceedings under biodiversity conservation legislation. Yet the main concern of private plant breeders has been to seek the proper balance between ensuring adequate reward for resource-intensive and uncertain innovative efforts, and safeguarding the essence of plant breeding, which continues to rely on the widest possible gene pools to create new diversity. In this regard, protection has been mostly ensured through the endorsement of the double reality of plant-related IP, considering all exclusive titles as necessary in their own right. It has also been translated into support for the extension of certain protection scope, notably with regards to "essentially derived varieties" in accordance to which compensation should be granted for those varieties retaining those essential characteristics of protected initial varieties that have been used in plant breeding programs under the UPOV 1991 rules. Action has in parallel been prominently attempted to maintain royalty collection prospects at their highest levels possible, not only before competitors who use protected varieties to come up with too similar plant varieties, but also before farmers and growers who save those varieties. Advocating for a legal basis for such farm-saved-seed royalties, breeders have also set up clearing-house like mechanisms to collect said royalties, coupled at times by contractual prerogatives allowing for greater control over the variety's use by growers. Designed so as to fight plagiaristic breeding, the extension of protection that is the concept of "EDV" has nonetheless demonstrated the limits put upon accumulation and the use of improved genetic diversity, especially in view of aggressive litigation tactics utilised against similar varieties that might create unwanted competition.

These trends have led to question whether plant breeding under the governance choices made under the strong paradigm still warrants all plant-related "improvements", even those minor in substance, which could produce beneficial public goods. Coupled with the newfound reality of the nebulous and aggressive clouds of plant-related patents, private plant breeders have tried to extend the opportunities available to use plant material and processes. Within plant variety protection, actors have tried to address such imparity by setting out arbitration opportunities, but also science-based protocols to determine the trigger of essential derivation, advocating in parallel a reversal in the burden of proof once a significant threshold of similarity has been observed. Unwilling to address issues linked to patentability requirements themselves, or at least extremely timidly, smaller-scaled plant breeders have nonetheless unanimously recognised the need for a wide reaching research exception, or even better, a purposefully tailored breeders' exception in both plant breeders' rights and patent legislation. Acting also as a benefit-sharing mechanism upholding the new PGRFA public domain, the nearly unequivocal support for the breeders' exception in IPR legislation stands out as the most beneficial result of the clash between the strong property paradigm and plant breeders relying on plant variety sales and royalties as their primary source of income. Even though maintaining a strong breeders' exception remains the cornerstone of smaller-scale private plant breeders' actions, due attention has also been given to negotiated licensing terms in order to ensure that socially beneficial innovation, in the form of better performing or adapted varieties, is distributed and not locked out by unacceptable conditions set out in a highly competitive marketplace.

TRENDS	**SHORT-COMINGS**	**SOCIAL INNOVATION, EMERGING PRACTICES and COPING STRATEGIES**	
		Self-regulation	**Beyond self-regulation**
Speedy reverse-engineering	Adequate protection: incentive to innovate?	Rights Infringement follow-up entities Royalty collection organisms	Advocate patent and PVP co-existence Essentially derived varieties (UPOV 1991) "Adequate remuneration" for farm-saved seed in national legislation
Exclusive individual rights	Biopiracy risk	Support for ITPGRFA and solution-seeking to contribute to Benefit-Sharing Fund	Disclosure of source in IPR applications, with civil or criminal liability compliance Breeders' exception as benefit-sharing
Patents - aggressive licensing	Uncertainty of freedom to operate	Promotion of arbitration Technical guidelines for EDV assessment and reversal of burden of proof	Breeders' exception in patent laws Compulsory licensing at commercialisation UPOV action for more detailed explanatory EDV guidelines with thresholds
	Rising search / transaction costs	Information clearing-house – patent/PVP database	Breeders' exception in patent laws
	Use-blocking licensing	Facilitated access (online platform) Pro-rata licensing, reference to FRAND terms	Breeders' exception in patent laws Cross compulsory licensing

FIG.7: Adjustments responding to the shortcomings faced by private plant breeders confronted to the strong PGRFA property paradigm

14. CHAPTER 14: ADJUSTMENTS FOR MASS SELECTORS, FARMERS AND HOME GARDENERS

The role of farmers' innovation in the preservation of agrobiodiversity, operating with the support of traditional or more modern seed exchange networks, is warily undisputed. Even though there is an unquestionable "lack of knowledge about how to maintain or enhance the socio-ecological resilience of local seed exchange networks, […] intuitive sense [upholds] that not intervening may be preferable to many of the well-intended seed improvement programs of the past"[1521]. Nonetheless, the absence of formal policy intervention has its own limits, and it especially cannot be interpreted as leading to the absence of legal amendments. Mere "laissez-faire" cannot and does not redress the detrimental impacts having accompanied the dominant policies that have dressed the lawful contours of seed production, use and dissemination. Landrace diversity is highly threatened by the "inadvertent consequences of the variety and seed certification system associated with the establishment of plant breeders' rights, which remunerate seed companies for the costly process of creating modern cultivars"[1522]. As aforementioned, farmers and their informal networks have been heavily hit by both formal seed regulations in the form of restrictive compulsory certification, but also by the exclusive prerogatives that accompany the widening and numerous intellectual property titles over plant varieties, their components or affiliated breeding processes. Regulatory exceptions to the principle of free competition need in their essence to strike a delicate balance between individual prerogatives and societal costs. Farmers have regrettably suffered the most from this balancing act's failures, as they have been pushed outside of the plant improvement realm, into forced illegality.

In light of the drastic changes operated upon the scheme of agricultural production first through the technological revolutions that have instilled new high-performance inputs on farm, and then through the novel regulatory frameworks that have constructed boundaries on the use of such inputs, farmers were gradually compelled to drastically rethink their traditional production chain. They have had to reclaim the rights and obligations appointed by international environmental law, and have tried to give greater substance to the loosely fenced public domain drawn by the CBD and the ITPGRFA. Farmers' role in the conservation and sustainable use of plant genetic diversity has indeed been steadily recognised in both instruments, proclaiming the need for *in situ* resource conservation efforts, all the while acknowledging the contributions of traditional knowledge and conceding the socio-economic bundle of farmers' rights. These idioms and principles are unfortunately not echoed in clear entitlements, and have in effect been trumped by the strong intellectual property paradigm. Farmers, in their more traditional or contemporary institutional forms, nonetheless reclaim approaches to environmental justice that are attached to distributive and equity-ridden aspects. Doctrinal thought is increasingly putting emphasis on the more-encompassing nature of environmental justice, highlighting a conception that would go beyond "equity in the distribution of environmental risk", by also "recognising the diversity of the participants and experiences in affected communities, and participation in the political processes

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[1521] MARCO ET AL. PAUTASSO, "Seed Exchange Networks for Agrobiodiversity Conservation. A Review," *Agron.Sustain.Dev.* 33, 2013: p.164.
[1522] NEGRI, MAXTED, and VETELAINEN, "European Landrace Conservation: An Introduction," *op.cit.*, pp.12-13.

which create and manage environmental policy"[1523]. Alongside the desire to actively push for local community participation into the exchange, the more traditional front of building participatory environmental justice is concerned with the inclusion of these networks and communities in political decision-making. These networks at times also act as more traditional advocacy groups pushing for legislative amendments, and push to be recognised as experts in the legislative process, or to be included in environmental management decisions through for instance participatory plant breeding schemes. Arguably, the ever-widening range of the environmental justice discourse has moved it into a "new realm, where environment and nature are understood to create the conditions for social justice"[1524]. Emerging practices and coping strategies of seed exchange networks and local seed banks fulfil, or at least aim to fulfil these goals.

14.1. Maintaining access to wild material and landraces: institutions for conservation and sustainable use

The desire of seed savers and exchangers to preserve agricultural biodiversity and revive old lost varieties is self-evident. They pursue activities that are not engraved in a productivity-driven and resource-depleting market economy. This approach remains the core norm that brings participants together, as "seed saving is a set of practices valued by growers and consumers interested in supporting more sustainable socio-natural systems"[1525]. The pivotal role of the preservation of agricultural diversity to tackle the world's biggest challenges in food production is being widely recognised. Indeed, diversity is said to be the key not only to develop sustainable agricultural practices, by putting less pressure on the natural environment, but also to ensure food security in light of the world's bitter realities of hunger and malnutrition, as reflected in the Millennium Development Goals[1526]. Sustainable agricultural practices, striving to achieve high production levels while being environmentally sensitive and safeguarding the social structure of rural communities, diminish the pressures of cultivation on agricultural biodiversity itself[1527]. It is in this sense, through the ingenous continuity of their activities, that both traditional and modern seed exchange networks challenge the precepts of the strong property paradigm and uphold the new PGRFA public domain shaped by international biodiversity law.

14.1.1. Conservation and sustainable use of agrobiodiversity

The preservation of genetic resources lies at the heart of the practice of seed saving and exchange. These practices' contribution to biodiversity conservation is loudly advocated for by certain initiatives, especially in Europe, where seed exchanges are organised as "planned activities with

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[1523] DAVID SCHLOSBERG, "Reconceiving Environmental Justice: Global Movements and Political Theories," *Environmental Politics* 13, no. 3, 2004.

[1524] "Theorising Environmental Justice: The Expanding Sphere of a Discourse," *Environmental Politics* 22, no. 1, 2013.

[1525] CATHERINE PHILLIPS, "Cultivating Practices: Saving Seed as Green Citizenship?," *Environments* 33, no. 3, 2005.

[1526] See particularly Target 2 of the first goal of the Millenium Development Goals (eradication of extreme poverty and hunger), which emphasises the need to reduce by half the proportion of people who suffer from hunger by 2015. Linking Biodiversity, Food and Nutrition has been accepted as a mean to achieve such target by the Parties to the Convention on Biological Diversity and resulted in the formalisation of a cross-cutting initiative dedicated to the subject in Decision VIII/23A in 2006.

[1527] Jules N. PRETTY; Regenerating Agriculture, Policies and Practice for Sustainability and Self-reliance, Earthscan, London, 1995, pp. 1-8.

the explicit aim of preserving agrobiodiversity"[1528]. These organisations are numerous, from *Arche Noah, Kokopelli, Pro Specie Rara, Red de Semillas, Reseau Semences Paysannes* to *Rete Semi Rurali*, amongst others. The conservation aspect is also present in all networks, which provide seeds for free or for relatively low prices that are only meant to incur maintenance costs. For instance, the 1981 established *Biau Germe* farmers' group in France provide seeds with an extremely clear purpose of preserving biodiversity and fighting genetic erosion. Most of the larger networks and organisations tend to go one step further and set up local seed banks and farms where the material to be distributed is multiplied in designated fields or maintained in gene banks through formal agreements with institutes possessing the technical capacity to do so. The French network "*AgroBio Périgord, Maison de la Semence*" for instance disseminates a technical book on the multiplication and selection of maize and sunflower on farm, based on the principles of mass selection. In order to conserve non-proprietary agricultural biodiversity, this network of two hundred and fifty growers located in Western France allocate a portion of their own land to local populations or 'landraces', which are maintained on a range of six hundred individuals in order to avoid degeneration and maintaining so-called "security stocks" to minimise loss risks. The experiment, which started in 2001 on a collective initiative, now receives support from regional institutions as an *in situ* biodiversity conservation project. Perhaps the widest and oldest seed exchange networks, the United States based *Seed Savers Exchange* (SSE) was established to "preserve our garden heritage by collecting and distributing thousands of samples of rare garden seeds to other gardeners", and have set up an eight hundred and ninety acre "Heritage farm" in Iowa. Interestingly enough, they also store their varieties in back-up locations through so-called "black box deposits", where the property of seeds remains with the donator, especially before the USDA Seed Bank. The SSE has also quite controversially sent about two thousand varieties to the Svalbard Global Seed Vault in Norway in 2008. In light of the complex links of the "Vault" to the ITPGRFA, as part of the Global Trust yet not the Benefit-sharing Fund, this move has attracted criticism as to the possible misappropriation of varieties by the private sector. Even though the likelihood of such event remains to be discussed, the controversies that have arisen in this regard clearly show the networks' focus on agrobiodiversity conservation outside of the formal seed market, as well as the sensibilities that are still present vis-à-vis the phenomenon of biopiracy and correlated pleas for equitable compensation.

In its recent report focusing on the need to shift from an approach focusing on mere conservation to the crowning of a sustainable use approach to agricultural genetic resources, the European Commission highlights that

> "Breeding activities are required at farm level on underutilised species, traditional and local breeds and crops. This requires the setting-up of Union-wide networks to valorise such material so as to promote the role of agriculture in the development of rural areas, maintenance of traditions and traditional farming practices, and the provision of environmental public goods. Action is needed to enable farmers to recover traditional

[1528] PAUTASSO, Marco et al, "Seed exchange networks for agrobiodiversity conservation. A review", Agron.Sustain.Dev., March 2012, knowledge and to provide them with the necessary skills and know-how needed to work with local breeds and crops, while taking account of changing climatic conditions”[1529].

The key role of informal seed networks and of farming communities in achieving such sustainable use is not only paramount in developing countries where such communities outnumber industry players, but also in developed countries that possess not only a solid seed industry but also larger-scaled professional farmers. This regulatory stint, or rather this undeniable acknowledgment of the importance of traditional farming relying on informal seed exchange mechanisms, stems from the aforementioned regime shifting operated by international environmental agreements. But it also stems from the realities of the ground and the crucial needs of plant innovation. Indeed, farming and mass selection practices which traditionally rely on informal seed exchanges undisputedly put less pressure on soil, water and ecosystems than industrialised agriculture. The maintenance and creation itself of local seed banks is a means in itself to create an alternative to the globalisation-led “destruction of the local environment, culture and sustainable ways of living”, against the annihilation of a livelihood and different communities’ ways of life[1530]. Fighting so-called genetic erosion and the considerable loss of plant varieties worldwide, both traditional farmers and contemporary seed savers, do cultivate, reproduce, save and exchange seeds to avoid the demise of varieties that may not respond to the postulates of today’s market. Indeed, farmers or gardeners who mostly produce crops for their own subsistence or to exchange on local markets and other social networks “are more likely to maintain a genetically diverse spectrum of plant species and varieties because it is more affordable and less risky to do so”, as their practices are not dictated by the global market that prefers uniform harvests[1531]. The active cultivation of a wide range of varieties or populations, all the while traditionally using less chemicals because of cost, access or other intrinsic motivations, dynamically contributes to the conservation objectives set out both by the CBD and the ITPGRFA.

The notion of sustainable use also craves consideration for future generations, it asks for biodiversity to be used through the lens of inter-generational equity and social stewardship. Most, if not all seed exchange networks put an emphasis on the need to preserve biodiversity, socio-cultural conventions and traditional knowledge for the sake of future generations. In this regard, the notion of “heritage” is heavily heralded by numerous initiatives. The Central European seed savers association is meaningfully baptised “*Arche Noah*”, while the infamous *SSE’*s farm and language heavily insist on the preservation of “their garden heritage”. Several (if not all) projects also focus on the dissemination of knowledge on seed saving techniques and experiences, much reminiscent of early public agricultural research initiatives, without perhaps their colossal budget. Organisations produce technical leaflets, frequently asked questions and other factsheets to disseminate knowledge. Most importantly, networks distribute their seeds to either the participants to the exchange, their “customers” and anyone who asks for them. Several projects (especially the larger ones) work on the basis of catalogues, such as *Real Seeds UK, SSE or Kokopelli.* The latter also has a special programme focusing on “seeds without borders”, which disseminates their seeds to the poorest rural communities “in countries that are assassinated by the West through

[1529] EUROPEAN COMMISSION, "*Report to the European Parliament, the Council and the European Economic and Social Committee: "Agricultural Genetic Resources- from Conservation to Sustainable Use’*'", COM (2013) 838 final, 28.11.2013. , notably cited in BORU DOUTHWAITE, "Enabling Innovation," *Zed Books: London*, 2002.
[1530] SCHLOSBERG, "Reconceiving Environmental Justice: Global Movements and Political Theories," *op.cit.*, p.525.
[1531] Ibid.

starvation". The benefit-sharing that is clearly provided for by seed exchange networks is non-monetary or in kind, i.e. in the access to the genetic resources and attached knowledge, but it also brings in the participatory feature of fairness, equity and justice.

14.1.2. Malleable institutions to support conservation activities

However, given the "complexity and social contextuality of biodiversity, […] sustainable use projects must be as diverse as the ecosystems they are meant to conserve, and their success depends crucially on the fate of local societies"[1532]. This inherent feature makes not only the enactment of strictly regulatory efforts extremely difficult and seldom efficient, it also pushes for the adoption of **broader yet malleable institutional solutions,** at times backed by supporting policies. A noteworthy institutional solution comes from Brazil, where the government has set up a creative "Zero Fome" (Zero Hunger) Food Acquisition program, through which agroecological farmers are given fair prices and incentives when purchasing food. In parallel, Brazil's National Supply Company (CONAB) also ensures the "distribution of local seed varieties to farmers, strengthening local seed systems and empowering the community-based organisations with whom they worked", both buying and redistributing seeds from and to local farming communities[1533]. More classic in its inception and content, a European Community programme was launched in 2004 "on the conservation, characterisation, evaluation and use of genetic resources in agriculture established conservation activities, both *in-situ* and *ex-situ"* and successfully implemented seventeen different projects[1534]. A specific project was dedicated to the *in situ* conservation of crop diversity, assessing different conservation techniques and advocating in its concluding remarks "the promotion of landrace management on farm [in order to] maintain a seed supply system that would increase the resilience of agricultural production by increasing the number of independently managed breeding populations in Europe"[1535]. Under the new Horizon 2020 programme, the European Commission has launched funding opportunities for ninety-three million EUR for the "management and sustainable use of genetic resources", including inter alia, the promotion of traditional and/or underutilised crops, and economic benefits for farmers, other types of SMEs and regional economies through the expansion or creation of new products and markets[1536]. Local seed exchange networks have and will in the future continue to be supported by such over-arching biodiversity conservation and rural development policies. Some initiatives reach beyond this global approach though, and also attempt to bridge the gap between **product development and local initiatives**. Launched in 2012 and inspired by the Access to Medicine Index, the Access to Seeds Index is sponsored by the Dutch government as an initiative encouraging global seed companies to bridge the gap with the small-scale farmer[1537]. The first index, the methodology of

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[1532] MCAFEE, "Selling Nature to Save It? Biodiversity and Green Developmentalism," *op.cit.*, p.138.

[1533] TERESA ANDERSON, "*Seeds for Life: Scaling up Agrobiodiversity*", Ecumenical Advocacy Alliance and The Gaia Foundation, 2013.

[1534] Community Programme, established by Council Regulation (EC) No 870/2004 on the conservation, characterisation, collection and utilisation of genetic resources in agriculture. The 17 supported projects of this programme represent important contributions to the conservation of cereals, fruits, vegetables, grapevine, forest resources and farm animals such as cattle and sheep. The projects involved around 180 partners located in 25 Member States and 12 non-EU countries, with a budget of EUR 8.9 million.

[1535] DEMAINE and FELLMETH, "Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent," *op.cit.*p.52.

[1536] European Commission, Call for proposals, Sustainable Food Security, H2020-SFS-2015-2, *OJ C* 361, 11.12.2013.

[1537] EISENBERG, "Patenting the Human Genome," *op.cit.*The main objectives lying behind the project are threefold: "create index indicators based on ongoing stakeholder dialogue, giving companies direction fortheir access activities;

which is currently being developed by an independent foundation, the Access to Seeds Foundation, based in Haarlem, The Netherlands, is planned to be published by the end of 2014, acknowledging positive actions that have in the past led to better interaction between farmers and the seed industry.

Perhaps more practically and straightforwardly, the development of so-called "**participatory plant breeding** programmes" should also be seen through such lens of sustainable agrobiodiversity use and community empowerment, embedded in the overarching goal of biodiversity conservation. Farming communities, local seed banks and exchange networks are increasingly included in crop development and environmental management projects. There is undoubtedly a growing need and interest in "integrating community-level seed collections with existing local seed exchange networks"[1538], thereby adding value to efforts undertaken to build extensive seed collections, as these would not be preserved in a vacuum, but in a network of transactions and cultivation decisions"[1539]. The rather new but promising approach of "participatory plant breeding" not only recognises the role of these communities in biodiversity conservation, it also appoints them back into the plant improvement landscape and biodiversity management policies. Concomitantly, it goes beyond the too simplistic opposition between those traditional and more modern agricultural ecosystems, which should rather be understood as complementary tools responding to different needs than a perpetual wrangle[1540]. Participatory plant breeding initiatives come with the promise of bringing the best of both worlds for the benefit of cultivators.

What is interesting in this specific section is what has been coined "farmer-led participatory plant breeding", where

> "Researchers or other professionals in farmer-led programs are expected to facilitate a process in which farmers establish breeding objectives. Farmers bear the main responsibility for and, often, the costs of conducting experiments, selecting materials for seed multiplication, and dissemination of these. Researchers are expected to take a support role in this process. Farmer-led PPB has the objective to provide varieties or populationswhich suit the specific local environment and local preferences and any broader applicability beyond local circumstances is fortuitous"[1541].

As farmers become researchers alongside plant breeders in most participatory schemes, they are involved in priority setting, screening, testing but also distribution activities[1542]. It may however prove efficient to choose enthusiastic and well-trained farmers who can spread the benefits of

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rank companies in a comparable and quantitative way to encourage positive competition to take an extra step stimulated by investor appreciation, media attention and public opinion; recognise access behaviour of companies, whilst creating transparency on best practices and raising awareness on corporate contributions" (at p. 6).

[1538] CONNY J.M. ALMEKINDERS and NIELS LOUWAARS, *Farmers' Seed Production: New Approaches and Practices* London: Intermediate Technology Publications, 1999. cited *in PAUTASSO, "Seed Exchange Networks for Agrobiodiversity Conservation. A Review," op.cit.*

[1539] "Seed Exchange Networks for Agrobiodiversity Conservation. A Review," *op.cit.*, at p. 162.

[1540] U. PASCUAL and CHARLES PERRINGS, "Developing Incentives and Economic Mechanisms for in Situ Biodiversity Conservation in Agricultural Landscapes," *Agriculture, Ecosystems and Environment* 121, 2007.

[1541] SPERLING et al., "A Framework for Analyzing Participatory Plant Breeding Approaches and Results," *op.cit.*, at p.441

[1542] JULIE C DAWSON, KEVIN M MURPHY, and STEPHEN S JONES, "Decentralized Selection and Participatory Approaches in Plant Breeding for Low-Input Systems," ibid.160, no. 2, 2008.

participatory plant breeding through seed exchanges or community plots[1543]. Numerous commendable examples exist, including the recent release of a sweet potato cultivar in Uganda, under the auspices of the Ugandan National sweet potato Program[1544]. In a project run in Rwanda on local bean selection, farmer-experts were asked to rank different breeding lines for traits of interest and take the best to grow next to their traditional mixtures; not only was an increase of eight per cent witnessed in average yields, the selected lines were also still being grown by more than seventy per cent of farmers six planting season later, often used to create new mixtures and thus new diversity[1545].

14.2. <u>Fighting Forced Illegality and Disregard</u>

Mass selectors relying on informal seed networks have increasingly been pushed towards forced illegality. First through extremely stringent seed certification regulations, which do not provide adequate manoeuvre margins to allow farmers to commercialise, or even merely exchange, their unstable yet locally adapted and biodiverse plant variety populations. Secondly by intellectual property titles covering protected improved varieties and built-in products or processes. Nevertheless, these reluctant outlaws have been exploring solutions to emerge from their prickly situation. They have notably adopted innovative practices circumventing existing restrictions, and advocated (at times successfully) regulatory action to accommodate their needs. A number of seed exchange initiatives indeed possess clear political lobbying components, directly advocating changes to both seed marketing and intellectual property legislation. *Arche Noah* members indeed “contribute to more diversity through cultivation of threatened varieties, shopping awareness and political commitment”[1546]. *Kokopelli* clearly advocates the “liberation” of seeds. Also in France, the *CNDSF* (“Coordination Nationale pour la Défense des Semences Fermières”) has infamously refused to pay farm-saved-seed royalties; a boycott that has notably led to the creation of a European-level alliance against these royalties, through the “*Union Européenne des Semences et Plants de Ferme*’[1547]. The *Réseau Semences Paysannes* has a “legal watchgroup” which follows legislative developments and issues detailed statements. More recently, twenty-four organisations, including several European informal seed networks have recently gathered around a “Joint Statement on the Proposal on legislation about plant reproductive material”, i.e. the new European seed laws, asking “farmers and gardeners to be able and allowed to produce and exchange their own seeds and propagating material”[1548]. The rhetoric found in pamphlets and official documents translates the strong presence of a politically active citizenship stance in the face of their precarious legal situation, coupled with an inventiveness used to curb infringement accusations.

[1543] O'ROURKE, "Toward a Doctrine of Fair Use in Patent Law," *op.cit.*; POLYAKOV and GORYUNOV, "(Non) Obviousness of Claims to Genetic Sequences: Finding the Middle Ground," *op.cit.*
[1544] R.W. GIBSON, I. MPEMBE, and R. MWANGA, "Benefits of Participatory Plant Breeding (Ppb) as Exemplified by the First-Ever Officially Released Ppb-Bred Sweet Potato Cultivar," *The Journal of Agricultural Science* 149, no. 05, 2011.
[1545] POLYAKOV and GORYUNOV, "(Non) Obviousness of Claims to Genetic Sequences: Finding the Middle Ground," *op.cit.*
[1546] Arche Noah, http://www.arche-noah.at/etomite/index.php?id=271 (accessed March 2012)
[1547] TOLEDO, "Saving the Seed: Europe's Challenge," *op.cit.*
[1548] Joint Statement on the Proposal on legislation about plant reproductive material, http://www.seed-sovereignty.org/EN/ (accessed July 2013)

14.2.1. ***Seed legislation: circumventing restrictions or advocating regulatory change***

In developed nations and the European continent, regulatory action has heavily pushed informal mass selection dangerously close to the formal seed market in the name of productivity. In developing countries, age-old seed improvement and distribution paradigms have been disturbed in the sake of economic development attuned to the needs of international trade. In these contexts, the inclusion of traditional farming communities and seed exchange networks into decision-making operates on different fronts, mostly outside the market. Although quality control mechanisms have been today made compulsory for seed provided by the formal sector in the wide majority of countries, the informal sector and traditional methods of seed provision did not disappear. This holds true even in developed countries where formal channels have taken over seed supply. The mass selection socio-technological innovation context survived; it did so by carving out room for themselves in restrictive regulatory environments, or by advocating legislative changes, often times successfully.

Self-regulation and voluntary labelling

First and foremost, these networks, that remain open to anyone who wishes to contribute to the exchange and preservation efforts, have been **actively trying to remain outside of the market** realm in its most classical sense. This trend draws in from the fear that "drawing Amateur and Conservation varieties into the market is likely to further purify (and reduce the genetic heterogeneity of) these older cultivars, [which rather need continued saving and circulation to allow genetic heterogeneity—rather than ''seed purity''—to be maintained][1549]. In more institutionalised networks, "seed donations" are always and unequivocally welcomed, although a number of initiatives have been obliged to change their structure into "private clubs" so as to avoid infringing on third party intellectual property rights or on stringent seed legislation. *The Real Seeds UK* initiative has for instance been morphed into a not-for-profit company relying on membership to ship heirloom seeds listed in their catalogue or accept new stocks. By charging a single penny of the first order for a year's membership, they avoid selling their seeds to the 'public'. The issue is a little trickier for more traditional exchanges operating around local seed markets, especially in developing countries. Informal rules cannot be insitutionalised that easily. Several case studies have highlighted that the decision to take part in seed exchanges or to accept an individual to the "free-handover of seed" is heavily influenced by the presence of relatives and socio-cultural ties between the farmers[1550]. At times big farmers willingly exclude smaller ones from the network, as documented in Peru for potato seed ware[1551], or new material is only offered in "handfuls" to close friends or important neighbours, outside of the local markets in Rwanda for beans[1552]. Staying in the outskirts of the formal seed market has as a result its inherent limitations, and the line will remain blurry for most initiatives and networks.

[1549] GILBERT, "Deskilling, Agrobiodiversity, and the Seed Trade: A View from Contemporary British Allotments," *op.cit.*, p.110.
[1550] ZEVEN, "The Traditional Inexplicable Replacement of Seed and Seed Ware of Landraces and Cultivars: A Review," *op.cit.*, p.187.
[1551] CONNY J.M. ALMEKINDERS, NIELS LOUWAARS, and G.H. DE BRUIJN, "Local Seed Systems and Their Importance for an Improved Seed Supply in Developing Countries," ibid.78, 1994.
[1552] LOUISE SPERLING, MICHAEL E. LOEVINSOHN, and BEATRICE NTABOMVURA, "Rethinking the Farmer's Role in Plant Breeding: Local Bean Experts and on-Station Selection in Rwanda," *Experimental Agriculture* 29, no. 04, 1993.

Another front of action of informal mass selection has thus been the advocacy of legislative change, bending seed certification to the needs of farmers-innovators and allowing for the lawful continuity of seed exchange and improvement networks. The advocacy element has been particularly vital in developed countries with very strict legislation, but also strong civil society involvement in policy-making processes. Indeed, as aforementioned, in developed countries where seed certification is voluntary, like the United States, informal seed exchange networks have not been confronted to major hurdles in the exchange or commercialisation of their plant varieties. This reality has urged commentators to advocate such **voluntary certification** approach worldwide[1553]. Indeed, the "truth-in-labeling" approach, which operates under established standards with respect to germination rates and physical purity that need to be accurately describe by the seed producer on the label, is notably used in the USA and has been used extensively in India[1554].

> "One solution to the dilemma of controlling marketed seed while allowing farmers' seed systems to thrive is to adopt a voluntary system of variety and seed controls instead of compulsory variety release and seed certification and testing. The voluntary system can support the private sector while leaving room for local initiatives. In this way, seed producers have the choice to have their varieties officially recommended and their seed lots certified and tested or not, while farmers have the choice to buy seed with or without an official certification label. This system operates in several parts of the United States, where the seed laws merely regulate the labelling requirements in the seed trade ('truth-in-labelling'), whereas in other areas seed association rules 'de facto' introduce a kind of compulsory quality control system. Farmers may rely on branded seed and thus on the information and trustworthiness of the seed company"[1555].

However, this loose approach relying on the regulatory functions on the markets does have its shortcomings, as it may fail to address the inherent informational asymmetry that is particularly addressed in seed certification schemes. This challenge especially resonates when applied to informal mass selection products, where seed producers seldom possess any labelling or marketing training, particularly in developing countries. Indeed,

> "Opponents of this approach point to the lack of competition in the seed market in most developing countries. This leads to a lack of incentive to provide quality seed. Also, illiterate farmers may not be able to understand the information on the label and be misled. Voluntary seed controls may thus facilitate fly-by-night seed suppliers"[1556].
> To support such schemes, it is necessary for farmers to be educated regarding what different labels and seed categories represent so that they can make informed judgements

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[1553] EDWARDS, "Case 3. The Global Biodiversity Information Facility (Gbif). An Example of an Information Clearinghouse," *op.cit.*; BOETTIGER and SCHUBERT, "Agricultural Biotechnology and Developing Countries: The Public Intellectual Property Resource for Agriculture (Pipra)," *op.cit*; VANUXEM, *op.cit.*

[1554] JONES, THOMAS A., AND STANFORD A. YOUNG. "Native seeds in commerce: more frequently asked questions." *Native Plants Journal* 6.3 (2005): 286-293.

[1555] LOUWAARS, "Seed Laws: Biases and Bottlenecks," *op.cit.*

[1556] Ibid.(emphasis added by the author).

> when buying seed. It also requires an enforcement system that penalises violations of the regulations".[1557]

Much in line with their inherent informal nature, seed exchange networks and mass selection initiatives have attempted to exist outside of the formal seed market, by drawing such lines as clearly as possible. However, such contouring is not always possible, and fails to address the blatant illegality in which detailed regulation (as opposed to market mechanisms) have put them. Self-regulation and voluntary labelling can indeed only go so far and cannot restore selection networks in the regulatory landscape.

<u>Tailored compulsory regimes</u>

In light of the shortcomings of purely voluntary redress, alternatives have been drawn up in order to include varieties or populations exchanged and developed by informal networks within a differently and appropriately defined compulsory system. As the main issue pertaining to seed registration legislation remains the stringent and the discriminatory nature of official catalogue systems based on criteria solely responding to products of modern plant breeding chains, the first solution to be sought could **work around a possible moderation of the DUS criteria** in the seed marketing framework. Indeed, variety registration systems based on both DUS and VCU criteria are designed with solely the formal system in mind, thereby targeting "varieties that are tested in a mono-cropping system under high-input agriculture, […not catering] for the real diversity in farming systems and are not suited to low-input agriculture"[1558]. Such moderation would lead to the development of mere seed quality control, setting aside certification mechanisms based on varietal identity and purity control, or variety release mechanisms validating the value of the variety in question[1559].

Alongside the rather weighty choice of relaxing the formal system so as to include a wider array of plant varieties and actors, the **establishment of derogatory regimes** in the form of book logs or flexible national (or regional) registers of uncertified seed could be options worth considering. These regimes could not only take farmers' innovation out of illegality, but also provide a "defensive protection system […] against acquisition and exploitation by third parties", documenting indirectly the traditional knowledge embodied in landraces[1560]. Other options that have been raised by commentators relate for instance to the establishment of "different lists or categories of marketable seed, with lower requirements and controls for certain kinds of varieties"[1561].

> In this context, "another strategy is to establish a category of *seed below certified seed* (e.g. "standard seed") that may or may not be subject to some minimal quality control

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[1557] REICHMAN and UHLIR, "A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment," *op.cit.*pp.60-61.
[1558] LOUWAARS, "Seed Regulations and Local Seed Systems," *op.cit.*
[1559] "Seed Laws: Biases and Bottlenecks," *op.cit.*, notably citing ROBERT TRIPP, *New Seed and Old Laws: Regulatory Reform and the Diversification of National Seed Systems* London: Intermediate Technology Publications, 1997.
[1560] GEERTRUI VAN OVERWALLE, "Protecting and Sharing Biodiversity and Traditional Knowledge: Holder and User Tools," *Ecological Economics* 53, 2005: pp.596-597.
[1561] LOUWAARS, "Seed Laws: Biases and Bottlenecks," *op.cit.*

> regulations, although in practice this type of classification is used principally for seed of lower priority crops or during seed shortages"[1562].
>
> "The formal seed sector [can be] regulated while avoiding interference with farmers' seed systems. Indonesia has a *specific exemption* for farm-produced seed that is marketed within the village, providing at least an opening for local seed production and dissemination. In some countries, the law applies to packed and certified seed only, leaving the farmers' seed system untouched. They basically protect the seed label and reserve it to truly controlled seed: seed should not be sold as 'government-certified seed' (Korea) or 'government-tested seed' (Botswana). In fact, the Morocco law reserves the word 'seed' for controlled seed only"[1563].

These solutions are based in effect on a dual approach that involves **catalogues or mere logs for both improved and conservation varieties, accompanied by adequate exemptions**, without undermining the main commercial system, nor blocking marketing possibilities for "un-traditional" models, such as the complemety informal sector or the organic, and biodynamic markets. Restricting seed marketing laws to a specific number of crops could be envisaged, as provided for in Bangladesh, just as a specific "commercial seed" category could be created, warranting greater productivity and uniformity without necessarily restricting the assortment of releasable varieties[1564]. In the same vein, networks of seed-exchanging and selecting farmers could formally remain outside the scope of seed marketing laws, an exoneration that would strictly need to be included in the appropriate laws, combined, with derogatory or restrictive conditions as to the scale of farmers or the varieties concerned, if necessary. Examples of such exceptional regimes do exist in the developing world, for instance in Brasil and Peru. In Brazil, the 2003 law provides for a legal definition for « *local, traditional or creole cultivars* », defined as "*all varieties developed, adapted or produced by small farmers […] with consideration for the social, cultural and environmental describers*", not just agronomical or economic criteria[1565]. Furthermore, the law establishes a double exemption from registration into the official catalogue, first with regards to cultivated varieties, as local cultivars are not to be reprised in the National Registry of Cultivars; and secondly with regards to specific actors, as family farmers, agrarian reform settlers and indigenous peoples do not need to be registered either[1566]. However, the latter exemption only targets individuals, and not organisations, and is conditional to the fact that the multiplication of seeds for distribution, exchange or sale has to occur amongst them. This exemption therefore targets those farmer-led mass selection efforts, but cannot extend to those selectors interested in low-input breeding or commercialisation opportunities.

In developed countries, where informal exchange networks are more modern in form than traditional, concerns for **low-input breeding, commercialisation and decentralised biodiversity conservation** opportunities are more present, calling for an adequate differentiated approach. It is

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[1562] REICHMAN and UHLIR, "A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment," *op.cit.*
[1563] LOUWAARS, "Seed Laws: Biases and Bottlenecks," *op.cit.*
[1564] "Seed Regulations and Local Seed Systems," *op.cit.*
[1565] SANTILLI, *Agrobiodiversity and the Law: Regulating Genetic Resources, Food Security and Cultural Diversity*, *op.cit.*
[1566] Ibid., pp.50-59.

in this context that many European countries have already developed seed laws allowing the maintenance and marketing of landraces and "obsolete" varieties.

> "The Swiss agricultural policy on varieties and propagating material is one of the first to have introduced a derogation clause that allows the commercialisation of non-certified propagating material and non-registered varieties in a national catalogue. In 1999, the list contained sixty landraces of cereals and about seventy landraces of potatoes. Requirements for derogation are quite simple: the demand must be accompanied by basic information about the applicant and the variety. Registration, for the time being, is free. Finland is establishing a different model with certain positive features. According to its proposal, the farmer applies for the registration to the Seed Testing Department for which the farmer pays a fee. This process is based on the methods and guidelines of UPOV, even if the variety does not fulfil uniformity or stability criteria. Less attention is also paid to the ability of seeds to germinate and species purity and old varieties are accepted. Some less positive aspects of this proposal is that it creates a relatively strict and inflexible regulatory framework governed by the Seed Testing Department. Other European country regulations provide little hope for local varieties. In France, legislation has maintained the DUS criteria and charges high registration fees (two hundred and twenty-one Euros per variety). Furthermore, in order to register, the plant variety must be shown to be more than twenty years old; a challenge for locally used varieties not collected from commercial catalogues or mentioned in historical archives".[1567]

The establishment of a **derogatory "light catalogue"** has been the way forward in the **European supranational legal order**, through Directives 2008/62 and 2009/145 on conservation varieties, to the dismay of both commentators and politically active farmers' associations[1568]. Several research projects were funded through the FP6 European Research Framework, known as Farm Seed Opportunities (FSO, 2007-2009), in order to overcome the inherent difficulty of uniformly regulating quite diverse farm-innovation systems. Targeted to support the implementation of seed regulations on conservation varieties, these projects also proposed complementary seed-regulation scenarios, the utility and effect of which may need further consideration. To all intents and purposes, opening the Catalogue to conservation varieties remains a means of reducing genetic erosion and preserving varietal heritage, even though critics have argued that such move entails the risk of undermining the main commercial system, and may potentially block completely open marketing possibilities for non-industrial models of agriculture such as organic farming or bio-dynamics in light of additional administrative obligations[1569]. This differentiated approach has also been to a certain extent mirrored by the new Regulation that is today being discussed at European level, which also aims to correct its shortcomings. The European regulatory machinery, aiming at the simplification of its seed marketing laws, has published the groundwork of its new **"Seed reform" in November 2012 through a Regulation proposal**, projecting to considerably alter the

[1567] TOLEDO, "Saving the Seed: Europe's Challenge," *op.cit.*
[1568] ANVAR SHABNAM, "Semences Et Droit: L'emprise D'un Modèle Économique Dominant Sur Une Réglementation Sectorielle" (Université Paris I Panthéon-Sorbonne, 2008).
[1569] RICCARDO BOCCI, "Seed Legislation and Agrobiodiversity: Conservation Varieties," *Journal of Agriculture and Environment for International Development* 103, no. 1-2, 2009.

regime for farmers' varieties[1570]. The proposal states that market regulation "should not apply to material intended to or maintained in gene banks, and networks of conservation of genetic resources or organisations associated with gene banks", but leaves those *in situ* seed exchange and conservation networks within the seed marketing realm.

The text has since then been re-amended and the current proposal provides an extremely interesting example of both restrictions of actions in the name of quality control, and of flexibility in the requirements for mass selection efforts, for all countries that have adopted the road of compulsory seed certification. As aforementioned, the **European Union** has developed legislation from 2008 onwards to taken into account the specificities of so-called "conservation or amateur varieties". Its legislation was challenged by mass selectors and modern seed exchange networks that were pushed forcefully into the illegal sidelines of the seed market. Yet the derogation-based but productivity-oriented regulatory framework was considered legitimate and proportionate in the aforementioned *Kokopelli* ruling of the European Court of Justice[1571]. Such ruling should be analysed in light of the fact that instruments targeting conservation varieties were not in force at the beginning of the proceedings, although the national Court has been invited to take account of such legislative development. The Luxembourg based Court indeed suggested that the forced move of *Kokopelli* into illegality and unfair competition has been remedied by the enactment of this parallel regime. Were it to be the case, the imposition of geographical, quantitative and packaging restrictions by the derogatory rules of the "conservation varieties" catalogue would seemingly not undermine the recognition of mass selection efforts, according to the ECJ's approach to the issue, although it might actually minimise their impact in practice. However, the tides are turning once more, and the European seed legislation is undergoing a major facelift. The twelve Directives that constitute the EU's seed legal web shall now be forged under the umbrella of a single Regulation currently under the European Parliament's review[1572]. Even though the proposal has been vehemently opposed by a number of farmers' or other civil society organisations, the text itself seems to provide a certain degree of flexibility for the informal seed sector, at least at first reading. Indeed, the proposed Regulation interestingly provides for a new criteria in registration, that of

> "*sustainable value for cultivation, in order to support sustainable development, direct plant breeding and meet breeders', producer and consumer demands concerning that type of development"*[1573].

[1570] Proposal for a Regulation of the European Parliament and of the Council on the marketing and production, with a view to marketing, of plant reproductive material, and repealing Council Directives 66/401/EEC, 66/402/EEC, 68/193/EC, 1998/56/EC, 1999/105/EC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC, with the provisional reference of SANCO/2012/11820. The rationale for this legislative review lies within the need for "legal simplification, cost reductions and efficiency gains, increased flexibility for operators, the level of harmonisation among Member States and the role of niche and emerging markets".

[1571] European Court of Justice, *Kokopelli vs. Graines Baumaux,* Case C-59/11.

[1572] Commission Directives 2008/62/EC of 20 June 2008, 2009/145/EC of 26 November 2009 and 2010/60/EU of 30 August 2010.

[1573] Proposal for a Regulation of the European Parliament and of the Council on the production and making available on the market of plant reproductive material, COM(2013), 262 Final (dated as of 6th May 2013)., hereafter "COM Proposal on the marketing of plant reproductive material", preamble, (35).

This concept, defined in the proposed Article 59, warrants taking into account the contribution of varieties

> "*characteristics, taken as a whole, at least as far as susceptibility to pests, input of resources, susceptibility to undesirable substances or adaptation to divergent agro-climatic conditions*», indicating the delicate turn taken away from a solely market oriented approach to seed laws.

The proposal also provides for a number of flexibilities that could accommodate the need of both traditional and more modern seed exchange networks and linked innovative endeavours. Firstly, it targets "**professional operators**", a concept designed to "exclude private persons"[1574], encompassing "*any natural or legal person carrying out as a profession, at least one of the following activities with regards to plant reproductive material: producing, breeding, maintaining, providing services, preserving, including storing and making available on the marke*t" (Article 3 (7)).

According to its Preamble, it also *inter alia* excludes reproductive material "*intended **solely** for*

> *testing, scientific and breeding purposes, to gene banks, **organisations and networks** devoted to the exchange and conservation of genetic resources (including on-farm conservation), or to reproductive **material exchanged in kind between persons** other than professional operators* »[1575] (emphasis added by the author).

Further derogations are established to the benefit of farmer-innovators not only through the fact that the Commission may introduce "delegated measures" concerning **heterogeneous material**, which does neither fulfil the definition of a variety nor satisfy the sustainable use criteria for cultivation. These varieties will still be produced and made available on the market without full registration obligations, taking into account their "*contribution to increase the genetic variability of agricultural crops, the genetic resource basis and biodiversity in the Union, as well as to the sustainability of agriculture and thusto the adaptation to climate change*".[1576]

Article 14§3 does nonetheless state that a number of minimal rules could be envisioned for such heterogenous material to be made available on the market[1577]. The proposal does not stop there, it also creates a "**niche market**" that is formally exempted stems from an affirmed need to establish

> « *proportionate and sustainable rules for small scale activities concerning plant reproductive material, which is adapted to local conditions, and made available on the market in small quantities* »[1578]. This *ad hoc* derogation from registration for "*niche market plant reproductive material* » set out in Article 36 of the proposal exempts "*plant reproductive material made available on the market in small quantities by persons other than professional operators, or by professional operators employing no more than ten persons and whose annual turnover or balance sheet total does not exceed EUR 2 million*"

[1574] Ibid., explanatory memorandum, p.5.

[1575] COM Proposal on the marketing of plant reproductive material, preamble, (7).

[1576] Ibid., preamble (17).

[1577] These "delegated measures" that can be adopted by the Commission include those rules on "labelling and packaging, the description of the material or breeding methods, fees and the establishment of registers by competent authorities eventually".

[1578] COM Proposal on the marketing of plant reproductive material, Explanatory memorandum, p. 6.

from registration although some basic rules on labelling and traceability of the material may be laid down[1579].

The exemption concerns « *e.g. farmer-breeders or gardener-breeders whether being professional operators or not* », and is designed to "*prevent undue constraints to the making available on the market of plant reproductive material, which is of lesser commercial interest, but is important for the maintenance of genetic diversity".*

A long-awaited breath of fresh air for mass selectors, this measure is nonetheless conditioned in order to avoid abuse and ensure that the derogation is "*only used by professional operators which cannot afford the costs and administrative burden of variety registration*".[1580] Its provisions therefore concern material made available on the market in a defined size of packages by professional operators employing a small number of persons and with a small annual turnover. Such restrictions, along with the record-keeping obligations that have been set out by the legislator may potentially raise the cost of mass selection efforts and may not be possible to comply with in extremely informal exchange environments, but they still have the merit of specifically leaving farmer or gardener innovators outside of the formal seed sector, which is subject to considerably stricter traceability obligations. It should be noted that this "niche market" may concern the entire range of varieties produced by mass selection or even more science-infused breeding efforts, including potentially new varieties developed through participatory breeding for instance. The flexibilities allowed do not stop there, as the draft legislation also targets

« ***old varieties****, such as conservation varieties (including landraces), or so called 'amateur varieties', (for which) less stringent requirements should continue to be laid down in view of promoting their on farm conservation and use as currently regulated under the Directives 2008/62/EC and 2009/145/EC* »[1581].

Not only does the new text abolishes currently applicable quantitative restrictions, even though georgraphical criteria ought to be catered for[1582], it also lightens up the registration procedure of these particular varieties, which will continue to operate under an « officially recognised description » for which DUS examination is no longer obligatory. The description needs to address

[1579] The plant reproductive material falling under such disposition has indeed to be labelled "niche market material", and records of quantities produced should be kept by producers, tob e made available to competent authorities on request.

[1580] COM Proposal on the marketing of plant reproductive material, Preamble (27).

[1581] Ibid., Explanatory memorandum, p.8.

[1582] The "varieties registered on the basis of an officially recognised description should be produced in the region where they have beenhistorically grown and adapted, to ensure their authenticity and their added value for the conservation of genetic diversity and the protection of the environment. Therefore, they should only be included in national variety registers. For the same reason, those varieties should have been available on the market and/or collected e.g. in gene banks before the entry into force of this Regulation, or, should have been deleted for more than five years from the national variety register or Union variety register, in casethey have been registered there on the basis of a technical examination concerning their distinctness, uniformity and stability », COM Proposal on the marketing of plant reproductive material, Preamble (27).

> « *the specific characteristics of the plants and parts of plants which are representative for the variety concerned and make the variety identifiable, including the region of origin* »[1583].

The material shall be identified through a « label indicating that this variety is identified by an officially recognised description and the region of origin », made available as «standard material ». All of these welcomed flexibilities, whether found in the definition of professional operators or varieties, the addition of « sustainable cultivation value », the consideration of "heterogenous material", the creation of a niche market for locally adapted varieties, and the renewed and relaxed stance on old conservation varieties provide, especially when viewed cumulatively, extremely valuable manoeuver margins for those involved in mass selection. Rendering solely a biodiversity conservation objective rather than an innovation fostering and institutional capacity-building mind-set, the proposal unfortunately also fails to acknowledge the socio-economic reality of mass selection and its integral part within the seed system as a whole. Crticis have been voiced over the content of this European reform. Reactions from farmers' organisations duly pointed out this unwarranted development and viewed it as "an attack on subsistence agriculture and small-scale food production, as well as the rights of peasants and farmers to exchange and sell their own seeds"[1584]. The outcry has been also backed by the European Greens and resulted in the introduction of high numbers of amendments into the proposed text. The main concern of such criticism was first directed towards the complete disregard of the informal seed sector and the modern exchange networks in the initial proposal. This worrying character was palliated by some "last minute additions to the text" that accommodated or at least addressed such reality. Nonetheless, this effort remains insufficient in the eyes of many, mainly due to the general stance that has been favoured, i.e., to view the informal seed sector as a "niche". Such "strategic niche management approaches" that have been advocated by economy scholars long before the European Commission proposal[1585] tend to underplay "the importance of identities, community dynamics and power relations in grassroots innovation"[1586].

In this tensed context, mere relaxation and adjustment has not always been considered enough, especially for the needs of developing countries. Acknowledging the inherent difficulties of establishing official catalogues, but also recognising the importance of different approaches to variety development and release, some actors have tried to rethink the principles of seed quality control from scratch. An alternative has for instance been constructed by the FAO, "particularly designed for countries with limited resources, which is less demanding than full seed quality

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[1583] Article 10(7) of the proposal adds that such destricption can be "obtained by means other than examination of the variety's distinctiveness, uniformity and stability". "This description can be based on an old official description of the variety, description produced at the time by e.g. a scientific, academic body or organisation. The accuracy of its content could be supported by previous official inspections, unofficial examinations or knowledge gained from practical experience during cultivation, repoduction and use".

[1584] Via Campesina, Position of European Coordination on the Marketing of Seeds, Plant Health and Controls, December 2012, available at http://www.reclaimthefields.org.uk/2012/12/20/via-campesina-europes-position-on-the-european-seed-legislation-reform/ (accessed July 2013).

[1585] See for instance R. KEMP, J. SCHOT, and R. HOOGMA, . , "Regime Shifts to Sustainability through Processes of Niche Formation: The Approach of Strategic Niche Management.," *Technology Analysis & Strategic Management* 10, no. 2, 1998.

[1586] SMITH and SEYFANG, "Constructing Grassroots Innovations for Sustainability," *op.cit.*

control systems but yet guarantees a satisfactory level of seed quality"[1587]. The "**Quality Declared Seed System**" was presented in 1993 and revised quite recently in 2006, in light of "the changing circumstances and needs in the seed sector", clarifying the role of national seed policies, the accommodation of local varieties into the QDS, the enlargement of its crop coverage and the adoption of standardised procedures to facilitate its operation[1588].

> "The QDS system offers considerable advantages for managing seed quality control where regulatory resources are severely constrained (as is the case in almost all African countries). But (as with any regulatory regime) it requires good administration and consistent enforcement in order to function properly"[1589].

> "In some countries, the certification agencies take a stand that their role to promote seed quality prevails over their control functions. The Seed Certification and Control Institute in Zambia, for instance, promoted the introduction of 'quality declared seed' in its regulations. This allows them to relax the certification procedures and interpret the seed quality standards more flexibly. Unfortunately however, seed certification organisations in many other countries stick to the rules that they have been given and cannot play a role in promoting new initiatives, but the Zambian example is now followed as well in other counties (e.g. Sri Lanka, Thailand)"[1590].

The bottlenecks of restrictive compulsory seed legislation that have been increasingly strangling mass selectors may be addressed in a plethora of ways. Amongst them lies the most liberal approach of voluntary marketing and labelling, which warrants for social actors to be accustomed to greater levels of self-regulation and education. Staying within the realms of compulsory certification so as to correct the inherent informational assymetries inherent to seed trade, a number of flexibilities can be drawn in to put informal mass selection within the realm of legality, with the risk of over-regulating and "niching" social organisation that in essence relies on socio-cultural norms that are difficult to embrace in technical marketing rules.

14.2.2. Intellectual property rights legislation: pushing for innovation-specific modalities

Aside from the choking effects of restrictive compulsory seed legislation, the innovative activities of mass selectors have also been affected by the expansion of the scope and multiplying presence of intellectual property titles. Viewing them as mere cultivators and customers, rather than innovators in their own right, the strong property paradigm has considerably shrunk the farmers' privilege that characterises plant variety protection and addressed the needs of this peculiar innovation context. The surge of patents within the proprietary landscape, coupled with restrictive contractual terms, has also considerably reduced mass selectors' range of action. Contractual clauses further serve the expansion of protection and the distinctive principles regarding the exhaustion of rights that have been put in motion with regards to harvested biological material. A

[1587] FOOD AND AGRICULTURE ORGANISATION, "*Quality Declared Seed- Technical Guidelines on Standards and Procedures*", Rome, 1993. http://www.fao.org/agriculture/crops/core-themes/theme/seeds-pgr/seed_sys/quality/en/
[1588] FOOD AND AGRICULTURAL ORGANISATION FAO, "*Quality Declared Seed System*", FAO, Rome, 2006. Preface.
[1589] REICHMAN and UHLIR, "A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment," *op.cit.*, p.60.
[1590] LOUWAARS, "Seed Laws: Biases and Bottlenecks," *op.cit.*

number of legislative and judicial practices have nonetheless attempted to correct these bottlenecks, often pushed to do so by farmers' organisations themselves. Ensuring the development and conservation of landraces thus entails a review of existing intellectual property regulatory tools, not only to be addressed through parallel legislation but also reconsidering existing flexibilities aimed at *in situ* biodiversity conservation within the strong paradigm, such as the farmers' exemption and those regulatory takes on farm saved seed.

Farmer's privilege in *sui generis* PVP and patent protection

The farmers' exception found in intellectual property titles is a **regulatory necessity** to uphold mass selection, since it not only allows farmers to resow protected varieties for their own socio-economic subsistence needs, but also may allow them to use the improved germplasm in their selection efforts. The latter concern is nonetheless more inconsequential, especially for hybrid varieties that will not maintain fixed characteristics the following seasons, rendering the selection of best-performing individuals less meaningful. Notwithstanding such drawback, the ability to use germplasm to generate new biodiversity is still an inescapable predicament of the PGRFA public domain set out both by traditional intellectual property rights and international biodiversity law. That is why the *ad hoc* defences against infringements or "statutory compulsory licensing" mechanisms such as the breeders' rights or the farmers' privilege need to be maintained. Both mechanisms have been criticised due to the resulting lack of contractual discourse after the grant of IP entitlements, if one trusts that transactional bottlenecks are likely to be overcome by so-called "repeat players" that frequently need to exchange rights[1591]. However, farmers, except maybe for the larger actors of the developed world, are not likely to become real "repeat players". Indeed, most farmers will be ill equiped to negotiate in all equity faced with professional plant breeders in an oligopolistic seed market. That is why the need to sustain, reinforce and especially clearly define farmers' privilege in both PVP and patent laws is very much a genuine necessity. Here, the approach to reward mass selection-based innovation and contribute to the sustainable use of biodiversity on farms is to situate the "traditional practices of farmers as exceptions to the exclusive rights of plant breeders under existing IPR tools", precluding breeders from demanding payment from farmers who save and plant seeds saved from prior purchases, or informally exchange purchased seeds[1592]. From judicial interpretations to restrictive regulation, aforementioned legal developments have pushed to question whether and to what extent the farmers' privilege should be recalibrated in order to maintain its initial *rationale* and ensure the survival of mass selection endeavours.

There is a definite need to envisage the contours of the farmers' privilege with much greater clarity and precision within plant variety protection for the sake of all actors concerned. Given the inherent flexibility of Article 27§3b of the TRIPS Agreement, allowing for **any type of *sui generis* protection for plant varieties,** as long as there is one, countries retain the right to draft PVP legislation with greater room for the so-called farmers' privilege. This prerogative was particularly highlighted in light of international and national development policy, which may warrant for the tailoring of plant breeders' rights to the specific needs of countries still undergoing the economic development process, whether at its tail or its edge. The need to include a complete farmers'

[1591] MERGES, "Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations " *op.cit.*
[1592] HELFER, "Intellectual Property Rights in Plant Varieties: An Overview with Options for National Governments."

exemption for the benefit of the mass selection chains' future and the conservation of agrobiodiversity cannot be disregarded. In order to balance out the incentive to innovate for breeders, such exemption can however only extend to seed-saving practices and exchanges within local communities, excluding thereby the sale of protected varieties. This option has indeed been followed in numerous countries, such as Brazil, where non-commercial exchanges of saved improved varieties are allowed except for sugar cane, or in Vietnam, Trinidad and Tobago, the Philippines, where exchanges are allowed for non-commercial purposes and for reproduction in farmers' own land[1593]. Countries' margin of manoeuvre is nonetheless wider. It has also led to the CoFaB covenant initiative, which clearly took the defence of farmers, stretching as far as the establishment of a farmers' rights fee to be levied by breeders "for the privilege of using traditional plant varieties either directly or through the use of those varieties in breeding programmes"[1594]. The 2001 Indian PVP law, which largely draws from CoFaB owing to virulent NGO advocacy, did establish a "farmers' rights' regime in addition to and distinct from the farmers' privilege regime" that follows the perspective of the 1978 UPOV text[1595].

Within the more **restrictive realm of the UPOV Conventions,** the evolutive withdrawal of farmers' privileges in recent legislative amendements has also triggered adverse and fervent reactions from lawmakers. For instance, Norway still refuses to adopt the 1991 UPOV terms. However, the country's relatively minor influence in the global seed industry, and its active political attachment to benefit-sharing principles, may maintain this particular practice as rather marginal progress. As aforementioned, the shrinking evolution of the farmers' privilege may have been the source of the recognition of farmers' rights within the FAO system as a bundle of socio-economic rights including those related to seed as such, as asserted by article 9 of the 2004 International Treaty for Plant Genetic Resources for Food and Agriculture[1596]. This provision nonetheless conditions farmers' rights to save seed to national policy decisions, and therefore cannot be wholly viewed as an absolute international prerogative granted to farming or gardening communities. A number of UPOV 1991 compliant national legislations have however tried to introduce the notion of a true-to-word "farmers' exemption" for the benefit of small farmers. Farmers who produce less than ninety-two tons of cereal in the European Union for instance are allowed to re-use the purchased seed without any payment, including for experimentation purposes, selecting material on their own farm, but without participating in seed exchanges. This prohibition to exchange has nonetheless been viewed as inconsistent with the aforementioned practices of farmers who exchange seeds for purposes of crop and variety rotation and selection[1597]. Furthermore, within the UPOV system, a reasonable compensation could be provided

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[1593] You can find a comprehensive list of the extent of farmers' privilege under PVP legislation in INSTITUTE, "The Relationship between Intellectual Property Rights (Trips) and Food Security," *op.cit.*, pp.63-64.

[1594] DUNCAN MATTHEWS, *Intellectual Property, Human Rights and Development: The Role of Ngos and Social Movements*, Cheltenham: Edward Elgar, 2011, p.195.

[1595] Taken on the 1978 approach was essential in the case of India in order to "ensure a broad leeway to farmers to save, exchange and re-sow seeds saved from the harvest of a season, in the next season", considering that the large portion of farmers cannot afford to buy proprietary seeds from the market each season; MRINALINI KOCHUPILLAI, "India's Plant Variety Protection Law: Historical and Implementation Perspectives," in *Is Upov 1978 Trips Compliant? Caveats for Developing Countries*, ed. JOSEPH STRAUS, Munich: Munich Intellectual Property Law Center, 2009.

[1596] PELEGRINA and SALAZAR, "Farmers' Communities: A Reflection on the Treaty from Small Farmers' Perspectives," *op.cit.*, pp.175-182.

[1597] LESKIEN and FLITNER, "Intellectual Property Rights and Plant Genetic Resources: Options for a Sui Generis System."

to safeguard the "legitimate interests of the breeder", which has been for instance specifically defined in the European Union so as to trigger a balancing exercise that should be adequately carried out:

> "*The legitimate interests shall not be considered to be safeguarded if one or more of these interests are adversely affected without account being taken of the need to maintain a reasonable balance between all of them, or of the need for proportionality between the purpose of the relevant condition and the actual effect of the implementation thereof*" (Commission Regulation 1786/95 implementing EC Regulation 2100/94, Art. 2).

Even if minor in their essence, these engagements nonetheless reclaim the public domain uses that have been enshrined in international environmental law. They have remained minor due to the concern that a largely unrestricted approach may in the long term have detrimental effects on other actors of plant improvement, namely private plant breeders, whether small or larger scaled. A clear-cut mechanism for the determination of the reasonable compensation stemming from farm-saved seed should be stipulated in applicable laws or decrees. These could provide for adequate procedures with satisfactory representation from both sides to reach an agreement on the rate or percentage of farm-saved-seed royalties, or could also directly fixate such rate in its text, according to crops if necessary. Legal certainty and clear implementation guidelines should in our opinion prove satisfactory for both royalty payers and collectors.

However, reflecting on the scope of the farmers' privilege under UPOV-linked or stand-alone plant variety protection only goes half the way to ensure its maintenance. As aforementioned, the inherent concern of the PVP system vis-à-vis farmers is not omnipresent within **patent laws** as such. Indeed, the latter tend to remain abstract in their nature, seeing that they are not designed to solely apply to agrobiodiversity-reliant innovations as PVP legislation is, with its inevitable links to loftier issues such as food security or environmental protection. As aforementioned, the patent system confronts farmers with even more restrictice terms, viewing them as sole licensees, and not as cultivators that form an integral part of the intrincately intertwined greater food system. In the United States, where the principle of independence between different IP systems did not warrant the adoption of specific rules addressing the co-existence of patents and plant variety rights, case law points towards the prevalence of patents. The legal challenge of multiple protection was epitomised by the wide array of enclosing instruments surrounding Round Up Ready canola, protected all at once through process and gene patents, plant variety rights, trademarks and the private contract that is the "Technology Use Agreement". In 1998, an infamous case opposed *Monsanto* to *Percy Schmeiser*[1598], a Canadian canola farmer who replanted the seed he saved from batches of Round Up Ready canola seeds he had bought from the plaintiff. Although he argued that he was cultivating his own traditionally bred canola seeds, and that the batches were unknowingly contaminated with Monsanto's technology on account of cross field breeding by wind or insects, he was found to be infringing patents by using technology without a license[1599]. The principle of independence between exclusive titles was reiterated in 2002, where farmers' right to save seeds of plants protected through plant variety protection was once again viewed not

[1598] *Monsanto vs. Schmeiser*, Supreme Court of Canada, 21st May 2004, SCC 34, 239; the first instance rulings had also found the patent valid and Mr. Schmeiser's acts to infringe on the title.
[1599] CHIAROLLA, *Intellectual Property, Agriculture and Global Food Security: The Privatization of Crop Diversity*, *op.cit.*, pp.96-97.and CULLET, *Intellectual Property Protection and Sustainable Development*, *op.cit.*

to convey the right to do so for patented technologies or plants[1600].

To counter such negative effect, certain countries have equipped themselves with patent legislation recognising the close knit of green biotechnology patents with food security, and acknowledging the differences that may exist between licensees in its most classical understanding, and farmers. This has been the case in the European legal order and its made-to-purpose Directive 98/44/EC, which addresses solely biotechnology-related patent protection. The text makes room for a **farmers' privilege in domestic patent systems** in its rather unique article 11§1, allowing farmers to retain material grown on his own farm for the following years, under the same terms warranted to the privilege in plant variety protection[1601].

> "*By way of derogation from Articles 8 and 9, the sale or other form of commercialisation of plant propagating material to a farmer by the holder of the patent or with his consent for agricultural use implies authorisation for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm, the extent and conditions of this derogation corresponding to those under Article 14 of Regulation (EC) No 2100/94*" (Directive 98/44/EC, Art. 11.1).

Even though this instrument has no direct effect in Member States' national legal orders and allows for restrictions of these rights awarded to farmers, it still acknowledges the specificity of agricultural innovation, just as more recent legislative endeavours have also been doing in other fora.

While the so-called "Doha round" and its Ministerial Conventions have seemingly failed to fashion a viable consensus on the terms of a new World Trade order, they have yet strengthened regulatory determination to include such privilege within domestic patent regulation. Discussions have for instance led to the 2007 amendment of the Swiss Federal Patents Act so as to include a farmers' privilege, limited to those uses of the patented material within the same farm[1602]. However, even though a farmers' privilege has been appearing in patent legislation, especially in the European continent, the increasingly restrictive approach to farm saved seed under plant variety protection has growingly restricted this statutory use's position within the strong intellectual property paradigm[1603]. The relatively rare recourse to the exception within patent legislation could be entrenched in a textual TRIPS interpretation, in accordance with which the recognition of such a privilege to farmers might prejudice the legitimate interests of the monopoly holders under Article 27[1604]. The feasibility and conformity of such exceptions in patent legislation has yet to be tested before the judiciary or the WTO dispute-settlement mechanisms, but we believe that the flexibilities inherent in the Agreement and its rationale may allow for the

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[1600] *Monsanto Co. vs. Mc Farling*, Federal Circuit Court, 64 USPQ 2d, 1161.
[1601] LYDIA NENOW, "To Patent or Not to Patent: The European Union's New Biotech Directive," *Houston Journal of International Law* 23, 2001: pp.569-607.
[1602] DE CARVALHO, "Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patents Applications without Infringing the Trips Agreement: The Problem and the Solution," *op.cit.*, citing the submission of Switzerland; *Article 27.3 (b), the relationship between the TRIPS Agreement and the Convention on Biological Diversity, and the Protection of Traditional Knowledge*, IP/C/W/400/Rev.1, 18th June 2003.
[1603] PHILLIPS, "Farmers' Privilege and Patented Seeds," *op.cit.,* pp.49-64.
[1604] J. WATAL, *Intellectual Property Rights in the Wto and Developing Countries* Brussels: Kluwer Law International, 2000.

recognition of the farmers' exception. Other commentators have in this regard highlighted the possibility that the existence of compensation in return for the right to use, save and exchange the protected material might actually encourage the doctrine of compulsory licensing, viewed as a "statutory license", rather than as a classical exception to IPR protection as grounded in Article 30 of TRIPS[1605]. Such a mechanism nonetheless warrants the further use of legal muscle by actors unaccustomed to these practices.

Farm-saved seed, harvested material and exhaustion

The possibilities offered to mass selectors to save, use and exchange seeds have been directly limited by the non-existence or restrictive implementation of the farmer's privilege in applicable UPOV legislation and co-existing patent protection. They have in parallel also seen their reach diminish through the extension of the scope of protection awarded by the two main plant-related IPR titles. Indeed, as UPOV was extending the breeders' rights to harvested material in 1991 in order to ensure efficient protection to innovators of self-replicating and easily reverse-engineered technologies, the same logic was applied to the doctrine of exhaustion of intellectual property rights.

As aforementioned, plant variety protection under UPOV has been extended to **harvested material** in the 1991 text through its article 14, where the authorisation of the breeders has also to be sought for certain acts, such as production, reproduction or sale of "*harvested material, including entire plants and parts of plants, obtained through the unauthorised use of propagating material of the protected variety [..], unless the breeder has had reasonable opportunity to exercise his right in relation to the said propagating material*". This extension directly impacts farmers active in territories where national laws have not established a farmers' exception. But it may also impact those active in Member States that have incorporated the optional exception since, subject to Articles 15(1) and 16 of the UPOV 1991 text, "unauthorised uses" would refer to acts that do not comply with the reasonable limits and the safeguarding of the legitimate interests of the breeder provided in the optional exception"[1606]. Such premise reinforces mass selectors' absolute need for a farmers' exception within PVP legislation in order to continue conserving and selecting agrobiodiversity, even if these provisions only concern improved and stable protected plant varieties. However, the extension of protection scope has made it extremely difficult for farmers to truly assess their rights and obligations with regards to protected varieties. In this nebulous context, plant breeders have furthermore been increasingly drafting stringent contracts in order to fully capture the added value of their improved varieties in royalties. The difficulties surrounding the farmers' privilege are not only attributed to legislative changes, but also relate to the practices surrounding the **negotiation of royalties,** both for harvested material and for farm-saved seed. Farm-saved seed royalties can be determined for each species through agreements between individuals or representative organisations from both parties to the transaction. Such agreements exist notably in the United Kingdom and in Germany, and seem to function well enough. Uproar did generate in France for instance, as the CNDSF ("Coordination Nationale pour

[1605] C. GARRISON, "*Exceptions to Patent Rights in Developing Countries*", International Centre for Trade and Sustainable Development, Geneva, 2006.
[1606] UPOV, "*Explanatory Notes on Acts in Respect of Harvested Material under the 1991 Act of the Upov Convention, Upov/Exn/Hrv/1*", UPOV, International Union for the Protection of New Varieties of Plants, UPOV Council, 47th ordinary session, Geneva, 2013.

la Défense des Semences Fermières") refused to pay royalties and called for a boycott of farm-saved-seed royalties[1607].

The aforementioned reference to the European Court of Justice for a preliminary ruling of the European Court of Justice in *Geistbeck v Saatgut*[1608] has shed some light on the interpretation of Community Regulation in this aspect, as the Bundesgerichtshof's questions trigger the core of the need to calculate the amount of "reasonable compensation" owed by a farmer who uses protected propagated material **outside the scope of the farmers' privilege**. The issue here was to determine whether the "reasonable compensation" that ought to be paid when faced with an infringement of the plant variety right should be considered as equivalent to the "equitable remuneration" that breeders can ask for in the derogative yet lawful uses of protected material on farm[1609]. The answer of Luxembourg provided an interpretation favouring the breeders' interests, since the acts perpetrated by the farmers were considered to be "unauthorised".

> "In so far as Article 94 of Regulation No 2100/94 is intended to make good the loss suffered by the holder of a plant variety who is the victim of an infringement, it must be held that, in the case before the referring court, since the Geistbecks cannot rely on the 'farmer's privilege' – namely, the derogation from Community plant variety rights allowed under Article 14(1) of Regulation No 2100/94 and as provided for in Article 14(3) of that regulation – that loss amounts to at least the fee that a third party would have had to pay for a C-Licence.
>
> Consequently, in order to determine, in the circumstances of the case before the referring court, 'reasonable compensation' as provided for under Article 94(1) of Regulation No 2100/94, it is appropriate to take as the basis for that calculation an amount equivalent to the remuneration payable for licensed production" (ECJ, *Geistbeck v Saatgut,* para.36-37).

The Bundesgerichtshof had also asked the Court whether the breeder should recoup the cost of royalty collecting schemes, asking whether "special monitoring costs of an organisation which protects the rights of numerous holders to be taken into account in such a way that double the compensation usually agreed, or double the remuneration due under the fourth indent of Article 14(3) of the CPVR Regulation, is awarded". The Court here held that the compensation had to be solely be interpreted within the realm of intellectual property law, therefore precluding the warrant of larger damages.

> "It is sufficient to note that Article 94(1) of Regulation No 2100/94 does no more than provide for reasonable compensation in the event of unlawful use of a plant variety, but does not provide for compensation for damage other than that connected to the failure to pay that compensation.

[1607] This boycott has notably led to the creation of a European-level alliance against these royalties, the "Union Européenne des Semences et Plants de Ferme', see TOLEDO, "Saving the Seed: Europe's Challenge," *op.cit.*

[1608] European Court of Justice, C-509/10 *Josef Geistbeck and Thomas Geistbeck v Saatgut-Treuhandverwaltungs GmbH*, reference for a preliminary ruling from the German Bundesgerichtshof, 5th July 2012.

[1609] European Court of Justice, C-509/10 *Josef Geistbeck and Thomas Geistbeck v Saatgut-Treuhandverwaltungs GmbH*, reference for a preliminary ruling from the German Bundesgerichtshof, 5th July 2012.

> In those circumstances, the answer to the third question is that the payment of compensation for costs incurred for monitoring compliance with the rights of the plant variety holder cannot enter into the calculation of the 'reasonable compensation' provided for under Article 94(1) of Regulation No 2100/94". (ECJ, *Geistbeck v Saatgut*, para.50-51).

Faced with a very restrictive farmers' privilege, mass selectors who wish to replant protected material therefore ought therefore to be extremely carefuly not to step outside of such privilege without adequately informing and compensating plant breeders, even though no additional damages should be calculated on the sole basis of plant variety rights legislation. In practice, royalties may be typically obtained from either the grower or trader purchasing the initial propagating material, or through a so-called "end-point royalty" from the grower, under contractual terms defined by the volume of harvested product. It is therefore of primordial importance for farmers to be aware of the limitations surrounding the re-use of protected material, and challenge them if need be. In 2012, Brazilian farmers brought together as a consortium of syndicates, have successfully and very vocally sued Monsanto for two point two billion of **unfair royalty collection** on the basis of its technology use agreements that were linked to technology that was no longer under patent protection[1610]. However, this particular scenario is not as likely to occur as the collection of dueful royalties under license agreements. The recourse to such lawful contracts nonetheless does bear negative effects on growers, especially smaller-scaled ones. In this context, the challenge to be addressed is to assess whether contracts can annihilate or diminish the scope of the farmers' privilege provided for in national legislation or farmers' rights? On the flipside, could the farmers' privilege warranted by national legislation be seen as a prerogative limiting contractual autonomy? Could the international biodiversity PGRFA public domain and the consecration of farmers' rights in the ITPGRFA also serve the same purpose? The answer to the latter question is most probably to be framed negatively, as the content of article 9 of the ITPGRFA, as aforementioned, has not been considered to bear any direct effect in the European legal order, and its conditional nature would prevent such conclusion to be drawn in other legal orders as well.

The former interrogation stands therefore at the core of establishing possible **limits to contractual freedom** when it comes to the collection of royalties on farm-saved-seed. To counteract the detrimental effect of contractual extensions of royalty collection on the scope of the farmers' privilege, certain national legislative instruments have introduced interesting provisions into their plant variety protection laws. This has been the case of Switzerland, where, according to article 8 of the Swiss federal plant variety protection law:

> "*any agreement which restricts or annuls the exceptions to the right to protection for the varieties referred to in art. 6 and 7 [which relate to the farmers privilege] shall be deemed to be null and void*".

In the absence of legislative amendment, alternative arguments have been put forward. The very active farmers' organisation Via Campesina states that the "legal basis for contracts allowing for vertical integration in the supply chain is dubious and may not comply with the UPOV

[1610] LUISA MASSARANI, "Monsanto May Lose Gm Soya Royalties in Brazil," *Nature News* 10837, 2012.

Convention, in particular with the **principle of exhaustion** of the breeder's right"[1611]. However, the turn taken in the interpretation of the principle of exhaustion in patents granted on self-replicating material does not present itself as a good omen to allow it to be used so as to limit contractual autonomy and allow farm seed saving. The exhaustion of patent and plant variety protection, especially the United States' judiciary's approach in patent rights indeed today rather present a major hurdle that restricts the actions of mass selectors. In 2006, the Federal Circuit[1612] was asked to consider by a Mississipi farmer, Mitchell Struggs, whether Monsanto's practice with regards to the replanting of seeds constituted patent misuse, or could be covered by the patent exhaustion doctrine. Struggs argued that the contractual license restrictions imposed by Monsanto on both seed distributors and growers impermissibly broadened the scope of exclusive rights awarded through patent protection. The Court held for the technology developer, as it considered that "applying the first sale doctrine to subsequent generations of self-replicating technology would eviscerate the rights of the patent holder", and sided with Monsanto, "as the new seeds grown from the original batch had never been sold".

The ruling was applauded by some commentators, who argued :

> « A Federal Circuit holding that patent exhaustion eliminated Monsanto's rights to future generations of seed would have significantly harmed incentives for investment in self-replicating technology and likely encouraged the use of genetic restriction technologies, thus shifting control of intellectual property rights out of the hands of the public and into the hands of private entities. […] While it is true that limiting the doctrine of patent exhaustion and prohibiting seed saving leads to higher prices, this economic argument focuses exclusively on the economic position of the farmer and completely ignores the larger economic framework in which many other parties play a role. While it may be beneficial in the short-term for the farmer to exact the most profits from his crops by means of saving seed, Monsanto and similar companies need the broader scope of rights to profit from their investment »[1613].

This approach is held of great value for technology developers since « contract law does not provide patentees recourse against unauthorised downstream users of second-generation seed, who are not in privity with the parties to the license and technology agreement »[1614]. However, others recalled :

> « What is an unequivocally good decision for intellectual property rights holders is not necessarily in the best interest of society as a whole. Considering the effects of Monsanto's no-replant policy on the agricultural industry, on farmers, and on consumers _held here to be within the bounds of Monsanto's patent rights_, [...] Congress will likely need to respond to allegations of unfairness regarding the benefits conferred upon biotechnology patent holders by this decision »[1615].

[1611] Paragraphs 14 and 15 of the UPOV, *op.cit.*, October 29 and 30, 2012.
[1612] United Stated Federal Circuit, *Monsanto Co. v. Scruggs*, 459 F.3d 1328 (Fed. Cir. 2006).
[1613] SAVICH, "Monsanto V. Scruggs: The Negative Impact of Patent Exhaustion on Self-Replicating Technology," *op.cit.*, pp.128-9.
[1614] SIEVERS, "Not So Fast My Friend: What the Patent Exhaustion Doctrine Means to the Seed Industry after Quanta V. Lg Electronics," *op.cit.*, p. 374.
[1615] PETER LUCE, "Monsanto Co. V. Scruggs: Has Federal Circuit Biotechnology Patent Scope Jurisprudence Gone to Seed," *Tul. J. Tech. & Intell. Prop.* 9, 2007., p. 394.

This does not seem to be the case yet. Indeed, the aforementioned most recent and very similar Bowman ruling held the patent exhaustion doctrine to be inapplicable for self-replicating technologies[1616]. One possible interpretation that could be brought to the table to allow for patent exhaustion to play a role in the continuity of certain seed saving practices is to construct the actions of Hugh Bowman as "**impermissible making**". Indeed, one could argue that it is when he "sprayed his commodity crop with herbicides with the intent of creating glyphosate-resistant seeds [that] he impermissibly constructed the patented article"[1617]. Had he not used such practice directly linked to the patented element, he would have arguably not recreated the product, thereby exhausting patent protection. However, the stretch is not likely to be made, neither in the United States, nor in the European Union.

Arguably, mass selectors pursuing their activities in the latter jurisdiction will not be adversely affected by this stretched understanding of the bundle of patent rights in self-replicating technologies, in light of the farmers' privilege, but also the aforementioned purpose-bound protection awarded in its realms. In the European legal order, the issue of exhaustion has been directly addressed by Article 10 of the aforementioned Biotechnology Directive 98/44/EC, which contains in effect a standard exhaustion of rights provision, applying the Silhouette/Davidoff ruling of the European Court of Justice[1618], has also aligned itself to the principles of exhaustion prevailing in plant variety protection[1619]:

> "*The protection referred to in Articles 8 and 9 shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market in the territory of a Member State by the holder of the patent or with his consent, where the multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation or multiplication*" (Art.10, Directive 98/48/EC).

This provisions, along with other articles of the Biotech Directive relatin to the scope of protection in biotechnological inventions, provide for instance the basis of the German Patent Law's Article 9c, which purposefully states that a farmer who has produced second generation seeds may continue to use them for replication in his own business, as long as this use matches the purpose for which the seeds were originally marketed, subject to reasonable compensation mirroring the farmers' privilege in UPOV 1991 compliant plant variety protection[1620].

Faced with the wide-reaching intellectual property titles that accompany improved plant varieties, the range of action of mass selectors to informally continue saving and exchanging seeds had been substantially reduced. Even though the challenge goes beyond farmers' capacity to innovate or conserve biodiversity and tackles also deeper socio-economic concerns, a number of mechanisms

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[1616] Supreme Court of the United States, 11-796, *Bowman v. Monsanto Company*, 569 U. S. (2013), 13th May 2013.
[1617] GARMEZY, "Patent Exhaustion and the Federal Circuit's Deviant Conditional Sale Doctrine: Bowman V. Monsanto," *op.cit.*, pp.215-216.
[1618] NORMAN, *Intellectual Property Law Directions*, *op.cit.*,pp.428-430.
[1619] NICOLAS BRAHY, "Cumul Et Chevauchement Du Brevet Et Du Certificat D'obtention Végétale: Beaucoup De Droit... Mais Peu De Faits," in *Le Cumul Des Droits Intellectuels*, ed. ALEXANDRE CRUQUENAIRE, SÉVERINE DUSSOLIER, and ALAIN STROWEL, Bruxelles: Larcier, 2009., pp.115-116
[1620] STEVEN ZEMAN and HEIKE VOGELSANG-WENKE, "Patents for Self-Replicating Products: Not So Exhausting after All," *Life Sciences Intellectual Property Review*, 2013.

found within the IPR system can be adequately used to restore the lost balance. The quintessential flexibility that farmers need to be able to rely on relates to the so-called farmers' privilege, which not only perdures age-old traditions, but may also counterbalance the need for technology and variety developers to recoup their investment. A clearer farmers' privilege, even, if need be, accompanied by reasonable yet distinctly established compensation for larger sized growers, could indeed level out the impediments of aggressive contractual royalty collection and an extensive protection scope striving to go beyond harvested material and the principles of exhaustion of rights.

14.3. Fighting Misappropriation, Protecting Landraces and Traditional Knowledge

The recourse to seed saving of protected improved varieties cannot sustain the farmers' innovation model in its own, even though better clarity on the contours of farmers' privilege would definitely contribute at encouraging seed saving and exchange networks by levelling fears of prosecution. Indeed, "the cost advantage of saving seed is eroded by the deterioration of saved seed, causing yield losses over time"[1621]. The mere possibility to use improved seeds does not adequately foster mass selection efforts, which rely on observations for mass selection of individuals or populations and not so much on deliberate crosses between varieties, where improved germplasm shows its best potential. Even though improved farm-saved-seed is of tremendous importance in terms of subsistence, this solution cannot in any case be viewed as sufficient enough to foster innovation on farm and maintain exchange networks built around non-proprietary varieties. This is why legal and institutional solutions ought to be carved in order to nurture mass selection innovation, and protect its products against all kinds of misappropriation that might be operated by third parties without compensation. Such need is transcribed in the new PGRFA public domain enshrined in international biodiversity law, through the obligation to protect traditional knowledge, ensure the continuity of farmers' rights, and at last ensure that the benefits arising from the use of genetic resources are shared equitably. However, the main question at stake here lies in a more global debate on the approach through which the international consecration of traditional knowledge and farmers' rights should operate at the national level. In this context, two opposing streams confront each other, especially when its implementation is viewed in a purely Western oriented intellectual property rights understanding:

> "Restricting ownership of [traditional] knowledge and placing it in the public domain because there has been no easily identifiable "original" contribution", which "may simply be a different form of effrontery [or] refusing to recognise traditional knowledge holders' intellectual property interests as valid merely because to do so conflicts with the received wisdom of western intellectual property systems." If we consider that "the aims of intellectual property are confined to those customarily recognised by the western systems – preserving democratic participation in the creation of meaning, fostering creative output for public consumption and rewarding creators – then the property interests of traditional knowledge holders apparently must yield before them. If however, we expand the goals to include distributive justice for traditional knowledge holders and acknowledge the ways in which the structure of western intellectual property systems prevents the economically

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[1621] J. VAN WIJK, J. COHEN, and J. KOMEN, "*Intellectual Property Rights for Agricultural Biotechnology: Options and Implications for Developing Countries*", ISNAR, The Hague, 1993.

> disadvantaged from realising such goals, then recognising new forms of property in traditional knowledge may be appropriate"[1622].

Whichever understanding prevails, the vital role of seed exchange networks and related farmer communities ought to be recognised as contributors to the distributive equity goals of international biodiversity law that aim to correct the "ecological debt" of follow-on plant genetic resource users. This acknowledgement has today come a long way, and takes centerstage on the desks of international and national IP policy-makers. While legislative drafting is under prolific way before the World Intellectual Property Organisation[1623], underlying doctrinal debates have on the one hand tried to determine how existing intellectual property titles may accommodate the issue of misappropriation through their inherent protection criteria and other mechanisms, in a "defensive protection" mindset. They have on the other hand also tried to determine how to best protect the results of mass selection and correlated information as such in order to trigger compensation, either through traditional IPR schemes, or more innovative approaches to collective rights and liability rules, enscribed in a "positive protection" approach.

14.3.1. Acting on the validity of intellectual property titles

The most straightforward means of action to ensure that landraces or low-input plant varieties are protected against misappropriation is to use the existing flexibilities of the IPR system with regards to the validity of protection titles. This entails two different yet compatible solutions, regarding first the assessment of novelty and prior art or common knowledge in plant variety and patent applications, and second the potential recourse to a disclosure of origin in such applications, either to defy the gauge of novelty, or to trigger parallel civil liability procedures under biodiversity legislation.

Tackling novelty and inventive step

As aforementioned, the gauges of novelty and inventive step (or non-obviousness) that need to be taken into account in patent applications, just as the novelty and common knowledge thresholds that generally open up UPOV-like plant variety protection, seldom encompass an exhaustive analysis of existing landrace populations and associated knowledge. A number of practical solutions have been advocated to cater such limitation, whether entirely self-regulatory or warranting formal intervention vis-à-vis the **interpretation and implementation of applicable protection standards**. With regards to the latter, it has been argued that

> "The novelty requirement should be carefully defined under national laws so as to avoid the misappropriation of traditional knowledge or knowledge that is already in the public

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[1622] This last option to include traditional knowledge within the realm of traditional intellectual property is defended by Anupam Chander and Madhavu Sunder, to whom David Skillman and Christopher Ledford are responding to; see ANUPAM CHANDER and MADHAVI SUNDER, "The Romance of the Public Domain," *California Law Review*, 2004., and also DAVID SKILLMAN and CHRISTOPHER LEDFORD, "Limiting the Commons with Uncommon Property: A Critique of Chander & (and) Sunder's the Romance of the Public Domain," *Or. Rev. Int'l L.* 8, 2006.

[1623] The latest draft of the treaty dates as of 5th February 2014, produced by the Intergovernmental Committee, whose members consider the basis for further discussion on the adoption of a binding international agreement on the protection of traditional knowledge, http://www.ip-watch.org/weblog/wp-content/uploads/2014/02/IGC-Consolidated-Doc-IP-and-GR-Rev-1-Feb-2014.pdf

> domain. Such definitions could involve the inclusion of all public domain knowledge – national and international – within the notion of prior art so as to avoid, for example, the use of prior art from a foreign country being used as the basis for a patent application."[1624]

It is in this context that large campaigns have, often quite successfully, been launched by farmers' organisations or non-governmental organisations dedicated to environmental conservation or food security and equality issues. The distributional impulses of seed exchange networks have also transpired into the legal arena, whether in **patent follow-up and opposition procedures or the establishment of traditional knowledge logs**. Biopiracy and misappropriation claims have found an important echo in contemporary international law, and also in the actions of seed exchange networks, which have actively fought against the misappropriation of their products and knowledge. Biopiracy campaigns were for instance led by the Indian *Navdanya*[1625] against patents granted by the European Patent Office for the fungicidal properties of the neem tree, several characteristics and breeding methods for basmati rice and the traditional Indian "Nap Hal" wheat variety. These campaigns have infamously led the Office to revoke or make serious amendments to these prior art violating patents respectively in 2000, 2001 and 2004. Another representative case relates to turmeric, for the healing properties of which were patented in the United States in 1995 by two expatriate Indians working at the University of Mississippi Medical Centre. The Indian Council for Scientific and Industrial Research (CSIR) filed a case with the US Patent Office challenging the patent on the grounds of "prior art", proving existing public knowledge through written documentation claiming traditional wisdom in an ancient Sanskrit text and a paper published in 1953 in the Journal of the Indian Medical Association[1626]. The patent was thereon cancelled by US Patent Office, along with several other applications that were pending for turmeric. Let us also recall the aforementioned Xa21 patented resistance gene from a variety developed by IRRI on the basis of traditional knowledge held by Malian communities. In this particular case, the UC Davis, who had patented the Xa21 resistance gene, established an International Fund for Plant Genetic Resources. The lump sum payments reached 52.000 USD for the first company and 30.000 USD for the second[1627]. This mechanism allowed the contribution of a traditional rice variety identified and conserved in Mali, which was later developed into a uniform cultivar by IRRI, which contained a patented resistance gene, to be taken into account in the complete life-cycle of the variety. A recent controversy is today shaking the European Patent Office, with regards to a patent (EP 2140023) granted to Syngenta on 8th May 2013 for "insect-resistant sweet pepper plants", which were produced by crossing a wild pepper plant from Jamaica with commercially grown pepper plants, carrying the insect resistance attached to the wild variety. This move has triggered a European wide alliance regrouping thirty-two non-governmental farmer, breeder and environmental organisations from twenty-six countries to file an opposition to the patent[1628]. All aforementioned successfully litigated or readily initiated misappropriation cases show that the patent and PVP systems both provide for mechanisms that allow for

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1624 SIMON WALKER, "*The Trips Agreement, Sustainable Development and the Public Interest*", Geneva, 2001.

1625 Navdanya was assisted by its parent organization, the Research Foundation for Science Technology and Ecology (RFSTE), but also other non-governmental organisations and associations, See http://navdanya.org/campaigns/biopiracy

1626 AUDIT, "Trade Related Intellectual Property Rights and Farmers' Rights : Appendix 7 to the Minutes of Evidence."

1627 BLAKENEY, *Intellectual Property Rights and Food Security, op.cit.*, p.141.

1628 The move is quite emblematically called the "Free pepper campaign", see http://no-patents-on-seeds.org/en/information/news/free-pepper misappropriation cases to be redressed. Nonetheless, these challenges remain extremely onerous and cannot always be followed all the way through by all agrobiodiversity users, especially indigenous or precarious communities. Pakistani rice growers were for instance thwarted in September 1999 from challenging Rice Tec's patent on basmati rice when American lawyers demanded a deposit of 300,000 pounds to initiate proceedings[1629].

That is why additional means of pressuring wrongful titleholders need to be and have been drawn up in parallel. Situated solely within the realm of applicable exclusive IPR appropriation systems, self-regulatory attempts to protect what essentially covers a body of environmental knowledge held by indigenous communities have mostly been concerned by the **establishment of listings** that would serve as "novelty-defeating prior art"[1630]. Adding an obligation to screen prior art around the globe for patent offices, together with a mandatory acknowledgement of the source of the knowledge or just the material in question could in this regard facilitate the mechanism[1631], even though its feasibility raises suspicions in terms of administrative burden and realism in a field where plant varieties are the result of hundreds of material crosses. Numerous initiatives are in this context found in India, which has been quite active with regards to traditional knowledge, especially because of its ancestral medicinal knowledge. Amongst these are the village-wise Community Biodiversity Registers (CBRs) that document all knowledge, innovations and practices, coupled with People's Biodiversity Registers (PBRs) in different districts, or the Kalpavriksh:

> « The members of the *Beej Bachao Aaandolan*— (Save the Seeds) a network of local farmers, who have been involved for a number of years now in reviving and spreading indigenous crop diversity, actively collaborated with the *Kalpavriksh* members. By mutual agreement between *Kalpavriksh* and the villagers, it was decided that a copy of the register would be kept in the village and another copy would be kept by *Kalpavriksh*, and that all the information in the register can be used and distributed only with the consent and knowledge of the villagers »[1632].

Another prominent and very successful example relates to the infamous "Honey Bee Network", established in 1988 as a "database backed by scouts who develop, sustain and reward grassroots innovators, without diminishing the value that the invention has for the inventor"[1633]. The premises upon which the network operates go beyond a traditional knowledge log, since it also has built-in benefit-sharing considerations and protective approaches.

> "First, people must be given credit for whatever knowledge they share with the network; they should not become anonymous. Second, the shared knowledge should be used only

[1629] AUDIT, "Trade Related Intellectual Property Rights and Farmers' Rights : Appendix 7 to the Minutes of Evidence." quoting the newspaper "The Guardian" dated as of 15th September 1999.
[1630] GRAHAM DUTFIELD, "Legal and Economic Aspects of Traditional Knowledge," in *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime*, ed. KEITH MASKUS and JEROME H. REICHMAN, New York: Cambridge University Press, 2005.
[1631] CULLET, "Intellectual Property Rights and Food Security in the South," *op.cit.*, pp.275-276.
[1632] MANGALA HIRWADE and ANIL HIRWADE, "Traditional Knowledge Protection: An Indian Prospective," *DESIDOC Journal of Library & Information Technology* 32, no. 3, 2012. p.245.
[1633] ANIL K GUPTA, "From Sink to Source: The Honey Bee Network Documents Indigenous Knowledge and Innovations in India," *innovations* 1, no. 3, 2006., p. 50.

> after the inventor has given his or her Prior Informed Consent; inventors have a right to know what we do with their knowledge. Third, inventors should be able to dip into the network's shared knowledge through their own language; we should not require inventors to learn English in order to participate actively in the network. Finally, if we get any income, including a consultancy or award, through exchanging or disseminating the knowledge, some reasonable share of that income shouldgo back to the source"[1634].

Policy-makers have at times backed these initiatives. This has been the case of the Indian National Traditional Knowledge Library, which acts like a bridge between informal logs and patent examination offices. Active within the auspices of the Council of Scientific and Industrial Research, and overseen by multiple ministerial entities, it effectively translates local language in a format that is understandable and also very importantly searchable, for patent offices worldwide[1635].

Debating the disclosure of origin in IPR applications

Using the conventional means to challenge patents has only been one side of the defensive strategies drawn up by indigenous and farmers' communities' advocates. A number of commentators and biodiversity rich countries also consider that the rights and obligations that have been assigned to the PGRFA public domain by the CBD warrant the disclosure of the origin of genetic material in intellectual property rights applications. However, a major point of discord in this specific topic relates to the strength to be awarded to such disclosure requirement. Indeed, it is not really clear whether such disclosure should be considered as an additional procedural obligation within patent or PVP applications, or whether its compliance should be effectively verified before the grant of exclusive titles, or whether it should be viewed in isolation of all intellectual property requirements.

Most of currently applicable laws that have given room to the issue of "disclosure of origin" have approached it as an **optional requirement that is not linked to patentability as such,** especially in the "North". In this context, recital 27 of the EU Biotech Directive 98/44/EC seems to establish such a moderate yet very much present consideration for the indication of origin in biodiversity-related patent applications:

> *"Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents"* (EC Directive 98/44, recital 27).

The binding power of recitals is heavily debated in doctrinal thought, as some consider their authority rests in their reproduction as articles within the adopted text itself, and others consider them binding unless they are trumped by overrinding considerations that would disallow their

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1634 *Ibid*. p.51.

1635 Access to the Digital Library has been granted to the European Patent Office, the German Patent Office, the Indian Patent Office and the United States Patents and Trademarks Office (the agreement for which was signed in November 2009), seeHIRWADE and HIRWADE, "Traditional Knowledge Protection: An Indian Prospective," *op.cit.*, p. 246-7.

implementation[1636]. National implementations of this recital are also very varied. For instance, the first Belgian bill drafted to ensure compliance with the EU Biotech Directive required that inventions related to biological material or any biological material obtained by a technical process should comply with the precepts of the CBD, even though the second draft dropped the idea in order to avoid “discrepancies in the legislation of Member States”[1637]. The Belgian patent law’s article 15 now prescribes applicants to include a statement on the geographical origin of the biological material of plant or animal origin on the basis of which the invention was developed, if known, making it merely a formal prerequisite sanctioned by the non-admissibility of the application until such statement is introduced[1638].

However, from the point of view of non-governmental organisations actively defending farmers and indigenous people’s rights, such moderate approach to disclosure does not go far enough, and disregards the new public domain enshrined in international biodiversity conservation law. Analysing the 2004 proposal to amend Swiss patent law, the Berne Declaration went on to state that

> “The true objective of the article should be to **exclude from patent recognition** any invention that is based on genetic resources or traditional knowledge acquired illegally, i.e. in violation of the provisions of the Convention on Biodiversity. Under CBD rules access to genetic resources always requires prior informed consent and an agreement for the equitable distribution of benefits derived from such resources”[1639] (emphasis added).

Considerable amendments would be required in international, European and national patent and plant variety protection legislation in order to implement this approach. Indeed, it would de facto lead to the adoption of an additional patentability requirement, the contours of which would have to be drafted very carefully so as to comply with the minimum standards approach set out by the TRIPS Agreement. A number of proposals have nonetheless been put forward, such as requesting “for inventions based on biological or genetic resources under Art. 2 of the CBD or on materials of human origin: a written declaration by the owner/user of resources confirming his prior informed consent and the conclusion of an agreement for reasonable compensation”[1640]. The 2002 amendments operated on the Indian Patent Act mirror such comprehensive defensive mechanism triggered by disclosure requirements in filings. The country’s biodiversity law has indeed further constrained the grant of exclusive property rights, since any application “by whatever name called in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity

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1636 The former approach seems to stem from a ruling of the European Court of Justice (paragraph 54 of the European Court of Justice, Case C-162/97, Gunnar Nilsson, 19th November 1998, while the latter has been for instance advocated by Deryck BEYLEVELD, DERYCK BEYLEVELD, "Why Recital 26 of the Ec Directive on the Legal Protection of Biotechnological Inventions Should Be Implemented in National Law," *Intellectual Property Quarterly*, 2000.

1637 This move was suggested by the Council of State, which considered the sentence to be a clear addition from the text of the Directive, VAN OVERWALLE, "Implementation of the Biotechnology Directive in Belgium and Its after-Effects," *op.cit.,* p.891.

1638 *Ibid*., p.896.

1639 Berne Declaration, “Disclosure of Origin –The proposals at the national level in Switzerland”, 2004.

1640 This amendment would be operated on rule 26 of the Rules of Procedures regarding the European Patent Convention, FRITZ DOLDER, "*Biopiracy and Patent Law: Implementing the Rio Convention (Cbd) in National and European Patent Law*", Berne Declaration, Swissaid and Blauen-Institut, 2001.

Authority"[1641] shall be excluded from patentability. This is also the case in South Africa, where the 2005 amendments warrants the applicants to "lodge with the registrar a statement in the prescribed manner stating whether or not the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resources, or traditional knowledge [and further imposing] to furnish proof as to his or her title or authority to make use of the material"[1642].

The challenges of reconciling the two views, i.e. either seing disclosure as a mere declaration of source triggering civil liability proceedings under biodiversity legislation, or seeing disclosure as a means to ensure compliance within the IP systems themselves, triggering not only civil liability but also disallowing the grant of exclusive rights without proof of prior informed consent and mutually agreed terms, have profoundly tainted the ongoing debates before WIPO. Indeed, in the latest version of the draft articles on the **protection of traditional knowledge**, provisions regarding the scope of protection that are linked to origin disclosure are still in brackets, and reflect the general unease in balance-setting:

The first option for Article 3 reads: *[Member States]/[Contracting Parties]/[This instrument] [should]/[shall] confer(s) the following [exclusive] [collective] rights on the beneficiaries, as defined in Article 2: […]*

(d) [to be informed of access to their traditional knowledge through a disclosure mechanism in intellectual property applications;]

(d bis) [require the mandatory disclosure of the identity of the traditional knowledge holders and the country of origin, as well as evidence of compliance with prior informed consent and benefit sharing requirements, in accordance with the national law or requirements of the country of origin in the procedure for the granting of intellectual property rights involving the use of their traditional knowledge.]

While Option 2 more moderately reads: *[[Member States]/[Contracting Parties] should provide [adequate and effective] legal, policy or administrative measures, as appropriate [and in accordance with national law], to:*

(a) discourage the unauthorised disclosure, use or other uses of [secret] [protected] traditional knowledge;

(b) where [protected] traditional knowledge is knowingly used outside the traditional context:

(i) [acknowledge the source of traditional knowledge and attribute its beneficiaries/holders/owners where known unless they decide otherwise]; […]

[(c) facilitate the development of national traditional knowledge databases for the defensive protection of traditional knowledge;

(d) facilitate, as appropriate, the creation, exchange and dissemination of, and access to, databases of genetic resources and traditional knowledge associated with genetic resources;

(e) provide opposition measures that will allow third parties to dispute the validity of a patent by submitting prior art;

[1641] The Authority may through this process impose benefit-sharing obligations on the applicant, ANTHONY TAUBMAN, "Genetic Resources," in *Indigenous Heritage and Intellectual Property: Genetic Resources, Traditional Knowledge, and Folklore*, ed. SILKE VON LEWINSKI, Kluwer Law International, 2008., p.247.
[1642] *Ibid*., p.248.

Only time will tell which approach will finally prevail in international policy-making. It is however undeniable that a sound requirement for the disclosure of origin in IPR applications concerned with biological material or any biodiversity-related invention may contribute to defensively protect the fruits of mass selection efforts all around the world. Just as much as stricter stances on prior art and novelty, ideally backed by searchable and complete traditional knowledge and landrace registrars that could also double up as informational or technology exchange clearing-houses. The onus of farmers' contribution to the conservation of biodiversity, coupled with the need to compensate for such contribution, has greatly flourished on account of the new boundaries of the PGRFA public domain carved by international biodiversity law. However, its relation with applicable exclusive IPR appropriation systems remains shaky and challenging, disallowing the efficiency of the defensive protection means against misappropriation. The adjusments proposed by farmers' organisations or policy-makers indeed merely transcribe a growing propensity to protect what essentially covers a body of environmental knowledge held by indigenous communities through for instance listings that would serve as "novelty-defeating prior art"[1643]. Indeed, farmers' knowledge cannot ever or extremely seldomly qualify as "state-of-the art" knowledge that opens the way to exclusive rights, thereby considerably devaluating local people's innovations[1644]. The inherent shortcomings of such defensive stance, notwithstanding the lack of consensus amongst its possible reach, thus call for more pro-active actions.

14.3.2. <u>Protecting Traditional Knowledge</u>

Carving out protection rules in the form of "*sui generis* IPR style compensation rights" for the discovery of wild genetic material can effectively create the economic incentive needed for the preservation of the resources' natural habitats, and also remedy the biopiracy and misappropriation concerns raised over the subsequent use of genetic resources by third parties without compensation[1645]. This option, when accompanied by a necessary rethinking of seed certification mechanisms, would effectively ensure the survival of the specific socio-technological context that is mass selection. In this context, the link that is maintained between traditional knowledge and the actions of mass selectors is anchored on an understanding of the former not solely as "age-old knowledge, where creativity and innovation are generally lacking, [but rather as] knowledge held and generated within 'traditional' societies", inevitably adapting to the needs of new generations[1646]. This approach does not emphasise the "antique" nature of knowledge, but rather the way in which it is acquired and used, building on "the social process of learning and sharing knowledge"[1647]. Considering the inherently collective, informal, and also unproprietary nature of the knowledge developed by farming communities on environmental and agricultural aspects of plant varieties and ecosystems, it is quite difficult to find adequate room for its positive protection against misappropriation under a dominant exclusivity oriented property paradigm. While certain authors and policy-makers have tried to provide adequate room in existing IPR titles, other have tried to design new mechanisms to the same end.

[1643] DUTFIELD, "Legal and Economic Aspects of Traditional Knowledge," *op.cit.*
[1644] CULLET, "Property-Rights Regimes over Biological Resources," *op.cit.*, p.659.
[1645] ROSE, "International Regimes for the Conservation and Control of Plant Genetic Resources," *op.cit.*, p.185.
[1646] DUTFIELD, *Intellectual Property, Biogenetic Resources and Traditional Knowledge*, *op.cit.*, pp.94-95.
[1647] RUSSEL LAWRENCE BARSH, "Indigenous Knowledge and Biodiversity," in *Cultural and Spiritual Values of Biodiversity*, ed. DARRELL A. POSEY, UNEP, 1999., p.73.

The traditional IPR route

Focusing either on the "collective community"[1648], or the "traditional"[1649] aspect of protection mechanisms, or on an extension of "farmers' rights" into a protective tool[1650], law-makers need to considerably alter the thresholds that we are accustomed to seeing in informational protection tools if the IPR route is taken to positively protect landraces and associated traditional knowledge. Indeed, initial protection requirements, as well as the scope, nature and extent of the rights awarded and the management of these prerogatives by appropriate institutions, all need to be suited to accommodate traditional agricultural knowledge and farming systems[1651]. These *sui generis* regimes, which can legitimately be argued for under the TRIPS Agreement, provided they are "effective" when covering plant varieties, have not yet been developed a great deal by countries. Besides the inherent need for regulatory construction and policy-making capacity, this setback also plays on account of the conservatism pushed by the existence of the non-contentious UPOV system and the lack of reward for regulatory innovation in this field, the so-called "chilling effect" infusing status quo on potential collective rights[1652].

When taking the protection route of existing IPR-based protection mechanisms, one of the options held by farmers' communities consists of **relaxing the DUS requirements** in seed certification legislation and in the UPOV system to allow for landrace protection and use. The International Law Association Committee on the International Law on Biotechnology in this regard suggests the creation of mechanisms facilitating access to international or national biological material collections for smallholders, and also "examining whether the UPOV system should be partly adapted and relaxed to allow protection of improved farmers' varieties that result from controlled on-farm breeding processes"[1653]. The recognition of biodiversity-related collective intellectual property rights in the hands of local communities has been pushed forward within the Indian legal order, through a system where property rights are granted on landraces yet shared with governmental authorities in an attempt to fill the gap in perception and ensure greater compliance[1654]. The 2001 Indian Act on the protection of plant varieties and farmers' rights not only requires the declaration of origin of the variety accompanied by pedigree details, but also provides for rewards for the contribution of farmers to the development of improved varieties by allowing for PVP protection for farmers' varieties. The 2001 Indian PVP Statute, allowing for the protection of farmers' varieties in the first place, does in parallel also consider the situation where

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[1648] M. LEISTNER, "Traditional Knowledge," in *Indigenous Heritage and Intellectual Property*, ed. S. VON LEWINSKI, The Hague: Kluwer, 2004, pp.52-144.

[1649] THOMAS COTTIER and M. PANIZZON, "Legal Perspectives on Traditional Knowledge," *Journal of International Economic Law* 2, 2004: pp.371-399.

[1650] CULLET, "Intellectual Property Rights and Food Security in the South," *op.cit.*, pp.281-282., using examples from legislation adopted in Thailand and Panama.

[1651] Ibid., For instance, emphasis has been put on the non-exclusive nature of these rights, the lack of temporal limitations, the communal nature of innovation, with a possible limit in actors for those small-scale farmers or the possible vesting of property rights to legal entities (democratically elected local bodies have been suggested in India).

[1652] CULLET, "Intellectual Property Rights and Food Security in the South," *op.cit.*, p.274.

[1653] INTERNATIONAL LAW ASSOCIATION ILA, COMMITTEE ON INTERNATIONAL LAW AND BIOTECHNOLOGY, "*Final Draft Report of the Hague Conference and Draft Recommendations*", available at http://www.ila-hq.org/en/committees/index.cfm/cid/1016 2010.

[1654] CULLET, "Revision of the Trips Agreement Concerning the Protection of Plant Varieties: Lessons from India Concerning the Development of a Sui Generis System " *op.cit.*

an EDV would be derived from such a landrace, and triggers benefit-sharing obligations with non-governmental organisations or individuals acting on behalf of a village or local community[1655].

There have been other attempts to protect traditional knowledge within existing IPR titles. Trying to adapt patents to farmers' innovations has been slightly precarious. Nevertheless, commentators have argued that **"second-tier" or "petty" patents** may serve a parallel purpose in protecting innovations stemming from informal communities[1656]. Designed as early as the 19th century to address inventions that would not qualify for the strict boundaries of patent monopoly, as another case of legal hybrid, they reward "technical proficiency" but not the idea or process behind[1657]. Through its relaxed approach to the inventive step criteria, petty patents may recognise the worth in seeing a local variety protected, allowing "a given farmer or farmers to acquire a measure of control over follow-up innovations derived from their variety"[1658]. Other initiatives have also attempted to bring farmers' innovations within the realm of intellectual property rights. Amongst these lies the infamous case of the Basmati rice, where the landrace originating from Northern India and Pakistan, is actively trying to be protected under Indian national legislation on geographical indications[1659]. However, geographical indications remain protection titles that are closely linked to quality and marketing policies. As a result, they grant protection solely against denominations that unduly use the indication. They do not in any means protect rightholders against the infusion of the genetic resources or knowledge in a research programme without compensation. Other proposals have a result tried to adapt the worlds of trademarks and geographical indications to biodiversity innovation, through for instance an alternative indigenous 'biocultural heritage indication' (BCHI)[1660]. But this approach is also limited to the use of names as such, and not knowledge attached to the biological material.

Furthermore, actors active in grassroots innovation have advocated more wide-scoped **institutional solutions** that would complement whichever protection mechanism is finally adopted at the international or national level. Indeed, just as much as public researchers and private plant breeders, mass selectors would benefit from information but also technology-exchange clearing-houses. In this context,

> "SRISTI, the institutionalised extension of the Honey Bee Network, has evolved into a very forceful voice to protect the intellectual property rights of both individuals and communities. SRISTI has discussed many policy reform proposals at meetings of the World Intellectual Property Organization, and has campaigned for an International Network for Sustainable Technological Applications and Registration (INSTAR). Such a

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[1655] DHAR, *op.cit.*, 2002.

[1656] SUSETTE BIBER-KLEMM, THOMAS COTTIER, and DANUTA BERGLAS, *Rights to Plant Genetic Resources and Traditional Knowledge: Basic Issues and Perspectives* Oxfordshire: CAB International, 2006., p. 246.

[1657] REICHMAN, "Legal Hybrids between the Patent and Copyright Paradigms," *op.cit.*

[1658] BIBER-KLEMM, COTTIER, and BERGLAS, *Rights to Plant Genetic Resources and Traditional Knowledge: Basic Issues and Perspectives*, *op.cit.*, pp.246-247.

[1659] This case infamously led to discussions during the 2003 WTO Ministerial Meeting following the challenge of patents awarded to RiceTec in the United States, showing the intricacies of TRIPS standards with regards to geographical indications, HARSH V CHANDOLA, "Basmati Rice: Geographical Indication or Mis-Indication," *The Journal of World Intellectual Property* 9, no. 2, 2006.

[1660] The indication draws in from geographical indications, design rights and unfair competition law as well, see ALEJANDRO ARGUMEDO and MICHEL PIMBERT, *Protecting Indigenous Knowledge against Biopiracy in the Andes*: IIED, 2006.

registry has yet to evolve. If implemented, however, this registry would allow people in one part of the world to learn from creative people in another part and would provide a low-cost clearinghouse for connecting innovations with investment and entrepreneurial support"[1661].

It should nonetheless be mentioned that grassroots innovations that are repertoried within the HoneyBee Network are mainly attributed to and claimed by individuals, which makes them more eligible or closer to patent protection[1662]. An element that is far too rarely present in the majority of activities involved in the development or maintenance of environmental and agricultural knowledge linked to biodiversity.

Amending principles related to protectable subject matter in the strong property paradigm would imply **far-reaching changes in rationale and attitude**, notably because of the inherently variable, non-uniform and collective nature of farmers' varieties[1663]. Indeed, the subject matter requirements of the existing strong-IPR approach relate to new and clearly distinguishable plant varieties, and thus "often cannot accommodate the contributions of individual farmers using more informal methods to select for better crops or sought-after plant characteristics"[1664]. Furthermore, even though the contribution of farmers' varieties to the development of improved varieties by both public and private institutions is recognised, it remains extremely modest and is difficult to quantify. Indeed, science-based breeding does put the emphasis on crosses operated amongst elite cultivars, with known market successes, and advanced lines developed by public institutions[1665]. On the contrary, local cultivars are "in some ways always a work in progress, [which] include incremental contributions of group participants who are not easily defined as individuals"[1666]. The difficulty to allocate with exactitude a person's or even a community's contribution to the development of a farmers' variety is the greatest challenge when attempting to design appropriation mechanisms to foster such development. The identification of appropriate communities or individuals that would raise proprietary claims remains tainted by "heroic assumptions" as to the feasibility of such endeavour, in light of the large and dispersed areas of production and development of traditional varieties[1667]. Besides, as farmers' varieties remain inherently local products that are highly unlikely to be commercialised even in neighboring countries or regions (unless the variety presents an extremely specific resistance that might save the day faced with unprecedented biotic or abiotic stresses like diseases), the IP realm might not be an adequate forum to address the issue of farmers' innovation. In this context, "even the seemingly positive benefits of granting intellectual property rights to local communities may lead to unintended consequences", not only with regards to the difficulties of assigning property rights to individuals or user groups, but also due to the fact that failed recognition of rights in too formal

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[1661] GUPTA GUPTA, "From Sink to Source: The Honey Bee Network Documents Indigenous Knowledge and Innovations in India," *op.cit.*, p. 61.
[1662] DUTFIELD, *Intellectual Property, Biogenetic Resources and Traditional Knowledge*, *op.cit.*, p.104.
[1663] CARLOS CORREA, "The Access Regime and the Implementation of the Fao International Treaty on Plant Genetic Resources for Food and Agriculture in the Andean Group Countries," *The Journal of World Intellectual Property* 6, no. 6, 2003.
[1664] HELFER, "Intellectual Property Rights in Plant Varieties: An Overview with Options for National Governments."
[1665] WRIGHT, "Intellectual Property and Farmers' Rights," *op.cit.*
[1666] ROSE, "Several Futures of Property: Of Cyberspace and Folk Tales, Emission Trades and Ecosystems," *op.cit.*, p.31
[1667] C.S. SRINIVASAN, "Exploring the Feasibility of Farmers' Rights," *Development Policy Review* 21, no. 4, 2003: p.426.

environments may facilitate the appropriation of exclusivity by external actors at the end of the day[1668]. Furthermore, the aforementioned FAO Treaty's recognition of "farmers' rights", to be viewed as a "retrospective equity" rather than economic incentive[1669], would, if translated into an intellectual proprietary perspective, not generate all expected socially desirable returns. Indeed, it has been argued that stringent requirements on consent to use farmers' varieties and compensate through licensing arrangements might very well adversely affect the development of new varieties by breeders[1670]. Not only would their returns be reduced, but they would also face restrictions on access to genetic material without the breeders' exception included in PVP laws and patent legislation, when applicable.

<u>Alternative protection? Registrars, Liability regimes amd Institutional solutions</u>

In an attempt to responds to the inadequacies of exclusive or strong IP tools to protect the fruits of farmers' innovation, other more collective minded tools have been put forward by different commentators and countries[1671]. Both in legal and realistic terms, advocates have voiced preference for environmental measures or rural development programs encompassing a plant diversity conservation and improvement angle[1672]. However, these solutions do not address the property regime of landraces and do not as a result bow down the challenge of misappropriation. That is why a number of alternative regimes, mostly in the form of **liability rules**, have been drawn up. These solutions build on the premise that the design of reciprocal liability rules might prove really effective in providing compensation to selectors in case their varieties are used in commercial breeding programs and subsequently marketed. This solution has been advocated for by numerous scholars[1673], as it provides an efficient trade-off between the recognition of entitlement to mass selectors, and the continued conservation, use and exchange of agrobiodiversity in the inherently cumulative and interdependent realm of plant improvement.

In this context, the aforementioned solution in seed marketing legislation, i.e. the constitution of a "light registry for farmers' varieties", could be used as a starting point of a minimalist liability rules regime. **Landrace registrars** may either bear a declarative nature, close to the aforementioned defensive protection mechanisms, or possess a "constitutive" nature, which attaches a number of exclusive rights to the registration process[1674]. The registry option could as a result provide not only a protection against misuse through official entitlement, but also may provide for a modest royalty rate to be forfeited by variety borrowers[1675], similar to the "equitable remuneration" perceived by patent or PVP right holders on farm-saved-seed. Taking due account

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[1668] EYZAGUİRRE and DENNİS, "The Impacts of Collective Action and Property Rights on Plant Genetic Resources," *op.cit.*, p.1496.
[1669] STEPHEN BRUSH, "Providing Farmers' Rights through in Situ Conservation of Crop Genetic Resources", ," ed. FAO COMMISSION ON PLANT GENETIC RESOURCES (Rome1994).
[1670] SRINIVASAN, "Exploring the Feasibility of Farmers' Rights," *op.cit.*, pp.444-445.
[1671] VAN OVERWALLE, "Protecting and Sharing Biodiversity and Traditional Knowledge: Holder and User Tools," *op.cit.*, p.595.
[1672] GROUP, *People, Plants and Patents: The Impact of Intellectual Property on Biodiversiy, Conservation, Trade and Rural Society*, *op.cit.*
[1673] See notably PETRA EBERMANN, *Patents as Protection of Traditional Medical Knowledge* European Studies in Law and Economics Series: Intersentia, 2012.; REICHMAN and LEWIS, "Using Liability Rules to Stimulate Local Innovation in Developing Countries: Application to Traditional Knowledge," *op.cit.*
[1674] ARGUMEDO and PIMBERT, *Protecting Indigenous Knowledge against Biopiracy in the Andes*, *op.cit.*, p.6.
[1675] REICHMAN, "Legal Hybrids between the Patent and Copyright Paradigms," *op.cit.*; and also "Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation," *op.cit.*

of national or regional stages of rural and economic development, liability rules may effectively counter the trend to limit mass selectors' activities to the realm of exceptions, reducing farmer's privileges to a "basic trickle of rights"[1676]. Farmers' communities may benefit from the establishment of a parallel regime for local varieties either in the form of a book log or a flexible national or regional register of *in situ* conservation of uncertified seed that could trigger a double-tier liability regime. If a parallel *ad hoc* protection regime for uncertified farmer seeds is privileged, special attention should be given to its contours, especially with regard to equity but also feasibility concerns, not undermining conservation or innovation along the plant improvement pipeline. Indeed, protection should only concern varieties in themselves, and not extend to their genotype, as it should allow for the acknowledgement of the efforts lying behind mass selection, that are often collective, while also reflecting on the adequacy of the "exclusivity" approach within such communities, where open licensing and remuneration systems might prove better-fitted[1677]. Indeed, regulators should take notice that the allocation of exclusion rights to mass selectors refutes the rationale upon which this rather unique partially open innovation system is built.

If such a compensatory liability regime is to be envisaged, this option would however also need to contemplate the tricky issues of designating the rightful interlocutor, addressing whether similarity or "substantial difference" thresholds should be established in the assessment of follow-on innovation, and whether litigation could be avoided through mediation mechanisms. It would also need to address whether compensation should be integrated into institutional frameworks such as participatory plant breeding schemes where contractual reward for subsequent commercial use could be envisaged at the start of the project. Parallel solutions for compensation, especially in the form of lump sum payment negotiations for contributions of traditional agricultural knowledge could in this regard be sought, as was the case for the contribution of a traditional rice variety identified and conserved in Mali, which was later developed into a uniform cultivar by IRRI, which contained a patented resistance gene[1678]. The compensatory angle of such reward regime might require an in-depth analysis of synergies with benefit-sharing obligations deriving mostly from international environmental but also agricultural legal instruments. In any case, this double-tier liability regime would warrant the creation of a supranational organisation for collective rights' interested in the use of the final product, monitoring the use of landraces and associated knowledge, such as (or within the auspices of) the Plant Variety or Seed Certification Offices that exist today.

The participatory plant breeding approach also has, or could easily have, the benefit of **apportioning clearer property rights** in seed exchange and conservation initiatives. Indeed, those involved in mass selection rarely address issues of ownership, as they remain bound by the informal rules that surround exchange practices. As the aforementioned example of the Seed Savers Exchange and its black box deposit with links to the International Treaty shows, they might also be very averse in playing the rules of the game that is still felt as being dictated by the strong

[1676] CULLET, "Revision of the Trips Agreement Concerning the Protection of Plant Varieties: Lessons from India Concerning the Development of a Sui Generis System " *op.cit.*

[1677] CARLOS CORREA, "*Options for the Implementation of Farmers' Rights at the National Level, Trade Related Agenda, Development and Equity*", Geneva 2000.

[1678] BLAKENEY, *Intellectual Property Rights and Food Security*, *op.cit.*, p.141.; recalling the establishment of the International Fund for Plant Genetic Resources at the UC Davis, who had patented the Xa21 resistance gene. The lump sum payments reached 52.000 USD for the first company and 30.000 USD for the second.

IP paradigm. While this non-exclusive and elusive approach is commendable and inherent to all mass selection efforts, including those enscribed in low-input or organic marketing prospects, its also prevents selectors from maintaining associated knowledge and resources within the protected public domain that is built through property rights. Participatory plant breeding may serve in this context as a cooperative means to build adequate boundaries against the misappropriation of mass selection efforts, just as it has been viewed as an efficient prospect to build different PGRFA commons that reclaim a wider yet still adequately fenced public domain. Indeed, a number of commentators have referred to participatory plant breeding as a future "BioLinux"[1679].

> "A biolinux model will also be based on the logic that farmers are both users and innovators of technology, coupled with the idea of Copyleft. A biolinux model can be applied for the development of plant varieties, agro machinery and sharing of information and knowledge. A biolinux model for a new variety developed using participatory plant breeding will be as follows. The variety will be made available with a GPL or a similar document explicitly stating rights and claims. The varieties will be in the public domain or covered under plant breeders' rights without restricting the rights of others to experiment, innovate, share the seeds or exchange seeds. There will be no restriction on using this to develop new varieties or to experiment with but it is essential that the variety derived from this should also be available without any monopolistic claims and restrictions on further development.
>
> Implementing such an idea can be done in many ways. There can be an agency, which can coordinate such activities and act as an agency for bringing together breeders and farmers and for guiding farmers on aspects related to IPRs. There could be a common pool to which farmers can contribute and from which they can ask for samples; and this common pool of germ plasm can also exchange materials with others under Material Transfer Agreements (MTAs). There can be crop specific agencies which collect information, support innovations and provide support to breeders and farmers working in participatory plant breeding"[1680].

In this context, the exchanges of material within the community would be done through a **standardised material transfer agreement**, which, much like the aforementioned attempts to create open-source biotechnology spaces, could operate under terms similar to those of the Free Software Foundation's Global Public License. Jack KLOPPENBURG argues for a mechanism building on the background of participatory plant breeding, where material from the germplasm

[1679] J. HOPE, *Biobazaar: The Open Source Revolution and Biotechnology* Cambridge: Harvard University Press, 2008.; SRINIVAS, "Intellectual Property Rights and Bio-Commons: Open Source and Beyond," *op.cit.*; GEERTRUI VAN OVERWALLE, *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Regimes* Cambridge: Cambridge University Press, 2009.; KRATTIGER, "Financing the Bioindustry and Facilitating Biotechnology Transfer," *op.cit*; VAN ZIMMEREN, "Clearinghouse Mechanisms in Genetic Diagnostics. Conceptual Framework," *op.cit.*

[1680] VAN OVERWALLE, *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Regimes*, *op.cit.*, p. 325.

pool would be transferred according to the terms of a standardised material transfer agreement, the "General Public License for Plant Germplasm" (GPLPG)[1681]:

> "To paraphrase the "four freedoms" specified by the Free Software Foundation, the GPLPG establishes a legal framework within which farmers can maintain:
>
> 1. The freedom to grow the seed, for any purpose.
> 2. The freedom to study how the seed works, and adapt it to their needs.
> 3. The freedom to redistribute the seed so they can help their neighbors.
> 4. The freedom to improve the seed, and release improvements to the public, so that the whole community benefits.
>
> The flip side of these freedoms is responsibility (and under the GPLPG, the obligation) to grant others within the collectivity the same freedoms; no one is entitled to impose purposes on others or to restrict the range of uses to which seed might be put. In the face of increasing restrictions on their degrees of freedom to access and use seed – patents, PBRs [plant breeders' rights]– application of the GPLPG offers a means for farmers to create a semi-autonomous, legally secured, "protected commons" in which they can once again work collectively to express the inventiveness that has historically so enriched the agronomic gene pool"[1682].

To this day, no such far-reaching and open source participatory plant-breeding project has been initiatied to the author's knowledge. Nonetheless, associations such as MASIPAG, "Farmer-Scientist Partnership for Development, Inc", established in 1985 in the Philippines, have advocated this solution[1683], and at times been viewed as the potential fora to try to create "Landrace Commons". Comparing farmers' active within the organisation to that of "hackers", Boru DOUTHWAITE writes:

> "Some farmers are seed "hackers." Although their source code-the DNA coding-is closed to them, nature itself or human intervention generates new "hacks" by crosses and mutation, and farmers select hacks that they judge beneficial. The tantalising prospect opens up that [participatory plant breeding] might be able to capture the power of the "bazaar" development model in the same way that the open-source software movement has"[1684].

What is undoubtedly sure is that "the protected commons might seem attractive in some abstract future, but there is a severe threshold constraint to be overcome. A functional protected

[1681] Jack KLOPPENBURG borrows the term from a proposal made by Tom Michaels in 1999; BENNETT and BOETTIGER, "Case 5. The Public Intellectual Property Resource for Agriculture (Pipra). A Standard License Public Sector Clearinghouse for Agricultural Ip," *op.cit.*; see p. 16.
[1682] Ibid., p.19.
[1683] MASIPAG stands for "Siyentipiko Para Sa Pag-unladng Agrikultura", see KRATTIGER, "Financing the Bioindustry and Facilitating Biotechnology Transfer," *op.cit.*, p. 2301.
[1684] DOUTHWAITE, "Enabling Innovation," *op.cit.*, pp.206-207.

> commons capable of innovative and fecund production requires a significant population of participants and a stock of quality material on which to work"[1685].

Furthermore, as plant-related information is less easily codifiable than source code, it needs to rely on an established communications and information platform before seeing the light of day. It also more problematically needs a mechanism of "quality control" and dispute resolution mechanisms between various contributors and follow-on users[1686]. It is nonetheless just as evident that the development and support of participatory plant breeding is an immense step towards a major adjustment that would both recognise the contributions of mass selectors to overarching goals of conservation and sustainable use of agrobiodiversity, while also disallowing the misappropriation of landraces, associated genetic resources and knowledge by other actors, whether corporate or public. This major adjustment has the great advantage of remaining within the lines of the strong property paradigm, creating a "protected public domain oriented commons" possibly through a standard material transfer agreement, but it nonetheless supposes that enough flexibility is granted within such paradigm to allow for informal seed exchange to operate. Indeed, if practices embedded within participatory plant breeding or other institutional approaches are considered illegal, these solutions will be doomed to fail from their inception.

The outlines of protection regimes for mass selection and landrace revival networks should be assessed in general terms but also with due regard to national specificities, in order to safeguard centuries-long seed-saving and exchange practices, distancing oneself from the reductionist perception that farmers merely cultivate biodiversity developed off-farm by breeders. National regulatory frameworks should in all accounts consider innovation stemming from mass selection as a parallel yet different (and not necessarily derogatory), seed-production scheme, raising different predicaments than dominant vertically integrated molecular plant breeding, and requiring incentives within a dual *sui generis* system for both modern and farmers' varieties.

CONCLUSIONS. Possible adjustments for actors involved in mass selection

Seed exchange networks, both in their traditional and more modern forms, in developing and developed countries alike, clearly act in a common-property approach to the intangible world of genetic resources. They act in the clear absence of individualised or exclusive control over these resources and the information contained therein, but fence and control their diffusion through informal norms of conservation and exchange. Their informal regulation mechanisms, embedded in emerging practices and coping strategies, embrace, support and validate international sustainability and environmental justice norms alongside (and at times against) the rigid formal seed markets that unequivocally exclude them. While sustainability aspects are unanimously found in all small-scale farming or gardening coalitions, emphasis may be pointed either on the conservation of genetic resources (especially in the seed saver, gardener or organic farmer model), or on their use (chiefly in subsistence farmers' informal networks and local seed markets). Farmers are also increasingly pushed to fight against misappropriation, praising by this means options to protect their traditional knowledge but also the genetic resources and landraces they conserve and

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[1685] BENNETT and BOETTIGER, "Case 5. The Public Intellectual Property Resource for Agriculture (Pipra). A Standard License Public Sector Clearinghouse for Agricultural Ip," *op.cit.*, p. 25.
[1686] KRATTIGER, "Financing the Bioindustry and Facilitating Biotechnology Transfer," *op.cit.*, p. 2305.

develop. Throughout their struggles, they also strive to maintain their practices within the new boundaries of lawfulness. Within the more general framework of successful agrobiodiversity use, local small-scale innovation and production stemming from mass selection endeavours comes across as a necessity, in as much so as improved varieties stemming from plant breeding efforts. The regulatory framework should therefore reward innovation stemming from mass selection, as a parallel but different seed production scheme, raising different predicaments than the dominant vertically integrated molecular breeding innovators.

Legislative action is absolutely needed to redress the suffocation of informal seed exchanges by restrictive compulsory seed legislation, and to a lesser extent also intellectual property laws. This necessity is quite a departure from the adjusments that have been identified for other actors of plant improvement, as it warrants clear and unescapable intervention from policy-makers. Self-regulation cannot indeed suffice to replace legislative interference, which is a challenge that preoccupies mass selection more warily than other agrobiodiversity innovation actors. With regards to the impediments created on the actions of mass selectors by intellectual property rights, most can be addressed through the recognition of the so-called farmers' privilege in both plant variety and patent protection, as is the case of the European Union. In the absence of such privilege, farmers' ability to re-sow protected varieties or build on them will be significantly weakened by extensive scopes of protection reaching to harvested material and circumventing exhaustion.

Some very welcomed interactions can nonetheless be identified within adjusments that attempt to redress forced illegality or misappropriation issues. For instance, a legal order that stays within the realms of compulsory certification so as to correct the inherent informational assymetries inherent to seed trade, can adjust its rules either by infusing a number of flexibilities or express derogations for informal seed exchange and even commercialisation, or by creating a parallel yet looser registrar not only for old conservation varieties but also new landraces. This log can afterwards be used so as to recognise the innovative contributions by mass selectors, within a liability rules scheme warranting compensation (or other kinds of benefit-sharing) if used by third parties in a research and development programme. This potential opportunity would nonetheless be lost if the issue of forced legality is merely addressed by voluntary marketing and labelling.

Furthermore, the recognition of farmers' contribution to agrobiodiversity-related knowledge and to the maintenance and development of genetic resources can also be achieved through alternative means. First, through the defensive stance of challenging patent applications for lack of novelty and prior art, either directly before patent and PVP offices or indirectly by the establishment of knowledge listings. Secondly, through the positive protection of 'traditional knowledge', either through relaxed and possibly more collective-minded intellectual property rights titles, or through flexible liability rules, possibly backed by institutions such as participatory plant breeding.

TRENDS	SHORTCOMINGS	SOCIAL INNOVATION, EMERGING PRACTICES and COPING STRATEGIES	
		Self-regulation	**Beyond self-regulation**
Restrictive seed legislation	Status as actors of plant improvement	Redefine networks in a conservation and sustainable use context (access and conservation through cooperative exchange programmes)	Rural development policies – Reputational index
	Illegality of activities	Voluntary seed certification – truth marketing Outside of formal seed market	Clear permissive stance in compulsory seed certification schemes: either through complete exceptions, derogations, or dual catalogue approaches
IPR proliferation / extension	Shrinking and nebulous farmers' privilege		Sui generis PVP protection outside UPOV - CoFab Farmers' privilege in PVP and in patent legislation If royalty collection, not for selection, small-scale subsistence and legal certainty
	Fate of harvested material		Farmers' privilege in PVP and in patent legislation
Exclusive individual rights	Misappropriation of TK (Defensive)	Challenging patents for lack of novelty Establishing Traditional Knowledge Logs Information/Technology Exchange Clearing Houses	Strict prior art assessment in patent applications, reference to TK registrars in rules of procedures Support for registrars – official status
	Lack of protection of landraces and TK (protective)	Participatory plant breeding with clearly apportioned property policy - Entry point of open-source plant germplasm movement and development	Relaxed IPR titles, either PVP, petty patents or geographical indication Double-tier liability regime, possibly based on landrace registry or other variety/knowledge log

FIG.8: Adjustments responding to the shortcomings faced by mass selectors confronted to the strong PGRFA property paradigm

PART V CONCLUSIONS. Adjustments to the strong property paradigm building on its flexibilities exploited through social innovation

Numerous adjustments have been presented for the different needs of the different actors of plant improvement. The flexibilities that directly stem from the content of the strong property paradigm typically ask for greater regulatory intervention, requiring most of the time direct legislative amendments or other types of interventions from public authorities. They are entrenched in national legislative texts but nonetheless complexify the rules that govern agrobiodiversity management. Given the wide array of plant improvement actors and the major differences that separate their approaches to innovation, there are a number of **evident but also indirect conflicts** between the adjusments they have advocated. These problematic areas will have to be carefully studied and assessed by policy-makers and self-regulators, so as to allow them to make adequate choices responding to local, national or regional needs for economic development, social welfare and environmental conservation, in accordance with their own political priorities.

Maintaining the **farmers' privilege** in plant variety protection laws and infusing it within patent laws is essential to avoid the prosecution of mass selectors. However, if the privilege extends to far, it might impede the **promotion of private plant breeding**, since it may seriously reduce the promise of royalty collection that acts as the main incentive to protect plant varieties. That is why it is absolutely necessary to assess whether a liberticide approach to the farmers' privilege will really foster farmers' innovation, or whether it will act as recognition of customary and international principles of farm seed saving, supporting broader socio-economic, rather than purely innovation-related issues. In light of such assessment, it is essential for the balancing role of IPR regulation, to complement the privilege with moderate royalty payments, when faced with the latter diagnosis as to the purpose of the farmers' privilege. In this context, negotiation-based collection institutions with fixed rates and complete transparency will support both the needs of smaller-scaled private plant breeders without flocks of lawyers, and also the wishes of farmers who replant protected seeds. Agreements between breeders and farmers organisations should nonetheless provision the payment of royalty to the effective sale of re-sown protected varieties, since the replanting should fall under the breeders' exception if perpetrated solely for selection or conservation purposes.

Even though **liability rules** embedded in the researchers', breeders', or farmers' exceptions aim at clarifying the range of authorised uses by third parties, they may also ignite legal conflicts where those entities with greater legal stamina will likely be privileged. Disputes concerning the exact reach of prerogatives awarded to rights-holders are extremely likely to arise, questioning the ability of an untrained judiciary to settle complex rows.

Conflicts between the need to **protect landraces** and associated traditional knowledge from misappropriation with a protective rather than defensive tactic may considerably restrict the PGRFA public domain that is essential for the conservation and sustainable use of agrobiodiversity. The protection regime carved in this context ought to provide as much diffusion rules as the patent and plant variety paradigms, and cannot be sustained on a solely sovereignty-oriented perspective. **Public researchers and private plant breeders** must continue to have equitable access to those farmer varieties, as much as they have for improved germplasm.

But the picture we have drawn of plant improvement regulation is abolsutely not all gloomy. **Synergies** indeed also exist within the diverse range of adjustments advocated by social actors of agrobiodiversity innovation, either in their own sphere of action, or even better, vis-à-vis other plant improvement actors. These synergies could therefore constitute priorities of action for policy-makers and self-regulators, so as to allow positive strokes to ensure the conservation, sustainable use and equitable improvement of agrobiodiversity. A number of solutions and adjustments can be used to **address several shortcomings that are experienced by a specific category of actors:**

Quite straightforwardly, **public researchers** may benefit doubly from less lenient patentability requirements, as such move would not only address the impediments arising from the enclosure of cumulative innovation (addressing anti-commons issues), it would also soothe the risks of misappropriation of public and traditional knowledge. In the same vein, compulsory or standardised licensing schemes may ease the need to reclaim the public goods dimension of public research, all the while providing a means to offset aggressive licensing practices that characterise the strong property paradigm.

With regards to **plant breeders**, the quintessential adjustment needed remains a viably clear and efficient breeders' exception, in both plant variety and patent protection, as this would address the many impediments felt by private breeders on account of aggressive licensing practices, all the while soothing the tensions linked to the misappropriation of public and traditional knowledge.

Notwithstanding the delicate conflicting balance that stems from the recognition of the farmers' privilege, this tool remains nonetheless an exemplary solution for **mass selectors** faced with growing IP titles. These actors fortunately also benefit from less controversial and "doubly beneficial" adjustments. Derogatory landrace and low-input plant variety registrars with relaxed requirements and few administrative burdens may indeed not only remove mass selectors from the dangerous realm of illegality, eliminating the Damocles sword threatening their existence, they may help them fight misappropriation. Within a well-articulated liability rules system, these registrars may also serve as a starting point to recognise and compensate both conservation and improvement efforts made by mass selectors, and upon which plant breeders have relied on, even if to a lesser degree than improved germplasm, easier to manipulate and acquire. They may also be used by PVP and patent offices to establish prior art and common knowledge in applications, effectively contributing to raising the bar of quality in awarded exclusive titles. Legal certainty over the possibility to use landraces will not only comply with the new PGRFA public domain enshrined in international biodiversity law, it will also address the shortcomings of the strong property paradigm itself, disregarding completely a whole range of plant improvement actors.

More ambitiously, a number of **adjustments may not only benefit one, but two, and even all three of agrobiodiversity innovation actors** that have been left partially or completely outside of the strong property paradigm.

For instance, the strict interpretations of patentability requirements, including wide prior art searches for molecular research tools, especially enabling technologies and nucleotide sequences, will not only benefit **public researchers** active in molecular biology or plant breeding, but also **private plant breeders**. Indeed, most of the adjusments targeting the anti-commons created by the proliferation of patents and the aggressive licensing practices that accompany them will benefit both of these actors. The creation of information clearing-houses falls within such win-win scenario, as would a technology exchange clearing-house that would manage to draft a common licensing or material transfer agreement with a thorough delineation of commercial and non-commercial research and clear rights and obligations, that would be acceptable for both public and private technology providers and users. To a certain extent, both actors would also benefit from a loose yet explicitly contoured liability rule targeting research and development, which would need to include plant breeding.

Another win-win situation for numerous agrobiodiversity innovation concerns the opportunity to create participatory plant breeding projects encompassing *ex ante* delineation of property rights, within a proprietary but preferably open mindset. The BioLinux rhetoric effectively merges the standard license based clearing-house and open biotechnology movements in both **public biotechnology and plant breeding** with participatory plant breeding opportunities, which would be profitable for **public researchers, private plant breeders** and **mass selectors**. Drawing a common license or material transfer agreement allocating *ex ante* the property rights of the decentralised plant innovation scheme, and delineating clear rights and obligations of participants, can be used to create a viable and efficient "commons" that would address the needs of all plant improvement actors. Not only does this scheme serve to address the communalism inherent to public research, it may also effectively fight misappropriation accusations that have tainted public research and private plant breeding, all the while additionally providing a means to "positively" protect and foster *in situ* biodiversity conservation and mass-selection based plant improvement, all the while addressing the socio-economic realities of subsistence farmers and the dilemma of orphan crops.

PART VI CONCLUSIONS

We hope our modest attempt to trace back the evolution of the agrobiodiversity public domain and to thereon identify the practices that reclaim new boundaries towards sustainability and equity for all plant improvement actors will prove beneficial for doctrinal thought, but also for policy-makers and the users of plant genetic resources. The management and control of agricultural biodiversity is still very much a contemporary and extremely contentious issue. As mentioned in the introductory section to this thesis, the specific implementation of solutions to these issues will very much co-evolve with the strategic choices made by society, including but not limited to policy-makers, with regards to the postulates of the agriculture of the future. These postulates, which will be determined in light of soaring population growth, resource scarcity, developmental divides and the changing climate, will indeed greatly impact the means and extent to which the shortcomings of the property paradigm will be redressed for the different categories of actors of plant improvement. This redress will nonetheless operate in a global context of "stark difference in economic interest between certain developing countries, in which the great bulk of PGR's are found, and developed nations where the universities, biotech companies and life science concerns wishing to develop them are overwhelmingly located"[1687]. Indeed, all intellectual property rights legislation, which is inherently national, is carved by States so as to advance individual State objectives, while being influenced by the powerful actors of the scene that represent the largest portions of their national or regional plant improvement landscapes[1688].

Our analysis leads us to an inevitable need to recognise the role played by other arguments, beyond the social and legal arguments developed in this thesis, when making regulatory decisions. It also leads us to recognise the inequitable and conflictious power plays and influence games that lie behind the use of flexibilities offered by intellectual property rights, and the extent to which a broader diversity of plant improvement actors finds voice and weight in policy negotiations. Furthermore, broader contextual values and collective decisions will play a role in the choice of the most adequate framework in a given society, such as the broader social choices to be made in order to tackle the challenges posed by climate change for world food security. These challenges can lead to opt for increased investments in transgenetic technologies on the one hand, or in global collaborations for experimental low-input breeding on the other. Our argumentation does not advocate one or another of these positions, but this short disclaimer does point to the fact that the choice of the most optimal regulatory regime for agricultural biodiversity in a given society will depend on such deeper democratic debate, beyond the technical analysis of the legal, social and economic rationales alone. Indeed, our analysis has the primary purpose of presenting a toolbox comprised of a wide array of TRIPS-compliant flexibilities that can be used in the enactment of national laws in order to not only ensure the respect of international environmental legal obligations, but also mend the shortcomings that may be experienced by certain actors of plant improvement. Its genuine contribution lies in its grounding on existing social organisational initiatives stemming from different only socio-technological contexts of plant improvement, which

[1687] K.E. MASKUS and PETERSON INSTİTUTE FOR INTERNATİONAL ECONOMİCS, *Private Rights and Public Problems: The Global Economics of Intellectual Property in the 21st Century*: Peterson Institute for International Economics, 2012., p.288.

[1688] REİCHMAN and MASKUS, "The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods," *op.cit.*

recalls and highlights that legal regimes tailored to foster innovation apply to extremely different realities, which should be acknowledged when the policy bargaining operates.

Short overview of the results of our research

Agrobiodiversity innovation is profoundly linked with basic human rights to food, development or to a healthy environment, and constitutes the elementary livelihood of both small-scale and industrialised farmers. Its products, plant varieties, and the information contained therein, present characteristics of public goods. Their direct and indirect social and economic impacts cannot be minimised. Their diffusion, both within and far from the innovation frontier is thus of primordial importance. Private appropriation presents in this context great risks, just as much as it has been viewed a necessity. Improperly balanced, exclusiveness, whether in the form of intellectual property or sovereign rights, can prevent the diffusion of innovative biological materials, products and processes, and inevitably instigate the under-production of socially beneficial innovation. Informational exclusive rights may produce diffusional challenges by considerably raising the cost of accessing technology. By conditioning research and development activities to the right holders' authorisation and to often arduous negotiations, it may wither both public and private plant breeders' sacrosanct freedom to operate in this inherently cumulative and incremental innovation context. It also may undermine the production of international knowledge goods possessing less certain commercially and socially lucrative value *per se*. In this highly pressurised context, the boundaries of the PGRFA public domain need to reflect the institutional, social, economic and legal needs of all actors involved in plant improvement, just as it needs to uphold its sustainable use and conservation for present and future generations. These boundaries need to adjust to regional, national and local specificities.

In this context, our analysis merely provides concrete yet flexible guidance to operate much needed adjustments within the strong intellectual property paradigm that has been enshrined in world trade law. It instigates means to revive the notional balance of the public and private domains in intellectual property laws, ever since their first enshrinement in the 16th century, taking into account the technological strides but also legal changes that influence the operations of all plant improvement actors. The issue of patenting of life forms took central stage in the policy agendas of industrialised countries that trail-blased the Gene Revolution. This proprietary instrument is today extensively used to control molecular research tools and processes that are later used to control plant hybridisation efforts. It is also used to protect those products and processes that constitute the nucleus or the outcome of DNA recombination. While the plant variety protection system has rather been viewed as a means to protect small advances in plant breeding at the variety level, patent regimes tentatively offer adequate protection for big leaps in technological achievements[1689]. Patents offer protection for inventions broader than mere plant varieties and provide a stronger array of prerogatives. As a result, they enable the recovery of important research and development investment costs, while not completely obliterating technology transfer prospects. Provided minimum protection standards are complied with, the extent and restrictions attached to patentability requirements, as well as the range of prerogatives allowing right holders to exclude third parties to use protected inventions, are all settled in national statutory and jurisprudential choices. *De lege rata* analysis shows that there are important

[1689] HELFER, "Intellectual Property Rights in Plant Varieties: An Overview with Options for National Governments."

differences from one legal tradition to the other, all the while demonstrating that patentability standards had to steadily be lowered in order to accept biotechnology and biological research tools within the realms of the patent paradigm[1690]. Mainly stemming from concerns with regards to the patenting of life forms, including but not limited to agrobiodiversity, the limits that have traditionally thereby put upon the intellectual protection paradigm have not sufficed to tone the controversies surrounding patents in plant improvement science down. Opponents still highlight moral dogmatic grounds, or the controversial scale of human intervention in the resulting final production of agrobiodiversity arguments to corroborate their standpoint[1691].

Our research in this sense has attempted to enshrine the boundaries of sound public domain elements of intellectual property law in their context of application, for each actor of plant improvement and also each specific type of innovation that is produced within a given legal order. The aim of this exercise is to ultimately show how the surprising lack of flexibility that national entities have shown in the implementation of the TRIPS-propelled agrobiodiversity property paradigm is not an immutable reality. Furthermore, it also strives to show that a definite shift of the paradigm has been advocated and sometimes successfully obtained by a plethora of actors actually involved in plant improvement. The delicate question that arises is to determine when these emerging practices and strategies may be considered strong or wide enough to warrant legal amendments or positive public policy changes. We are in our analysis not so much disposed to determine an eventual threshold that would trigger effective changes to the property paradigm outside of proven regulatory intervention. Indeed, as our analysis remains based on the documented shortcomings of the latter on certain agrobiodiversity users, we rather show that the regime shifting towards a looser public domain is already operating to different extents around the world, and that the "international environmental law public domain" is already espoused by certain categories of plant innovation actors and States. This espousal unescapably alters the balance of the strong property paradigm, pushing its metrical ticks closer to the pulse of overlooked plant improvers, especially farmer-selectors.

The numerous strategies and tools that we have highlighted in the course of this study all regain different public domains to different extents. Indeed, some address the ontological domain, as for instance the push for less lenient patentability requirements of novelty and non-obviousness by public researchers, or for more established prior art searches by mass selectors. Other adjustments are rather concerned with the regulatory public domain, as for instance the debates on the reach of "essentially biological products and processes" exceptions by public researchers, the different exceptional use conditions warranted to researchers, breeders and farmers, or the discourse on harvested material and exhaustion principles. At last, most (if not all) of the institutional solutions that have been drawn up or proposed in fact represent a consented public domain, whether in the form of humanitarian or standard licensing practices, other forms of cooperative patent pooling, such as the establishment of technology exchange clearing-house. These last attempts, coupled with other institutional alternatives such as compensatory liability regimes, represent prime examples of "positive commons", reshaping the agrobiodiversity public domain through another

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[1690] RAI and BOYLE, "Synthetic Biology: Caught between Property Rights, the Public Domain and the Commons," *op.cit.*

[1691] Like the "No Patents on Seeds" advocacy platform; http://www.no-patents-on-seeds.org/en/about-us/home (accessed on October 2012).

understanding of the allocation of rights between agrobiodiversity users. The innovative means through which these agrobiodiversity users address the dominant paradigm's shortcomings should in this sense be viewed as solutions to adjust the paradigm and retrieve its inherent balance to the extent favoured or allowed by political will. This approach bears the advantage of being flexible but also high adaptable to national or local conditions and circumstances. It allows legislators and policy-makers to take into account the weight, strength and presence of relevant stakeholders in their own range of regulatory action. It allows the adoption of public policy to materially enhance the social welfare inducing public domain uses, favouring a wider domain to the uses of molecular biologists, plant breeders or farmers, or all of them to different extents. The absence of such threshold for a new property paradigm stems from the variety of options available to reclaim the public domain. Opening such domain in all fronts and thus applying all potentially balancing and welfare inducing solutions indeed bears the risk of undermining the rationale for the grant of intellectual property rights and occasioning the inherent challenges to produce public goods. Indeed, if both patents and plant variety rights become completely obsolete and non-favourable to industry players, developed technologies and precious information will not be disclosed or at least be available to a very lucky few, and therefore end up being lost to secrecy. In the same vein, both intellectual property rights and the sovereignty-ladden enclosing discourses of international biodiversity law, may shrink the different public domains to their weakest, hampering greatly not only with the impetus of general interest needed for innovative brilliance, but also overarching goals of sustainability and environmental conservation.

Cross-cutting disciplines and further research

Grounded primarily in its initial study of the PGRFA public domain defined in the framework of intellectual property and genetic resources law, our analysis may benefit from the further exploitation of other fields of legal scholarship and scholarly domains in order to seek means to carve a balanced, sustainable and equitable public domain. It could benefit from evident synergies or contrasts to better assist legislators in achieving lost equilibriums, and possibly address the conflicts that arise between different adjusments serving the needs of different plant improvement actors. With regards to legal analysis as such, the most prominent of these fields are civil, competition and human rights law. Even if these fields do not target the property regime of agrobiodiversity as such, they indeed may have an indirect yet efficient effect on public domain uses that need to be reclaimed by all actors faced with inadequate restrictions on their innovation actions. Furthermore, our analysis could also perhaps benefit from quantitative studies trying to assess the efficiency and need of advocated solutions, taking less traditional routes within law and economics analysis, accounting thoroughly for actor preferences and public good production opportunities.

Civil law principles, especially those related to torts and contracts interpretation may, and have been used to redress the shortcomings of the property paradigm. These principles include the notions of "abuse of rights" or "liability thresholds", which have been used mostly to the benefit of mass selectors, which are faced with restrictive seed production contracts. Both national and European case law has been steadily building around civil law principles to interpret obligations surrounding the farmers' privilege in PVP legislation, balancing the interests of farmers and those of the breeders, with those human rights to privacy and avoiding an abuse of rights on all accounts. As aforementioned, the interlocutory ruling of the tribunal of commerce of Huy, Belgium given on 18 June 2004[1692] has for instance considered that the information on farm-saved seed ought to be obtained through or with the consent of the growers. This assertion is based on several grounds. First it strives to protect the farmers' interests residing in the avoidance of systematic invoicing for seeds that are saved but not used for sowing or multiplication purposes. But it also strives to avoid a potential abuse of rights by eluding other available remedies for information collection, without any indication as to the possible infringement of its rights, as asserted by the European Court of Justice in *Schulin vs. Saatgut*[1693].

> "The provisions of the sixth indent of Article 14(3) of Regulation No 2100/94 on Community plant variety rights in conjunction with Article 8 of Commission Regulation No 1768/95 implementing rules on the agricultural exemption provided for in Article 14(3) of Regulation No 2100/94 cannot be construed as meaning that the holder of a Community plant variety right can require a farmer to provide the information specified in those provisions where there is no indication that the farmer has used or will use, for propagating purposes in the field, on his own holding, the product of the harvest obtained by planting, on his own holding, propagating material of a variety other than a hybrid or synthetic variety which is covered by that right and belongs to one of the agricultural plant species". (para. 72, ECJ, *Christian Schulin vs. Saatgut*).

Furthermore, the reluctance to adopt formal farmers' privileges in patent laws themselves could also be overturned through jurisprudential liability thresholds, especially if national plant-breeders' rights recognise growers' right to save and exchange seeds, as established before Canadian courts. Indeed, even though the aforementioned patent-infringing canola farmer could not benefit from the privilege enshrined in PVP legislation to save the seed, monetary compensation deriving from the infringement was overturned on the grounds that no financial or other benefit was generated by the technology[1694]. This argument could fuel the debate on the liability thresholds that might be introduced for re-use conditions.

Competition law issues arise when faced with oligopolistic markets with monopolistic tendencies such as the biotech traits market, but also in light of joint venture and research partnerships, patent pools, or any other institutional arrangements that would merge existing or future intellectual property titles. "Antitrust concerns may arise if the industry is concentrated and the patent pool members account for a substantial share of sales or output in the industry or there are high barriers to entry in the market"[1695]. Furthermore, a patentee "may not impose the condition to impermissibly broaden the physical or temporal scope of the patent grant with anticompetitive effect, as such a broadening constitutes patent misuse"[1696]. The TRIPS Agreement itself concedes ample room for competition law boundaries to be used as a means to reclaim a public domain

1692 Comm. Huy (réf.) 18 May 2004, *I.R.D.I.*, 2005, liv. 2, p. 163, note VAN OVERWALLE, G., "Over kwekers, boeren en trieerders: driehoeksverhoudingen in het kwekersrecht onder de loep", pp. 168-169.
1693 European Court of Justice, C-305/00, *Schulin vs. Saatgut Treuhandverwaltungs GmbH*, 10 April 2003.
1694 PHILLIPS, "Farmers' Privilege and Patented Seeds," *op.cit.*, analysing *Monsanto vs. Schmeiser*.
1695 HERTZFELD, LINK, and VONORTAS, "Intellectual Property Mechanisms in Research Partnerships," *op.cit.*
1696 SAVICH, "Monsanto V. Scruggs: The Negative Impact of Patent Exhaustion on Self-Replicating Technology," *op.cit.*

shrunk by the incumbents of artificial monopoly rights. Indeed, its article 8.2 recognises the need to adopt appropriate measures to disallow

> "*practices which adversely affect the transfer of technology*", while it also further "*controls the anti-competitive practices in voluntary licenses*", which "*may have adverse effects on trade and impede [not only] the transfer [but also] the dissemination of technology*" in its article 40.

Following a case-by-case assessment of restrictive practices in order to determine whether these constitute "*an abuse of intellectual property rights*" with "*an adverse effect on competition in the relevant market*", signatories of the Agreement can "*establish policies to deal with technology pricing and other aspects of technology transfer transactions*", without a strong reified code establishing clear criteria for the assessment that needs to operate at national level[1697].

More concretely, competition law principles and rules may on the one hand hinder the adjustments advocated within the intellectual property paradigm, just as they may on the other hand, effectively provide for much needed adjustments themselves. With regards to the latter **impediments** that may be created by anti-trust principles on the IPR flexibilities, the most obvious ones relate to the strict conditions that surround the establishment of patent pools and to a certain extent clearing-houses, especially those functioning around standardised licenses. On the other side of the spectrum, **anti-trust defences** may also usefully be advocated for in patent infringement disputes, even though the efficiency of such defences has been put to test with the shift towards stronger patent protection and greater sympathy towards licensing[1698]. Notwithstanding its possibly limited reach, claims of "unfair business practices" may be successfully advocated when faced with monopoly extending practices such as "reach-through licensing" or other abusive clauses such as the "assign-back" or "exclusive grant-brank" provisions that may unlawfully limit the diffusion of innovations[1699]. Other scholars have advocated the use of the "essential facility theory" to overcome the hurdles imposed on downstream innovators by the upstream patenting of essential enabling technologies such as genetic sequences[1700], even though Courts, and especially the European Court of Justice, have been reluctant to declare refusals to license as abusive in non-exceptional circumstances[1701].

[1697] CORREA, "Can the Trips Agreement Foster Technology Transfer to Developing Countries?," *op.cit.* The author compares the TRIPS standards to the International Code of Conduct on the Transfer of Technology, which did propose internationally agreed (yet unfortunately completely voluntary) rules on the specific practices that are deemed to be anti-competitive, while also setting a clear line for the rights and obligations of actors involved and dispute settlement. The TRIPS Agreement only adopts a "rule of reason" approach by staying mute on these issues, only providing a non-exhaustive list of practices.

[1698] This opinion has for instance been voiced by eminent scholar BARTON, "Patents and Anti-Trust: A Rethinking in Light of Patent Breadth and Sequential Innovation," *op.cit.*

[1699] Imposing restrictive conditions on transactions "with respect to derivative inventions goes beyond the scope of the exceptions [to the prohibition of monopoly] granted for the exercice of intellectual property rights and may be deemed to fall under the definition of unfair business practices"; KOICHI SUMIKURA, "Intellectual Property Rights Policy for Gene-Related Inventions: Toward Optimum Balance between Public and Private Ownership," in *The Role of Intellectual Property Rights in Biotechnology Innovation*, ed. DAVID CASTLE, Cheltenham: Edard Elgar, 2009., pp.80-81.

[1700] SHAMNAD BASHEER, "Block Me Not: How Essential Are Patented Genes," *U. Ill. JL Tech. & Pol'y*, 2005.

[1701] Indeed, the "refusal to grant a license cannot in itself constitute an abuse of dominant position (ECJ, *Volvo vs. Veng*, 1988)". Such abuse would need to be shown to cause the elimination of all competition, just as the refusal to license ought to be objectively unjustifiable, and that no alternative, actual or potential substitute to the licensed invention could be found, in accordance with the criteria of subsequently set out by European Court of Justice, joined

Human rights instruments, if carefully understood and weighed, may also bring about a range of solutions to the issues faced by the aforementioned agrobiodiversity actors. Even though they are designed to pursue different objectives, both human rights and intellectual property rights have also been viewed as complementary to achieve human welfare and development[1702]. The shortcomings experienced by agrobiodiversity users, especially farmers, but also to a lesser extent public and private plant breeders, may be addressed in the framework of the right to food or the right to benefit from science. The former right to food is engraved in article 11 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), which, through its three tenets, requires States to "respect existing access to adequate food", "to protect the right to food" and lastly "to fulfil the right to food"[1703]. The exact reach of such obligation and the correlated obligations that accompany its ratification and endorsement by signatories to the International Covenant are disputed[1704], even though it is argued that,

> "the introduction of legislation or other measures which create obstacles to the reliance of farmers on informal seed systems may violate the obligation [to respect existing access to adequate food], which would deprive farmers from a means of achieving their livelihood […] the current intellectual property regime is suboptimal to ensure global food security today"[1705].

The implementation of restrictive IPR may detrimentally impact the realisation of the right to food. However, the very same framework that suffers much discomfort may very well also provide roadmaps in order to reclaim a sustainable and equitable balance in informational exclusive rights granted over components and processes of biodiversity.

> "The decision to subject intellectual property decision making to adjudication within the trade system has led to overly restrictive interpretations that do not respect the intentions of the parties or the needs of intellectual property policy making. A human rights presumption [may] remedy these overly restrictive interpretations, as panels should consider and respect the purposes states attempt to achieve through intellectual property regulation and should give greater presumptive weight to state policies that seek to fulfill human rights and protect human health and dignity"[1706].

Scholars have not only attempted to adjust the "wrongdoings" of the developmental intellectual property paradigm in the right to food discourse. They have also delved upon both the right to education and research, and the right to access to science and culture respectively enshrined in

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C-241/91 and C-242/91, *RTE and ITP v Commission (Magill)*, 1995, later confirmed in several cases, including C-418/01, *IMS Health v NDC Health*, 2004, and *Oscar Bronner GmbH v Mediaprint*, 1998, which stated that the refusal to license would need to prevent the emergence of a new product. See C. WAELDE et al., *Contemporary Intellectual Property: Law and Policy* Oxford: OUP Oxford, 2013., pp. 887-892.

[1702] RUTH OKEDIJI, "Securing Intellectual Property Objectives: New Approaches to Human Rights Considerations," in *Casting the Net Wider: Human Rights, Development and New Duty Bearers*, ed. M. SALOMON, A. TOSTENSEN, and W. VANDENHOLE, Antwerp and Oxford: Intersentia, 2007.

[1703] DE SCHUTTER, *op.cit.*, 2009.

[1704] For different accounts of such diverging range, see notably LAURENCE R. HELFER, "Towards a Human Rights Framework for Intellectual Property," *U.C. Davis Law Review* 40, 2007., LAURENCE R. HELFER and GRAEME W. AUSTIN, *Human Rights and Intellectual Property: Mapping the Global Interface* New York: Cambridge University Press, 2011, pp.366-378.or HANS MORTEN HAUGEN, MANUEL RUIZ MULLER, and SAVITA MULLAPUDI NARASIMHAN, "Food Security and Intellectual Property Rights: Finding the Linkages," in *Intellectual Property and Human Development*, ed. TZEN WONG and GRAHAM DUTFIELD, New York: Cambridge University Press, 2011., but also more generally MATTHEW CRAVEN, *The International Covenant on Economic, Social and Cultural Rights: A Perspective on Its Development*: Clarendon Press, 1995.

[1705] DE SCHUTTER, *op.cit.*, 2009.

[1706] MOLLY LAND, "Rebalancing Trips," *Michigan Journal of International Law* 33, 2012: p.434.

Articles 26 and 27 of the Universal Declaration of Human Rights, and Articles 13§1 and 15§3 of the ICESCR. Especially with regards to the shrinking margins of research exceptions,

> "The situation could be improved by resorting to human rights discourse and claiming that the right to research is a fundamental human right also in an IP context, which justifies the introduction of a mandatory, wide, and clear-cut experimental use exception in patent law on the international level"[1707].

The two above-mentioned human rights may serve best in filling the content of laws and policies targeting the conservation or sustainable use of biodiversity, trying to ensure food security, or fostering innovation. For instance, the constitutional protection of the right to food in India has been seen as the trigger of several legislative amendments on seed marketing rules, but also on intellectual property rights legislation, including but not limited to its wider recognition of farmers as more than cultivators[1708]. Whether such framework will allow for judicial redress in cases related to plant innovation and the implementation of exclusive IPR titles, based on sole contentions of human rights violations is however less certain.

Aside from these strictly legalistic perspectives, the most manifest need to bring the study one step further is to implement the proposed adjustments and solutions of this thesis through **a multi-disciplinary field study**, carving out the characteristics, motivations, needs and challenges faced by each agrobiodiversity user groups within a given locality, country or region. Policy and regulatory adjusments will indeed not only depend on a thorough analysis of a given regional, national or local socio-technological plant improvement context, its reach and impact would also benefit from a thorough identification of existing ecological, social, economic and political narratives that accompany but also condition their implementation. Grounded mostly on inter-disciplinary social science approaches, notably those embedded in a "science, technology and innovation" background, there are numerous methods to establish such contextualised depiction, as well as to identify possible alternative or transitional pathways[1709]. Succesful policy deployment should rely on an all-encompassing and accurate picture of plant improvement. A picture that would identify not only the policy environment and dominant discourses but also highlight the socio-economic conditions that surround the development of biotechnology research tools and plant varieties by public researchers, those fostering or blocking private sector involvement, just as those anthropological and socio-economic considerations edging mass selector presence and proliferation in the identified area. The biodiversity found within national borders, the number of small-scale farming communities and their informal practices, the levels of State expenditure in public agricultural research, the existence and strength of a national private seed sector, may all influence the legal allocation of genetic resources and its corresponding property regime, just as much as the ratification and implementation of international agreeemnts that have an impact on the management of agricultural biodiversity.

[1707] GEERTRUI VAN OVERWALLE, "Human Rights' Limitations in Patent Law," in *Intellectual Property and Human Rights: A Paradox*, ed. WILLEM GROSHEIDE, Cheltenham: Edward Elgar, 2010.
[1708] HELFER, "Towards a Human Rights Framework for Intellectual Property," *op.cit.*, pp.409-416.
[1709] See for instance ROB RAVEN, JOHAN SCHOT SCHOT, and FRANS BERKHOUT, "Space and Scale in Socio-Technical Transitions," *Environmental Innovation and Societal Transitions* 4, 2012; JOHAN SCHOT and FRANK GEELS, "Typology of Sociotechnical Transition Pathways," *Research Policy* 36, no. 3, 2007.

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