# Harnessing Intellectual Property Rights for Development Objectives

## *The Double Role of IPRs in the Context of Facilitating MDGs Nos. 1 and 6*

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Willem van Genugten, Anna Meijknecht (Project-coordinators), Bernard Maister, Caspar van Woensel, Bram De Jonge, Godber Tumushabe, Julian Barungi, Niels Louwaars, Grant Napier, Sibongile Gumbi, Tobias Rinke de Wit

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Cover image: Mr Mohamed Budarhaman. Vegetable seed merchant from Darfur in Konjo - Konjo market Juba, South Sudan selling commercially imported and locally produced vegetable seed (january 2009). Photo: Niels Louwaars.

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# Overall Introduction

## 1. History of the Project

In 2007, the then Minister of Development Cooperation of the Netherlands, Bert Koenders, launched the so-called Schokland Agreement, named after the area of Schokland, a former island in the middle of the Netherlands and in 1995 recognized by UNESCO as a World Heritage Site. The Minister did do so in order to stimulate companies, NGOs, individuals – in short, everybody with a possible interest in development issues – to do their utmost to help realize the UN Millennium Development Goals (MDGs). In reaction to the initiative, a number of people with a background in universities, ministries and platforms with links to international education and research decided to join efforts, leading to the establishment of the '*Platform MDG-Profs*'.[1] As a first step, the Platform developed a plan to make better use of Dutch research institutions and higher education for the benefit of realizing the MDGs. The second step was to develop a large research project on the topic of 'intellectual property rights and development'. The Platform felt that the capacity to open up, generate, share, and use knowledge is an important prerequisite for worldwide development, while intellectual property rights (IPRs) play a central, but also double, role in the management and sharing of knowledge in innovation systems: one the one hand, they are meant to protect knowledge, to stimulate investments in innovation and to support R&D following inventions. On the other hand, they might as well reduce use of technological innovations forthcoming through IPR protected knowledge, because commercialization of knowledge impedes innovation by and for societies that, for instance, cannot provide a (legal) framework to effectively manage IPRs or that cannot promise financial returns. Thus, it was felt by the Platform that poorly developed IPR management hinders equal research partnerships between the South and the North, and often results in a reticent or one-dimensional Northern investment policy and unnecessary delays in the realization of some of the MDGs. This double side of IPRs – also to be labelled in terms like protecting legitimate economic interests *versus* (or alongside) the need to contribute to worldwide development from the perspective of sharing *global public goods*, to which also knowledge is often said to belong – inspired the initiators to set up the present project.

In 2008, the Platform was offered funding by the Ministry of Foreign Affairs and NWO-WOTRO, the division for scientific research on development issues of the Netherlands Organisation of Scientific Research (NWO).

## 2. Contributors to the Project and Acknowledgements

The project has been carried out by a large team of people, in various roles and with a variety of backgrounds relevant to the project. Nine people have acted as researchers, their names being mentioned on the cover of the present book and repeated here in alphabetical order: Julian Barungi (Uganda); Sibongile Gumbi (South Africa); Bram De Jonge (the Netherlands);

[1] See for its history and mandate: <http://www.vsnu.nl/Focus-areas/International-policy/Development-cooperation/Platform-MDG-Profs.htm>. The Platform is now called: Knowledge Forum for Development. The Platform is chaired by Prof. Martin Kropff, Rector Magnificus of Wageningen University, and is financially supported by NWO-WOTRO.

Niels Louwaars (the Netherlands); Bernard Maister (South Africa); Grant Napier (South Africa); Tobias Rinke de Wit (the Netherlands), Godber Tumushabe (Uganda); and Caspar van Woensel (the Netherlands). More information on each of them can be found in the List of Contributors.

The project could not have been carried out without the knowledge and the diversity of practical experiences of a group of experts in the field of intellectual property rights, together being the 'Steering Committee': Victoria Henson-Apollonio, former manager Central Advisory Service on Intellectual Property, Rome; Ruth Okediji, Nigeria, Professor of International Intellectual Property Law, University of Minnesota; Peter Munyi, IP Lawyer, Nairobi; William New, Director and Editor-in-Chief, *Intellectual PropertyWatch*, Geneva; Geertrui van Overwalle, Professor of Intellectual Property Law, Universities of Leuven and Tilburg; Michael S. Pepper, Professor in Health Sciences, Pretoria (had to step aside halfway); Orlando de Ponti, President of the International Seed Federation; and Rosemary Ann Wolson, Professor, Intellectual Property & Technology Transfer, Council for Scientific & Industrial Research, Pretoria. The Steering Committee members played a major role at all stages of the project. All of them attended two plenary meetings to discuss the set-up and the interim findings, while they delivered numerous contributions to the fine-tuning of the end-results. William New also co-edited the final report.

As will become clear below (Par. 3.3. especially), the project consisted of three sub-projects. While the Law School of Tilburg University served as the 'home base' for the project as a whole, as well as for the first sub-project, Wageningen University hosted the second sub-project, while the University of Amsterdam in cooperation with the Foundation PharmAccess hosted the third sub-project. Apart from the people already mentioned, the projects have profited greatly from the input by Julian Kinderlerer, University of Cape Town (sub-projects 1 and 2), while Wendy Stevens, Wits University, South Africa (sub-project 3) and Nico Schrijver as well as Dirk Visser, both Leiden University, the Netherlands, acted as co-readers of specific parts of the report of sub-project 1.

As said, the project had Tilburg University as its home base, but Bram De Jonge and Niels Louwaars, both Wageningen University, and Tobias Rinke de Wit, University of Amsterdam, Center for Poverty-related Communicable Diseases (currently: the Amsterdam Institute for Global Health and Development) and the Foundation PharmAccess International, played an important role as co-coordinators and 'sparring partners'.

## 3. The Project Itself

### 3.1 Introduction

The project focuses on one cumbersome aspect of globalization: the relationship between the international system for the protection of intellectual property and the achievement of the development objectives as formulated the MDGs, in particular MDG 1 ("Eradicate extreme hunger and poverty", target 1c: "Reduce by half the proportion of people who suffer from hunger"); and MDG 6 ("Combat HIV/AIDS, Malaria and other diseases", target 6b: "Achieve, by 2010, universal access to treatment for HIV/AIDS for all those who need it."). While intellectual property rights play a central role in the management and sharing of knowledge in innovation systems, the assumption of the project is that understanding both the enabling

and limiting factors of such rights in improving access to knowledge and technology for those who can most benefit from it, is of key importance for the realization of the MDGs.

The project aims at understanding the role of intellectual property rights in relation to development. Its purpose is to strengthen the awareness, capacity, and knowledge of scientists, research organizations, and governments in the "South" and the "North" with regard to international and national strategies and attitudes in the field of IP and development. In this way, this projects aims to contribute to the development of sustainable scientific cooperation relationships between "North" and "South" and to the realization of MDGs Nos. 1 and 6. Due to the need to limit the research, this project will focus on two Sub-Saharan African countries (Uganda and South Africa) and the Netherlands. The project thus is situated on the interface between serving the direct (economic) interests of research centres and institutions in the "North" as well as the "South" and the need to contribute to the *global public good*.

## 3.2 Research Questions

The central question of the project is the following: What is the role of intellectual property rights (IPRs) in the management and sharing of knowledge for development, in particular, the achievement of the MDGs 1 and 6?

This central question builds upon 'a web' of four sub-questions. In order to obtain a balanced view of the role of IPRs in the context of the enhancement of the MDGs, it is not only relevant to find out what possible obstacles are created by IPRs in the context of the realization of development objectives (sub-question 1), but also to get a clear picture of best practices or positive experiences with using IPRs to deal with access to knowledge and technology (sub-question 2). Whereas the first two sub-questions define the (negative and positive) role of IPRs in the realization of MDGs, the other two sub-questions concern the way forward. How can the possibly negative relationship between IPRs and the achievement of the MDGs be repaired (sub-question 3)? And in what way can the results of the present project be used by the variety of relevant actors: practical recommendations (sub-question 4)?

These research questions are addressed by three interlinked sub-projects (placed in Parts I, II and III of this report), each covering different disciplines and applying a different method to establishing the relationship between IPRs and the achievement of the MDGs. In Part IV, the conclusions and recommendations of the three sub-projects, are brought together and analyzed in order to obtain a nuanced answer on the central research question (also see Par. 3.4 on Methodology).

## 3.3 Structure of the Report; Description of the Sub-Projects

Part I of this report contains the findings of sub-project 1: *Trade vs. Development: the International Intellectual Property Rights' Regime and the UN Millennium Development Goals*. This project provides the background to and a discussion of the current policy and legal debate taking place in governments, universities and international organizations on the impact of the international intellectual property rights' system on the realization of development objectives. It outlines the development and history of IPR law in general and frames the obstacles to development created by IPR law and the application of the international IPR regime to developing countries. Most attention is given to the Agreement

on Trade-Related Aspects of Intellectual Property Rights (TRIPS), as the dominant international IPR agreement in the modern era, and on patents as the most significant of the IPR instruments in this context. Other issues specifically covered include the need to have the domestic capacity to build an IPR system, the 'power differential' between developed and developing countries and the question how this differential impacts negotiations on and enforcement of existing IPR law. This is followed by discussion of the 'post-TRIPS world', e.g., the renewed importance of bilateral trade agreements.

Part II of the report consists of the findings of sub-project 2: *Agricultural Seeds That Reduce Hunger and Poverty – Policies, Perceptions and Practices in Intellectual Property Rights*. This project examines the relationship between IPRs, agriculture, and MDG 1c (see above). The study analyzes the roles that different IPR policies and practices play in agricultural research and development trajectories in both a developed context (in particular the Netherlands) and a developing context (in particular Uganda). Ultimately, the aim of the sub-project is: 1) to map the main obstacles and opportunities that IPRs create for the development and transfer of knowledge and technologies for the benefit of resource-poor farmers in developing countries; and 2) to contribute to the realization of IPR strategies and recommendations that improve the development and accessibility of agricultural inputs that are relevant for resource-poor farmers and that increase food security in developing countries. The research focuses on the full chain of actors involved, from ministries in the North and the South and research centres in both worlds, to the local end-users and producers of relevant IPR knowledge.

Part III of this report consists of the outcome of sub-project 3: *Affordable HIV Drug Resistance Test for Africa (ART-A) Intellectual Property*. This study focuses on the relationship between IPRs, the medical diagnostics sector, and MDG 6b (see above). The study examines a European and African research consortium called the Affordable Resistance Test for Africa (ART-A: http://www.arta-africa.org/) that was established to develop technologies for affordable HIV drug resistance testing in Africa. The end goal of the study is to ensure that products and services developed by the ART-A research consortium can be successfully produced and effectively used in combatting the HIV and AIDS epidemics. For that purpose, the study describes the IPR environment of the ART-A research consortium and explores suitable IP protection models that could be used by public-private partnerships developing medical diagnostic technologies to facilitate broader access to diagnostic testing in Africa.

Part IV contains the synthesis, concluding remarks and recommendations of this research project. The synthesis and concluding remarks are based on a comparison and analysis of the conclusions formulated at the level of the sub-projects (Parts I, II, and III of the report). The last part of Part IV contains practical recommendations based on the outcomes and recommendations of the individual sub-reports and on the synthesis and concluding remarks. These recommendations are directed towards policy makers at the global, regional and national level, funding organizations, and universities and (other) research institutes.

## 3.4 Methodology; Complementarity of the Sub-Projects

Each of the sub-projects covers different disciplines, has a different focus and applies a different method to establish the relationship between IPRs and the achievement of the MDGs. They have been chosen this way in order to be complementary to one another. However, they also have commonalities: the binding element between the three sub-projects

consists of a framework of questions, i.e., the above-mentioned core question together with the 'web' of four sub-questions. In the end, all three projects do search, each in its own way and applying its own method, for answers to the same set of questions. The outcomes of the individual sub-projects can be found at the end of each sub-report, while in Part IV the outcomes of the three sub-projects are linked.

When perceived together, the three sub-projects reflect a rather unique combination of researchers, disciplines and entrances to the debate on 'IPRs and development': a combination of North-South research partnerships, with multi-, inter- and trans-disciplinary cooperation between technological expertise in the field of agriculture/food and medicines and expertise in the field of international as well as national regulations and legislation on IPR law. This combination adds several dimensions to the outcomes of the three sub-project reports and offers a number of opportunities for comparison and analysis.

For instance, as already visible from the above descriptions, the three sub-projects approach the questions from a different angle: while sub-project 1 discusses the general theoretical and legal background that bears on the role of the current international IP regime in achieving the MDGs 1 and 6, the two case-studies shed light on the implications of IPRs for knowledge development and transfer in the field agriculture (MDG 1) and medical devices (MDG 6). Further to that, the first sub-project approaches the field of international IPRs with an overall 'helicopter' view, while the second sub-project provides a macro perspective by analyzing the chain of knowledge transfer from Dutch universities and research institutes to smallholder farmers in Uganda, and *vice-versa*. Next to that, the third sub-project provides a micro perspective on the relevant research questions by zooming in on the search for suitable IP protection models in the context of the ART-A consortium which aims to develop technologies for affordable HIV drug resistance testing in Africa.

Taking the findings together, it will become clear that due to the set-up of the project and the way the sub-projects have been carried out, conclusions can and will be drawn on a variety of levels. To conclude this introductory Part, we would like to mention three such levels and accompanying perspectives:

- The geographical perspective: a) the local level: farmers in Uganda, b) the national level: governments in the Netherlands, Uganda, and South Africa; c) the regional level: the Organisation Africaine de la Propriété Intellectuelle (OAPI), the African Regional Intellectual Property Organisation (ARIPO) and the EU (to some extent); d) the global level: the WTO, the International Union for the Protection of New Varieties of Plants (UPOV), and the World Intellectual Property Organization (WIPO).
- The actors' perspective: a) local farmers and breeders in Uganda, researchers and staff of medical laboratories in Uganda and South Africa; other private sector people in the South and the North, applying the findings analogously; b) research institutes and universities in the Netherlands, Uganda and South Africa; c) governments in the Netherlands, Uganda, and South-Africa.
- The perspective of the complementary approaches, chosen by and for each of the sub-projects: a) an overall approach, providing insights in historical developments and present international debates on the relation between IPRs and MDGs (sub-project 1), b) a chain-analysis conducted on IPRs in the agricultural context (sub-project 2) and c) a micro-analysis of a concrete model in the medical context (sub-project 3).

In conclusion: it has been an intense project, to be conducted in two years overall, with 1.5 years for the actual research only. However, the cooperation of totally different disciplines indicates that it would and actually will be very useful to establish more such coalitions, addressing North-South topics 'that really matter'. The confrontation between disciplines and the inclusion of the actors' perspective on a variety of levels has lead to insights that would not have been reached should the problem under scrutiny in this report have been defined in a mono-disciplinary and purely scientific way only. It has become clear again that research which finds its inspiration in practical issues can lead to innovate scientific insights. We hope the readers of this report feel as inspired as we do.

Willem van Genugten
Anna Meijknecht
Tilburg, 15 July 2011

## Acronyms

| | |
|---|---|
| AATF | African Agricultural Technology Foundation |
| ABL | Advanced Biological Laboratories |
| AIDS | Acquired Immunodeficiency Syndrome |
| AGRA | Alliance for a Green Revolution in Africa |
| AGT | Agro-Genetic Technologies Limited |
| AMC | Amsterdam Medical Centre |
| ANDi | African Network for Drugs and Diagnostics Innovation |
| ARIPO | African Regional Intellectual Property Organisation |
| ART-A | Affordable Resistance Test for Africa |
| ARV | Antiretroviral |
| ASARECA | Association for Strengthening Agricultural Research in Eastern and Central Africa |
| ASR | Analyte Specific Reagent |
| AUC | African Union Commission |
| AUTM | Association of University Technology Managers |
| AVRDC | World Vegetable Centre |
| AWT | Advisory Council for Science and Technology Policy (Netherlands) |
| BEE | Black Economic Empowerment |
| CAADP | Comprehensive Africa Agriculture Development Programme |
| CBD | Convention on Biological Diversity |
| CDA | Confidential Disclosure Agreement |
| CDC | Center for Disease Control and Prevention |
| CDIP | Committee on Development and Intellectual Property |
| CFC | Common Fund for Commodities |
| CGIAR | Consultative Group on International Agricultural Research |
| CIAT | International Centre for Tropical Agriculture |
| CIMBAA | Collaboration on Insect Management for Brassicas in Asia and Africa |
| CIMMYT | International Maize and Wheat Improvement Centre |
| CIP | International Potato Centre |
| CIPIH | Commission on Intellectual Property Rights, Innovation and Public Health |
| CIPRO | Companies and Intellectual Property Registration Office |
| CMH | Commission on Macroeconomics and Health (WHO) |
| CPA | Africa's Science and Technology Consolidated Plan of Action |
| CPA | Copyright and Patent Agreement |
| CPCD | Center for Poverty Related Communicable Diseases |
| CRP- Santé | Centre de Recherche Publique de la Santé |
| DDPSC | Donald Danforth Plant Science Centre |
| DFID | United Kingdom Department for International Development |
| DGIS | Netherlands Ministry of Development Cooperation |
| DMCA | Digital Millennium Copyright Act |
| DNA | Deoxyribonucleic Acid |

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|---|---|
| DuRPh | Durable Resistance against Phytophthora |
| EC | European Commission |
| ECOWAS | Economic Community Of West African States |
| EL&I | Netherlands Ministry for Economy Agriculture and Innovation |
| EPAs | Economic Partnership Agreements |
| EPO | European Patent Office |
| EU | European Union |
| EZ | (former) Netherlands Ministry of Economic Affairs (now part of EL&I) |
| FAO | Food and Agriculture Organisation |
| FDA | Food and Drugs Administration (US) |
| FDC | Fixed-Dose Combination |
| FDI | Foreign Direct Investment |
| FTAs | Free Trade Agreements |
| FTO | Freedom to Operate |
| GATB | Global Alliance for TB Drugs |
| GATT | General Agreement on Tariffs and Trade |
| GAVI | Global Alliance Vaccine Initiative |
| GBS | Global Bio-Collecting Society |
| GFATM | Global Fund to Fight AIDS, Tuberculosis and Malaria |
| GI | Geographical Indications |
| GM | Genetic Modification |
| GMO | Genetically Modified Organism |
| GMP | Good Manufacturing Practice |
| GNU | GNU's Not Unix |
| GPL | General Public License |
| GSK | GlaxoSmithKline Plc |
| HIV | Human Immunodeficiency Virus |
| HIVDR | Human Immunodeficiency Virus Drug Resistance |
| HIV VL | Human Immunodeficiency Virus Viral Load |
| IAVI | International Aids Vaccine Initiative |
| ICCPR | International Covenant on Civil and Political Rights |
| ICTSD | International Centre for Trade and Sustainable Development |
| IFAD | International Fund for Agricultural Development |
| IFC | International Finance Corporation (World Bank Group) |
| IGWG | Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (WHO) |
| IITA | International Institute for Tropical Agriculture |
| IITC | Inter-Institutional Trade Committee |
| IMPACT | International Medical Product Anti-Counterfeit Taskforce |
| IP | Intellectual Property |
| IPC | International Patent Classification |
| IPFA | International Project Finance Association |
| IPGRI | International Plant Genetic Resources Institute |
| IPRs | Intellectual Property Rights |
| IPSF | Intellectual Property Support Fund |

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|---|---|
| ITPGRFA | International Treaty on Plant Genetic Resources for Food and Agriculture |
| IVD | *In Vitro* Diagnostic |
| IUO | Investigational Use Only |
| IUPGR | International Undertaking on Plant Genetic Resources |
| JCRC | Joint Clinical Research Centre |
| JITAP | Joint Integrated Technical Assistance Programme |
| KNAW | Royal Netherlands Academy of Arts and Science |
| LDC | Least Developed Country |
| LDT | Laboratory Developed Test |
| LNV | (former) Netherlands Ministry of Agriculture, Nature and Food quality (now part of EL&I) |
| MCC | Medicines Control Council |
| MDG | Millennium Development Goal |
| MOU | Memorandum of Understanding |
| MPEP | Manual of Patent Examining Procedure |
| MSF | Médecins sans Frontières |
| MTA | Material Transfer Agreements |
| MTTI | Ministry of Trade, Tourism and Industry |
| MVI | Malaria Vaccine Initiative |
| NACCAP | Netherlands-African Partnership for Capacity Development and Clinical Interventions against Poverty-Related Diseases |
| NaCRRI | National Crops Resources Research Institute |
| NANEC | National Network of Cassava workers |
| NARO | National Agricultural Research Organisation |
| NGI | Netherlands Genomics Initiative |
| NGO | Non-Governmental Organisation |
| NEPAD | New Partnership for Africa's Development |
| NIH | National Institutes of Health (US) |
| NIPMO | National Intellectual Property Management Office |
| NRM | Natural Resource Management |
| NWO | Netherlands Organisation for Scientific Research |
| OAPI | Organisation Africaine de la Propriété Intellectuelle |
| OAU | Organisation of African Unity |
| OECD | Organisation for Economic Cooperation and Development |
| OC&W | Netherlands Ministry for Education, Culture and Science |
| OIN | Open Invention Network |
| OSDD | Open Source Drug Discovery |
| PASER | PharmAccess African Studies to Evaluate Resistance |
| PBR | Plant Breeders' Rights |
| PCDA | Provisional Committee on Proposals Related to a WIPO Development Agenda |
| PCR | Polymerase Chain Reaction |
| PCT | Patent Cooperation Treaty |
| PEPFAR | US President's Emergency Plan for AIDS Relief |
| R&D | Research and Development |
| PIC | Prior Informed Consent |

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|---|---|
| PIIPA | Public Interest Intellectual Property Advisors |
| PIPRA | Public Intellectual Property Resource for Agriculture |
| PPPs | Public-Private Partnerships |
| PRAPACE | Regional Potato and Sweet Potato Improvement Network in Eastern and Central Africa |
| PTAs | Preferential Trade Agreements |
| PVP | Plant Variety Protection |
| R&D | Research and Development |
| RUO | Research Use Only |
| SAHPRA | South African Health Products Regulatory Authority |
| SANAS | South African National Accreditation Service |
| SAP | Structural Adjustment Programme |
| SME | Small and Medium-sized Enterprise |
| SNP | Single Nucleotide Polymorphisms |
| STD | Sexually Transmitted Disease |
| STI | Sexually Transmitted Infection |
| STW | Technology Foundation (Netherlands) |
| TB | Tuberculosis |
| TDR | WHO Special Programme for Research and Training in Tropical Diseases |
| TK | Traditional Knowledge |
| TKDL | Traditional Knowledge Digital Library |
| TRALAC | Trade Law Centre for Southern Africa |
| TRIPS | Agreement on Trade-Related Aspects of Intellectual Property Rights |
| TTI-GG | Technological Top Institute – Green Genetics (Netherlands) |
| TT(O) | Technology Transfer (Office) |
| UBOS | Uganda Bureau of Statistics |
| ULRC | Uganda Law Reform Commission |
| UMCU | University Medical Centre Utrecht |
| UN | United Nations |
| UNAIDS | Joint United Nations Programme on HIV/AIDS |
| UNBS | Uganda National Bureau of Standards |
| UNCST | Uganda National Council for Science and Technology |
| UNCTAD | United Nations Conference on Trade and Development |
| UNDP | United Nations Development Programme |
| UNESCO | United Nations Educational, Scientific and Cultural Organisation |
| UNIDO | United Nations Industrial Development Organisation |
| UNSSPA | Uganda National Seed Potato Producers' Association |
| UPOV | International Union for the Protection of New Varieties of Plants |
| URSB | Uganda Registration Services Bureau |
| US | United States of America |
| USAID | United States Agency for International Development |
| USDA | United States Department of Agriculture |
| USPTO | United States Patent and Trademark Office |
| VCA | Visitors Confidentiality Agreement |
| VSNU | Association of Universities in the Netherlands |

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| WCO | World Customs Organization |
| WHC | Wits Health Consortium (Pty) Ltd. |
| WHO | World Health Organisation |
| WIPO | World Intellectual Property Organisation |
| WITS | University of the Witwatersrand |
| WOTRO | Science for Global Development Programme (of NWO) |
| WRR | Dutch the Scientific Council for Government Policies |
| WTO | World Trade Organisation |
| WUR | Wageningen University and Research Centre |

# PART II

## AGRICULTURAL SEEDS THAT REDUCE HUNGER AND POVERTY – POLICIES, PERCEPTIONS AND PRACTICES IN INTELLECTUAL PROPERTY RIGHTS


**By**

**Bram De Jonge**
**Godber Tumushabe**
**Julian Barungi**
**Niels Louwaars**

## Contents

## EXECUTIVE SUMMARY

### *Goals and Objectives*

1. The Millennium Declaration contains a set of ambitious goals and targets that countries committed to, including under Goal 1 dealing with the eradication of extreme poverty and hunger, setting themselves a target to halve, between 1990 and 2015, the proportion of people who suffer from hunger (MDG 1c). Agriculture and particularly smallholder agriculture is central to meeting MDG 1c, and the use of good seed of adapted varieties is a major prerequisite for improving agriculture. Access by farmers to new varieties and access by breeders to the technologies and materials to develop them is central in this research, which aims to investigate the roles of Intellectual Property Rights (IPRs) in the management and sharing of knowledge for development.

2. We have studied the Intellectual Property Rights systems relevant to plant breeding (patents and Plant Breeder's Rights). We have taken the innovation chain approach, analysing the policies underlying the rights, perceptions and practices in applying the rights by stakeholders at funding organizations of fundamental and strategic research, research institutions and researchers in the Netherlands down to research for development funders and researchers in Africa (notably Uganda) down to smallholder farmers. The aim was to map the main obstacles and opportunities that IPRs create for the development and transfer of knowledge and technologies for the benefit of resource-poor farmers in developing countries, and secondly to contribute to the realization of IP strategies and recommendations that improve the development and accessibility of agricultural inputs that are relevant for resource-poor farmers and which increase food security in developing countries.

3. The innovation chain can be read in terms of a "push", where technology is translated to products for farmers, but also as a "pull" starting from the end user. It addresses what are the needs of smallholders and how is their access to the different seed systems (see below) translated into breeding objectives and research programs.

4. The research involved interviews with a large number of stakeholders along this innovation chain, and the analysis of relevant policy documents, contracts, and literature. Uganda is selected as it represents a typical African least developed country which is highly dependent on agriculture. The Netherlands has a leading position in agricultural research and development, and has a thriving seed sector.

***IPRs may create obstacles at various points along the innovation chain:***

5. Since resource-poor farmers almost exclusively source new varieties from informal sectors, any IPR system that effectively disallows the informal sharing of seeds such as patents and some forms of Breeder's Rights will obstruct access to new protected varieties. Even though awareness of IPRs is generally low with public research directors in Africa, a broadly shared perception is that such rights, when applied to publicly bred varieties, could solve budgetary constraints of public research (including breeding), and

supplement low wages of breeders in the public service. Few realize the potential to tilt the focus of these institutions towards more commercially viable crops and farmers and away from poverty reduction goals. A low capacity to manage intellectual property in public research and breeding organizations either shies away potential foreign research partners from collaboration, or puts the African partner in a disadvantaged position in negotiations towards access of technologies. Such institutes furthermore operate in a policy environment where the framing of national IP policies is strongly influenced by international pressures, which makes it impossible for developing countries to balance the rights of inventors with those of their society. Ugandan institutions exercising IP-related mandates are quite disjointed or only coordinate with each other in an ad hoc manner, not contributing to tangible benefits to the country and its resource-poor farmers.

6. Dutch IP law and national innovation policies lack a specific development clause despite several international agreements that emphasize the responsibility of the industrialized countries to promote technology transfer to least-developed nations. There is no general IP policy at the ministries that finance agricultural research, and opinions diverge on the need for such a policy, while awareness among policymakers is low with respect to possibilities for IP to impede access to technologies in developing countries. International development policy and knowledge and innovation policy are organizationally divided and generally perceived as two worlds apart.

7. Some Dutch funding agencies and programs, however, have "valorisation" strategies, which is the basis for public-private partnerships in research. These strategies lack specific references to international development. Valorisation of research is commonly narrowly understood by such programs as the need to turn knowledge into (economic) value for the Dutch society - through IPR protection - and by universities, the acquisition of royalties of new research contracts. The involvement of the private sector in public research affects the conditions under which university IP can be accessed, and commonly leads to more exclusive arrangements.

8. Dutch public research organizations hardly include humanitarian licensing strategies in their research and IP contracts with (private) research partners, which could increase availability of technologies for development purposes. The perception is widespread that such humanitarian licenses can negatively affect the organization's own interest in the negotiations.

9. It is difficult and costly to secure freedom to operate for humanitarian projects given the IP landscape in agricultural biotechnology: Material Transfer Agreements (MTAs) often do not allow for product development; strategic patenting and restrictive licensing conditions are common; many IP laws only include a weak research exemption;n biosafety procedures for GM crops are very expensive and regulatory dossiers are held confidential. All these issues create restrictions for the sharing of technology in both industrialized and developing nations. A lack of research capacity in the developing country or the capacity to effectively deal with IP may be additional impediments to the use of potentially useful technologies for development.

***Policies and practices that are likely to ensure a positive role of IP in facilitating the development, transfer and access to agricultural innovations for smallholder farmers:***

10. This includes a recent recognition in several African countries of the informal seed system leading to a more careful balancing of rights and obligations in seed and Breeder's Rights regulation. International research agencies and some donors investing in agricultural research provide safeguards for access to new varieties by smallholders. Moreover, Plant Breeder's Rights may - when carefully framed and implemented - support the uptake of new varieties in the product portfolio of a seed enterprise, where otherwise the variety might be left 'on the shelf'.

11. In the Netherlands, there are some developments worth mentioning: An "Incentive Fund for Open Access Publications" has been established by the Netherlands Organization for Scientific Research (NWO); and there are some recent voices calling on the Dutch government to create more synergy between the organizationally divided worlds of international development policy and research and innovation policy. Finally, the Plant Sciences Group of Wageningen UR concluded an important humanitarian use license with a CGIAR partner and one in the US, which is a sign of a policy shift towards making technology more readily available for contributing to MDG1c.

12. Several solutions have been proposed in order to counteract the blocking effect of patents on the availability of genetic material for further breeding; and several humanitarian and open licensing tools have become available to secure and facilitate the accessibility or transfer of IP protected knowledge, materials and technologies for development purposes.

***We recommend that:***

13. If Uganda and other African countries are to support poverty reduction through research for development, they should formulate IPR laws that take into account the need for farmer-to-farmer technology transfer.

14. Public research organizations in Africa need to frame their institutional policies in such a way that both commercial and (near-) subsistence agriculture of the country can be supported. They need to increase their capacity in IP management in order to avoid concluding contracts that are not to the benefit of the country or the poorer constituency of farmers.

15. African countries should actively pursue the integrated seed system development pathway that recognizes the importance of farmers' seed systems next to the formal system.

16. Uganda should increase its policy coherence relevant to seeds and IPRs by making sure that the various institutions involved and their mandates are properly coordinated.

17. The Dutch government should create much more synergy between its research and innovation policy and its international development policy in the formulation of a general IP policy with respect to public research. This should involve an evaluation of the current research funding system and the development of criteria and incentive mechanisms for valorisation that go beyond mere economic outputs for the Dutch society and reach across borders. More expertise needs to be developed with respect to humanitarian licensing strategies at public research organizations and funding agencies.

18. The current patent system may need to be evaluated at the global level with respect to the need for a breeder's exemption in patent law, mechanisms to curtail strategic patenting, expanding possibilities for compulsory licenses, reducing the costs and inefficiency of the patent system, and the expansion of the "private and non-commercial use" exemption in Plant Breeder's Rights to all resource-poor farmers.

19. Obligations in international agreements to facilitate technology transfer for development purposes need to be actively pursued, and generic competition secured after termination of IP protection.

***Extending the outcomes to stakeholders and further research:***

20. The outcomes of the study will be communicated with the relevant stakeholders in Europe and Africa, starting with the various actors interviewed.

21. The outcomes will be included in curriculum on IPRs in the Life Sciences at Wageningen University, and invitations have been accepted to discuss them with the Uganda Seed Trade Association and the African Union Secretariat in Addis Ababa. They will also be discussed in the Network of IP-Professionals of the Central Advisory Service on IP of the CGIAR (the National Partners' Initiative) during its annual meeting – scheduled in South Africa in July 2011.

22. The project results will be included in international mid-career training programs of the Centre for Development Innovation in Chennai (2011) and Wageningen (2012). There is also an interest from a SIDA-funded training program on Genetic Resources and Intellectual Property Policy that will be held in Alnarp – Sweden, and (probably) in Nairobi, Kenya in 2011.

23. The results also warrant further research. They will be included in the work plan of a project sponsored by Netherlands Organisation for Scientific Research (NWO) on "Intellectual Property Regimes for Pro-poor innovation in agriculture" under its "Responsible Innovation" program, and other research proposals on the development of criteria and incentive mechanisms for valorisation of agricultural research across borders.

# CHAPTER 1 INTRODUCTION

*Niels Louwaars & Bram De Jonge*

## 1.1 Research Objectives

The adoption of the Millennium Development Goals (MDGs)[1] in 2000 was heralded as an important milestone in the global development discourse. Adopted at the United Nations Millennium Summit, the Millennium Declaration contains a set of ambitious goals and targets to which countries committed, setting themselves a deadline of 2015. Under Goal 1 dealing with the eradication of extreme poverty and hunger, countries set themselves a target to halve, between 1990 and 2015, the proportion of people who suffer from hunger (MDG 1c). However, the MDG Report 2009 indicated that most of Sub-Saharan Africa suffers from moderate to extremely alarming hunger and that, for the sub-region, the declining trends in hunger registered since 1990 were reversed in 2008 as the proportion of people going hungry increased.[2] Agriculture and particularly smallholder agriculture are central to the capacity of states and the international community to meet MDG 1c. However, a combination of adverse ecological conditions, diseases and pests, and the lack of access to appropriate technologies constitute some of the most important impediments to achieving improvements in agricultural productivity in most of Sub-Saharan Africa.

The lack of access to appropriate agricultural technologies in many developing countries is the main focus of this research project, which aims to investigate the impact of IPRs on the attainment of the MDGs. The central research question holds: *What is the role of IPRs in the management and sharing of knowledge for development?* This part of the report examines the relationship between IPRs, agriculture, and MDG 1c. For that purpose, we will analyse the roles that different IP policies and practices play in agricultural research and development trajectories in the developed and developing contexts. Ultimately, the aim is 1) to map the main obstacles and opportunities that IPRs create for the development and transfer of knowledge and technologies for the benefit of resource-poor farmers in developing countries, and 2) to contribute to the realization of IP strategies and recommendations that improve the development and accessibility of agricultural inputs that are relevant for resource-poor farmers and that increase food security in developing countries.

## 1.2 Research Approach and Structure

In order to get an overview of what issues are at play, we focus on the main actors that directly or indirectly impact upon IP policies and practices in relation to agricultural research and technology transfer. Hereby, we focus particularly, but not exclusively, on two countries: one developed country – the Netherlands, and one Least Developed Country – Uganda. Uganda is selected because it not only represents a typical African least developed country but its economy and an estimated 85% of the rural population are dependent on agriculture.

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1 See <http://www.un.org/millenniumgoals/>(accessed on March 16, 2011).

2 UN 2009. Available at <http://www.un.org/millenniumgoals/pdf/MDG_Report_2009_ENG.pdf> (accessed on March 16, 2011).

The Netherlands, meanwhile, is a developed country that holds a leading position in agricultural research and development, and that has a thriving seed sector, particularly in potato, vegetable and ornamental crops.

Key players in the agricultural innovation chain are governmental organizations at various levels, funding agencies, research organizations, companies, and last but not least, farmers. Along this chain, we will analyse the IP regulations, policies, and practices that are implemented by the various actors and report on their experiences and perceptions with respect to the effects of IPRs on the development, transfer and availability of knowledge and technologies for the benefit of resource-poor farmers and the attainment of MGD 1c. Input for these analyses is derived from literature studies and semi-structured interviews with stakeholders. In addition, the relation between IPRs and pro-poor innovation is analysed in more detail on the basis of several case studies that focus on different crops.

In this *Chapter 1*, we will set the scene by introducing the key elements that form the basis of this research project. Starting with a reflection on MDG 1c, we will subsequently introduce the innovation chain and its various actors, the notion of formal and informal seed systems, and the Intellectual Property Rights (and some other rights) that are particularly relevant for the agricultural sector and biological research leading to improved seed.

The next three chapters focus on Uganda, with *Chapter 2* starting at the level of resource-poor farmers by investigating how Ugandan farmers access improved seed. The analysis of the ways that farmers acquire seeds and particular through which kind of ways new varieties reach the poorer and/or more commercial farmers is a basis for analysing the waysthat IPRs could affect seed related technology transfer. The chapter is based on case studies in Uganda on the important food security crops beans, cassava, maize and (Irish) potato.

*Chapter 3* examines the current trends in the development of IP regimes in Africa, the key influencing factors and how these regimes impact on agricultural R&D and access to new seed varieties by resource-poor farmers. By looking at the case study of Uganda, we analyse the formal policies at national and institutional levels and what the drivers are/have been to arrive at these.

*Chapter 4* then concentrates on the institutional policies of research organizations that develop new technologies for farmers in Africa, and their funders. This chapter takes a broader perspective than the case study of Uganda and is based on a significant number of interviews with research managers from various African countries. By analysing some research contracts, the chapter studies the impact of international agricultural research centres and funding partners on IP policies of the African agricultural research institutions.

*Chapters 5 and 6* deal with the Netherlands. *Chapter 5* focuses on the policy level. It analyzes how agricultural research is organized in the Netherlands, what IP laws and policies apply, and how these factors impact upon the room for pro-poor innovation. It analyzes coherence in public policy by studying different ministries, public funding agencies, national research programs, science associations, and (public) research organizations.

*Chapter 6* then deals with IPRs in practice, focusing on the experiences of public researchers, public IP managers, and industry representatives with accessing and transferring research materials. We study four research projects that aim specifically at transferring agricultural technologies to developing countries, and analyse the use and management of the IPRs involved and their positive/negative roles in reaching the project's objectives.

Finally, *Chapter 7* will sum up the main IP obstacles and best-practices that we encountered, and present our recommendations on IP policies and instruments that can be applied by different actors along the innovation chain in order to make IPRs work towards meeting MDG 1c. Lastly, we will list our ideas regarding the valorisation and follow-up of this research project.

## 1.3 MDG 1c

The Millennium Development Goal 1c sets an ambitious target of halving the number of people who suffer from hunger during the period 1990 to 2015. Production of food is one of the cornerstones of this MDG. A distinction has to be made here between coping with hunger in urban and in rural areas. For the former, food should be as cheap as possible; for the latter the only way out of poverty is to have a fair price for the surplus food that is produced by smallholder farmers. Linking smallholders to markets is considered key in fighting rural poverty and hunger.[3] Producing food where it is most needed is the strategy for fighting hunger and malnutrition and has been a basis of the concept of food sovereignty. Recent hikes in food prices in the global market have indeed shown governments that relying on cheap imports is not a good strategy. The same accounts for food security within a country: promoting market-oriented production by large-scale farmers is an important strategy for national food security in developing agricultural economies. But for improving household food security and reducing hunger and malnutrition in rural areas, also improved production by rural smallholder farmers is necessary. Where increasing the yield potential and closing the yield gap are imperative in commercial production systems, smallholder farmers also prioritize yield stability as a key challenge, notably in situations of climate change.

Technology is important for farmers to improve their situation or even to cope with changing conditions such as climate change, decreasing soil fertility and reduction of farm sizes in many developing countries. Seed is an important carrier of technology that enables farmers to meet their pressing needs. The quality of seed determines the germination and health of the emerging crop and thus provides the yield potential; the genetic information embedded in seed, furthermore, provides the opportunities for the crop to withstand abiotic (e.g., drought, heat) and biotic (insects, diseases) stresses and it determines to a large extent the culinary and nutritional qualities of the harvested product. Seed – in combination with other agronomic improvements – has proven to be responsible for major transitions in agriculture both in industrialized and developing countries. A distinction has to be made, though, between "seed" as an input for any crop production - with its important features "quality" and "availability" - and "variety", which is the kind of seed, determined by the genetic build-up, and transferred from one generation to the next. Seed is the tangible and variety the intangible carrier of technology in crop production.

Opposite to inputs like fertilizers and pesticides, where inputs are bought on the basis of the needs per hectare, is improvement of varieties, which have since the start of the Green Revolution been considered scale-neutral, as a small investment in seed could bring large and lasting benefits for farmers. However, two major insights put questions to this widespread idea:

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[3] World Bank 2007. Available at <http://publications.worldbank.org/index.php? main page=product_ info&products _ id=22727> (accessed on March 16, 2011).

1) Crop improvement is in many cases directed to particular agro-ecologies, and improved varieties do better in the ecologies for which they have been selected and may even perform worse than the local materials in other situations.[4] Investment in breeding, both in the public and private sectors, needs to go to the largest 'recommendation domains'.[5] This means that breeding is much easier for uniform and ecologically benign conditions, and that variety development for resource-poor farmers in ecologically diverse areas is difficult.
2) When the technology embedded in seed has to be purchased every season (like with hybrids or under some intellectual property regimes), seed becomes as scale dependent as fertilizer.

This case study intends to contribute to MDG 1, target 1c by investigating the effects of different types of Intellectual Property Rights systems on the delivery of technology (embedded in the variety and delivered through seed) to resource-poor farmers in developing countries. We use a chain approach to analyse the flow of technology from high-tech innovation - in our case in the Netherlands - through a number of steps until it may reach resource-poor farmers in Africa, using Uganda as a typical example of an African least developed country.

## 1.4 The Innovation Chain

The chain from technology development (e.g., using molecular biology), through variety development (plant breeding), and seed production and distribution, is long and diverse. Different agents – researchers, breeders, seed technologists, businessmen – are involved and all have their specific environment that they work in. Funding is – parallel to profit expectations in the private sector - an increasingly important driver for providing direction of upstream public sector research, and for the research partnerships that are built. These in turn greatly affect the chance of the research products reaching – or being relevant for – resource-poor farmers. It is therefore important to identify to what extent, or if at all, MDG 1c is taken into account in such research funding policies.

Furthermore, public agricultural research institutions in both industrialized and developing countries have their own strategies in choosing the direction of research and in making available their products – in this case varieties or improved materials that commercial breeders can use to further develop varieties. These are based on their own mission and vision, which are affected by their sponsors. It is thus important to see how MDG 1c is reflected in such mission and vision and how these are translated into action.

Of particular interest is how the variety is translated into a usable product that can perform the promised transition: the seed. Who will multiply and distribute the seed and how may such seed reach the particular focus of this study – the smallholder farmer. This requires an analysis of the seed systems in the developing countries and the regulations that guide them.

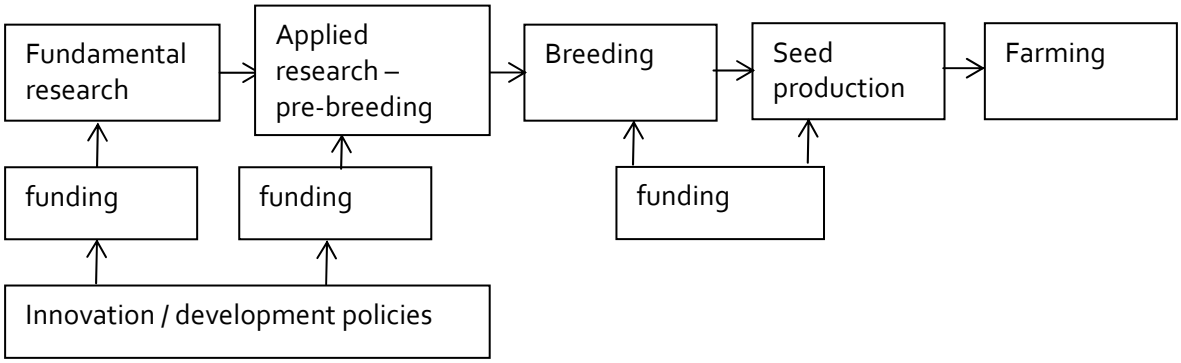
Intellectual Property Rights play a role in all these components – in public research policies and research partnerships, in expectations for financial revenue, and in downstream

4 Ceccarelli 1994.

5 Chambers, Pacey and Thrupp 1989.

arrangements between breeders and seed producers. Research on the impact of IP on technology for smallholder rural farmers thus needs to take into account the whole innovation chain where public, private and civil society partners play their respective roles.

***Figure 1.1: The innovation chain in Agriculture***




The innovation chain can be read in terms of a "push" where technology is translated into products for farmers, but also as a "pull" starting from the end user: how are the needs of smallholders and their access to the different seed systems (see below) translated into research programs and breeding objectives. Or – how are policies to increase agricultural productivity and reduce hunger translated into action with regard to seed-related research and development in both developing and industrialized countries? In the organization of this case study we take the latter approach. The smallholder rural farmer is the starting point of the analysis (Chapter 2).

## 1.5 Seed Systems: Formal – Informal

We know that for different crops, seed systems operate – even in the same country – in rather different ways. Seed has since the dawn of agriculture been produced by farmers themselves. In that process, they domesticated plant species and selected them to serve their crop production and consumption needs. The saving and selection of seed on-farm and the sharing of seed among neighbours and kin is called the *informal*, traditional,[6] local[7] or farmers' seed system.[8] Only in the 19th century, specialized seed production emerged in Europe and the US, and only since the rediscovery of Mendel's laws of heredity in 1900 scientific plant breeding started. In the 1970s, advances in molecular biology started to affect plant breeding, leading to a range of biotechnologies that can be used in breeding. Such seed provision by specialized actors, who are commonly regulated by government and industry rules, is dubbed the *formal* seed system.

Government involvement in seed systems originates from the late 19th century in Europe when farmers called for independent quality controls of seed (and varieties) in the market.[9] Seed quality and availability became not only a worry for each farmer, but also – within the framework of food security and rural development policies – a focus of government policies.

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6 Cromwell 1996.

7 Louwaars & van Marrewijk 1996.

8 Almekinders & Louwaars 1999.

9 Louwaars & Burgaud in press.

Public plant breeding research started in European countries in the early 20th century and was soon after introduced in their colonies, where investments were initially geared to cash crops like cotton and coffee. These initiatives formed the basis for public food and crop research institutes at the national level and – since the late 1950s - the international level. In this respect, agriculture is unique in that it has attracted significant public investment in research and development. With the development of a private seed sector, such investment went upstream towards more fundamental research in industrialized countries for most crops (in the Netherlands today only varieties of fruits such as the 'Elstar' apple, and small industrial crops, are bred by the public sector).

The fact that farmers can in principle reproduce their own seed is critical in the analysis of seed systems. In most developing countries, less than 10% of all the seed that farmers use is produced by specialized producers; the remainder is produced by farmers themselves or sourced locally (neighbours, relatives, and local grain markets). Also in most of southern Europe, these informal systems are predominant for major food crops.

In many developing countries, governments have invested in producing seed in order to boost national agricultural production. Since the structural adjustment strategies in the 1980s,[10] policy is to stimulate private sector involvement. However, in most developing countries, this is limited to crops where competition from farm-saved seed is less (e.g., hybrid maize and vegetables) and to farmers that can afford a good price for good seed. The importance of formal and informal system depends largely on:[11]

- the breeding method of the crop: self-fertilizing crops can easily be multiplied on-farm,
- the multiplication factor: for some crops, over 10% of the physical harvest has to be invested in the seed – e.g., groundnut - for others less than 1% - e.g., maize,
- the use of the crop: for marketed crops, smallholders commonly have some cash available for inputs such as seed and for mainly home consumed crops such cash and thus opportunities to purchase seed of new varieties is commonly lacking,
- Government policies.

Formal seed systems are organized and regulated through seed laws. These prescribe how the identity and purity of the seed has to be guaranteed (certification), how the physical qualities are to be tested and the minimum standards that have to be met. A certification system identifies different classes of seed in order to maintain the genetic qualities from the small amounts of seed that a breeder maintains to the quantities that farmers need. New varieties are tested for their 'value for cultivation and use' (VCU) in both Europe and most developing countries before they can be marketed. These rules protect farmers from using substandard seed and provide a level playing field for competing seed companies. Even though according to the letter of the law in many countries these rules also apply to informally exchanged or sold seed,[12] they are hardly ever implemented since they are not being policed in most situations. The rules and the effectiveness of their implementation have a significant effect on the operation of the formal seed sectors.

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10 Policies by the international Monetary Fund and the World Bank that made loans to developing countries subject to reduced public expenditure.

11 Almekinders & Louwaars 1999.

12 Louwaars 2005. Available at <http://www.grain.org/seedling_files/seed-05-07-2.pdf> (accessed on March 16, 2011).

In developing countries, the formal seed systems are very weak or non-existent for most food crops (cereals other than maize, most pulses and root crops like cassava) and do not easily reach resource-poor farmers with seed. Governments continue to invest in breeding of such crops, and researchers try to find ways to reach smallholders with varieties through alternative mechanisms such as participatory variety selection.[13]

Next to an indispensible input for agricultural production, seed is also a valuable commodity. In the Netherlands, the seed sector (including vegetative planting materials) is thriving. It has been responsible for a steadily increasing export value of seeds and planting materials over the last 20 years rising to an estimated € 2.5 billion, and involving a labour force of approximately 10 000.[14] The most important sector is horticulture: all top ten vegetable seed companies have their main office or an important research establishment in the Netherlands. The Netherlands is the global market leader in the development of new potato varieties and the export of certified seed potatoes, which amounts to some 700 000 tons a year.[15] It is therefore not an accident that the Netherlands is increasing its focus on seeds in its development policy.[16]

### 1.6 Intellectual Property Rights in Seeds

IPRs aim at stimulating innovation by providing a market incentive through exclusive rights. The patent system has not been applied for long in the seed sector because of ethical, legal, technical and food security reasons.[17] Separate, so-called '*sui generis*' systems emerged to support private investments in the sector. The US introduced a separate amendment to the patent law in 1930 to provide protection for some vegetatively propagated crops and in various European countries Plant Breeder's Rights (PBR) systems emerged soon after.

#### 1.6.1. Plant Breeder Rights

Plant Breeder's Rights systems were harmonized from 1961 onwards in the Convention on the Protection of New Varieties of Plants, and supported by the Union for the Protection of New Varieties of Plants (UPOV)[18] as the secretariat. They combine protection of the end product (the variety) while maintaining the agricultural tradition of exchange of materials and saving of seed by farmers –i.e., the *farmers' privilege*. By protecting only the end product (the variety) and by keeping these freely available for anybody for further breeding – i.e., the *breeder's exemption*, PBR systems have a strong open source character compared to patents. The right of farmers to save seed has been gradually restricted over the past 50 years in subsequent Acts of the UPOV Convention. In the latest Act of 1991, developed in response to the changes in agriculture in the then – developed country – members of the Union, countries may identify crops and conditions for which this applies, and the use of the saved seed is explicitly

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13 Almekinders & Hardon 2007.

14 TTI GG 2007. Available at <http://www.groenegenetica.nl/pro1/ general/start.asp?i=0&j= 0&k= 0&p=0&itemid=71> (accessed on March 16, 2011).

15 See FAOSTAT. Available at <http://www.potato2008.org/en/world/europe.html> (accessed on March 16, 2011).

16 WRR 2010.

17 Louwaars 2007.

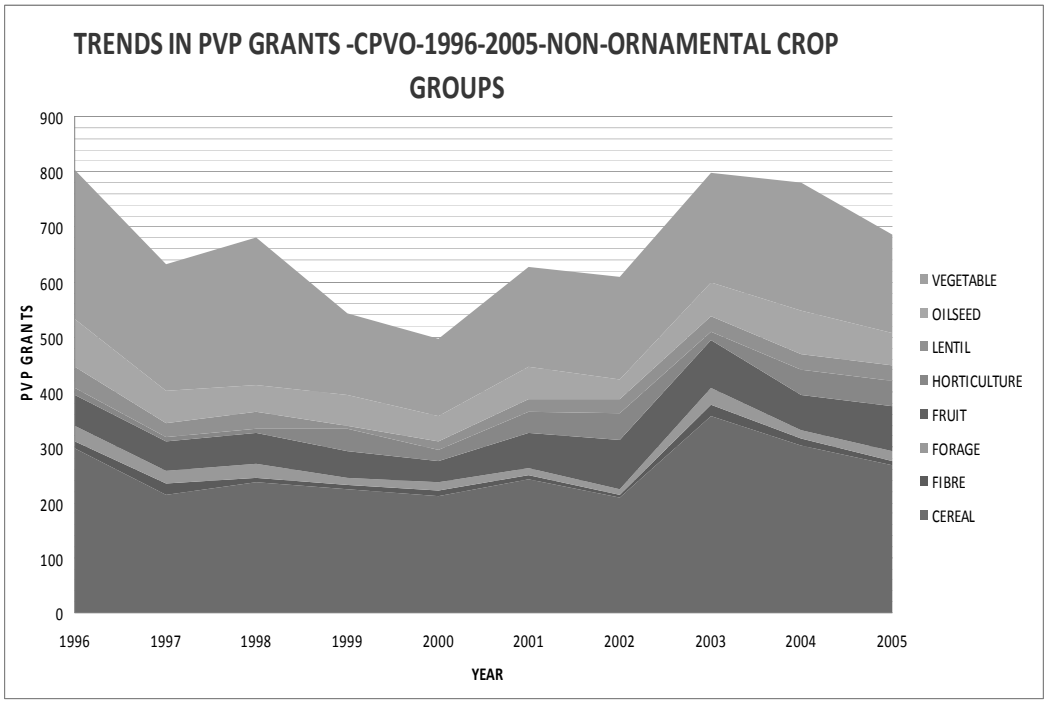
18 See <www.upov.int> (accessed on March 16, 2011).

restricted to the farmers' own holding. Thus, exchanging seed of protected varieties is not allowed anymore since this falls within the scope of the breeder's right.

The existence of such special protection systems for plant varieties was reflected in the TRIPS Agreement of the WTO,[19] which includes special provisions – in Article 27(3)b - for plant varieties. Countries may exempt plants and animals from patent protection, but when they do they should "provide for the protection of plant varieties either by patents, or an effective *sui generis* system or any combination thereof".[20] Many developing countries choose for the *sui generis* option – and some have become members of UPOV. Most countries follow the European example to exempt varieties from patentability. However the USA promotes the patent system in most of its bilateral trade negotiations.

The number of new Plant Breeder Rights[21] certificates issued by the Community Variety Protection Office of the European Union is some 2000 per year, mainly for ornamentals and some 700 for all other crops (fig 1.12).[22] Yet, it should be noted that for many vegetable crops no Breeder's Rights are applied for because of the hybrid nature of the varieties and because the economic lifetime of a new variety is often relatively short (3 to 5 years) due to on-going improvements.

***Figure 1.2: PBRs for non-ornamental crops in the EU (CPVO), 1996-2005.[23]***




19 See http://www.wto.org/english/tratop_e/trips_e/trips_e.htm (accessed on March 16, 2011); See PART I.

20 TRIPs 1995, Article 27(3)b.

21 Also referred to as Plant Variety Protection (PVP) or Plant Variety Rights (PVR).

22 Louwaars et al. 2009. The number of PBRs for ornamental crops is much higher, constituting about half of all PBR applications to the CPVO in 2008.

23 Idem, p. 31.

### 1.6.2 Patents

The patent system became relevant in the seed sector following court cases on the protection of biotechnological inventions in the US in the 1980s (see Box II-1) and the 'Biotechnology Directive' of the European Commission (98/44/EC) in 1998.[24] The number of patents in the field of plant breeding has rapidly increased, and together with technological developments and general globalization trends triggered a significant concentration in the global seed industry. A recent study reports that a total of 4.048 EPO patent applications relevant to plant breeding were submitted between 1980 and 2006. In the US, 5.506 patents were granted between 1980 and 2006, and 5.070 new ones applied for between 2001 and 2007 only (patent application data became available in 2001 only). Relevant patents are very much concentrated in the hands of a few multinational companies, with the top five patent applicants in Europe submitting 31.4% of all applications in the period 2000-2004, and even 71.7% in the US in the period 2003-2007.[25]

**Box II-1: Developments in the Patentability of Plants: Extension of Rights in the US**

- *Diamond vs. Chakrabarty* (1980)[26] involved the first patent on a man-made micro organism
- In 1985, plants were considered patentable following the ruling in *Ex parte Hibberd*.[27]
- *J.E.M. AG Supply, Inc. vs. Pioneer HiBred International, Inc.*,[28] made plant varieties protectable by utility patents independent of rights under either the Plant Patent Act of 1930 or the Plant Variety Protection Act of 1970.

The public research sector (including universities, governmental agencies, and private non-profit organizations) plays a significant role with some 25% of plant-based patent applications (fig 1.2),[29] which is considerably more than the 2.7% over all sectors.[30] The rate is however decreasing sharply of late in the US, likely because of changes in institutional policies following reports that only very few universities gain a net profit from the management of their protected intellectual assets. In Europe, this fall in the share of the public sector is much lower.

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24 See PART I.

25 Louwaars et al. 2009, pp. 34-36. The top five applicants in the EU and US, although in different order, are Pioneer Hi-Bred, Monsanto, Syngenta, BASF and Bayer CropSciences.

26 *Diamond vs. Chakrabarty* 1980.

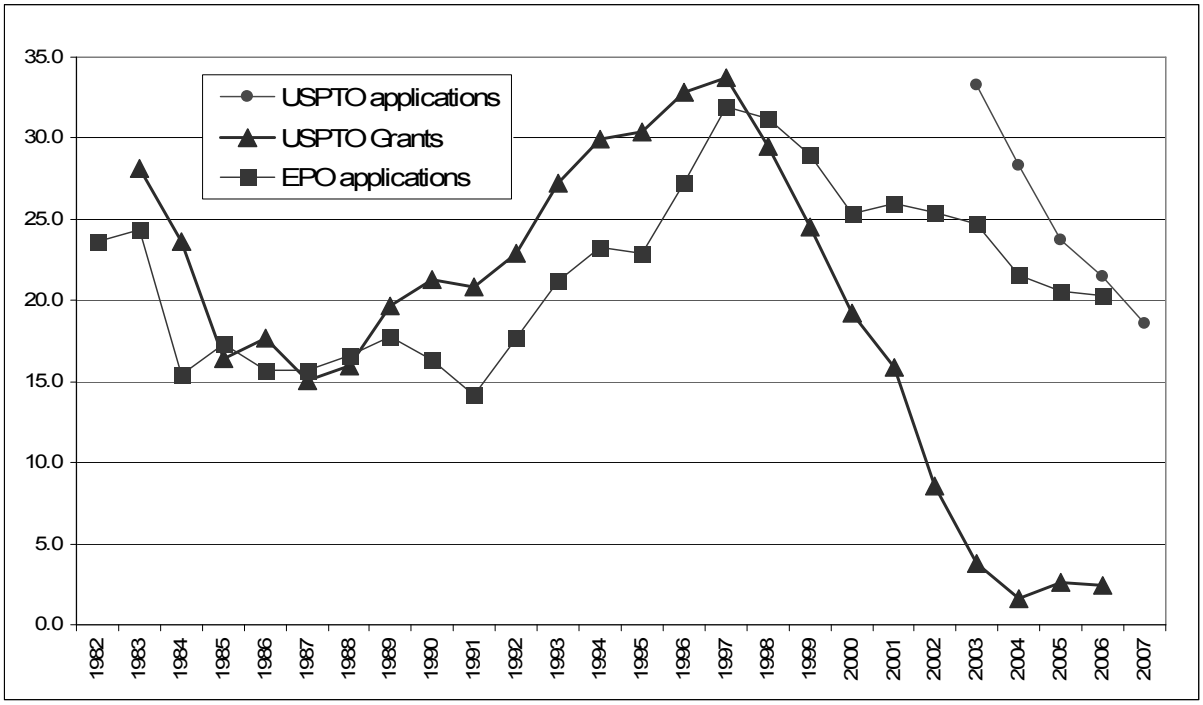
27 *Ex parte Hibberd* 1985.

28 *J.E.M. Ag Supply vs. Pioneer HiBred* 2001.

29 Louwaars et al. 2009, pp. 36-37.

30 Graff et al. 2003, p. 990.

***Figure 1.3: Share of the public sector in applied and granted plant-based patents (in %).***[31]




The strengthening of Intellectual Property Rightson plants indicates a gradual shift in the balance of power from farmers to breeders following the reduction of the farmers' privilege in Plant Breeder's Rights and from breeders to biotechnologists following the evolving patent system. A response is currently visible with some downward trend on the patentability of life science technologies in the US and Europe following recent court cases (see Box II-2), a more stringent approach by the European Patent Office under the title 'raising the bar', and debates in Europe to change the patent system to reduce the impact of biotechnology patents in the sector by various forms of breeders' exemptions in patent laws. African countries generally exclude plants and plant varieties from patent protection, following policies agreed upon at the level of the African Union.[32]

**Box II-2:** ***Developments in the Patentability of Plants: Recent Reduction of Patentability***

*A recent trend in case law in the US indicates that the applicability of the patent system in agriculture is reduced to some extent. Patents on expressed sequence tags (ESTs) have not been accepted since 2005 because of insufficient proof of 'industrial application' and the publication requirements (In Re Fisher).*[33] *Recent rulings on patents on (human) genes indicate further restrictions based on a perceived lack of inventiveness (In Re Kubin and Goodwin)*[34] *and novelty (Association for Molecular Pathology et al. vs. U.S. Patent and Trademark Office et al.).*[35] *The United States Patent and Trademark Office (USPTO) will respond to these rulings with a more restrictive policy towards granting patents on plant traits.*

[31] Louwaars et al, 2009. p. 37.

[32] Louwaars *et al.* 2006.

[33] Re Fisher 2005.

[34] Re Kubin and Goodwin 2009.

[35] *Association for Molecular Pathology et al. vs. U.S. Patent and Trademark Office et al.* 2010.

*In Europe, recent decisions are also curtailing patents on plants to some extent. The European Court of Justice ruled in July 2010 (In* Monsanto Technology LLC vs. Cefetra BV and Others*)[36] that Monsanto cannot claim rights on soybean meal imported into Europe grown from soybean seeds that are reproduced without the consent of Monsanto in Argentina (where the company does not hold a patent on the Roundup Ready technology).It ruled that under the Biotechnology Directive genetic material can be protected only when it is performing its function, and that because the DNA sequences in the imported soy meal are considered "dead material" no longer performing their function, they were no longer protectable pursuant to Article 9 of the Directive.*

*In an appeal by Limagrain and Syngenta before the Enlarged Board of Appeal of the European Patent office against a patent on a breeding method for broccoli, the board decided in December 2010 that the methods are to be considered essentially biological and thus not patentable.[37]*

IPRs aim at stimulating innovation by providing a market incentive through the exclusive rights attached. However, how IPRs affect predominantly non-market actors, such as food insecure smallholder farmers, is unclear. Could IPRs stimulate the development of varieties specifically adapted to smallholder conditions, and could they support the development of more effective distribution mechanisms of improved seed materials to near-subsistence farmers? Or could they steer research priorities in the public sector away to more profitable crops and markets? And what are the consequences of the growing role of patents in the biotechnology sector for research partnerships between industrialized and least developed countries? These are just a few questions that relate to the overall research question of the project about the roles of IPRs in agriculture and meeting the target of halving the proportion of hungry people by 2015 as set out in MDG 1c.

### 1.7 Other Rights

Apart from patents and Plant Breeder's Rights, some other rights are important in the agricultural sector. These are other Intellectual Property Rights, and rights arising from biodiversity law, and market/contract regulations.

#### 1.7.1 Other IPRs

In the commercial seed sector, similar to all other businesses, trademarks are of vital importance to protect a company's reputation and thus the value of its products in the market. Seed producers in developing countries have indicated that in an emerging seed market, trademarks are at least as important as other IPRs.[38] In few cases, Geographical Indications may – when connected to particular local varieties – provide some protection as well. In advanced plant breeding, trade secrets are gaining importance. This is particularly the case in protecting the parent lines of commercial hybrids. There is also an increasing tendency to protect parent lines through PVP.

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36 *Monsanto Technology LLC vs. Cefetra BV and Others* 2010.

37 See <http://documents.epo.org/projects/babylon/eponet.nsf/0/E72204692CFE1DC3C12577F4004BEA42/$File/G1_08_en.pdf> (accessed on March 16, 2011).

38 World Bank 2006.

### 1.7.2 Rights on Biodiversity and Traditional Knowledge

National laws based on international agreements on biodiversity are being developed in an increasing number of African countries. Such laws regulate access and use of genetic resources, the building blocks of plant breeding, both in terms of international exchange and with regard to the use of farmers' varieties as parents in breeding programs. The Convention on Biological Diversity (CBD)[39] formalized national sovereign rights over (plant) genetic resources and allowed countries to make access to such resources subject to "Prior Informed Consent" and "Mutually Agreed Terms". It also assigns rights to local and indigenous communities on their biodiversity and related traditional knowledge. The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)[40] furthermore includes Farmers' Rights, including the right of farmers to:

- protect their traditional knowledge relevant to PGRFA
- share in the benefits arising out of the use of PGRFA
- participate in decision-making at the national level relevant to PGRFA
- save, exchange and sell farm-saved seed (subject to national law)

Such rights affect the access to genetic resources and their use by plant breeders and farmers, and may create some confusion with regard to the operation of the patent and breeder's rights.[41]

In November, the Nagoya Protocol was concluded by the Conference of Parties of the CBD[42]. This protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their use provides an important step towards globally agreed norms. For the purpose of this report it is particularly important to note that agreements for particular components of biological diversity can be made, and that the international treaty is explicitly mentioned in the Protocol.

### 1.7.3 Market Regulations

A number of market regulations also affect the use of seeds and/or agricultural technologies in a variety of ways:

- Seed certification
  Seed certification regulations aim at guaranteeing seed quality. They regulate a generation system starting with small amounts of very pure breeder's seed that are the basis of each multiplication cycle. Access to such breeder's seed creates some opportunities for the breeder to exclude parties from producing certified seed. This can thus be considered a non-IP exclusive right.

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39 CBD 1992.

40 ITPGRFA 2001.

41 Louwaars 2007.

43 Involves production of high quality seeds of improved varieties in a seed program and this may include commercial companies, parastatals, regulatory agencies and registered cooperatives. The seed program is involved in plant breeding and development of varieties, controlled seed multiplication, careful seed processing and packaging, seed quality control and certification.

- Biosafety laws
  National biosafety laws – based on the Cartagena Protocol of the CBD – require parties who introduce a genetically modified crop to provide evidence of the environmental and food and feed safety of their products. In most countries, these biosafety dossiers are proprietary and confidential. Even though breeders may use these plants for further breeding under plant breeder's rights, they may not be able to market their new (GM) varieties without negotiating access to the biosafety dossier – leading to non-IP exclusive rights again. The alternative would be to do the whole biosafety research all over again, which is extremely costly.

- Contract law
  Finally, the role of contract law should not be underestimated. Intellectual Property Rights are implemented by the holder through research and /or license contracts. Depending on the contract law, they are free to agree on any clause affecting research with and commercialization of the protected subject matter. When technologies are accessed by a research institute under a contract with the provider, they are commonly not allowed to transfer it to third parties, which might affect collaboration with developing countries. When developing country research institutes want to access proprietary technology, they may enter into a contract with a foreign technology provider even if the technology itself is not protected in their country, for example if the patent holder did not claim protection in the developing country or if the national patent authorities did not grant the application. In such cases, the signatory parties to the contract are bound by the agreement. Contract law determines what kinds of clauses are permissible, and thus what the reach of the agreement in the innovation chain may be.