Imagined Nature: Narratives and Metaphors in the Co-Production of Biotech Patentable Inventions

By

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Abstract

Since the 1970s, modern biotechnology and its innovative products have been central to the development of what is considered to fall within the scope of patent eligible subject matter.
In major patent systems, an interpretation of the definition of patentable invention has evolved to allow matter qualifying as patent eligible to include techno-scientific products and processes that could not have been envisaged when patent systems were first established.
However, modern biotechnology and its bio-artifacts have proved challenging, as they have increasingly raised social opposition and ethical concerns from non-governmental organisations and civil society.
Biotech patent claims on genetically modified organisms, DNA sequences and genes, isolated human biological materials and human embryonic stem cells have questioned more radically than other technological claims the meaning of nature and artifact, subject and object, discovery and invention.
In the United States, Canada and under the European Patent Convention (EPC), several landmark biotech patent cases involving these kinds of inventions have settled the patent eligibility of these products. In these cases, judges, parties, patent officers and *amici curiae* have drawn on a rich repertoire of metaphors that, by defining the "nature" and ontology of the claimed invention, sustained or rejected the allocation of intellectual property rights over it.
This thesis addresses whether and how metaphors and the analogies they entail have been resorted to in judicial decisions and the administrative discourse of patent offices (practices and guidelines) to expand and limit the scope of patentable subject matter. Moreover, the thesis is engaged in explaining the discrepancies that marked the development of what is a patentable invention in these three jurisdictions.
The main hypothesis of the thesis is that the use of the metaphors of the *machine*, *molecule* and *code* has proved pivotal in expanding the scope and stabilizing the meaning of patent eligible matter.
These metaphors have been endorsed in technoscientific domains of research and they could be deemed what Ruse has called "root metaphors", metaphors that were pivotal in orienting the study of the phenomena of life. All these metaphors, as this work illustrates, imply an atomistic and reductionist view of the living organisms, which has largely sustained their patent eligibility.
Drawing on the insights offered by cognitive linguistics, the thesis explains that, by prompting analogies, metaphors define the "is" and the "ought" of a concept. Their analysis, therefore, enables an account of how descriptive and normative issues have been entangled in sustaining and settling the meaning of molecular biotech products, so that the metaphorical definition of the nature of the invention conveyed or not its patent eligibility.
The thesis argues and shows, furthermore, that the judicial and administrative narratives in which these metaphors have been employed have been likewise influential and backed particular sociotechnical imaginaries of life and nature, which have been pivotal in defining what is natural and artificial and in framing individual and collective identities in molecular terms.
This work relies, in particular, on Science and Technology Studies' framework centered on concept of co-production, namely the insight that the natural and social orders are produced together. According to this framework, the *is* and *ought* of the world are continuously established, through the authoritative discourses of science and law, which define what is a claimed invention within a technological field and how it should be governed.
The co-productionist framework is fundamental to pinpoint and understand the relevant *nexus* that narrative analysis should address and explain in the thesis (which has been articulated by Calvert and Joly): the relationship between making knowledge – the creation of ontologies – and the production of intellectual property.

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BPAI – Board of Patent Appeals and Interferences of the United States Patent and Trademark Office

CAFC – United States Court of Appeals for the Federal Circuit

cDNA – Complementary Deoxyribonucleic Acid

CIPO – Canadian Intellectual Property Office

CJEU – Court of Justice of the European Union

CNIPA – China National Intellectual Property Administration

DNA – Deoxyribonucleic Acid

EBA – Enlarged Board of Appeal of the European Patent Office

EPC – European Patent Convention

EPO – European Patent Office

EST – Expressed Sequence Tag

FCA – Federal Court of Appeal of the United States of America

GMO – Genetically Modified Organism

HBMs – Human Biological Materials

hESC – Human Embryonic Stem Cell

IP – Intellectual Property

IPRs – Intellectual Property Rights

NGO – Non-Governmental Organisation

rDNA – Recombinant Deoxyribonucleic Acid

RNA – Ribonucleic Acid

SCC – Supreme Court of Canada

SCOTUS – Supreme Court of the United States of America

SIPO – State Intellectual Property Office of China

S&TS – Science and Technology Studies

TBA – Technical Board of Appeal of the European Patent Office

TRIPs Agreement – World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights

USPTO – United States Patent and Trademark Office

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Introduction

Biotechnology and its innovative products have been increasingly at the core of the development of the concept of "patent-eligible matter" over the last forty years,[1] as genetic engineering technologies have developed.

In the 1970s, the improvements in recombinant DNA technology made the commercial products and applications of biotechnology less speculative and resulted in a series of patent applications involving genetically modified microorganisms and organisms.

Several national and regional patent systems (such as the one established by the European Patent Convention)[2] of developed countries had, first, to tackle the patentability of genetically modified microorganisms and organisms and decide whether these kinds of products fulfilled the threshold of patent eligibility and qualify as "patentable inventions".

They had later, since the 1990s, to focus on the patent eligibility of DNA sequences and human and primate cell lines (such as stem cells lines) and determine whether particular patentability rules should be set out to draw the boundaries between the molecular body as a natural object and as an artificial patent eligible one.

Furthermore, these systems had to address whether the scope of protection for gene sequences should be absolute[3] or limited to the possible function and uses set out in the patent application.[4]

The decisions of patent examiners, offices and judges on this matter have impinged on the definition and ontology of these products as possible objects of intellectual property. Although patent litigation focusing on patent eligibility may seem to involve just techno-legal

[1] See on the point, Dan L Burk, 'Patents and Related Rights. A Global Kaleidoscope' in Rochelle C Dreyfuss and Justine Pila (eds), *The Oxford Handbook of Intellectual Property Law* (Oxford University Press 2018) 461, 470.

[2] The European Patent Convention or Convention on the Grant of European Patents of 5 October 1973 is an international patent treaty, which entered into force on 7 October 1977 and established a system for granting national patents in any number of the Contracting States. Justine Pila, *The Subject Matter of Intellectual Property* (Oxford University Press 2017) viii, 45.

[3] Absolute protection on a product entails that "the patent on a new product applies without restriction, independent on how the product is used". Franz-Josef Zimmer and Svenja Sethmann, 'Act Implementing the Directive on the Legal Protection of Biotechnological Inventions in Germany (BioPatG)' (2005) 24(5) Biotechnology Law Report 561.

[4] For example, the German implementation of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions with the BioPatG introduced in 3 December 2004 by the Federal government limited the patent protection for human gene sequences to the specific function of the sequence or its application. ibid.
However, as Pila illustrated, under Directive 98/44/EC (Recital 23 and Article 9) "isolated genes and other products 'containing or consisting of genetic information' are protected as purpose-limited products, namely products of (and intended for) used for a specific purpose only". Pila (n 2) 107.

issues which are confined to intellectual property, it has proved to be far more challenging and has entailed broader public policy implications for biotechnology.

IPRs over these kinds of inventions, in fact, have turned out to be controversial in different political and legal contexts, as many biotechnological patents have been questioned and challenged because of the ethical and social concerns related to their use and commercialization voiced by NGOs and civil society.[5]

In 1980, the Supreme Court of the United States settled, first, the issues of the patentability of genetically modified microorganisms in *Diamond v. Chakrabarty*,[6] by claiming that the liveliness of a product was not relevant to determine its patent eligibility and concluding that "anything under the sun that is made by man" was patentable, provided it fulfilled the other patent requirements of novelty, usefulness and non-obviousness.

As Bracha pointed out, in the United States new patent subject matter has not engendered "legal fragmentation":[7] Innovative products have been subsumed under the existing flexible statutory classes of patentable subject matter and, therefore, specific rules for particular industries have not been set out.

The product of nature doctrine, which originated in the 19th century, instantiates this approach, centered on the application of a general definition of "patentable subject matter" and possibly adjusts it. The doctrine excludes the patent eligibility of laws of nature, physical phenomena and abstract ideas, and constitutes the main form of adaptation of the general rule of "patentable invention".[8]

Just a few years later, the Canadian courts and the boards of the European Patent Office had to confront with the patent eligibility of GMOs. Their ruling and arguments on the patentability of GMOs partially differed from the U.S. view that "anything under the sun that is made by man" is inherently patentable.[9]

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[5] For example, the birth of "Dolly" in 1996, the first mammal cloned by nuclear transfer, raised a large public debate about the morality of patenting clones in several countries, in the 1990s. In the United States, the Congress enacted the Human Cloning Prohibition Act, in 1998, which banned human-somatic-cell-nuclear transfer technology (H.R. 2235, 90th Leg., 1997-98 Reg. Sess. (III. 1997)).

[6] *Diamond v. Chakrabarty* 447 U.S. 303 (1980) 206 USPQ 193.

[7] Oren Bracha, 'The Emergence and Development of United States Intellectual Property Law' in Rochelle C Dreyfuss and Justine Pila (eds), *The Oxford Handbook of Intellectual Property Law* (Oxford University Press 2018) 235, 254.

[8] ibid. See also Christopher Beauchamp, 'Patenting Nature: A Problem of History' (2013) 16(2) Stanford Technology Law Review 257.

[9] On the concept of "inherent patentability" or "patent eligibility" see Justine Pila, 'Patent Eligibility and Scope Revisited in Light of *Schütz v. Werit*, European Law, and Copyright Jurisprudence' in Rochelle Cooper Dreyfuss and Jane C Ginsburg (eds) *Intellectual Property at the Edge: The Contested Contours of IP* (Cambridge University Press 2014) 382.

In 2002, more than 17 years after the patent application was filed, the Supreme Court of Canada, in *Commissioner of Patents v. President and Fellows of Harvard College*,[10] judged genetically modified higher life forms not patent eligible, even though genetically modified microorganisms had been held patentable in Canada since 1982.[11]

The European Patent Office (EPO) granted in 1992, following a decision of the Technical Board of Appeal (case T19/90 Onco-mouse/HARVARD)[12] a patent regarding the same kind of invention litigated in Canada, "transgenic non-human mammals" genetically modified to be cancer-prone, but had to face several patent oppositions from NGOs which led it to restrict the patent to mice.

How could these differences of rulings and rationale in judicial decisions be adequately explained across the patent systems of these developed countries, which had worked towards the substantial harmonisation of the concept of patent eligibility and the requirements for invention?[13]

How could these differences across jurisdictions be accounted for, in particular after the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) established a common definition of patentable subject matter[14] and a standard for patent protection in the WTO's countries?[15]

Why did the major patent offices in the world still apply different standards of patentable subject matter regarding biotechnology and living matter?[16]

How, furthermore, can this hiatus be accounted for in jurisdictions with similar patent statutory rules, such as the United States and Canada, in which the definition of patentable

[10] Supreme Court of Canada, *Commissioner of Patents v. President and Fellows of Harvard College*, 5 December 2002, (2002) 4 R.C.S. 425.

[11] *Re Application of Abitibi* CO, 62 C.P.R. (2d) 81 (1982).

[12] Decision of Technical Board of Appeal 3.3.2 dated 3 October 1990, T19/90 Onco-mouse/HARVARD, (1990) 12 OJ EPO 476.

[13] The United States and Member Countries of the EPC and European Union highly promoted and supported the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights. See Duncan Matthews, *Globalising Intellectual Property Rights: The TRIPs Agreement* (Routledge 2002) xii, 30-40.

[14] Article 27, WTO, Agreement on Trade-Related Aspects of Intellectual Property Rights (opened for signature 15 December 1993 and entered into force 1 January 1995) 1869 UNTS 299, available at <https://www.wto.org/english/docs_e/legal_e/27-trips.pdf>.

[15] See in particular, with reference to patents, Articles 27-34, WTO, Agreement on Trade-Related Aspects of Intellectual Property Rights, available at <https://www.wto.org/english/docs_e/legal_e/27-trips.pdf>.
On the efforts made by patent offices of developed countries, in the 1990s, to harmonise patent systems, see *Patent Leaders Endorse Efforts to Harmonize Protection Systems No.7*, (1999) 13 World Intellectual Property Report (BNA) 245.

[16] Michael North, 'The U.S. Expansion of Patentable Subject Matter: Creating a Competitive Advantage for Foreign Multinational Companies' (2000) 18 Boston University International Law Journal 111, 112.

invention is alike and includes the same classes of patentable subject matter, namely "machine, manufacture, composition of matter and process"?[17]

Although in Europe the full operation of the Unified Patent Court[18] might be able to narrow down these discrepancies in the future, it is questionable whether some fundamental differences in framing the scope of patent eligible matter could be eliminated, not least because of the uncertainties of its actual implementation.[19]

Major differences in interpreting and applying the concept of patentable subject matter persist in developed countries and their stability cannot be fully explained by resorting to the distinctive national and regional provisions, which characterize specific patent systems, and the flexibilities allowed by the TRIPs Agreement for its implementation.

Scholars have long been engaged in understanding why contemporary biotechnology and its inventions raised such controversies. Consequently, biotechnology has become the test-bed of the concept of patent eligibility in recent years.

However, they have struggled to explain why biotechnological inventions prompted substantial discrepancies in the interpretation of what a patentable invention is across jurisdictions and also within the EPC patent system, which seemed to have settled the issues of their patent eligibility.

It has been illustrated that the development of biotechnology industry has hinged on the favorable patent system framework offered in some countries, such as the United States,[20] whose case-law and guidelines of the United States Patent and Trademark Office (USPTO), which addressed some of the legal issues concerning the patentability of biotech products,[21] backed its expansion since the 1980s.[22]

Nevertheless, in the last few years the U.S. Supreme Court has partially reversed course and re-framed the interpretation of patentable subject matter as far patents on isolated human

[17] In the U.S., Title 35 U.S.C. § 101. In Canada, Section 2, Patent Act, R.S.C., 1985, c. P-4.
In 1869, Canada enacted the first federal patent statute, which was aligned with the U.S. Patent Act. Daniel Gervais, 'The Emergence and Development of Intellectual Property Law in Canada' in Rochelle C Dreyfuss and Justine Pila (eds), *The Oxford Handbook of Intellectual Property Law* (Oxford University Press 2018) 265, 286.
[18] Agreement on a Unified Patent Court [2013] OJ C 175/1 ("UPC Agreement").
[19] Several uncertainties regard the decision of the United Kingdom, in June 2016, to leave the European Union and how the UK will be able to ratify the UPC Agreement. Moreover, some uncertainties are related to the impact of the decisions of the CJEU on the UPC jurisprudence.
[20] In the U.S., the USPTO and the courts have rarely addressed issues of morality and public policy. Jasemine Chambers, 'Patent Eligibility of Biotechnological Inventions in the United States, Europe and Japan: How Much Patent Policy Is Public Policy?' (2002) 34 George Washington International Law Review 223, 226.
[21] The Utility Examination Guidelines set out the criteria of isolation and purification to back the patent eligibility of DNA sequences. Department of Commerce, United States Patent and Trademark Office, Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, 1092-1099.
[22] Chambers (n 20) 224.

native DNA sequences[23] and therapeutic methods[24] are concerned, by holding that they fall within the exclusions of the product of nature doctrine.

In order to tackle these differences part of the scholarship has focused on the debates on biotechnology and genetic engineering in different political contexts and their relationship with IPRs, focusing on the attitudes of the public towards this technology and its regulatory policies.[25]

A substantial amount of scholarship has been devoted to internal IP debates about the function and evolution of "inherent patentability" across jurisdictions, in order to make a critical assessment of its development in specific areas of biotechnology (for example, genetic diagnostic methods) and has suggested more balanced approaches to sustain IPRs over biotech inventions without hindering innovation.[26]

Another part of the legal literature has been committed to examining the moral problems related to patenting biotech inventions, in particular the ones involving human embryonic stem cells (hESCs).[27]

The modern concept of invention was outlined in the 18th century, "when lawyers and administrators began systematically to make the distinction between ideas and embodiments, or between the invention and the material artefact in which it was expressed".[28] It has been noted that the process of construction of the modern invention as an intangible abstract thing entailed jurisprudential and administrative decisions and technoscientific practices to back the separation of the abstract idea and knowledge from its embodiments and the de-materialization of the material artifact.[29] However, this process turned out to be complex and cumbersome, especially in particular areas of technological innovation, [30] such as biotechnology.

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[23] Supreme Court of the United States, *AMP, et al, v. Myriad Genetics*, et al., 13 June 2013, 133 S.Ct. 2107 (2013).

[24] Supreme Court of the United States, *Mayo Collaborative Services, et al. v. Prometheus Laboratories* 132 S.Ct. 1289 (2012).

[25] See Martin W Bauer and George Gaskell (eds), *Biotechnology: The Making of a Global Controversy* (Cambridge University Press 2002) v.

[26] See, in particular, Pila (n 2 and 9). Isabelle Huys, Gertrui Van Overwalle and Gert Matthijs, 'Gene and Diagnostic Method Patent Claims: A Comparison under Current European and US Patent Law' (2011) 19 European Journal of Human Genetics 1104. Geertrui van Overwalle (ed), *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Regimes* (Cambridge University Press 2009) v.

[27] Aurora Plomer and Paul Torremans (eds), *Embryonic Stem Cell Patents: European Law and Ethics* (Oxford University Press 2009) vii.

[28] Alain Pottage and Brad Sherman, *Figures of Invention: A History of Modern Patent Law* (Oxford University Press 2010) v, 1.

[29] ibid, 1-14.

[30] It has proved particularly difficult as far as computer programs and business methods patent claims are concerned, but these kinds of inventions have not elicited social opposition and moral concerns. See Kelvin W

The problems that patent systems of developed countries faced in this area are related to the fact that establishing this distinction has proved to be more difficult, as contemporary biotechnology and its bio-artifacts challenge deeply socially shared ontological and practical views about what is natural and artificial, moral and immoral.

As far as patent law and biotechnology are concerned, the main issues regard setting the epistemic and ontological boundaries between discovery and invention, nature and technical artifact and providing a rationale for them. The definition of these boundaries has, nevertheless, beckoned substantial public attention in developed countries.

Landmark biotech patent decisions of the courts and boards have brought about the development of patent eligible matter. Although they have been largely commented and analysed, with the exception of few scholars,[31] the literature has totally overlooked the metaphorical dimension embedded in these judgements, centered on defining what the claimed invention was.

In particular, it has disregarded to what extent, in handling the delicate problem of defining "the nature of the claimed invention", judges and parties have drawn upon metaphors which backed or undermined the subsumption of products, such as GMOs, DNA sequences and human embryonic cell lines, under the statutory classes of patentable inventions.

Moreover, the relevance of metaphors as means of legal interpretation and integration of the law has been completely neglected by the general theory of legal interpretation. Metaphors are not contemplated as a matter of legal inquiry, because it is assumed that they should not be resorted to in legal reasoning, which aims at providing certainty in defining statutory categories.

This thesis aims to fill this gap in the literature concerning the development of patentable subject matter prompted by new biotechnological innovative products, by fully examining whether and to what extent metaphors have been at the core of the development of patent eligibility in three jurisdictions of highly developed countries: the United States, Canada and the EPC system.

Willoughby, 'How Much Does Technology matter in Patent Law? A Comparative Analysis of Doctrines of Appropriate Patentable Subject Matter in American and European Patent Law' (2008) 18(1) Federal Circuit Bar Journal 63, 95-119.

[31] Graham Dutfield, "'The Genetic Code is 3.6 Billion Years Old: It's Time for a Rewrite': Questioning the Metaphors and Analogies of Synthetic Biology and Life Science Patenting" in Lever Annabelle (ed), *New Frontiers in the Philosophy of Intellectual Property* (Cambridge University Press 2012) 172; Graham Dutfield, 'Who Invents Life: Intelligent Designers, Blind Watchmakers, or Genetic Engineers?' (2010) 5(7) Journal of Intellectual Property Law & Practice 531. Mariachiara Tallacchini, 'Diritto e scienza' in Bruno Montanari (ed), *Luoghi della filosofia del diritto* (Giappichelli Editore 2012) 145; Mariachiara Tallacchini, 'La trappola e il topo: la brevettabilità della materia vivente' in Amedeo Santosuosso (ed) *Le tecniche della biologia e gli arnesi del diritto* (Ibis 2003) 203.

Although the thesis comments also the landmark Australian biotech patent case *D'Arcy v Myriad Genetics*, which involved the BRCA1 gene,[32] Australia it is not one of the jurisdictions of comparison. The main purpose of its analysis is rather to show that the same metaphors and judicial arguments employed in the U.S., in the case concerning the same patent, have been largely embraced by the Australian courts, because of their rationale.

The main research hypothesis of the thesis is that the use of metaphors in the legal-jurisprudential discourse, because of the analogies that they entail, has substantially contributed to shape the scope of patentable subject matter, by eliciting a shifting in the meaning of the statutory classes of patentable subject matter and the definition of invention in the three jurisdictions subject to analysis.

Moreover, the hypothesis deems the conceptual metaphors of the *molecule*, *machine* and *code* pivotal in framing and re-framing the scope of patent eligibility, by fostering particular views of the nature of claimed biotech inventions which sustained the allocation of IPRs over them.

Scholars[33] have explained that, in understanding and litigating inventions, the concept of the machine has proved pivotal in the U.S. and in Canada. This concept is embedded in the definition of patentable invention and has been at the core of what has been called "mechanical jurisprudence".[34] As Pottage and Sherman illustrated, in the 19th century the machine has been used by U.S. patent lawyers to draw rules for the very concept of invention and its material embodiment.[35]

This kind of approach rested on the fact that patent litigation in the first part of the 19th century focused on mechanical devices, but has turned out to be far more influential, as the discourse of the mechanical jurisprudence used in infringement patent cases has been applied to GMOs and genetically modified microorganisms that are viewed and dealt with, judicially and administratively, as bio-artifacts like machines.

Ruse has illustrated that some metaphors, which he called "root metaphors", have largely oriented the scientific discourse throughout the centuries and proved to be more important and basic than others epistemically and heuristically.[36] In Western Modern Age the metaphor of the machine turned out to be the main metaphorical device in order to understand and explain the functioning of organisms and, in particular human beings, society and the world.[37]

[32] High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, 115 IPR 1, 41.
[33] See Bracha (n 7) 251; Pottage and Sherman (n 28) 14.
[34] Pottage and Sherman (n 28) 14.
[35] ibid.
[36] Michael Ruse, *Science and Spirituality: Making Room for the Faith in the Age of Science* (Cambridge University Press 2014) vii, 24.
[37] ibid, 54-116.

All these metaphors, but primarily the metaphor of the *molecule*, have been embraced in scientific domains of research and entail a molecular view of life, as they all convey an atomistic and reductionist description of what claimed inventions – such as GMOs, genes, cell lines – are (see, on this point, chapter two).

Furthermore, the thesis is engaged in probing whether these metaphors and narratives about the patent eligibility of biotech products prompted different sociotechnical imaginaries of life and nature which marked the U.S., Canada and the EPC[38] system.

In all these systems, as it will be illustrated in the chapters of the thesis, the development of biotechnology has been fostered by narratives of social progress, industrial modernization and competitiveness. Institutional support to biotechnology has been deemed fundamental in order to produce socially valuable products, benefit society and promote desirable futures. However, in particular as far as IP over gene sequences is concerned, the metaphors and narratives in patent litigation have led to a public re-discussion of the contract between the inventor and society and the already settled sociotechnical imaginaries of life and nature constructed around biotechnology.

The thesis will address the following research questions related to the hypothesis:

1. How and to what extent has the use of metaphors and the narratives in which they are embedded impinged on settling and unsettling the scope of patentable subject matter?
2. Which are the main recurring metaphors in the patent judicial discourse?
3. How, and to what extent, have these metaphors been validated by the scientific expertise, jurisprudential arguments and the practices of patent offices?
4. What were the effects and implications of drawing on metaphors in the legal discourse in defining the "nature of the biotechnological invention"?
5. Have the metaphors of molecule, code and machine, been endorsed in specific areas of research, such as molecular biology and genetics, which are linked to the development of biotechnology? If yes, how in these domains of research have they been validated?
6. Are there other factors which, together with metaphors and narratives, proved to be pivotal in settling the patent eligibility of biotechnological inventions?

[38] The EPC has established a system for granting national patents in any Member State of the Convention. This system is supplemented by the EU Biotech Directive (Directive 98/44/EC) and Supplementary Protection Certificate Regulations under Article 114 TFEU. See Pila (n 2) 45.

7. How have these narratives and counter-narratives impinged on the construction of collective and individual identities and backed a different interpretation of the social contract between the inventor and society?
8. Did metaphors and narratives contribute to the creation of techno-imaginaries of what is life and nature in these three political and legal contexts?

In order to address these questions, the thesis draws on narrative analysis, which offers a set of valuable methodological resources to examine whether and how the metaphors of molecule, machine and code have been resorted to in the scientific and jurisprudential discourse, in the administrative guidelines of patent offices and also in patent drawings (see, on this point, chapter three).

The recourse to narrative analysis as an appropriate means of inquiry to deal with these specific research questions has several benefits.

Narrative analysis is a qualitative methodology which focuses on meaning and discourse to understand how individuals, collectivities and institutions make sense of human experience. Narrative is any kind of "spoken or written presentation", whose organizational scheme is expressed in a story form.[39] It is a powerful practice of knowledge-making particularly when it is employed by institutions, since it supports and justifies their decision-making process and its outcome.

It entails several analytical advantages in order to understand the technoscientific and social decisions which involved biotechnology and its innovative products, as it is contextual and textually accurate. Its practices, therefore, enable the researcher to pinpoint and characterize through a precise textual analysis how, in the face of technologies and products which challenge well-established understanding of nature such as genetic engineering, new emerging orders have been settled and justified. Moreover, they help the scholar notice how and where the shifting of meanings of terms has been brought about.

A narrative-based methodology offers several benefits in terms of pursuing and achieving what the anthropologist Clifford Geertz referred to as "thick description",[40] namely a description which explores how human behavior becomes meaningful by focusing on the context and does not take coherence as a major test of validity.[41]

[39] Donald E Polkinghorne, *Narrative Knowing and the Human Sciences* (State University of New York Press 1988) vii.
[40] Clifford Geertz, 'Thick Description: Toward an Interpretive Theory of Culture' in Clifford Geertz, *The Interpretation of Cultures* (Basic Books 1973), viii, 3-30.
[41] ibid 18.

As it provides a more inclusive kind of explanation which is oriented towards making-sense, not towards fact-making, it forces the researcher not to focus on the consistency of the jurisprudential holdings or administrative decisions as a major element to be explained. Conversely, it looks at how parties and judges constructed their story to endorse prescriptive conclusions. It, therefore, draws the attention of the scholar towards some unnoticed details in the plot and discourse of the narrative that have been crucial in justifying judicial and administrative patent decisions.

A significant part of the legal literature has pointed out the narrative character of jurisprudential decisions and viewed case-law as "chain of novels".[42] This thesis draws on this insightful perspective in order to tackle the hypothesis and research questions, by focusing of three main aspects of the narrative methodology: the themes, structures and frames that narratives embed.

In the thesis, narrative methodology will be used to examine and discuss landmark biotech patent decisions, patent offices' practices and guidelines involving biotechnological products and also patent claims and drawings. The cornerstone of the inquiry will be understanding whether and how a metaphorical definition of the nature of the claimed invention, because of the analogies it entails, has contributed to stretch the concept of patent eligibility in these different patent systems.

Although the work will take into account the technoscientific and legal practices of patent offices which favoured particular metaphors and narratives, the analysis will be mainly textual. The narrative method, in fact, requires a dimension of textuality, namely a text as a medium in which the narrative is fixed, in order to allow a comprehensive and detailed examination the kind of plot and discourse that characterize it.

The thesis will employ a methodological narrative approach focused on "frames" which, however, does not neglect the relevance of thematic and structural modes of analysis that deal with the content of the story (what is told) and how it is told. Frames, as the sociologist Goffman, illustrated, are human means to organize meaning, involvement and action in specific contexts, as they offer an understanding of what is going on in a specific situation.[43]

[42] The legal philosopher Ronald Dworkin referred to the judge as "a writer of chain novels". Ronald Dworkin, *Law's Empire* (Harvard University Press 1986) 28.

[43] Erving Goffman, *Frame Analysis. An Essay on the Organization of Experience* (1st edn 1974, Northeastern University Press 1986) viii, 8.

In particular, part of the scholarship showed that frames have proved pivotal in order to devise national and regional public policies on biotechnology, which has been addressed as "product", "process" or "programme" in different political contexts.[44]

This work will address how the use of well-established frames have been drawn upon in patent litigation and backed a shifting the discourse of IPRs over biotechnological inventions accordingly.

Furthermore, the thesis will apply the insights of metaphorical analysis provided by cognitive linguistics theory, according to which metaphors ought *not* to be viewed as rhetorical devices, but as c*oncepts*. This perspective, formulated by Lakoff and Johnson in 1980, argues that, since the nature of human conceptual system is fundamentally metaphorical,[45] metaphors are conceptual. It rejects the assumption that metaphors are a matter of language alone. Conversely, it has explained that they structure human perception and thought, orienting human action accordingly.

This theory (Conceptual Metaphor Theory or CMT), which has become the dominant framework to study metaphors,[46] has epistemically questioned the cornerstones of other theories about the nature of metaphors. In particular, it has overturned the traditional theory of metaphor as comparison, as well as some of the entailments of rhetorical tradition: for example, the distinction between dead metaphor and metaphor *tout court*, concept and metaphor.

Its implications for the legal theory of interpretation are relevant, as it undermines the idea that there is a rigid distinction between literal and figurative language and metaphors are fundamentally rhetorical devices to argue persuasively in legal prosecution.

Moreover, it highlights the intrinsically cognitive and practical dimensions linked to the use of metaphors, which are fundamental concepts to make sense and order of the world, in particular of what is novel, abstract and unknown.

By providing linguistic evidence that the human conceptual system is inherently metaphorical, this theory offers a fresh perspective on how IP statutory classes are actually constructed and the definition of patent eligible invention has been brought about in patent case-law.

This thesis, on this issue, points out that there is a gap in the theory of legal interpretation in addressing and explaining how metaphors as conceptual means are applied in the legal

[44] Sheila Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton University Press 2005) vi. Herbert Gottweis, *Governing Molecules: The Discursive Politics of Genetic Engineering in Europe and the United States* (The MIT Press 1998), vi.

[45] George Lakoff and Mark Johnson, *Metaphors We Live By* (1st edn 1980, The University of Chicago Press 2003) vii, 3.

[46] Raymond W Gibbs Jr, 'Evaluating Conceptual Metaphor Theory' (2011) 48 Discourse Processes 529.

discourse, as well as in the technoscientific one, and this work substantially contributes to offer some answers.

The use of this perspective points out that making sense of new technologies and dealing with the issues of patent eligibility of their products is a more open ended cognitive and practical process, in which experts and professionals ordinarily apply metaphors that entail analogies which structure their understanding of the nature of the thing.

In order to understand the development of patent eligible matter prompted by biotechnology, the contribution of this work is significant, as it points out that judges, patent examiners, scientific experts, parties are used to make sense and order of new technoscientific products in this way and that metaphors cannot be eliminated from the scientific and IP legal discourse. Conversely, they are an integral part of them, because the human conceptual system is fundamentally metaphorical.

By applying this innovative perspective, this work aims to show that far from claiming the irrelevance of drawing on different conceptual metaphors, the theory of legal interpretation should question more consistently the work of defining statutory classes and concepts, especially in hybrid legal systems, such as the patent one, where technoscientific and legal expertise are entwined in defining the nature of the claimed invention.

In the thesis, narrative methodology and metaphorical analysis will be applied consistently with Science and Technology Studies' (STS) perspective, which provides several theoretical insights on how the methodology should be drawn upon, what is the relevant nexus to be accounted for and the kind of explanation that should be sought.

STS has been epistemically engaged, as a field, in explaining the social and contingent dimension of the production of knowledge. Moreover, it has provided a view of causation and explanation which rejects deterministic [47] ways of addressing the relationship between systems of production of formal knowledge (i.e. technoscience) and of production of norms (i.e. law).

The STS approach largely shares with narrative analysis the critique to the realist epistemology and a constructivist point of view, according to which making sense of the world is contingent and contextually related.[48]

[47] In particular forms of natural and social determinism: the law lag and the deference model, illustrated in chapter one, instantiate models of explanation which offer kinds of deterministic explanation of the relationship between scientific knowledge and the law.

[48] Catherine Kohler Riessman and Lee Quinney, 'Narrative in Social Work' (2005) 4 Qualitative Social Work 391, 393.

It refrains from endorsing linear, mono-causal narratives of technoscientific and social progress. Conversely, it offers a more comprehensive and complex framework of explanation, as it hinges on the concept *co-production*, namely the insight that the natural and social order are produced together and that the *is* and *ought*, the descriptive and prescriptive dimension are tied inextricably.

In this work, the concept of co-production establishes the scope of narrative and metaphorical analysis, as it points out that science, as much as law, is the place where influential narratives and metaphors have been nurtured. As a result, the validation of metaphors and narratives in the technoscientific discourse should be accounted for, together with their use in judicial decisions.

It highlights that the practices and guidelines of patent offices should be taken into consideration in analysing the construction of what is patent eligible, in order to achieve a more accurate and complex explanation of the shifting of meaning that patentable subject matter underwent.

Moreover, it highlights that also technoscientific practices and theories elaborated in the laboratory have been influential in framing the issues of the patent eligibility of biotech products (for example the practices of isolation and purification).

Part of the STS literature has illustrated that, although the discussion on genomic property tends to focus on the decisions of the patent and trademark office and the courts as the sites of property production, the laboratory is equally fundamental as a site for the creation of scientific property.[49] It pointed out that making knowledge and making property rights do not constitute two separate moves, temporally and institutionally.[50] Conversely, the creation of patents is deeply embedded in the laboratory's practices and routines.[51]

The co-productionist framework, in addition, pinpoints what is the relevant nexus that narrative analysis and metaphorical analysis should address and account for: the relationship between making knowledge – the creation of ontologies – and the production of intellectual property.[52]

The significance of this work rests in showing that metaphors and the analogies they entail about the nature of biotechnological inventions have been largely validated by the practices

[49] Stephen Hilgartner, 'Mapping Systems and Moral Order. Constituting Property in Genome Laboratories' in Sheila Jasanoff (ed), *States of Knowledge. The Co-Production of Science and Social Order* (Routledge 2004) 131.
[50] ibid.
[51] ibid.
[52] Jane Calvert and Pierre-Benoit Joly, 'The Ontology of the Gene and the Patenting of DNA: How Did the Gene Become a Chemical Compound?' (2011) 50(2) Social Science Information 1.

and visions of molecular biology and genetics and they were crucial in re-framing the concept of patentable invention. Moreover, it lies in explaining how the laboratory and the courts are the expert sites which, by promoting a molecular and atomistic view of life, created a specific kind of semantics of appropriation centered on conceptual metaphors.

Although other theoretical approaches could be resorted to in order to address the research hypothesis and its questions, Science and Technology Studies' approach has been preferred, as it provides several insights in order achieve a more inclusive and complex account of technoscientific phenomena.

STS has offered a more accurate epistemic perspective about how knowledge making is brought about. In particular, STS has substantiated the *social* character of technoscientific knowledge-making, by showing that technoscience, as much as law, involves a process of social construction.

STS scholars, moreover, have extensively examined the process of establishing frames in the policymaking of new technologies and showed how frames lie at the interface of the descriptive and prescriptive dimensions. Moreover, they illustrated how political and scientific institutions enjoy a substantial power in terms of establishing enduring frames and creating master narratives to assess and govern new technologies, such as rDNA biotechnology.

Jasanoff and Gottweis, for example, analysed how the frames of "product", "process" and "programme" have been pivotal, in different national contexts, to set up diverging policies of biotechnology.[53]

However, more significantly, STS literature pinpointed that the specific frames endorsed in different national political contexts of developed countries and the institutions of the European Union reflect specific national and regional modes of understanding and governing techno-scientific innovation in terms of what constitutes the public good.

The thesis, furthermore, argues that these metaphors have oriented how life and nature is characterized in different political contexts, promoting different technoscientific and legal imaginaries, according to specific narratives concerning what is the role of IP in these political and legal contexts and biotechnological innovation in terms of fulfilling social desires and promoting the public good.

[53] Jasanoff (n 44) v. Gottweis (n 44) vi.

This work does not overlook the relevance of other factors, beyond metaphors themselves, in settling the meaning of what is patent eligible. Conversely, it highlights that several other elements came into play in framing the scope of patent eligible matter.

Whereas in the U.S. and Canada the definition of patentable subject matter is centered on the formulation statutory classes, in the EPC system it hinges on whether the invention fulfills the *technical* threshold and falls within the patent exclusions and exceptions set out in Articles 52(2) and 53 EPC.

In the United States, moreover, the so-called IP clause, Article I § 8, clause 8 of the Constitution, as chapter three shows, has proved fundamental in devising a narrative of progress which has supported a broad interpretation of patentable subject matter.

In Europe, it has been the reference to the "technical" character of the invention, set out in Article 52(1) EPC 2000, which has largely shaped the concept of patent eligibility. As Huys, Van Overwalle and Matthijs pointed out, the implementing regulations of the EPC clarify that "the invention must have technical features (Rule 43(1)), be related to a technical field (Rule 42(1)(a)) and concerned with a technical problem (Rule 42(1)(c))".[54] Although the technical element of the invention has been considered ambiguous, it operates as a demarcation concept between discovery and invention.

In addition, the establishment of the legal criteria of isolation and purification in these three patent systems, as in particular chapter four and six illustrate, have proved to be pivotal in settling the patent eligibility of DNA sequences and human biological materials. Both the "technical" character of the invention under the EPC and these two criteria serve within patent systems demarcation purposes, which are epistemic and ontological. However, part of the literature has noted that isolation and purification fall short, nevertheless, in fulfilling the requirement of patent eligibility.[55]

The thesis also considers the construction and use of legal doctrines as a crucial factor in settling the scope of patent eligibility: for example, chapter three illustrates how and why the doctrine of the product of nature has been recalled, in the U.S., in judicial decisions which clearly have expanded the scope of patentable invention.

Furthermore, the judicial omission of doctrines should be also noticed and accounted for. Beauchamp has, for example, pointed out that in the main landmark biotech decisions on the patent eligibility of gene sequences, no reference has been made to the long-standing doctrine

[54] Huys, Van Overwalle and Matthijs (n 26) 1104.
[55] Burk (n 1) 471.

of useful difference that for decades has been applied by U.S. courts to foster the patent eligibility of chemical products.[56]

Also the legal theory of legal fictions, which are strictly linked to metaphors and analogies, offers an insightful approach to understand how analogical reasoning is brought about in the legal discourse, as section 1.5 explains.

Moreover, Pottage and Sherman highlighted that taxonomic practices have been crucial in providing the rules which govern the patentability of biological inventions.[57] This thesis, however, does not focus on these practices in the three patent systems of comparison, since their analysis would require an autonomous monographic work.

In the thesis, chapter one explains the methodology focused on narrative analysis and frames and illustrates STS theoretical framework. In particular, it clarifies the explanatory relevance of the concept of co-production. It, then, expounds how the role of metaphor (and analogy) has been increasingly acknowledged in science and law, as well as the theoretical perspective of metaphor offered by cognitive linguistics. Finally, it clarifies how the concept of sociotechnical imaginaries will be used in order to address the comparison.

Chapter two explores how the molecular view of life has become established and how the metaphors of *molecule* and *code* have proved to be epistemically pivotal in tackling the problems of molecular biology and genetics and oriented them as disciplines. It clarifies how biotechnology largely relied on the legacy of these disciplines, as well as on their metaphors, and presents the main narratives on its origin and evolution (which has also been employed in patent judicial discourse).

Chapters three to six are devoted to the patent landmark judicial decisions which involve different areas of biotech inventions.

Whereas chapter three focuses on the case law concerning the patent eligibility of genetically modified microorganisms and organisms in the three jurisdictions of comparison, chapter four deals with all the controversies arising from Myriad Genetics' patents on isolated DNA sequences of the BRCA1 and 2 genes. Although chapter four analyses also the High Court of Australia decision on one of Myriad Genetics' patent on the BRCA1 gene, Australian patent system is not part of the comparison. The reference and comment on this decision has been included to show how the same metaphors and arguments used in other jurisdictions, namely the U.S., has been largely resorted to as the rationale to decide on the same socially controversial patent claims.

[56] Beauchamp (n 8) 311.
[57] Pottage and Sherman (n 28) 18.

Chapter five deals, mainly, with the construction of the patent eligibility of transgenic seeds and plants. It analyses the different metaphors and narratives which have sustained the definitions of their nature and other technical factors that, under the EPC, contributed to establish their patentability.

Chapter six examines the issues related to the settlement of the *legal* and *ontological* status of human biological materials (HBMs) in U.S., Canada and Europe, and how it has impinged on the allocation of IPRs over them. It also engages in explaining why the question of the morality of patenting human embryonic stem cells has become the focus of the European debate, as far as HBMs are concerned.

Finally, several conclusions are drawn on the co-production of the technoscientific and legal order that metaphors and narratives have entailed in terms of re-framing the scope of patent eligible matter in the three jurisdictions, which has been analysed. These conclusions point out how much opening the "black boxes" of metaphors and narratives used to sustain technoscientific, judicial and administrative definitions of the products of genetic engineering is crucial in order to construct, at present, a more reflexive debate on the problems raised by gene editing technologies and, in particular, CRISPR-cas9.

Chapter One
Theoretical Framework and Methodological Approach

1.1 S&TS Mode of Explanation

S&TS' theoretical approach differs from other modes of studying and explaining the relationship between society and "technoscience", which is referred to by Latour and other S&TS scholars as the unitary dimension of making and applying science.[58] The distinctive features of S&TS' view and style of explanation are related to the concerns and focus of the field on the contextual and material dynamics of scientific and technological practices, which S&TS have shown are a "fertile ground for social, political and ethical analysis",[59] as well as being a workbench for legal inquiry.

Science and Technology Studies' multidisciplinary origins offer a vast set of methodological resources to address the issues of technological innovation as social process. Throughout the years of S&TS' development, these resources underwent cross-fertilization and hybridization among the disciplines and provided the field with fresh tools to tackle the complex issues involved in knowledge making. Place, time, actors, materiality, practices and conceptualization, as well as the construction of individual and collective identities and institutional discourses, matter in S&TS analysis.[60]

Science and Technology Studies' framework enables it to gain a better understanding of the processes and practices through which science and law make sense and order of technological objects, such as biotechnological inventions, as it accounts for a non-deterministic explanation of choices which specific societies and institutions make about innovation, risks and allocation of rights.

This chapter will, first, illustrate some of the main features of S&TS approach, which is considered a kind of "constructivism", explaining the issues and implications related to this definition.

The second part of the chapter will, then, examine the framework of "co-production", as an analytical resource that challenges reductionist and deterministic explanatory accounts of the role and status of technoscience in society.

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[58] Peter Dear and Sheila Jasanoff, 'Dismantling Boundaries in Science and Technology Studies' (2010) 4 Isis 759, 761.
[59] ibid 761.
[60] Sheila Jasanoff, 'Ordering Knowledge, Ordering Society' in Sheila Jasanoff (ed), *States of Knowledge. The Co-Production of Science and Social Order* (Routledge 2004) xii.

In the third part of this chapter, it will be explained how "narrative" analysis and, in particular, the concept of "frame", as a qualitative methodological tool, has been applied by S&TS' scholars to make sense of how, in complex settings, normative choices are made and justified. The final part of the chapter will be devoted to illustrating how a comparative overview of different legal and social contexts, where intellectual property rights on biotech inventions have been granted and litigated, can provide further insights in explaining why some choices gain stability or not. In particular, it will be explained how introducing and using the idea of "sociotechnical imaginaries" can fill a theoretical gap in order to account for choices made in specific national or regional contexts.

1.1.1 S&TS' Constructivism

Science and Technology Studies' theoretical approach is deemed "constructivist". Under the term "constructivism" heterogeneous programs and theories in the social studies of science, philosophy and other disciplines, such as psychology, neurobiology, psychiatry and information science, have been subsumed.[61] "Constructivism" has been referred to a particular epistemic point of view on the human relationship to the world and reality, according to which the world is not discovered, but is, at least to a certain extent, "made" by the people who probe and inhabit it.[62] "Constructivism" challenges the fundamental assumption of realism that "there is a way that the world is, and is possible to discover and represent it"[63] and, in particular, of scientific realism, according to which "entities, states and processes described by correct theories really do exist".[64]

As far as scientific realism is concerned, Hacking distinguishes two kinds of realism: *realism about entities*, which asserts that "a good many theoretical entities really do exist"[65] and *realism about theories*, which claims that "scientific theories are either true or false independent of what we know",[66] as "science at least aims at the truth, and the truth is how the world is".[67] However, he notes[68] that three elements can be identified in scientific realism,

[61] Uwe Flick, 'Constructivism' in Uwe Flick, Ernst von Kardoff and Ines Steinke (eds), *A Companion to Qualitative Research* (Sage Publications 2004) 88, 89; David J Hess, *Science Studies: An Advanced Introduction* (New York University Press 1997) V, 34-35.
[62] ibid 89.
[63] Sergio Sismondo, *An Introduction to Science and Technology Studies* (Blackwell Publishing 2004) 1, 52.
[64] Ian Hacking, *Representing and Intervening. Introductory Topics in the Philosophy of Natural Science* (Cambridge University Press 2007) vii, 21.
[65] ibid 27.
[66] ibid.
[67] ibid. 21.
[68] ibid 28.

as Newton-Smith pinpointed:[69] 1. An *ontological* element, according to which "scientific theories are either true or false, and that which a given theory is, is in virtue of how the world is";[70] 2. A *causal* element, according to which "if a theory is true, the theoretical terms of the theory denote theoretical entities which are casually responsible for the observable phenomena";[71] 3. An *epistemological* element, according to which "we can have warranted belief in theories or in entities (at least in principle)".[72]

The word "constructivism" conveys the metaphor of "construction" in its root, "construct", and therefore the *activity* which is involved in knowledge-making. Theories and fields labeled as "constructivist" may endorse more or less radical versions of it. Scholars, however, disagree on what radical and moderate kinds of constructivism claim. Hess, for example, points out that "in its extreme version, constructivism amounts to more than an instrumentalist account of theories".[73] In particular, he refers to social idealism, "in which there is no material reality that constrains or structures sensory observations"[74] and theory choice. He notices that an alternative version to radical constructivism consists in "the position that scientific theories are realistic maps or explanations of the real world and at the same time vehicles that encode culture-bound linguistic categories and cultural values and/or are shaped by social interests and other social variables".[75]

Glasersfeld, nevertheless, highlights that "radical constructivism *in no way denies* an external reality".[76] In his view, radical constructivism entails a modified concept of cognition and knowledge, which endorses Vico's perspective that human knowledge is a human construct and rejects the claim that cognition is true if it reflects objective reality.[77] Constructivism relies, therefore, on *viable* knowledge, which is knowledge that fits into the experiential world of the one who knows.[78] Flick illustrated that the different kinds of constructivism share questioning "whether external reality is *directly* accessible – that is to say, independent of perceptions and concepts that we use and construct".[79]

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[69] William H Newton-Smith, 'The Underdetermination of Theory by Data', (1978) 52 Proceedings of the Aristotelian Society 72.
[70] ibid.
[71] ibid.
[72] ibid.
[73] David J Hess, *Science Studies: An Advanced Introduction* (New York University Press 1997) v, 35.
[74] ibid.
[75] ibid
[76] Flick (n 61) 89.
[77] ibid.
[78] ibid 89-90.
[79] ibid 89.

In S&TS the expression "social construction" became widely used in the 1970s and was introduced after the publication of "The Social Construction of Reality. A Treatise in the Sociology of Knowledge" by the sociologists Berger and Luckmann, in 1966. In the essay, they argue that "reality is socially constructed and that the sociology of knowledge must analyse the process in which this occurs".[80] As "all human 'knowledge' is developed, transmitted and maintained in social situations",[81] they maintain that "the sociology of knowledge must seek to understand the processes by which this is done in such a way that a taken-for-granted 'reality' congeals for the man in the street".[82] It has been noted[83] that, according to their theory, knowing social reality consists of "apprehending the objectivated social reality"[84] and "ongoingly producing this reality".[85] Sismondo explained that the fundamental point that the two sociologists are making concerns the mataphysics of the social world: "To construct X we need only that: (a) knowledge of X encourages behaviors that reduce other people's ability to act as though X does not exists; (b) there is reasonably common knowledge of X; and (c) there is transmission of knowledge of X".[86]

Berger and Luckmann recognized how much the legacy of the sociologist Alfred Schütz influenced their work.[87] Schütz showed that the knowledge of the world, in common-sense and in scientific thinking, implies constructs: a set of abstractions, generalizations, formalizations and idealizations, which are specific to the level of thought organization.[88] Moreover, he clarified that there are no pure and simple facts, as such. Facts are selected "from a universal context of the activities of our mind".[89] Facts, therefore, are always already interpreted, from the outset.

Although their work contributed to the widespread use of the expression "social construction" in S&TS, some scholars questioned the outcome of their theoretical efforts. Bruno Latour and Steve Wolgar in "Laboratory Life. The Construction of Scientific Facts"[90] pointed out that "the tension between the existence of knowledge as pre-given and its creation by actors has long been a theme which has preoccupied philosophers (Bachelard, 1953) and sociologists of

[80] Peter L Berger and Thomas Luckmann, *The Social Construction of Reality. A Treatise in the Sociology of Knowledge* (1st edn 1966, Penguin Books 1991) 7, 13.
[81] ibid 15.
[82] ibid.
[83] Sismondo (n 63) 53.
[84] Berger and Luckmann (n 23) 62.
[85] ibid.
[86] Sismondo (n 63) 53.
[87] Berger and Luckmann (n 80) 7, 9 and 27.
[88] Flick (n 61) 89.
[89] ibid.
[90] Bruno Latour and Steve Wolgar, *Laboratory Life. The Construction of Scientific Facts* (1st edn 1979, Princeton University Press 1986) 5, 175.

knowledge".[91] They, however, concluded that, although some sociologists – and they refer to Berger and Luckmann – have attempted a synthesis of the two views, the results are "somewhat unsatisfactory".[92] Latour and Wolgar made clear that, despite these attempts, "facts refuse to become sociologized".[93]

It has been noted, however, that the objects that S&TS hold are "socially constructed" means that "they are *real* objects, though contingently real".[94] In comparison to other constructivist perspectives, S&TS have added a further dimension to the metaphor of "social construction",[95] considering and examining the processes in which it occurs. Moreover, by applying and extending the principle of explanatory symmetry, S&TS have offered a more reflexive and complex account of how objects gain social stability or fail to do so.

In two decades, the metaphor of "social construction" has become ubiquitous in academic writings. The philosopher of science Hacking, who published, in 1999, a book in which he discussed the meaning and implications of the metaphor, counted more than twenty titles claiming that "things" are socially constructed. He judged the metaphor redundant and tired and stigmatized the arguments that are common to social constructivists, summing them up in the following way:

> "Social constructionists about x tend to hold that:
>
> (1) X have not have existed, or need not to be at all as it is. X, or X as it is at present, is not determined by the nature of things, it is not inevitable. Very often they go further, and urge that:
>
> (2) X is quite bad as it is.
>
> (3) We would be much better off if X were done away with, or at least radically transformed".[96]

Although the work of scholars labeled as "social constructivists" shows the contingent and not inevitable character of the nature of things and mostly consists in de-constructing well-established narratives and discourses, it is actually this kind of theoretical effort that contributed to provide a more reflexive and non-reductionist explanatory outlook.

It has been noted[97] that the growing debate about the meaning and implications of constructivism is related to the different forms of relativism that constructivism could entail

[91] ibid.
[92] ibid.
[93] ibid.
[94] Sismondo (n 63) 53.
[95] ibid.
[96] Ian Hacking, *The Social Construction of What?* (Harvard University Press 2000) vii, 6.

and, in particular, epistemic relativism, that is the stance that knowledge is rooted in a particular time and culture.

Some scholars suggest that there is no necessary connection between constructivism and relativism, however, constructivist perspectives imply to a certain extent a relativist account of the world, as they show the contingency of facts and things. This contingency is a problem which, however, turns out to be more difficult to be handled by non-relativistic scholars. The S&TS scholars Barnes and Bloor, debating in the 1980s on relativism, rationalism and the sociology of knowledge, pointed out that relativism is considered pernicious as a threat to rationality and scientific standards.[98] However, they argued that they are more comfortable with relativism, since "there is more evidence to be cited for relativism than against it".[99] According to them, more than representing "a threat to the scientific understanding of forms of knowledge, relativism is required by it".[100]

Nevertheless, some questions about the epistemic relativism, which is embedded in S&TS constructivist approach, could be raised especially in relationship to the engagement of the field in the politics of science. The concerns about "the uneasy fit between epistemological relativism and normative belief or action"[101] have been addressed by Jasanoff, who argued that these issues depend on a misunderstanding of the implications of science and technology studies for social and political analysis. She noticed, by showing some concrete examples of the political use of S&TS' work, that the field "provides a different and more comprehensive, accounting of order in society, by integrating a critical understanding of our systems of formal knowledge with an equally deep appreciation of the institutions, practices, cultural beliefs and material resources that sustain particular ways of knowing".[102] One of the modes in which S&TS could contribute to improving normative action is through its style of explanation, which, she points out, is "qualitative rather than quantitative, thickly descriptive rather than reductionist or model-dependent, deconstructive rather than paradigmatic, and self-consciously, often ironically, narrative".[103] This style largely endorses a specific view of causation and explanation, which will be further addressed in this thesis and accounts for the choice to apply S&TS' theoretical approach.

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[97] Barry Barnes and David Bloor, 'Relativism, Rationalism and the Sociology of Knowledge' in Martin Hollis and Steven Lukes (eds), *Rationality and Relativism* (Basil Blackwell 1982) 21.
[98] ibid.
[99] ibid 24-25.
[100] ibid 21.
[101] Sheila Jasanoff, 'Beyond Epistemology: Relativism and Engagement in the Politics of Science' (1996) 2 Social Studies of Science 393.
[102] ibid 409-410.
[103] ibid 411.

1.2 The Co-Productionist Framework

The term "co-production" has been introduced for the first time within S&TS by Latour in *We Have Never Been Modern*.[104] In this work, Latour addressed the main problem S&TS scholars' face in their analytical effort, namely to retie what he considers "the Gordian knot": the dichotomy nature/culture, "the divide that separates exact knowledge and the exercise of power"[105] which marks Western modernity.[106] The Actor-Network Theory devised and relied on the notion of translation or network in order to compose this dichotomy,[107] but the nature/culture separation is still a resilient analytical key that encumbers the social sciences and results in overshadowing alternative frames to explain the world. In his "final examinations", Latour remarked:

> "Since the invention of longer networks and the increase in size of some collectives depends on the silence they maintain about quasi-objects, how can I promise to keep the changes of scale and give up the invisibility that allows them to spread? Worse still, how could I reject from the premoderns the lasting nondifferentiation of natures and societies, and reject from the moderns the absolute dichotomy between natures and societies? How can size, exploration, proliferation be maintained while the hybrids are made explicit? Yet this is precisely the amalgam I am looking for: *to retain the production of nature and of society that allow changes in size through the creation of an external truth and subject of law, but without neglecting the co-production of sciences and societies*".[108]

Latour envisaged the concept of "co-production" as a theoretical tool which could foster the process of explanatory symmetrization of hybrid networks, such as modern biotechnologies and their products, avoiding the dualism of ascribing explanations to one or the other side of the divide. According to Latour, the social sciences are part of the problem, not of the solution,[109] since the sociological categorizations and frameworks are not useful in examining the elaboration of technology.[110] In his analysis, the theoretical problems related to the persistency of the nature/culture divide are linked to political philosophy, as he calls for the

[104] Sheila Jasanoff, 'Ordering Knowledge, Ordering Society' in Sheila Jasanoff (ed), *States of Knowledge. The Co-Production of Science and Social Order* (Routledge 2004) xii, 22.
[105] Bruno Latour, *We Have Never Been Modern* (Harvard University Press 1993) vii, 3.
[106] ibid 10-11.
[107] ibid 3.
[108] ibid 133-134.
[109] Bruno Latour, 'The Politics of Explanation: An Alternative' in Steve Wolgar (ed), *Knowledge and Reflexivity: New Frontiers in the Sociology of Knowledge* (Sage 1988) 155, 161.
[110] Michel Callon, 'Society in the Making: The Study of Technology as a Tool for Sociological Analysis' in Wiebe E Bijker, Thomas P Hughes and Trevor J Pinch (eds), *The Social Construction of Technological Systems: New Directions in the Sociology and History of Technology* (The MIT Press 1987) 83, 100.

need to rethink the essence of modernity in terms of a "Parliament of things", where the natural, social and discursive dimensions of networks are recognized.

The concept of "co-production" has been, however, the focus of S&TS research in several domains for decades, even before the term "co-production" has become widely used and established in the S&TS community. Since the 1990s, S&TS scholars referred to the process of producing natural and social order together as a theoretical perspective with promising explanatory power. Some of them, such as Taylor,[111] preferred the term "co-construction",[112] whereas most of the S&TS community endorsed the form "co-production".

In 2004, most of the work carried out in the field has been expounded in the volume "States of Knowledge. The Co-Production of Science and Social Order", edited by Sheila Jasanoff, which collects a series of essays aiming at capturing how the idiom of co-production filled a theoretical gap in the vocabularies and analytical frames of the social sciences. "Co-production" has been elaborated within S&TS research in order to provide more thorough and accurate accounts and interpretations of complex phenomena at the crossroads of science, technology, culture and power.[113]

"Co-production" is an interpretive framework based on the insight that "thinking of natural and social orders as being produced together"[114] constitutes a theoretical resource that enables to address some of the limits that the social sciences have confronted with in explaining how the production of science and technology is intertwined with the legal and social normative dimensions. As Jasanoff illustrated, "co-production is shorthand for the proposition that the ways in which we know and represent the world (both nature and society) are inseparable from the ways in which we choose to live in it".[115]

Although the effort of creating and refining fundamental categories provided the social sciences with analytical explanatory tools, this heredity proved to be a bottleneck in explaining the interface between the social processes of making of knowledge and the production of norms. Constructs as "structure and agency", "nature and culture", "science and politics",[116] in the concrete analysis of complex phenomena tend to turn into irresoluble

[111] Sergio Sismondo, 'Science and Technology Studies and an Engaged Program' in Edward J Hackett, Olga Amsterdamska, Michael Lynch, Judy Wajcman (eds), *The Handbook of Science and Technology Studies* (The MIT Press 2008) 13, 17.
[112] Peter J Taylor, 'Building on Construction: An Exploration of Heterogeneous Constructionism, Using an Analogy from Psychology and Sketch from Socioeconomic Modeling' (1995) 1 Perspectives on Science 66.
[113] Sheila Jasanoff, 'The Idiom of Co-Production' in Sheila Jasanoff (ed), *States of Knowledge. The Co-Production of Science and Social Order* (Routledge 2004) xii, 2.
[114] ibid.
[115] ibid.
[116] ibid.

dichotomies, which lack the explanatory power to make sense of sociotechnical formations. These divides favour explanations centered on the categorization of factors, subsumed under one or the other banner and classified either as "internal" or "external", which do not accommodate untidy processes where practices, materiality, identities, institutions, narratives and norms are entangled.[117] As S&TS, as a field, examines and questions the social production of knowledge and norms in its complexity, showing how it is socially embedded,[118] it dismisses realistic accounts and *a priori* demarcations about the world.

In the volume, Jasanoff engaged in explaining the meaning and relevance of co-production as a framework, pinpointing that it avoids any form of natural or social determinism: "science, in the co-productionist framework, is understood as neither a simple reflection of the truth about nature nor an epiphenomenon of social political interests".[119] Whereas technoscientific and social determinisms provide simplistic explanation of the nexus of knowledge and its products, materiality and normativity, claiming for the priority of one dimension in explaining complex phenomena, co-production shows the hidden links which tie together these dimensions, which are socially constructed, challenging the assumption of privileged explanatory factors and discourses. The co-productionist framework fulfills, therefore, the epistemic need for explanatory symmetrization, which S&TS maintained and pursued.

Jasanoff, the S&TS scholar who largely contributed to the definition of this framework, pointed out that the co-productionist literature addresses issues which are metaphysical and epistemological, namely "about the way the world is and how we find out about it".[120] She identified two co-productionist streams of analysis: the *constitutive* and the *interactional*. The former deals with "the ways in which stability is created and maintained, particularly for emergent phenomena, whether in a particular site where knowledge is made, such as research laboratory, hospital or legal proceeding, or around a novel technoscientific object, such as the human genome or a periodic table for chemicals".[121] This kind of analysis is focused on "how people perceive elements of nature and society, and how they go about relegating part of their experience and observation to a reality that is seen as immutable, set apart from politics and

[117] ibid.
[118] ibid.
[119] ibid 3.
[120] Sheila Jasanoff, 'Afterword' in Sheila Jasanoff (ed), *States of Knowledge. The Co-Production of Science and Social Order* (Routledge 2004) xii, 274.
[121] Jasanoff (n 104) 18-19.

culture".[122] Its concerns are more metaphysical, as it has to confront with questions related to the meaning of what is natural or social, human or non-human.[123]

The latter is qualified as *interactional*, since it engages in examining "knowledge conflicts within worlds that have already been demarcated, for practical purposes, into the natural and the social".[124] As new phenomena challenge or destabilize human knowledge about "what counts as nature or science and what as society or culture",[125] it examines how people reshape these boundaries in these kinds of contingencies, in which different epistemologies contend. The interactional stream addresses, therefore, more epistemological issues.

These two kinds of analysis are concerned with metaphysics and epistemology; however, the co-productionist perspective dismisses the kind of *a priori* demarcations[126] that conventional studies in these fields endorse. Jasanoff points out that co-production undermines the distinction between metaphysics and epistemology, "showing how our knowledge of things as they are relates to earlier choices about how we wish to know things in the first place".[127]

The co-productionist framework, in her analysis, entails several theoretical benefits in term of description and explanation, normativity and prediction. Whereas the former two will be explained in this section, the latter will be illustrated in the next one.

As far as description is concerned, co-production is grounded on contextualization. Co-productionist accounts have gained "descriptive thickness"[128] through the cross-fertilization of different disciplinary perspectives and methodologies, which provide a wide range of useful theoretical tools to analyze the context of the production of knowledge and norms. Moreover, these accounts are less centered on *fact*-making, which has been privileged by science studies, and more concerned with *sense*-making.[129] This shift entails that society's efforts to order experience have become part of S&TS scholars' analytical work.

With regard to explanation, co-production challenges linear and mono-causal narratives of technoscientific and social progress.[130] In particular, the constant methodological attention to the concrete context in which phenomena take place reveals some unnoticed elements to the analyst, which make more complex the questions related to the "why" and expand the

[122] Jasanoff (n 104) 19.
[123] ibid.
[124] ibid.
[125] ibid.
[126] Jasanoff (n 120) 274.
[127] ibid.
[128] ibid 276; see Clifford Geertz, *The Interpretation of Cultures* (Basic Books 1973) 1, 5-10.
[129] ibid.
[130] ibid 277.

questions connected to the "how".[131] The co-production frame could, therefore, improve significantly the scholar's explanatory capacity to inquire human activity.

In the next section, it will be explained how this interpretive framework also offers insights into the normative discourses of the law and judicial decisions.

1.2.1 Science, Law and Policy: The Idiom of Co-Production

Edge, tracing back the origins of S&TS, showed how its origins and growth as a field have been largely marked by a "democratic impulse", which resulted in a demand for institutions to become more socially responsible in the terms of democratic accountability for their scientific policies and the democratization of science and technology.[132] He suggested that the different strains of S&TS scholarship could contribute addressing the issues at the interface of the "is/ought" dimensions in the form of the question: "Given that critical STS scholarship paints a distinctive and fresh picture of science – a new 'is' – what are the policy implications (if any) – the new 'ought' that follow?".[133]

Edge pinpointed one of the main ambitions of S&TS' scholarship, which the frame of co-production concurs to fulfill. The theoretical relevance of "co-production" stands mainly at the interface of the "is/ought" dimensions of inquiry, since it is centered on considering the concomitant social processes of making sense of the world and making order of it.

Science and the law are two of the most influential institutional places of collective knowledge-making and sense-making, as they are conferred social authority. When new phenomena are emerging, these are the institutions which are at the forefront of making sense and order of what is new. Both these institutions are called upon to establish facts, which underpin and legitimize normative decisions, such as the rules regarding regulatory science and jurisprudence holdings and arguments.

It has been illustrated that the emergence of order is a significant moment, in which the processes of co-production become noticeable.[134] When new phenomena are stabilized it is more difficult to understand how the natural and the social, as well as knowledge and power, affect each other.[135] As Jasanoff remarked, relevant normative decisions are made at this stage: "in the resolution of conflicts; the classification of scientific and social objects; the standardization of technological practices; and the uptake of knowledge in different cultural

[131] ibid.
[132] David Edge, 'Reinventing the Wheel' in Sheila Jasanoff, Gerald E Markle, James C Petersen and Trevor Pinch (eds), *Handbook of Science and Technology Studies* (rev edn, Sage Publications 1995) 3, 10-11.
[133] ibid 16.
[134] Jasanoff (n 120) 278.
[135] ibid.

contexts".[136] Employing the co-productionist framework in examining the emergence of new sociotechnical formations, such as modern biotechnologies, enables one to gain access to how power is exercised through the concrete institutional practices of knowledge-making. In particular, how science, law and politics exercise a mutual elicitation in establishing a dominant frame about what a technology is, if it entails risks or not, what kind of assessment and management it should undergo, if any, whether it should be considered patent eligible or not. The choices related to these issues affect the normalization and naturalization of these phenomena. However, the co-productionist analysis draws the scholar's attention to how knowledge and power are mutually constituted, how alternative viewpoints are eluded or marginalized and settlements gain stability or fail to do so within specific political, scientific, legal and cultural contexts.[137]

In that respect, the co-productionist idiom provides an alternative framework in comparison to other well-established ways of examining the relationship between science, policy and law. These main frames have been pinpointed and confronted by Jasanoff in the third edition of the *Handbook of Science and Technology Studies* and are the following: the "law lag", the "culture clash", the crisis and the deference framework.[138]

The "law lag" is a recurring narrative of the relationship between science and law, whose origins Jasanoff located in the work of the American sociologist Ogburn. Ogburn's "law lag" narrative is embedded in his "cultural lag" theory, which he, first, articulated in a chapter entitled "The Hypothesis of Cultural Lag" published in 1922 and, then, illustrated in the monograph "Social Change with Respect to Culture and Original Nature" in 1923.[139] The term "cultural lag", however, was first used by him, in 1914, as a professor of economics and sociology at Reed College[140] in order to point out that the time factor in social causation was more important than the so called "disguise factor", namely the latent factor, which was highly valued at the time in the economic interpretation of history.

The "cultural lag" framework is grounded on the assumption that culturally related institutions,[141] such as science and law, advance at "unequal rates of change"[142] and the lag

[136] ibid 279.
[137] ibid 280.
[138] Sheila Jasanoff 'Making Order: Law and Science in Action' in Edward J Hackett, Olga Amsterdamska, Michael Lynch, and Judy Wajcman (eds), *The Handbook of Science and Technology Studies* (The MIT Press 2008), 761.
[139] William F Ogburn, *Social Change with Respect to Culture and Original Nature* (George Allen & Unwin Ltd. 1923) v.
[140] William F Ogburn, 'Cultural Lag As Theory' (1957) 3 Sociology and Social Research 167, 168.
[141] ibid 171.
[142] ibid 169.

between them results in maladjustments: "A cultural lag occurs when one of the two parts of culture which are correlated changes before or in greater degree than the other part does, thereby causing less adjustment between the two parts that existed previously".[143] Although Ogburn acknowledged that maladjustments are difficult to be proved, since they involve subjective factors as value judgments which are not subject to measurement, he deemed most maladjustments demonstrable, regardless of the variation in value systems.

The "cultural lag" theory consisted of the following steps: "(1) the identification of at least two variables; (2) the demonstration that these two variables were in adjustment; (3) the determination by dates that one variable has changed while the other has not changed or has changed in a greater degree than the other; and (4) that one variable has changed earlier or in a greater degree than the other, there is less satisfactory adjustment than existed before".[144]

In the examples and data[145] that Ogburn provided, law was predominantly shown to be the dependent variable entailing the lag, which required adjustments.

Ogburn did not strictly endorse economic determinism,[146] however he maintained that "in our times in the Western world, technology and science are the great prime movers of social change"[147] and, therefore, allocated to science and technology the lead of social change. Moreover, referring to the increasing number of patents, discoveries in applied science and inventions in modern times and to the related amount of lag to them, he incorporated an *addendum* to the theory:[148] "lags accumulate because of the great rapidity and volume of technological change".[149]

The "law lag" narrative has proved to be a very popular means to deal with the relationship among science and technology, and society and has been recurrently used by legal scholars and judges to frame biotechnology and biotech inventions. However, it has been noted that this narrative is imbued with a deterministic view of science and technology as "the prime movers"[150] of social change and entails normative implications: in order to eliminate the lag, the law should adjust and comply with the rapid pace of science and technology and "speed up" its legal processes.

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[143] ibid 167.
[144] ibid 169.
[145] Ogburn (n 139) 237-256.
[146] Ogburn (n 140) 168.
[147] ibid 170.
[148] ibid .
[149] ibid 172; William F Ogburn, 'The Influence of Invention and Discovery' in *Recent Social Trends in the United States. Report of the President's Research Committee on Social Trends* (I, McGraw-Hill Book Company 1933) 122, 166.
[150] Jasanoff (n 138) 768.

The *culture clash* framework endorses the view that science and law are institutions which pursue different, opposing, goals and are marked by distinctive characteristics, which generate conflicts between them.[151] This view has been mainly advanced[152] by the American legal scholar Goldberg, who argued that science and scientists are engaged in promoting the *progress* of knowledge on the natural world, whereas law and legal scholars are conversely interested in the *process* of solving human disputes.[153] Although he principally refers to these institutions in the United States, he considers their divergent characteristics more broadly as the defining features of their nature.[154] Whereas science is deemed a self-governing republic of peers, whose cumulative enterprise[155] aims at the progress of knowledge, resulting from the empirical testing of scientific hypothesis,[156] law "stresses the process by which a decision is reached in an attempt to ensure that the decision will be, at the very least, something with which society can live".[157]

Goldberg considers the science-technology link indirect and uncertain,[158] as he argues that "it is rare for a scientific discovery to immediately lead to a new device".[159] Many areas of scientific research do not lead to practical developments or payoffs and the relevant applications of a scientific theory are mostly far and not envisaged by scientists.[160]

However, when scientific research results in commercially relevant products, it is under the intense scrutiny of regulatory agencies and Courts' decisions. The regulatory agencies address very thoroughly the implications of commercializing new technologies, such as biotechnology. As a result, scientific applications suffer what he defines as "a regulatory gap". The regulatory gap is a gap between research and application, which originates "from the fact that basic research receives unusually little public scrutiny while applications of that research receive an extraordinary dose of public involvement".[161] Although he acknowledges that new technologies can entail risks, Goldberg suggests speeding up the legal and political democratic process in order to promote the smooth commercialization of new technological

[151] ibid.
[152] See also Peter H Schuck, 'Multi-Culturalism Redux: Science, Law and Politics' (1993) 1 Yale Law & Policy Review 1.
[153] Steven Goldberg, 'The Reluctant Embrace: Law and Science in America' (1986-87) 75 Georgetown Law Journal 1341, 1345.
[154] ibid 1342.
[155] ibid; Steven Goldberg, *Culture Clash. Law and Science in America* (New York University Press 1994) vii, 8.
[156] Steven Goldberg, 'The Central Dogmas of Law and Science' (1986) 36 Journal of Legal Education 371.
[157] Goldberg (n 153) 1348.
[158] Goldberg (n 155) 11.
[159] ibid 12.
[160] ibid 12.
[161] Goldberg (n 155) 94.

products. Scientists as counselors are charged with the task of creating one culture, in which progress and process are efficiently and successfully merged.[162]

The crisis and the deference frames emerge, especially in the United States, from litigation involving scientific evidence and scientific expertise in trials.

Jasanoff pointed out that the crisis narrative is more focused on the threat that science suffers because "junk science" and "crackpot scientists" are allowed in the courtroom than on the cost of litigation that this entails.[163] She illustrated that this kind of genre encompasses several viewpoints. Whereas the positivist lawyer Peter Huber has a radical position and accused the traditional American adversary system to allow pseudoscientific expertise in trials, producing "scientific anarchy in court",[164] the former executive editor of the "New England Journal of Medicine" Marcia Angell expressed a more careful view of the relationship of science and law in trials in her analysis of the U.S. breast implant lawsuit.[165] Angel, according to Jasanoff, drew upon both the culture clash and crisis narrative and claimed that "the law's adversarial zeal, coupled with high financial stakes, produced a settlement based on nonexistent evidence and the consequent withdrawal of a product that many women found beneficial or enabling.[166]

The narrative of "deference" has been, conversely, advanced and claimed by the Courts in the U.S. and refers to the attitude of consideration towards science and scientists showed by judges. Jasanoff and Tallacchini illustrated that this narrative emerged in contests concerning the admissibility of scientific evidence and in the significant U.S. Supreme Court case *Daubert v. Merrell Dow Pharmaceuticals* and was centered on the metaphor of judges as "gatekeepers", whose role is to guarantee that only the evidence that comply with the scientific standards of validity and reliability is admitted.[167]

In comparison to these frameworks, the co-productionist framework shows that "the is" and "the ought" of human experience are entangled and, in knowledge societies, science, law and society make sense and order simultaneously. Furthermore, co-production draws the attention on how science and law contribute to maintain specific understandings about agency, human identity, the role of the market and the collective good. Courts' decisions on biotechnological

[162] ibid 182.
[163] Jasanoff (n 138) 769.
[164] Peter W Huber, 'Junk Science in the Courtroom' (8 July 1991) *Forbes* 68; Peter W Huber, *Galileo's Revenge. Junk Science in the Courtroom* (Basic Books 1993), x.
[165] Marcia Angell, *Science on Trial. The Clash of Medical Evidence and the Law in the Breast Implant Case* (W.W. Norton & Company 1996) 10.
[166] Jasanoff (n 138) 770.
[167] ibid 761.

inventions, in the U.S, Canada and Europe, illustrate this co-productionist interplay and this thesis aims at explaining it through narrative analysis.

1.3 Narrative Analysis

Narrative analysis is a qualitative approach that has gained momentum in research after the so called "narrative turn" in the human sciences in the 20th century,[168] which fostered a methodological shift towards textuality, meaning and discourse as means of understanding and explaining social life.

The "narrative turn" has complex origins and is related to the emergence of different national traditions in several fields of research. The psychologist Polinghorne illustrated that Russian formalism, U.S. new criticism, French structuralism and German hermeneutics contributed to fostering the study of narrative and establishing its centrality in making sense of human experience.[169] He, therefore, located the origins of narrative scholarship in the first half of the 20th century. Kristin Langellier has related the "narrative turn" to the critique of the realist epistemology and realism at large and to several movements in the 1960s: the critiques in social science of positivist modes of inquiry and their realist epistemology; the "memoir boom" in literature and popular culture; new emancipation movements concerned with identity; and a therapeutic culture examining and using personal life for therapies of various kinds.[170] The "narrative turn" involved many disciplines, such as literary studies, history, anthropology and folklore, psychology and sociolinguistics, sociology and communication studies.[171] However, narrative inquiry has been endorsed also in other fields as a theoretical approach, such as law and political sciences.[172]

Narrative analysis deals with meaning and is engaged in explaining *how* and *why* events and action are embedded in narratives.[173] The focus of its inquiry is, therefore, language.

Although understanding the cultural contexts, practices, theories and movements which have been involved in devising this kind of qualitative inquiry is fundamental, this chapter will deal with addressing its theoretical relevance in qualitative research and S&TS' co-productionist framework.

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[168] On the history of the narrative turn in social studies, see Barbara Czarniawska, *Narratives in Social Science Research* (Sage Publications 2004) viii, 1-16.
[169] Polkinghorne (n 39) vii.
[170] Kristin M Langellier, 'Personal Narrative' in M Jolly (ed), *Encyclopedia of Life Writing: Autobiographical and Biographical* Forms (Fitzroy Dearborn 2001) 699; Catherine Kohler Riessman, *Narrative Methods for the Human* Sciences (Sage Publications 2008) vii, 14-15.
[171] Kohler Riessman and Quinney (n 48) 392.
[172] ibid.
[173] ibid 394.

In this part of the chapter, it will be illustrated what is narrative and why narrative analysis provides a useful set of methodologies in order to explain how, in different cultural contexts, biotechnology has been framed and biotech inventions have gained intellectual property protection or failed to obtain it.

The analysis will be, then, focused on the meaning of "frame" as the core concept of one kind of narrative analysis and its theoretical relevance within Science and Technology Studies' co-productionist approach.

1.3.1 What Is a "Narrative"?

Most of the scholars committed to narrative analysis agree that defining "narrative" could be cumbersome for its polysemy and for the disputes surrounding its meaning. The sociologists Kohler Riessman and Quinney remarked that, as narrative inquiry is marked by realist, postmodern and constructionist diverging views and strands, a final and inclusive definition of "narrative" cannot be articulated.[174]

As Polkinghorne illustrated, the word "narrative" can be used in a general way to refer to "any spoken or written presentation",[175] such as the answers to a questionnaire in the form of sentences or paragraphs. However, "narrative" is mostly referred to, in narrative analysis, as "the kind of organizational scheme expressed in a story form".[176] In this case, it can indicate the process of making a story, the cognitive scheme of the story or the result of the process.[177] "Narrative" is mostly considered a synonym of "story",[178] which is a special mode of organizing human experience, linking action and events in a chronological way, in order to make sense of them. Griffin and May pointed out "that a narrative is an account of a non-random sequence of events that conveys some kind of action and movement through time".[179] Moreover, they explain that the sequence of events is made non-random by the articulation of a *plot* which provides "a logical and meaningful connection between events so that prior events seem inevitably to lead to later ones, providing a sense of causality".[180] The plot revolves around a particular point or meaning which the narrator wants to communicate to his audience. The plot of a narrative is considered "the organizing theme that identifies the

[174] ibid 393.
[175] Polkinghorne (n 39) 13.
[176] ibid.
[177] ibid.
[178] ibid; Hayden V White, *The Content of the Form. Narrative Discourse and Historical Representation* (1st edn 1987, The Johns Hopkins University Press 1990) ix, 1-25.
[179] Ann Griffin and Vanessa May, 'Narrative Analysis and Interpretative Phenomenological Analysis' in Clive Seale (ed), *Researching Society and Culture* (1st edn 1998, Sage Publications 2012) 441, 443.
[180] ibid.

significance and the role of the individual events",[181] that "waives together a complex of events to make a single story".[182]

The cognitive psychologist Bruner showed that narrative is a *mode of knowing* and cognitive functioning which is complementary to the logic-scientific mode, follows its own criteria of well-formedness and verification and has its own operating principles.[183] These two modes of knowing rely on different kinds of causality to connect events, as the logic-scientific or paradigmatic mode pursues universal truth, while the narrative mode searches for "particular connections between events".[184] Referring to Bruner's work, Polkinghorne explained that the narrative mode provides a different *kind of explanation* in comparison to the logic-scientific mode. In the logic-mathematical reasoning "the power of explanation by laws comes from its capacity to abstract events from particular contexts and discover relationships that hold among all the instances belonging to a category, irrespective of the spatial and temporal context".[185]

Conversely, explanation by narrative is *contextually related*:

> "When a human event is said not to make sense, it is usually not because a person is unable to place it in the proper category. The difficulty stems, instead, from a person's inability to integrate the event into a plot whereby it becomes understandable in the context of what happened (…). Thus, narratives *exhibit* an explanation instead of demonstrating it.
>
> In narrative organization, the symmetry between explanation and prediction, characteristic of logic-mathematical reasoning, is broken. Narrative explanation does not subsume events under laws. Instead, it explains by clarifying the significance of events that have occurred on the basis of the outcome that has followed. In this sense, narrative explanation is retroactive".[186]

Although narratives can concern individual personal stories, they are inevitably *social*, as they are the most common form of communication among people. It has been noted that narrative frameworks provide a fundamental resource to structure the events in order to make them more understandable to other people.[187] Narrative frameworks "do not originate from the individual but are shared cultural tools that offer us a repertoire of possible stories and set

[181] Polkinghorne (n 39) 18.
[182] ibid 19.
[183] Jerome Seymour Bruner, *Actual Minds, Possible Worlds* (Harvard University Press 1986) ix, 11.
[184] Polkinghorne (n 39) 17.
[185] ibid 21.
[186] ibid.
[187] Griffin and May (n 179) 443.

limits on what can be told".[188] However, nations, governments, institutions and groups also use frames to make narratives. These narratives build up and reinforce identities and also establish the horizon of possible human action. They tell "who collectivities and individuals are",[189] "where they come from"[190] and settle roles and boundaries of action. Since narratives which are produced by groups who are vested of social authority gain stability easily, marginal groups have to elaborate counter narratives in order to challenge and oppose the dominant ones.[191]

In S&TS, scholars have frequently drawn upon narrative analysis as a theoretical approach that offers insights to explain how individuals and collectivities make sense of their experience. Narrative analysis constitute a valuable means of inquiry, as narratives provide a contingent and much more inclusive kind of explanation, which accounts for how identities, action, reality are contextually construed.

Moreover, narratives are at the forefront of emerging orders and new identities. When something new, for example a new technology and its related products such as modern biotechnology, destabilizes and challenges well-established ideas of nature, narrative frames are relied upon in order to make sense and order of it.

Narratives are powerful practices of knowledge-making especially when they are deployed by institutions which are conferred authority. This can result in the normalization of the new technology or in the elaboration of a counter narrative.

The French philosopher Lyotard portrayed the postmodern condition as marked by the decline of master narratives[192] or metanarratives on progress and emancipation of mankind, that modernity[193]endorsed and relied upon in order to legitimize power in society. The fading of master narratives in his analysis entails that culture, in postmodernity, is a "patchwork of little narratives",[194] too fragmentary and discontinuous to allow a universal point of view.

Notwithstanding this philosophical perspective on human postmodern condition and the breakdown of narratives, S&TS' scholarship shows that master narratives, as much as narratives, are still lively and constitute influential rhetoric resources in order to legitimize power and action within society as far as science, technology and law are concerned. The

[188] ibid.
[189] Dawne Moon, 'Who I Am and Who Are We? Conflicting Narratives of Collective Selfhood in Stigmatized Groups' (2012) 5 American Journal of Sociology 1336.
[190] ibid.
[191] ibid 1337.
[192] Bill Reading, *Introduction to Lyotard. Art and Politics* (Routledge 1991) v, 63.
[193] ibid 65.
[194] ibid.

Report entitled "Taking the European Knowledge Society Seriously"[195] by the Expert Group on Science and Governance to the Science, Economy and Society Directorate of the European Commission, mostly formed by S&TS scholars, illustrated that master narratives are institutionally and socially very influential for what they entail, as "They reflect prevailing institutional structures and reinforce collective aspirations. In worlds of policy practice, narratives (…) tacitly define the horizon of possible and acceptable action, project and impose classifications, distinguish issues from non-issues, and actors from non-actors".[196]

In master narratives of policy, descriptive and prescriptive dimensions are deeply intertwined, so that the description of situations entails how they should be dealt with and regulated. It has been observed[197] that dominant master narratives could be considered "performative",[198] as their issuing consists in the performing of an action: telling a narrative on something can make it so.

Policy narratives on science and law are centered on frames which exhibit these normative and performative dimensions. In the next section, it will be explained what "frames" are, which is their relevance within narrative analysis and how they have been applied to biotechnology in order to sustain its normalization or to challenge it.

1.3.2 Frame Analysis

The concept of "frame" in the social sciences has been explored by the influential Canadian-born sociologist Goffman in his monograph entitled "Frame Analysis. An Essay on the Organization of Experience",[199] published in 1974. In his essay, Goffman addressed the organization and "structure of experience individuals have at any moment of their social lives",[200] without aiming at proposing any theory on the organization and structure of society.[201] The sociologist Bennett Berger, in the foreword to his essay, observed that Goffman's "frame" concerns the "inevitably relational dimension of meaning"[202] and "is only a particularly tangible metaphor for what other sociologists have tried to invoke by words like

[195] Ulrike Felt and Bryan Wynne, *Taking the European Knowledge Society Seriously*, 2007, Expert Group on Science and Governance to the Science, Economy and Society Directorate, Directorate-General for Research, European Commission, available at <https://www.bmbf.de/pub/EuropeanKnowledge(6).pdf> 5.
[196] ibid 73.
[197] ibid 75.
[198] John L Austin, *How to Do Things with Words* (1st edn 1962, Oxford University Press 1976) vii, 4-24.
[199] Goffman (n 43) viii.
[200] ibid 13.
[201] ibid.
[202] Bennett M Berger, 'Foreword' in Erving Goffman, *Frame Analysis. An Essay on the Organization of Experience* (1st edn 1974, Northeastern University Press, 1986) xi, xiii.

'background', 'setting', 'context', or a phrase like 'in terms of'".[203] According to Berger, all these words "attempt to convey that what goes on in interaction is governed by usually unstated rules or principles more or less implicitly set by the character of some larger, though perhaps invisible, entity (for example, 'the definition of the situation') 'within' which the interaction occurs".[204]

Goffman undertook his study, showing that the analysis of social *reality* had been at the core of social psychology and sociology since the 19th century. He commented on the American sociologist William Isaac Thomas' *dictum* "If men define situations as real, they are real in their consequences",[205] noting that, although "defining a situation as real certainly has consequences",[206] these may have a slight impact on the events. According to Goffman, "all the word is not a stage"[207] and despite "presumably a definition of the situation is almost always to be found, those who are in the situation ordinarily do not *create* this definition".[208] People try to assess accurately what the situation "ought to be for them"[209] and, then, act in accordance with their assessment.

Goffman drew upon Gregory Bateson's work, in which the term "frame" was, firstly,[210] proposed. The anthropologist and psychologist Bateson, in "A Theory of Play and Fantasy" published in 1954,[211] showed that any communication, verbal or nonverbal, implies sets of levels of abstraction, which are implicit. One set of abstract levels is called "metalinguistic" and encompasses "those explicit or implicit messages where the subject of discourse is the language".[212] The other set is called "metacommunicative" and regards messages where "the subject of discourse is the relationship between the speakers".[213]

The reference to metacommunicative set of abstractions proves to be fundamental in order to understand any message.[214] These metacommunicative sets of signals concern "what is going

[203] ibid.
[204] ibid.
[205] Goffman (n 43) 1.
[206] ibid.
[207] ibid
[208] ibid.
[209] ibid 2.
[210] See Deborah Tannen, 'What's in a Frame?' in Deborah Tannen (ed), *Framing in Discourse* (Oxford University Press 1995) 14, 18.
[211] Gregory Bateson, "A Theory of Play and Fantasy" in Katie Salen and Eric Zimmerman (eds), *The Game Design Reader. A Rules of Play Anthology* (1st edn 1954, The MIT Press 2006) 314.
[212] ibid 315.
[213] ibid.
[214] ibid 316.

on" and were named by Bateson "frames".[215] Bateson reached this conclusion, by observing two monkeys *playing* at Fleishhacker zoo in San Francisco, in January 1952. The animals were "engaged in an interactive sequence of which the unit action or signals were similar to but not the same as those of combat"[216] and "it was evident, even to the human observer, that the sequence as a whole was not combat, and evident to the human observer, that to the participant monkeys this was 'not combat'.[217] Bateson, therefore, inferred that the phenomenon, play, "could only occur if the participant organisms were capable of some degree of metacommunication, i.e., of exchanging signals that would carry the message 'This is play'".[218] Bateson meant the term "frame" as a psychological concept and used two kinds of analogies in order to discuss it: "the physical analogy of the picture frame and the more abstract, but still not psychological, analogy of the mathematical set".[219] However, he pointed out that the two analogies partially fall short in expressing the psychological dimension of the term, as one is too physical and concrete and the other is too abstract.[220]

Likewise, Goffman dealt with the question that individuals confront with in any current situation, namely "What is it that's going on here?" and tried to provide a framework that could offer an answer.[221] His aim was to identify some of the basic frameworks of understanding, which individuals use to make sense of events, and their specific vulnerabilities.[222] In addressing this issue, he explained that, since roles in activity are differentiated, the view that one individual has of "what is going on" differs from that of another person and different interests elicit different motivational relevancies. Moreover, the retrospective portrayal of the same event or situation may diverge widely among the individuals who were involved.

In order to isolate these basic frameworks, Goffman focused his analysis on "strips", namely "any arbitrary slice or cut from the stream of ongoing activity, including here sequences of happenings, real or fictive, as seen from the perspective of those subjects involved in sustaining an interest in them".[223]

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[215] Goffman pointed out that also Edward T Cone used the term "frame" in a similar way as Bateson did in his first chapter of *Musical Form and Musical Performance* (W.W. Norton & Company 1968). However, he deemed that Cone developed a similar line of inquiry in an independent way. See footnote 13, Goffman (n 43) 7.
[216] Bateson (n 211) 316.
[217] ibid.
[218] ibid
[219] ibid 322; Tannen (n 210) 18.
[220] ibid.
[221] Goffman (n 43) 8.
[222] ibid 10.
[223] ibid 11.

Goffman referred to Bateson's use of the term "frame"[224] and provided a general definition of it in the context of "frame analysis":

> "I assume that definitions of a situation are built up in accordance with principles of organization which govern events–at least social ones–and our subjective involvement in them; frame is the word I use to refer to such of these basic elements as I am able to identify. That is my definition of frame. My phrase "frame analysis" is a slogan to refer to the examination in these terms of the organization of experience".[225]

In his view, frames regard the organization of experience, "something that an individual actor can take into his mind",[226] and are not related to the organization of society. Frames organize *meaning* and *involvement* for individuals, as "during any spate of activity, participants will ordinarily not only obtain a sense of what is going on but will also (in some degree) become spontaneously engrossed, caught up, enthralled".[227] Moreover, frames entail and involve expectations of a *normative* kind:

> "All frames involve expectations of a normative kind as to how deeply and fully the individual is to be carried into the activity organized by the frames. Of course frames differ quite widely in the involvement prescribed for participants sustaining them".[228]

He, therefore, did not make any claim, in his essay, on social organization and social structure. Conversely, he preferred to concentrate his attention on the principles by which experience is subjectively organized. He, firstly, identified and characterized "primary frameworks" as the "schemata of interpretation" that the individual recognizing a particular event tends to imply in his response.[229] These frameworks are defined "primary", since their application is considered by those who are applying them "as not depending on or harking back to some prior or 'original' interpretation".[230] A "primary framework", therefore, "is seen as rendering what would otherwise be a meaningless aspect of the scene into something that is meaningful".[231] These frameworks may differ in degree of organization, as some resemble "a system of entities, postulates and rules"[232] and others are more akin to a perspective or an understanding.

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[224] Tom Burns, *Erving Goffman* (Routledge 1992) v, 250.
[225] Goffman (n 43) 10-11.
[226] ibid. 13.
[227] ibid 345.
[228] ibid.
[229] ibid 21.
[230] ibid.
[231] ibid.
[232] ibid.

He distinguished them in two classes of frameworks: natural and social.[233] Whereas natural frameworks offer an understanding of pure physical events undirected and unguided, due from start to finish to "natural determinants",[234] social ones regard events and situations that involve "the will, aim, and controlling effort of intelligence, a live agency, the chief being the human being".[235] All types of frameworks provide a way of describing the event to which they are applied. Goffman is, in particular, interested in how primary frames are transformed and reworked through activity. Frameworks can be converted into keys or fabrications and designs. Whereas keys entail transformations in which all the participants to a certain activity are aware of what is occurring, namely that a reworking occurred, fabrications and designs are *asymmetrical*, as some of the participants are unaware that a transformation occurred. A key is "the set of conventions by which a given activity, one already meaningful, in terms of some primary framework, is transformed into something patterned on this activity but seen by the participants to be something quite else".[236]

In the essay, frames are deemed organizational premises sustained in the mind and corresponding "to the way in which an aspect of the activity is itself organized".[237] Goffman explained that "given their understanding of what it is that is going on, individuals fit their actions to this understanding and ordinarily find that the ongoing world supports this fitting".[238]

Goffman's "frame analysis" has nurtured and inspired theoretically and methodologically several fields. In the human sciences, *frame* analysis and, particularly, the *dramaturgical/performance* analysis that Goffman devised and applied, has become a kind of narrative methodology. Kohler Riessman explained that the *dialogic/performance* analysis is a type of narrative methodology which, unlike *thematic* and *structural* approaches, deals with "how talk among speakers is interactively (dialogically) produced and performed as narrative",[239] focusing widely on contexts and, therefore, examining the setting, the impact of the investigator and the social circumstances which condition the production and interpretation of the narrative. Whereas *thematic* and *structural* approaches are concerned with the content of the story (what is told) and the narrative itself (the telling of the story), *frame* analysis is engaged in exploring the *performative* character of narratives. This kind of

[233] See Greg Smith, *Erving Goffman* (Routledge 2006) vi, 56.
[234] Goffman (n 43) 22.
[235] ibid.
[236] ibid 43-44.
[237] ibid 247.
[238] ibid.
[239] Catherine Kohler Riessman, *Narrative Analysis* (Sage Publications 1993) v, 105.

analysis hinges on the awareness that "stories are social artifacts",[240] that are created and sustained in institutional, historical and discursive contexts. It addresses how a story is coproduced in a specific context.

The family of methodologies named "narrative analysis" in the human sciences, however, encompasses a set of models and the articulation of formal practices in order to sustain it, namely interviewing, transcribing and analyzing transcripts of narrative to draw some conclusions. However, it has been noted that "prevailing concepts of verification and procedures for establishing validity (from the experimental model) rely on realist assumptions and consequently are largely irrelevant to narrative studies".[241] Consequently, any evaluation based on narrative analysis does not refer to verification criteria,[242] since narratives are not mirrors of the world.[243] Narratives and, in particular, frames are sense-making tools that enable individuals and collectivities to deal with what they experience.

Frame analysis, as a kind of narrative analysis, consists of a set of formalized models and practices linked to ethnographical and sociological studies. It has been embraced, however, in other fields of research, such as policy and communication studies, which have drawn on Goffman's legacy in order to gain a better understanding of how institutions, individuals and groups make sense of their experience.

Frame analysis has become a salient approach in order to understand the processes of policymaking and their implementation, as policy problems result from the construction made by different actors and how they are framed affects policy solutions and their rationale,[244] as well as causality and responsibilities. In particular, collective action and social movement scholars[245] have pinpointed how framing entails diagnostic and prognostic aims, as it defines problems and establishes responsibilities and set out solutions. Moreover, they pointed out that it is an interactive and contested process in which frame alignment, namely "the actions taken by those who produce and invoke frames in an attempt to connect these frames with the interests, values and beliefs of those they seek to mobilize",[246] and resonance, namely how groups and individuals respond, are intertwined.[247]

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[240] ibid.
[241] ibid 64.
[242] See Jerome Bruner, 'The Narrative Construction of Reality' (1991) 18 Critical Inquiry, 1.
[243] Kohler Riessman (n 239) 64.
[244] Cynthia E Coburn, 'Framing the Problem of Reading Instruction: Using Frame Analysis to Uncover the Microprocesses of Policy Implementation' (2006) 3 American Educational Research Journal 343.
[245] Robert D Benford and David A Snow, 'Framing Processes and Social Movements: An Overview and Assessment' (2000) 26 Annual Review of Sociology 611.
[246] Coburn (n 244) 347.
[247] ibid.

Furthermore, frames have also been significantly probed in order to explain global IP policymaking. The IP scholar Duncan Matthews, in particular, has illustrated how framing and re-framing IP issues in terms of right to health and access to medicines proved pivotal to pursue national patent policies and foster development for developing countries, before and after the entry into force of the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPs Agreement).[248] He has explained that in Brazil, South Africa and India[249] framing strategies set up by coalitions of NGOs have reshaped the debate on IPRs and led to re-framing also global IP policymaking.[250] These coalitions of NGOs were able to 'frame' and "re-frame" "intellectual property-related issues by using the emotive language of human rights to underpin substantive arguments"[251] to undermine and hinder the dominant IPRs frames that powerful transnational firms and their governments were supporting.[252]

The insights of this analytical perspective have been also applied to legal decisions. Frame analysis constitute a useful theoretical perspective in order to understand legal decisions, as frames provide a sense of continuity, by organizing facts in a selective way, according to an axial matter where will, agency and purpose of social actors are accommodated. Peter Manning and Keith Hawkins drew attention to the specific features of legal frames, observing that legal frames are oriented towards decision-making and highlighting their reflexivity, as "they both constitute 'reality' and they selectively identify the facts that sustain a social reality".[253]

Framing is at the core of judicial dynamics: lawyers select the matters of fact and law and the relevant precedents related to a case and this activity amounts to framing the case. Their framing undergoes negotiations with prosecutors and judges who, in turn, contribute to the framing process. Frames are ways of stabilizing meaning. However, stabilizing a frame largely depends on the power and authority of the actors and institutions which sustain it. In this respect, judges and courts, as powerful embodiments of legal authority, provide an official version of reality whose frames tend to prevail over other possible ones.

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[248] Duncan Matthews, 'When Framing Meets Law: Using Human Rights as a Practical Instrument to Facilitate Access to Medicines in Developing Countries' in Gustavo Ghidini, Rudolph JR Peritz and Marco Ricolfi (eds), *TRIPS and Developing Countries: Towards a New IP World Order?* (Edward Elgar 2014) 12.

[249] See, in particular, chapters four, five and six, Duncan Matthews, *Intellectual Property, Human Rights and Development: The Role of NGOs and Social Movements* (Edward Elgar 2011) v; Matthews (n 248) 12.

[250] Matthews (n 249) 3.

[251] ibid 7; Matthews (n 248) 12.

[252] ibid 8; Matthews (n 249) 13.

[253] Peter K Manning and Keith Hawkins, 'Legal decisions: A Frame Analytic Perspective' in Stephen Harold Riggins (ed) *Beyond Goffman: Studies on Communication, Institution, and Social Interaction* (Mouton de Gruyter 1990) 203, 213.

Although frames have been interpreted as "cognitive schemata", Goffman pointed out that they are not a matter of the mind, but "correspond in some sense to the way in which an aspect of the activity itself is organized".[254] Therefore, he pinpointed that these organizational premises (frames) are "sustained both in the mind and in the activity",[255] since they are something cognition "sometimes arrives at, not something cognition creates or generates".[256] Frame analysis, thus, should also take into consideration the particular kind of activity which maintains the frame. In the legal context the kind of activity supporting the frame is mostly formalized by a set of procedural rules which differs according to the judicial system and the kind of legal process.

Whereas this section examined the significance and meaning of "frame analysis" as a narrative method in the human sciences, the next section will explain how, in Science and Technology Studies, this theoretical approach has been applied and developed.

1.3.3 Frame Analysis in S&TS

S&TS have extensively drawn upon the theoretical and methodological insights of Goffman's frame analysis. Narrative analysis and, in particular, frame analysis have been privileged by several S&TS scholars, in order to pursue and provide what the anthropologist Clifford Geertz referred to as "thick description",[257] namely a description which explores how human behavior becomes meaningful by focusing on the context and does not take coherence as a major test of validity.[258]

S&TS work showed that frames are at the interface of the is/ought dimension. Frames define "what is going on" and their definition entails a series of descriptive and normative expectations from participants, individuals and groups, which are involved in the frame. Power, agency, causality, risks and accountability are all dimensions embedded in frames, which S&TS scholars have been committed into examining as concerns policymaking and its implementation.

S&TS scholars, moreover, have more specifically taken up Goffman's awareness of the power which is embedded in framing as an activity and frames as a result, as well as of the asymmetries related to it. An established frame constitutes, in fact, an official version of "what is going on". Dominant groups and institutions enjoy a consistent power to create

[254] Goffman (n 43) 247.
[255] ibid.
[256] ibid.
[257] Geertz (n 40) 3-30.
[258] ibid 18.

enduring frames, whereas for less powerful groups and individuals it is harder to challenge a frame and can require a significant amount of time and resources.

As far as technoscientific phenomena are concerned, framing is a fundamental activity which is carried out by political institutions and agencies, which deal with regulatory science, in order to assess a new technology and its potential risks and, eventually govern them.

With regard to the rise of commercial biotechnology, the political scholar Herbert Gottweis[259] illustrated how two alternative frames were considered in order to make sense of biotechnology and genetic engineering: the "process" frame and the "product" frame. Jasanoff, [260] furthermore, illustrated and explained the relevance of the "product", "process" and "programme" frames in defining specific policies of biotechnology in different countries: the United States, the United Kingdom and Germany. Frames contribute to mark, as she pointed out, national specific modes of addressing what is new and can challenge well-established views of what is natural, of identities and what represents the public good.

1.3.4 Narrative (and Metaphors) and Law

The significance of the narrative in the law has been increasingly acknowledged in the last thirty years, in particular in common law countries in which judicial precedent have been understood as providing successive narratives in terms of a chain.[261] Court's trials and decisions, largely hinge on competing narratives of the parties involved and of the judges as the legal scholar Anthony Amsterdam and the psychologist Jerome Bruner have illustrated in "Minding the Law: How Courts Rely on Storytelling, and How Their Stories Change the Ways We Understand the Law – and Ourselves".[262]

The number of allowed narratives, their mode and structure are dependent from the specific context, legal system, kind of jurisdiction and phase of trial involved. In some jurisdictional systems, judges can express their dissent through dissenting opinions, in others the judgement is devised as a *univocal* institutional answer to a legal controversy.

[259] Gottweis (n 44) vi.
[260] Jasanoff (n 44) vi.
[261] The legal philosopher Ronald Dworkin referred to the judge as "a writer of chain novels". Dworkin (n 42) 28. See Jefferson White, 'Analogical Reasoning' in Dennis Patterson (ed), *A Companion to Philosophy of Law and Legal Theory* (Wiley-Blackwell 210), 571, 574.
[262] Anthony G Amsterdam and Jerome Bruner, *Minding the Law: How Courts Rely on Storytelling, and How Their Stories Change the Ways We Understand the Law – and Ourselves* (Harvard University Press 2000).

Academic programs and conferences on law and narrative have been flourishing in different countries and that the "narrative turn" has definitely marked legal studies[263] has been illustrated by Peter Brooks in "Narrative in and of the Law".[264] In the Unites States, it has been pointed out,[265] it was the work by Robert Cover entitled 'Nomos and Narrative', published in 1983, and, then, "Violence and the Word", which largely contributed to foster narrative studies centered on the law. However, Stern noted that the narrative approach has been restricted mostly to narrow areas of the law, such as "trial advocacy, 'outsider' jurisprudence, and occasionally topics such as search and seizure, and the 'grand' narratives of constitutional law".[266]

Lately, narrative analysis has also been drawn upon to examine intellectual property law of biotechnology[267] and specific case law concerning the property over human biological materials.

Narrative scholars, however, have overlooked the relationship between technoscientific and legal narratives in judicial decisions, which has been addressed by the S&TS scholar Sheila Jasanoff in "Science at the Bar",[268] in which she focused on how shifting of meanings are brought about and stabilized by the intertwining of different kinds of narratives.

Greta Olson has explained that narrative can be employed "a form of rhetoric", but also as *grand récits*, namely "larger narratives about what the law does".[269]

In narrative analysis *what* is narrated and *how* are referred to as "story" and "discourse". Whereas the former "denotes what a jurist might call the facts of a case, or the known sequence of events",[270] the latter "describes the form that the narrative takes, including the perspective from which the story is told, from a position within or outside of the story world, and in a first- or third-person voice, and from a singular perspective or multiple ones".[271]

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[263] Michael Hanne and Robert Weiseberg (eds), *Narrative and Metaphor in the Law* (Cambridge University Press 2018) v; Peter Brooks and Paul Gewirtz (eds), *Law's Stories: Narrative and Rhetoric in the Law* (Yale University Press 1996), v.

[264] Peter Brooks, 'Narrative in and of the Law' in James Phelan and Peter J Rabinowitz (eds), *A Companion to Narrative Theory* (Blackwell 2005) 415.

[265] Greta Olson, 'On Narrating and Troping the Law: the Conjoined Use of Narrative and Metaphor in the Legal Discourse' in Michael Hanne and Robert Weisberg (eds), *Narrative and Metaphor in the Law* (Cambridge University Press 2018) 19, 21.

[266] Simon Stern, 'Narrative in the Legal Text: Judicial Opinions and Their Narratives' in Michael Hanne and Robert Weisberg (eds), *Narrative and Metaphor in the Law* (Cambridge University Press 2018) 121, 123.

[267] Hyo Yoon Kang, 'An Exploration into Law and Narratives: The Case of Intellectual Property Law of Biotechnology' (2006) 17 Law Critique 239. Hyo Yoon Kang, 'Identifying John Moore. Narratives of Persona in Patent Law relating to Inventions of Human Origin' in Peter Glasner, Paul Atkinson and Helan Greenslade (eds), *New Genetics, New Social Formations* (Routledge 2006) 138.

[268] Sheila Jasanoff, *Science at the Bar* (Harvard University Press 1997).

[269] Olson (n 265) 24.

[270] ibid.

[271] ibid 24-25.

Linda Berger has explained that narratives and metaphors are intertwined in legal settings because they "reassure us that things hang together, providing a sense of coherence to the patterns and paths we employ for perception and expression".[272] In particular, she pointed out their cognitive dimension from the point of view of legal rhetoric, which is focused on persuasion.[273]

However, from an S&TS perspective, the analysis of the relationship between narrative and metaphors in specific legal contexts,[274] such as judgements on biotech patent claims in particular jurisdictions, account for specific ways of "making sense and order" of new technoscientific products (and processes) and stabilizing their collective meaning by continuously drawing the line between nature and artifacts (as inventions), nature and culture. In that relationship, S&TS points to a mutual shifting of metaphors and narratives between technoscience and law which results in the settlement and unsettlement of meanings, which justifies and legitimises legal and policy choices.

1.4 Metaphor (and Analogy) in Science and Law

Metaphor is defined in the Oxford English Dictionary as "A figure of speech in which a name or descriptive word or phrase is transferred to an object or action different from, but analogous to, that to which it is literally applicable".[275] Its etymology comes from the ancient Greek *μεταφορά*, formed by the prefix *μετα- and φορά*, which means carrying, bearing, "after *μεταφέρειν*"[276] which signifies to transfer.[277]

Metaphor has been viewed, for most of the twentieth century, with mistrust and scepticism by legal and science scholars for methodological and epistemic reasons. Justice Cardozo, addressing the problem of the relation between parent and subsidiary corporations in 1926, pointed out that it was "still enveloped in the mists of metaphors"[278] and famously censured their use in the law:

> "Metaphors in law are to be narrowly watched, for starting as devices to liberate thought, they end often as enslaving it. We say at times that the corporate entity will

[272] Linda L Berger, 'The Lady, or the Tiger? A Field Guide to Metaphor and Narrative' (2011) 50 Washburn Law Journal 275.
[273] ibid.
[274] Hyo Yoon Kang, has applied narrative analysis specifically to study the intellectual property law of biotechnology. Kang (n 267).
[275] Headword "metaphor", *Oxford English Dictionary*, available at <http://www.oed.com/view/Entry/117328?redirectedFrom=metaphor&>.
[276] ibid.
[277] ibid.
[278] Court of Appeals of New York, *Berkey v. Third Ave. Ry. Co.*, 31 December 1926, 155 North Eastern Reporter 58, 61 (244 N.Y. 84).

be ignored when the parent corporation operates a business through a subsidiary which is characterized as an 'alias' or a 'dummy'".[279]

This statement epitomizes how low the appraisal of metaphors in law has been by legal scholars, because of the misleading character which is coupled with it. However, at present, still many legal textbooks express distrust towards resorting to metaphors in the legal discourse.[280]

Likewise, in science, drawing metaphors as useful theoretical tools has been disdained and largely disregarded, in the twentieth century. Only from the 1960's the study of the use of metaphors in different scientific fields has gained momentum, from the hard sciences to biology. As both science and the law, because of the significant influences of neo-positivism and legal positivism, were posited to have epistemic and methodological claims to certainty and truth, as far as "the is" and "the ought" of the world is concerned, the recourse to metaphors in these areas seemed, for decades, an admission of failure or betrayal of these aspirations. Moreover, civil law systems, like the French, German and Italian ones, are grounded on a specific idea of rationality linked to the enactment of codes as complete and coherent legal statute, under which any concrete legal case can be subsumed simply applying the canons of interpretation. Under this idea of rationality, the ambiguities of metaphorical polysemy are banned in the name of the certainty and clarity offered by the rules of the code.

This partially accounts for the fact that legal scholars have long ignored its pervasiveness in legal narratives as a means of interpretation and integration and, in particular, more recently its use in the definition of legal concepts at the crossroads of science and technology.

Metaphors have been studied from different perspectives since ancient times in several fields of knowledge, such as rhetoric, philosophy, literature,[281] linguistics, psychology and science. These theories have a specific focus and offer different answers to the issues of its meaning (linguistics theories) and use (pragmatics theories). The bibliography on metaphor and its theory is, therefore, boundless. The so called "classic" theories account for the metaphor in terms of *comparison, anomaly* or *interaction*.[282] However, a new generation of theories has arisen, which view metaphor as *class-inclusion statement* or as a *conceptual* means, rather a figure of thought than a figure of speech.[283]

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[279] ibid.
[280] Olson (n 265) 31-32.
[281] G R Boys-Stones, *Metaphor, Allegory, and the Classical Tradition* (Oxford University Press 2003) 1.
[282] Cristina Cacciari, 'La metafora: da evento del linguaggio a struttura del pensiero' in Cristina Cacciari (ed), *Teorie della metafora: l'acquisizione, la comprensione e l'uso del linguaggio figurato* (Raffaello Cortina 1991) 1, 4.
[283] ibid.

Metaphor has, nevertheless, elicited considerable attention in the last decades. The relevant role of analogy and metaphor in science has been studied, since the 1960s, by the philosopher of science Mary Hesse,[284] who showed the "all-pervasive character of metaphor in natural language"[285] and that metaphors mediate a kind of social knowledge[286] and challenged the deductive model of scientific explanation, arguing that it should be modified and integrated by a concept of theoretical explanation as a metaphorical re-description of the domain of the *explanandum*.[287] Max Black,[288] whose work on metaphor Hesse mostly referred to, in the same years, devised a new interaction theory of metaphor. Several scholars, later, further explored the pivotal role of metaphor in different scientific fields, such as biology, chemistry, and physics.[289] Moreover, the publication of the two editions of "Metaphor and Thought", edited by Andrew Ortony, in 1979 [290] and 1993, [291] the first volume collecting interdisciplinary essays on metaphor by eminent scholars in several disciplines, was a seminal moment for the study of metaphor, as it brought together and linked the research in different fields and its contributions are still extensively referred to and discussed at present. [292] This publication was followed by a third volume entitled "The Cambridge Handbook of Metaphor and Thought" which was edited by the linguistic psychologist Raymond W. Gibbs Jr. and published in 2008, which aimed at providing further developments about contemporary research on metaphor, showing how it contributes to human cognition, communication and culture.[293]

With reference to legal theory, the significance of metaphor has been addressed and illustrated, since the 1950s, by the logician and legal scholar Chaïm Perelman, who authored with the social sciences' scholar Lucie Olbrechts-Tyteca, a pivotal work entitled "The New

[284] Mary B Hesse, *Models and Analogies in Science* (University Notre Dame Press 1966) 3.
[285] Mary B Hesse, "The Cognitive Claims of Metaphor", (1988) 1 The Journal of Speculative Philosophy (New Series) 1, 7.
[286] ibid 8.
[287] Hesse (n 284) 157.
[288] Max Black, *Models and Metaphors. Studies in Language and Philosophy* (1st edn 1962, Cornell University Press 1968) ix.
[289] Fernand Hallyn, *Metaphor and Analogy in the Sciences* (Kluwer Academic Publishers 2000) vi; Theodore L Brown, *Making Truth: Metaphor in Science* (University of Illinois Press 2003) x; M Bradie, "Models and Metaphors in Science: The Metaphorical Turn", (1998) 12 *Protosociology* 305; Elena Gagliasso and Giulia Frezza (eds), *Metafore del vivente. Linguaggi e ricerca scientifica tra filosofia, bios e psyche*, (Franco Angeli 2010) 5.
[290] Andrew Ortony (ed), *Metaphor and Thought* (Cambridge University Press 1979) vi.
[291] ibid 2.
[292] Raymond W Gibbs Jr., "Metaphor and Thought. The State of the Art", in Raymond W Gibbs Jr. (ed) *Metaphor and Thought* (Cambridge University Press 2008) 3.
[293] ibid.

Rhetoric: A Treatise on Argumentation".[294] Their work questioned the centrality of *demonstration* (which is meant as logical deduction)[295] as means of proof and logical justification. In particular, they pointed out that, although demonstration is employed in scientific disciplines, it should not be regarded as the only means of practical rational justification. Conversely, they claimed and showed the value of *argumentation* in providing reasonable arguments for persuasion, which results from conveying *effective* arguments. In particular, Perelman, in his further work, showed that the law and its logic centered on argumentation shall be taken as a model of reasoning in other practical fields.

Although their theory drew on a longstanding Western rhetorical tradition, which it is not specifically rested upon, in this thesis, their analysis of the relationship between metaphor and analogy[296] might be insightful to understand how metaphors have been applied in defining and ruling biotech patentable subject matter.

In their treatise, they refer to Aristotle's definition of metaphor in *Poetics* as "the application of a word that belongs to another thing: either from genus to species, species to genus, species to species, or by analogy".[297] Under the definition of metaphor, Aristotle included figures of speech that scholars have later distinguished from it, namely metonymy and synecdoche, and devised a theory of metaphor as comparison. According to this view a metaphor is, as Searle explained, an ellipsis of a simile, in which "like" or "as" has been deleted.[298]

Among the examples offered by Aristotle of metaphor, there is one in which, according to Perelman and Olbrechts-Tyteca, the analogical relationship is brought into focus, because it pinpoints how "a metaphorical expression can rise from an analogy".[299]

Aristotle, in fact, further clarified: "I call 'by analogy' cases were *b* is to *a* as *d* is to *c*: one will then speak of *d* instead of *b*, or *b* instead of *d*. Sometimes people add that to which the replaced term is related. I mean, e.g., the wine bowl is to Dionysus as the shield to Ares: so one will call the wine bowl 'Dionysus' shield', and the shield 'Ares' wine bowl'. *Or the old*

[294] Chaïm Perelman and Lucie Olbrechts-Tyteca, *The New Rhetoric. A Treatise on Argumentation* (1st edn 1958, Notre Dame Press 1971) v.
[295] Robert Alexy, *Teoria dell'argomentazione giuridica* (Giuffrè 1998) viii, 125.
[296] Perelman and Olbrechts-Tyteca (n 294) 399.
[297] Aristotle, *Poetics* 1457b, 7-9, Stephen Halliwell (ed and traslator) (Loeb Classical Library, Harvard University Press 1999) 3, 105.
[298] John R Searle, 'Metaphor', in Andrew Ortony (ed), *Metaphor and Thought* (Cambridge University Press 1993) 83, 95.
[299] Perelman and Olbrechts-Tyteca (n 294) 399.

age is to life as evening to day: so one will call evening 'the day's old age', or like Empedocles, call old age 'the evening of life' or 'life's sunset'".[300]

In this last example, they commented that "the analogy 'A is to B as C is to D' yields the expression 'C of B' to designate A".[301] They, therefore, argued that a metaphor can be well-described as "condensed analogy, resulting from the fusion of an element from the phoros with an element from the theme".[302] As a result of this fusion, the analogy is not conveyed as a suggestion, but as a *datum*.[303]

As Perelman elucidated the formula of analogy is: "a/b as c/d"[304] and, in case of a mathematical proportion, is "a/b = c/d".[305] He addressed the relationship of metaphor and analogy also in other texts, explaining that analogy means "proportion" and it establishes a similarity of relationship, in which two heterogeneous domains are confronted in order to clarify or assess the first couple (called "theme") in the light of the second couple (called "phoros").[306]

The concept of analogy expounded by Aristotle in *Poetics* must be distinguished from analogical reasoning, which he referred to in *Prior Analytics* as "example" (or proof by example),[307] which has been deemed, since the Middle Ages, an autonomous form of reasoning, which proceeds from particular to particular.[308] The development of legal analogy, which has been devised and elaborated in the legal sciences as a means of integration of the law, arose from Aristotle's work on "example" as analogical reasoning.

Legal analogy is a form of reasoning which aims at filling legal gaps, in Latin *lacunae*, which is allowed to be drawn upon by judges when a particular concrete case (*species facti*) cannot be solved by subsuming it under one or more legal provisions. The logical structure of analogical reasoning, as Bobbio illustrated, is the following: "S is similar to M; M is P: S is P".[309] This kind of analogical reasoning has been referred to an *analogia legis*, which is

[300] Aristotle, *Poetics* 1457b, 15-24, Stephen Halliwell (ed and traslator) in (Loeb Classical Library, Harvard University Press 1999) 3, 106-107.
[301] Perelman and Olbrechts-Tyteca (n 294) 399.
[302] ibid.
[303] ibid 400.
[304] Chaïm Perelman, 'Analogia e metafora' *Enciclopedia Einaudi* I (1977) 523. Translation mine.
[305] ibid.
[306] Chaïm Perelman, 'Analogia e metafora', *Enciclopedia Einaudi* I (1977) 523.
[307] Aristotle, *Prior Analytics*, II. XXIV, in Hugh Tredennick (ed and translator) (Loeb Classical Library, Harvard University Press 1938) 182, 515 and 517.
[308] Norberto Bobbio, 'Analogia' *Contributi ad un dizionario giuridico* (Giappichelli 1994) 1, 3.
[309] ibid 3. Translation mine.

distinguished from *analogia iuris*, namely a process of legal integration, not strictly analogical, in which a legal gap is solved by resorting to general legal principles.[310]

Canale and Tuzet explained that the legal gap "is filled by arguing analogically from a source case to a target case"[311] and the scheme of analogy is:

> "C_1 falls under N_1.
>
> C_2 does not fall under any actual norm of the system (there is a gap in the law).
>
> There is relevant similarity between C_1 and C_2.
>
> C_2 falls under N_2 obtained by analogical reasoning (filling the gap)".[312]

In analogical reasoning, therefore, the regulation of the source case C1 is extended to the target case C_2, by creating analogically a new norm N_2 from N_1.[313]

As legal analogy is not a deductive argument, which is the logically valid form of inference, it does not guarantee the truth of the conclusion, even if its premises are true.[314] The conclusions drawn from legal analogy are not causal or predictive, as White pointed out, but normative, as they regard the "correct legal outcome".[315]

Golding pinpointed that, as far as the use of metaphor is concerned, "the crucial question is whether the compared objects resemble (and differ from) one another in *relevant* respects, that is, respects that are relevant to possession of the inferred resemblance".[316] In particular, he highlighted that the assessment of the factors, such as "the number of respects in which the compared objects resemble one another (positive analogies) and the number of respects in which they differ (negative analogies)"[317] is complex. In this assessment, the judge makes several relevant personal choices on the factors that should privileged over others and, therefore, exercise his discretion. However, a good analogical argument should be possibly based on relevant characteristics (albeit few) rather than many irrelevant ones.[318]

Furthermore, it has been illustrated[319] that stating that "A is similar to B", which is at the core of analogical reasoning entails two problems. The first problem was explained by Goodman,

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[310] ibid 11.
[311] Damiano Canale and Giovanni Tuzet, 'Analogical Reasoning and Extensive Interpretation' in Hendrik Kaptein and Bastiaan van der Velden (eds), *Analogy and Exemplary Reasoning in Legal Discourse* (Amsterdam University Press 2018) 66, 69.
[312] ibid.
[313] ibid.
[314] Martin Golding, 'Argument by Analogy in the Law' in Hendrik Kaptein and Bastiaan van der Velden (eds), *Analogy and Exemplary Reasoning in Legal Discourse* (Amsterdam University Press 2018) 123, 124.
[315] Jefferson White, 'Analogical Reasoning' in Dennis Patterson (ed) *A Companion to Philosophy of Law and Legal Theory* (Wiley-Blackwell 2010), 571, 572.
[316] Golding (n 314) 124.
[317] ibid.
[318] ibid.
[319] White (n 315) 572-574.

who pointed out that this statement is incomplete, in so far as "the properties to which the similarity claim refer" have been identified. Since A and B could be stated to be alike in numberless ways, restrictions on the relevant properties should be made, but any kind of restriction hangs on "an intrinsically relative judgment".[320] Moreover, White pinpointed that, before adjudication, "the similarities which bear upon various specific issues within a case must be *collectively* assessed in order for a determination of overall fit between precedent cases and the case at hand to be made".[321]

Several different theories have been developed in order to understand the analogical patterns of inference,[322] in particular by Klug,[323] Alexy,[324] Brewer[325] and Weinreb.[326]

It should be noted that whereas, in civil law systems, judges rather refrain from acknowledging the need for analogical reasoning, because of the uncertainty and judicial discretion which have been coupled with it in the civil law cultural tradition; in common law countries, as the analysis of the case law regarding biotech patent claims also shows, justices refer to its use in a much more liberal way, as a practical resource to adjudicate in a new case.

Weinreb remarked that, in the United States, "Not only do analogical arguments figure prominently in briefs and opinions, but they are also a standard feature, one might almost say a defining feature of legal education; the content of Socratic dialogue, on which law school classes are typically built in, is mostly an exercise in reasoning by analogy".[327] He referred, in particular, to the U.S. scientific tradition of studying that stemmed from the "case method of legal education",[328] which was introduced, in 1870, at the Harvard Law School by Langdell.[329] This method is posited to replicate what occurs in the process of adjudication, in which lawyers and judges relentlessly recur to analogical reasoning.[330]

However, as this work will illustrate, in common law patent jurisdictions, such as U.S. and Canada, judges, lawyers and *amici curiae* make reference to analogies mostly not acknowledging the need to fill a legal gap and drawing on metaphors which convey

[320] ibid 573.
[321] ibid.
[322] Fabrizio Maccagno and Douglas Walton, 'Argument from Analogy in Law, the Classical Tradition, and Recent Theories' (2009) 42(2) Philosophy & Rhetoric 154.
[323] Ulrich Klug, *Juristische Logik* (1st edn 1951, Springer 2014) 2.
[324] Robert Alexy, *A Theory of Legal Argumentation: The Theory of Rational Discourse as Theory of Legal Justification* (1st edn 1978, Oxford University Press 2010) viii.
[325] Scott Brewer, 'Exemplary Reasoning: Semantics, Pragmatics, and the Rational Force of Legal Argument by Analogy' (1996) (109)5 Harvard Law Review 923.
[326] Lloyd L Weinreb, *Legal Reason: The Use of Analogy in Legal Argument* (1st edn 2005, Cambridge University Press 2016) v.
[327] ibid 10.
[328] ibid 128.
[329] ibid 128-130.
[330] ibid 132.

analogical features across cases. It has been noted that, when courts in the U.S. reason analogically, the principle that they elaborate "appears not to reach further than what is required by a comparison of the specific facts before the court with other facts, equally specific, for which the result is known".[331] Furthermore, only in a few cases the arguments of the courts provide the statement of a general rule.[332] Nevertheless, the use of precedent is focused on the use of the relevant rule which grounds the decision, which constitutes the precedent[333] and how to differentiate[334] the *ratio decidendi* from *obiter dictum*.[335]

Several differences emerge across particular national jurisdictions, such as the United States and Canada, as far as what judges recognize as the appropriate limits of their role in recurring to legal analogy.

Nevertheless, as this work will show, when the reference to an analogy is made in patent case law is general, not strictly linked to formal analogical reasoning. However, in several cases metaphors are drawn upon in order to create analogies.

The perspective that will be applied to analyse the metaphors used in legal discourse, in order to establish the patentability of biotech products, is centered on "conceptual metaphor" and was developed by the cognitive linguists George Lakoff and Mark Johnson in the seminal monograph "Metaphors We Live By",[336] firstly published in 1980, in which they argued that metaphor should be interpreted as "metaphorical concept".

Cognitive linguistics defines metaphor as understanding and experiencing[337] one conceptual domain (the target domain) in terms of another conceptual domain[338] (the source domain), namely "CONCEPTUAL DOMAIN (A) is CONCEPTUAL DOMAIN (B)".[339] The source domain (B) is, as Kövecses illustrated, "the conceptual domain from which we draw metaphorical expressions to understand another conceptual domain",[340] whereas the target domain is the conceptual domain which is understood by resorting to the source domain (A).

Understanding one domain (a) in terms of another (B) means that "there is a set of systematic correspondences between the source and the target in the sense that conceptual elements of B

[331] ibid 34.
[332] ibid 35.
[333] Alexy (n 324) 218.
[334] In that respect, the doctrine of *dictum* in Anglo-American jurisprudence has pivotal significance. See White (n 258) 571-572.
[335] Alexy (n 324) 218-219.
[336] Lakoff and Johnson (n 45) vii.
[337] ibid 5.
[338] Zoltán Kövecses, *Metaphor: A Practical Introduction* (Oxford University Press 2002) viii, 4.
[339] ibid.
[340] ibid.

correspond to conceptual elements of A",[341] which are named "mappings". The use of a metaphor, therefore, implies a set of systematic correspondences between the two domains.

Conceptual metaphor is related to metaphorical linguistic expressions, which are "words or other linguistic expressions that come from the terminology of the more concrete conceptual domain (i.e. domain B)",[342] since the latter contribute to settle and reinforce the former. Nevertheless, conceptual metaphors are differentiated from linguistic metaphors or metaphorically linguistic expressions. Linguistic metaphors have been defined as "the linguistic realizations or manifestations of underlying conceptual metaphors".[343]

As metaphorical linguistic expressions in language are *systematically* linked to metaphorical concepts, their study proves to be fundamental in order to understand metaphorical concepts and how they make sense and order human activity.[344]

Lakoff and Johnson's theory of metaphor is based on the view that "metaphor is pervasive in everyday life, not just in language but in thought and action"[345] and that the nature of the conceptual system is *fundamentally* metaphorical. Metaphorical concepts structure human perceptions (what and how humans perceive), relationships (how humans relate to things, animals and other people) and actions (what humans do). Furthermore, they point out that they are not just a matter of words, figures of speech and rhetorical means, but regard *ordinary* language and structure both thought and action.[346]

According to cognitive linguistics, metaphor is characterized by *sistematicity*, which allows understanding a concept in terms of another, but hides some aspects of it: understanding one aspect of a concept in terms of another entails that some aspects of it are highlighted, but others, inconsistent with the metaphor, are hidden.[347] Embracing a metaphor implies, therefore, the dismissal of some aspects of experience which are inconsistent with it.

Furthermore, Cognitive linguists highlight that metaphors are "built into the conceptual systems"[348] of the cultures and are context-dependent.[349]

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[341] ibid 6.
[342] ibid 4.
[343] ibid 29.
[344] Lakoff and Johnson (n 45) 7.
[345] ibid 3.
[346] ibid 4-5.
[347] ibid 10.
[348] ibid 64.
[349] Zoltán Kövecses, *Where Metaphors Come From: Reconsidering Context in Metaphor* (1st edn 2015, Oxford University Press 2017) ix.

This theory shows that metaphor is pervasive in ordinary life,[350] that the conceptual system is "fundamentally metaphorical in nature"[351] and metaphors orient perceptions, thought and actions.[352]

The theoretical view of cognitive linguistics has been favoured and endorsed, in this work, for its explanatory power in comparison to other theories of metaphors, as it fills a gap in addressing how metaphors are pervasive in everyday life, scientific disciplines and the law. Moreover, as the thesis will show, metaphors in different scientific and legal contexts are still enduring, even though their contingent role seems to be accomplished. Without positing that human conceptual systems is metaphorical it would be difficult to understand why metaphors are so enduring and why patent law in defining the model of patentability refers to them constantly, even though they are considered outdated and unsuitable to define a new technology and its products.

Kövecses illustrated that metaphors are classified according to the degree of "conventionality" that they entail, namely how deeply they are well established and well entrenched "in everyday use by ordinary people for everyday purpose". [353] Moreover, they have been distinguished according to their function. Whereas *structural* metaphors "enable speakers to understand target A by means of the structure of source B",[354] the cognitive function of *ontological* metaphors is to provide "an ontological status to general categories of abstract target concepts". [355] *Orientational* metaphors, moreover, provide "basic human spatial orientation, such as up-down, center-periphery, etc.".[356]

In this work, it will be argued that the seminal metaphors used in the legal discourse concerning the patent eligibility biotech claims are *structural* and *ontological*. Lakoff and Johnson explained that *ontological* metaphors have different purposes, such as referring, quantifying, identifying aspects and causes, setting goals and motivating action. They also provide metaphorical *models* for what something is. They instantiate their statement referring to the metaphor "THE MIND IS A MACHINE". The use of this metaphor allows specifying certain kinds of objects, by highlighting specific features of them. In this case, they remark, the metaphor offers a "conception of the mind as having an on-off state, a level of efficiency,

[350] Lakoff and Johnson (n 45) 3.
[351] ibid.
[352] ibid 4.
[353] Kövecses (n 338) 29-30.
[354] ibid 33.
[355] ibid 34.
[356] ibid 35-36.

a productive capacity, an internal mechanism, a source of energy, and an operating condition".[357]

By drawing on the conceptual theory developed by Lakoff and Johnson, it will be explained in the following chapters that some metaphors, such as "machine", "molecule" and "code", were pivotal in order to decide whether new biotechnological products and processes fell within the legal concepts of "patentable subject matter" and "invention".

It will be shown that, even though these metaphors have been referred to by judges, parties and *amici curiae* as concepts which provide a description of claimed inventions, their origins and use is metaphorical and to a large extent they have been constructed and endorsed in molecular biology and genetics, but they have become so entrenched in the way in which professionals (patent lawyers and attorneys, patent examiners and judges) and common people think and act about these objects.

The legal use of metaphors and the analogies they imply has been overlooked in specific areas of the law. However, more recently, scholars have addressed how narrative and metaphor are intertwined in the law.[358] As far as patent law is concerned, only a few scholars have illustrated the metaphorical and analogical dimension which marks the definition of patent eligible invention in biotechnology. Graham Dutfield,[359] a scholar in the global governance of IP, and the S&TS scholar Mariachiara Tallacchini[360] have devoted part of their work to open up the arguments carried out by judges in patent decisions and pinpointed how metaphors are at the core of construction of meanings and the settled "nature" of patentable objects.

This work aims at filling partially this gap, by addressing a large area of the biotech IP case law and focusing on landmark judicial patent decisions in different systems which involved the definition of what is patent eligible. The aim of this analysis is to account for the shifting of meanings between science, law and society in defining legal concepts. The focus of the research will be, therefore, the concepts of "patentable subject matter" and "invention", as the threshold and core of the definition of what is patentable. The requirements of patentability will sometimes be referred to, when claimants and judges have raised issues of their fulfillment in these cases, which shaped the boundaries of patent eligibility.

1.5 Legal Fictions, Metaphors and Analogies

[357] Lakoff and Johnson (n 45) 28.
[358] Hanne and Weiseberg (n 206) v.
[359] Dutfield (n 31a) 172; Dutfield (n 31b) 531.
[360] Tallacchini (n 31a) 145; Tallacchini (n 31b) 203.

Legal Fictions, metaphors and analogies have been at the forefront of the development and evolution of legal concepts, statutory classes and doctrinal categories for centuries. Their salience lies in being creative means of interpretation and integration of the law, which have been applied to address statutory gaps and scientific uncertainties emerging in litigation.[361] Their theory offers significant insights in understanding how the scope of patent eligible invention has been constantly re-framed. In particular, their analysis shows the cognitive, practical and creative work which is involved in the evolution of law.

Legal fictions, which characterised Roman law and had also a relevant role in the common law tradition,[362] have elicited new theoretical interest in the 20th century after the publication of Hans Vaihinger's philosophical work on fiction "The Philosophy of 'As-If'. A System of the Theoretical, Practical and Religious Fictions of Mankind" in 1922.[363] Following its publication, great theorists of law, such as Hans Kelsen and Lon Fuller, devoted considerable attention to legal fictions and their prominence in the development of the law, as regards its theory and concepts.

Fictions perform numerous functions in legal systems, from solving problems of proof to mitigating the harshness of rules, but they are primary means to enable legal change,[364] as much as analogies and metaphors.

However, scholars have disagreed on what a legal fiction is and whether it pertains to the practice of the law or just its theory. In fact, the scholarship devoted to legal fictions made a significant distinction between fictions of theory and fictions of practice, claiming that fictions of practice were not authentic fictions.[365]

Legal fiction has been authoritatively defined by Fuller as "either (1) statement propounded with a complete or partial consciousness of its falsity, or (2) a false statement recognized as having utility".[366]

This definition narrows down the scope of what could be deemed a fiction to situations in which legal scholars and practitioners draw on a statement and are aware that it is false.

[361] The scholarship on legal fiction has largely commented cases of negligence in tort law regarding the exposure to asbestos, in which the recourse to fiction was prompted by the "indeterminacy of scientific evidence". Maksymilian Del Mar, 'Introducing Fictions: Examples, Functions, Definitions and Evaluations, in Maksymilian Del Mar and William Twining (eds) *Legal Fictions in Theory and Practice* (Springer 2015) v, xiv.
[362] ibid xiv.
[363] Hans Vaihinger, *The Philosophy of 'As-If'. A System of the theoretical, Practical and Religious Fictions of Mankind* (1922, 1st edn, Routledge and Kegan Paul 1924) v.
[364] Del Mar (n 361) xvi-xx.
[365] ibid xi.
[366] Lon L Fuller, *Legal Fictions* (1930-31, 1st edn, Stanford University Press 1967) viii, 9.

However, they do acknowledge its utility in terms of solving a legal issue, often arising from a statutory gap.

According to the theory of fiction articulated by Vaihinger, a fiction is characterised by the following elements: 1. a contradiction with reality or self-contradiction; 2. it must be provisional; 3. there must be awareness of its fictitious character; 4. it must be deemed an expedient.[367]

Kelsen, coherently with his general theory of law, endorsed an even narrower concept of legal fiction, which rejected the idea that fictions applied in the practice of the law were true fictions, arguing that legal fictions were only related to the theory of law.[368]

Under this restricted definition of legal fictions, in most jurisprudential cases in which the judge has to deal with a gap in the law, it would be hard to ascertain the existence of all these elements in the solution endorsed by the judge.

In the classic theory of fiction established by these theorists, the idea of fiction implies a realist epistemology, namely that there is a correspondence between language and the external world,[369] which supports the first and third elements of fiction formulated by Vaihinger.

The most recent development of the theory of fiction, conversely, has been predominantly marked by the endorsement of constructivist perspectives[370] and a more open definition of fiction,[371] which relates it to metaphor and analogy.

The distinction between fictions and metaphors is complex and difficult to outline. It largely depends on the kind of theory that the scholar endorses.

The work of the Danish legal realist Alf Ross on the types of legal fictions has addressed this distinction.[372] Fiction and metaphor are, according to him, both techniques of analogical extension of legal rules, by asserting an equivalence or identity.[373]

However, as a specific kind of legal fabrication, legal fictions are "posed proposition, which hazard a premise only to secure a particular doctrinal result".[374]

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[367] Christoph Kletzer, 'Kelsen on Vaihinger' in Maksymilian Del Mar and William Twining (eds) *Legal Fictions in Theory and Practice* (Springer 2015) 23, 24.

[368] Hans Kelsen, 'Zur Theorie der Juristischen Fiktionen: Mit besonders Berücksichttigung von Vaihingers Philosophie des Als Ob' (1919) 1 Annalen der Philosophie 630.

[369] Del Mar (n 361) xxi.

[370] ibid xxi-xxiii.

[371] See, for example, Geoffrey Samuel, 'Is Law Fiction?' in Maksymilian Del Mar and William Twining (eds) *Legal Fictions in Theory and* Practice (Springer 2015) 31.

[372] Alf Ross, 'Legal Fiction' in Graham Hughes (ed) *Law, Reason, and Justice* (New York University Press 1969) 217.

[373] Simon Stern, 'Legal Fictions and Exclusionary Rules' in Maksymilian Del Mar, 'Introducing Fictions: Examples, Functions, Definitions and Evaluations, in Maksymilian Del Mar and William Twining (eds) *Legal Fictions in Theory and Practice* (Springer 2015) v, 157, 158.

Stern has illustrated that, in his perspective, "legal fictions lack the generative potential of metaphors, because fictions depend on a truncated causal chain that exclude any consequence other than the doctrinal consequence the fiction was created to license, whereas metaphors spur on the imagination to make further connections".[375]

Moreover, fictions differ from legal doctrines because they are *not affirmed*: although their proposition consists apparently in an affirmative statement, their status is still hypothetical and does not allow drawing the broader consequences that a doctrine entails.[376]

The thesis embraces the distinction between legal fiction and metaphor set out by Ross, which highlights the further "generative potential" that metaphors involve in comparison with fictions.

It acknowledges, moreover, that legal fictions can be structured on metaphors, as part of the literature has illustrated, but several legal fictions "do not take the form of a metaphors" when no identity between terms is asserted.[377]

Furthermore, the thesis deems legal fictions significant in the evolution of the patentability of inventions, in particular as far as the development of the statutory requirements of novelty and originality/inventive step are concerned.

It argues and engages in showing, however, that conceptual metaphors (and the analogies that they entail), rather than fictions, played a more relevant role in settling the boundaries of patent eligible matter. This emerges clearly from the judicial narratives, which will be analysed in the thesis, in which metaphors are embedded.

In these narratives the courts, parties and *amici curiae*, far from acknowledging a statutory gap concerning the definition of patentable invention, *affirm* a conceptual metaphor as the very technoscientific and legal definition of the nature of the claimed invention.

Furthermore, as the following chapters will highlight, in their narratives the use of machine, molecule and code has open up a potential of practical consequences, which are not limited to one doctrinal consequence.

As Stern has illustrated, linguists have pointed out that metaphors are deemed "more productive than similes, because the former are less confined to a particular ground of similarity".[378]

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[374] ibid 157.
[375] ibid.
[376] ibid 158.
[377] Footnote 4, Stern (n 373) 159.
[378] Derdre Gentner et al., 'Metaphor is Like Analogy' in Dedre Gentner (ed) *The Analogical Mind: Perspectives from Cognitive Sciences* (The MIT Press 2000) 199, 200.

According to cognitive linguists, metaphors entail a more creative dynamic, because the identity that they establish involves *sistematicity*: namely the use of a metaphor prompts understanding a concept in terms of another and hides some aspects of it.[379] However, the grounds of similarity that the use of a metaphor involves and raises are manifold and culturally related.

Metaphors, as section 1.4 has illustrated, foster and establish analogies between different domains. This characteristic of the metaphor has been pointed out by Perelman and Olbrechts-Tyteca, who clarified that "a metaphorical expression can rise from an analogy",[380] because "the analogy 'A is to B as C is to D' yields the expression 'C of B' to designate A".[381] As a result, they argued that a metaphor can be defined as "condensed analogy, resulting from the fusion of an element from the phoros (the first couple) with an element from the theme (the second couple)".[382] The fusion entails that the analogy is not conveyed as a suggestion, but as a *datum*.[383]

Max Black,[384] who formulated the interaction theory of metaphor, as Hesse illustrated, has explained how the use of metaphors leads to "brings together the 'associated commonplaces' of the primary system in which the metaphor is used and the secondary system in which the word is literal". In his classic example, he clarified that: "When we say 'main is wolf', we are bringing wolf-like characteristics to bear upon our understanding of 'man' in such a way as to modify, emphasize and suppress certain of our previous held commonplaces about man. The metaphor is a filter through which we view the primary system. The effect of meaning, however, is a symmetrical interaction, because not only the connotations and hence the meaning of 'man' shifted, but also the connotations of 'wolf'. Wolves become more human after the metaphor is used: 'bestial' for instance becomes a term of abuse for beasts as well as men. *Since meanings are thus affected, there can be no explicit translation or paraphrase of a metaphor without cognitive loss*".[385]

The thesis will address these kind of analogies established though metaphors, not what are technically defined as legal analogies (*analogia legis* and *iuris*), which are means of integration of the law illustrated in section 1.4.

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[379] ibid 10.
[380] Perelman and Olbrechts-Tyteca (n 294) 399.
[381] ibid.
[382] ibid.
[383] ibid 400.
[384] Max Black, *Models and Metaphors. Studies in Language and Philosophy* (1962, 1st edn, Cornell University Press 1968) ix.
[385] Mary B Hesse, "The Cognitive Claims of Metaphor", (1988) 1 The Journal of Speculative Philosophy (New Series) 1, 6. Emphasis added.

Cognitive science scholars have noted that analogy, in a general sense" is "the ability to think about relational patterns" and crucial for human cognition.[386] It involves picking out patterns and identifying "recurrences of these patterns despite variation in the elements that compose them, to form concepts that abstract and reify these patterns, and to express these concepts in a language".[387] Analogy, therefore, is the ability to identify the sameness in the relations across domains.

This literature have pointed out that the fundamental processes of analogy characterize also metaphor.[388] In particular, scholars refer to the processes of structural alignment[389] (namely "an explicit set of correspondences between the representational elements of the two situations"),[390] inference projection,[391] progressive abstraction and re-representation which play a pivotal role in processing metaphors.[392] Metaphors, in this respect, have been considered similar to analogies, but their structure is more variable.[393]

Moreover, whereas analogies are deemed to be drawn upon more in "explanatory-predictive contexts", metaphors are also applied in "expressive-affective contexts".[394]

The thesis will show that the metaphors used in the IP judicial discourse are kinds of analogical legal and technoscientific "fabrications" that do not involve the recognition of the existence of a statutory gap. They constitute a common system of reasoning in the process of adjudication, which allows extending or limiting the application of a rule and legal category.

It should however be noted that, in civil law systems, judges tend to refrain from acknowledging the need for analogical reasoning, because of the uncertainty and judicial discretion which have been coupled with it in the civil law cultural tradition.

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[386] Keith J Holyoak, Dedre Gentner and Boicho N Kokinov, 'Introduction: The Place of Analogy in Cognition' in Dedre Gentner, Keith J Holyoak and Boicho N Kokinov (eds) *The Analogical Mind: Perspectives from Cognitive Science* (The MIT Press 2001) 1, 2.

[387] ibid.

[388] Gentner et al. (n 378) 243.

[389] Structural alignment has been strudied as "the mechanism that mediates analogical reasoning and similarity of judgments". Miriam Bassok, 'Semantic Alignments in Mathematical Word Problems' in Dedre Gentner, Keith J Holyoak and Boicho N Kokinov (eds) *The Analogical Mind: Perspectives from Cognitive Science* (The MIT Press 2001) 401, 402.

[390] ibid 200.

[391] The systematicity principle characterises structural alignment, but also the analogical inference as "people do not import random facts from base to target, but instead project inferences that complete the common system of relations. Gentner et al. (n 378) 201.

[392] ibid.

[393] Cognitive science's scholars pointed out that metaphor varies more than analogy structurally, as it can "be attribute matches, relation matches or both". Moreover, metaphors could encompass "complex blends that combine structure-mapping with metonymy and other processes". ibid 240.

[394] ibid.

Conversely, in common law countries, as the analysis of the case law regarding biotech patent claims also shows, justices refer to the use in a much more liberal and open way, as a practical resource to adjudicate in a new case.

Weinreb observed that in the United States, "Not only do analogical arguments figure prominently in briefs and opinions, but they are also a standard feature, one might almost say a defining feature of legal education; the content of Socratic dialogue, on which law school classes are typically built in, is mostly an exercise in reasoning by analogy".[395]

In particular, this work argues that the analogies conveyed by conceptual metaphors used in the judicial discourse passed mostly unnoticed, because of their validation from technoscience and their conventionality in the patent discourse.

This partially explains why the metaphorical dimensions of these judgements have been mostly overlooked by the IP legal literature[396] and this work aims at filling this gap.

1.6 A Matter of Imaginaries: Epistemology and Topography of Comparison

The aim of this thesis is to draw a comparison of the sociotechnical imaginaries of nature and life which biotechnology and the intellectual property over biotech inventions maintained and conveyed in different Western nation-states, namely the United States and Canada, and Europe (EPC member states). The main question that will be addressed is whether and how, in different sociopolitical contexts, distinct ways of imagining what biotechnology is and entails in terms of public good shaped different legal and policy responses. The suggested hypothesis is that, notwithstanding the globalization of intellectual property law and the increasing convergence in defining patentable subject matter and the requirements of patentability, the institutional and social modes of tackling biotechnology were contextual and partially diverged.

In this section, the reasons for the comparison, its boundaries and epistemic premises will be illustrated, as well as how the conceptual tool of "sociotechnical imaginaries" fills a gap in accounting for why biotechnology underwent such different reactions.

The theoretical relevance of comparison of political and legal systems in understanding how different societies, groups and individuals make sense and order of complex technoscientific phenomena should not be overlooked. In some areas of the law, such as intellectual property and more specifically patent law, the increasing convergence of the criteria for patentability

[395] ibid 10.

[396] With the exception of Graham Dutfield and Mariachiara Tallacchini. See Dutfield (n 31a) 172; Dutfield (n 31b) 531. Tallacchini (n 31a) 145; Tallacchini (n 31b) 203.

across states due to international treaties, has boosted accounts where differences across the countries are side lined in favor of more globalized views about how rules are implemented and enforced. Although some judicial cases, which will be analysed in the thesis, show that the interpretation and implementation of the patentability criteria are far from uniformly and univocally established, too often these differences are explained in terms lack of rationality, coherence and/or scientific knowledge exhibited by judges, citizens and parties involved in patent decisions. However, a more attentive and extensive comparison, where differences are not sidelined and dismissed, would contribute to gain a better understanding of how the boundaries of what is natural and artificial, patentable or not are drawn and re-drawn in specific sociopolitical contexts.

This thesis will draw upon the methodological and epistemic questions and problems that comparative legal theory has, partially, envisaged and refined. Its purpose, however, is not providing a comparative legal study, due to the epistemological and methodological lines that most comparative legal scholars endorse, which largely contrast with the S&TS co-productionist and narrative-based framework of this work. Comparative legal studies rely on a long and well-established tradition which dates back to the 19th century[397] and distinctive ways of addressing the basic questions of comparison: Why compare? What to compare? How to compare?

Although the present epistemic underpinnings of comparative legal research are more diversified than in the past,[398] it still largely relies on the concept of validation of the research assertions[399] or Popperian corroboration and non-falsification which does not fit with the post-Kuhnian constructivist epistemology that several streams of S&TS sustained and nurtured since the 1960s, as it has been explained in the appendix.

Although, at present, the comparative legal scholar Pierre Legrand points out that "law is a social phenomenon", [400] at least because it operates within society, and therefore the comparatist should rely on the insights offered by other fields, such as anthropology, linguistics and cognitive psychology,[401] most scholars still confine the boundaries of the field to the study of rules, judicial cases, legal concepts and institutes within definite legal traditions and cultures.

[397] Konrad Zweigert and Kurt Siehr, 'Jhering Influence on the Development of Comparative Legal Method' (1971) 19 American Journal of Comparative Law 215.
[398] Geoffrey Samuel, *An Introduction to Comparative Law Theory and Method* (Hart Publishing 2014) 79-120.
[399] Gérard Lenclud, 'L'Anthropologie et Sa Discipline' in Jean Boutier, Jean-Claude Passeron and Jacques Revel (Éditions de l'École des Hautes Études en Sciences Sociales 2006) 69.
[400] Pierre Legrand, 'How to Compare Now', (1996) 16 Legal Studies 232, 238.
[401] ibid.

Comparatists admit the need for an interdisciplinary approach,[402] however they do not question the concept of interdisciplinarity and how the boundaries among disciplines are drawn and the power that disciplinary discourse involve.

Furthermore, although comparative theory has been elaborating and focusing on alternative methodologies,[403] the functional method[404] is dominant. The functional method focuses on the facts behind the law and is marked by a *praesumptio similitudinis*.[405] It is mostly applied to judicial decisions, comparing the responses offered by different legal systems to the same situation.[406] As Michaels noted, it considers its objects in a functional relation to society and the function is intended as a *tertium comparationis*, namely institutions are comparable *only* if they fulfill a similar function in the various legal systems examined.[407] Moreover, in some forms of functionalism, functionality becomes a criterion of evaluation in order to establish the best law: the law that fulfills best its function in comparison to the others.[408]

The functional methodology underwent criticism by comparative law scholars and other legal fields, such as Critical Legal Studies (CLS).[409] Frankenberg criticized comparative legal scholars for their "faith in objectivity"[410] and for their mode of comparison marked by *cognitive control*, namely "the formalist ordering and labeling and the ethnocentric interpretation of information, often randomly gleened from limited data".[411]

S&TS epistemic perspective shows that these comparative methodological stances can be censured on the ground that facts, scientific and legal, result from a construction and that every distinction between legal and extralegal phenomena is the outcome of what the sociologists call "boundary work", namely the discursive attribution of selective qualities, in this case, to legal scholars, their method and their claims for the purpose of drawing a rhetorical boundary between the law and some less relevant phenomena.[412]

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[402] ibid.
[403] Samuel (n 398) 79-120.
[404] See Ralf Michaels, 'The Functional Method of Comparative Law' in Mathias Reimann and Reinhard Zimmermann (eds), *The Oxford Handbook of Comparative Law* (1st edn 2006, Oxford University Press 2008) 339-382.
[405] ibid 342.
[406] ibid.
[407] ibid.
[408] ibid.
[409] Ugo Mattei, 'Comparative Law and Critical Legal Studies' in Mathias Reimann and Reinhard Zimmermann (eds), *The Oxford Handbook of Comparative Law* (1st edn 2006, Oxford University Press 2008) 815.
[410] Günther Frankenberg, 'Critical Comparisons: Rethinking Comparative Law' (1985) 26 Harvard Journal of International Law 411.
[411] ibid 421.
[412] Thomas F Gieryn, *Cultural Boundaries of Science. Credibility on the Line* (The University of Chicago Press 1999) vii, 5.

Alternative methods could be applied in comparative legal analysis. The hermeneutical method, which focuses on the "cultural *mentalité*" or cultural structure that legal rules *signify*, and therefore on the historical, social, economic, political, cultural and psychological context which has shaped the rule [413] is characterized more by "an acknowledgement of 'difference'"[414] than similarity.

Notwithstanding the differences across all these methodologies, comparative law theory is marked and endorses, more or less implicitly, a *realist* cognitive perspective which contrasts with S&TS constructivist view of knowledge. The acceptance of the realist view of knowledge shines through the choice of language.

Moreover, comparative legal studies neglect the relevance of *materiality* and *technoscientific practices* in shaping legal concepts. For example, although Legrand pinpoints the relevance of the cultural structure which is expressed by legal rules in order to make a comparison, he does not consider both these elements as part of the comparative analysis. However, as far as intellectual property on genomic inventions is concerned, the S&TS scholar Stephen Hilgartner showed that, although the discussion on genomic property tends to focus on the Patent and Trademark Office and Courts' decisions as the sites of property production, the laboratory is equally fundamental as a site for the creation of scientific property. He pointed out that making knowledge and making property rights do not constitute two separate moves, temporally and institutionally. Conversely, the creation of patents is deeply embedded in laboratory's practices and routines.[415]

Finally, most comparative legal scholars argue for a *praesumptio similitudinis* that should inspire comparative work, but social studies of science and technology have proved that the judgments of similarity and difference are contingent.[416]

Comparative law studies are largely informed by the idea of comparing in order to find a better solution which could be exported or in order to harmonize. Comparative law analysis was devised as legal knowledge with practical purposes.

Conversely, S&TS view is not strictly prescriptive in its aims and is more focused on gaining a contextual view of how people make sense and order of what is new and maybe socially disruptive. In particular, the S&TS' comparative approach hinges on the concept of civic epistemologies, which has been elaborated by Jasanoff. Civic epistemology has been defined as "the institutionalized practices by which members of a given society test and deploy

[413] Legrand (n 400) 236.
[414] ibid 239.
[415] Hilgartner (n 49) 131.
[416] Jasanoff (n 44) 13.

knowledge claims used as a basis for making collective choices".[417] This theoretical comparative tool is crucial to understand why technoscientific societies make diverging choices about how to frame new technologies.[418] This concept draws upon the insight that "modern technoscientific cultures have developed tacit knowledge-ways through which they assess the rationality and robustness of claims that seek to order their lives".[419] Civic epistemology is a useful comparative tool in addressing how publics challenge patent policies and decisions in different jurisdictions, as chapter three to six will show.

The reasons for focusing this work on the comparison of different political systems rely on its main research assumption, namely that different sociotechnical imaginaries shaped the way in which biotechnology has been addressed in different political contexts, at the nation-state level and the regional and international ones. Only a comparison would allow understanding whether these differences emerged and account for distinctive policy and legal responses or not. Comparison, moreover, entails the constant questioning of legal categories, institutes and cultures, as well as the "point of view" of the scholar, which is far from being a "view from nowhere".

In order to assure the consistency of the comparison, this work will take into consideration two nation-states, the United States and Canada, which are industrially and technologically advanced and with high interests in the development of biotechnology, since the 1970s, and Europe, namely the Member Countries of the EPC that are mostly members of the European Union, which in the same years envisaged biotechnology as a promising field to be sustained and fostered, but is regional political entity whose member states equally possess technoscientific and industrial resources. Biotechnology, as it will be shown in the thesis, has been an important benchmark on which the European identity was tested.

The comparison draws on the concept of sociotechnical imaginaries in order to address why, even though the definition of patent eligible matter was alike in different jurisdictions, it has evolved dissimilarly.

Political science scholars and theorists have devoted, since the 1980s, a considerable amount of their work to the concept of "imaginary" in order to explain several collective phenomena, in broader or smaller scales. The political scientist Benedict Anderson illustrated how the nation should be explained as "an *imagined* political community" and that the national imaginary accounts for how heterogeneous individuals, inhabiting a different place and time,

[417] ibid 255.
[418] ibid.
[419] ibid.

make sense of their identity and experience as "common".[420] The political philosopher Charles Taylor, in *Modern Social Imaginaries*,[421] examined how forms of social imaginaries have marked and supported the settlement of Western modernity and its new moral order. The political theorist Yaron Ezrahi, in *Imagined Democracies*,[422] explored why and how democracies rely on performative imaginaries in order to legitimise their power and agency before citizens.

In Science and Technology Studies, the concept of "sociotechnical imaginaries" has been devised, in the last decade, as an analytical tool in order to address "the sources of the long-lasting cross-national variations in S&T policy"[423] and a theoretical gap in explaining "the relationship of science and technology to political institutions".[424] This work relies on it in addressing how different modes of envisioning life and nature arose from the construction of IP over biotech inventions in different "Western nation-states".

Sociotechnical imaginaries have been defined as "collectively imagined forms of social life and social order reflected in the design and fulfillment of nation-specific scientific and/or technological projects".[425] Their relevance as cultural resource lies in their descriptive and, at once, prescriptive dimension, in their conveying a specific description of an attainable future and prescribing that it ought to be pursued and achieved:

> "They project visions of what is good, desirable, and worth attaining for a political community; they articulate feasible futures. Conversely, imaginaries also warn against risks or hazards that may accompany innovation if it is pushed too hard or too fast. In activating collective consciousness, imaginaries help create the political will or public resolve to attain them".[426]

They provide a cultural resource to understand how policies of innovation are promoted and justified in terms of "what constitutes public good"[427] by political institutions, but also by administrative and judicial ones. In fact, through their practices and decisions, national patent offices, the European Patent Office (EPO), as well as judges deciding on patent cases, endorse and foster sociotechnical imaginaries of innovation, progress and public good, as

[420] Benedict Anderson, *Imagined Communities* (Verso 2006) xi.
[421] Charles Taylor, *Modern Social Imaginaries* (Duke University Press 2007) 2.
[422] Yaron Ezrahi, *Imagined Democracies. Necessary Political Fictions* (Cambridge University Press 2015) vii.
[423] Sheila Jasanoff and Sang-Hyun Kim, 'Containing the Atom: Sociotechnical Imaginaries and Nuclear Power in the United States and Korea' (2009) 47 Minerva 119, 120.
[424] ibid; Les Levidow and Theo Papaioannou, 'State Imaginaries of the Public Good: Shaping UK Innovation Priorities for Bioenergy' (2013) 30 Environmental Science and Policy 36, 38.
[425] ibid.
[426] ibid 123.
[427] Sheila Jasanoff and Sang-Hyun Kim (eds), *Dreamscapes of Modernity. Sociotechnical Imaginaries and the Fabrication of Power* (The University of Chicago Press 2015) 2; Levidow and Papaioannou (n 424) 38.

much as political institutions. In this work, the concept of "sociotechnical imaginary" will be resorted and applied to as a pivotal analytical key to account for the specificities and continuities in the judicial and administrative decisions regarding the patentability of biotech inventions.

As the S&TS scholar David Winickoff argued, technological imaginaries are part of "the interpretative framework of judging"[428] and they condition and orient the doctrinal choices and legal reasoning.[429] This thesis will, further, point out that these imaginaries are built up and oriented by the endorsement of specific metaphors, which were sustained in technoscientific contexts and shaped judicial arguments and decisions on the patent eligibility of biotech inventions.

The next chapter will, therefore, engage in explaining how the metaphors of *molecule*, *code* and *machine* have been crucial in shaping the theoretical framework (and imaginary) of particular fields of research and what are the views of life and nature that they entail. The chapter, moreover, will clarify how the molecular imaginary of life that these disciplines fostered has sustained biotechnological claims over the definition of the "nature" of its products and processes and backed their legal status as patentable subject matter. The following chapters will, then, examine how these metaphors have been employed in judicial arguments and impinged on the adjudications issued in several areas of biotech innovation and also shaped particular sociotechnical imaginaries of life.

[428] David E Winickoff, 'Judicial Imaginaries of Technology: Constitutional Law and the Forensic DNA Databases' in Sheila Jasanoff (ed), *Reframing Rights. Bioconstitutionalism in the Genetic Age* (The MIT Press 2011) 147, 165.
[429] ibid.

Chapter Two

Molecular Imaginaries of Life

2.1 Molecular Imaginaries of Life

This chapter will illustrate how a "molecular" mode of studying and investigating life was devised, since the 1930s, in the United States and then took hold. The establishment of a scientific field of research named "molecular biology", its theoretical premises, focus, practices and methodologies affected the development of biotechnology and the molecular imaginaries which inform it. The process of "molecularization of life", namely the "formulation of particular strategic approaches in biology and medicine centred on molecules",[430] in the 20th century, has proved pivotal in order to sustain and promote the patentability of biotech products since the 1980s, in the United States, Canada and Europe.

As historians of science de Chardarevian and Kamminga have pointed out, the expressions "molecularization", "molecular vision", "molecular revolution" and "molecular politics" are associated with molecular biology and its successfulness in addressing the structure and function of proteins and nucleic acids since the 1950s and 1960s, "the development of recombinant DNA technologies in the 1970s,[431] and the making of the Human Genome Project with its promise of genetically based molecular medicine".[432]

Tracing back the origins and development of molecular biology, recombinant DNA technology and the Human Genome Project enables to explain some of the basic features of the scientific and legal narratives regarding biotechnology, namely descriptive atomism, reductionism and determinism, which will be later analysed in the chapter. These features mark the imaginaries of life which are endorsed or challenged in different social, legal and policy contexts and also affect, as it will be shown in the thesis, the patentability of biotech products and processes.

The first part of the chapter will illustrate how molecular biology arose and became established as an independent research field and offer an outlook of its epistemic premises and aims.

The second part of the chapter will, then, address how molecular biology shifted from the notion of the gene as a material physicochemical molecule to a carrier of sequence of

[430] Soraya de Chardarevian and Harmke Kamminga, 'Introduction' in Soraya de Chardarevian and Harmke Kamminga (eds), *Molecularizing Biology and Medicine. New Practices and Alliances, 1910s-1970s* (Harwood Academic Publishers 1998) v, 1.

[431] Alan E H Emery and Sue Malcolm, *An Introduction to Recombinant DNA in Medicine* (John Wiley & Sons 1995) vii, 1-11.

[432] Chardarevian and Kamminga (n 430) 1.

information[433] and how its research program implied and endorsed descriptive atomism and, at least to a certain extent, reductionism and determinism as its main features.

The last part of the chapter will, finally, examine how the program of molecular biology conflated, in the 1970s, into biotechnology. Moreover, it will consider the different kinds of narratives on biotechnology and how they impinge on the definition of biotech products and processes and the risks and benefits they might entail.

2.2 The Origins of Molecular Biology

The origins of molecular biology are complex and controversial. The expression "molecular biology" has been, firstly, devised and used, in 1938, by Warren Weaver,[434] at the time director of the natural science division at the Rockefeller Foundation, to name a field and its related research program aimed at studying biological entities in their minimal and essential dimensions, namely the molecular level and processes which occur at the submicroscopic region.[435]

The historian of science Lily Kay illustrated that "molecular biology" was born as a scientific program, funded by the Rockefeller Foundation from the 1930s to the 1950s, involving several academic institutions in the United States, such as the California Institute of Technology (Caltech), which became in a few years one of the major research and training center in the field.[436] Its meaning and impact in the history of biological sciences, however, should not be confined and circumscribed to what an ordinary long-term research project entails. It was a vision of biology far more ambitious in its premises and objectives, since it became, as Kay's pointed out, the indispensable "Occam's razor"[437] in order to define what life is.

[433] Hans-Jörg Rheinberger, 'Gene Concepts: Fragments from the Perspective of Molecular Biology' in Peter Beurton, Raphael Falk, Hans-Jörg Rheinberger (eds), *The Concept of the Gene in Development and Evolution* (Cambridge University Press 2000) 219, 221 and 225-232.

[434] Warren Weaver, 'Molecular Biology: Origins of the Term' (1970) 170 Science 581, 582; Robert Olby, 'The Molecular Revolution in Biology' in Robert C Olby, G N Cantor, J R R Christie and MJ S Hodge, *Companion to the History of Modern Science* (1st edn 1990, Routledge 1996), 503.

[435] The term "submicroscopic" refers to the region between 10^{-6} and 10^{-7} cm, which could be explored and studied only after a series of scientific instruments and technologies became available, such as electron microscopes, ultracentrifuges, electrophoresis, spectroscopy, x-ray diffraction, isotopes. Lily E Kay, *The Molecular Vision of Life. Caltech, the Rockefeller Foundation and the Rise of the New Biology* (Oxford University Press 1993) viii, 5.

[436] ibid viii.

[437] ibid 3.

Although molecular biology is compared to molecular genetics of DNA, it is entrenched in an original and coherent framework to study phenomena related to "life", which emerged before the description of DNA's double helix, in 1953.[438]

The historian of science Rheinberger defined molecular biology as a "hybrid science"[439] which combines "experimental systems from biophysics, biochemistry, and genetics, and it uses widely different model organisms in its search for the biological function at the molecular level".[440] Molecular biology is, furthermore, a research program marked by its radical novelty because of its structural premises, which distance it from the background of previous biological research, and its "physicochemical approach".[441]

It was defined, since its inception, as a "new biology", as it addressed the *unity* of life phenomena, namely phenomena which regard all the organisms.[442] In its theoretical effort, this new biology privileged, as models of research, the simplest biological systems, such as bacteria or viruses, on the assumption that organisms marked by different levels of complexity can be compared.

As the philosopher of science Evelyn Fox Keller noticed, molecular biology took "epistemological and technological benefits of *reductio ad simplicitatum*",[443] which is the premise of whichever kind of control: its power laid "in identifying the simplest unit of analysis, on the construction of *E[scherichia] coli* and bacteriophage as a model organisms for the study of genetics and development […]. *E. coli* is small, simple, and, above all, culturally homogeneous (by which I mean that all cells in a bacterial culture are identical). It is by its very nature insulated from the heterogeneity that is so central to the organization of higher organisms – the problem of differentiation and development".[444]

In order to understand the physical and chemical laws, which govern life phenomena, molecular biologists, however, drew their attention mainly to protein molecules, deeming that an improved knowledge of proteins' structure and functions would have inevitably led to the explanation of the basic vital functions, such as reproduction and growth.[445]

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[438] J D Watson and F H C Crick, 'Molecular Structure of Nucleic Acids: A Structure for Deoxyribose Nucleic Acid' (25 April 1953) 171(4356) Nature 737.
[439] Rheinberger (n 433) 224.
[440] ibid.; Michel Morange, *A History of Molecular Biology* (1st edn 1994, Harvard University Press 2000) 1, 1-2.
[441] Kay (n 435) 5.
[442] ibid 4.
[443] Evelyn Fox Keller, 'The Body of a New Machine: Situating the Organism between Telegraphs and Computers', in Evelyn Fox Keller, Refiguring Life. Metaphors of Twentieth-Century Biology (Columbia University Press 1995) 81, 92.
[444] ibid 92-93.
[445] Kay (n 435) 5.

Several scholars in history and philosophy of biology showed that new links between the laboratory, the clinic and industry had to be created in order to support the study, production, use and circulation of molecules.[446]

Multiple opposing views about what is life and what are biological entities confront. The first question on the origins of molecular biology regards its foundational hypothesis: that life is molecular. Conversely, this molecular view can be considered one of the possible scientific visions of life, which has been privileged in the course of history. However, "the molecular vision of life" gained consensus. Its success did not rely, exclusively, on its explanatory power, but depended on the cognitive and social aims that molecular biology promoted since its origins. The molecular vision of life, therefore, became established, but bore a heavy legacy: a heritage of scientific evidences and metaphors intertwined with a mixture of expressed or implicit interests and intents. This way of thinking of life has become very influential, as it has shaped individual and social visions about what life is, as well as political and legal understanding of what could be the uses of molecular entities in the life sciences.

2.2.1 Descriptive Atomism and Genetic Control

This section and the next two will explain how molecular biology, in comparison to classical genetics, devised firstly the gene as a physicochemical unit and, then, as carrier of information. Moreover, they will show how some of the main features of the "molecular vision of life", such as descriptive atomism, reductionism and determinism, are linked to the construction of the meaning of the gene.

The word "gene" was coined in 1909 by the Danish botanist Wilhelm Johannsen and has become one of the most significant terms in the glossary of molecular biology.[447] Fox Keller has illustrated that, by its use, Johannsen wished to free his research from any previous biological hypothesis and, in particular, from any association with preformationist theories.[448] "Gene" was a new term to denote the fundamental unit of the biologic specificity of organisms, "the evident fact that, in any case, many characteristics of the organism are specified in the gametes by means of special conditions, foundations, and determiners which are present in unique, separate, and thereby independent ways".[449]

[446] Chardarevian and Kamminga (n 430) 1.
[447] Evelyn Fox Keller, *The Century of the Gene* (Harvard University Press 2000) 1, 2.
[448] ibid 1-2.
[449] Wilhelm Johannsen, *Elemente der Exakten Erblichkeitslehre* (Gustav Fisher 1909), 124, in Evelyn Fox Keller, *The Century of the Gene* (Harvard University Press 2000) 1, 2.

The geneticists were, originally, aware of the ambiguous and fictitious character of these entities. The "gene", therefore, amounted only to a concept of the first Mendelian research, which could not refer to any material entity and on which there was no undisputed agreement.[450] However, in the 1930s, molecular biologists had already endowed the genes with material and real status: genes, as Fox Keller observed, were described as biological unit analogous to physical atoms and molecules, provided with a set of properties, which would supply an explanation of life phenomena.[451]

This analogy often recurred in the arguments of the first molecular biologists and some physicists, who deemed that, even though with reserves, biological phenomena could be understood and explained by conventional concepts of physics.[452] This convergence fitted with a common approach to investigate and describe physical and biological entities, which were broken up in their elementary units – atoms, molecules, cells, genes – in order to understand their functioning. As the genetist Lewontin noticed, this descriptive modality, defined "atomism", is an integral part of modern science and "makes the atom or individual the causal source of all the properties of larger collections"[453] and prescribes a particular way of studying the world, breaking it up in its individual causative fragments, in order to analyse, then, its properties.[454] The use of this analogy pinpoints that molecular biologists endorsed a particular descriptive model of biological organisms and signals the peculiarities of a research program, in which the fundamental structural unity represents also the explanatory and functional unit and in which the knowledge of the structure entails understanding the function. The gene, in that respect, constitutes a unifying concept for molecular biology: structural and functional unit, to which was conferred, since the 1920s, causal action, notwithstanding the absence of any knowledge about *how* it could act.[455] It is apparently odd that a set of properties related to structure, function and causal action were fully ascribed to the same object: the gene. The concept of the gene, as the historian of science Rheinberger noted, has never been "unified and generalized"[456] by molecular biologists. Conversely, there was "no

[450] Keller (n 447) 2.
[451] H J Muller, "The Gene as the Basis of Life". Symposium on "The Gene" – Ithaca N. Y., August 19, 1926, *Proceedings of the International Congress of Plant Science* I, 897-921, in Evelyn Fox Keller, *The Century of the Gene* (Harvard University Press 2000) 1, 3.
[452] Niels Bohr, 'Light and Life' (1933) 131 *Nature* 457.
[453] Richard C Lewontin, 'A Reasonable Skepticism', *Biology as Ideology. The Doctrine of DNA* (HarperCollins 1992) 4, 13.
[454] ibid.
[455] Evelyn Fox Keller, 'Language and Science: Genetics, Embryology, and the Discourse of Gene Action' in Evelyn Fox Keller, *Refiguring Life. Metaphors of Twentieth-Century Biology* (Columbia University Press 1995) 3, 9-21.
[456] Rheinberger (n 433) 223.

singular, unique, and rigidly determined usage of the term"[457] in the relevant literature and the concept is, therefore, context dependent.[458]

Since its introduction, however, the idea that these properties were localized into the gene had been linked to the confidence in its material reality. This assumption can partially be explained through the analogy with the atom. The explicative power of these entities, atoms and genes – interpreted, firstly, as hypothetical and, then, as real – originate from the mechanistic metaphor in which are embedded.

Modern science and biology have accommodated the Newtonian and Cartesian metaphor of the world and organism as a clock/machine made out of gearwheels, whose knowledge entails the comprehension of the functioning of the whole clock/machine. Atoms, genes and molecules have been at the core of research programs, since they were considered fundamental units and, therefore, by definition, explanatory within the mechanistic metaphor. To these units were conferred, moreover, the property of *stability*. Their nature of "prime elements" validated the hypothesis of their stability. Although scientific research has showed that atoms undergo spontaneous transmutations and genes individual mutations, their structure has been always considered *essentially* stable. Genes have been related to the concept of immutability, since they secure hereditary continuity and have been studied mainly as causes of hereditary *constancy*.

The publication, in 1944, of the conferences entitled "What is life?"[459] held by quantum physicists Erwin Schrödinger had relevant role in fostering the incipient molecular biology program and encouraging a whole generation of physicists to reshape their view of biology. Explaining life meant, for Schrödinger, defining genetic structure. In "What is life?" he expounded one of the most influential genetic macromolecular models, in the 1940s: the so called Delbrück model.[460]

Beyond these theoretical premises, molecular biology and genetics embraced and endorsed a specific conception of causality, which later became the core of its central dogma, formulated by Francis Crick in 1958:[461] unidirectional causality, which implied "the rejection of any possible substantial influence over the genes from the intracellular and intercellular

[457] ibid.
[458] Thomas Fogle, 'The Dissolution of Protein Coding Genes in Molecular Biology' in Peter Beurton, Raphael Falk, Hans-Jörg Rheinberger (eds), *The Concept of the Gene in Development and Evolution* (Cambridge University Press 2000) 3.
[459] Erwin Schrödinger, *What is Life?* (1st edn 1944, Cambridge University Press 2013) vi.
[460] J C Kendrew, 'How Molecular Biology Started' in J Cairns, G S Stent and J D Watson (eds), *Phage and the Origins of Molecular Biology. The Centennial Edition* (Cold Spring Harbor Laboratory Press 2007), 343.
[461] Francis Crick, 'On Protein Synthesis', (1958) 12 *Symposia of the Society for Experimental Biology* 138, 153.

environments".[462] Rather that thinking that between genes and environment could exist a *feedback*, namely a process of circular back-action, biologists deemed that the causal influence was linear: from DNA the information was transmitted to proteins and it could not overflow from these.[463] Descriptive atomism calls for and prescribes a specific way to study the world, breaking it up in isolated fragments, but divides it into two separate autonomous and independent domains: the interior and the exterior.[464]

The molecular view has, thus, maintained an interpretation of biological activities in which living organisms are determined by significant *internal* factors: the genes. This perspective implicitly excludes the theoretical relevance of a series of causal factors, which are positioned outside the space and time frames of gene action. As Fox Keller pointed out, this exclusion characterized the first phase of molecular biology, which was marked by the development of a framework focused on the discourse of "gene action", which the geneticists referred to between the mid1920s and the 1960s as "the causal processes that connect the gene and the characters".[465] It has been observed that "for many years geneticists had little reason to refer to eggs and their cytoplasmatic structure and even less reason to talk about events before fertilization. The discourse of gene action has established a spatial map that lent to the cytoplasm scientific invisibility (…). and a temporal map that defined the moment of fertilization as origin with no meaningful time before fertilization. This schema offered neither time nor place in which to conceive of the egg's cytoplasm as exerting *its* effects".[466]

The molecular physic-chemical approach ignored, as Kay clarified, the *historical* explanations of life processes, which are at the core of evolutionary and developmental biology. It, therefore, neglected the mechanisms of downward causation – implicitly overlooking their explanatory relevance – in order to focus on upward causation.[467]

The avoidance, from the early molecular biology, of the historical accounts typical of the evolutionary approach championed a static and deterministic view of living organisms, seen "essentially" as the product of their genes. Lewontin observed that this perspective confers to genes and their action a metaphysical or almost metaphysical value.[468]

Furthermore, the atomistic description of the biological processes can surreptitiously involve even a more questionable "corollary": as genes determine individuals and individuals

[462] Keller (n 455) 21-35.
[463] Keller (n 443) 93.
[464] ibid 93.
[465] Keller (n 447) 46.
[466] Keller (n 455) 24.
[467] Kay (n 435) 5.
[468] Lewontin (n 453) 13.

compose society, genes determine society.[469] Although genes can be considered as not strictly deterministic factors, the fact that molecular biology deemed the gene as the basic, if not exclusive, causal unit of hereditary characters has conferred the genes an extraordinary power of *control* over single organisms. Notwithstanding this power has been lessened and reduced by further genetic research, the dogmatic force of the discourse of "gene action" is still present and rhetorically effective.

However, new data and information showed that genetic stability results from a dynamic process, but also the genetic function itself must be seen dynamically.

Yet, the idea that the gene has a nearly absolute power to establish the biological identity of the individual is resilient and fundamental piece in scientific popularization narratives. The gene is, therefore, at the core of a paradox: although the scientific community does not see it as the structural, functional and causal unit, as in the past, however it still retains rhetorical power in numerous contexts, such as the ones linked to support new research programs or the patentability of new biotechnological products.

Its rhetorical power is largely based on the idea of control and is connected to the original project of molecular biology, in which the possibilities of control provided by the field were functional to social control. Kay pointed out that the birth of molecular biology involved the promotion of a certain kind of science, whose form and content fitted perfectly with the dominative models inspired to the binomial "to know and make",[470] even though possible practical applications could not be fully envisaged at the time. The discovery, in the 1970s, of rDNA techniques, made the promises of genetic engineering concrete, but roused questions about the impact of molecular biology on society.

2.2.2 Molecular Biology and the Information Paradigm: Metaphors and Analogies of Genetic Heredity

Molecular biology has been a prolific field of analogies and metaphors on cells, molecules, genes and DNA. The physicist Erwin Schrödinger, illustrating the structure of the cell, introduced the analogy between chromosomes and *code-script*, which gained consensus during the process of gradual establishing of molecular biology as a research field:

> "*In calling the structure of the chromosome fibres a code-script we mean that the all-penetrating mind, once conceived by Laplace, to which every causal connection lay immediately open, could tell from their structure whether the egg would develop,*

[469] ibid.
[470] Kay (n 435) 17-18.

> *under suitable conditions, into a black cock or into a speckled hen, into a fly or a maze plant, a rhododendron, a beetle, a mouse or a woman.* […]. But the term code-script is, of course, too narrow. The chromosome structures are at the same time instrumental in bringing about the development they foreshadow. They are law-code and executive power – or, to use another simile, they are architect's plan and builder's craft – in one".[471]

The metaphoric of the "legibility" of the hereditary factors began to be affirmed through these brief considerations, full of implications, made by Schrödinger. Schrödinger was not the first physicist to draw upon the metaphor of the "text". However, Schrödinger applied the metaphor of the code to a different object, to organic phenomena, and meant to explore the issue of the stability of genetic inheritance in relation to the action of the environment. In his discourse, the metaphor fulfills more an illustrative significance, but it achieved such a theoretical salience that, also at present, it seems to be unavoidable, even though its inadequacies have been remarked.

The use of the metaphor of the code was marked by its novelty. This figure of speech, even though was already embedded in the metaphorical tradition of Galileo's "book of nature", embeds elements of originality. Longo observed that Schrödinger's code-script is more similar to a "program", in the sense of the computing sciences and, in particular of universal Turing machine, which was "at once program, compiler and operating system".[472] This idea still informs contemporary informatics, namely the idea of the program which is codified and transformed into data.[473]

On the use of this metaphor, it has been observed that "by transferring the linguistic-symbolic nature of the notion of *discrete code* over a natural system, one obtains a structure of determination of Laplacian type". [474] Laplace claimed that determination entails predictability.[475] This view applied to hereditary factors, according to Blumenberg, implies that at the Laplacian conditions, "the whole genetic potential"[476] is "like a state completely determined by a physical system, starting from which"[477] the Laplacian demon can "predict by differential equations every other state of the system, equally in the past or in the future at

[471] Schrödinger (n 459) 21-22.
[472]Giuseppe Longo, 'From Exact Sciences to Life Phenomena: Following Schrödinger and Turing on Programs, Life and Causality', (2009) 207 *Information and Computation* (Special Issue) 545, 546.
[473] ibid.
[474] Hans Blumenberg, *La leggibilità del mondo* (1st edn 1981, il Mulino 1999) 1, 393.Translation mine.
[475] Longo (n 472) 547.
[476] Blumenberg (n 474) 393. Translation mine.
[477] ibid. Translation mine.

a given moment".[478] The demon would be able, as regards the chromosomes, to ascertain if "the egg will develop, at the right conditions, in a black cock or in a speckled hen".[479] The association of the term "code" to the chromosomes and the "Laplacian reader" suggests, thus, that the possible fulfillment of the de-codification of the information that they enclose would allow the biologist to gain a complete capability to predict the organism's development.

The Laplacian demon, as Blumenberg illustrated, can exert his omniscience, however, only on close systems. The "gene code", nevertheless, is not a close system and cannot be connected to a set of causal factors inferable by the demon, as a text, as such, does not produce the state which describes or prescribes.[480]

The analogy between the genetic heredity and the code introduced, therefore, in the discourse of molecular biology, a fundamental property of the code: the fact that programs, the kinds of data in computer systems are *given* in an exact and precise way and that this determination implies predictability.[481] Longo remarked that the model of Laplacian intelligibility, with its pseudo-implications, gained consensus in biology.[482] In the 1960s, the French biologists Francois Jacob and Jacques Monod still contrasted determination and causality and, thus, suggested again for the DNA the concept of program and the concept of determination as predictability.[483]

In the aftermath of the Second World War, this metaphor enlarged its repertoire of variations through the semantic hybridization of molecular biology with other fields. As Kay has explained "*information, messages, texts, codes, cybernetic systems, programs, instructions, alphabets, words*"[484] are only some of the terms that recurred in the language of molecular biologists and altered the way in which biological phenomena were described in the 1950s and 1960s. The rhetoric power exercised by these metaphors can be understood analyzing the shift of meaning that the concept of *chemical and biological specificity* underwent.[485] As Kay noted, at the beginning of the 20th century, the life sciences focused on the concept of specificity, which was considered within the discourse on the *organization* of the organisms

[478] ibid. 393-394. Translation mine.
[479] ibid 394.
[480] ibid 394.
[481] Longo (n 472) 547-551.
[482] ibid 547.
[483] ibid 549.
[484] Lily E Kay, *Who Wrote the Book of Life? A History of the Genetic Code* (Stanford University Press 2000) 1, 26.
[485] ibid.

and microorganisms; however, some decades later, the word "information" seemed to have forced out any other rival reference in defining specificity.[486]

Kay illustrated accurately how much the cybernetics promoted by Norbert Wiener and, particularly, the theory of communication developed by Robert Shannon influenced the metaphorics of molecular biology after Second World War.[487] The new metaphors of the "legibility" are connected to the development of these areas of research and have been applied to genes, DNA (then to RNA) and the genome.

"The genetic code", as an autonomous object of investigation, is the result of a construction largely supported by the theory of information. Before molecular biology underwent, since 1953 (the year of the publication of the article on the molecular structure of nucleic acids by Watson and Crick),[488] the shift of its theoretical-explanatory axis of genetic heredity from proteins to DNA, it had already faced a process of re-orientation due to the sciences of communication, according to Kay.[489]

The experience of the Second World War, in the United States, represented a watershed for scientific research, since in its aftermath and under the auspices of the Bush Report a new way of devising, funding and organizing scientific research was established, as well as links among industry, military power an academic world. The origins of the so-called "discourse of information", which affected molecular biology in the second half of the 20th century, as Kay illustrated, is part of this complex weave of relations sustained by military research on machines and living organisms, which created the links among the theory of communication, artificial intelligence, cybernetics, control systems, genetics and theory of automata.[490] From the intersection of these fields a new view of information emerged: information became seen and understood as a mere physical parameter, in which the distinctions between animate and inanimate worlds were undermined.[491] Wiener's work on cybernetics contributed to foster this perspective, as he argued that living organisms and human beings had to be understood in terms of information, but he made clear that the semantic aspects of communication were irrelevant.[492]

The impact of Wiener's cybernetics was relevant as it led to the redefinition of terms such as *message, information, feedback* and *control*, according to a new space of representation at the

[486] ibid 38-41.
[487] ibid 73-127.
[488] Watson and Crick (n 438) 737.
[489] Kay (n 484) 128-192.
[490] ibid 73-78.
[491] ibid 79-91.
[492] ibid 84-85.

intersection of physics, biology and the social sciences.[493] However, it was only after Shannon elaborated his theory of communication, that information was intended as a physical quantity measured in bit (binary digit).[494]

In the 1950s, molecular biology shifted its focus from proteins to DNA. As a result, the metaphor of "legibility" changed its object, according to the discourse of information. Information has been more and more linked to DNA and nucleic acids, conferring it a "privileged status" among organic molecules. This status was recognized in the "central dogma" of molecular biology formulated by Francis Crick in 1958:

> "This states that once 'information' has passed into protein it cannot get out again. In more detail, the transfer of information from nucleic acid to nucleic acid, or from nucleic acid to protein may be possible, but transfer from protein to protein, or from protein to nucleic acid is impossible. Information means here the precise determination of sequence, either of bases in the nucleic acid or of amino acid residues in the protein".[495]

Crick expressed and articulated the problem of protein synthesis as a flux of information and localized biological *specificity* in the sequence of nucleic acids pairs.[496] All those that for a long time have been considered indisputable dogmas, in molecular biology, have been supported by the metaphor of the flux of information, whose implications have been wide and pervasive.

2.2.3 From Genetics to Genomics: Molecular Biology after the Human Genome Project

The metaphoric of information has contributed to back and stabilize models of biological specificity, which became well-established. The authority, gained by them, is proved by the dissemination and popularity of some locutions, which are, at present, part of everyday language. The expression "genetic code" recurs so often that can be considered a catachresis, namely a silent metaphor of which nobody is any more aware, when people are talking about genes, DNA and, in general, nucleic acids.

Metaphors, which are largely endorsed, contribute to the construction of the social imaginary, so that questions about their introduction result vacuous or redundant, in comparison with their persuasive power. It has been observed that "what did the genes do before transferring

[493] ibid 78-91.
[494] ibid 91-102.
[495] Crick (n 461) 153.
[496] Kay (n 484) 174-175.

information?" is a superfluous question, at present, when the conflation of the genome with information has been achieved.[497]

Kay noted that the code "is, by definition, a relation, or a set of rules of transformation from plaintext to cryptogram",[498] but "neither a language nor a 'thing'".[499] Yet, the connection between this word and the genes has contributed to sustain the "genetic code" as an object of theoretical study. The use of this metaphor contributed to confer reality to a theoretical entity: the genetic code.

Although some scholars deem that the metaphors of information and, in particular "the code" have exhausted their heuristic function and, maybe, are just a scaffolding currently in dismantlement, as now it has been understood how the genome produce identical proteins, they still keep their rhetoric vitality.

Other scholars[500] remarked how many contemporary biologists still apply the metaphor of the code and program devised by Schrödinger, in order to illustrate the DNA, even though the Laplacian predictability which is linked to them, is rather doubtful. It has been noted that this use is even more unsuitable following the "de-codification" of the DNA of some animals. After all these attempts, it is still not possible to know how to connect the so called "wild DNA" with the normal phenotype. Moreover, the kind of circular feedback of the code, in physics, does not seem like the circularity of vital phenomena in biology. Longo pinpointed these kinds of problems, starting from the kind of circularity which is far more complex in the organisms, owing to the different levels of organization which are involved.[501]

This *complexity* makes the relation between DNA and the development of the organism difficult to understand and, therefore, and undermines predictive chances at the molecular level.[502]

The fulfillment of the Human Genome Project (HGP) offers some hints in order to account for the reasons why the metaphoric of information is so resilient, notwithstanding its manifest inconsistencies. The achievement of its main purpose, in 2000, namely the sequencing of the

[497] Paul Billings and Sophia Koliopoulos, "Che cos'è il genoma umano?" in Jean-François Mattei (ed), *Il genoma umano. Uno sguardo etico* (1st edn 2001, Sapere 2000 2002) 28-29.
[498] Kay (n 484) 14.
[499] ibid.
[500] Giuseppe Longo and Pierre-Emmanuel Tendero, 'The Differential Method and the Causal Incompleteness of Programming Theory in Molecular Biology' (2007) 12 *Foundations of Science* 337.
[501] Longo (n 472) 554.
[502] ibid.

human genome,[503] arose some questions about the promises of its supporters and the concrete results that will actually follow.

The Human Genome Project was defined as an international research project "whose goal was the complete mapping and understanding of all genes of human beings".[504] This simple definition, on the web site of the Program, already encompasses several metaphors, such as "de-ciphering" and "program".

This project arose in the mid-1980s, due to the initiative of American molecular biologist Robert Sinsheimer and the physicist Charles Di Lisi, who was at the time the Director of the Office of Health Environment at the United States Department of Energy (DOE).[505] De Lisi and the Senator Pete Dominici drew the project to the political attention since 1987, in order also to re-launch the activity of some U.S. national laboratories, such as Los Alamos, Livermore and Lawrence Berkeley.[506] Although the National Institutes of Health is the main federal agency devoted to research in the life sciences, the project was actively encouraged by the Department of Energy.[507]

Following the political action undertook by Dominici, who in 1987 submitted a bill with the aim to revitalise research in national laboratories, through genomic research, the U.S. Congress decided to fund further research on the human genome at the NIH and DOE.[508] However, only after the publication of a favorable report by the National Research Council, in 1988, the project became more definite in its goals, phases and areas of competence. In the report, it was suggested to fund the project for a long-term, 15 years, with a sum amounting to $200 million and that the sum should be used in order to complete the mapping of human genome, as well as to develop technologies that could make the sequencing faster and less expensive.[509]

In the meantime, in Europe, similar projects of research on the human genome had started. These projects had, then, been coordinated with the United States' one through the Human Genome Organisation (HUGO), composed by scientists from all over the world.[510]

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[503] Website <http://www.nhgri.nih.gov/HGP/>. Juan-Ramòn Lacadena, 'Un codice etico per la genetica umana, in Jean-François Mattei (ed), *Il genoma umano. Uno sguardo etico*, (1st edn 2001, Sapere 2000 2002), 45.
[504] Website of the Human Genome Project <http://www.genome.gov/12011238>.
[505] Hallam Stevens, *Biotechnology and Society: An Introduction* (The University of Chicago Press 2016) 1, 181-182; Juan-Ramòn Lacadena, 'Un codice etico per la genetica umana, in Jean-François Mattei (ed), *Il genoma umano. Uno sguardo etico* (1st edn 2001, Sapere 2000 2002), 45.
[506] Stevens (n 505) 181-182; Lacadena (n 505) 45.
[507] ibid.
[508] ibid.
[509] ibid.
[510] Chamundeeswari Kuppuswamy, *The International Legal Governance of the Human Genome* (Routledge 2009) viii, 3.

In 2000, the Human Genome Sequencing Consortium, together with the private company Celera Genomics presided by Craig Venter, announced that they completed the first assemblage of the sequence of DNA of the human genome.[511] What was with emphasis called "the vision of the Grail"[512] did not seem so far and, thus, justified the enormous amount of money spent for the project. However, Lewontin noted that these kinds of programs "are administrative and financial organisms, rather than research projects".[513] They require an amount of financial resources in order to sustain the vast network of research centers, as well as a considerable public consent.

The metaphors of information have contributed to raise social support to back the project, in terms of public interest. If the DNA is described as the carrier of information, which is read by the cellular mechanism in the production process, like the code that must be de-cyphered in order to disclose its information, the inevitable prescriptive consequence is that this effort should be pursued without any postponement. The metaphor of the code embeds an implicit call for the reading, as far as scientists and society are concerned.

The U.S. Office of Technology Assessment significantly concluded its report on mapping the human genome holding that "one of the strongest arguments for supporting human genome projects is that they will provide knowledge about the determinants of the human condition"[514] and that scientists have backed it as they "will provide one of the most powerful tools humankind has ever had for deciphering the mysteries of its own existence".[515]

Similar points of view had been expressed, during the initial phase of the project, by the director of *Science*, Koshland, who drew openly the prescriptive consequence: denying or withdrawing support to this project, even though it was highly engaging, amounted to incur in the "immorality of omission", as it could have helped the poor and the infirm.[516] One of the most eloquent examples of this combination of ill-concealed determinism, linked to an undisputed predictive potential, related to the de-codification of the human genome, was expressed by the well-known biochemist Walter Gilbert (one of the founders of Myriad Genetics, in 1991), when he illustrated the theoretical relevance of the project:

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[511] Lacadena (n 505) 45.
[512] Walter Gilbert, 'A Vision of the Grail' in Daniel J Kevles and Leroy Hood (eds), *The Code of Codes: Scientific and Social Issues in the Human Genome Project* (Harvard University Press 2000) 83.
[513] Richard C Lewontin, 'The Dream of the Human Genome' (28 May 1992) The New York Review 31, 33.
[514] U.S. Congress, Office of Technology Assessment, *Mapping Our Genes*, Government Printing Office, Washington D. C. 1988, 85.
[515] ibid.
[516] Daniel Koshland, 'Sequences and Consequences of the Human Genome' (1989) 246(4927) *Science* 189.

> "What does that mean for biology? For example, if we were given a sequence data base of the human genome today, could we understand anything from it? The answer, I think, is yes; we could understand a tremendous amount. Today we learn a great deal about the functioning of genes by looking at the sequence of proteins they produce. For example there is a set of about a hundred thousand genes called oncogenes: each one identified as a DNA fragment, isolated from a tumor line or a tumor cell that will endow a normal cell with the ability to grow indefinitely".[517]

The grounds for the assumed predictability, that the knowledge of DNA should provide, rely on the construction of DNA as a "master molecule", consistently promoted by the metaphors of information. Lewontin has insightfully observed that the most accurate description of DNA sees in the DNA the carrier of the information, which is read by the cell mechanism in the production process. However, the DNA has been immediately transformed in "blueprint", "plan", "master plan", "master molecule".[518]

The ideological implications of this way of defining DNA are that the information, namely the relevant information, conflates with genome's DNA and that its knowledge becomes knowledge of the specificity of organisms and their functioning. The scientists involved in the Human Genome Projected voiced their critique towards determinism. However, their utterances proliferate with references, which are implicitly deterministic.

As Fox Keller remarked, if the technological progress made possible the HGP, "it was the concept of genetic disease that created the climate in which such a project could appear both reasonable and desirable".[519] The conversion of knowledge on the genome into therapeutic power turned out to be far more strenuous that its supporters envisaged. The HGP fostered the emergence of "genetic predictive medicine", which allows quantifying the probability of getting a disease, but does not provide, in most cases, therapeutic solutions.

The metaphoric of legibility, therefore, far from representing a theoretical scaffolding in dismantling, is recurrently invoked in order to socially justify research projects. The HGP represents one of the most exemplary cases of a certain use of the rhetoric of information. The wide appeal of the "book of life", by now identified with DNA and the genome, has proved pivotal in the construction of a special imaginary of life, with the aim to promote public consensus towards the project.

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[517] Gilbert (n 512) 90.
[518] Lewontin (n 513) 33.
[519] Evelyn Fox Keller, 'Nature, Nurture, and the Human Genome Project', in Daniel J Kevles and Leroy Hood (eds), *The Code of Codes. Scientific and Social Issues in the Human Genome Project* (Harvard University Press 2000) 293.

2.3 The Origins of Biotechnology: Narratives of Continuity and Novelty

The history of biotechnology has been at the core of alternative and contrasting kinds of narratives: narratives of *continuity* and narratives of *novelty*, which are relevant in order to support and maintain particular frames about what is biotechnology and its social implications.

The origins of biotechnology, according to the former kind of narratives, are remote. Record of biotechnology can be traced back to primordial human civilization, when agriculture and livestock began to be developed.[520] The chronicles embedded in biotechnology textbooks illustrate that in Mesopotamia, already in 6000 B.C., beer was produced by processes of fermentation, which entailed the use of microorganisms and in Egypt rising bread was prepared since 4000 B.C.[521] The history of biotechnology, therefore, is studded with a series of practices in which it is possible to see a nexus of diachronic continuity: from fermentation linked to food production to the utilization of agricultural surplus in order to produce biomass and to intensive agriculture and breeding.[522] These techniques are encompassed in the concept of "traditional biotechnology", which differs from innovative biotechnology for its empirical character and a less scientific and technological dimension.

"Innovative biotechnology" is, conversely, marked by a "solid scientific and cognitive foundation, which draws upon several scientific disciplines"[523] coupled with "a likewise strong practical and planning activity".[524] Although innovative biotechnology is characterized by these elements of novelty, it still keeps a bond with its traditional version. Both of them have been engaged in research on microorganisms.

This kind of description has been influential. It recurs in biotechnological course books,[525] historical monographs and patent biotech textbooks. It involves a prescriptive corollary: as biotechnological practices are not radically new and do not constitute a departure from technics already used, they should not entail substantially different risks for human beings, animals and the environment. They do not need, therefore, a special regulation. Although the existence of a "frontier" zone, in biotechnology, which arise ethical problems, as well as issues concerning communication with the public, is recognized, it is pointed out that the vast

[520] William J Thieman and Michael A Palladino, *Introduction to Biotechnology* (1st edn 2004, Pearson 2013) vii, 3.
[521] S Russo and G Poli, 'Bio & Tecnologia', in G Poli (ed), *Biotecnologie. Conoscere per scegliere* (Utet 2001) 1, 4.
[522] ibid 3, 287 and 317.
[523] ibid 3. Translation mine.
[524] ibid. Translation mine.
[525] ibid. Translation mine.

majority of bio-processes and bio-pharmaceuticals of the present biotechnology industry has not roused objections nor fostered social alarm.[526]

A series of alternative narratives recount a different history of biotechnology, centered on its irreducible novelty in the scenario of scientific research and industrial production.

According to the latter, the development, in the 1970s, of recombinant DNA techniques and the need recognized by the scientific community to control the risks arising from the latest application of molecular biology have been fundamental in constructing a social image of contemporary biotechnology as a "technology of the future". The use of this image, largely employed also in the political and institutional context, entails the open recognition of the "innovative nature" of a whole field of research: "technologies of the future" are only those with a high growth potential and which are envisaged with an effective power to transform society.

As proof of the character historically "revolutionary" of biotechnology has been advanced a series of events culminated in the international Asilomar Conference on recombinant DNA, held in 1975, and, afterwards, in the approval, on 23 June 1976, of the first Recombinant DNA Research Guidelines by the U.S. National Institutes of Health[527] (the regulatory model which inspired also regulation in the European states).[528]

Although some scientists, already in the 1960s, expressed concerns about the developments of molecular biology, the risks related to genetic engineering emerged as major focus of scientific debate afterwards. In the early 1970s, a group of researchers leaded by Paul Berg was able to create a DNA hybrid molecule, by using DNA from the bacterial virus lambda and the Simian Virus 40 (SV40), which triggers tumours in rodents.[529] The aim of the experiment was to introduce new genes into mammalian cells by utilizing SV40, in order to understand how foreign DNA was expressed in them.[530] After this first attempt, Berg and his colleagues decided to postpone the final phase of the experiment, as its effects could not be predictable and controllable.

It has been illustrated that the first doubts on the safety of research on rDNA had been voiced only at the Gordon Conference on the nucleic acids, in 1973,[531] which resulted in the

[526] ibid 3.
[527] US Department of Health, Education and Welfare, National Institutes of Health, "Recombinant DNA Research Guidelines", *Federal Register*, 7 July 1976.
[528] Bauer and Gaskell (n 25) 21-94.
[529] Paul Berg, 'Asilomar 1975: DNA Modification Secured' (18 September 2008) 455(7211) Nature 290.
[530] ibid.
[531] Sheldon Krimsky, *Genetic Alchemy: The Social History of the Recombinant DNA* Controversy (The MIT Press 1985) 70-80.

publication of the "Berg Letter", which recommended postponing type II and III experiments until a better assessment of risks could be made.[532] The "Berg Letter", therefore, proposed a voluntary *moratorium* for these kinds of experiments in order to develop adequate precautionary measures and asked the National Institutes of health to draft guidelines for people working with potentially harmful rDNA molecules.[533]

During the second Asilomar Conference on recombinant DNA technology, held on 24-27 February 1975, had been agreed the principles of the first regulatory phase: rDNA research should be classified according to levels of risk (fundamentally four levels, from P1 to P4), to which corresponded different levels of physical and biological containment. [534] This Conference, which was attended mostly by invited scientists together with a restricted group of legal scholars and journalists, has marked the history of biotechnology.

It has been noted that "the risks that preoccupied scientists at Asilomar were *biological*, conceived in terms of possible harm to human health and the environment through the unchecked spread of undesired genes. Participating scientists worried about the introduction of dangerous traits, for antibiotics resistance or toxin formation, for instance, into molecules that might prove unexpectedly hard to contain within the lab or within the altered organism".[535] Moral and social issues fell outside from their concerns, even though some scientist and activists deemed they should be dealt with.[536] Research on rDNA, which later became the scientific and technological platform for producing and commercializing biotechnological products, according to Asilomar's scientists, was more marked by the novelty of its risks than by ethical and political questions that it could pose to society.

2.3.1 Narratives of Continuity: From Zymotechnology to Biotechnology

The historian of science Robert Bud, in his monograph *The Uses of Life. A History of Biotechnology*, provides an accurate example of a narrative of continuity, whose effect is the normalization of biotech revolutionary potential, by bringing it back to ancient fermentation processes and linking the development of "zymothechnology", in the 20th century, to these remote methods.[537] A brief account of his narrative is examined in this section, in order to show that narratives of continuity entail the normalization of the technology they refer to and the institutional places where this research is made.

[532] Gottweis (n 44) 84.
[533] Paul Berg, *et al.*, 'Potential Biohazards of Recombinant DNA Molecules' (1974) 185 *Science* 303.
[534] Krimsky (n 531) 99-152.
[535] Jasanoff (n 44) 47.
[536] Krimsky (n 531) 99-112.
[537] Robert Bud, *The Uses of Life. A History of Biotechnology* (Cambridge University Press 1993) vii, 1-7.

Bud illustrated that the word "zimotechnology", which embeds the Greek root "zyme", namely leaven, refers to any kind of industrial fermentation, such as the production of beer and citric acid and leather tanning.[538] A pre-existing term "zymotecnia"[539] was coined in the 17th century by Prussian physician Georg Ernst Stahl, in order to name the study of practical fermentation.[540] Zymotecnia might become, according to Stahl, the fundamental science that could promote the growth of one of the most important German industries: the production of beer.[541] Stahl wished that the scientific knowledge of fermentation processes could be used for industrial and commercial purposes and endorsed a specific concept of chemistry, which entailed a bond between scientific and empirical analysis with practical application.[542]

Bud explains that the meaning of zymotechnology would merge into biotechnology.[543] He pinpoints that between 1917 and 1919 the term "biotechnology"[544] was, firstly, coined and used by Karl Ereky, a Hungarian agrarian engineer, who became Food Minister during the counter-revolutionary Horthy government.[545] "Biotechnology" referred to a modernization project of agriculture and pork breeding in Hungary. Ereky aimed to organize a capitalistic agricultural industry on scientific basis and his biotechnological scientific approach consisted of the series of processes through which raw materials could be biologically improved.[546] The word "biotechnology", therefore, was related to the qualitative transformation and the increase of raw materials on industrial scale. Within some years, the term became established, even though the word "biotechnics" was preferred by some scholars.[547]

The science, that Stahl deemed could have great practical possibilities, was according to Bud the joining link between traditional biotechnology and contemporary one. In order to understand this transition, it is useful to note that the term "biotechnology" appeared, when zymotechnology turned from agrarian technology to scientific application, namely when it began to incorporate several biological perspectives.[548] Biotechnology, as a field, drew upon the legacy of zymotechnology. Both disciplines fostered the intertwining of different biological sciences, such as bacteriology, microbiology and, in 1950s, molecular biology.

[538] ibid 6.
[539] ibid 8.
[540] ibid.
[541] ibid 8-9.
[542] ibid.
[543] ibid 7.
[544] ibid 32.
[545] ibid.
[546] ibid 34.
[547] ibid 35.
[548] ibid 27-50.

Moreover, elements of continuity can be traced back at the institutional level. In some European countries the institutes established in order to study fermentation processes had been involved also in modern biotechnological research. For example, the German Institut für Gärungsgewerbe had a pivotal role in promoting biotechnology in Germany, in the 1960s. However, also the Institut Pasteur, in Paris, played a salient part in sustaining biotechnological research on recombinant DNA.[549]

In his account, therefore, biotechnology is viewed in terms of continuity. Although the methods and processes applied could differ, substantially he does not envisage them as eliciting a solution of continuity within biotechnology, even though he acknowledges that it underwent significant changes.[550]

2.3.2 Narratives of Novelty: Biotechnology and Genetic Engineering

The analysis of the meaning of biotechnology and its political, social and cultural implications has to take into account its definitions and how they have been constructed. Its definitions, in fact, show the kind of narrative about biotechnology: "technology of the past" or "technology of the future", field of research or industrial activity, normal or innovative intervention, risky processes or controllable ones. The descriptive elements are embedded in a narrative frame, with prescriptive implications for institutions and society. The law is one of the fields more affected by the construction of these frames**.** These frames are significant, as they suggest whether a technology entails risks or not, if regulating it is suitable or not, if its products fall within the definition of patent eligible matter and what kind of policy should be devised and implemented. However, the narratives paths are not so linear, as this section will show.

Several are the definitions of biotechnology proposed by international and national institutions. "Biotechnology", according to the OECD, is "the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services".[551] This definition, which dates back to 1982, was based on the one offered by the Biosociety Group of the FAST (Forecasting and Assessment in Science and Technology) unit, which was established by the European Commission in 1979, that pointed out the promising technologies and sectors involved:

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[549] ibid 21.
[550] ibid 189-218.
[551] OECD, *Biotechnology – International Trends and* Perspectives, 1982, <http://www.oecd.org/sti/biotech/2097562.pdf>,1, 18-19.

> "The meaning that is most widely accepted is that it is the industrial processing of materials by microorganisms and other biological agents to provide desirable products and services. It incorporates fermentation and enzyme technology, water and waste treatment, and some aspects of food technology".[552]

The central theme which brings together the two descriptions is the concept of "transformation" of raw materials at the industrial level, namely the economic dimension of this activity devoted to the production of goods and services. In addition to it, is made a reference to the material means of transformation – microorganisms and other biological agents – and to the techniques of genetic engineering as a resource for expanding biotechnological production.

Several features, which were in Ereky's definition of the 1910s,[553] are embedded in it: notably the scientific-technological dimension of biotechnology. These definitions, however, are the milestones of a path undertook in the 1970s and, then, pursued in the 1980s, which led to the extension and improvement of biotechnologies and the fulfillment of most of their industrial and commercial promises. They convey, therefore, the institutional acknowledgement that biotechnology had a high economic potential for industry.

Beyond this narrative, however, other ways of interpreting the meaning and implications of biotechnology had been formulated, centered on the innovative character of genetic engineering. In 1984, the U.S. Office of Technology Assessment published a Report entitled "Commercial Biotechnology: An International Analysis". The Report distinguishes "the old biotechnology" from "the new biotechnology", explaining that the discovery and application of rDNA techniques and cell fusion accounted for it.[554]

The expression "new industrial revolution" largely used in the 1970s, when biotechnology became one of the major areas of policy interest, at the European Community and state levels, well expresses the promises which it in an industrial modernization perspective. The discourse of "modernization" has been very influential in promoting biotechnology as a "technology of the future", together with information technologies.

Gottweis[555] and Wright[556] illustrated how the institutional debate on biotechnology has been inscribed in Europe, at the national and Community level, in the perspective of international

[552] Commission of the European Communities, "FAST Subprogramme C: Bio-Society", FAST/ACPM/79/14-3E, 1979, 1, 3.
[553] Bud (n 537) 32.
[554] U.S. Congress, Office of Technology Assessment, *Commercial Biotechnology: An International Analysis* (Washington D.C.: U.S. Congress, Office of Technology Assessment, OTA-BA-218, January 1984) 1, 3-5.
[555] Gottweis (n 44) 159-163.

competitiveness and modernization, as far as declining scientific research and industrial sectors were concerned. The European policies on genetic engineering in the aftermath of the Second World War had been marked, notably in France, Germany and the United Kingdom, by the awareness of the backwardness of European scientific research in molecular biology and of the United States' worldwide superiority in the field.[557]

The prospect of modernization contributed to back the narrative of the innovative character of biotechnology. Nevertheless, this narrative also relied on the *new* representation that rDNA techniques involved.

The innovative potential of a technology can be "normalized" by bringing it back in the circle of previous technologies whose risks have been already assessed and regulated. As a result, the technology does not require any special regulation. However, if the revolutionary feature of the technology is recognized, as well as some new potential risks, it will follow the need to deal with and manage these risks. The policy of biotechnology was affected by these issues. One of the main divergences regarded the "process approach" or the "product" approach, which was at the core of the contrast between EEC (at present European Union) and the United States. Under the former approach, biotechnology is understood as a technological *process*, which solicits a special political and legal attention owing to its new inner characteristics; under the latter, conversely, it is considered as "an innocuous means to obtain products, which can be assessed pursuing to already existing regulatory principles".[558] Directive 90/220/EEC on the deliberate release of genetically modified organisms represents an eloquent example of the "process approach", as the control to which it refers to regards all genetically modified organisms, not single products. This kind of choice is also important as far as the legislative EU competence is concerned, namely the drafting of regulatory bills. Genetically modified organisms fall within a unique horizontal legislative mandate of the DG XI, whose General Council, which deals with the environment, drafted the two most important directives on biotechnology (even though in collaboration and competition with the DG XII, whose focus is research).

The alternative between "process approach" and "product approach", which are two different ways of framing, implies as well a selection between horizontal or vertical legislation. A staff member of the Green Party in the European Parliament, in a briefing cited by Gottweis,

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[556] Susan Wright, *Molecular Politics: Developing American and British Regulatory Policy for Genetic Engineering, 1972-1982* (The University of Chicago Press 1994) ix, 19-64.
[557] Gottweis (n 44) 153-228.
[558] Jasanoff (n 44) 79.

pointed out that these were crucial choices in the biotechnological debate:[559] "Should the products of the new biotechnology be regulated on the basis of the process by which they were manufactured, requiring a new set of laws covering all GMOs, no matter of their function (horizontal legislation)? Or is it the process by which something is manufactured irrelevant as far as the legislation is concerned? According to this view, regulation should only be concerned with the end product (vertical legislation) and for that, the existing laws need only be slightly adapted to cover GMOs".[560]

Fundamental regulatory choices can change in time. As it has been illustrated,[561] Directive 2001/18/CE, which superseded Directive 90/220/CEE on the deliberate release of GMOs, introduced a new regulatory regime, in which single products derived from GMOs are regulated by vertical or sectorial provisions, which regard the *n* categories of products.

These basic choices seem apparently technical, but involve an axiological dimension, as in situations of scientific uncertainty they can strike a different balance among biotechnological production, citizens' and animal health and environment protection.

What has been called "the micropolitics of meaning"[562] emerges through the complex systems of representation that derive from different sectors, such as technoscience, medicine, economics, law, which shape the semantics of a field. Biotechnology has been at the core of this kind of micropolitics.

It is worth noting that, at present, to the term "biotechnology" is preferred the more reassuring expression "life sciences". After the 1990s, when some political choices about biotechnology were challenged at the European level, as well as in some states, the word "biotechnology" seems compromised. In the reconstruction of twenty-five years of debate on biotechnology in Europe, a group of sociologists remarked that, paradoxically, exactly when the commercial advent of biotechnology has become inescapable, the companies working in the sector has begun to abandon its use, owing to a negative sense which is associated to it.[563]

The preference for the new locution "life sciences", in order to designate the whole productive field, in fact evokes calmer, less conflicting sceneries of medical applications. This preference has also marked the language of legal monographs concerning the intellectual

[559] The Member of the European Parliament is Linda Bullard.

[560] Linda Bullard, *Briefing for NGOs. Some Lines of Argumentation on Legislation of Pesticides Containing or Consisting of Genetically Modified Organisms (GMO – Pesticides)*, Memo, Brussels, June 18, 1991, 1, in Gottweis (n 44) 251.

[561] Jasanoff, (n 44) 83.

[562] Gottweis (n 44) 330.

[563] H Torgesen et al., 'Promise, Problems and Proxies: Twenty-Five Years of Debate and Regulation in Europe' in M W Bauer and G Gaskell (eds), *Biotechnology – the Making of a Global Controversy*, (Cambridge University Press 2002) 21, 73.

property on biotech inventions, where "life sciences" has substituted, in the title and in the text, the compromised word "biotechnology".[564]

Gottweis noticed that the history of biotechnology highlights a specific mode of representing the past by the dominant biotechnology narratives: in an ahistorical way or in monologically historical one. Ahistorical narratives present biotechnology as a "technology of the future", whose potential will be fulfilled in a distant unspecified time, whereas the monological narratives represent it as "stemming from a long tradition, with beer and cheese production as 'forerunners' of genetic engineering".[565] In these kinds of narratives there are significant omissions, which will be accounted for in the next chapters.

[564] Paul England (ed), *Intellectual Property in the Life Sciences. A Global Guide to Rights and Their Applications* (1st edn 2011, Globe Law and Business Limited 2015) 5.
[565] Gottweis (n 44) 256.

Chapter Three

Imaginaries of Intellectual Property: Patenting Microorganisms and Organisms

3.1 A Matter of Metaphors, a Matter of Narratives

As set out in the Introduction, the main research hypothesis of this thesis is that the use of metaphors in patent case law, because of the analogies that they entail, proved pivotal in defining the nature of biotech patent claims and settling the boundaries of what is natural and artificial in the United States, Canada and under the EPC.

This chapter will show that the recourse to the metaphors of the *machine* and *molecule* entailed, as chapter two has illustrated (section 2.2.1), an atomistic and reductionist view of life which allowed qualifying new rDNA biotechnological products as patent eligible in the U.S. and Canada. Their use, together with other relevant factors that will be explained, has substantially contributed to enlarging the scope of patent eligible matter in both countries.

Although in these two countries the statutory definition of patentable subject matter is alike, patent examiners and courts drew its scope in different ways and according to distinct narratives.

It will be shown that, in Europe, the EPO's Boards did not resort to metaphors in order to define transgenic animals, but relied on a molecular view of life that did back the patent eligibility of cells isolated and/purified.

The analysis carried out in this chapter, in addition, will illustrate that the recourse to particular narratives have contributed to support and champion these metaphors in specific national contexts and settle a particular view about the *nature* and *ontology* of biotech products.

This chapter and the following ones will, therefore, address the main research hypothesis of the thesis, namely whether the scope of the definition of "patentable subject matter" and "invention" have been analogically expanded, by drawing on metaphors in judicial patent decisions.

The analogical interpretation of the definitions provided by national, regional and international patent law entail several legal problems, which involve the general theory of the law and the criteria of legal interpretation in different legal systems and, as far as patent decisions are concerned, the descriptive and prescriptive dimensions of technoscientific and legal definitions, which are embedded in statutory and case law.

In order to account for whether and how analogical reasoning through metaphors extended the meaning of patent eligible matter and shaped the boundaries of what is "natural" and

“artificial”, these chapters will examine the main landmark cases which marked the way in which these categories and concepts have been understood and devised since the 1970s. Despite these cases having been widely commented on and analysed by legal scholars for their relevance as case law, their analogical and metaphorical dimensions have never been examined in their assumptions and implications for the general theory of legal interpretation. A thorough and contextual examination of these cases questions the meaning and role of analogy and metaphor in different legal systems, such as common law and civil law ones, as a means of integration and interpretation of the law.

These landmark patent decisions and the arguments that they set out will be considered and studied according to the narrative framework illustrated in chapter one, as “narratives” providing and fostering descriptive/prescriptive frames about biotechnology and its products, which must be viewed within the context of national, regional and international wider narratives about its risks and benefits.

The cases that will be examined in this chapter and in the following ones concern GM microorganisms and organisms, as well as chimeric cells, GM seeds and plants, human biological materials and genes, as isolated elements of the body. They are all focused on the definition of “patentable subject matter" and “invention” and marked the ways in which collectivities imagine what life and nature are, what is attainable through biotechnology and how individuals and groups understand their own identity.

The narrative analysis of these cases will substantiate the main hypothesis of the thesis, namely that the arguments affirmed in these decisions drew on a large repertoire of metaphors and analogies, which by defining the *nature* of the claimed invention shaped the scope of patentable subject matter. Most of the metaphorical expressions employed in these landmark decisions suggest and argue that patent claimed living microorganisms and organisms should be considered in their molecular/atomistic dimension, not as forms of life.

Some of the metaphors and analogies used in judicial arguments are well-established in scientific fields and their laboratory practices, such as molecular biology and genetics, as illustrated in chapter two. These metaphors reframed the meaning and scope of patent eligible matter, but also oriented sociotechnical imaginaries of life, because they have promoted in these patent systems a social perspective of life, linked to the development of biotechnology, which is inherently molecular and reductionist.

Genetically modified microorganisms, GMOs, DNA sequences, genes and embryonic stem cells have been at the core of a process of molecularization of life, namely a mode of defining, regarding and handling life in molecular terms, which was maintained by metaphors and

analogies embedded in the arguments that judges developed in their decisions on patents. These decisions defined the legal status of claimed inventions and also impinged on the definition of the "nature" and ontology of the kinds of products and methods involved. In deciding whether these kinds of biotechnological products might fall within the definition of "patent subject matter" or "invention", patent examiners and judges largely drew upon a repertoire of metaphors which are embedded in the patent system as general statutory classes, have been supported as appropriate definitions of the "nature" of the invention by the scientific community and are socially shared and endorsed. However, the definition of these inventions, which resulted from the co-production between technoscience and law in patent litigation, has influenced how collectivities and individuals think of life (in molecular and atomistic terms) and their view about what is natural and artificial.

Opening up the metaphorical and analogical dimensions of the arguments articulated by judges allows understanding of what extent descriptive and normative issues are entangled in sustaining and stabilizing the meaning of molecular biotech products as "patent eligible matter" and how it affected and devised contemporary sociotechnical imaginaries of life.

The perspective that will be applied in order to analyse the metaphors used in legal discourse, in order to establish the patentability of biotech products, is centered on "conceptual metaphor" and was developed by the cognitive linguists George Lakoff and Mark Johnson in the seminal monograph "Metaphors We Live By",[566] in which they argued that metaphor should be interpreted as "metaphorical concept". This theory of metaphor and its entailments have been illustrated in chapter one.

In scrutinizing the meaning and use of the metaphors applied in the case law concerning patent eligible matter, particular attention will be devoted to the underlying analogy that they convey. In this effort, the analysis of the narratives in which metaphors are embedded proves to be crucial, as they elaborate the metaphor and clarify its use. Moreover, the plot and discourse of judicial and technoscientific narratives serves to support and justify metaphors and, therefore, its study accounts for their settlement in patent legal discourse.

3.2 Narrating Origins in the United States of America: *Diamond v. Chakrabarty*

As Jasanoff pointed out, science and the law are at the forefront of making sense and order of emerging technologies.[567] When several recombinant DNA ("rDNA") biotechnological experiments were conducted in the 1970s, science (and the scientific community) and the law

[566] Lakoff and Johnson (n 45) vii.
[567] Jasanoff (n 138) 767.

(the legislators, judges and administrative agencies), had to define what this technology was, the kind of regulatory framework that should be devised for it, whether it ought to be centered on "process", "product" or "programme",[568] whether it entailed risks and if the products and processes involving rDNA fell within the definition of "patentable subject matter" or "invention" and, therefore, could be patented.[569] Although these issues may seem mostly descriptive, since they offer possible answers to "what a technology *is*", they all embed a prescriptive dimension: defining what a new technology "is" involves a series of decisions about the "ought". These two dimensions are intertwined and the definition, framing, assessment and management of the technology and its risks is a complex process of co-production between science and the law, in which intellectual property plays a fundamental role, and hinges on the political and regulatory culture.[570]

In this regard, Jasanoff noted that that "science and the law wield enormous power in society" [571] as they are the "prime custodians of the 'is' and the 'ought' of human experience", [572] since they play a part "in deciding how things are in the world, both cognitively and materially".[573]

Patent law and examiners, as well as judicial courts, have been involved early in the process of defining, as far as intellectual property's categories were concerned, whether the inventive products and processes of the "new biotechnology", which was applying genetic engineering, could fit into the existing concepts of statutory patent eligible matter or patentable invention. At the time, however, specific statutory rules regarding the patentability of biotechnological inventions or guidelines in order to assess them did not exist, in the nation-states where the first patent applications were filed. Patent examiners and judges, therefore, had to face some of these issues and decide about the legal status of these products and processes. Their decisions and practices have shaped the boundaries of "patent eligible matter" and the scope of patent protection. Most of these decisions rest on metaphors, which supported and validated analogies between inorganic and organic matter, between microorganisms and organisms, between genes and molecules or genes and information. Metaphors proved to be fundamental in fostering the patent eligibility of genetically modified microorganisms and GMOs and also challenging it.

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[568] Sheila Jasanoff, 'Product, Process or Programme. Three Cultures and the Regulation of Biotechnology' in Sheila Jasanoff, *Science and Public Reason* (1st edn 2012, Routledge 2013) 22-41; Gottweis (n 44) 81.
[569] Jasanoff (n 44) vi.
[570] Jasanoff (n 568) 22-41.
[571] Jasanoff (n 138) 767.
[572] ibid.
[573] ibid.

In the United States, the patent case which shaped future decisions on the patent eligibility of the products of "genetic engineering" has been the landmark case *Diamond v. Chakrabarty* ("*Chakrabarty*"),[574] decided on 16 June 1980 by the Supreme Court of the United States. The case concerned the patentability of bacteria of the genus *Pseudomonas*, modified by applying molecular techniques (not rDNA technology), having multiple compatible energy-generating plasmids containing degradative pathways for different components of hydrocarbons.[575] The patent application (Application serial No. 260,563) was filed on 7 June 1972 and entitled "Microorganisms Having Multiple, Compatible Degradative Energy-Generating Plasmids and Preparation thereof" by Dr Ananda Chakrabarty, a scientist working for General Electric at the time. Although the patent examiner admitted the patentability of some of the claims, he denied a patent on the microorganisms, rejecting claims 7-9, 13, 15, 17, 21, and 22-26, on two grounds: that they were living things and products of nature, therefore they did not fall within the definition of patentable subject matter pursuant to Title 35 U.S.C. § 101.

Title 35 U.S.C. § 101 provides that: "Whoever invents or discovers any new and useful process, *machine*, *manufacture*, or *composition of matter*, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title". The Court of Customs and Patent Appeals ("CCPA") reversed the decision twice and, finally, a 5 to 4 majority of the Supreme Court affirmed the CCPA's decision, holding that "A live, human-made micro-organism, is patentable subject matter under § 101" and that Chakrabarty's micro-organism was a ' manufacture' or 'composition of matter' within that statute.[576]

The opinion of the majority, delivered by Justice Burger, conveys a *narrative of the origins* of the U.S. patent system and the United States as a nation centered on *progress*, which justified a *broad* interpretation of the definition of "patentable subject matter" under Title 35 U.S.C. § 101. It is a narrative centered on a rendition of the beginnings, which is linked to a contemporary development of them and carries legal descriptive/prescriptive conclusions, which are consistent with the view of progress purported by the majority.

Justice Burger, first, recalled Art. 1 § 8, clause 8 of the Constitution of the United States as the foundation of U.S. patent system, pointing out that it granted Congress "broad power" to legislate to "promote the Progress of Science and of the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and

[574] *Diamond v. Chakrabarty* 447 U.S. 303 (1980) 206 USPQ 193.
[575] United States Patent No. 4,259,444 entitled "Microorganisms having multiple compatible degradative energy-generating plasmids and preparation thereof" granted on 31 March 1981.
[576] *Chakrabarty* (n 574) 197.

Discoveries".[577] The interpretation of this clause has been crucial, in the decision, to devise a narrative of collective progress centered on expanding the scope of patentable subject matter, in order to promote research and social access to the innovative products of genetic engineering.

The promotion of the progress of science by granting to inventors intellectual property rights, under article 1 § 8, clause 8 of the Constitution, entailed for the majority "a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens".[578]

Justice Burger, then, set the boundaries of the case, by limiting it to the statutory interpretation of 35 U.S.C. § 101 and clarifying that the words would "be interpreted as taking their ordinary contemporary common meaning".[579] In constructing its meaning the majority relied on the dictionary's definition of "manufacture" and "composition of matter", deemed consistent with their common usage.

Justice Burger explained that the term "manufacture" means "the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties or combinations, whether by hand-labor or by machinery", [580] whereas "composition of matter" denotes "all compositions of two or more substances and (…) all composite articles, whether they be the result of chemical union, or of mechanical mixture, or whether they be gases, fluids, powder or solids".[581] Moreover, he pointed out that these "expansive" terms were modified by the comprehensive "any" and they should, therefore, be given wide scope.

The statutory interpretation of section 101, however, hinged on the narrative of the origins, whose preamble of the beginnings was further unfolded by the majority.

Justice Burger, after providing a literal construction of the meaning of 35 U.S.C. § 101, combined it with a reconstruction of the legislative history, namely the intention of the legislator. By highlighting the similarity of the definition of patentable subject matter in the Patent Act of 1793 with § 101, he argued that section 101 ought to be interpreted broadly. In order to support this conclusion, he invoked the authority of Thomas Jefferson, one of the founding fathers of U.S. democracy, Secretary of State and member of the first Patent Board

[577] ibid 196.
[578] ibid.
[579] ibid.
[580] ibid 197.
[581] ibid.

under Act of 10 April 1790 and considered, as such, the first administrator of the patent system and the first patent examiner.[582]

In particular, the Patent Act of 1793, which was authored by him, was deemed to be inspired by his philosophy, according to which "ingenuity should receive liberal encouragement".[583] The same language and philosophy were, then, tied to all the following patent statutes enacted in 1836, 1870 and 1874.[584] It should be noted that in the Jeffersonian mythology,[585] which has been illustrated by Waltersheid and was largely recalled by the majority, Jefferson was also credited to have incorporated the locution "composition of matter" in the 1793 Act.[586]

The narrative reaches its narrative *climax*, when the majority held that "the Committee Reports accompanying the 1952 act inform us that Congress intended statutory subject matter to include '*anything under the sun that is made by man*'".[587] This phrase, which at present epitomizes the United States' view of what is patent eligible, was referred to Congress' intention. It was, rather, used during the hearings by Pasquale Federico, at the time the examiner in chief of the USPTO. During the hearings before subcommittee No. 3 of the Committee on the Judiciary House of Representatives on the bill H.R.3760 to revise and codify the laws related to patents and the patent office, P. J. Federico, who was one of main promoters of the codification and the Examiner in Chief, was asked to give an explanation of the background of the bill and any information related to the patent laws. In addressing the content of § 101, Federico commented: "Now under section 101 a person may have invented a machine or manufacture, *which may include anything under the sun that is made by man*, but it may not necessarily be patentable unless the conditions are fulfilled".[588]

Federico's remark expressed possibility and contingency, however, the abridged phrase referred to by the Court is more inclusive and solemn. The phrase is imbued with biblical solemnity, as it is the reversal of a verse in the biblical book Qohelet or Ecclesiastes 1:9,

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[582] P J Federico, 'Operation of the Patent Act of 1790' (1936) 18(4) Journal of the Patent Office Society 237, 238.
[583] *Chakrabarty* (n 574) 197.
[584] ibid.
[585] Edward C Waltersheid, 'Patents and the Jeffersonian Mythology', (1995) 29 John Marshall Law Review 269; Edward C Waltersheid, 'The Use and Abuse of History: The Supreme Court's Interpretation of Thomas Jefferson's Influence on the Patent Law' (1998) 39 IDEA 195; James Boyle, 'The Second Enclosure Movement and the Construction of the Public Domain' in James Boyle (ed), (2003) 66(1&2) Law and Contemporary Problems 33, 53-58.
[586] Waltersheid (n 585) 293.
[587] *Chakrabarty* (n 574) 197.
[588] Statement of P. J. Federico, Examiner in Chief, United States Patent Office, Washington D.C., Patent Law Codification and Revision, Hearings before Subcommittee No. 3 of the Committee on the Judiciary, House of Representatives, 82nd Congress, First Session on H.R. 3760, June 13, 1951, at 37.

according to which "What has been will be again, what has been done will be done again; *there is nothing new under the sun*".[589] This phrase has become a kind of adage in the English language. It is listed among the proverbs in the Oxford Dictionary of English Proverbs.[590]

However, whereas in Qohelet the term "under the sun" is linked 8 times to the verb of labour ("amal") and 9 times to the verb "make"[591] in order to point out the uselessness of human efforts and troubles, in Justice Burger's opinion, *anything under the sun that is made by man*, conversely, affirms and stands for the endless human creative technoscientific potential and its usefulness, which deserves to be rewarded with a patent.

The majority did not acknowledge therefore that, with this broad interpretation of §101, it was reshaping the boundaries of patentable subject matter. Nevertheless, since its re-definition seemed limitless, the majority made clear that section 101 still retained some limits: the laws of nature, physical phenomena and abstract ideas ought not to be held patentable. Justice Burger reaffirmed the so called "product of nature" doctrine,[592] under which these three kinds are considered discoveries and, as such, "manifestations of nature, free to all men and reserved exclusively to none".[593]

Eisenberg pointed out that the doctrine retained considerable vitality before the Supreme Court in the 1970s,[594] but *Chakrabarty* awaked its potential, since afterwards it has become one of the main grounds to establish the boundaries of what is natural and artificial within the patent system in the United States.

Under Title 35 U.S.C. § 101, however, discoveries are not legally and epistemically distinguished from inventions, as far as their patent eligibility is concerned. It was, rather, the majority's opinion in *Chakrabarty* that set forth these boundaries, by holding that:

> "This is not to suggest that § 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena and abstract ideas have been held not patentable. […] Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his

[589] Ecclesiastes 1:9, *Holy Bible (New International Version)* (Hodder & Stoughton 2011) vii, 498.
[590] Proverb "Nothing new under the sun" from Eccl. 1.9 "There is no new thing under the sun", *The Oxford Dictionary of English* Proverbs (3rd edn, Claredon Press 1970) 580. See also proverb "There is nothing new under the sun" listed in Bartlett Jere Whiting, *Modern Proverbs and Proverbial Sayings* (Harvard University Press 1989) 454.
[591] Gianfranco Ravasi, *Qohelet* (Edizioni Paoline1991) 6, 72.
[592] The origin of the "product of nature" doctrine can be traced back to the 19th century, at least in 1889 when *Ex parte Latimer* [Commn. Dec. 123(1889)] was decided by the Commissioner of patents.
[593] *Chakrabarty* (n 574) 197.
[594] Rebecca S Eisenberg, 'The Story of Diamond v. Chakrabarty: Technological Change and the Subject Matter Boundaries of the Patent System' in Jane C Ginsburg and Rochelle Cooper Dreyfuss (eds), *Intellectual Property* Stories (Foundation Press 2006) 325, 337.

> celebrated law that $E=mc^2$: nor could Newton have patented the law of gravity. Such discoveries are 'manifestations of nature free to all men and reserved exclusively to none'".[595]

Justice Brenner, finally, relied on the mechanistic metaphor which is embedded in section 101, namely that the microorganism was a *bio-artefact,*[596] alike to a machine or a manufacture, to sustain its patentability, as it was "a new bacterium with *markedly different* characteristics from any found in nature".[597]

Section 101 U.S.C., as far as products are concerned, is informed to a mechanistic model of invention, which entails two features: the invention must be to a certain degree "man-made" and consist of parts. These features are related to the meaning of the three general concepts of *machine, manufacture,* or *composition of matter* set out in §101. The term "machine" is defined in the Oxford Dictionary as "an apparatus using mechanical power and having several parts, each with a definite function, and together performing a particular task".[598]

"Machine, manufacture and composition of matter" are categories that, in modern patent law, largely reflect the kinds of inventions that the patent system was envisaged to offer intellectual property protection: mainly mechanical artefacts. This kind of protection has been extended, later, to chemical inventions and finally to microorganisms and higher life forms, as well as genes. However, this process of extension of IP protection, by subsuming new kinds of inventions under these general concepts, occurred under the aegis of the mechanistic model of invention which is embedded in the definition of "patentable subject matter" or "invention" in several countries, such as the U.S. and Canada. This model implicitly requires the atomization and molecularization of inventions, in order to make them patentable.

The narrative unfolded by the majority shows that the court made sense and order of this biotech invention reshaping the boundaries of the natural and artificial by drawing on the mechanistic metaphor, a move which allowed it to elude all the issues about the liveliness of the claimed invention.

Justice Burger, moreover, dismissed as irrelevant the concerns on the potential risks related to genetic research products and the particular responsibility of the judges in deciding on this case in the name of scientific determinism, which conflates with economic determinism. He argued that: "The grant or denial of patents on microorganisms is not likely to put an end to

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[595] *Chakrabarty* (n 574)197.
[596] Mariachiara Tallacchini, 'La trappola e il topo: la brevettabilità della materia vivente', available on <researchgate> 1, 8.
[597] *Chakrabarty* (n 574) 197.
[598] Headword "machine", Oxford English Dictionary.

genetic research or its attendant risks. The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides".[599]

The reference to the famous story about the Medieval Danish king Cnut the Great, is insightful about the approach of the majority, which disclaimed the responsibility and power of the court in deciding on the matter of the case.

According to the legend, King Cnut or Canute "sat enthroned on a beach and commanded the waves to go back, thus receiving wet feet for his trouble".[600] This story was, first, narrated in the second quarter of the twelfth century in the *Historia Anglorum* by Henry of Huntingdon[601] and, as the historian Timothy Bolton explained, must be examined in the context of the tales of Anglo-Saxon saints who could control nature. Although the story has been truncated in most modern retellings and interpreted throughout the centuries in different ways, either as a prideful[602] or foolish act or as an act of humility,[603] it is focused on reminding a ruler that "his power is nothing before God and the Church".[604]

By recalling this story in relationship with the grant or denial of patents on microorganisms, the majority displayed humbleness in settling a significant dispute as to the future patentability of biotech products, but eluded the responsibility and power related to any "legislative or judicial fiat" on the matter. By enshrining a deterministic view of scientific progress, the judges of the majority disguised and concealed the power and authority of any legal and judicial choice on the matter and, in particular, the ones carried out in their own decision. They, therefore, rather acted as the *gatekeepers* of the technoscientific progress envisaged in the United States' patent system.

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[599] *Chakrabarty* (n 574) 200.

[600] Timothy Bolton, *Cnut the Great* (Yale University Press 2017) vii, 214.

[601] Henry, Archdeacon of Huntington, *Historia Anglorum* (edited and translated by Diana Greenway, Clarendon Press 1996) xi, 366-369.

[602] One of the truncated versions was narrated by Holinshed, who interpreted it as a prideful act, though followed by a supplication to God: "his intollerable pride in commanding the waters of the flouds not to rise, he humbleth himselfe and confesseth Christ Iesus to be the king of kings, he refuseth to weare the crowne during his life". See footnote 1, Timothy Bolton, *Cnut the Great* (Yale University Press 2017) vii, 1. Bolton relied for the reference on Elaine Treharne, 'The Performance of Piety: Cnut, Rome, and England' in Francesca Tinti (ed), *England and Rome in the Early Middle Ages: Pilgrimage, Art and Politics* (Brepols 2014) 343, 360.

[603] In William Slayter's *The History of Great Britaine*, published in 1621, Cnut's legend is interpreted more as an act of humility: "This Cnute command the seas to shew,/ His Sycophants flattering Terms vntrew, / And knowledging Christ his only trust,/ Return'd from Rome, returnes to dust". See footnote 1, Timothy Bolton, *Cnut the Great* (Yale University Press 2017) vii, 1. Bolton relied for the reference on Elaine Treharne, 'The Performance of Piety: Cnut, Rome, and England' in Francesca Tinti (ed), *England and Rome in the Early Middle Ages: Pilgrimage, Art and Politics* (Brepols 2014) 343, 360.

[604] Timothy Bolton, *Cnut the Great* (Yale University Press 2017) vii, 216.

As Jasanoff noticed, the majority dodged in particular the main meta-question regarding the character of invention, whether it had changed radically because of molecular biology, as to make Jefferson's view of IP outdated.[605]

This deterministic view of the relationship amidst science, law and society must be considered, however, within the preamble of the narrative of the origins centered on the idea of progress, according to which biotech research would be beneficial to American society, as it would lead to "the introduction of new products and processes of manufacture into the economy".[606]

Koselleck and Meier pointed out that the modern concept of progress emerged in the last quarter of the 18th century and arose from the incorporation of an ideal of perfection into time as a growth projected in an open future.[607] The opinion of the majority shows, in this respect, how much U.S. legal discourse is product-centered in the way of imagining social progress.

The introduction of the clause in article 1 has been largely interpreted as connected to the commercial clause in the same article. According to Commissioner of patents Lawrance Kingsland, the framers of the U.S. Constitution "viewed the grant of limited monopolies to inventors primarily as a means of promoting the industrial development of the new republic and emphasized this primary objective by the phraseology of the constitutional provision".[608]

The narrative of the court eluded therefore the main issue raised by Chakrabarty's claims to the bacteria, namely whether allowing the patentability of living things constituted a departure from well-established practices of the USPTO and a constant interpretation of patentable subject matter in the United States. Yet, the decision stretched out the scope of the definition of patentable subject matter and made clear to the biotech industry that its products could be patented, provided they fulfilled the requirements of patentability.

Furthermore this narrative, as this chapter and the following ones will explain, proved far more influential in the development of the patent eligibility of biotech products. It would be constantly drawn upon and reiterated by the USPTO, in several guidelines involving biotech products, and the U.S. courts in the landmark decisions which have extended the boundaries of patentable subject matter in different areas of biotech innovation in order to justify their choices.

[605] Jasanoff (n 44) 49.
[606] *Chakrabarty* (n 574)196.
[607] Reinhart Koselleck and Christian Meier, *Progresso* (Marsilio 1991) vii, 51-61.
[608] Lawrence C Kingsland, 'The United States Patent Office' (1948) 13 *Law and Contemporary Problems* 354.

Although the narrative has provided the influential plot and discourse to sustain the holding, the analysis in this section has showed that it was the recourse to the mechanistic metaphor of the microorganism as a *bio-artefact* that has brought about the enlargement of the scope of §101. By assimilating the claimed invention to artefacts already covered by patent protection, new subject matter has been included as patentable in the U.S. patent system.

3.2.1 Micro-Organisms as "Chemical Molecules": *In re Bergy, Coats and Malik*; *In re Chakrabarty*

Whereas the definitional approach of the majority of the Supreme Court focused on the metaphor of micro-organisms as *bio-artefacts*, the one endorsed by the CCPA centered on the metaphorical concept of "chemical molecule". This approach was supported, in particular, by Justice Rich, who was one of the judges who largely influenced CCPA's approach of limiting patent exclusions and fostering patent protection for all fields of invention[609] and was one of the promoters and drafters of the codified Patent Act in 1952.[610]

As Helen Longino pointed out, "reductionism is both a methodological practice and a metaphysical view. Methodologically, reductionism is the practice of characterizing a system or process in terms of its smallest functional units. Metaphysical or ontological reductionism argues that those smallest functional units are what is real and that all causal processes can ultimately be understood as a function of interactions among these least bits".[611] Since methodological reductionism – she notices – has proved to be useful in guiding the work of researchers in addressing "the mechanisms or material constituents of a process",[612] its pragmatic success has been conflated by metaphysical reductionism "with both a guarantor of truth and the promise of universal reducibility".[613]

As chapter two has pointed out (section 2.2.3), molecular biology and genetics have methodologically embraced reductionism as a practice in order to study organisms and life. However, their scientific discourse, which has focused on the smallest functional biological units, has shifted towards deeming these units as the very definition of the organisms object of study. Since these technoscientific domains have been successful in providing an

[609] Eisenberg (n 594) 330.
[610] Giles S Rich, *A Brief History of the United States Court of Customs and Patent Appeals*, (U.S. Government Printing Office 1980) iii, 132.
[611] Helen Longino, *Science as Social Knowledge: Values and Objectivity in Scientific Inquiry* (Princeton University Press 1990) x, 226.
[612] ibid.
[613] ibid.

understanding of life phenomena since the 1950s, their view has become dominant in defining organisms and their identity in reductionist terms. This kind of ontological reductionism, as this section will explain, has proved fundamental in arguing for the patent eligibility of GM microorganisms.

This need for molecularization and reduction emerged in the first patent cases focused on the patent eligibility of GM microorganisms and organisms, but must be examined within the U.S. narrative of the origins focused on progress.

Patent examiners and judges were aware, at the time, that their decisions could affect the commercial opportunities of newly established biotech companies and the use of genetic engineering in order to bring new products to the market. They had to decide whether Title 35 U.S.C. § 101 ought to be interpreted strictly and literally or extensively, in an evolutionary way.

As Eisenberg noticed, before the first wave of patent applications on these advances in biotechnology, "living organisms had generally been assumed to fall outside the range of patent-eligible subject matter under a time-honored exclusion for 'products of nature'".[614]

The molecular dimension of microbial life validated the analogy between chemical molecules and microorganisms in the United States. This emerges clearly from the CCPA's second judgment, which decided *In re Chakrabarty* together with *In re Bergy, Coats and Malik*.[615]

Judge Rich, delivering the opinion of majority of the Court, argued:

> "The nature and commercial uses of biologically pure cultures of microorganisms like the one defined in Bergy's claim 5 and the modified microorganisms claimed by Chakrabarty are *analogous* in practical use *to inanimate chemical compositions such as reactants, reagents, and catalysts used in chemical industry*. (…) we see no reason to deprive it or its creator or owner of the protection and advantages of the patent system by arbitrary excluding it at the outset from the § 101 categories of patentable invention on the sole ground that it is alive. It is because it is alive that it is useful. (…) We see no sound reason to refuse patent protection to the microorganisms themselves, or to pure microorganism cultures, – *the tools used* by chemical *manufacturers in the same way as they use chemical elements, compounds, and compositions* – when they are new and unobvious. In fact, we see no *legally significant difference between active*

[614] Eisenberg (n 594) 327.
[615] CCPA *In re Bergy, Coats and Malik*; *In re Chakrabarty* 201 USPQ 352 (1979).

chemicals which are classified as 'dead' and organisms used for chemical reactions which take place because they are 'alive'".[616]

The argument employs several metaphorical expressions related to the metaphor of "molecule", in order to link microorganisms to chemical molecules and maintain that they *are* inanimate chemical molecules. The metaphor was supported by the expertise of Upjohn's molecular biologists and questions, as Calvert and Joly have pointed out, the nature of the relationship between knowledge, ontologies and the production of intellectual property.[617]

Cognitive linguistics defines metaphor as "understanding one conceptual domain" (the target domain) "in terms of another conceptual domain"[618] (the source domain), such as "conceptual domain (A) is conceptual domain (B)".[619] This is what is defined as conceptual metaphor.

In Justice Rich's main argument, microorganisms (the target domain) are devised in terms of chemical compounds (the source domain). The use of this metaphor entail that a set of properties of the source domain are attributed to the target domain.

In order to point out the focus of the metaphor within the discourse carried out by Judge Rich, it is useful to refer to Perelman's and Olbrechts-Tyteca's reflection on the metaphor as a condensed analogy explained in chapter one, namely a "condensed analogy, resulting from the fusion of an element from the phoros with an element from the theme".[620]

In this case, an example of analogical metaphorical fusion can be recognized in the argument: modified and pure cultures of microorganisms (A) are the chemical molecules (C) of the biotechnological industry (B). The analogy from which it is drawn upon is the following: modified and pure cultures of microorganisms (A) are to the biotechnological industry (B) as inanimate chemical molecules (C) are to chemical industry (D).

The main effect of this fusion is that it rules out, as *ontologically* and *legally* irrelevant, one fundamental difference between microorganisms and inanimate chemical molecules: their being *alive*. The significance and relationship between these cultures of microorganisms and biotechnological industry is stated in the premise to the argument: "American industry is on the threshold of a new advance in microorganism technology in which man is exploring more intensely and learning to better convert to his use the micro-world of living cells, the field of molecular biology, a new branch of a useful art which has existed for many years".[621]

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[616] ibid 372-373.
[617] Calvert and Joly (n 52) 1.
[618] Kövecses (n 338) 4.
[619] ibid.
[620] Perelman and Olbrechts-Tyteca (n 294) 399.
[621] *In re Chakrabarty* (n 615) 372.

The Supreme Court' decision, likewise, dismissed the significance of the *living thing* distinction, opting for a broad construction of §101 statutory provision and pointing out that the terms "manufacture" and "composition of matter" ought to be interpreted expansively. Since these terms are modified by the comprehensive "any", the majority pinpointed that Congress "plainly contemplated that the patent laws would be given wide scope".[622] However, the majority did not reject the relevance of the "alive" distinction on the basis of the molecular analogy, but on the grounds of the mechanistic metaphor of life. According to the mechanistic metaphor, modified micro-organisms are bio-artefacts,[623] if they have *markedly different* characteristics from any found in nature. They are, thus, patentable.

As the Court deemed that Chakrabarty had produced "a *new* bacterium with *markedly different* characteristics from any found in nature and one having the potential for significant utility",[624] it concluded that it was patentable. Justice Burger, delivering the opinion of the Court, maintained that the enactment of the 1930 Plant Patent Act, which afforded patent protection to certain asexually reproduced plants, and of Plant Variety Protection Act, in 1970, which offered protection for certain sexually reproduced plants, were not related to the fact that § 101 did not include living things.

Conversely, Justice Brennan, who delivered the dissenting opinion, focused his reasoning on the *lex specialis* argument, namely that *lex specialis derogat legi generali* ("special law makes an exception to general law"), which is a criterion of general legal theory of interpretation. It is one of the criteria applied to solve legal antinomies. However, Justice Brennan referred to it for what it implies: had the lawmaker wanted living organisms, such as plants, covered by the Patent Act, he would have not enacted two special laws in order to offer them IP protection. Furthermore the legislator would not have introduced particular provisions to accord patent protection to the developers of asexually reproduced plants, in 1930 with the Plant Protection Act, or of certain new plant varieties obtained through sexual reproduction, with the Plant Variety Protection Act in 1970, had he thought that living things fell within the general utility patent protection. The enactment of these two acts offered, therefore, evidence of congressional limitation, which excluded bacteria from patentability.[625]

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[622] *Chakrabarty* (n 574) 197.
[623] Mariachiara Tallacchini, 'La trappola e il topo: la brevettabilità della materia vivente' in Amedeo Santosuosso (ed) *Le tecniche della biologia e gli arnesi del diritto* (Ibis 2003) 203.
[624] *Chakrabarty* (n 574) 197.
[625] ibid. 201-202.

Furthermore, he argued that although Congress considered bacteria in the legislative debate on the PVPA, it nevertheless did not include them in the scope of patent protection.[626] Since in the legislative history there was no reference to the exclusion of microorganisms, the Court should not take "license to invent reasons"[627] and, instead, drew the conclusion that "Congress, assuming that animate objects as to which it had not specifically legislated could not be patented, excluded bacteria from the set of patentable organisms".[628]

The minority opinion is marked, hence, by the evident concern not to dodge the boundaries of judicial power in interpreting the scope of patentable subject matter, by expanding it in an area which entailed public concern, in the absence of a clear intention in the statutes.[629]

In contrast with the majority, he undermined their narrative of progress and economic determinism positing a different meaning of Article 1, § 8, clause 8 of the U.S. Constitution, according to which patent laws had to reconcile the U.S. Nation "deep seated antipathy to monopolies with the need to encourage progress".[630] Consequently, he contended that, in the absence of legislative direction, Congress should decide whether and to what extent expand the patent privilege into areas where the common understanding was that patents were not available.[631]

However, as the next sections will point out, the mechanistic metaphor of the bio-artefact, together with the molecule, would prove the dominant means of legally defining biotech GM living products under patent law.

3.2.2 From Microorganisms to Organisms: Patenting Animals in the Aftermath of the *Chakrabarty* Case

In the United States, SCOTUS' decision on *Chakrabarty* paved the way to the patentability of GM organisms and other biotechnological products, as its narrative of progress and metaphor of living things as bio-artefacts enabled the accomodation an endless range of organic matter where there was a human intervention and it fulfilled the patent requirements.

In 1987, Donald J Quigg, Assistant Secretary and Commissioner of Patents and Trademarks of the USPTO, issued a brief guideline on "Animals-Patentability", in which he explained that, following a decision by the Board of Patent Appeals and Interferences in *Ex parte Allen* that held that claimed polyploid oysters are nonnaturally occurring manufactures or

[626] ibid 202.
[627] ibid.
[628] ibid.
[629] ibid 201-202.
[630] ibid 201.
[631] ibid 202.

compositions of matter within the meaning of 35 U.S.C. § 101, "the Patent and Trademark Office is now examining claims directed to multicellular living organisms, including animals".[632]

Ex parte Allen[633] was decided in 1987 by the PTO Board of Patent Appeals and Interferences ("BPAI") and concerned four product-by-process claims directed polyploid Pacific oysters produced by a method of inducing polyploidy in oysters by using a hydrostatic process. The claims were rejected by the patent examiner on grounds of obviousness in light of the prior art under 35 USC § 103 and as "living entities" not falling within statutory subject matter under 35 USC § 101,[634] since the animal obtained was "controlled by laws of nature and not a manufacture by man that is patentable".[635]

Although the BPAI rejected the claims on grounds of obviousness, it affirmed the patent eligibility of living organisms. It drew upon the narrative developed in *Chakrabarty*, according to which Congress intended "patent laws would be given wide scope",[636] so that statutory subject matter was to "include anything under the sun that is made by man".[637] Accordingly, the only relevant point the BPAI had to address was whether the claimed invention was *made by man* and concluded that claimed polyploid oysters were non-naturally occurring manufactures or compositions of matter.[638] In *Ex parte Allen*, therefore, the BPAI endorsed the mechanistic metaphor set out in *Chakrabarty* and contributed to its extension from microorganisms to organisms in the U.S.

The USPTO's notice rested, moreover, on the BPAI's administrative decision in *Ex parte Hibberd* (which will be examined in chapter five),[639] which held that plants were patentable subject matter "under general utility patent provisions",[640] and SCOTUS's judgement in *Chakrabarty*.

Quigg clarified, however, that "a claim directed to or including within its scope a human being will not be considered to be patentable subject matter", as the grant of a limited but exclusive property right in a human being is prohibited by the Constitution".[641]

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[632] J Quigg, "Animals-Patentability" (1987) 6 Journal of the Patent and Trademark Office Society 328.
[633] BPAI, *Ex parte Allen*, 3 April 1987, 2 USPQ2d 1425.
[634] ibid 1426.
[635] ibid.
[636] ibid.
[637] ibid.
[638] ibid 1427.
[639] USPTO BPAI, *Ex parte Hibberd*, 24 September 1985, 227 USPQ 443.
[640] U.S. Congress, Office of Technology Assessment, *New Developments in Biotechnology: Patenting Life-Special Report*, OTA-BA-370 (Washington, DC: U.S. Government Printing Office, April 1989) iii, 30.
[641] Quigg (n 632) 328.

The Notice was published when several patent applications on transgenic animals or organisms were pending.[642] Philip Leder and Timothy Stewart filed on 22 June 1984 a patent on transgenic non-human mammals, the so called *Harvard mouse*, which would be granted in 1988[643] and raised Congressional debate in the United States, but triggered long patent litigation in Canada and Europe, as this chapter will show.

However, USPTO's commitment to fully embrace *Chakrabarty*'s narrative, by issuing this guideline on the patentability of animals, was not shared by animal protection associations and several farmers groups, as well as members of Congress.

Animal Legal Defense Fund and other animal-rights organizations, together with individual farmers and groups of animal husbanders, challenged the rule embedded in the USPTO's notice before the District Court, N.D. California, alleging that the rule was promulgated in violation of the Administrative Procedure Act, 5 USC 500 et seq., as the USPTO's Commissioner and the Secretary of Commerce failed to provide for a period of public notice and comment under 5 USC 551 et seq. Moreover, they claimed that the rule was issued in excess of statutory authority.[644]

Both the District Court and the U.S. Court of Appeals for the Federal Circuit, which decided in 1991, rejected the claims also for lack of standing, but the Court of Appeals significantly embraced and endorsed the narrative of economic determinism set forth by the majority in *Chakrabarty*. The Court, in fact, stated: "However, were we to enjoin issuance for patents for non-naturally occurring animals, the requested relief would not prevent the development of such animals. It should hardly need saying that the issuance of a patent gives no right to make, use or sell a patented invention, or that the absence of a patent creates no legal prohibition against continued research and development".[645] It, then, cited the same full argument endorsed in *Chakrabarty*.[646]

The Notice, nevertheless, was at the core of Congressional debate, in 1987, when the U.S. Senate adopted a moratorium on animal patents which was part of a supplemental bill, even though the moratorium was dropped.[647] In 1987 and, then, 1988, House Resolution 3119 and Senate Bill 2111 directed to amend Title 35 of the United States Code in order to prohibit the

[642] U.S. OTA (n 640) 32.
[643] U.S. Patent No. 4,736,866 "Transgenic non-human mammals", 12 April 1988.
[644] District Court, N.D. California, *Animal Legal Defense Fund v. Quigg*, 9 USPQ2d 1816 (1989).
[645] ibid 935.
[646] ibid.
[647] U.S. OTA (n 640) 30.

patenting of genetically modified animals.[648] Whereas the former would have imposed a two-year moratorium on animal patents, the latter would have entailed a ban on animal patents. However, both bills died when the 100th Congress adjourned.[649]

Moreover, in 1989, Robert Kastenmeier a Wisconsin Democrat member of the House of Representatives backed the *Transgenic Animal Patent Reform Act* (HR4970).[650] The Act passed the House of Representatives, but was not debated at the Senate before the end of the Congress and since Kastenmeier lost his seat in 1990, the bill was never reintroduced. The Act would have introduced for GM animals a form of IP protection closer to Plant Breeders' Rights and included a farmers' exemption from royalty payments.[651]

Nevertheless, after the USPTO granted a patent on the so-called *Harvard mouse* in 1988, for some years a voluntary moratorium on animal patents was established, which ended in 1993.[652] At the time 180 patent applications on GM animals were pending before the USPTO.[653]

As this section has pointed out, the initiatives aiming at challenging the patent eligibility of GM organisms failed to undermine the definition of patent eligible matter according to mechanistic and molecular metaphors, which will turn out to be also the focus of the judicial re-definition of the concept of "invention" in Canada.

3.3 Thresholds of Artificiality in Canada: *Re Application of Abitibi CO*

This section and the next two will show that, in Canada, the metaphor of the *chemical metaphor* has been largely resorted to in order to settle the patent eligibility of GM microorganisms and organisms.

In 1982, the Patent Appeal Board and Commissioner of Patents, deciding in *Re Application of Abitibi CO*[654] ("*Abitibi*"), a case concerning the patentability of a mixed microbial culture, considered and endorsed the U.S. Supreme Court's decision in *Chakrabarty* and ruled likewise, but limited the scope of the judgment to all microorganisms and excluded higher

[648] ibid 30; William Lesser, 'Animal Patents in the USA: Are the Concerns Justified?' in William H Lesser (ed) *Animal Patents: The Legal, Economic and Social Issues* (Stockton Press 1989) 353.
[649] U.S. OTA (n 640) 30; Lesser (n 648) 353.
[650] 100th Congress 2d Session, House of Representatives, Transgenic Animal Patent Reform Act, Report together with additional views to accompany H.R. 4970, 100-888, available in William H Lesser (ed) *Animal Patents: The Legal, Economic and Social Issues* (Stockton Press 1989) 185.
[651] Lesser (n 648) 353.
[652] Edmund L Andrews, 'U.S. Resumes Granting Patents on Genetically Altered Animals' (3 February 1993) The New York Times A1, available at <https://www.nytimes.com/1993/02/03/business/us-resumes-granting-patents-on-genetically-altered-animals.html >.
[653] ibid.
[654] Patent Appeal Board and Commissioner of Patents, *Re Application of Abitibi CO*, 62 C.P.R. (2d) 81 (1982).

life organisms. The definition of "invention", according to section 2 of the Canadian Patent Act, R.S.C. 1985, c. P-4, includes "any new and useful art, process, machine, manufacture or composition of matter" and is similar to the definition of "patentable subject matter" set out in Title 35 U.S.C. § 101, in the U.S.

The Patent Appeal Board and the Commissioner of Patents rested their decision on the metaphor of the *molecule*. Microorganisms were defined as chemical compounds, since they can be produced *en masse* and possess *uniform properties*:

> "Certainly this decision *will extend to all micro-organisms*, yeasts, moulds, fungi, bacteria, actinomycetes, unicellular algae, cell lines, viruses or protozoa; in fact to all new life forms which are produced *en masse* as chemical compounds are prepared, and are formed in such large numbers that any measurable quantity will possess uniform properties and characteristics".[655]

In *Abitibi*, however, micro-organisms were considered *like* chemical compounds because of their *process* of production, which is *en masse* and allows them to retain *uniform characteristics/properties*. The metaphor and analogies on which this decision is grounded pinpoint the relevance of *reproducibility* in order to deem genetically modified microorganisms patentable.

In this case, modified and pure cultures of microorganisms (target domain) are defined as the chemical molecules (source domain) of the biotechnological industry. However, the argumentation hinges on this analogical feature: their *reproducibility en masse* like chemical compounds. Therefore, although the metaphor of the chemical molecule is identical to what has been applied by Justice Rich in *In re Bergy*, the analogy that it conveys differs, as the judicial narratives point out.

The Canadian Patent Appeal Board, yet, recognized and stated clearly in the editorial note, that the judgment was significant, as it entailed a change in the Canadian Intellectual Property Office ("CIPO") practice and laid down criteria for the patentability of living matter. Moreover, it pointed out that it had implications for subject matter as genetic-engineering and plant patents.[656]

The Board endorsed a different approach from the USPTO and U.S. courts. It compared the policy answers in the U.S., Australia, Germany, Japan and the UK as to the patent eligibility of microorganisms and the sufficiency of the deposit of the microorganism in a culture collection to fulfil the description requirement for the invention, in order to justify Canadian

[655] ibid 89.
[656] ibid 82.

patent policy choices. The Board acknowledged the relevance of the decision for the biotech industry. It sets out, however, a threshold of artificiality only for microorganisms, leaving the decision about higher life forms to the Parliament.

Chakrabarty and *Re Application of Abitibi CO* removed some legal uncertainties about the patentability of genetically modified microorganisms in the United States and Canada. Whereas, in the United States, in the aftermath of *Chakrabarty*, the USPTO clarified, in 1987,[657] that patent claims on "multicellular living organisms, including animals" could be examined, the CIPO considered genetically modified higher life forms excluded from patentability under *Abitibi*. In that respect, CIPO's more cautious approach differed from USPTO's one, which further backed the passage from the patent eligibility of GM microorganisms to organisms.

The CIPO, following the approach of other patent systems, endorsed a molecular view of GM microorganisms, which affirmed their artificiality and patent eligibility. However, it refrained from backing its extension to complex organisms because of its possible implications for human beings.

3.3.1 Patenting "Higher Life Forms" in Canada: The "*Oncomouse* case"

Whereas the USPTO, in the aftermath of *Chakrabarty*, displayed a full commitment to embrace its holding and narrative, by considering patent applications on GM animals, CIPO seemed more reluctant to deem that *Abitibi* had paved the way to the patentability of complex life forms. Its more careful approach emerged when CIPO had to examine the patent application concerning "transgenic non-human mammals" genetically modified in order to develop cancer.[658] Although the patent on this invention was granted in the U.S. in 1988, in Canada patent examiners and judges considered the issue of patenting life deserving more careful consideration.

Whilst patent application '723 was lodged in 1985, claims1-12 were rejected as directed to non-statutory subject matter by the Commissioner of Patents on 4 August 1995. President and Fellows of Harvard College ("Harvard"), the assignee, appealed against the rejection and the case triggered one of the longest and most debated patent controversies in Canadian history. The claims all concerned a "transgenic mammal, who is a mammal containing a gene that has

[657] Quigg (n 632) 328.

[658] The case refers to Patent application No. 484,723 filed on 21 June 1985 and claimed priority from a corresponding U.S. patent application which was filed on 22 June 1984.

been artificially introduced into the chromosomes of the mammal or its ancestor at the embryonic stage".[659]

The rationale for the dismissal was that the claimed invention did not fall within the words "manufacture" or "composition of matter" under s. 2 of the Patent Act,[660] which set forth the definition if invention, as the inventor did not have full control over the characteristics of the mammal.

Judge Nadon of the Federal Court, Trial Division, articulated the main questions posited by the case as follows: 1. "Is it appropriate to examine the *degree of the inventor's control* over the creation of the claimed invention?";[661] 2. "Is it appropriate to distinguish between *human intervention* and the *laws of nature*?";[662] 3. "What is the relevance of the *test of reproducibility* in the present instance?";[663] 4. "Is it appropriate in determining whether something is patentable subject matter to make *distinctions between higher and lower life forms*?".[664]

He, first, remarked that processes entailing the use of microorganisms were patentable in Canada since 1965, when *American Cyanamid Co. v. Charles E. Frost & Co.*[665] was decided by the Exchequer Court, and microorganisms were held patentable in *Abitibi*.[666] *Abitibi*, however, established a threshold test of reproducibility focused on *uniform reproducibility* of the claimed life form, namely that "any measurable quantity would possess uniform properties".[667] In *Abitibi*, the Patent Appeal Board clarified that, insofar as microorganisms could be produced *en masse*, they were to be deemed *like* chemical compounds and, therefore patentable. The patentability of microorganisms resulted from drawing on the metaphor of the chemical molecule, which entailed a similarity, the reproducibility *en masse*.

He, then, recalled *Pioneer Hi-Bred Ltd. V. Canada (Commissioner of Patents)*,[668] a case concerning the patentability of a soybean variety obtained by cross-breading, in which the Federal Court of Appeal ("FCA") showed awareness of how much judges largely relied on metaphors in order to define biotech products and address their patentability. The FCA

[659] Federal Court of Canada, Trial Division, *President and Fellows of Harvard College v. Comissioner of Patents*, 79 C.P.R. (3d) 98 (1998), 100.
[660] Patent Act, R.S.C. 1985, c. P-4.
[661] *President and Fellows of Harvard College* (n 659) 109.
[662] ibid 111.
[663] ibid 113.
[664] ibid 114.
[665] *American Cyanamid Co. v. Charles E. Frost & Co.* (1965) 47 C.P.R. 215.
[666] *President and Fellows of Harvard College* (n 565) 102.
[667] ibid 102-103.
[668] *Pioneer Hi-Bred Ltd. V. Canada (Commissioner of Patents)* (1987) 14 C.P.R. (3d) 491.

referred to the use of the terms "manufacture" and "composition of matter" applied in *Chakrabarty* by SCOTUS and commented:

> "I have not been convinced. Even if those definitions were held to be applicable to a micro-organism obtained as a result of a laboratory process, I am unable to go further and accept that they can also adapt to a plant variety produced by cross-breeding. *Such a plant cannot really be said, other than on the most metaphorical level, to have been produced from raw materials or to be a combination of two or more substances united by chemical or mechanical means*. It seems to me that the common ordinary meaning of the words 'manufacture' and 'composition of matter' would be distorted if a unique but simple variety of soybean were to be included within their scope".[669]

Judge Nadon, therefore, pointed out that "raw material"[670] and "combination of substances united by chemical or mechanical means"[671] were considered to be applied "for ordinarily understood industrial tools",[672] not for plants.

Discussing the definitions of "manufacture" and "composition of matter" offered by the appellants, he remarked that:

> "On even the broadest interpretation I cannot find that a mouse is a 'raw material' which was given new qualities from the inventor. Certainly the presence of the myc gene is new, but the mouse is not new nor is it a 'raw material' in the ordinary sense of the phrase.
>
> A mammal is a very complex form of life and therefore it is more difficult to make analogies to chemical reactions as was done in *Abitibi*".[673]

He, therefore, rejected the chemical metaphor[674] endorsed in *Abitibi*, as far as higher life forms were concerned, concluding that:

> "I agree with the appellant's argument with respect to chemical processes. In a chemical process A + B = C is always true. However, in the creation of mammals A + B = C, D, E, F, … N. The chemical reaction and its products are known (once

[669] *President and Fellows of Harvard College* (n 659) 104.
[670] ibid.
[671] ibid.
[672] ibid 105.
[673] ibid 110.
[674] In Pioneer Hi-Bred, Judge Marceau acknowledged the metaphorical dimension linked to defining patent claims within the general concepts of invention: "I have not been convinced. Even if those definitions were held to be applicable to a microorganisms obtained as a result of a laboratory process, I am unable to go further and accept that they can also adapt to a plant variety produced by cross-breeding. Such a plant cannot really be said, other than on the most metaphorical level to have been produced from raw materials or to be a combination of two or more substances united by chemical or mechanical means. It seems to me that the common ordinary meaning of the words 'manufacture' or 'composition of matter' would be distorted if a unique but simple variety of soybean were to be included within their scope".

discovered) and constant, whereas the parameters of the resulting mammal are largely unknown and change every time. Thus, what is involved here, i.e. the insertion of the *myc* gene and the subsequent breeding, cross-breeding and back-breeding is more analogous to the process involved in the Hi-Bred case than it is to the process seen in *Abitibi*".[675]

He examined the following definitions of these locutions submitted by the appellant:[676]

"Manufacture"

1. "An article made by hand; a person's handiwork … an article or material produced by physical labour or machinery, now *spec.* one produced on a large scale" (*The New Shorter Oxford English Dictionary on Historical Principles* (Clarendon 1993) at 1691).
2. "… something made by the hands of man" (*Hornblower v. Boulton* (1799), 8 T.R. 95, Dav. Pat. Cas. 221, 101 E.R. 1285 at p. 1288 *per* Lord Kenyon C.J.).
3. "Something of a corporeal or substantial nature, something that can be made by man from the matters subjected to his art and skill … is requisite to satisfy this word" (*R. v. Wheeler* (1812), 2 B. & Ald. 345, 106 E.R. 392 at P. 395 *per* Abbott C.J.).
4. "… the production of articles for use from raw materials prepared by giving to these materials new forms, qualities, properties or combinations whether by hand labor or by machinery" (*Diamond, Commissioner of Patents and Trademarks v. Chakrabarty*, 206 U.S.P.Q. 193 (1980) at 196-197).

"Composition of Matter"

1. "a 'composition of matter' may be taken broadly to mean chemical compounds, compositions and substances. In *Electric Fireproofing Co. of Canada v. Electric Fireproofing Co.* Archibald J. defined the term 'composition of matter' as including all composite matter whether it was the result of chemical reaction or of mechanical mixture" (H.G. Fox, The Canadian Law and Practice Relating to Letters Patent for Inventions, 4th ed. (Toronto: Carswell, 1969, at 18).
2. "… all compositions of two or more substances and all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids" (*Diamond, Commissioner of Patents and Trademarks v. Chakrabarty*, 206 U.S.P.Q. 193 (1980) at 197).

He, finally, focused on the questions raised by the case and contended that the degree of control of the claimed inventor over the GM organisms was not very high as "the ultimate product which will result from the process is completely unknown and unknowable".[677] He highlighted that all the cited definitions implied an element of control and, since the *Oncomouse* was a complex form of life, applying the analogy with the chemical compounds, employed in *Abitibi*, was arduous.[678]

[675] *President and Fellows of Harvard College* (n 659) 113.
[676] ibid 108-109.
[677] ibid 110.
[678] ibid.

Moreover, he pinpointed that the claimed invention failed the test of *reproducibility*, which was set out in paragraph 27(3)(b) of the Patent Act. As the claims regarded all the mammals, too much was left to luck and chance: "The location and even the presence and quality of the gene are totally uncontrollable. Thus, although the gene will be present in some mice, at some place, with some characteristics, the precise mouse, the precise location and the precise quality of the gene are irreproducible".[679]

Although Judge Nadon disputed the adequacy of the metaphor of the *chemical molecule* to address the patent eligibility of GM organisms, the majority of the Federal Court of Appeal of Canada disagreed with his opinion and holding.

Justice Rothstein, who delivered the opinion of the majority, fully embraced the *narrative of progress* posited by SCOTUS in *Chakrabarty*.

He, first, pointed out that the purpose of the Patent Act "is to provide an incentive for the creation of processes or products which are new, useful and unobvious".[680]

Justice Rothstein, dismissed the policy questions concerning the animal sufferance, human health and environment as to be addressed by Parliament, but adduced the need for harmonization to draw prescriptive policy conclusions: "The evidence is that the oncomouse has been patented in the United States and Europe. It is arguable on policy grounds that there is merit to uniformity and that Canada should follow suit".[681] He, therefore, resorted to the law lag argument. However, in this case the lag did not concern the relationship between science and the law, but the one between different patent systems and their case law.

He, then, drew on Justice Burger's arguments in *Chakrabarty*, purporting that the definition of invention should be given *wide scope*, as inventions are "necessarily unanticipated and unforeseeable".[682] The inevitable conclusion was that the *Oncomouse* was a "composition of matter":

> "The process here involves injecting a plasmid containing the oncogene into a fertilized mouse egg. The oncogene is comprised of DNA. Kreuzer and Massey define DNA as: 'the chemical molecule that is the basic genetic material found in all cells (…) DNA belongs to a class of biological molecules called nucleic acids'.

[679] ibid 113.
[680] Federal Court of Appeal of Canada, *President and Fellows of Harvard College v. Commissioner of Patents*, 3 August 2000, (2000) 7 C.P.R. (4th) 1, 12.
[681] ibid 14.
[682] ibid 16.

> DNA is a physical substance and is therefore matter. The fertilized mouse egg is a form of biological matter. The combination of these two forms of matter by the process described in the specifications is thus a 'composition of matter'".[683]

After defining the *Oncomouse* as a "composition of matter", he pinpointed that this locution did not imply the exclusion of living organisms.[684] Nevertheless, the subsumption of a living organism under the concept of "composition of matter" rested on endorsing a reductionist scientific view of what a biological organism is, namely *chemical molecules*. In that respect, the definition of biotech patent eligible matter resulted from a process of co-production between science and law, in which the conflation of methodological and ontological scientific reductionism was implicitly incorporated in the patent legal discourse and supported a re-definition and re-framing of the scope of "composition of matter".

However, the majority recalled that, like in *Chakrabarty*, this conclusion did not entail that there were no limits to patentability. Natural phenomena, scientific principles and abstract theorems were excluded from the scope of invention, as in Canada subsection 27(8) of the Patent Act [685] formally ruled out scientific principles and abstract theorems from patentability.[686]

Judge Rothstein argued that, although the laws of nature were involved in the gestation process, the insertion of the oncogene into the mammal substantially marked the resulting transgenic mammals as a product of inventive ingenuity.[687]

Inasmuch the majority consistently relied on the majority's judgement in *Chakrabarty*, it needed to justify the peculiar reliance on a piece of case law of another jurisdiction, even though influential in the U.S. for its impact on the patentability of biotech products. The majority acknowledged that the origins of Canadian patent law rested in the common law of England and the royal prerogative of granting monopolies. Therefore, the law of the U.K. was referred to as authoritative in interpreting Canadian patent law.[688]

Nonetheless, it justified the reliance on the high *similarity* of the definition of invention in the two jurisdictions: as the first Canadian Patent Act, enacted in 1869, was shaped according to U.S. patent statutes of 1836, the likeness of provisions legitimized the similarity in their

[683] ibid 17.
[684] ibid 18.
[685] Subsection 27(8) Patent Act R.S.C. 1985 c. P-4, 35, states: "No patent shell be granted for any mere scientific principle or abstract theorem".
[686] *President and Fellows of Harvard College* (n 680) 18.
[687] ibid 19-20.
[688] ibid 22.

interpretation by courts in different jurisdictions.[689] The majority noted that, although U.S decisions do not operate as *stare decisis* or constitute an estoppel in Canada, Fox pointed out that they ought to be considered with respect.[690]

Since the U.S. opinion was persuasive, Justice Rothstein believed its rationale ought to be employed in defining the boundaries of the scope of invention in Canada. In explaining why he preferred the majority's opinion in *Chakrabarty* rather than the minority's arguments, he pointed out that he could not share that there was a "common understanding" that the patent legislation did not cover living organisms.[691] Consequently, he relied on Justice Burger's interpretation of what was common understanding in the U.S. and considered it applicable in Canada, notwithstanding a constant opposite patent examination practice. However, the majority championed an approach that will be embraced by courts in several jurisdictions deciding on biotech patent cases, namely to use the arguments' rationale of landmark patent adjudications in other jurisdictions, even though they could not be considered as precedents.

The majority, finally, addressed the issues of control over the claimed invention and its degree of reproducibility. It noted that a reference to a control test was made in the CIPO's Manual of Patent Office Practice, which set forth that: "In assessing whether subject matter falls within the meaning of the definition of patentable subject matter under Section 2 of the Patent Act, the prerequisites established by Canadian jurisprudence and legislation that must be satisfied are inter alia: (b) whether the subject matter is operable, controllable and reproducible by the means described by the inventor so that the desired result inevitably follows whenever it is worked".[692]

Justice Rothstein clarified that the wording of this guideline was modelled on the Patent Appeal Board's decision in *Organon*, in which the Board deemed the test implicit in the requirement of usefulness.[693] As the claimed invention has been judged *useful*, it was deemed to pass the control test.[694]

Moreover, as he pinpointed that the invention was sufficiently disclosed by the applicant, reproducibility did not constitute a major problem affecting the patentability of the challenged claims.[695]

[689] ibid 23.
[690] ibid.
[691] ibid 25.
[692] ibid 26.
[693] ibid 26-27.
[694] ibid 27.
[695] ibid 30.

Judge Isaac, who dissented, mainly based his opinion on the *reasonableness* of the Commissioner's conclusion and the *deference* that courts ought to pay to the technical expertise of patent examiners in assessing and deciding on the patentability of inventions. He cited salient case law pinpointing that examiners "are persons with technical expertise" and concluded that the Commissioner was "an expert tribunal".[696]

Examining the second question, the Judge noted that the *complexity* of life forms made the distinction between the laws of nature and human intervention difficult to draw.

He addressed a basic problem in applying the chemical metaphor and the analogies it implies to complex life forms. His argument was centered on the *complexity* of organic processes, which could hardly be curtailed under the aegis of forms of reductionism.

He, consequently, concluded that the issues of the patentability of "higher life forms" should be addressed by the legislature, since the *Oncomouse* did not meet the standard of reproducibility *en masse* established in *Abitibi*.

As this section has illustrated, the majority of the FCA has endorsed the metaphor of the *chemical molecule* to define both the oncogene, as DNA sequences, and the transgenic mammal and subsumed them under the locution "composition of matter", concluding they were patentable. Moreover, it relied on the narrative of progress set out in *Chakrabarty* in order to justify a broad interpretation of the concept of "invention" in Canada.

3.3.2 Setting Boundaries on Life: the Supreme Court of Canada's Judgement

The metaphor of the chemical molecule was, afterwards, rejected by Supreme Court of Canada ("SCC") as adequate to characterize transgenic organisms.

In December 2002, the SCC finally judged in *Commissioner of Patents v. President and Fellows of Harvard College* and, in a 5 to 4 decision, held that "a higher life form is not patentable because it is not a 'manufacture' or 'composition of matter' within the meaning of 'invention' in s 2 of the Patent Act".[697]

Whereas the majority rejected the recourse to the metaphor of the chemical molecule to characterize a living organism, the minority conversely maintained it as the appropriate way to qualify both microorganisms and organisms.

[696] ibid 55.

[697] Supreme Court of Canada, *Commissioner of Patents v. President and Fellows of Harvard College*, 5 December 2002, (2002) 4 R.C.S. 425, 426.

In order to sustain a broad interpretation of patent eligible matter, the dissenting opinion, delivered by *Justice Binnie*, recounted a narrative focused on Canadian public interest in biotechnology.

The minority, first, pointed out that the discovery of the structure of DNA in the 1950s fostered the biotech revolution, which attracted large private investments. These investments boosted innovation in the field.[698]

It, then, highlighted that issuing patents "reflects the public interest in promoting the disclosure of advancement in learning by rewarding human ingenuity"[699] and expressed awe towards "the extraordinary scientific achievement of altering every single cell in the body of an animal which does not in this altered form exist in nature".[700]

Justice Binnie unfolded the narrative of the law lag, illustrated previously. According to it, Canadian patent case law could not stand behind the new technoscientific inventions, in the context of the global governance of intellectual property.[701] The law lag that he envisaged did not affect only the relations between patent law and technoscience, but also involved Canadian patent case law in respect to other jurisdictions.

He pointed out that, in many of states, the *Oncomouse*[702] or similar transgenic mice[703] were already held patentable and questioned why Canada had to stand apart from other patent jurisdictions. Since its statutory definition of invention was not unique, but like the U.S. one, he suggested that this gap should not exist.

He acknowledged that, in 1869, when the post-Confederation Patent Act was enacted, Parliament did not consider GM "higher life forms" patentable.[704] He pointed out, nevertheless, that other technological products which were not envisaged at the time, such as genetically modified micro-organisms, became patentable later.[705]

Although he allowed that legal interpretation consists in "reading the words 'in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament'".[706] In contrast with the majority, he nevertheless deemed that the context and scheme of the Act supported an *expansive*

[698] ibid 427-428.
[699] ibid 429.
[700] ibid 430.
[701] ibid 428.
[702] Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxemburg, The Netherlands, Portugal, Spain, Sweden, the U.K., the U.S. Ibid.
[703] In Japan was granted a similar patent and in New Zealand a GM Mouse susceptible to HIV infection was patented. Ibid.
[704] *Commissioner of Patents* (n 697) 430.
[705] ibid.
[706] ibid 431.

interpretation of "composition of matter" and the intent of Parliament highlighted the *public interest* to foster new and useful inventions.[707]

The minority fully expanded the law lag argument by illustrating the global dimension of IP, the present and past efforts of its harmonization and the relevance of the biotech sector for the Canadian economy.[708]

Moreover, it illustrated that "even university research" had to be paid for, as the case at issue prompted, and IPRs largely contributed to cover its cost.[709]

The opinion, subsequently, addressed the patenting of life forms in Canada and other jurisdictions.

It noted that microorganisms had been held patentable, in Canada, already in the 1940s and were, further, settled as patent eligible in *Abitibi*.[710] Furthermore, it highlighted that the case at issue regarded GM organisms, not plants and seeds resulting from hybridization and cross selection like in *Pioneer Hi-Bred*.[711]

Then, it relied on Justice Burger's narrative in *Chakrabarty*, as a proper way of filling the law lag gap that was likely to increase, judging otherwise.[712] He clarified that "composition of matter" was an "open-ended expression"[713] embedded in the Patent Act in order to contemplate the unforeseeable and the *Oncomouse* fell within its definition. Any other questions, the minority argued, did not regard the law, but "murine metaphysics"[714] and, therefore, did not have to be addressed by the court.

It is worth considering that Judge Binnie's opinion handled the lack of regulatory framework provided by the Patent Act reaffirming the law lag argument. He maintained that "regulation necessary follows, rather than precedes, the invention"[715] and "there are many areas of potential regulation as there are areas of invention",[716] concluding that "these regulatory regimes cannot and should not be put under the inadequate umbrella of the Patent Act".[717]

In addressing whether the claimed invention consisted in applying laws of nature to obtain a GM organism whose control was not principally under the inventor, he drew on the narrative of continuity of biotechnology illustrated in chapter two (section 2.3.1). According to it, the

[707] ibid.
[708] ibid 431-432.
[709] ibid 434-435.
[710] ibid 436-437.
[711] ibid 436-437.
[712] ibid 439.
[713] ibid 441.
[714] ibid 443.
[715] ibid 453.
[716] ibid.
[717] ibid.

laws of nature have always been involved in biotechnology, from the fermentation processes to pharmaceutical drugs, such as AZT, and its patented inventions.[718] He, therefore, did not deem that a solution of continuity had occurred between modern biotechnology, which was drawing on genetic engineering, and previous biotechnology. In his argument, GMOs were normalized as a kind of biotech product not very different from others, which had already been held patent eligible.

Since this narrative supported a broad interpretation of invention, all the ethical issues regarding animal sufferance, environmental risks, and policy concerns about patenting higher life forms were dismissed by drawing on an accurate *boundary work*, in which they were construed as completely outside the jurisdiction of the Courts. Justice Binnie pinpointed that if the commodification of animals and life, as well as the protection of the environment, were major concerns against the patentability of higher life forms, "the genie was already out of the bottle",[719] patents or no patents, thus he dodged the responsibility of the court in terms of closing or leaving it open.

The opinion of the *majority*, delivered by *Justice Bastarache*, pinpointed that the sole question before the court was "whether the words 'manufacture' or 'composition of matter', within the context of the *Patent Act*",[720] were "sufficiently broad to include higher life forms such as 'inventions'".[721] By analyzing the meaning of the terms of the Act, he rejected Judge Rothstein's interpretation grounded on the majority's opinion in *Chakrabarty*. He drew on the following definitions of the relevant terms:[722]

"Manufacture"

1. "[T]he action or process of making by hand … The action or process of making articles or material (in modern use, on large scale) by the application of physical labour or mechanical power (*Oxford English Dictionary*, 2nd ed. 1989, vol. IX, 341)".
2. "Fabrication": "[TRANSLATION] Act or action of manufacturing … The manufacture of technical object (by someone). Manufacturing by artisans, by hand, by machine, industrially, by mass production … (*Le Grand Robert de la langue française*, 2nd ed, 2001, vol.3, 517)".
3. "The production of articles for use from raw or prepared materials by giving to these materials new forms, qualities., properties, or combinations, whether by hand labor or by machinery (*Diamond v. Chakrabarty*, 16 June 1980, 447 U.S. 303, 308)".

"Composition of Matter"

1.1 "Composition": "[a] substance or preparation formed by combination or mixture of various ingredients (*Oxford English Dictionary*, 2nd ed. 1989, vol. III, 625)".

1.2 "Composition": "[TRANSLATION] action or manner of forming a whole, a set by assembling several parts, several elements (*Le Grand Robert de la langue française*, 2nd ed, 2001, vol.2, 367)".

2.1 "Matter": "[p]hysical or corporeal substance in general ... contradistinguished from immaterial or incorporeal substance (spirit, soul, mind), and from qualities, actions, or conditions (*Oxford English Dictionary*, 2nd ed. 1989, vol. IX, 480)".

2.2 "Matière": "[TRANSLATION] corporeal substance 'that is perceptible in space and has mechanical mass (*Le Grand Robert de la langue française*, 2nd ed, 2001, vol. 4, 1260)".

In contrast with the minority, he argued in favour of a narrow, *grammatical* interpretation of the terms, since the definitions of the relevant categories of patentable inventions fell short in being applied to "higher life organisms", which were "generally regarded as possessing qualities and characteristics that transcend the particular genetic material of which they are composed".[723]

Although the majority acknowledged that the definition of invention in s 2 was broad enough to encompass unforeseen and unanticipated technologies, it deemed that the definition was not unlimited, such as "to include anything under the sun that is made by man", as in the U.S. As to the word "manufacture", they relied on the Oxford English Dictionary definition. They disagreed on the fact that a mouse could be deemed *like* a man-made "article", "material" and "object technique" and pinpointed that the word would be commonly understood to denote *a non-living mechanistic product or process*.

The majority, therefore, censured the scientific reductionism that the minority, drawing on *Chakrabarty*'s arguments, embraced, which allowed the subsumption of complex life forms under the locution "composition of matter".

Since Parliament did not include in the definition of invention categories that could be applied to life forms, the majority inferred that these kinds of products was intended not to be covered by patent law. Judging otherwise would have entailed "a radical departure from a traditional patent regime".[724]

The majority clarified that it was easier to conceptualize and analogize a microorganism to a chemical compound or another inanimate object rather than do it with a plant or an animal.[725]

The justices recalled the definition of composition of matter of the *Oxford English Dictionary* and *Le Grand Robert de la langue française*. They would consider the fertilized egg, in which the oncogene was injected, as a composition, but they would not admit the *Oncomouse* to be understood in such terms. They, in particular, remarked that the meaning of "matter" expressed one aspect of life forms, as "matter is a physical or corporeal substance in general (…), contradistinguished from immaterial or incorporeal substance (spirit, soul, mind), and from qualities, actions, or conditions"[726] or "corporeal substance 'that is perceptible in space and has mechanical mass'".[727] They argued that these definitions do not fit well with the common understandings of human and animal life, which are regarded as having qualities

[723] ibid 481.
[724] ibid 482.
[725] ibid 497.
[726] ibid 480.
[727] ibid.

and characteristics that transcend the particular genetic material of which they are composed.[728] In particular, they observed that *reproduction* is one of the specific features which mark living organisms.[729]

Moreover, the problem of tracing the boundaries between higher and lower life forms was deemed fundamental: "there is no defensible basis within the definition of invention itself to conclude that a chimpanzee is a composition of matter while a human being is not".[730] Such a relevant issue was considered a matter to be addressed by Parliament, not by the courts.

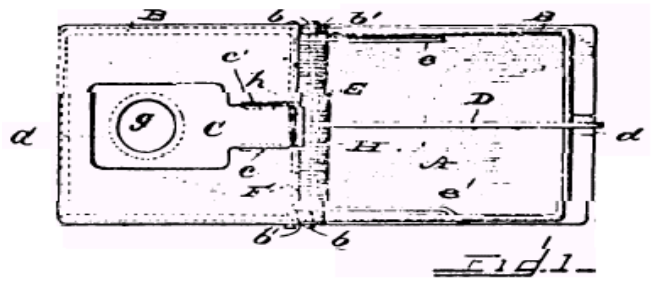
The Supreme Court of Canada, therefore, drew a line between GM microorganisms, which were judged patent eligible, and transgenic organisms, which were deemed to fall outside the definition of "invention".

In this respect, it should be noted that the definition of "patentable invention" in the U.S. and Canada embeds a mechanistic model of invention,[731] which has marked the way in which the concept of patentable subject matter has been developed.

Tallacchini illustrated accurately how this model impinged on deciding on the patentability of transgenic organisms. She commented the following illustration[732] included in the U.S. Office of Technology Assessment's Report entitled "New Development in Biotechnology: Patenting Life":

[728] ibid 481.
[729] Supreme Court of Canada, *Commissioner of Patents v. President and Fellows of Harvard College*, 5 December 2002, (2002) 4 R.C.S. 45, 133.
[730] ibid 487.
[731] See Finn Makela, 'Metaphors and Models in Legal Theory' (2011) 52(3-4) Les Cahiers de Droit 397.
[732] U.S. Congress, Office of Technology Assessment, *New Developments in Biotechnology: Patenting Life-Special Report, O*TA-BA-370 (Washington, DC: U.S. Government Printing Office, April 1989) iii, 19.

Figure 1-2-Figures, Mousetrap and Mouse Patents



Above--Two figures were submitted for U.S. Patent No. 661,068, the mousetrap, which was issued in 1900. The invention is "a trap of simple construction which can be manufactured inexpensively" in which "the bait cannot be removed without releasing the engaging jaw."

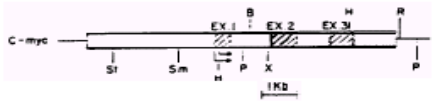


FIG 1

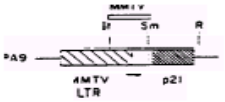


FIG 2

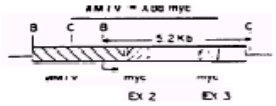


FIG 3

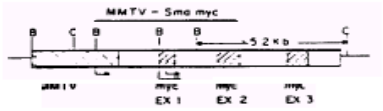


FIG 4

FIG 5

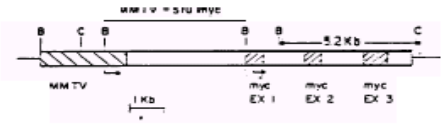


FIG 6

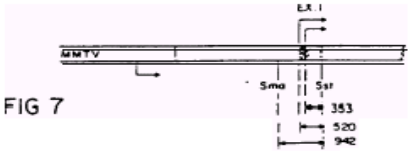


FIG 7

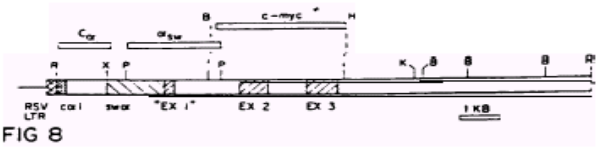


FIG 8

Right column—Eight figures were submitted for U.S. Patent No. 4,736,866, "Transgenic Non-Human Mammals," which was issued in 1988. The invention "features a transgenic non-human eukaryotic animal (preferably a rodent such as a mouse) whose germ, cells and somatic cells contain an activated oncogene sequence introduced into the animal, or an ancestor of the animal, at an embryonic stage." The eight figures represent plasmids, activated oncogene fusions, and a probe.

SOURCE Office of Technology Assessment, 1989; adapted from U.S. Patents 661,068 (1900) and 4,736,866 (1988)

The OTA pulled together the two patent figures of the mousetrap (on the left side), which was patented in 1900 in the U.S., and the eight ones that were part of the *Oncomouse* patent (on the right side). She pointed out that this illustration offers several insights about how the discourse of patent eligibility relied on metaphors and their rhetorical-persuasive power: both sets of drawings show the deterministic features of mechanical products and suggest that the

"nature" of the two inventions is the same.[733] Nevertheless, she pinpointed, "the insertion of genetic material is not brought about in such a precise way that the illustrations suggest"[734] and "its effects are not limited to one genomic sequence, but potentially impinge on the whole phenotype".[735]

The OTA's Report used this illustration to address the *sui generis* administrative issues related to biotech inventions, whose literal description proved to be inadequate to enable a person skilled in the art to reproduce them.[736]

This juxtaposition, however, clarifies how the homologation between non-living and living matter has occurred in the United States, namely by fully applying the mechanistic model of life embedded in the definition of patentable invention to microorganisms and organisms. Also in Canada the model embedded in the definition of invention impinged on accommodating microorganisms within the scope of it. However, the assimilation of organisms failed, because the majority of the Supreme Court's decision hinged on the *relevant differences* that made transgenic mammals not *like* a machine or a chemical compound. Therefore, although the statutory definition of patentable subject matter in these two countries is alike, the case law shows that the courts embraced partially *different epistemic legal models* of complex living organisms.[737]

3.4 Patenting Micro-Organisms before the EPO

Whereas in the U.S. the patentability of micro-organisms has been questioned before SCOTUS in *Chakrabarty*, the European Patent Office ("EPO") had not faced major challenges related to this issue, in the same years. Whilst in the U.S. the *Chakrabarty* judgment attracted public attention, in 1976 the British Patent Office had already granted the corresponding British patent, but the fact went unnoticed.[738] This shows, however, how much the patentability of microorganisms, as such, was not a controversial matter for legal scholars, NGOs and citizens at the time.

[733] Tallacchini (n 31) 164-165; Tallacchini (n 596) 8.
[734] Tallacchini (n 596) 8. Translation mine.
[735] ibid.Translation mine.
[736] U.S.OTA (n 640), 19.
[737]Tallacchini (n 31) 166.
[738] UK Patent No. 1,436,573, published on 19 June 1976. See Graham Dutfield, 'Claiming Life: are Organisms Inherently Unpatentable' in Catherine Ng, Lionel Bently and Giuseppina D'Agostino (eds), *The Common Law of Intellectual Property: Essays in Honour of Professor David Vaver* (Hart Publishing 2010) 161, 162.

The European Patent Convention ("EPC"), which is a multinational treaty in operation since 1978,[739] lacks any explicit rule allowing the patentability of microorganisms as such, as Art. 53(b) and Rule 31 EPC do not refer to microorganisms as such.[740] Rule 26(3) EPC defines "biological material" as "any material containing genetic information and capable of reproducing itself or being reproduced in a biological system". Microorganisms are encompassed in the definition.

The term "microorganism", according to EPO Guidelines, G-II, 5.5.1, "includes bacteria and other generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory, including plasmids and viruses and unicellular fungi (including yeasts), algae, protozoa and, moreover, human, animal and plant cells.[741]

Article 53(b) EPC sets out the patentability exception of plants or animal varieties or essentially biological processes for the production of plants or animals, but it clarifies that the provision "shall not apply to microbiological processes or the products thereof". Therefore, if a product resulting from a microbiological process other than a plant or animal variety is a microorganism, it may be patentable.[742]

Moreover, Art. 52(2) EPC sets out subject matter and activities which shall not be regarded as inventions within the meaning of paragraph 1, and includes "(a) discoveries, scientific theories and mathematical methods".

However, the patentability of micro-organisms as *discoveries* has never been at the core of a major judicial challenge and European social debate, in 1970s and 1980s.

At present, Section G-II, 3.1 of the Guidelines, specifies the threshold of patentability for micro-organisms, which is characterized as the "production of a technical effect".[743]

Although the EPC does not provide a definition of what "invention" is, the standard established in Section G-II, 3.1 of the Guidelines is consistent with the technical nature of the invention. As Huys, Van Overwalle and Matthijs pointed out the implementing regulations

[739] Sigrid Sterckx and Julian Cockbain, *Exclusions from Patentability. How Far Has the European Patent Office Eroded Boundaries?* (Cambridge University Press 2012) vii, 17.

[740] Franz-Josef Zimmer, Steven M Zeman, Jens Hammer, Klara Goldbach, Bernard Allekotte, *Protecting and Enforcing Life Science Inventions in Europe* (C.H. Beck-Hart 2015) *Protecting and Enforcing Life Science Inventions in Europe* , 219-220.

[741] EPO Guidelines for Examination, G-II, 5.5.1. Zimmer, et al. (n 740) 219.

[742] EPO Guidelines for Examination, G-II, 5.5.1, clarifies that microorganisms may be obtained as products of a microbiological processes: "The product of a microbiological process may also be patentable per se (product claim). Propagation of the microorganisms itself is to be construed as microbiological process for the purposes of Art. 53(b). Consequently, the microorganism can be protected per se as is a product obtained by a microbiological process (see Guidelines at section G-II, 3.1)". EPO Guidelines for Examination, G-II, 5.5.1. Zimmer, et al. (n 740) 220.

[743] Section G-II, 3.1, EPO Guidelines for Examination.

clarify that "the invention must have technical features (Rule 43(1)), which is related to a technical field (Rule 42(1)(a)) and concerned with a technical problem (Rule 42(1)(c))".[744]

Under the EPC system, the "technical" character of the invention and the "production of a technical effect" as a threshold of patent eligibility have proved to be central for the settlement of the patent eligibility of genetically modified microorganisms and organisms.

Issues regarding the patent eligibility of microorganisms have been raised, in the 1990s, when the NGO Greenpeace opposed European Patent No. 0 242 235, granted to Plant Genetic Systems on 10 October 1990, entitled "plant cells resistant to glutamine synthetase inhibitors, made by genetic engineering" (which made them resistant to herbicides inhibiting glutamine synthetase).

The patent, according to the specification, regarded a process "for producing plants and reproduction material of said plants including a heterologous material stably integrated therein",[745] but also "plant cells, reproduction material, particularly seeds, as well as plants containing a foreign or heterologous DNA fragment stably integrated in their respective genomic DNAs, said fragments being transferred throughout generations of such plant cells, reproduction material, seeds and plants".[746]

Greenpeace opposed the patent on several grounds and argued that the claims concerned non patentable subject matter under Art.53(a) and (b). In particular, Greenpeace maintained that the grant of a patent for plant life forms and its exploitation was contrary to morality and *ordre public*; that the claims related to plants and the processes for their production were not patentable under Art. 53(b) EPC and plant products from any generation beyond the first one did not constitute an invention under Art. 52 EPC.

The Technical Board of Appeal ("TBA") of the EPO decided, finally, on the case, T 356/93 Plant cells/Plant Genetic Systems, on 21 February 1995.

The TBA drew on a technical approach to the kind of claims involved, refraining from engaging in any discussion of the nature and risks of genetically engineered microorganisms and organisms. The Board relied on the narrative of naturalization and normalization of contemporary biotechnology which has been illustrated in chapter two: rDNA biotechnology should not be considered differently from the previous biotechnology, as it only entails a better control over the patented products.

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[744] Huys, Van Overwalle and Matthijs (n 26) 1104.

[745] Jan Leemans, Johan Botterman, Marc de Block, Charles Thomson and Rao Maoura, *Plant cells resistant to glutamine synthetase inhibitors, made by genetic* engineering, European Patent No. 242236, Munich: EPO, at 7, in Sigrid Sterckx and Julian Cockbain, *Exclusions from Patentability. How Far Has the European Patent Office Eroded Boundaries?* (Cambridge University Press 2012) vii, 201.

[746] ibid.

As far as claim 14 was concerned, which regarded plant cells (which fall within the definition of microorganisms), Greenpeace argued that the grant of a patent on plant cells contravened Article 53(a) and (b).

The Board pointed out that "plant cells were considered to be microbiological products under the current practice of the EPO"[747] and addressed whether any of the claimed subject matter constituted an exception to patentability under Art. 53(a) and (b). Art. 53(a) EPC 1973 excluded from patentability "inventions the publication or exploitation of which would be contrary to 'ordre public' or morality, provided that the 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".

The Board clarified that there was no European definition of morality and *ordre public* and that the meaning of these concepts "must be defined by way of interpretation".[748]

Ordre public was considered to cover the protection of public security and the physical integrity of individuals as part of society, which also encompasses the environment. Therefore, the inventions whose exploitation is likely to breach public peace, social order, or seriously prejudice the environment can be considered contrary to *ordre public*. The TBA construed "morality" as "related to the belief that some behavior is right and acceptable, whereas other behavior is wrong"[749] on the basis of the "totality of accepted norms which are deeply rooted in a particular culture".[750]

It, then, affirmed that, according to the historical documentation relating to the EPC the concept of patentability must be as wide as possible, pinpointing that the exceptions to patentability should be narrowly construed.[751]

The Board maintained the opposed patent claims, as it deemed that no challenged claim included subject-matter contrary to the clause, [752] as Greenpeace failed to prove a sufficiently substantiated threat to the environment linked to the invention and its contrariety to morality, as no misuse or destructive use of the invention could be devised "in light of the conventionally accepted standards of conduct of European culture".[753] Moreover, the Board

[747] Technical Board of Appeal of the European Patent Office, Decision of 21 February 1995, T 356/93 Plant cells/Plant Genetic Systems, 13.
[748] ibid 15.
[749] ibid 16.
[750] ibid.
[751] ibid 17.
[752] Zimmer, et al. (n 740) 221.
[753] T 356/93 (n 747) 24.

affirmed that the processes involved were not essentially biological, but technical, and microbiological and, thus, did not fall within the patent exceptions set out in Art. 53(b).[754]

The case was finally remitted to the Opposition Division, which maintained it in an amended form in 1996.[755] However, the claims to transgenic seeds and plants had already been deleted, following the decision of the Opposition Division in 1993 and the TBA affirmed its decision.

It has been illustrated that patents became "socially sensitive" institutions in Europe in the 1990s, when growing awareness of NGOs and groups about the social impact and effects of IPRs emerged and, in the process of political integration towards the future European Union, ethics was increasingly considered and devised as a relevant means to build the European identity.[756]

As Tallacchini explained, the institutionalization of ethics in the European Community began when "the European Commission decided to incorporate ethics into the decision-making process for Community research and technological development policies by setting up the Group of Advisers on Ethical Implications of Biotechnology (GAEIB)",[757] in November 1991. This incorporation concerned, first, biotechnology and, then, from 1997, when the GAEIB was replaced by the European Group on Ethics on Science and New Technologies (EGE), all the areas of science and technology, as the Group's mandate was extended to cover all areas of application of science and technology.[758] This integration, Tallacchini noticed, was deemed as a fundamental political factor in the transition from Rome Treaties to the Unique Market, up until the Maastricht Treaty.[759] However, this process of integration turned to be particularly difficult and the efforts of constructing a European ethical shared view went amiss also within the EPC system as no settled vision emerged from patent case law, as chapter six will show.

3.5. Patenting GM Organisms in Europe: The *Onco-mouse* Case I and II

This section will illustrate that, in Europe, the Boards did not draw on metaphorical expressions in order to decide on the patent eligibility of "transgenic non-human mammals" in the so-called "Onco-mouse" case, but had for the first time to engage in addressing

[754] ibid 34-42.
[755] Sterckx and Cockbain (n 739) 261.
[756] ibid 255-261.
[757] Commission Decision of 11 May 2005 on the renewal of the mandate of the European Group on Ethics in Science and New Technologies, 2005/383/EC, OJ L 127, at 17; Mariachiara Tallacchini, 'I saperi specialistici tra *science advice* e *soft law*: *technology assessment* e *expertise* etica', in Stefano Rodotà and Mariachiara Tallacchini (eds) *Trattato di biodiritto. Ambito e fonti del biodiritto* (GiuffrèEditore 2010) 861, 875-876.
[758] ibid.
[759] Tallacchini (n 757) 876.

thoroughly the meaning of the term "animal variety" under Article 53(b) EPC. However, as this section and the next will point out, the Boards resorted to analogies between microorganisms and organisms in order to assess the *sufficiency of disclosure* of the claimed invention.

Moreover, this case proved to be the test bench of the morality clause embedded in Article 53(a) EPC. As several IP scholars pointed out,[760] for more than a decade, after the entering into force of the EPC, Article 53 EPC had not been drawn upon in order to oppose biotech patent claims and challenge biotechnological products and processes. Nevertheless, the EPO had for the first time to face the moral dimension of IPRs by examining the patent eligibility of a biotech transgenic organism.

On 24 June 1985 President and Fellows of Harvard College filed European Patent application No. 85 304 490.7 and the EPO Examining division raised two objections to the application: 1. That the patent claimed animals *per se*, which had to be considered not patentable as covered by the exceptions to patentability under Article 53(b) EPC; that the application was objectionable under Article 83 EPC, as it unduly extrapolated "to 'transgenic non-human eukaryotic animals' from what has actually been carried out, namely transgenic mice".[761] The application was rejected, because of the issues related to claims 1, 17 and 18.[762]

The applicant, President and Fellows of Harvard College, argued that the claims *were not directed to an animal variety* and the claimed process was *not essentially biological*. Consequently, claims 17 and 18 had to be deemed patent eligible.

Article 53(b) EPC sets forth a specific exception to patentability, which concerns "plant or animal varieties or essentially biological processes for the production of plants or animals",[763] even though the provision is not to be applied to microbiological processes or the products thereof.

The Examining Division's decision relied on an historical narrative, which focused on the interpretation of the purpose of the provision. It argued that the wording of the article was taken unchanged from Article 2(b) of the Strasbourg Patent Convention devised in 1962, when the issue of patenting transgenic animals was "scarcely conceivable",[764] and deemed

[760] Peter Drahos, 'Biotechnology Patents, Markets and Morality' (1999) 21(9) European Intellectual Property Review 441, 444; Sterckx and Cockbain (n 739) vii.
[761] Decision of the Examining Division dated 14 July 1989, Onco-mouse/HARVARD, (1989) 11 OJ EPO 451.
[762] ibid 452.
[763] Article 53(b) EPC 1973.
[764] ibid 454.

that the *purpose* of the exclusion of animal varieties from the scope of patentable inventions was that they were not "an appropriate subject-matter for patent protection".[765]

Furthermore, it pointed out that whilst in the provision, with regard to plants, the legislator used identical designations in all the three official languages, with respect to animals different taxonomic terms had been employed: the German version "Tierarten" diverged from the English one, "animal varieties", as well as the French one, "races animales".[766] According to the Division, these differences suggested that the intention of the legislator was not to exclude some specific groups of animals, but animals in general from patentability.[767]

Accordingly, it contended that the purpose of the provision implied that the EPO should reject claims directed not only to a specific variety, but to animals.[768]

The examiners dismissed the ethical issues under Article 53(a), pointing out that patent law was not "the right legislative tool for regulating"[769] these kinds of problems, especially as the invention might have beneficial effects for mankind. The Examining Division recalled that the Guidelines for Examination, in C-IV, 3.1, assisted in deciding on cases involving morality by clarifying that the purpose of Article 53(a) EPC was to exclude from patent protection inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour and referred to a letter-bomb as the typical example falling under the provision.[770]

The Examining Division, moreover, raised the question of *reproducibility* of the claimed invention. As far as sufficiency of disclosure under Article 83 EPC was concerned, it pinpointed that the claims regarded non-human mammalian animals and were not limited to mice or rodents. However, the specification did not offer any instruction on how to successfully obtain other transgenic non-human mammals. The examiners referred to one of the inventors' declaration (Philip Leder's statement) before the USPTO in order to support the non-obviousness of his invention, in which he professed how surprised he was to achieve positive results on mice, even though he was aware of several factors that could have made his efforts fail.[771] Relying on his statement, the Division deemed that the subject matter was not sufficiently disclosed.

[765] ibid.
[766] ibid 455.
[767] ibid.
[768] ibid.
[769] ibid 459.
[770] ibid.
[771] ibid 460.

On appeal against this decision, the TBA, in its decision T19/90 dated 3 October 1990,[772] overturned the arguments of the Examining Division.

The TBA argued that, although the claimed invention was broad, as it concerned "all non-human mammalian animals", it was sufficiently disclosed under Article 83 EPC. It acknowledged that non-human mammals other than mice have different immune systems and numbers of genes, but it did find that the claimed invention could be carried out also on these organisms by a person skilled in the art.[773] The TBA, furthermore, disagreed that the claims should be limited to rodents, instead of mammals, because grounded on the assumption that rodents are *alike* mice for the purpose of the invention.[774]

The TBA did not resort to metaphors in order to define the "nature" of the patent claims and the boundaries of patent eligible inventions, but it drew on the analogy between different kinds of organisms and microorganisms to assess the sufficient disclosure of the patent claims. The Board endorsed the appellant's reference[775] to case T292/85 Polypeptide expression/GENENTECH I, which involved a recombinant plasmid and bacterium and its polypeptide expression.[776] A patent on the claimed invention was, firstly, rejected by the Examining Division as not sufficiently disclosed. The claim over bacteria was deemed so broad that could encompass unsuitable species or variants, but the TBA considered the "unsuitability of unspecified variants of a functionally defined component feature of the invention"[777] as *immaterial* to sufficiency, "as long as there are suitable variants known to the skilled person through the disclosure or common general knowledge which provides the same effect for the invention".[778] It ruled, therefore, that a biological invention was sufficiently disclosed if "it clearly indicated at least one way in which the skilled person could carry it out".[779]

The TBA agreed on the relevance of T292/85 to determine the sufficiency of disclosure on the *Onco-mouse* case and pointed out that: "the invention clearly indicates now the skilled person can achieve chromosomal incorporation of an activated oncogene sequence into the genome of a non-human mammal disclosing as it does an activated mouse myc gene

[772] Decision of Technical Board of Appeal 3.3.2 dated 3 October 1990, T19/90 Onco-mouse/HARVARD, (1990) 12 OJ EPO 476.
[773] ibid 484.
[774] ibid.
[775] ibid 485.
[776] Decision of the Technical Board of Appeal 3.3.2, dated 27 January 1988, T292/85 Polypeptide expression/GENENTECH I.
[777] T19/90 (n 772) 485.
[778] ibid.
[779] ibid.

introduced into a suitable plasmid and then micro-injected into mouse eggs at a given stage of cellular development". [780] According to the TBA this ensured that the invention was reproducible in mice and, therefore, it might be posited that the invention could likewise be performed in suitable mammals. By drawing this conclusion, the TBA has implicitly established that the claimed invention fulfilled an adequate standard of reproducibility, but, as the Courts' decisions on the *Oncomouse* case in Canada showed, the reproducibility turned out to be one of the main issues raised against its patent eligibility.

This decision points out that the *sufficiency of disclosure* sets out a standard of reproducibility, which is largely based on assumptions of control, precision and efficiency about the kind of technology related to the claimed invention. In this case, as the claimed "transgenic non-human mammals" resulted from recombinant DNA technology, metaphorically named "genetic engineering", and this *kind* of technology was assumed to guarantee precision in their reproducibility, the claimed invention was considered sufficiently disclosed.

The TBA reversed also the Division's interpretation of the terms embedded in Article 53(b) EPC as excluding the patentability of animals as such. It admitted that the meaning of the German term "Tierarten" was broader than the English and French locutions, however, it observed that patent exceptions should be narrowly construed and found that the Examining Division broad construction was not sufficiently supported.[781]

The Board offered, therefore, a historical counter-narrative of the origins of Article 53(b), excluding, first, that the reference to specific categories of animals resulted from a mistake in drafting the exception.[782] Accordingly, the TBA regarded the language of the article as not covering animals as such, pointing to the preparatory documents were completely silent on the purpose of this patent exclusion and, hence, ruling out the centrality of the historical interpretation.[783]

It, then, backed an evolutionary interpretation of its meaning focused on the presumed intention "in the light of the changes in circumstances which have taken place since"[784] when the law was adopted. In construing thus the *ratio legis*, the Board was aware of acting as a *gatekeeper* in making a balance involving the role of the patent system on the face of the interests of inventors and society: "It is now the task of the European Patent Office to find a solution to the problem of the interpretation of Article 53(b) EPC with regard to the concept

[780] ibid 485.
[781] ibid 486.
[782] ibid 487.
[783] ibid.
[784] ibid 487.

of 'animal varieties', providing a proper balance between the interest of inventors in this field in obtaining reasonable protection for their efforts and society's interest in excluding certain categories of animals from patent protection.[785]

The TBA significantly devised a particular approach to address whether a claimed invention fell within the moral exception to patentability set forth in Article 53(a). In contrast with the Examining Division, which dismissed the moral questions as part of examining process of the claimed invention, the TBA took on the responsibility of the EPO and the Boards in dealing with ethical problems arising from patent claims. It pointed out that the genetic modification of animals was problematic, since the insertion of activated oncogenes made the animal prone to develop tumors and created a suffering animal model for research.[786] In addition, it involved environmental issues: there was a danger that the animal released by mistake in the environment could cause "irreversible adverse effects".[787] It, therefore, set out a moral utilitarian approach[788] to these issues based on *weighing the risks and benefits* involved: "The decision as to whether or not Article 53(a) EPC is a bar to patenting the present invention would seem to depend mainly on a careful weighing up of the suffering of animals and possible risks to the environment on the one hand, and the invention's usefulness to mankind on the other".[789] The TBA, therefore, deemed that the usefulness of the transgenic animals as models for cancer research outweighed the animal sufferance and the potential risks to the environment.[790] This weighing up approach, which is consequentialist, as it considers the risks and benefits that can follow from granting IPRs on an invention, would become in the following years the dominant way to handle and solve the Gordian knot of patent exclusions on morality grounds embedded in the EPC.

The case was finally remitted to the Examining Division for further prosecution. The patent was, then, granted on 15 May 1992,[791] but between 18 December 1992 and 13 February 1993 seventeen oppositions were lodged against the patent[792] and opened up a wider European debate over the patentability of animals.

In 1990, the decision of the TBA in the *Onco-mouse* case widened the scope of patent eligibility, under the EPC, to accommodate transgenic animals, as it narrowed the patent

[785] ibid 487.
[786] Ibid 490.
[787] ibid.
[788] Lionel Bently and Brad Sherman, 'The Question of Patenting Life' in Lionel Bently and Spyros M Maniatis (eds), *Intellectual Property and Ethics* (Sweet & Maxwell 1998) 111, 113.
[789] T19/90 (n 772) 490.
[790] Bently and Sherman (n 788) 113.
[791] European Patent No. 0 169 672B1 Method for producing transgenic animals.
[792] Decision of Technical Board of Appeal 3.3.8 dated 6 July 2004, T 315/03 – 3.3.08, (2006) OJ EPO 15, 21.

exception under article 53(b) EPC. Moreover, it devised the morality test to be applied when a claimed invention might fall within the patent exceptions of Article 53 EPC. Still, this settlement proved to be uncertain, as NGOs and civil society have grown aware of the political and ethical relevance of IPRs on biotech inventions and become more willing to oppose patents.

After the grant of the patent in 1992, 17 oppositions were filed against it. The opponents included several NGOs which requested the revocation of the patent on several grounds, but mainly under Articles 53(a) and 53(b) EPC.[793]

On 7 November 2001, the Opposition Division decided on the case[794] and focused most of its analysis on whether the invention fell within the exceptions to patentability under Article 53(a) and (b) EPC.

The Division judged Rules 23(b) to 23(e) EPC applicable and addressed whether animals should be considered patentable under Article 53(b) EPC. It relied on Rule 23(c)(b) EPC, which referred to the same issue, and applied it as "a supplementary means of interpretation".[795]

It agreed with the TBA that exceptions to patentability should be construed narrowly and that the use of both terms "animals" and "animal varieties" in the same half-sentence of Article 53(b) EPC unequivocally suggested that the locution "animal varieties" was not drafted in order to cover animals.[796] However, the Division deemed that case G 1/98 Transgenic plant/Novartis II case (that will be analysed in chapter five), which concerned the patent eligibility of transgenic plants and seeds under Article 53(b) EPC, could be applied to animal varieties.[797]

The Examining Division's arguments rested on an analogy between the conclusions drawn in that case and the *Onco-mouse* case, as the first patent case concerning the patentability of animals. The Division admitted that T 356/93 drew different conclusions on the patentability of plant varieties, but it did not offer any reasons for the preference accorded to G 1/98, whose holding was applied to handle the exclusion of animal varieties.[798]

[793] Decision of the Opposition Division dated 7 November 2001, Onco-mouse/HARVARD, (2003) 10 OJ EPO 473, 474-487.
[794] ibid 473.
[795] ibid 498.
[796] ibid.
[797] ibid.
[798] ibid 499.

In G 1/98, the EBA argued that the purpose of the exclusion of plant varieties was to avoid a dual protection for plant varieties, according to the ban set forth in the UPOV Convention[799] and endorsed "the higher taxonomic level approach"[800] for transgenic plants that supported their patent eligibility.[801]

However, the Division had to fill up the gap concerning the rationale for animal exclusion, positing that in the absence of any form of IP protection for animal varieties, at the time, as products of animal breeding, the "most obvious reason for this must have been the intention or at least the keeping open of the possibility to create such a law for the protection of animal varieties later on".[802]

It, therefore, concluded that Article 53(b) did not establish any bar to the patentability of the subject-matter claimed in the patent.

As to the exclusion under Article 53(a) EPC, the Opposition Division observed that Rule 23(d)(d) dealt precisely with this invention, since it clarified that "(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes" shall not be patented.

It maintained its intention not to endorse extreme positions in examining the meaning of Article 53(a) EPC. It, then, re-framed the balancing test set forth in T19/90, by substantiating the evidence of the European moral order.

It stated the test was superseded by the similar approach contained in Rule 23(d)(d).[803] According to the Opposition Division morality should be assessed primarily by considering the laws and regulations which are common to most of the European countries. As these provisions do exist, they rejected other kind of evidence as means of assessment, such as public opinion polls, which were adduced by the opponents. [804]

It, then, pinpointed that the relevant regulation on use of such animals for testing, namely Directive 86/609/EEC (no longer in force), the *Council Directive of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes*,

[799] The reference was to Article 2 of the UPOV Act 1978 (see chapter five). The UPOV (Union Internationale pour la Protection des Obtentions Végétales) Convention was agreed upon on 2 December 1961 and came into force on 10 August 1968 and has established a plant breeders' rights system. Mark D Janis, Herbert H Jervis and Richard Peet, *Intellectual Property Law of Plants* (Oxford University Press 2014) vii, 69.
[800] Sterckx and Cockbain (n 739) 241.
[801] Onco-mouse/HARVARD (n 793) 499.
[802] ibid.
[803] ibid 503.
[804] ibid.

implied that the exploitation of the invention was allowable in Europe and, therefore, not immoral.[805]

The two relevant criteria to be balanced were the suffering of the animal and the substantial medical benefit to man and animal.[806] However, the Division foresaw a problem that the TBA did not deal with, namely at which date the assessment must be made, since this approach is consequentialist.

According to the Division the assessment ought to be made at the effective date and it was linked to the probability element stated in Rule 23(d)(d), otherwise the element of probability would have been superfluous.[807] Suffering, the Division acknowledged, existed irrespectively of the date assessment, as the animals were prone to develop tumours.

Nevertheless, the substantial medical effect had to be assessed at the effective date of the patent and was centred on "whether at the effective date the inventor had bona fide reasons to believe that his invention would have a substantial medical benefit".[808] Since this was judged undisputed, there was no bar to the patentability of the animals.

Consequently, the Division allowed auxiliary request 4, directed to rodents, which included "representative animal species useful for allowable animal testing",[809] but rejected the main request directed to non-human mammalian animals, as only testing animals were considered to pass the morality test.[810]

On the 16 January 2003 the Opposition Division decided to maintain the patent in this amended form. However, the boundaries of the patent scope that were re-drawn by the Division did not satisfy the opponents, who argued against the patent eligibility of animal varieties and requested the patent be fully revoked.

The TBA had, therefore, to examine again the issues related to the patent eligibility of the invention and decided, finally, on 6 July 2004.[811]

The *Onco-mouse* case has proved to be the first European patent case in which the moral dimension of IPRs emerged as a pivotal issue for civil society, even though the opponents were not completely successful. In its aftermath, "the moral respectability"[812] of IPRs, as Drahos and Braithwaite called it, has been increasingly questioned and challenged by a

[805] ibid 502-503.
[806] ibid 503.
[807] ibid.
[808] ibid 504.
[809] ibid 505.
[810] ibid 504.
[811] Decision of Technical Board of Appeal 3.3.8 dated 6 July 2004, T 315/03 – 3.3.08, (2006) OJ EPO 15.
[812] Peter Drahos with John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (Earthscan 2002) vi, 16.

higher level of transnational activism,[813] which was a clear signal that intellectual property was becoming a legal area constantly under the scrutiny of NGOs, political groups and citizens, notwithstanding its highly technical character.

The TBA addressed the relationship between Article 53(a) and Rule 23(d)(d), making clear that the rule set out a non-exhaustive list of biotech inventions excluded from patentability.[814] Whereas Rule 23(d)(d) established a balancing test for assessing the patentability of processes for genetically modifying animals or animals produced by such processes, Article 53(a) involved a different kind of test. The first balancing test entailed weighing the suffering of animals against the medical benefit to animals and humans and was focused on the likelihood of the suffering, which triggered the application of the rule.[815]

Furthermore, it pinpointed that, although T19/90 set forth a balancing test very similar (as adapted to the one embedded in Rule 23(d)(d)), it differed for its reference to the "usefulness to mankind" and "possible risks to the environment".[816] In particular, it acknowledged that the locution "usefulness to mankind" could encompass a wider range of beneficial factors than the "substantial medical benefit". In order to apply the test under Rule 23(d)(d) the relevant point of time was deemed the effective date, namely the filing date or priority date of the patent or patent application which was challenged.[817] Moreover, it limited the evidence to the relevant matters: the likelihood of suffering, the likelihood of substantial medical benefit and the necessary correspondence between the two.[818]

As to the exclusions under Article 53(b) EPC, the TBA addressed fully the inconsistencies of languages in defining "animal varieties" and admitted that "a definition by reference to a taxonomical rank would be both consistent with the position in relation to plant varieties and in the interests of legal certainty".[819]

Nevertheless, it agreed that, notwithstanding these inconsistencies of the wording in the three languages, the same principle, upheld by the EBA in G1/98 Novartis II case concerning transgenic plants should be applied to cases involving animals, namely that in the absence of the identification of a specific plant variety in a product claim, the subject-matter of the

[813] ibid.
[814] T 315/03, 40.
[815] ibid.
[816] ibid 42.
[817] ibid 46.
[818] ibid 47.
[819] ibid 58.

claimed invention should not be considered as directed to a plant variety or variety within the meaning of Article 53(b) EPC.[820]

The TBA rejected, then, the respondent's main request, pertaining to "a transgenic rodent" and a method to produce it, since it deemed that there was no likelihood of substantial medical benefit to be derived from applying the claimed process to all rodents apart from mice and allowed, accordingly, the first auxiliary request, which was limited to mice.[821] All the other moral issues raised by the appellants were dismissed for lack of conclusive evidence: environmental risks, viable non-animal alternatives, degree of animal suffering, threat to evolution, increased use of transgenic mice.[822]

As Bently and Sherman pointed out, the Onco-mouse case highlighted that "while in many other situations patent law has been able to accommodate alien concepts within its own logic and procedures, in its encounter with the ethical, patent law is now confronted with a set of problems for which it manifestly lacks not only an appropriate conceptual, procedural, or institutional framework, but also a suitable language to deal with ethical questions".[823]

They refer to the difficulties that the Opposition Division and, later, the Boards encountered, because they could not "quantify the objections raised against the patent that the [morality] test required",[824] as they were "abstract in nature, based on *a priori* principles, and not readily reducible to a quantifiable form".[825] In this respect, they illustrated that patent law underwent a process of closure and objectification that has led to "marginalizing non-legal concerns".[826]

In particular, they explained that the invention was devised and handled as a "closed, secure and fixed entity" [827] and patent law was meant and applied positing that qualitative judgements on the invention could be averted.[828] This also accounts why patent law has been deemed by the EPO and IP professionals as a neutral, technical system, isolated from ethical and political issues.[829]

[820] ibid 60.
[821] ibid 63-66.
[822] ibid 68-77.
[823] Bently and Sherman (n 788) 116.
[824] ibid 114.
[825] ibid.
[826] ibid 122.
[827] ibid 117.
[828] ibid.
[829] ibid 111.

The troubles of opening up patent law to ethical concerns lie therefore, partially, in their potential destabilizing effects, as they have been viewed as undermining "those practices which depend upon the invention as a closed and stable entity".[830]

3.6 Not So Artless Metaphors: Conclusions

In the United States and Canada, judges, patent examiners and scientific experts largely relied on the conceptual metaphors of the *machine* and *chemical molecule* in order to decide whether GM microorganisms and organisms ought to be accommodated within the scope of "patentable subject matter" or "invention". As this chapter has explained, these metaphors were crucial to affirm the patent eligibility of these biotech products, as they entail reductionist analogies about the ontology and nature, which allowed patent examiners and judges to subsume microorganisms and organisms under the already settled categories of patentable inventions.

As chapter two (sections 2.2, 2.2.1 and 2.2.2) has highlighted, these metaphors have been epistemically and heuristically influential in orienting how organisms have been studied in Western philosophical and technoscientific tradition and could be considered the "root metaphors"[831] which, together with the genetic code, have offered a definition of life and human identity at the atomistic level. This chapter has explained how these metaphors have been relevant in the development of the scope of patent eligible matter offering a definition of the biotech nature of the invention which largely supported its expansion.

In all the three political contexts, molecular biology, genetics and biotechnology have been institutionally fostered and flourished. As anthropologists pointed out,[832] these fileds of research have influenced how individuals and collectivity interpret their identities: atoms, molecules and DNA sequences are considered the relevant units that determine what/who organisms are and their actual and possible future pathologies.

However, the analysis of case-law in these jurisdictions shows that these metaphors, together with other factors, have largely contributed to settle the meaning of patentable subject matter.

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[830] ibid 123.

[831] Michael Ruse, *Science and Spirituality: Making Room for the Faith in the Age of Science* (Cambridge University Press 2014) vii, 24.

[832] Margaret Lock and Judith Farquhar (eds), *Beyond the Body Proper: Reading the Anthropology of Material Life* (Duke University Press 2007) 2. Nikolas Rose, *The Politics of Life Itself: Biomedicine, Power and Subjectivity in the Twenty-First Century* (Princeton University Press 2007) *3.* Margaret Lock and Vinh-Kim Nguyen, *An Anthropology of* Biomedicine (2nd edn, Wiley Blackwell 2018) ix. Tamar Sharon, *Human Nature in the Age of Biotechnology* (Springer 2014) v. Megan Warin and Aryn Martin, 'Emergent Postgenomic Bodies and Their Non(Scalable) Environment' in Maurizio Meloni et al. (eds) *The Palgrave Handbook of Biology and Society* (Palgrave 2017) 703. See also John Cairns, *Matter of Life and Death: Perspectives on Public Health, Molecular Biology, Cancer, and the Prospects for the Human Race* (Princeton University Press 1997) x.

The recourse to these metaphors sustained, therefore, in both jurisdictions a *semantic of appropriation*, which has marked the development of patent eligible matter in these countries. Whereas in the United States *Chakrabarty* re-shaped the boundaries of patent eligibility by describing micro-organisms as *bio-artefact*s, not different from the kinds of products set out in Title 35 U.S.C. § 101, in Canada the Patent Appeal Board, in *Re Abitibi*, took the decision of re-framing the scope of "invention" in s 2 relying on the metaphor of the *chemical molecule*. However, it limited the enlargement of its scope to microorganisms.

Subsequently, in the *Oncomouse* case, both the Trial Division of the Federal Court and, later, the SCC, pointed out that the metaphor of the "chemical molecule" fell short in describing a transgenic mammal and, hence, the claimed invention could not be subsumed under the definition of invention in s 2. The SCC, moreover, highlighted the political nature of the decision on the patent eligibility of higher life forms, which accordingly ought to be discussed by Parliament and should not be left to administrative practices or judicial *fiat*.

The narrative of progress set out in *Chakrabarty*, however, proved to be influential also outside the boundaries of the U.S., as the Canadian FCA largely drew on it to back the patent eligibility of transgenic organisms. As Graham Dutfield illustrated, although "both the Unites States and Canada require *physical* inventions to be machine, manufactures or composition of matters, and yet both have accepted that life forms are patentable",[833] this have been brought about in different ways.

The sociotechnical imaginary of what was collectively desirable related to the development of biotechnology differed in these nations.

In the United States, the narrative of progress linked to the Constitutional IP clause sustained a sociotechnical imaginary in which the patent eligibility of genetically modified products was crucial in fostering the needs and wealth of American society.

In Canada, even though the public policy favoured biotech products and their patentability, the SCC showed a cautious approach in granting IPRs over higher organisms when fundamental rights could be involved.[834]

Although in both countries biotechnology has been framed in terms of products, a different sociotechnical imaginary emerged in Canada which questioned the support to biotechnology

[833] Dutfield (n 31) 198.

[834] In 1982, the Canadian Charter of Rights and Freedoms has been enacted by the Parliament of Canada, which is part of the Constitution. The main purposes of its enactment were to reinforce the basic rights of Canadian citizens and offer a possible solution to some of the political claims formulated by the French community in Quebec. Parliament of Canada, Charter of Rights and Freedoms, available at <https://laws-lois.justice.gc.ca/eng/const/page-15.html>.

tout court in the face of the constitutional rights just set out in a state still largely in the making.

Under the EPC patent system, the patent eligibility of microorganisms was not widely disputed. The Board of Appeals did not resort to metaphors in order to address the problems related to the possible patent exclusion of genetically engineered plant cells, under the *ordre public* and morality clause embedded in Art 53(a) EPC, but relied on a narrative of continuity and boundary work in order to decouple biotechnology from its applications, which were distinguished as good and bad, and then building a moral analogy between traditional selective breeding and plant biotechnology based on genetic engineering, which was set out in T 356/93 Plant cells/Plant Genetic Systems: "Indeed, in the Board's judgement, *plant biotechnology per se cannot be regarded as being more contrary to morality than traditional selective breeding because both traditional breeders and molecular biologists are guided by the same motivation*, namely to change the property of a plant by introducing novel genetic material into it in order to obtain a new and, possibly, improved plant. However, compared with traditional breeding techniques, genetic engineering techniques applied to plants allow a *more powerful and accurate control* of genetic modifications".[835]

However, in the 1990s, when ethics was emerging as a central epistemic element in the construction of the identity of the European Community, significant concerns about the patent eligibility of GM organisms were raised by NGOs, political parties and civil society in the *Onco-mouse* case.

Their opposition forced the EPO's Opposition Division and Boards to address the meaning of the patent exception set out in Article 53(b) on "animal varieties" and the morality clause in Article 53(a). The Division and Boards did not rely on a metaphorical definition of transgenic organisms, but endorsed the "higher rank approach" set out in the Novartis II case, without fully engaging in explaining the preference for this approach in comparison to T 356/93 Plant cells/Plant Genetic Systems and filling a gap in the historical narrative of the origins of the provision (Article 53(b)) in favour of the patent eligibility of animals.

They, however, drew on analogies to assess the *sufficiency of disclosure* of the claimed invention, by assimilating the threshold of sufficient disclosure for transgenic organisms to the one settled for microorganisms and positing that "genetic engineering" entailed a high degree of control and reproducibility over the claimed invention.

[835] T 356/93 (n 747) 22-23.

The Boards, as it will emerge in several cases concerning other areas biotech innovation, relied on historical narratives tracing back the meaning of the terms of the EPC, however sometimes in an ambiguous way, by filling the gap when a clear intention, in the *travaux préparatoires*, could not be construed.

Under the EPC system, a clear support to the expansion of patent eligible matter emerged and a molecular view of life and nature characterized technoscientific practices and the social imaginary: biotechnology and its GM products, as chapter two has illustrated (section 2.3.2), were linked to creating a brighter future in terms of the protection of the environment, promoting medical research and industrial modernization.

However, as the long opposition to the "Onco-mouse" patent shows, a particular perspective of what was desirable and attainable through the allocation of IPRs on GMOs was emerging and this view challenged their morality and fulfillment of collective needs.

Chapter Four
Intellectual Property on Gene Sequences

4.1 Information, IP and Gene Sequences

Whereas the previous chapter illustrated how the use of metaphors on biotech micro-organisms and organisms has shaped the boundaries of what is natural and artificial, as far as the interpretation of patent eligible matter is concerned, this chapter will address how these boundaries have been further expanded by patent offices' practices and guidelines in order to accommodate other biotechnological products, such as isolated and purified DNA sequences.

Although resorting to metaphors proved to be a significant move to expand analogically the scope of "patentable subject matter" or "invention", likewise the judicial and institutional narratives in which metaphors were embedded turned out to be fundamental in order to sustain their use and implementation in particular national and supranational contexts. These narratives concern the construction of the definition of the threshold of artificiality, which is statutory required to deem a product or process patentable. Yet, alongside this, they set out the aims of intellectual property in specific national settings, champion views about the boundaries between patent jurisdiction, policy-making and patent offices' administrative authority, which can result in the normalization or not of technoscientific products and processes within patent systems.

Furthermore, this chapter will show that alternative metaphors (mainly the metaphor of the genetic code) and counter-narratives have been used in the systems of comparison to reframe sociotechnical imaginaries of life, as far as IP over DNA sequences and genes is concerned. The metaphor of the genetic code conveys an atomistic and reductionist view of life, as much as the metaphors of the machine and molecule. However, it has been supported by scientific researchers, associations of clinicians and cancer patient advocacy groups to argue for the patent ineligibility of DNA sequences as products of nature.

The chapter will focus, in particular, on how the established boundaries of what is "patentable subject matter" have been unsettled, when the validity of patent claims on the BRCA1 and 2 genes have been, successfully, challenged in the United States, Europe and Australia, in the last decade.

Several IP scholars [836] engaged in analysing the role that information is playing in contemporary societies, in the global economy and the entitlement issues that it elicits. They showed that information and its commodification is problematic in terms of market efficiency, liberal political theory and allocation of property rights.[837] Information carries the features of "public goods", as it has high social value, it is expensive to produce and acquire, even though its results are cheap to copy.[838] Economic theorists argue that, in order to produce this kind of good which, otherwise, would be under produced, intellectual property rights are fundamental to providing incentives for its creation. Nevertheless, it has been noticed,[839] that social access to information is pivotal to keep the market efficient, foster scientific research, promote creativity and benefit the public. North American and most European contemporary democracies, in addition, are largely grounded in liberal political theory, which devises the public sphere and its liveliness as depending upon the free access to information and its communication,[840] as freedom of speech is the cornerstone of constitutionally recognized human rights. At present, IP systems are facing some of the tensions engendered by the policy of information, which is ultimately deemed and handled as a form of wealth.

James Boyle pinpointed[841] that the "information society" or the "information age" is marked by the "universalizing logic of the information relation", namely "the tendency is toward the economic and conceptual separation of the information message from the medium – cells, diskettes, telephone directories or whatever – and the progressive devaluation (literally the diminishing marginal cost) of the medium as compared to the message".[842] As a consequence, he notices, "as the information content is decontextualized, the location or form of the information comes to seem increasingly – as irrelevant as the color of two books would be to a comparison of their arguments".[843]

He refers to the Human Genome Project ("HGP") and the relevance of information technology and, in particular, bioinformatics in devising the project and, then, mapping and sequencing the genome, which entailed the use of special computer software in order to

[836] Drahos with Braithwaite (n 811) 1-18; James Boyle, *Shamans, Software, & Spleens: Law and the Construction of the Information Society* (Harvard University Press 1997) ix, 1-11; Anne Wells Branscomb, *Who Owns Information?* (Basic Books 1994) vii.
[837] Boyle (n 836) xi-xii.
[838] ibid xi.
[839] ibid xii.
[840] ibid xii.
[841] Mariachiara Tallacchini, 'Human Tissues in the 'Public Space': Beyond the Property/Privacy Dichotomy' in Giovanni Pascuzzi, Umberto Izzo and Matteo Macilotti (eds), *Comparative Issues in the Governance of Research Biobanks* (Springer 2013) 87, 96.
[842] Boyle (n 836) 7.
[843] ibid.

collect, organize and analyse large amounts of data to identify introns and exons,[844] which are stored on disk.

The analysis of the patent decisions on the BRCA1 and 2 genes case illustrates the kind of issues that the logic of the information relation engenders in terms of access, distribution, control and allocation of rights and how it actually operates, as it has shaped for decades patent offices' practices and guidelines, judicial approaches and patentability criteria, such as isolation and purification.

4.2 DNA's Threshold of Artificiality: USPTO's Utility Examination Guidelines and the Narrative of the Origins

The legal status of the human genome has been uncertain and ambiguous during and after the completion of the HGP.

On 26 June 2000, in the joint press conference[845] issued by U.S.A. President Bill Clinton and U.K. Prime Minister Tony Blair that announced the successful conclusion of the mapping of the human genome, they both expressed the excitement for the historic breakthrough, which would "revolutionize the diagnosis, prevention and treatment of most, if not all, human diseases".[846] However, they both acknowledged that this achievement was only a starting point for further public and private scientific research, which is required to address the legal, social and ethical implications of the project concerning responsibility on the uses of this kind of information.

Prime Minister Blair, in particular, pointed out: "We, all of us, share a duty to ensure that the *common property* of the human genome is used *freely* for the *common good of the whole human race*; to ensure that the *powerful information* now at our disposal is used to transform medicine, not abused, to make man his own creator or invade individual privacy".[847]

Blair's speech conveys a specific understanding and qualification of the human genome, coherent with the common guiding principles that all the participants to the HGP were asked to comply with, since the beginning of the undertaking: "Article 1. The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense it is the heritage of

[844] Burton E Tropp, *Molecular Biology: Genes to* Proteins (4th edn, Jones & Bartlett 2012) v, 846.
[845] The White House, Office of the Press Secretary, Remarks Made by the President, Prime Minister Tony Blair of England (via satellite), Dr. Francis Collins, Director of the National Human Genome Research Institute, and Dr. Craig Venter, President and Chief Scientific Officer, Celera Genomics Corporation, on the Completion of the First Survey of the Entire Human Genome Project.
[846] ibid.
[847] ibid.

mankind";[848] "Article 4. The human genome in its natural state shall not give rise to financial gains".[849]

According to these principles, set out by the Universal Declaration on the Human Genome and Human Rights, adopted by the General Conference of UNESCO on 11 November 1997, the participants to the HGP seemed to endorse the qualification of the human genome as a part of a "common heritage of mankind",[850] which "in its natural state shall not give rise to financial gains".[851] Although the interpretation of this legal qualification in international law and its implications are debated,[852] the announcement took place after years in which the U.S. National Institutes of Health and Craig Venter's group and his newly founded company, Celera Genomics, had already patented a substantial amount of DNA sequences before the USPTO.[853]

In 1990, the legal scholar Eisenberg had already examined the trend of patenting DNA sequences and pinpointed some of the doctrinal problems regarding their assessment, as far as the threshold of patentable subject matter and the requirements of novelty and non-obviousness are concerned.[854] Moreover, she discussed the policy considerations of patenting human DNA sequences in the aftermath of the 1980 Patent & Trademark Act Amendments,[855] also known as Bayh-Dole Act, whose aim was "to use the patent system to promote the utilization of inventions arising from federally supported research or development",[856] by allowing nonprofit research institutions and small businesses to retain title to inventions and grant exclusive licenses for specific uses of the inventions to large businesses.[857]

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[848] Universal Declaration on the Human Genome and Human Rights, adopted by the General Conference of UNESCO on 11 November 1997 and implemented at the General Assembly of the United Nations in 1998.
[849] ibid.
[850] Chamundeeswari Kuppuswamy, *The International Legal Governance of the Human* Genome (1st edn 2009,Routledge 2012) viii, 49-79; Andrea Stazi, *Biotechnological Inventions and the Patentability of Life. The US and European Experience* (Edward Elgar 2015) v, 67; Jasper A Bovenberg, 'Mining the Common Heritage of Our DNA: Lessons Learned from Grotius and Pardo' (2006) 5 Duke Law & Technology Review, 1-20.
[851] UNHGHR (n 751).
[852] Kuppuswamy (n 850) 49 and 67-72.
[853] Alex Berenson and Nicholas Wade, 'Clinton-Blair Statement on Genome Leads to Big Sell-Off' (15 March 2000) The New York Times, available at <http://www.nytimes.com/learning/students/pop/articles/031500sci-human-genome.html?mcubz=0>.
[854] Rebecca S Eisenberg, 'Patenting the Human Genome' (1990) 39 Emory Law Journal 721-745; M Scott McBride, 'Patentability of Human Genes: Our System Can Address the Issues without Modification' (2001) 85 Marquette Law Review 51-535.
[855] Public Law No. 96-517, 94 Stat. 3015, 3019-29 (1980), codified at 35 U.S.C. §§ 200-211 (1988).
[856] Title 35 U.S.C. § 200 (1988).
[857] Title 35 U.S.C. § 202 (1988).

Since the 1980s,[858] the USPTO had granted many patents on genes and DNA sequences, whose commercial uses for the production of therapeutic proteins or diagnostic tests for genetic diseases were rather predictable and clear.[859]

As Calvert and Joly pointed out,[860] the reduction of genes and DNA sequences to chemical molecules is linked to the development of molecular biology, which shifted the representation of the gene from "Mendelian" to "molecular",[861] namely from genes as "hypothetical factors which are responsible for phenotypic differences between organisms"[862] to stretches of DNA which code for particular polypeptides. They remarked that the earliest patents involving genes were granted by the USPTO on Mendelian genes, which were not considered as chemical compounds. As an example, they refer to US patent No. 3,710,511, which was granted in 1973, on "Procedures for use of genic male sterility in production of commercial hybrid maize".[863] Although the patent is on a method to produce hybrid maize, it centrally involves a Mendelian gene, as it describes a gene for a particular trait.[864]

Some years later, in 1998, Rebecca Eisenberg and Michael Heller published in Science a well-known article, entitled "Can Patents Deter Innovation? The Anticommons in Biomedical Research",[865] in which they expressed some concerns that the practice of granting patents on basic tools of research could stir anticommons effects in certain areas of innovation, such as biomedical science. They drew on the metaphor used by the ecologist Garrett Hardin, "the tragedy of the commons", in an article published as well in Science thirty years before,[866] in which he questioned the negative effects of the regime of the commons, as to the preservation and protection of the environment. Heller and Eisenberg, overturned his metaphor and questioned whether and how an anticommons regime, marked by the proliferation of IPRs granted to much upstream, could have a negative impact on scientific research.

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[858] For example, U.S. Patent 4,370,417, claiming DNA sequence for plasminogen activator protein, 1026 Official Gazette Patent Office 1315, 25 January 1983; U.S. Patent 4,7003,008, claiming DNA sequence for erythropoietin, 1083 Official Gazette Patent Office 2038, 27 October 1987; U.S. Patent 4,713,332, claiming DNA sequence from human T cell antigen receptor, 1085 Official Gazette Patent Office 1386, 15 December 1987; U.S. Patent 4,757,006, claiming recombinant vectors containing DNA sequence for human factor VIII:C, 1092 Official Gazette Patent Office 878, 12 July 1988. Eisenberg (n 867) 721.

[859] Eisenberg (n 854) 721-745.

[860] Calvert and Joly (n 52) 159. Calvert and Joly noticed that: "Traditional Mendelian genetics was based on the statistical association between an elementary genetic unit and a phenotypical character, but it did not have the tools to analyze the material substrate of hereditary mechanisms".

[861] John Dupré, 'Understanding Contemporary Genomics' (2004) 12(3) Perspectives on Science 320-338.

[862] Calvert and Joly (n 52) 159.

[863] E B Patterson, "Procedures for use of genic male sterility in production of commercial hybrid maize", US Patent No. 3,710,511, 16 January 1973.

[864] Calvert and Joly (n 52) 160.

[865] Michael A Heller and Rebecca S Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280(5364) Science 698-701.

[866] Garrett Hardin, 'The Tragedy of the Commons' (1968) 162(3859) Science 1243-1248.

One of the main examples provided by them regarded the proliferation of U.S. patents on expressed sequence tags (ESTs),[867] namely cDNA[868] fragments (usually 200-500 nucleotides long) which result from "copying one or both ends of an mRNA which are often used in place of a full length cDNA".[869] These DNA sequences have been named "expressed sequence tags" because, as the molecular biology scholar Tropp explained, "they (1) represent a snapshot of the genes that are expressed in specific tissues, specific developmental stages, or both; and (2) can be used as hybridization probes to tag complementary chromosomal DNA sequences".[870]

What, in particular Heller and Eisenberg pinpointed was that the function of ESTs sequences was largely unknown.[871]

On 5 January 2001 the USPTO published the revised Utility Examination Guidelines[872] which established "the policies and procedures to be followed by Office personnel in the evaluation of any patent application for compliance with the utility requirements of 35 U.S.C. 101 and 112".[873] The Guidelines describe the procedures to be followed by patent examiners and make clear that they shall assess whether the claims involve a *specific*, *credible* and *substantial* utility or not.[874]

The revised Utility Examination Guidelines have been issued in order to address the problems related to patent claims on DNA sequences, namely the risk of granting patents whose scope is too broad, if no *specific*, *credible* and *substantial* utility is requested and provided.

The USPTO had to reply to several public comments on the Revised Interim Utility Examination Guidelines, which pointed out that: 1. "a gene is not a new composition of matter because it exists in nature"; 2. an inventor who isolates a gene does not actually invent or discover a patentable composition because the gene exists in nature"; 3. "naturally occurring DNAs are part of our heritage" and hence not inventions; 4. the fact that a person

[867] See the editorial 'Patenting ESTs: Is It Worth It?' (1999) 21(2) Nature Genetics 145.
[868] Complementary DNA or cDNA is "DNA molecule copied from an mRNA molecule by reverse transcriptase and therefore lacking the introns present in the DNA of the genome". Headword "cDNA", Harvey Lodish, Chris A Kaiser, Anthony Bretscher, Angelika Amon, et al, *Molecular Cell Biology* (7th edn, MacMillan 2013) vii, G-4. Tropp (n 844) 202-203.
[869] Tropp (n 844) 846.
[870] ibid.
[871] Marta Díaz Pozo, *Patenting Genes: The Requirement of Industrial Application* (Edward Elgar Publishing 2017) v, 68-72.
[872] Department of Commerce, United States Patent and Trademark Office, Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, 1092-1099.
[873] ibid 1097.
[874] ibid 1098.

whose body includes a patented gene could be found guilty of patent infringement.[875] Several comments urged the USPTO not to issue patents for genes on the grounds that they are *products of nature* and these kinds of patents can hinder and delay medical research.[876]

In response, the USPTO rejected the comments and affirmed *isolation* and *purification* as the two guiding criteria in order to assess the patent eligibility of DNA sequences:

> "A patent claim directed to an isolated and purified DNA molecule could cover, e.g. a gene excised from a natural chromosome or a synthesized molecule. An isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is eligible for a patent because (1) an excised gene is eligible for a patent as a composition of matter or as an article of manufacture because the DNA molecule does not occur in that isolated form in nature, or (2) synthetic DNA preparations are eligible for patents because their purified state is different from the naturally occurring compound".[877]

The USPTO's responses to specific comments and, notably, to the substantial ones resorted to the same narrative of the origins that the majority of SCOTUS set out in *Chakrabarty*, scattered its main narrative units. This narrative sustains the de-naturalization of isolated and purified DNA sequences/molecules and, hence, their normalization as patentable subject matter in the U.S. patent system, under the aegis of the analogy with the *chemical compounds*.

The first comment noticed that, while inventions are patentable, discoveries are not, pointing out that since genes are discoveries rather than inventions, patents on genes should not be issued.[878] Rejecting the comment, the USPTO recalled Article 1, section 8, clause 8 of the U.S. Constitution which does use the term "discoveries" instead of inventions and linked it to Title 35 U.S.C. § 101, which does not discriminate between inventions or discoveries as patentable subject matter, in order to conclude that discoveries are also patentable.[879]

The third set of comments pointed out that "the USPTO should seek guidance from Congress as to whether naturally occurring genetic sequences are patentable subject matter".[880] The USPTO replied that legislative history shows that Congress intended "anything under the sun that is made by man" to be patent eligible, under *Chakrabarty*.[881]

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[875] ibid 1092-1097.
[876] ibid 1092-1094.
[877] ibid 1093.
[878] ibid 1092-1093.
[879] ibid 1093.
[880] ibid.
[881] ibid.

Rebutting the fourth set of comments, which argued that patents should not be issued on genes "because the sequence of the human genome is at the core of what it means to be human and no person should be able to own/control something so basic",[882] the USPTO reaffirmed that the patent system promotes progress through the kind of exchange embedded in the Article 1, section 8, clause 8 of the US Constitution.[883]

Most of the answers rejected the adoption of the comments by drawing on the analogy between chemical molecules and DNA sequences.[884]

Several comments stated that DNA should be freely available for research and patents on ESTs could inhibit biomedical research. In response, the USPTO pointed out that the office "must administer the laws as Congress has enacted them and as the Federal Courts have interpreted them".[885]

USPTO acted mainly as a policy-maker. The Utility Examination Guidelines were issued by the USPTO in order to set out the threshold for the patentability of genes. Their adoption and implementation proved pivotal in strengthening the patentability of DNA sequences, reducing the risks for patent holders to incur in the objections of the "product of nature" doctrine.

Before the approval of the new Utility Guidelines, the USPTO had granted a large number of patents on DNA sequences. The formal introduction of the criteria of isolation and purification has, however, established the rationale to legally demarcate naturally occurring DNA sequences from "artificial" isolated/purified ones.

4.2.1 Genes as Information: *Association for Molecular Pathology et al. v. United States Patent and Trademark Office and Myriad Genetics, Inc., et al.*[886]

In the United States, the patent eligibility of biotech genetically engineered living products seemed to be settled for decades, in the aftermath of *Chakrabarty*, by drawing on the conceptual metaphor of the *machine*, namely microorganisms and organisms defined as *bio-artifacts*.

As far as patent applications on DNA sequences are concerned, the USPTO relied on the conceptual metaphor of the *chemical molecule*, in order to uphold their patent eligibility

[882] ibid.
[883] ibid 1093-1094.
[884] ibid 1095: "patent law provides no basis for treating DNA differently from other chemical compounds that are compositions of matter".
[885] ibid.
[886] Some of the ideas and arguments expressed in this section and the next ones have been published in Emanuela Gambini, 'The Product of Nature Doctrine in the Myriad Saga' (2012) 2 EJRR 218; Emanuela Gambini, 'The Product of Nature Doctrine in the Myriad Saga II' (2013) 3 EJRR 409.

status, and on the criteria of *isolation* and *purification* to establish a threshold of artificiality, which would exclude the application of the product of nature doctrine.

This outline of the boundaries of what is natural and artificial was due, however, to be challenged.

In 2006, Tania Simoncelli who was a science advisor at the American Civil Liberties Union (ACLU) between 2003-2010,[887] together with Chris Hansen, a senior ACLU attorney, started to examine the possibility of undertaking a judicial case to challenge Myriad's patents[888] on the BRCA1 and 2 genes. They were joined, afterwards, by Sandra Park, an attorney in ACLU's Women's Rights Project.

Simoncelli's work, at the time, "involved identifying emerging and important issues in science and technology that had implications for civil liberties"[889] and the patenting of human genes was pinpointed by her as an area of concern, which deserved to be probed.[890]

Their endeavor aimed, first, at speaking to pathologists, medical geneticists and counselors, activists and researchers to understand whether to challenge gene patents or not and what kind of goals should be pursued. The foundation of the case required some years of work, in which they benefited from the support of scientific experts and professionals, health and patients organizations, which proved to be pivotal to undermine USPTO's long-standing policy and practice of granting patents on naturally occurring isolated DNA sequences,[891] as affecting the public interest. Their aim was to challenge radically the patent eligibility of DNA sequences and genes.

They, subsequently, filed a case against Myriad Genetics and the USPTO contesting the validity of its product and method patent claims involving the BRCA1 and 2 genes. Their lawsuit hinged on undermining the narrative of progress maintained by the majority of the U.S. Supreme Court in *Chakrabarty*, by backing a counter-narrative which proposed a different interpretation of the relationship between 35 U.S.C. § 101 and Article I, Section 8 Clause 8 of the United States Constitution in the light of the First and Fourteenth Amendments of the Constitution. In particular, the plaintiffs pinpointed the tensions between Article I, Section 8 Clause 8 of the United States Constitution, which supports and justifies

[887] Tania Simoncelli, 'AMP v. Myriad: Preliminary Reflections' (2013) 26 (2-3) *GeneWatch* 5, 7.
[888] Shobita Parthasarathy, *Patent Politics: Life Forms, Markets & the Public Interest in the United States and Europe* (The University of Chicago Press 2017) 1, 162-171.
[889] Simoncelli (n 887) 7.
[890] ibid 5; Tania Simoncelli and Sandra S Park, 'Making the Case against Gene Patents' (2015) 23 (1) Perspectives on Science 106, 106-145.
[891] ibid.

patent law and IPRs, and the First Amendment which protects freedom of speech and thought.[892]

This counter-narrative, together with the metaphor of the genetic code, have been employed to re-frame the sociotechnical imaginary of biotechnology in the United States, by showing that the patent eligibility of these genomic products was not desirable for researchers and would not benefit cancer patients and American society at large.

The claims have been challenged on legal and constitutional grounds. According to plaintiffs, they fell within the judicial patentability exclusion established in *Chakrabarty* on the laws of nature, natural phenomena and abstract ideas. Furthermore, they infringed the First Amendment, which deals with liberty of expression and association, and Article I, section 8, Clause 8, U.S. Constitution, the Constitutional IP clause.

Myriad was accused of having pursued, since the 1990s, a commercial strategy aimed at gaining the monopoly on the testing of BRCA1 and 2 mutations: Myriad patented several mutated and wild-type BRCA1 and 2 sequences, as well as the methods in order to analyze and compare them and, then, enforced its patents and exclusive licenses against other researchers and laboratories offering similar services, by sending "cease and desist letters" and sometimes proposing collaboration licenses.[893] This monopolistic strategy was considered to have hindered clinical research on cancer, limited the performance of alternative/complementary diagnostic tests, having considerably raised health insurance expenses related to BRCA1 and 2 mutations testing and restrained access to health care for patients.

The BRCA1 gene was discovered in 1990 by a group led by Mary-Claire King at the University of California, Berkeley,[894] and is a tumor-suppressor gene located on chromosome 17, whose mutations have been linked to genetic breast cancer. In 1991, scientists found that its mutations were connected with genetic ovarian cancer too and, in September 1994, a group of Myriad Genetics' scientists, together with researchers from the National Institute for

[892] Debra Greenfield, 'Freedom of Genes. The Myriad Case Carries After Overlooked First Amendment Implications', (2010) 23(5-6) GeneWatch 36.

[893] This point and the following one have been expressed also in Emanuela Gambini, 'Gene Patenting and Public Interest: Narratives on the BRCA1 and BRCA2 case' in Anand Nair, Claudio Tamburrino and Angelica Tavella (eds), *Masters of Laws in Intellectual Property. Collection of Research Papers 2011* (ESI 2013) 103, 106

[894] Jeff Hall, et al, 'Linkage of Early-Onset Familial Breast Cancer to Chromosome 17q21' (1990)250 Science 1684-1689.

Environmental Health Sciences (which is a subdivision of the NIH), completed the mapping and sequencing of the gene.[895]

In 1991 the BRCA2 gene was discovered, which is a tumor-suppressor gene located on chromosome 13, whose mutations entail an increased risk to develop breast cancer and ovarian cancer and can affect both women and men. In 1995, a group of investigators led by Michael Stratton at UK Institute for Cancer Research announced the mapping and sequencing of the BRCA2 gene.[896] The mapping and sequencing of these genes attracted considerable media coverage and attention for its scientific and social significance.

ACLU was able to involve PubPat, several medical organizations and potential and actual cancer patients and on 12 May 2009 they sued Myriad Genetics Inc., the directors of the University of Utah Research Foundation, and USPTO. The plaintiffs challenged fifteen claims of seven patents**,** owned or exclusively licensed to Myriad Genetics, a molecular diagnostic company based in Salt Lake City (Utah, US), and asked for a summary judgment on their invalidity.

The claims-in-suit belonged to two different kinds of claims: *composition* or *product* ones and *method* or *process* ones.

The product claims covered the isolated BRCA1 gene: claim 1 and 2 of the ’282 patent, claims 5 and 6 of the ’282 patent were directed to fragments as short as 15 nucleotides long of the DNA molecules in claims 1 and 2 of the ’282 patent, claim 7 of the ’282 patent and claim 1 of the ’473 patent were directed to “isolated DNA possessing one of the specified mutant *BRCA1* gene sequences.

Moreover, they covered the BRCA2 gene: claims 1, 6, and 7 of the ’492 patent.

The method claims were directed to compare and analyse mutated BRCA1 and 2 and “genes sequences with the normal ones or “wild-type” ones in order to identify the presence of cancer-predisposing mutations: claim 1 of the ’999 and ’001 patents, claim 1 of the ’441 patent, claim 1 of the ’857 patent, claim 2 of the ’857. Claim 20 of the ’282 patent concerned a “method for screening potential cancer therapeutics” which comprised growing cells carrying a mutated BRCA1 gene causing cancer in the presence of the therapeutic, comparing the growth rates of the cells and determining whether the therapeutic has slowed the growth rate or not.

[895] Shobita Parthasarathy, *Building Genetic Medicine: Breast Cancer, Technology, and the Comparative Politics of Health Care* (The MIT Press 2007) viii, 5.

[896] Richard Wooster, et al, ‘Identification of the Breast Cancer Susceptibility Gene BRCA2’ (1995) 378 Nature 762-763.

Significantly, the claims-in-suit covered also "wild-type" DNA sequences, which refer to the "normal" non-mutated human gene sequence, "i.e. the sequence of a gene without any variations, against which individuals' gene sequences are compared".[897] Gaining IPRs over these isolated sequences, together with the mutated ones, is strategically relevant for companies selling genetic predisposition and diagnostic tests, as it allows them to prevent other companies and research groups to develop and market alternative and complementary tests because, even if they identify and isolate mutations of the same gene, they cannot compare them with patented wild-type DNA sequences owned by a competitor.

This litigation has reshaped the scope of patentable subject matter in the United States and changed the long-standing practice of the USPTO to grant patents on isolated DNA sequences.

The litigation focused on whether the claims fell within the scope of "patentable subject matter" under Title 35 U.S.C. § 101 or not and on the definition of DNA sequences, either as *chemical molecules* or *information*, as far as product claims were concerned.

The Plaintiffs devoted a considerable amount of resources and expertise to de-construct and overturn the influential narrative of the origins and progress set out by the majority of the Supreme Court in *Chakrabarty*, endorsed by the USPTO in the Utility Examination Guidelines and relied on by Myriad Genetics in order to rebut the challenges against the validity of its patents.

They argued that these patents hindered the work of clinical researchers, the improvement of genetic diagnostic tests, scientific progress and did not benefit society, as Myriad's diagnostic tests were too costly and not accessible to every possible patient.

ACLU et al. and Myriad offered two different views about what genes and DNA sequences are, which are centered on conceptual metaphors and the case was focused on their description in order to decide on their patentability.

The Plaintiffs, relying on the scientific expertise of biologists, argued that *genes are information*, which is naturally occurring in the body and their isolation from it does not make them patentable subject matter under Title 35 U.S.C. § 101. They drew on the metaphor of the *genetic code* as the *book of nature*, which as such does not belong exclusively to anybody:

> "Genes are not like carburetors. The function of a gene is to convey information to the body. […] A genetic sequence is *biological information itself*. A gene is represented

[897] Association for Molecular Pathology, et al., v. United States Patent and Trademark Office, et al. U.S. District Court, S.D. New York, 29 March 2010, 702 F.Supp.2d 181 (S.D.N.Y.) 195.

by a series of letters. Like strings of alphabetic text, the genetic sequences are the same regardless of whether the data reside in the DNA of an organism, a computer, or as letters on a printed page. The physical form in which they occur is unimportant; what matters is the informational content. The information in a gene sequenced in a lab is identical in function to that in the body.

The sole reason for sequencing a gene is to uncover that information. In that respect, sequencing can be compared to using a microscope to read small letters. Alterations or mutations are recognized exactly as typographical errors are recognized, by a letter being seen as out of place. The comparisons between two genes are done by comparing the letters, exactly like proof-reading a book. Because of the informational aspect of genes, it is inaccurate to treat genes as if they were carburetors or chemicals. Thus, the patent claims in this case directly limit information in a manner far different from patents on true inventions, such as carburetors. They limit pure information".[898]

By referring to carburetors or chemicals, the plaintiffs pinpointed the metaphors which have guided contemporary IP imaginary of biotech products, according to which GMMs, GMOs, DNA sequences are either *artefacts*, like *machines*, or *chemical molecules* and therefore, as such, falling within the statutory definition of patentable subjected matter developed by the U.S. case law. The main argument maintained by the plaintiffs was directed to undermine the description of DNA sequences and genes as *chemical molecules* and affirm their characterization as *information*.

This metaphor has been endorsed by Justice Sweet of the U.S. District Court Southern District of New York, who declared invalid all Myriad's claims on the DNAs' sequences and on the method claims.

Judge Sweet, drawing upon some cases[899] concerning patentable subject matter and, in particular, *Chakrabarty*, addressed whether the composition and method claims were directed to products "markedly different" from products of nature or not.

As far as the product claims were concerned, he pointed out that, although Myriad claimed that purification of "naturally occurring" compounds does not exist in nature, "purification of a product of nature, without more, cannot transform it into patentable subject matter".[900] He remarked that the central premise of Myriad's argument that the claimed DNA is "markedly

[898] United States District Court Southern District of New York, Plaintiffs' Memorandum of law in support of the motion for summary judgment, *AMP, et al, v. Myriad, et al*, 35-36.

[899] U.S. Supreme Court, *American Fruit Growers Inc, v. Brogdex Co*, 2 March 1931, 283 U.S. 1 (1931), 13-14. U.S. Supreme Court, *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 16 February 1948, 333 U.S. 127 (1948).

[900] U.S. District Court Southern District of New York, *Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al.*, 29 March 2010, 94 USPQ2d 1683, 121.

different" from DNA found in nature is that "*isolated DNA molecules should be treated no differently than other chemical compounds for patent eligibility*".[901]

This definition was overturned by the Judge, who highlighted the unique characteristics which differentiate DNA from chemical compounds, namely its unique informational quality, that makes the analogy unsuitable:

> "Myriad's argument that all chemical compounds, such as the adrenaline at issue in Parke-Davis, necessarily convey some information ignores the biological realities of DNA in comparison to other chemical compounds in the body. *The information encoded in DNA is not information about its own molecular structure incidental to its biological function, as it is the case with adrenaline or other chemicals found in the body. Rather, the information encoded by DNA reflects its primary biological function*: directing the synthesis of other molecules in the body – namely, proteins, 'biological molecules of enormous importance' which 'catalyze biochemical reactions' and constitute the 'major structural materials of the animal body'".[902]

The conclusion that follows from this definition, which Judge Sweet supported, is that genes are "products of nature".

Myriad, conversely, maintained the *chemical nature* of DNA (as tangible chemical molecule), alleging the structural and functional different properties of isolated DNA. In particular, it significantly drew on the holding of *Parke-Davis & Co. v. H.K. Mulford Co.*[903] to argue that "isolated DNA should be treated no differently than other chemical compounds for patent eligibility".[904] *Parke-Davis* was a landmark case, decided by Justice Hand, which involved the validity of two patents[905] for a glandular extractive product covering *purified* forms of adrenaline and the compound in a solution with salt and a preservative. The holding of this case backed the patent eligibility of purified chemical compounds and, as Myriad's defense pointed out, settled that the purification of a natural product makes it patentable.[906]

As Graham Dutfield has illustrated, this case concerning a purified hormone has paved the way to the patent eligibility of "other chemicals found in living things as long as they were purified or at least isolated in a way that made them available to the public for the first

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[901] *AMP* (n 900) 122.
[902] ibid 124.
[903] *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (S.D.N.Y.1911).
[904] *AMP* (n 900) 228.
[905] U.S. Patent No. 730,176 "Glandular extractive product", granted 2 June 1903 and U.S. Patent No. 753,177 "Glandular extractive compound", granted23 February 1904. Both patents were granted to Jokichi Takamine, who licensed them to Parke-Davis. See Dutfield (n 31) 533.
[906] *AMP* (n 900) 225.

time". [907] It, therefore, backed the metaphorical and analogical assimilation of microorganisms and genes to chemical molecules.[908]

The District Court dismissed the relevance of the case as it focused on novelty (under 35 U.S.C. § 102, in modern days), not on patentable subject matter (35 U.S.C. § 101), which was the question before the Court. Justice Hand, in fact, clarified that the validity of the claims was challenged mainly because they were "anticipated in the art" and, then, on several other "technical grounds". His conclusion, the District Court observed, was focused on the fact that "the patented purified extract was not in fact different from the prior art 'only for a degree of purity', but rather was a different chemical substance from that found in the prior art",[909] because it was not anticipated.[910]

Although Justice Sweet conceded that in that judgment it was stated "But, even it were merely an extracted product without change, there is no rule that such products are not patentable",[911] he noted that this statement was a *dicta* that lacks accuracy in light of more recent decisions and especially *Chakrabarty*, which has established that a claimed invention must have "markedly different characteristics" over the products of nature.[912]

Moreover, as far as method claims were concerned, he rejected the precedents adduced by Myriad and pointed out they consisted simply in comparing and analyzing and did not pass the "machine or transformation test" set out in *Bilski*, whose nature is mechanistic. Under the "machine or transformation test", a claimed process is patent eligible if it fulfills one of these two conditions: "(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different thing". Judge Sweet highlighted that transformation should be a pivotal element of the claimed process.[913]

In particular, he pointed out how the claims under dispute did not embed any element of transformation, since they did not refer to any particular method of analysis or comparison

[907] Dutfield (n 31) 533.
[908] Ibid; see also Graham Dutfield, 'Patents on Steroids: What Hormones Tell Us about the Evolution of Patent Law and the Pharmaceutical Industry' (2011) 23 I.P.J. 249.
[909] *AMP* (n 900) 225.
[910] Justice Hand, in particular, argued: "no one had ever isolated a substance [adrenaline] which was not in salt form" and that the claimed form of adrenaline "was an original production" of the [patentees']. *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (S.D.N.Y.1911), at 103. See *AMP* (n 800) 225.
[911] *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (S.D.N.Y.1911), at 103. Association for Molecular Pathology, et al., v. United States Patent and Trademark Office, et al. U.S. District Court, S.D. New York, 29 March 2010, 702 F.Supp.2d 181 (S.D.N.Y.) 225.
[912] *AMP* (n 900) 226.
[913] ibid 226.

and were directed to the abstract mental processes of comparing and analyzing gene sequences.[914]

In contrast with the *Prometheus* decision of the Federal Circuit, which was recalled by Myriad, he pinpointed that the claims-in-suit did not involve the transformative steps of extracting and measuring in order to determine metabolite levels, which involved high pressure liquid chromatography.[915]

Consequently, Justice Sweet held the challenged patent claims invalid, but his main argument regarding the nature of DNA sequences was centered on the endorsement of the metaphor of the code.

4.2.2 Genes as Chemical Molecules: The *AMP* Case before the Court of Appeals

In contrast with the District Court, the United States Court of Appeals for the Federal Circuit supported the *chemical molecule* as the most appropriate definition of isolated genes and DNAs sequences. The Court of Appeals affirmed and reversed in part the District Court's decision and each member of the panel wrote a separate opinion. All the judges of the panel deemed that *Chakrabarty* and *Funk Bros.* provided the legal framework in order to assess the patent eligibility of the product claims. As far as the product claims were concerned, the majority of the Court judged the isolated DNA sequences and cDNA sequences patentable, but disagreed on the rationale.

Justice Alan Laurie, who has a background in chemistry,[916] pointed out the *chemical* nature of DNA sequences and the chemical *structural* differences between native DNA, which is in the human body, and isolated DNA. According to him, the cleavage of the covalent bonds of DNA's backbone was sufficient to change structurally the nature of the sequences. He argued that:

> "Isolated DNA, in contrast [with native DNA], is a free-standing portion of a native DNA molecule, frequently a single gene. Isolated DNA has been cleaved (i.e. had covalent bonds in its backbone chemically severed) or synthesized to consist of just a fraction of naturally occurring DNA molecule. […] Accordingly, BRCA1 and BRCA2 in their isolated state are not the same molecules as DNA as it exists in the body; human intervention in cleaving or synthesizing a portion of a native

[914] ibid 234.
[915] ibid 234.
[916] See Justice Lourie's *curriculum vitae*, available at <http://www.cafc.uscourts.gov/judges/alan-d-lourie-circuit-judge>.

chromosomal DNA imparts on that isolated DNA a distinctive chemical identity from that possessed by native DNA".[917]

However, he clarified that the claims-in-suit on isolated DNA sequences had not been purified by being isolated. He, therefore, dismissed the significance of the case law regarding purified chemical compounds adduced by Myriad and, in particular, *Parke-Davis & Co. v. H.K. Mulford Co* and *In re Marden.* Purification, he noted, "makes pure what was the same material, but was previously impure".[918] Conversely, he pinpointed that isolated DNA sequences, once the cleavage occurs, are chemically manipulated and result in molecules that are "markedly different from that which exists in the body".[919]

He acknowledged that isolated DNA sequences have similar informational properties to native DNA sequences, but he deemed their informational content irrelevant in terms of determining their patent eligibility, since he endorsed a *structural rather than functional* view of the gene: "We recognize that biologists may think of molecules in terms of their uses, but in genes are in fact materials having a chemical nature and, as such, are best described in patents by their structures rather than their functions".[920]

He considered, therefore, the chemical alteration dispositive for the isolated DNA sequences.

However, he judged the method claims directed to compare and analyse the DNA sequences falling outside the scope of § 101 as claiming "only abstract mental processes"[921] and, therefore, failing to pass the "machine or transformation test" as re-framed in the *Prometheus* judgement. Claim 20 of the 282 patent, which concerned a method for screening potential cancer therapeutics, was held involving transformative steps and, thus, patent eligible.

Justice Kimberly Ann Moore, who has a background in electrical engineering,[922] disagreed with the majority that the different chemical structure made isolated DNA markedly different from a product of nature.[923]

In her opinion, she dwelled on the deference that should be accorded to USPTO's longstanding and consistent practice (and policy) of granting patents on isolated DNA sequences and the need to preserve "the settled expectations of the biotechnology

[917] *AMP, et al, v. Myriad, et al*, United States Court of Appeals for the Federal Circuit, 29 July 2011, 653 F.3d 1329 (Fed. Cir. 2011), 1351-1352.
[918] ibid 1352.
[919] ibid 1352.
[920] ibid 1352.
[921] ibid 1355.
[922] See Justice Moore's *curriculum vitae*, available at< http://www.cafc.uscourts.gov/judges/kimberly-moore-circuit-judge>.
[923] *AMP* (n 917) 1364-1365.

industry".[924] In particular, she illustrated the research investments of time and money made by the U.S. industry in this sector, as well as its success, for example in the case of the isolated DNA sequence encoding human erythropoietin.[925] She, therefore, claimed that the unsettlement of these expectations would hinder the "progress of science and the useful arts".[926] She brought her argument further by inferring an implicit approval of the USPTO's policy because no moratorium on gene patents was passed and prohibited patents on human beings, but did not intervene on isolated DNA sequences.

Justice William Bryson, in contrast, found the claims on genes and gene fragments not patent eligible. He allowed that Myriad put efforts and resources in locating and identifying the BRCA1 and 2 gene sequences, but he pinpointed that "the only material change made to those genes from their natural state is the change that is necessarily incidental to the extraction of the genes from the environment in which they are found in nature".[927] He found the characterization of the isolated DNA sequences of the majority unconvincing, arguing that: "Yet there is no magic to a chemical bond that requires us to recognize a new product when a chemical bond is created or broken, but not when other atomic or molecular forces are altered. A chemical bond is merely a force between two atoms or groups of atoms strong enough 'to make it convenient for the chemist to consider [the aggregate] as an independent molecular species'".[928]

He pointed out that the case law involving the purification of natural substances clarified that a substance is patentable only if purification results in a change of functionality, a new thing therapeutically and commercially.

He, furthermore, suggested that the most appropriate language to understand the claims directed to DNA sequences was genetics, not chemistry[929] and embraced a functional view of DNA sequences. The judge, then, explained that the test set out in *Chakrabarty* involved addressing two issues: "(1) the similarity in structure between what is claimed and what is found in nature and (2) the similarity in utility between what is claimed and what is found in nature".[930] Since the claimed isolated DNA sequences are the same as the native ones, both structurally and functionally, he concluded that they fell within the product of nature exclusions and were not patent eligible. He concurred with the majority that cDNA

[924] ibid 1368.
[925] Justice Moore referred to Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (Fed.Cir. 1991).
[926] *AMP* (n 917) 1371.
[927] ibid 1375.
[928] ibid.
[929] ibid 1376.
[930] ibid 1378.

sequences, as they were created in the laboratory and not simply isolated from nature, were patent eligible. He, nevertheless, judged two claims too broad and deemed them invalid.

In contrast with Justice Moore, he endorsed a different narrative of progress, which considered patents on gene sequences as preempting future research, hindering the development of future diagnostic genetic tests and possibly creating in a near future patent thickets which could be hardly be solved and affects "the next generation of innovation in genetic medicine".[931]

The Court of Appeals decided twice on the case and used, as far as the composition claims directed to isolated DNA sequences were concerned, the same kind of argument centered on the *chemical molecule*. The majority of the Court concluded that the challenged claims to isolated DNAs, whether limited to cDNAs or not, were directed to patent-eligible subject matter under § 101, as they covered "molecules that are markedly different-have a distinct chemical identity and nature from molecules that exist in nature".[932]

On remand of the U.S. Supreme Court in light of *Mayo*[933] the Court of Appeals for the Federal Circuit dismissed the significance of the case in order to address the patent eligibility of DNA sequences and affirmed its previous holding.

Moreover, the majority argued that the structural definition of DNA sequences, focused on chemical molecule, was a better description than the one based on function: "We recognize that biologists may think of molecules in terms of their uses, but genes are in fact materials having a chemical nature and, as such, are best described in patents by their structures rather than their functions".[934]

The majority did not explain the grounds on which this preference should be given. It referred to the fact that "many different materials may have the same function (e.g., aspirin, ibuprofen, and naxopren)",[935] but overlooked that DNA sequences have different functions (largely unknown) and that the USPTO, in 2001, enacted new Utility Guidelines to address the problems related to the description of DNA claims and requested the claims to pass the specific, substantial and credible utility test, according to which the inventor must not indicate a speculative use of the invention, in order to have granted a patent.

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[931] ibid, 1380.
[932] ibid 1380.
[933] *Mayo Collaborative Services, et al. v. Prometheus Laboratories* 132 S.Ct. 1289 (2012).
[934] United States Court of Appeals for the Federal Circuit, *AMP, et al, v. Myriad Genetics*, et al., 16 August 2012, at 48. See also United States Court of Appeals for the Federal Circuit, *AMP, et al, v. Myriad Genetics*, et al., at 45.
[935] Supreme Court of the United States, *AMP, et al, v. Myriad Genetics*, et al., 13 June 2013, 133 S.Ct. 2107 (2013).

4.2.3 A New Settlement: *AMP* before the U.S. Supreme Court

The U.S. Supreme Court, finally, took on the task of settling whether isolated native DNA sequences should be deemed patent eligible under 35 U.S.C. § 101.

The Court did not align with any of the views expressed by the District Court's and Federal Court's judges, which focused on devising DNA sequences as "chemical molecules" or "information". It rather focused on the delicate balance that patent protection strikes.

Justice Thomas, who delivered the opinion of the court, first clarified that Myriad "did not create or alter any of the genetic information encoded in the BRCA1 and 2 genes",[936] but it contributed to locating the genes and identifying the sequences.

He, then recalled *Chakrabarty*, but it highlighted that the Myriad's patent claims directed to isolated DNA sequences "fell squarely within the law of nature" exceptions.[937]

Justice Thomas did not dwell on the "nature" of genes and DNA sequences, but on the form of the claims. In particular, he pinpointed that they were not "expressed in terms of chemical composition"[938] and did not "rely in any way on the chemical changes that result from the isolation of a particular section of DNA".[939] Conversely, the claims were focused on "the genetic information encoded in the BRCA1 and 2 genes".[940]

However, as cDNA sequences differed from natural DNA ones, since the intron regions had been removed, they were found patent eligible as *synthetic* products created in laboratories.

The Court, therefore, concluded that "a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated".[941] Nevertheless, the Court deemed cDNA patent eligible, as it results in an exons-only molecule that is not naturally occurring.

The judges did not linger over the nature of genes and DNA sequences, but looked at Myriad's claims, concluding that they were not expressed in terms of chemical composition nor do they rely on chemical changes that result from the isolation of a specific section of DNA. Conversely, they were focused on genetic information encoded in the BRCA1 and BRCA2 genes. As Parthasarathy illustrated, the Supreme Court did not tackle policy and "distributional concerns" related to gene patents.[942] The Court, rather, embraced a technical approach and claimed to apply the product of nature doctrine, as set forth in *Chakrabarty*. Its

[936] ibid.
[937] ibid 2117.
[938] ibid 2118.
[939] ibid.
[940] ibid.
[941] ibid 2109.
[942] Parthasarathy (n 888) 170-171.

decision, however, substantially reshaped the boundaries of the natural, which have been stabilized for decades by the practices of the USPTO and courts decisions following *Chakrabarty*.

On March 4, 2014 the USPTO issued a new guidance memorandum[943] titled "Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws Of Nature, Natural Phenomena & Natural Products",[944] superseding the June 13, 2013, memorandum and implementing a new procedure "to address changes in the law relating to subject matter eligibility under 35 U.S.C. § 101 in view of recent court decisions".[945]

In the guidance, the overall process to assess subject matter eligibility under 35 U.S.C. § 101 is set out and the examiners should consider whether a patent claim is "significantly different" from a judicial exception, such as a natural product or phenomenon, or not. Some factors weigh for and against patent eligibility. As far as nucleic acids are concerned, the memorandum clarifies that their patent eligibility assessment would be based only on whether "a product claim reciting something that initially appears to be a natural product" is *markedly different* in structure from naturally occurring products or not.[946] As *AMP* suggests, this evaluation relies considerably on how the structure of nucleic acids, such as DNA, is interpreted and defined: whether they are considered chemical molecules or carriers of information.

The influential historian of the life sciences[947] Hans-Jörg Rheinberger, together with other biologists,[948] noticed that "the spectacular rise of molecular biology has come about without a comprehensive, exact, and rigid definition of what a gene is".[949] In particular, Rheinberger illustrated that:

> "This claim can be substantiated for both aspects distinguishing the gene concept of molecular biology from that of classical genetics: the aspect of representing a material

[943] This comment and the following has been published in Emanuela Gambini, 'In the Aftermath of the 'Myriad Case' – Myriad is Denied Preliminary Injunction Against Ambry Genetics' (2014) 3 EJRR 407, 411-412.
[944] USPTO, Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws Of Nature, Natural Phenomena & Natural Products, 4 March 2014, available on the Internet at <http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf>.
[945] ibid.
[946] ibid 4.
[947] This long remark, together with the following citations, has been published in Emanuela Gambini, 'In the Aftermath of *D'Arcy v. Myriad Genetics Inc*: Patenting Isolated Nucleic Acids in Australia' (2016) 7(2) European Journal of Risk Regulation 451, 458.
[948] Fogle (n 458) 3.
[949] Rheinberger (n 433) 221.

entity, and that of being a carrier of information.[950] The meaning of both these notions has remained fuzzy and tied to the experimental spaces that the new biology was going to explore, from the identification of DNA as the hereditary material in bacteria in 1944 to the genome sequencing projects of the late 1980s".[951]

He pointed out that the gene is a "boundary object",[952] namely "an analytic concept of those scientific objects which both inhabit several intersecting social worlds (…) and satisfy the informational requirements of each of them".[953] Boundary objects, such as the atom in physics and the molecule in chemistry, he observed, are provided with "organizing power" in research fields and "are embedded in experimental operations".[954] Within molecular biology the "gene" underwent several shifts of meaning:

> "At the beginning, molecular genetics, with its set of biochemical practices and genetic manipulations, was characterized by switching from higher plants and animals to bacteria and phages as model organisms. First, it transformed its boundary object, the gene, into a *material physicochemical entity*. Second, it has made a unit endowed *with informational qualities* from the object. The first transformation provided a solution to the problem that classical genetics had with the stability of its units. The answer was: Genes consist of metastable macromolecules of such as nucleic acids. The second transformation provided a solution to the problem that classical genetics had with its units' mode of reproduction, and the connection between genotype and phenotype. The answer was: Nucleotide sequences and DNA in particular, can be replicated specifically and faithfully by virtue of the stereochemical properties of their building blocks".[955]

Understanding the gene as a "boundary object" accounts for the different views of the gene which molecular genetics endorsed and has become legally pivotal in order to argue about the very nature of DNA sequences and their patent eligibility in isolated/purified form.

However, the analysis of *AMP* further shows that the "genetic code" and "chemical molecule" have been used as conceptual ontological metaphors in the judicial discourse to

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[950] Sahotra Sarkar, 'Biological Information: A Skeptical Look at Some Central Dogmas of Molecular Biology' in Sahotra Sarkar (ed), *The Philosophy and History of Molecular Biology: New Perspectives* (Kluwer Academic Publishers 1996), 187.
[951] Rheinberger (n 433) 221.
[952] Susan Leigh Star and James R Griesmer, 'Institutional Ecology, Translations and Boundary Objects: Amateurs and Professionals in Berkeley's Museum of Vertebrate Zoology 1907-1939' 19 Social Studies of Science 387.
[953] ibid 393.
[954] Rheinberger (n 433) 220.
[955] ibid 221.

support and foster a particular definition and view of the gene and its patent eligibility. These two conceptual metaphors have also largely shaped and oriented the work of molecular biologists and geneticists throughout decades and are still influential in their fields, as chapter two has illustrated. The legal discourse has relied on these very influential scientific metaphors on the genome and DNA sequences to validate a view and a definition of the gene in order to solve the issues related to its patent eligibility in the U.S. patent law. The counter-narrative maintained by the plaintiffs, based on the metaphor of the genetic code, undermined the well-established view of the genes as chemical molecules embraced by the USPTO in the Utility Examination Guidelines.

Furthermore, it questioned the well-established sociotechnical imaginary life and nature linked to biotechnology. It pointed out in particular that, if the promotion of biotechnology in terms of products available to the public hinged on their patent eligibility, IPRs over DNA sequences did not contribute to fulfill the needs of patients and bring about a suitable future environment for American scientific research.

4.3 Canada and the Patents on the BRCA1 and 2 Genes

The STS scholar Parthasarathy showed that genetic medicine has developed in different ways in the last part of the twentieth century and that the divide largely hinges on "different health-care systems and approaches to commercialization in biomedical research and technology".[956] She focused her analysis on genetic testing for breast and ovarian cancer, comparing how the architecture of genetic testing[957] was built and devised in two national contexts, the United States and United Kingdom, which are dissimilar as to the provision of health care and the approach to university-industry relationships. In particular, she pointed out that, in the United States, genetic medicine grew in the context of a private health care system, in which the government was attempting, but not succeeding, to provide universal coverage through Medicare and Medicaid programs, aiming at offering health insurance to the poor and elderly. However, approximately 40 million people, at the time still, had inadequate or no insurance at all.[958]

The same kind of matters should be taken into account in order to explain how Myriad Genetics' patents have been challenged in Canada, but not before a patent court.

[956] Parthasarathy (n 888) 27.
[957] ibid 57-114.
[958] ibid 27.

In Canada, Myriad was granted four patents related to the BRCA1 and 2 genes and their testing by the Canadian Intellectual Property Office. On 10 October 2000, CIPO granted patents No. 2,196,797 and 2,196,790, which covered the BRCA1 gene and its mutations, and, on 3 April 2001, patent No. 2,196,795 on the diagnostic test.[959] Moreover, on 3 April 2001, the company was granted patent No. 2,239,733 on the BRCA2 gene sequences.[960]

Although the *Oncomouse* judgment by the Supreme Court of Canada, in 2002, clarified that higher life forms fell outside the definition of patentable invention, when the CIPO granted these patents to Myriad, it simply complied with a long-standing practice of granting patents on DNA sequences, which had never been questioned. CIPO issued quite broad patents to the company, but did not expect that they would spark social, institutional and political turmoil across the country in the next decade.

Myriad Genetics (Myriad) designed a strategic business model centred on gaining IPRs on the BRCA1 and 2 gene sequences (wild-type and mutated sequences) and the diagnostic methods to compare across several jurisdictions.[961]

In Canada, MDS Laboratories, a private Canadian-based diagnostic testing laboratory, was exclusively licensed as the sole provider of single mutation testing on 9 March 2000 and in the same year it began, together with Myriad, to offer its genetic testing services to provincial government officials who managed diagnostic centres.[962] At the time, however, genetic tests for BRCA1 and 2 genetic mutations were already offered, on a research basis, by several Canadian provinces to residents with a family history of multiple breast and ovarian cancer cases.[963]

As Gold and Carbone pointed out, these provincial government officials and the federal ministers of health, who are in charge of allocating the provincial budget on health care services, "soon realized that Myriad's commercialization model – of requiring patent samples to be collected, sent outside the country, and analysed using a methodology determined by Myriad and not health care authorities – not only represented a higher cost (three times the cost of the test already in use in Ontario) but also more importantly, a challenge to the way the province provided services".[964] Moreover, they were aware that any kind of settlement

[959] Canadian patents CA 2,196,790, CA 2,196,795, and CA 2,196,797; E Richard Gold and Julia Carbone, 'Myriad Genetics: In the Eye of the Policy Storm' (2010 Supplement) 12(4) Genetics in Medicine, S39, S43.
[960] Canadian patent CA 2,239,373; Gold and Carbone (n 862) S43.
[961] Matthew Rimmer, *Intellectual Property and Biotechnology: Biological Inventions* (Edward Elgar 2008) v, 188.
[962] Gold and Carbone (n 959) S50.
[963] ibid.
[964] ibid.

that they would agree upon with Myriad would establish the framework for future genetic services offered by provinces.[965]

The issue of accessibility of genetic tests, together with the sustainability of the new genetic medicine for the Canadian health care system, has been at the forefront of the national narrative over Myriad's IPRs over the BRCA1 and 2 genes and their related diagnostic products.

Canada, since the 1980s,[966] has set up a policy of biotechnology in order to foster one of the major industries in the country and the patent eligibility of DNA sequences have never been questioned by CIPO. However, these patents related to diagnostic genetic tests have prompted a political counter-narrative, according to which they would hinder the national health care system and affect the right to health of Canadian citizens.

The policy debate over Myriad's genetic tests took place, from the early to mid-1990s, in which provincial governments and, in particular Ontario and Saskatchewan, curbed health care expenditures and closed several hospitals.[967] These controversial choices evoked criticism from citizens, who called for major financial support to health care system. As a result, several commissions and advisory committees were established to set out recommendations on how to devise the future of Medicare in Canada.[968]

Gold and Carbone illustrated that, in 2000, MDS Laboratories and Myriad approached Ontario province's government officials (Ontario has the largest health care budget in Canada) and, by the end of the year, Ontario's Health Ministry's policy unit began a consultation with scientists and laboratory directors in order to address the concerns regarding their diagnostic services.[969] Since MDS and Myriad did not obtain any reply from the laboratory branches of Ontario's Ministry of Health after several months, in spring 2001 Myriad started to send cease-and-desist letters to Alberta, Quebec, Ontario and British Columbia, four provinces which were offering and carrying out BRCA1 and 2 gene testing, asking to comply with its IPRs by 18 June 2001.[970]

Ontario's Health Minister, Tony Clement, significantly, pinpointed that "predictive breast and ovarian cancer tests should be available to women who require them" and that neither the

[965] ibid S51.

[966] Under the National Biotechnology Strategy, named since 1998 Canadian Biotechnology Strategy, the preferred "product" frame for biotechnology has largely supported CIPO's long-standing practice of allowing the patentability of DNA sequences.

[967] Gregory P Marchildon, 'Canadian Medicare: Why History Matters' in Gregory P Marchildon (ed), *Making Medicare: New Perspectives on the History of Medicare in Canada* (University of Toronto Press 2012) 3.

[968] ibid.

[969] Gold and Carbone (n 959) S51.

[970] ibid.

payments to hospitals for providing these services nor the services offered by the hospitals themselves constituted infringements of Myriad's patent claims.[971]

It has been noticed that in his firm rejection of Myriad's claims, Ontario's Health Minister "was opening up the question of the validity of Myriad's Canadian patents".[972] Furthermore, Ontario's government officials were shifting the debate over genetic testing from the provincial level to the federal one, as Industry Canada deals with biotechnology policy and is in charge of the Patent Act.[973]

The debate triggered by Myriad's claims and business model was framed in terms of *access* to genetic mutation tests for patients and *sustainability*[974] of genetic medicine for the Canadian health care system. As Bryn William-Jones observed, the Canadian health care system, in the 1990s, was falling short in providing "comprehensive and timely genetic testing and counselling for hereditary breast and ovarian cancer" and Ontario was one of the provinces which were attempting to expand the number of laboratories providing this kind of testing.[975]

Moreover, the standard of care, as far as genetic testing was concerned, was notably below the United States' one, since Canadian hospitals were able to offer testing for only 120 genetic diseases, while in U.S. more than 600 tests were available.[976]

Facing a strong reaction from Myriad and the threat of trade sanctions from the U.S. Ambassador to Canada, Clement took the position that the federal government should consider revising the Patent Act with regard to the patentability of genes.[977]

He organised, in December 2001, a wide roundtable in Toronto to debate genetic testing and, in January 2002, the Ministry of Health and Long-Term care published a report entitled *Genetic Testing and Gene Patenting: Charting New Territories in Health Care*,[978] in which they called for the assessment of new health technologies and suggested that the government

[971] ibid.
[972] ibid.
[973] Ibid.
[974] Vandna Bhatia and Michael Orsini, 'Narrating Sustainability in Canadian Health Care reform Discourse' (2016) 50(3) Social Policy and Administration 297.
[975] Bryn William-Jones, 'History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing' (2002) 10 Health Law Journal 123, 141.
[976] Richard Gold, Timothy A Caulfield and Peter N Ray, 'Gene Patents and the Standard of Care' (2002) 167(3) JAMC 256, 257.
[977] Gold and Carbone (n 959) S51.
[978] Ontario Ministry of Health and Long-Term Care, *Genetic Testing and Gene Patenting: Charting New Territories in Health Care* (Ontario Ministry of Health and Long-Term Care 2002).

had to limit the negative impact of gene patents over the health care system.[979] The Report was backed by all Canadian provincial leaders.

In the meanwhile, Industry Canada's Patent Policy Directorate did not consider any of the concerns over gene patents and did not put forward any clear proposal to solve the controversy.[980]

After 7 years, Myriad, finally, renounced to enforce its IPRs in Canada against provinces and the federal government and decided to invest more in the U.S. as a more profitable market.[981]

Also the CIPO did not contemplate issuing new guidelines for the examination of patent claims covering DNA sequences. At present, the Canadian Intellectual Property Office's practice manual, at ch 17.02.04 clarifies that "biomolecules are chemical compounds, and claims to nucleic acids, polypeptides, proteins and peptides are therefore directed to statutory matter".[982] It is still, therefore, embracing an understanding and definition of genes and DNA sequences as chemical compounds and, as such, patentable inventions, even though this view has been challenged in later patent cases.[983]

However, this patent case that was never debated before a court has produced a shift in the way of imagining the benefits of IPRs over biotech products for Canadian society, making clear that they could also hinder the protection of the right to health.

4.4 Patenting Genes in Europe

Isolation and purification are technoscientific laboratory practices which have acquired legal relevance in patent systems in order to demarcate, as far as some biotech products are concerned, patent eligible matter from non-patent eligible ones. In the European Community, they were set out in the *European Directive 98/44/EC of the European Parliament and the Council of 6 July 1998 on the legal protection of biotechnological inventions* ("Biotech Directive").

Article 5.1 of the Directive establishes limits to the patentability of the human body and gene sequences, as it provides: "The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or

[979] Gold and Carbone (n 959) S52.
[980] ibid S53.
[981] ibid S54.
[982] CIPO, *Manual of Patent Office Practice* (MOPOP), (Ottawa-Gatineau, 1998 Edition), last update April 2017, at ch. 17.02.04.
[983] *Children's Hospital of Eastern Ontario v. Transgenomic, Inc*., which was settled on 9 March 2016; *Monsanto Canada Inc v Schmeiser* [2004] 1 S.C.R. 902, 2004 SCC 34.

partial sequence of a gene, cannot constitute patentable invention".[984] Article 5.2, however, limits the boundaries of these exclusions, by establishing the criteria of *isolation* and *purification* (also referred to in Recitals 20 and 21): "An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element".[985]

Although the European Community (at present European Union) and EPOrg are formally independent supranational institutions, on 16 June 1999, by a resolution of the EPOrg's Administrative Council, the articles of the Biotech Directive became effective as Rules 23(b)-(e) of the EPC Implementation Regulation, on 1 September 1999. The implementation of Directive has been justified in terms of a uniform, harmonized European approach to biotech patenting.[986] However, its implementation has raised criticism as it should have entailed a Diplomatic Conference.[987] As a result, isolation and purification were set out in Rule 23(e)(2) EPC, at present Rule 29(2), which provided that "elements isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of the natural element".

These criteria operate within the EPC system as "criteria of *legal* and *ontological* surgery",[988] as they demarcate what is patent eligible from what is not and they determine also the legal and ontological status of things. The formal introduction of the criteria has established the rationale to legally demarcate naturally occurring DNA sequences from "artificial" isolated/purified ones.

The Boards of Appeal have settled patent cases regarding DNA sequences by affirming and applying adamantly these criteria and rejecting any opposition under Article 52(2)(a) EPC, which sets out that discoveries shall not be regarded as inventions.

Although EPO's Boards of Appeal decisions are marked by the use of technical language, the metaphor of the *code* and *chemical molecule* were drawn upon in order to argue against and for the patent eligibility of genes and DNA sequences.

[984] Article 5.1, Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, Official Journal of the European Communities, L 213/18, 30.7.98.
[985] Article 5.2, Directive 98/44/EC.
[986] Ingrid Schneider, 'Governing the Patent System in Europe: The EPO's Supranational Autonomy and Its Need for a Regulatory Perspective' (2009) 36(8) Science and Public Policy 619, 623.
[987] Christine Godt, *Eigentum an Information* (Mohr Siebeck 2007) V.
[988] This expression has been devised and employed by the STS scholar Mariachiara Tallacchini.

In T 0272/95, *Relaxin/Howard Florey Institute* case, which concerned the opposition to patent EP 0112149 entitled "Molecular cloning and characterization of a further gene sequence coding for human relaxin", on 23 October 2002 the TBA dismissed the appeal against the Decision of the Opposition Division and confirmed the validity of the challenged claims. Two oppositions against this patent were filed in 1992 by a group of 26 individuals representing the Green group of the European Parliament and their president[989] on the following grounds: 1. lack of novelty under Article 54 EPC; 2. lack of inventive step under Article 56 EPC; 3. contrariety to *ordre public* and morality under Article 53(a) EPC; 4. the claims should not be regarded as inventions, but discoveries under Article 52(2)(a) EPC.[990]

In this case, the opponents contended that the claimed invention amounted to a *discovery* by applying the metaphor of the *code*, pointing out that: "The essence of the invention was the elucidation of the genetic sequence of the H2-relaxin gene. In simple terms, the proprietor has obtained a *code book* from the donors (the genetic material) and '*cracked the code*' (discovered the number and sequence of human relaxin genes".[991]

The Opposition Division held that the invention was not an exception to patentability, as it would not be universally considered as outrageous, arguing that "DNA is not life, but a chemical substance which carries genetic information and can be used as an intermediate in the production of proteins which may be medically useful".[992]

The TBA implicitly endorsed this view applying the criterion of isolation in order to define the nature of the invention. The TBA maintained that the challenged claims concerned either "biological material originating from the human body"[993] which was isolated or DNAs encoding the human protein prorelaxin or the protein per se which resulted from technical processes[994] and, therefore, concluded that they fell within Rule 23(e)(2).[995] Consequently, they could not be qualified as "discoveries".[996] Moreover, by drawing on the criterion of isolation and the technical nature of the invention,[997] the TBA also quickly dismissed any objection in terms of contrariety to *ordre public* or morality.[998]

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[989] T 0272/95, *Relaxin/Howard Florey Institute*, Decision of the Technical Board of Appeal 3.3.4, 23 October 2002, 1.
[990] ibid 2.
[991] ibid 4-5.
[992] Decision of the Opposition Division dated 8 December 1994, *Relaxin/Howard Florey Institute*, (1995) 6 OJ EPO 388, 400, at 6.3.4.
[993] T 0272/95 (n 989) 10.
[994] Luigi Palombi *Gene Cartels: Biotech Patents in the Age of Free Trade* (Edward Elgar 2010) v, 242.
[995] T 0272/95 (n 989) 11.
[996] ibid.
[997] Sterckx and Cockbain (n 739) 122.
[998] T 0272/95 (n 989) 11.

As Bently and Sherman noticed, the *Relaxin* case shows the reluctance of the EPO's Opposition Division (and TBA) to tackle ethical issues: they both favoured the "scientific understanding of DNA as chemicals"[999] and rejected their characterization as information and "life", which would have requested a more burdensome analysis of the ethical objections.

The same kind of approach has been resorted to in the cases arising from the opposition to Myriad's European patents on the BRCA1 and 2 genes.

The history of Myriad's patents on BRCA1 and 2,[1000] granted by the European Patent Office, and how they were challenged is complex. One of the patents, EP 0705902, regarded "17q-Linked breast and ovarian cancer susceptibility gene" and had the same content of the abstract of EP 0699754 on "Method for diagnosing a predisposition for breast and ovarian cancer" (granted on 10 January 2001).[1001]

Moreover, on 8 January 2003, Myriad was granted EP 0785216 on "Chromosome 13-linked breast cancer susceptibility gene BRCA2", which was opposed by several groups and, in 2005, amended and limited in a highly questionable way to diagnosis of "predisposition to breast cancer in Askenazi-Jewish women".[1002]

The patent, which referred to the mutations in the BRCA1 sequence, was granted on 28 November 2001, but was opposed by many organisations and individuals: Switzerland's Social Democratic Party, Greenpeace Germany, the French Institut Curie, Assistance Publique Hôpitaux de Paris, Institut Gustave Roussy, the Belgian Society of Human Genetics, and the Netherlands (represented by the Minister of Health), and others.

These organizations opposed both patents (EP 0705902 and EP 0699754) on the grounds that the claimed inventions lacked novelty, inventive step and industrial application. Moreover, they pointed out that the inventions were not disclosed sufficiently for a person skilled in the art. Along with more technical arguments challenging the validity of the patent, other ethical and policy issues were raised about the equity of patentability of gene sequences.[1003] In particular, some opponents claimed that these patents impaired national public health care systems in Europe.[1004]

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[999] Bently and Sherman (n 788) 115.

[1000] The patents involved are EP0785216 on BRCA2 gene, EP0699754 on "Method for diagnosing a predisposition for breast and ovarian cancer" and EP0705902, which refers to "17q-Linked breast and ovarian cancer susceptibility gene".

[1001] Mariachiara Tallacchini, 'Gene Patenting in Europe', forthcoming, 9.

[1002] Palombi (n 994) 312.

[1003] Tallacchini (n1001) 9.

[1004] Rimmer (n 961) 189.

Patent EP0705902 was amended in January 2005 as a result of the decisions in opposition proceedings of the Opposition Division[1005] and the Boards of Appeal[1006] (T-1213/05 *Breast and ovarian cancer/University of Utah*).

It has been illustrated that at the oral hearings in January 2005 Greenpeace and Dr Wilhelms argued that genes were not patentable discoveries and that the claimed invention consisted in the discovery of a link between a gene and a disease.[1007] The opponents, moreover, relied on the definition of DNA sequences, such as probes, as information and, hence, argued that they were not patent eligible as discoveries.

However, the Opposition Division dismissed the definition of the claimed subject matter, namely probes, as information,[1008] Conversely it pointed out that "The claimed probes cannot be reduced to a presentation of information"[1009] and "The facts that a link between the claimed probes, BRCA1 and breast cancer exists does not preclude the claimed probes to be patentable".[1010] The Division, therefore, ruled out that the sequence could be assimilated to a discovery of what could be found in nature. Moreover, it reaffirmed the *technical* nature of the invention, by upholding the criterion of isolation set out in Rule 23(e)(2) EPC.[1011]

Likewise, the TBA maintained and supported the criterion of isolation against any claim that the subject matter was not patentable under Article 52(2)(a) EPC, as the sequences of the probes occurred in nature and were, therefore, discoveries.[1012]

The Opposition division and the TBA endorsed a technical approach to the kinds of inventions that were challenged and avoided engaging in a thorough discussion on their nature. They mostly refrained from drawing on metaphorical expressions in addressing the

[1005] Interlocutory decision of the Opposition Division of the European Patent Office posted 19 September 2005 concerning maintenance of European patent No. 0705902 in amended form.

[1006] Decision of the Technical Board of Appeal 3.3.2 of 27 September 2007, T1213/05 *Breast and ovarian cancer/University of Utah*.

[1007] Sterckx and Cockbain (n 739) 125.

[1008] Interlocutory decision (n 1005) at 11.2.

[1009] ibid.

[1010] ibid.

[1011] ibid.

[1012] EPO, Boards of Appeal, T1213/05 (Breast and Ovarian Cancer/University of Utah) of 27.9.2007, <http://www.epo.org/law-practice/case-law-appeals/pdf/t051213eu1.pdf> at 44-45: "According to the case law of the Boards of Appeal (see decision T 272/95 of 23 October 2002), Article 52 (2) (a) EPC is to be interpreted in accordance with the implementing Rule 23e (2) EPC which states: '(2) An element isolated from the human body or otherwise produced by means of a technical process including the sequence or partial sequence of a gene may constitute a patentable invention, even if the structure of that element is identical to that of a natural element'. Claims 1 to 3 relate to nucleic acid probes comprising partial DNA sequences of the human BRCA1 gene, which are described in the patent in suit as having been obtained by *technical processes* […]. These probes are thus *isolated elements of the human body* as defined in Rule 23e(2) EPC and thus patentable subject matter. Accordingly, the subject-matter of claims 1 to 3 does not fall within the category of inventions which may not be patentable as being discoveries (Article 52 (2) (a) EPC)".

patent eligibility of DNA sequences, a discursive approach which marks the EPO's narrative in comparison to U.S. and Canadian courts' ones.

However, in the BRCA1 and 2 cases, their narrative discourse aimed at technically upholding the settled criteria of patent eligibility and patentability.

Sigrid Sterckx and Julian Cockbain pointed out that in all the major cases[1013] regading the patent granted to University of Utah (Myriad) on the BRCA1 and 2 genes the Boards' decisions were based on reaffriming the criteria of isolation and purification and the technical character of the claimed invention[1014] and mostly maintained the patents in an amended form. In this respect, they followed the approach devised in the Relaxin case.

However, the way in which the strong opposition to these patents has been handled by the EPO Boards conveyed the idea that the EPO system, as a whole, was sound and embedded the procedural and judicial resources, under Article 100 EPC, to revoke patent claims that did not fulfill the patent requirements. The discourse unfolded in these decisions conveyed the implicit assertion of the adequacy of the EPC system to address any kind of problem arising from questionable patented inventions and resulted in the overall legitimization of the Boards' technocratic work of re-assessment.

4.5 Patenting Genes in Australia: *D'Arcy v. Myriad Genetics Inc*.[1015]

Likewise in Australia, patenting genes and DNA sequences has been at the forefront of public debate since Yvonne D'Arcy ("D'Arcy"), a former breast cancer patient, and a cancer patients' advocacy group named Cancer Voices Australia started revocation proceedings before the Federal Court of Australia.[1016] They questioned the validity of claims 1, 2 and 3 of Australian Patent No 686004, granted to Myriad Genetics in 1990 and regarding "in vivo mutations and polymorphisms in the 17q-linked breast and ovarian cancer susceptibility gene", as the invention should not be considered patentable under s 138 of the *Patents Act.*

The patent eligibility of isolated genes and DNA sequences has been settled in 1995 with the decision on *Kirin-Amgen Inc. v. Board of Regents of University of Washington*.[1017] Following

[1013] T1213/05.
[1014] Sterckx and Cockbain (n 739) 124-128.
[1015] Most of the concepts and analysis set out in this section has been published in the following article: Emanuela Gambini, 'In the Aftermath of *D'Arcy v. Myriad Genetics Inc*: Patenting Isolated Nucleic Acids in Australia' (2016) (7) 2 European Journal of Risk Regulation 451.
[1016] Federal Court of Australia, *Cancer Voices Australia and Another v Myriad Genetics Inc and Another*, 15 February 2013, [2013] FCA 65, 99 IPR 567.
[1017] *Kirin-Amgen Inc. v. Board of Regents of University of Washington* (1995) 33 IPR 557.

it, the Australian Patent Office granted a number of patents on isolated DNA sequences and this practice was well-established when Ms D'Arcy challenged one of Myriad's patents.

Whereas Justice Nicholas of the Federal Court of Australia and, then, Full Court of the Federal Court of Australia deemed that isolated nucleic acids constituted "an artificial state of affairs" and were, therefore, patentable subject matter, the High Court disagreed.

The Full Court of the Federal Court upheld Justice Nicholas' judgement and largely relied its opinion on the tenet of the U.S. Courts of Appeals' for the Federal Circuit decision in *AMP*, fully embracing the metaphor of the *chemical molecule*. In particular, the Full Court contended that isolation entailed *chemical*, structural and *functional* changes in naturally occurring polynucleotides, which were removed from the cell[1018] and concluded in favor of the validity of the patent.[1019]

In contrast with the Full Court's adjudication, the justices of the High Court endorsed the view that *genes are information*, hence the metaphor of the *code*. Although they shared the same perspective on the nature of the genes, their opinions focused on different legal and policy issues.

Under Section s 18(1)(a) of the Australian *Patents Act* 1990 an invention, in order to be patentable, shall be "an invention that, so far as claimed in any claim: Is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies". [1020] The Dictionary in Sched 1 to the *Patents Act* 1990 provides the definition of "invention", which is "any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the Statute of Monopolies, and includes an alleged invention".[1021] However, the implementation of the 17th century Statute of Monopolies has proved more complex in the last century for patent courts, as patents were applied and granted on new technological products and methods, which question the meaning and scope of "manner of manufacture" under it.

In the development of Australian patent law, *National Research Development Corporation v Commissioner of Patents* ("*NRDC*") has been the landmark case which fostered the accommodation of new products and processes within the locution "a manner of manufacture" set out in section 6 of the old Statute of Monopolies. In *NRDC*, which was adjudicated in 1959 and concerned a method involving the use of two known chemical compounds for new

[1018] Full Court of the Federal Court of Australia, *D'Arcy v Myriad Genetics and Another* [2014] FCAFC 115, 107 IPR 478.
[1019] ibid.
[1020] Australian *Patents Act* 1990 (Cth), s 18(1)(a).
[1021] The *Patents Act* 1990, Sched 1, definition of "invention".

herbicidal purposes,[1022] the High Court set out the rationale to assess whether a claimed invention is a "manner of manufacture". According to the Court, two elements were relevant in finally considering the patent valid, as regarding a product, namely because it consisted in *an artificially created state of affairs* and its *significance* was economic. [1023]

Following this decision, the expression "artificially created state of affairs of economic significance" has been largely deemed to provide the definition of "a manner of manufacture", in Australian case law.

The majority pointed out that the primary judge and the Full Court characterized very narrowly the effect of *NRDC* and that determining what is "a manner of manufacture" mandated a case-by-case analysis.[1024]

Moreover, they argued that part of IP scholarship and jurisprudence highlighted that there was no consensus on continuing to expand the scope of patent eligible matter "into all fields of endeavour so as to remove all the remaining fetters on patentable subject matter".[1025]

The majority illustrated that other factors might be relevant in addressing whether the invention was a manner of manufacture[1026] and policy considerations could play a part in it.[1027]

The majority, significantly, rejected the narrative carried out in *Chakrabarty*, according to which "anything under the sun that is made by man" is patentable. Conversely, it showed awareness of the responsibility involved in the court's task of developing a broad statutory concept,[1028] which required a more careful consideration of any enlargement that could have a significant impact on the Australian patent system.

It questioned Myriad's main argument, centered on the characterization of the claims as directed to a class of chemical compounds[1029] and argued that the invention referred to a sequence of nucleotides that, "in a cellular environment, can ultimately be translated into the BRCA1 polypeptide".[1030] Furthermore, the majority noted that this isolated information was

[1022] Stephen Hubicki and Brad Sherman, "We Have Never Been Modern: the High Court's Decision in *National Research Development Corporation v Commissioner of Patents*" in Andrew T Keyton, Megan Richardson and Sam Ricketson (eds), *Landmarks in Australian Intellectual Property Law* (Cambridge University Press 2009) 73.
[1023] *National Research Development Corporation v Commissioner of Patents*, (1959) 102 CLR 252, 277.
[1024] High Court of Australia, *D'Arcy v. Myriad Genetics Inc. and another* [2015] CLR 334, 348.
[1025] *D'Arcy* (n 1024) 348.
[1026] ibid 351.
[1027] ibid 348.
[1028] ibid 349.
[1029] ibid 350.
[1030] ibid 371.

the same embodied information "contained in the DNA of the person from which the nucleic acid was isolated",[1031] namely the essential and valuable element of the invention.

It observed, in addition, that Myriad did not express the claims in terms of chemical composition and, therefore, concluded that its definition of the claims elevated "form over substance to the detriment of the developmental function entrusted to the Court as explained in *NRDC* and reflected in the continuing use of the 'manner of manufacture' formula in s 18(1)(a) of the Act".[1032]

The majority, consequently, held that the subject matter of the claims, as genetic information, lied "at the boundaries of the concept of 'manner of manufacture'".[1033] In the opinion, the majority focused, in particular, on the risk of a chilling effect on innovative activity of legitimate improvers and inventors due to the patenting of a large amount of nucleic acids, embedding information.[1034]

The IP scholar Brad Sherman[1035] remarked that "the process of determining whether subject matter is patent-eligible is essentially an exercise of labeling, classifying, and categorizing".[1036] *D'Arcy*, as much as the U.S. and EPO cases regarding Myriad's patents show that this effort has been carried out by the courts, scientific experts, patent lawyers and offices by drawing on conceptual metaphors which oriented how the scope of patentable subject matter has been envisaged and designed. The courts' endorsement of the genetic *code* rather than the *chemical molecule* as an alternative metaphor to define genes and DNA sequences has sustained the re-framing of patent eligible matter in the U.S. and Australia where the strategy of the plaintiffs aimed at narrowing down the constant expansion of patent protection to any kind of valuable information.

Moreover, even though in Australia *NRDC* has expanded the scope of "manner of new manufacture" and encouraged the development of new technological products, the narrative of the High Court and the metaphor of the genetic code undermined the master narrative according to which patents on DNA sequences could promote scientific research and benefit society.

[1031] ibid 371.
[1032] High Court of Australia, *D'Arcy v Myriad Genetics Inc*, 7 October 2015, [2015] HCA 35, 115 IPR 1, 41.
[1033] ibid 372.
[1034] ibid 372.
[1035] This point has been illustrated in Emanuela Gambini, 'In the Aftermath of *D'Arcy v. Myriad Genetics Inc*: Patenting Isolated Nucleic Acids in Australia' (2016) 7(2) European Journal of Risk Regulation 451, 458.
[1036] Brad Sherman, '*D'Arcy v Myriad Genetics Inc*: Patenting Genes in Australia' (2015) 37 Sydney Law Review 135, 136. This comment has been published in Emanuela Gambini, 'In the Aftermath of *D'Arcy v. Myriad Genetics Inc*: Patenting Isolated Nucleic Acids in Australia' (2016) 7(2) EJRR 451, 458.

4.6 Conclusions: Imagining Property, Imagining Nature and Life

Several scholars have been engaged in probing how the gene became a chemical molecule or information.[1037] The analysis of the patent cases regarding the BRCA1 and 2 genes, carried out in this chapter, has shown how the boundaries of the natural and artificial have been shaped and reshaped by resorting to different, alternative, definitions of what genes and DNA sequences are, centered on conceptual metaphors, which were devised within molecular biology and genetics and became legal and social means to make sense and order of new technoscientific products, such as isolated genes.

Narratives and counter-narratives, however, have proved likewise crucial in order to sustain judicial decisions and arguments, scientists' and patent examiners' practices, activists' and patients' legal action, as they make a particular definition credible and acceptable within a national context and patent system.[1038]

Stephen Hilgartner, in examining how genome research has been creating new forms of property and simultaneously large quantities of data in the public domain, has showed that making knowledge and making intellectual property are not two separate moves, institutionally and temporally.[1039] He argued, conversely, that, in order to understand the creation of intellectual property, the laboratory, as much as the law, is a site in which appropriation mechanisms are institutionalized in specific research contexts.[1040]

This chapter explained how the laboratory and the law are expert sites which created a specific kind of semantics of appropriation, centered on conceptual metaphors, which backed the patent eligibility of biotech products in different national contexts, as well as technoscientific imaginaries of life and nature. This semantics results from the co-production of technoscientific and legal language which, by sustaining the patent eligibility of DNA sequences, also fosters a specific mode of repreesenting, defining and using life and nature.

Metaphors oriented patent examiners' and judges' decisions regarding the patentability of several kinds of biotech products, in different legal contexts, as far as their description as "patentable subject matter" or "invention" is concerned. Metaphors such as "molecule" and "genetic code" have been collectively endorsed and became part of a sociotechnical

[1037] Calvert and Joly (n 52) 157; Matthew Cobb, '1953: When Genes Became 'Information'' (2013) 153 Cell 503;Matthew Cobb, *Life's Greatest Secret: The Race to Crack the Genetic Code* (Profile Books 2016) xiii; Michel Morange, *Life Explained* (Yale University Press 2008) viii; John Maynard Smith, 'The Concept of Information in Biology' (2000) 67(2) Philosophy of Science 177.

[1038] Duncan Matthews, 'The Right to Health and Patents' in Christoph Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2015) 496; Matthews (n 248) 38.

[1039] Hilgartner (n 49) 131.

[1040] ibid.

imaginaries of life, which shaped the way in which molecular biologists and geneticists oriented methodologically and epistemically their research, how patent systems and their actors accommodated several biotech products as patent eligible and how individuals and collectivities redefined their identities.

Sociotechnical imaginaries are "collectively imagined forms of social life and social order reflected in the design and fulfillment of nation-specific scientific and/or technological projects".[1041] Their relevance as cultural resource lies in their descriptive and, at once, prescriptive dimension, in their conveying a specific description of an attainable future and prescribing that it ought to be pursued and achieved: "They project visions of what is good, desirable, and worth attaining for a political community; they articulate feasible futures. Conversely, imaginaries also warn against risks or hazards that may accompany innovation if it is pushed too hard or too fast. In activating collective consciousness, imaginaries help create the political will or public resolve to attain them".[1042]

They can provide, therefore, an analytical resource to understand how policies of innovation are promoted and justified in terms of "what constitutes public good"[1043] by political, administrative and judicial institutions, but also by citizens, scientific communities, experts, NGOs.

Through their practices and decisions, patent offices, as well as judges, endorse and foster sociotechnical imaginaries of innovation, progress and public good, as much as political institutions. A closer examination of the metaphors, which were introduced and used in these landmark patent cases in order to affirm or challenge the patent eligibility of some products concerning life, suggests that they have fostered a molecular and atomistic view of life, which results from the co-production of science, law and society. This vision has informed and shaped the definition of "patentable subject matter" and "invention" in the last decades and has impinged on the definition of individual and collective identities. Patents on products in the field of biotechnology and molecular diagnostics, such as isolated DNA sequences, embed a molecular description of life which support and purport bodies and identities ought to be understood in molecular terms. Human beings have become aware that they can carry mutations of the BRCA1 and 2 genes and are, therefore, "molecular patients" who should undergo diagnostic tests and make fundamental decisions about their health and lives. Groups

[1041] Jasanoff and Kim (n 423) 120.
[1042] ibid 123.
[1043] Jasanoff and Kim (n 427) 2.

gained awareness of being at risk of developing breast and ovarian cancer in the future and of the need to have access to adequate and affordable molecular diagnostic tests.

The patent cases regarding the BRCA1 and 2 genes pinpoint that, although the process of molecularisation has already affected identities and oriented collective sociotechnical imaginaries of life, it can be also challenged if it fails in projecting a collective vision of "what is good, desirable, and worth attaining for a political community".[1044]

The molecular sociotechnical imaginary has consistently oriented the legal reasoning of judges and their doctrinal choices, as well as the practices of patent examiners, in defining and deciding patent eligibility. Nevertheless, this imaginary has been questioned and undermined in the cases regarding the BRCA1 and 2 genes by several communities of clinicians, geneticists and patients under the aegis of the metaphor of the code: genes encode information. This metaphor has been, partially, endorsed by judges and will re-orient the future sociotechnical imaginary of intellectual property.

[1044] Jasanoff and Kim (n 423) 123.

Chapter Five

Intellectual Property Rights on Biotech Plants and Seeds

5.1 Kinds of Artificiality: Plant Breeding's Narratives and Intellectual Property

Plant breeding has been the focus of the narratives on biotechnology in order to sustain and prove its seamless development throughout the centuries or its rift with the advent of rDNA technologies and genetic engineering. As it has been illustrated in chapter two, biotech narratives of continuity firmly hinge on crop improvement as a biotech multimillennial human activity as old as agriculture,[1045] whereas narratives of novelty rest upon the development of rDNA techniques for industrial purposes as a qualitative break within biotechnological conventional methods of genetic manipulation, such as selection and crossing.

The U.S. OTA, in the report entitled "Commercial Biotechnology: An International Analysis" offers an expansive definition of biotechnology as "any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses".[1046] This definition encompasses any kind of human technique of production and/or alteration of living organisms for practical purposes. As far as plant breeding is concerned, its techniques entail making natural history and evolution, at least to a certain extent. However, as the report points out, several novel technologies, such as rDNA and cell fusion, improved in the 1970s and early 1980s, allowed more control over biological systems and overcoming several natural barriers, namely interspecific and sexual reproduction barriers. Both recombinant DNA transfer and cell fusion enable, in fact, "direct manipulation of the genetic material of individual cells".[1047]

These technologies involve a higher degree of specificity in the modification of living organisms in comparison to other conventional techniques.[1048] They have been deemed, therefore, to open up a new, more rapid and extensive way to "outdo evolution", as the molecular biologist David Baltimore declared.

[1045] Mark D Janis, Herbert H Jervis and Richard Peet, *Intellectual Property Law of Plants* (Oxford University Press 2014) vii, 11-13.

[1046] U.S. Office of Technology Assessment, *Commercial Biotechnology: An International Analysis* (Washington, D. C.: U.S. Congress, Office of Technology Assessment, OTA-BA-218, January 1984) vi, 3.

[1047] ibid 4.

[1048] Jack R Kloppenburg Jr, *First the Seed: The Political Economy of Plant Biotechnology, 1492-2000*, (The University of Wisconsin Press 2004) vii, 3.

In this chapter, it will be examined how these contrasting narratives, along with frames and metaphors, have been employed in several landmark patent cases in order to support specific definitions of the kind of artificiality which marks patent eligible inventions and their scope. Moreover, this chapter will illustrate that the co-production of the technoscientific and legal metaphorical discourse has validated a semantics of artificiality regarding the definition of patented GM seeds and plants has promoted sociotechnical imaginaries of life as an artificial chattel.

5.2 Seeds as "Reproductive Technologies": the "Bowman Case" in the United States

Seeds are peculiar objects of intellectual property, since they are together *products* and *means of production*, as they can reproduce. According to the Oxford Dictionary, the seed is "the typically small roundish structure by which certain higher plants reproduce and disperse themselves, which develops from a fertilized ovule and consists of an embryo plant and (often) nutritive endosperm enclosed in a protective coat".[1049]

As Kloppenburg Jr. illustrated, although seeds are biologically "*unstable* as a commodity-form" [1050] because of their biological specificity, they have been turned stable by technological and legal means. He refers to the process of commodification of the seed which started, in the U.S., with the funding of the agricultural sciences and led to the production of hybrid seeds. This process has allowed the *separation* of the product from the means of production: as "the progeny of hybrid seed cannot economically be saved and replanted, it has use-value and exchange-value only as grain, not as seed".[1051] Farmers planting hybrid seeds cannot reproduce them and, consequently, need to buy seeds each year. The reason why a farmer cannot save seeds from the previous hybrid seeds crop and plant them the following year, as Janis, Jervis and Peet explained, is that "the seed produced by a hybrid plant does not exhibit the same degree of phenotypic uniformity as the F_1 parents".[1052] In order to plant seeds which have the same "consistent performance" [1053] of F_1 hybrids, farmers must, therefore, buy seeds again from hybrid seeds suppliers, who try to keep the inbred parental lines (which breed true and can be easily propagated)[1054] under trade secret[1055] to prevent competitors from obtaining easily hybrid seeds.

[1049] Headword "seed" 1.b, *Oxford English Dictionary*.
[1050] Kloppenburg (n 1048) 11.
[1051] ibid.
[1052] Janis, Jervis and Peet (n 1045) 29.
[1053] ibid.
[1054] ibid.
[1055] Kloppenburg (n 1048) 11.

This process of commodification has been expanded and further accomplished with the production of transgenic seeds and plants. rDNA technology, together with protoplast fusion and cloning, has improved and increased the possibilities of genetic modification of seeds and plants. It has been pointed out that these technologies are advantageous in comparison to conventional breeding: whereas conventional breeding hinges on whole organisms, these technologies intervene at the molecular level;[1056] moreover, while the former rely on sexual means in order to achieve a genetic alteration, the latter allow bypassing sexual reproduction and breaching the "walls of speciation" [1057] by transferring genes across unrelated organisms.[1058]

This biological "double nature" of the seeds has been at the heart of several patent infringement cases concerning transgenic seeds, in which the courts' decisions implicitly downplayed its significance and, conversely, pinpointed the artificial nature of seeds by referring to them metaphorically as "reproductive technologies".

In this section, it will be argued that the process of commodification of seeds, which has been legally endorsed by these judicial decisions, has drawn on metaphors which largely affirmed the artificial nature of seeds and plants, condidering them analogous to *chemical compounds* or *machines*. In this respect, the process of their *commodification* coincides with the process of their *de-naturalization*[1059] through a constant definition of plants and seeds resorting to metaphors of artificiality.

Vernon Hugh Bowman v. Monsanto Company et al. ("*Bowman*"),[1060] which was decided by the U.S. Supreme Court, on the 13 May 2013, constitutes one case which shows how intellectual property contributed to re-shape and re-define the "nature" of the seed, by fostering it as a *product*, a "reproductive technology", whose intellectual property and control is totally vested on the patentee.

The Bowman case concerns a lawsuit for patent infringement brought by Monsanto Company against Vernon Hugh Bowman, a farmer in Knox County, Indiana. Monsanto alleged that he infringed two of Monsanto's patents on Roundup Ready® transgenic soybeans: claims 1,2,4 and 5 of U.S. Patent No. 5,352,605 ("*'605 Patent*")[1061] and seventeen claims of Patent No.

[1056] ibid 2-3.
[1057] ibid 3.
[1058] ibid.
[1059] Emanuela Gambini, 'The Seeds of Dispute. The Doctrine of Patent Exhaustion in the '*Bowman* Case'', in Fernando Leonini, Mariachiara Tallacchini and Matteo Ferrari (eds) *Innovating Food, Innovating the Law* (Libellula 2014) 345.
[1060] *Vernon Hugh Bowman v. Monsanto Company et al.* 569 U.S. 1 (2013).
[1061] Monsanto alleged infringement of claims 1, 2, 4, 5 of the '605 Patent.

RE39,247E ("*'247E Patent*").[1062] Both patents regarded the development of Roundup Ready® transgenic soybeans, which are marked by resistance to N-phosphonomethylglycine, which is commonly named as "glyphosate".

The first patent was granted to Monsanto by the USPTO in 1994 and concerned "chimeric genes for transforming plant cells using viral promoters". Monsanto's invention consisted in employing viral nucleic acids from the cauliflower mosaic virus (CaMV) as a vector to alter genetically plant cells by inserting a chimeric gene. The second patent was reissued by the USPTO, on 22 August 2006, and involved glyphosate-tolerant 5-enolpyruvylshikimate-3-phosphatesynthases (EPSPS).

Bowman purchased from Pioneer Hi-Bred, one of Monsanto's licensed seed producers, Roundup Ready® transgenic soybeans from 1999 to 2007 and planted them as first-crop seeds.[1063] When he purchased the seeds, Bowman signed a Monsanto Technology Agreement, according to which he agreed not to save seeds from the crop.[1064] Although he complied with this clause of the agreement, Bowman bought commodity seeds from Huey Soil Service, a local grain elevator, in order to plant them as second-crop.[1065] In 1999 he sprayed glyphosate-based herbicides in the fields to ascertain whether the plants resulting from the commodity soybeans were glyphosate resistant.[1066] Since most of the resulting plants exhibited glyphosate resistance, he decided to purchase these seeds in the following years for his second crops and then apply to them the glyphosate herbicide.[1067]

Between 2006 and 2007, Monsanto began to investigate eight of Bowman's fields and ascertained that his second-crop soybean seeds embedded the patented Roundup Ready® technology. Consequently, on 12 October 2007, Monsanto sued Bowman before the Southern District Court of Indiana.

Bowman raised, as a defense before the District Court, the doctrine of patent exhaustion, claiming that "*when the soybeans from a licensed Roundup Ready crop are harvested and sold to a grain elevator or dealer, they are sold without restriction, mixed with all other soybean crops and, therefore, when purchased and used by farmers to plant as seed (commodity soybeans) for another crop, they are not protected by patent*".[1068]

[1062] Monsanto alleged infringement of seventeen claims of the '247E Patent. See U.S. Patent No. RE39,247E,.
[1063] *Monsanto Company and Monsanto Technology LLC v. Vernon Hugh Bowman* 657 F.3d 1341 (2011), 1345.
[1064] ibid.
[1065] ibid.
[1066] ibid.
[1067] ibid.
[1068] *Monsanto CO. v. Vernon Hugh Bowman*, 686 Federal Supplement, 2d Series, 834, 836.

He disputed the constitutionality of allowing Monsanto to threaten patent infringement against anyone planting Roundup Ready® transgenic soybeans, irrespective of the way in which seeds came into his possession.

Moreover, he questioned how Monsanto's claims to patent protection over Roundup Ready® seeds were undermining the possibility to buy and plant cheaper commodity soybeans for farmers.

Conversely, Monsanto claimed that they invested a large amount of money and research efforts in developing an effective technology to grow soybeans glyphosate-resistant and, although the resulting beans belonged to the farmer, the technology embedded in the progeny belonged to Monsanto and should not be duplicated without its authorization.[1069]

Justice Young allowed that "the monopolizing effect of the introduction of patented genetic modifications to seed producing plants on an entire crop species" was a compelling policy argument, however, he deemed that the doctrine of patent exhaustion could not be applied as a defense in the case. He recalled that patent exhaustion was drawn upon in several patent infringement cases concerning Roundup Ready® seeds, namely *Monsanto Co. v. Scruggs* and *Monsanto v. McFarling*. In *Scruggs*, the farmer, as much as Bowman, relied on *Quanta Computer, Inc. v. LG Electronics, Inc.*, to support the patent exhaustion defense. Nevertheless, resorting to *Scruggs* and *McFarling*, he pointed out that "No unconditional sale of the Roundup Ready® trait occurred because the farmers could not convey to the grain dealers what they did not possess themselves",[1070] namely the right to plant the seeds. He, therefore, affirmed the patent infringement and granted compensatory damages to Monsanto amounting to $30,873.80.

On appeal, Bowman argued that the sales of the second-generation seeds to grain elevators and from these to farmers were authorized by Monsanto under the Technology Transfer Agreement and covered by the doctrine of patent exhaustion. Furthermore, he pinpointed that, since the seed is "a substantial embodiment of all later generations"[1071] the doctrine of exhaustion if it is interpreted in a "robust" way should cover the progeny of the seeds and other self-replicating technologies.

Monsanto contested this highlighting the conditional nature of the first sale to farmers, according to which should never be sold for planting.[1072]

[1069] ibid 837.
[1070] ibid 839.
[1071] *Monsanto* (n 1068) 1346.
[1072] ibid 1347.

The Court of Appeals disagreed that the only "reasonable and intended use for seeds" is to be planted and endorsed the argument in *Scruggs* that "The fact that a patented technology can replicate itself does not give the purchaser the rights to use replicated copies of the technology" and that "applying the first sale doctrine to subsequent generations of self-replicating technology would eviscerate the rights of the patent holder".[1073] It, therefore, upheld the decision, which was finally affirmed by the SCOTUS.

Whereas in other infringement cases involving patented Roundup Ready® transgenic seeds, the U.S. Supreme Court did not take on the issue of deciding upon the exhaustion of IPRs, in *Bowman* the Court showed its willingness to clarify that patent exhaustion could not be raised as a defense for using/making patented seeds.

Before SCOTUS Bowman claimed again the doctrine of patent exhaustion as main defense, arguing that "Monsanto could not control his use of the soybeans because they were the subject of a prior authorized sale (from local farmers to the grain elevator)".[1074]

Nard illustrated that according to the doctrine of patent exhaustion (also referred to as "first-sale doctrine") "the patentee is stripped of his rights *in the product* that embodies the claimed invention once he (or his licensee acting within the scope of his license) sells the product".[1075]

Its acknowledged rationale consists in restricting the control of the patent holder over a patented product or process, after an authorized sale has occurred, because the patentee has "presumably received consideration, which includes remuneration for the use and resale of the product".[1076]

In the Bowman case, as much as in other patent infringement cases involving Monsanto's Roundup Ready® patented seeds, the judges characterized the case as involving a "reproductive technology". Although this locution is largely employed within IP and the scientific community dealing with biotechnology as a kind of technology, is metaphorical. A technology is according to the Oxford English Dictionary: "a. The branch of knowledge dealing with mechanical arts and applied sciences; (…) b. The application of such knowledge for practical purposes, esp. in industry, manufacturing, etc.; the sphere of activity concerned with this; the mechanical arts and applied sciences collectively. (…) c. The product of such application; technological knowledge or know-how; a technological process, method or

[1073] ibid 1348.
[1074] *Bowman v. Monsanto Co. Et al.*, 13 May 2013, 133 S.Ct. 1761 (2013), 1765.
[1075] Craig Allen Nard, *The Law of* Patents (Wolters Kluwer 2017) ix, 671.
[1076] ibid 672.

technique. Also: machinery, equipment, etc., developed from the practical application of scientific and technical knowledge".[1077]

The definition focuses on the knowledge or result of mechanical or applied sciences, which can hardly be semantically connected to a reproducible biological "roundish structure by which certain higher plants reproduce and disperse themselves".[1078] Conversely, this definition should be regarded as a metaphorical oxymoron, since it pulls together opposite concepts, as the word "reproductive" refers to "of or relating to biological reproduction; bringing about reproduction in animals or plants. Also in an extended use".[1079]

Justice Kagan, who delivered the opinion of the court, first clarified the meaning and the rationale of the doctrine. She, then, pointed out that Bowman did not challenge the principle that "the exhaustion doctrine does not extend to the right to 'make' a new product".[1080] She, therefore, argued that this endorsement decided the case against him, as he could have used or resold the patented soybeans which he bought from the grain elevator without infringing the patents, but since he planted them and made "*additional* patented soybeans without Monsanto permission (either expressed or implied)",[1081] he clearly infringed.

In defining "make" as "cause to exist, occur or appear, or more specifically plant and raise a crop",[1082] the court concluded that Bowman's activities amounted to making a new product.

She, therefore, rejected Bowman's claim that "seeds are meant to be planted"[1083] and that "allowing Monsanto to interfere with that use would create an impermissible exception to the exhaustion doctrine for patented seeds and other replication technologies".[1084]

Justice Kagan's narrative followed consistently from *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.* ("*J.E.M.*"), which upheld *Chakrabarty*'s narrative of progress. She pointed out that the holding of the court stemmed from this decision, in which SCOTUS addressed whether inventors could be entitled to patents on seeds and plants or only certificates under the PVPA and considered the two legal form of protection not conflicting, but different, endorsing the patentability of transgenic plants and seeds.[1085]

[1077] Headword "technology", *Oxford English Dictionary*.
[1078] Headword "seed" 1.b, *Oxford English Dictionary*.
[1079] Headword "reproductive", *Oxford English Dictionary*.
[1080] *Bowman* (n 1074) 1766.
[1081] ibid.
[1082] ibid 1767.
[1083] ibid 1768.
[1084] ibid.
[1085] ibid 1767.

In that respect, the Bowman decision offered the seed industry the certainty of the *effectiveness* of the IP protection over seeds and plants, whose utility patent eligibility was settled judicially by the *J.E.M. Ag Supply*'s holding, as explained later in the chapter.

In assessing the use of the doctrine of patent exhaustion, the court did not regard significant the differences between biological products, like seeds, and other patentable products.

This approach proved to be coherent with the definition of seeds as "reproductive technologies", as referred to by the Supreme Court and is part of the ordinary way of defining transgenic seeds and plants in patent infringement cases. This definition has been largely endorsed and promoted also by the scientific community involved in biotechnology.

Commenting this decision, William Simons in *Nature Biotechnology* referred to seeds as "replicative biologic technologies".[1086] The adjectives "replicative" and "biologic" have been applied as labels to mark this kind of technology from others which are not. He pinpointed that the final decision of the Supreme Court relied on *Quanta Computer, Inc V. LG Electronics* a case of patent infringement concerning licensed microprocessors and chipsets, which upheld the first sale doctrine.[1087]

Resorting to the term "replicative" in comparison to "reproductive" weakens the differences between mechanistic and chemical inventions and biologic ones, but does not eclipse the fundamental difference among these kinds, namely that a seed can potentially *reproduce* itself, with and without human intervention.

Although this issue was not considered crucial by the U.S. Supreme Court, it will be raised in another patent infringement case, *Schmeiser v. Monsanto Canada Inc.*, in Canada.

Moreover, the Court dismissed as captious the argument raised by Bowman under the banner that "seeds are special",[1088] namely "that soybeans naturally self-replicate or sprout unless stored in a controlled manner",[1089] drawing the consequence that "it was the soybean, not Bowman himself that made replicas of Monsanto's patented invention".[1090] Justice Kagan, by contrast, pinpointed that "it was Bowman, not the soybean who controlled the reproduction (unto the eight generation) of Monsanto's patented invention".[1091]

The Supreme Court's decision, hence, handled the case as regarding a "reproductive technology", the same definition used by the courts in *Scruggs* and *McFarling* and referred to

[1086] William J Simmons, '*Bowman v. Monsanto* and the Protection of Patented Replicative Biologic Technologies' (2013) 31(7) Nature Biotechnology 602, 603.
[1087] ibid 605.
[1088] *Bowman* (n 1074) 1768.
[1089] ibid.
[1090] ibid 1768-1769.
[1091] ibid 1769.

by biotechnologists, which implies that transgenic seeds and plants do not significantly differ from other kinds of technologies, but for replication.

This definition assimilated biological entities to mechanical products and chemical compounds. This assimilation meant that the court did not have to engage with the distinctive feature of the seed, namely the fact that it is a product and means of production and can reproduce. Although seeds can be used as feed for animal or human consumption, their characteristic use entails a conflation of using and making and, therefore, entails a short circuit within the doctrine of patent exhaustion.

The judgment, however, is consistent with the watershed that was brought about, in the U.S. system of protection of plants and seeds, by *Ex Parte Hibberd* and, then, *J.E.M.* and will be explained in the next section.

As it has been observed,[1092] the decision in *Bowman* has been significant beyond the IP interests of the agribusiness market, since a contrary decision of the Supreme Court would have impaired the patent protection over molecular biologic inventions.

5.2.1 A Matter of Narratives[1093]

The significance of judicial narratives does not lie only in supporting adjudication in particular cases, but in sustaining enduring technoscientific imaginaries of life and nature. *Chakrabarty* has offered a stable narrative of the origins and progress centered on *continuity* which has impinged on defining the nature of plants and seeds and their patent eligibility in the U.S.

In the absence of specific rules providing that GM microorganisms, animals and plants were patentable under the U.S. Patent Act, the Courts, that must solve patent controversies, have taken up the task of deciding what is the nature of these things and whether they can fit the definition of patentable subject matter, according to Title 35 § 101 U.S.C. In that respect, the U.S. Courts have played a pivotal role in the policymaking of biotechnology since *Chakrabarty,* where the majority of the Supreme Court held that "*anything under the sun that is made by man*" is patentable.

Bowman confirms how thoroughly the Courts have shaped the ground for biotechnology agribusiness, stretching the borders of the definition of patentable inventions to encompass

[1092] William J Simmons, '*Bowman v. Monsanto* and the Protection of Patented Replicative Biologic Technologies' (2013) 31(7) Nature Biotechnology 602, 603.

[1093] Most of the arguments expressed in this section have been published in Emanuela Gambini, 'The Seeds of Dispute. The Doctrine of Patent Exhaustion in the '*Bowman* Case'', in Fernando Leonini, Mariachiara Tallacchini and Matteo Ferrari (eds) *Innovating Food, Innovating the Law* (Libellula 2014) 345, 357-367.

products that were never envisaged in the Patent Act, while pleading deference to the statutes.[1094]

Ex Parte Hibberd and *J.E.M.* represent the two decisive judicial steps towards the complete *de-naturalization* and *commodification* of seeds and plants in the U.S. intellectual property system.

In the U.S., the IP protection of plants and seeds proved difficult, since the 19th century, for several reasons.

The definition of patentable subject matter dates back to the 1793 Patent Act, which included "*any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement thereof*".[1095] Although in 1952 – when the Patent Act was codified – the word "*art*" was replaced by the word "*process*", the wording remained unchanged.[1096] The definition does not explicitly refer to life forms. In the 19th century, plants were considered to be patent ineligible under the Patent Act, but the rationale has been debated. Several scholars[1097] point out that they were considered to fall outside the scope of patentable subject matter, because of the "products of nature" patent exclusion settled, in 1889, in *Ex parte Latimer*.[1098]

In 1889 deciding on *Ex parte Latimer*,[1099] the U.S. Commissioner of Patents rejected a patent application claiming a fiber "consisting of the cellular tissues of *Pinus australis*".[1100] The Commissioner argued that the "the mere ascertaining of the character or the quality of trees that grow in the forest and the construction of the woody fiber and tissue of which they are composed is not a patentable invention, recognized by the statute, *any more than to find a new gem or jewel in the earth would entitle the discoverer to patent all gems which should be subsequently found*".[1101] The Commissioner's ruling has set out the "*product of nature*" doctrine, according to which products of nature, such as natural phenomena and laws, as well as abstract ideas, are not patent eligible, since their discovery does not entail any decisive human inventive act.

[1094] This concept has been expressed in Emanuela Gambini, 'The Seeds of Dispute. The Doctrine of Patent Exhaustion in the '*Bowman* Case'', in Fernando Leonini, Mariachiara Tallacchini and Matteo Ferrari (eds) *Innovating Food, Innovating the Law* (Libellula 2014) 345.

[1095] Section 1, Patent Act of 1793. 21 February 1793, Ch. 11, 1 Stat. 318-323.

[1096] Daniel J Kevles, *A History of Patenting Life in the United States with Comparative Attention to Europe and Canada*, A Report to the European Group on Ethics In Science and New Technologies, 12 January 2002, 1.

[1097] ibid 1-2. Janis, Jervis and Peet (n 1045) 244.

[1098] U.S. Commissioner of Patents, *Ex parte Latimer*, 12 March 1889, 46 O.G. 1638.

[1099] ibid.

[1100] ibid.

[1101] ibid.

However, in establishing IP protection on plants, other hurdles proved to be more cumbersome than the conviction that plant varieties were products of nature. As the U.S. OTA illustrated in *New Developments in Biotechnology: Patenting Life*, "the view that a new plant variety could not be adequately described to comply with the description requirements of the general patent statutes"[1102] weighed against patenting plants and plant varieties. In addition, the legislature considered plant breeding "not sufficiently reproducible to allow for stable, uniform, and true-to-type material suitable for patent protection".[1103]

During the Great Depression, in 1930, Congress enacted the Plant Patent Act (PPA), which allows intellectual property protection for new and distinct asexually reproducing plant varieties.[1104] The PPA was the result of the promotional work carried out by the lobbying group of nurserymen. As the work of the breeder was thought to be a considerable aid to nature, Congressmen concluded it deserved to be ruled as a patentable invention. This was the first legal act establishing that plants and plant varieties could be considered "*artificial*" enough to deserve the IP protection accorded to inventions.

The PPA, nevertheless, did not imply a right to exclude others from propagating the patented plant variety by seeds and provided a more relaxed written description requirement, "*by permitting it to be in accordance with traditional botanic descriptions*".[1105] As plant asexual reproduction consists of cuttings, grafting and budding, but does not involve seeds' use,[1106] the PPA did not impact upon the traditional plant breeders' rights and the possibility for farmers to re-plant seeds. The PPA partially answered the needs of the proponents, who pleaded that establishing a plant patent system would foster private investments in developing superior plant varieties, and fulfilled the auspice of the Hatch Act of 1887, whose purpose was "*to assure agriculture a position in research equal to that of industry*".[1107]

However, by ruling that new and distinct asexually reproducing plant varieties were *like* human inventions and, thus, patentable under the PPA, U.S. Congress moved them from the realm of nature to that of culture and started a process of legal de-naturalization of plants. In the conceptual shift of meaning from plants regarded as "*products of nature*" to "*artificial products*", the mechanistic and chemical analogies were fundamental and proved legally successful. The mechanistic and chemical analogies conveyed by metaphors affirmed a way of imagining life detached from the environment and emptied of its organic properties (i.e.

[1102] U.S. OTA (n 732) 71.
[1103] ibid.
[1104] Plant Patent Act. 1930. Title 35 U.S.C. § 161.
[1105] U.S. OTA (n 732) 71.
[1106] ibid 69.
[1107] The Hatch Act (Ch. 314, § 2, 24 Stat. 440). 2 March 1887, Title 7 U.S.C. § 361b.

reproduction and growth). This kind of imaginary hinged on the advantages that these biotechnological products could entail in terms of social and economic progress and on the incentives that IP protection could offer to plant and seed breeders.

The House Committee on Patents, addressing the issue of the constitutionality of the PPA according to Article 1, Section 8, Clause 8 of the U.S. Constitution, had to decide on whether a new plant variety would be a "*discovery*" in the constitutional sense and its originator an inventor or not.[1108] The answer was positive, as in the Report the Committee argued that there is no difference between "*the part played by the plant originator in the development of new plants and the part played by the chemist in the development of new compositions of matter*".[1109]

However, it has been observed[1110] that the utility patent requirement of disclosure was difficult to fulfill for plants, which were hardly identically reproducible, and in this respect, as living matter, they differed from chemical compounds.

The approval, in 1970, of the Plant Variety Protection Act (PVPA) was the further step towards the legal protection of plant varieties. The PVPA was passed after an unsuccessful attempt to amend the PPA to include sexually reproduced plant varieties, in 1968,[1111] and provides a form of IP protection for new, distinct, uniform and stable varieties of sexually reproducing plant varieties.[1112] Under the PVPA a breeder can be granted a Plant Variety Protection Certificate (PVPC) by the Plant Variety Protection Office (PVPO), which administers the act within the U.S. Department of Agriculture. Although the extension of patent-like protection to sexually reproducing plant varieties came about under the aegis of stimulating private investments in plant breeding and enhancing plant varieties, nonetheless it raised sharp criticisms. The PVPA was viewed as a means to promote economic concentration in the seed industry, to limit the free exchange of germplasm, to favor genetic uniformity and weaken the relevance of public breeding.[1113]

However, it provided two exemptions that would mitigate its effects on plant breeders' activities: although the holder of a PVPC can exclude others from selling, offering for sale, reproducing (sexually or asexually), producing a hybrid from the variety and importing or exporting it, the certificate does not prevent farmers from saving seeds for crop production[1114]

[1108] Kevles (n 1096) 7.
[1109] Plant Patents, House Report 1129, 16-17, in Kevles (n 998) 7.
[1110] ibid 8.
[1111] U.S. OTA (n 732) 107-108.
[1112] Plant Variety Protection Act of 1970, Title 7 U.S.C. § 2402 (a). Janis, Jervis and Peet (n 947) 94-95.
[1113] Kloppenburg (n 1048) 131.
[1114] Plant Variety Protection Act of 1970, Title 7 U.S.C. § 2543.

and breeders from using it for research purposes.[1115] By preserving these exemptions, the PVPC implicitly recognized and maintained the intimate "*natural*" biological relationship between seeds and plants, the link between seeds as "products" and "means of production", as well as their socio-economical relevance for different stakeholders.

The complete assimilation of new plants and seeds to man-made inventions[1116] resulted from the decision of the Board of Patent Appeals and Interferences ("BPAI") in *Ex parte Hibberd*, in 1985, and occurred five years after the U.S. Supreme Court made clear in *Chakrabarty* that life forms, like human modified microorganisms, were patent eligible.

Stephen Bent illustrated that, in the early 1980s, the USPTO rejected utility patent applications on hybrid plants and seeds, drawing on the legal principle of *preemption*, namely "the principle (Derived from the Supremacy Clause) that a federal law can supersede or supplant any inconsistent state law or regulation".[1117] He referred, in particular, to the reply that the USPTO provided to questions submitted, in 1984, by the Biotechnology Patent Study Team of the Japan Patent Association which pointed out that: "In the absence of judicial guidance, the Patent and Trademark Office has for the present adopted a practice based on the legal principle of 'preemption'. Any subject matter protectable under either the plant patent law or the Plant Variety Protection Act is preempted by that law and cannot be protected under the general patent law".[1118]

However, in 1985, the USPTO's practice began to shift, when *Ex Parte Hibberd* was decided and was definitively overturned by SCOTUS' judgement in *J.E.M.* Between 1985 and 2001 the USPTO granted 1,800 utility patents on plants, plant parts and seeds under Title 35 § 101.[1119] However, until 2001, when *J.E.M.* was decided by SCOTUS, there were still some uncertainties on whether *Chakrabarty* had changed something in the intellectual property system of protection of plants and seeds. In *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.* the Supreme Court carried out the final discursive effort for the de-naturalization of plants and seeds and their normalization as patentable subject matter in the U.S. IP protection system, upholding that "*newly developed plant breeds fall within the subject matter of § 101, and neither the PPA nor the PVPA limits the scope of § 101's coverage*".[1120]

[1115] Plant Variety Protection Act of 1970, Title 7 U.S.C. § 2544

[1116] Alain Pottage and Brad Sherman, 'Organisms and Manufactures: on the History of Plant Inventions' (2007) 31 Melbourne University Law Review 539.

[1117] Headword "preemption*", Black's Law Dictionary* (8th, edn,, Thomson West 1999) 1216.

[1118] Stephen A Bent, 'Protection of Plant Material under the General Patent statute: A Sensible Policy at the PTO?' (March 1985) 4 Biotechnology Law Report 105, 106.

[1119] The PTO issued some 1,800 utility patents between 1985 and 2001 for plants, plant parts and seeds under Title 35 § 101 U.S.C. See *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*122 S. Ct. 593 (2001), 127.

[1120] *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l*, 124.

In *Ex parte Hibberd*, the BPAI dealt with the patent examiner's rejection of several patent claims related to maize plant technologies that included seeds, plants and tissue cultures, which had increased free tryptophan levels or were capable of producing plants or seeds having increased tryptophan content.[1121]

The examiner argued that these claims were not patentable according to the statutory construction of the scope of patentable subject matter under Title 35 §101 U.S.C., in relationship with the PPA and PVPA. He purported that, by enacting the PPA in 1930 and the PVPA in 1970, Congress had specifically set forth how and under what conditions plant life covered by these Acts should be protected. He contended, therefore, that the only reasonable statutory interpretation was that "*the PPA and PVPA, which were later in time and more specific than section 101, each carved out from Section 101, for specific treatment, the subject matter covered by each*",[1122] concluding that the plant-specific acts (PPA and PVPA) were the exclusive forms of protection for plant life covered by those acts.

The examiner showed full awareness of the practical implications in departing from PTO's unbroken practice and allowing utility patents on plants and seeds, by pointing out all the differences between the plant-specific Acts and § 101 U.S.C. and, in particular, that "the PVPA contains both research (experimental use) and farmer's crop exemptions, while Section 101 does not explicitly contain such exemptions".[1123]

Moreover, he contended that according utility patent protection under the circumstances of the case would have been a violation of Article 2 of the UPOV Convention that, although it was only an Executive Agreement not ratified by the U.S. Senate at that time, should be considered "*in interpreting a statute on which it bears*".[1124] Article 2(1) of the UPOV Act, which was revised in 1978, regarded the forms of protection for new varieties of plants and embedded a ban on double protection of plant varieties.

The BPAI reversed his decision and, relying on the Supreme Court's majority reconstruction of the legislative history of the PPA and PVPA in *Chakrabarty*, purported that, in the absence of any clear intention of Congress to remove plants and seeds from patent protection, the legislative intent of these acts was to extend patent protection to plant breeders.[1125]

J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc. is a case of patent infringement filed by Pioneer Hi-Bred International, one of the world's largest seed corn producers, involving the

[1121] *Ex parte Hibberd*, 227 USPQ 443 (Bd Pat. App. & Inter. 1985).
[1122] ibid 2.
[1123] ibid 4.
[1124] ibid 5.
[1125] ibid 3.

validity of 17 utility patents covering the manufacture, use sale, and offer for sale of its inbred and hybrid corn seed products. Pioneer Hi-Bred International alleged that J.E.M. Supply, trading as Farm Advantage, purchased from the company its patented hybrid corn seeds in bags bearing a license agreement. Although Farm Advantage was not a Pioneer's licensed sales representative, it then resold these bags to other distributors and customers, infringing these patents, as well as the licensing agreement. J.E.M. Ag Supply, in turn, denied Pioneer's allegations and counterclaimed that its patents were invalid, as sexually reproducing plants are not patentable subject matter within the scope of 35 U.S.C. § 101. Recalling the examiner's arguments in *Ex Parte Hibberd*, Farm Advantage contended that the PPA and PVPA set forth the *exclusive* statutory means for the protection of plants, since these statutes are more specific than § 101 U.S.C. and carve out a special treatment for them.[1126]

In this case two opposite narratives confronted. In the wake of *Chakrabarty*, the majority of the Court developed a narrative of continuity. Relying on this precedent, the majority embraced its reasoning, where a certain imaginary of ineluctable progress is tied and weaved together with the rhetoric of deference to the statutes. Thus, it reaffirmed that § 101 U.S.C. should be given wide scope and rejected the argument that Congress must expressly authorize protection for new patentable subject matter, recalling the Jeffersonian mythology.[1127]

Although the majority of the Court admitted that USPTO's unbroken practice of conferring utility patents on plants was established in the aftermath of *Ex Parte Hibberd*,[1128] the judges did not consider this decision a major departure from the former way of applying IP rules to plants and seeds. *Ex Parte Hibberd* was regarded, on the contrary, as *Chakrabarty*'s natural judicial follow-up, as it confirmed that plants could be subsumed within the meaning of "manufacture" or "composition of matter" under § 101 U.S.C., together with the more general statement that "*anything under the sun that is made by man*" is virtually patentable.[1129]

According to this narrative of continuity, the PPA and PVPA did not foreclose utility patent coverage for plants, since they do not contain any statement of exclusivity and do not expressly restrict the scope of patentable subject matter. As *Judge Thomas* pointed out, the PPA should be interpreted in the light of the "*forward-looking*" perspective of the utility patent statute and the reality of plant breeding then: "*in 1930, seed companies were not primarily concerned with varietal protection, but were still trying to successfully commodify*

[1126] *J.E.M.* (n 1120) 129.
[1127] ibid 130-131.
[1128] ibid 131.
[1129] ibid.

seeds. There was no need to protect seed breeding because there were few markets for seeds".[1130]

In the Court's reasoning, the logic of progress seemed to converge with the present economic needs and interests of the seeds' industrial market.

Conversely, *Judge Breyer*, who delivered the dissenting opinion, set forth a narrative of discontinuity. According to him, as *Chakrabarty* concerned a "*man-made microorganism*" (that SCOTUS defined as a "life form", but not as a "*plant*"), it could not be applied to support the patentability of plants and seeds under the scope of the words "*manufacture*" or "*composition of matter*" in § 101.

Judge Breyer firstly provided a semantic interpretation of the PPA, remarking that by referring to "*any* distinct and new variety of plants" asexually reproduced, this statute could potentially encompass *all* plants, as long as they met its three requirements. He, then, carried out an historical interpretation of the PPA, reducing *ad absurdum* the majority's evolutionary construction. The judge imagined how, before and after 1930, a *prescient* court – knowing what SCOTUS would say in *Chakrabarty*, namely that Utility Patent Statute language in principle might cover "anything under the sun" – would answer the following question: "could a plant breeder who, in 1931, sought to patent a new, distinct variety of plant that he invented, but which he has never been able to reproduce through grafting (i.e. asexually), patent it under the more general Utility Patent Statute language "*manufacture, or composition of matter*?"[1131] His conclusion was that, after 1930, the court would not consider the plant variety inside the scope of the Utility Patent Statute, otherwise it would "*virtually nullify the PPA's primary condition, namely that the plant breeder has reproduced the new characteristic through a graft, reading it out of the Act*".[1132] In addition, he pointed out that, "*since the Utility Patent Statute would cover, and thereby forbid, reproduction by seed, such a holding would also have read out of the statute the PPA's more limited lists of exclusive rights*".[1133]

Moreover, Judge Breyer contended that the enactment of the PVPA in 1970 could not change this conclusion. Nothing in the history, language, or purpose of the PVPA showed the intent to reintroduce into the scope of the general words "*manufacture, or composition of matter*"

[1130] ibid 136.
[1131] ibid 152.
[1132] ibid.
[1133] ibid.

the subject matter that the PPA had removed, namely, plants.[1134] Any such reintroduction would make meaningless the research and plant breeders' exceptions embedded in this statute. The narrative of continuity, however, prevailed. Since then, utility patents have been issued on hybrid and genetically modified plants and seeds, with several relevant consequences for the socio-economic organization of agricultural labor. Enabling utility patents to cover plants and seeds has consolidated seeds' companies control over their use by agricultural producers, has eroded farmers' independence towards agro-biotech corporations and disrupted and eradicated their traditional practice of saving and replanting seeds.

The story of the de-naturalization of plants and seeds in the U.S. IP system is entwined with the creation of hybrid plants and seeds.

Kloppenburgh Jr has illustrated that, although hybridization proved successful with some important species, for others it turned out to be too impervious.[1135] In that respect, the development of recombinant DNA techniques in the 1970's, which converged with the rise of industrial genetics, provided the technological means to bypass the obstacles that agricultural science was facing with hybridization. It has been noted that, by allowing seed breeders to overcome biological barriers across species, rDNA techniques offered a short cut towards a wider range of opportunities to enhance plant varieties than hybridization.[1136]

When according to the scientific community and U.S. institutions these techniques seemed to be brought under control and amenable to manageable risks, shortly after the approval in 1976 of the *Guidelines for Research Involving Recombinant DNA Molecules* by the National Institutes of Health[1137] and their relaxation in 1980,[1138] the Supreme Court's decision in *Chakrabarty* paved the way to the patentability of GM plants and seeds. The *Guidelines*, that were approved in order to control laboratory research with genetically modified organisms, represent a significant piece of U.S. regulatory science, which concurred in normalizing the risks related to GMO's deliberate release and the industrial-scale application of agricultural biotechnology.

[1134] ibid.
[1135] Kloppenburg (n 1048) 11.
[1136] ibid 191-207.
[1137] National Institutes of Health, 'Guidelines for Research Involving Recombinant DNA Molecules', *Federal Register*, n. 41, 7 July 1976, 27902-27943.
[1138] NHEW-NIH, 'Revised Guidelines for rDNA Research', *Federal Register*, n. 43, 22 December 1978, 60134-60135.

However, if hybridization provided the technical means for the commodification of the seeds,[1139] granting plant utility patents made GM seeds "effectively legally sterile",[1140] as it tolled the bell for farmers' rights in the U.S.

In this respect, technoscience and the law have co-produced a descriptive and normative order for biotechnological GM plants and seeds which favored their commodification and the allocation of IPRs over them.

Kloppenburg Jr. pinpointed the benefits[1141] that utility patents entail in comparison with PVP certificates:

(1) "At $300 per application, PTO fees are substantially less than those levied by the Plant Variety Protection Office ($ 2,000 per application)";[1142]

(2) "Moreover applicants get more for their money. The PVPA and the Plant Patent Act permit only a single claim for a new plant variety as an indivisible whole. Utility patents may encompass claims not only to multiple varieties but also to the individual components of those varieties: DNA sequences, genes, cells, tissue cultures, seed, and specific plant parts, as well as the entire plant";[1143]

(3) "Unlike the PVPA, the utility patent statute does not include a farmer-exclusion clause. Farmers are no more exempt from the legal obligation to respect the property rights of developers of patented seed than are their corporate competitors. Legal precedent is that the purchase of a patented product brings with it the right to use the product, but not the right to make it. Applied to seed, this principle implies that a farmer purchasing patented seed would have the right to use (to grow) the seed, but not the right to make the seed (to save and replant)".[1144]

Utility patents have, actually, proved to be a highly requested form of IP protection for both transgenic and non-transgenic seeds and plants in the last two decades. As Janis noted, the

[1139] Kloppenburg (n 1048) 130.
[1140] The expression was used by Scrinis and is quoted in A Magnan, 2004. 'Social and Political Implications of Genetically Modified Crops in Saskatchewan' (2004) 29 (2) Prairie Forum 306 in Birgit Müller, 'Infringing and Trespassing Plants: Patented Seeds at Dispute in Canada's Courts' (2006) 48 European Journal of Anthropology 87.
[1141] This remarks and citations have been published in Emanuela Gambini, 'The Seeds of Dispute: Vernon Hugh Bowman v. Monsanto Company et al.' (2013) 4(4) EJRR 579, 583-584.
[1142] Kloppenburg (n 1048) 263.
[1143] ibid 263.
[1144] ibid 265.

USPTO has granted at least 9,000 utility patents covering non-transgenic plant varieties, over 4,000 directed to maize varieties and more than 3,000 to soybean varieties.[1145]

Notwithstanding the legislative momentum built by the PPA and PVPA to the privatization of germplasm, the final discursive effort towards the de-naturalization of plants and seeds was performed by the Courts, which implicitly endorsed their full commodification.

The de-naturalization of plants and seeds has been legally brought about through a process of judicial re-definition of their nature in artificial and reductionist terms, as chapter two has explained (sections 2.2 and 2.2.1), by resorting to metaphors of artificiality. Nevertheless, the narrative of the origins, progress and continuity set out in *Chakrabarty* proved to be a powerful discourse to support the normalization of different biotech products within the U.S. patent system.

5.3 Metaphors of Patent Infringement: *Schmeiser v. Monsanto Canada Inc.*

Canola (or rapeseed) is a major crop in Canada. The first record of production of *B. campestris* (*B. rapa*) dates back to 1936 and was started in Shellbrook, Saskatchewan, by a Polish immigrant farmer, Fred Solvoniuk.[1146] In the following decades its production was extended to several Western provinces and, by the early 1970s, *B. rapa* was the main cultivated species[1147] in that area of Canada.[1148] It has been illustrated that the term "canola" was coined in order to differentiate the Canadian rapeseed oil product, characterized by low erucic acid oil and low glucosinolates meal, in comparison to other brand-rapeseed oils, such as "colza oil" commercialized by France.[1149] The word "canola" was devised by a committee which was appointed by the Rapeseed Association of Canada and embeds "an abbreviation of Canadian "can" and the "suffix 'ola' which could have stood for –ol, or a chemical compound containing a hydroxyl group, or equally for –ole, oleo (French) for oil"[1150] and was registered as a trademark in 1978. In Canada, Canola epitomizes a successful innovation

[1145] Mark D Janis, 'Non-Obvious Plants' in Duncan Matthews and Herbert Zech (eds) *Research Handbook on Intellectual Property and the Life* Sciences (Edward Elgar 2017) 160.
[1146] George G Khachatourians, Arthur k Summer and Peter W B Phillips, 'An Introduction to the History of Canola and the Scientific Basis for Innovation' in Peter W B Phillips and George G Khachatourians (eds) *The Biotechnology Revolution in Global Agriculture: Innovation, Invention and Investment in the Canola Industry* (CABI Publishing 2001) 33, 38-39.
[1147] R Keith Downey, A Klassen and S Pawlowski, ''Breeding Quality Improvements into Canadian Brassica Oilseed crops' in *Proceedings of the 4° International Rapeseed Congress*, Giessen-Germany (1974), 57.
[1148] Khachatourians, Summer and Phillips (n 1146) 39.
[1149] ibid.
[1150] ibid.

process, undertaken first by publicly funding R&D, which has been later sustained by private research and led to commercialization of products.[1151]

Canadian breeding efforts and investments regarded, first, traditional rapeseed breeding[1152] and, successively, biotechnological research to develop new traits in the main areas of breeding: "(i) seed yield; (ii) seed quality (i.e. oil type and composition), meal quality (glucosinolate content) and seed fibre and colour; (iii) plant resistance to pests (i.e. resistance to microbial phytophatogens and resistance to insects) and (iv) agronomy traits (i.e. winter hardiness, herbicide resistance, height, lodging, maturity time, shatter resistance and others)".[1153]

Although in the *Harvard College* case the Supreme Court of Canada ("SCC") addressed the patentability of GMOs and resolutely rejected the use of either the mechanistic model of life or the metaphor of the chemical molecule to higher life forms, the settled boundaries of patent ineligible inventions become blurred thereafter, when the Court took a more ambiguous position.

In 2004, the SCC decided in *Percy Schmeiser and Schmeiser Enterprises Ltd. v. Monsanto Canada Inc. and Monsanto Company* ("*Schmeiser*"), a case of patent infringement involving a canola breeder from Saskatchewan who was sued by Monsanto Canada and Monsanto Company. The plaintiffs accused him of planting, cultivating and harvesting Roundup Ready® canola seeds and plants, which embedded the chimeric plant gene and cell covered by Patent No. 1,313,830 *Gliphosate-Resistant Plants* by Monsanto in Canada, without purchasing a license to use the seed and paying the company the due fees per acre.

In a 5 to 4 decision the majority[1154] of the court held that Monsanto's patent was valid and Percy Schmeiser had infringed it, but since he earned no profit from the invention, the company was entitled to nothing on its claim on the account.

The Court did not discuss the salient facts of the case, deeming them ascertained by the Court of Appeal and the Trial Court of the Court of Appeal and dealt mainly with the issues related to the infringement. Moreover, it did not address the possibility that accidental GM contamination occurred,[1155] although Schmeiser contended that the presence of Roundup

[1151] Peter W B Phillis and George G Khachatourians, 'Approaches to and Measurement of Innovation' in in Peter W B Phillips and George G Khachatourians (eds) *The Biotechnology Revolution in Global Agriculture: Innovation, Invention and Investment in the Canola Industry* (CABI Publishing 2001) 23.
[1152] Khachatourians, Summer and Phillips (n 1146) 41-42.
[1153] ibid 44.
[1154] *Percy Schmeiser and Schmeiser Enterprises Ltd. v. Monsanto Canada Inc. and Monsanto Company* [2004] 1 S.C.R. 902, 910.
[1155] James Allred, 'Transgenic Plants' in Duncan Matthews and Herbert Zech (eds) *Research Handbook on Intellectual Property and the Life Sciences* (Edward Elgar 2017) 179, 187-192.

Ready canola seeds and plants on his fields resulted from "inadvertent contamination" from this kind of canola cultivated on neighboring fields.[1156]

The Court started its analysis by pointing out that "canola is a valuable crop grown in Canada and used to make edible oil and animal feed".[1157] Patent No. 1,313,830 was granted to Monsanto US, on 23 February 1993[1158] and Monsanto Canada was its licensee. The patent claims were for a chimeric gene, expression and plant transformation vectors, various species of plant cells into which the chimeric gene has been inserted and a method of regenerating a glyphosate-resistant plant. The chimeric gene, once inserted into canola plants, increases their tolerance to glyphosate-based herbicides.

The focus of the Court's judgement was section 42 of the Canadian Patent Act, which refers to the *Contents of patent* and establishes the rights of the patentee and the patentee's legal representatives, and, in particular, the meaning of the word "using", in French "exploiter".

Section 42 of the Patent Act (R.S.C., 1985, c. P-4) sets out that: "Every patent granted under this Act shall contain the title or name of the invention, with a reference to the specification, and shall, subject to this Act, grant to the patentee and the patentee's legal representatives for the term of the patent, from the granting of the patent, the exclusive right, privilege and liberty of making, constructing and *using* the invention and selling it to others to be used, subject to adjudication in respect thereof before any court of competent jurisdiction".[1159]

As the majority dismissed the view that Schmeiser "made" the gene or the cell, the judges examined his possible infringement by "using" them.

In determining the meaning of the word "use" or "exploiter" in French, the majority resorted to the work of lexicographers as the traditional hermeneutic starting point to determine the "plain meaning" of words. The majority clarified that "use", according to the Concise Oxford Dictionary, denoted "cause to act or serve for a purpose, bring into service; avail oneself of",[1160] therefore utilization for a purpose. Moreover, the French term "exploiter", which was defined as "tirer parti de (une chose) en vue d'une production ou dans un but lucratif […]

[1156] *Monsanto Canada Inc. v. Schmeiser*, 2001 FCT 256, 11.
[1157] *Percy Schmeiser and Schmeiser Enterprises Ltd. v. Monsanto Canada Inc. and Monsanto Company*, [2004] 1 S.C.R. 902, 912.
[1158] The patent term of Patent No. 1,313,830 ended on 23 February 2010.
[1159] S 42, Patent Act (R.S.C., 1985, c. P-4) iii, 45..
[1160] Headword "use", *The Concise Oxford Dictionary of Current English* (Clarendon Press 1995, 9th, edn) 1545. *Schmeiser* (n 1212) 918.

Utiliser d'une manière avantageuse",[1161] indicated in a clearer way an "utilization with a view to production or advantage".[1162]

The majority applied three well-established rules or practices of statutory interpretation: it applied the *purposive* hermeneutical canon ("the reasons for which patent protection is accorded"),[1163] *contextual* examination of the meaning of the word (examining the other words also of the provision) and how the *case law* defined "use" in the past.[1164]

As the purpose of s 42, according to the majority was to define the exclusive rights of the patent holder and these rights were directed to the full enjoyment of the monopoly granted to the patent, the court framed the question over the infringement as whether the defendant's activity deprived the inventor in whole or in part, directly or indirectly, of full enjoyment of the monopoly conferred by the law.[1165]

The judges, though, did not engage in a detailed contextual examination of s 42, but affirmed that the patentee's monopoly generally protects its business interests, by referring to the doctrine.[1166]

Metaphors embedded and employed in relevant case law and doctrine proved to be the analogical benchmark to judge on the patent infringement.

The majority allowed that "patent infringement actions often proceed in a manufacturing context"[1167] and "case law has for that reason focused on situations where a patented part or process plays a role in production",[1168] but still they drew on manufacturing metaphors in order to define patented genes and cells which are part of an organic process of reproduction.

The judges, first, recalled one comment of Professor Vaver on the term "use":[1169]

> "'Use' applies both to patented products and processes, and also to their output. A patent that covers a *zipper-making machine or method* extends to *zippers* made by the machine or method. Each zipper sold without authority infringes the patent, even if the zippers themselves are unpatented. This expansive doctrine applies, however, only if the patent plays an important part in production".[1170]

[1161] Headword "exploiter", *Le Nouveau Petit Robert* (Le Robert 2003) 1004. *Percy Schmeiser and Schmeiser Enterprises Ltd. v. Monsanto Canada Inc. and Monsanto Company*, 21 May 2004, [2004] 1 S.C.R. 902, 918.
[1162] *Schmeiser* (n 1157) 918.
[1163] ibid.
[1164] ibid 918-927.
[1165] ibid 919.
[1166] David Vaver, *Intellectual Property Law: Copyright, Patents, Trade-Marks* (Irwin Law 1997) 151.
[1167] *Schmeiser* (n 1157) 921.
[1168] ibid.
[1169] ibid.
[1170] Vaver (n 1166) 152.Vaver was referring, in particular, to *Colonial Fastener Co. Ltd. V. Lighting Fastener Co. Ltd.*, [1937].

They, then, unravel the analogy from the metaphor of the *zipper*:

> "By analogy then, the law holds that a defendant infringes a patent when the defendant manufactures, seeks to use, or uses a patented part that is contained within something that is not patented, provided the patented part is significant or important. In the case at bar, the patented genes and cells are not merely a 'part' of the plant; rather the patented genes are present throughout the genetically modified plant and the patented cells compose its entire physical structure".[1171]

Finally they drew on another manufacturing[1172] metaphor in order to bolster the analogy:

> "In that sense, *the cells are somewhat analogous to Lego blocks*: if an infringing use were alleged in building a structure with patented Lego blocks, it would be no bar to a finding of infringement that only the blocks were patented and not the structure. If anything the fact that the Lego structure could not exist independently of the patented block would strengthen the claim, underlying the significance of the patented invention to the whole product, object, or process".[1173]

In assessing whether the infringement took place, therefore, the majority endorsed a *mechanistic* metaphor of higher life forms, namely that transgenic plants and seeds are bio-artefacts, like *zippers* or *constructions* made up of Lego blocks.

The use of these metaphors allowed the majority to ignore *Harvard College* and its holding. Since the object of the patent was defined by drawing on artefacts, namely capsules and tires[1174] as metaphors for seeds and plants saved, planted and grown by Schmeiser, the majority dodged the questions related to the unpatentability of higher life forms in the Canadian patent system.

The employment of artefacts metaphors coupled with the interpretation of "use" as utilization with a view to product advantage bolstered the conclusion of infringement.[1175]

The opinion of the minority, which dissented in part and was delivered by *Justice Arbour*, conversely, addressed the relevance of *Harvard College* in deciding the case.

The minority pinpointed that there were two main issues of the case: the scope of Monsanto's patent and whether the production of Roundup Ready® canola constituted a patent infringement or not.

[1171] *Schmeiser* (n 1157) 921.

[1172] Davis Vaver explaining the meaning of "manufacture" as one category of patentable inventions within the Canadian patent system points out that it "connotes a product made manually or by industrial process, by changing the character or condition of material objects". Vaver (n 1166) 294.

[1173] *Schmeiser* (n 1157) 921-922.

[1174] ibid 922-923.

[1175] *Schmeiser* (n 1157) 930.

Justice Arbour vividly articulated the fundamental dilemma of the case: a narrow construction of Monsanto's claims would have rendered the claims valid, but not infringed, whereas a broader construction of the claims would have rendered them invalid.[1176]

She noticed that the case was decided by the lower Courts without giving due consideration to the holding of the Supreme Court of Canada judgement in *Harvard College*, that higher life forms, including plants, were not patentable[1177] and their decision would invalidate the Patent Office's long-standing policy of not granting IPRs on higher life forms in the aftermath of this decision.[1178]

She, then, applied the same hermeneutical criteria used by the majority and overturned its conclusions.

With regard to purposive construction, she highlighted that the commercial value of the exclusive rights of the patentee were not the only considerations: fairness and predictability, the classic rule "what is not claimed is considered disclaimed" and patent claims must be interpreted from the point of view of the hypothetical worker skilled in the art. Examining the patent claims in light of these three considerations, Justice Arbour drew the conclusion that "a person skilled in the art, upon filing of Monsanto's patent, could not reasonably have expected that the exclusive rights for gene, cell, vector, and method claims extended exclusive rights over unpatentable plants and their offspring".[1179]

Moreover, she rejected any mechanistic analogy on plants or seeds as appropriate to describe the process in which the patented invention was involved, by pointing out that:

> "In any event, there is no genuinely useful analogy between growing a plant in which every cell and every cell of all its progeny are remotely untraceable to the genetically modified cell and putting a zipper in a garment, or tires on a car or constructing with Lego blocks. The analogies are particularly weak when it is considered that the plant can subsequently *grow*, *reproduce* and *spread* with no further human intervention".[1180]

In light of the rejection of these kinds of metaphors and the analogies they entail, together with *Harvard College*, the minority drew the conclusion that Monsanto's patent claims could

[1176] ibid 940.
[1177] ibid 939.
[1178] Para 16.05, Patent Office, Manual of Patent Office Practice (Patent Office Manual 1998).
[1179] *Schmeiser* (n 1157) 945-946.
[1180] ibid 954.

not "be interpreted to extend patent protection over whole plants and that there was no infringing use".[1181]

The adjudication, in *Schmeiser*, proved to be inconsistent with the Supreme Court's holding in *Harvard College* and reshaped the scope of patentable subject matter which seemed to be settled. It, nevertheless, mirrored the product-based approach to biotechnology that has characterized Canadian biotech policy since 1983, when the Canadian Government launched the National Biotechnology Strategy.[1182] As Pechlaner has illustrated, the regulatory framework of agricultural biotechnology,[1183] in Canada, is similar to the U.S. one and is *product* rather than process based, since it does not embed "special provisions for the method by which GM products are produced".[1184] Accordingly, rDNA biotechnology has been deemed not to require special regulation and few amendments were made to existing federal statutes regarding it, in Canada.[1185]

This decision, moreover, is consistent with the Canadian investments carried out in those years to back the development of the canola market.[1186]

5.4 Framing Transgenic Plants in the EPC Patent System: The *Novartis II* Case

In Europe, the patent eligibility of GM plants and seeds has been established under the EPC by the Decision G1/98 ("*Novartis II*") of 29 December 1999 of the Enlarged Board of Appeal ("EBA"),[1187] on referral from the TBA 3.3.4.[1188]

The case concerned European patent application No. 91 810 144.5, published under No. 0 488 511 with the title "Anti-pathogenically effective compositions comprising lytic peptides and hydrolytic enzymes", which was refused by the Examining Division. The application

[1181] ibid 940.
[1182] U.S. Congress, Office of Technology Assessment, *Biotechnology in a Global Economy*, OTA-BA-494 (Washington, DC:U.S. Government Printing Office, October 1991) iii, 231.
[1183] The Regulatory Framework for Biotechnology in Canada was established in 1993, seven years later than in the U.S.
[1184] Gabriela Pechlaner, *Corporate Crops: Biotechnology, Agriculture, and the Struggle for Control* (University of Texas Press 2012) 2, 59; W Leiss and M Tyshenko, 'Some Aspects of the 'New Biotechnology' and Its Regulation in Canada' in D Van Nijnatten and R Boardman (eds) *Canadian Environmental Policy* (2nd, edn, Oxford University Press 2001) 321, 324-325.
[1185] ibid 56.
[1186] Richard S Gray, Stavroula T Malla and Peter W B Philips, 'Industrial Development and Collective Action' in Peter W Phillips and George G Khachatourians (eds) *The Biotechnology Revolution in Global Agriculture: Innovation, Invention and Investment in the Canola Industry* (CABI Publishing 2001), 83-104; Peter W B Phillips, 'The Role of Private Firms' in in Peter W Phillips and George G Khachatourians (eds) *The Biotechnology Revolution in Global Agriculture: Innovation, Invention and Investment in the Canola Industry* (CABI Publishing 2001), 129-159.
[1187] Enlarged Board of Appeal, Decision of 20 December 1999 G 1/98.
[1188] EPO Referral-Decision of Technical Board of Appeal 3.3.4 dated 13 October 1997 T 1054/96-3.3.4, (1998) 11 Official Journal EPO 511.

related to the control of plant pathogens in crops and embedded claims to transgenic plants containing genes whose expression resulted in the production of antipathogenically active substances and to methods for preparing such plants.[1189] Claims 19-24 were at the core of the rejection, as directed to a transgenic plant and seed and their further embodiments, as well as to a method of preparing a transgenic plant.

The TBA was concerned about whether these kind of plant claims would be allowable in the future in view of Article 53(b), which sets out a patent exclusion regarding " (b) *plant or animal varieties or essentially biological processes for the production of plants or animals*", *b*ut does not extends to microbiological processes or the products thereof. The TBA in decision T1054/96 (Transgenic plant/Novartis) referred four points of law to the EBA and focused, in particular, on whether (2) a claim which relates to plants but wherein specific plant varieties are not individually claimed *ipso facto* avoid the prohibition on patenting in Article 53 (b) EPC even though it embraces plant varieties and (4) a plant variety, in which each individual plant of that variety contains at least, one specific gene introduced into an ancestral plant by recombinant gene technology, fall outside the provision of Article 53 (b) EPC. [1190]

In addressing these questions, the EBA drew upon a narrative of novelty in order to frame genetic engineering technologies.

It acknowledged that the "legislative history suggested that all problems posed by the patenting of self-reproducing living organisms at the level of higher plants or animals were simply to be by-passed by excluding them from patentability under EPC".

However, it focused its decision on re-interpreting this history according to an evolutionary and dynamic view, which framed genetic engineering as a biotechnological breakthrough in plant breeding.

Addressing the second question, the EBA endorsed a substantive[1191] approach to Novartis' claims to assess the subject-matter to which the claim is directed, but it pointed out that the subject-matter of a claim should not be equated with the scope of a claim and, therefore is fundamental to identify the underlying invention and take into consideration "how generic or specific an invention is".[1192]

[1189] G 1/98 (n 1242) para II, 2.
[1190] ibid 1-2.
[1191] ibid 15.
[1192] ibid.

The EBA, then, noticed that the referring decision made clear that the invention could be carried out by modifying plants, which may or may not be varieties, but "*assumed* that one of the main applications of the claimed subject matter" was plant varieties.[1193]

It recalls that "plant varieties" are generally deemed to result from a breeding process of selection and crossing, which encompasses also modern techniques, such as cell fusion that is a laboratory technique. It drew on Article 2(2) of the UPOV Convention 1961, as specified in decision T 49/83 and T 320/87, to highlight that "plant varieties" means "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". Moreover, it added that under Article 1 (vi) of the UPOV Convention 1991, variety[1194] "means a plant grouping within a single botanical taxon of the lowest rank, which grouping irrespective of whether the conditions for the grant of a breeder's right are fully met, can be defined by the expression of the characteristics resulting from a given genotype or combination of 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". This definition, in substance, was identical to the ones provided in Article 5(2) of EC Regulation on Plant Variety Rights and Rule 23b (4) EPC.

A plant defined by single rDNA sequences, conversely, the EBA argued, "is not an individual plant grouping to which an entire constitution can be attributed" and Novartis' plant patent claims did not specify neither the taxonomic category within the traditional classification of the plant kingdom to which the claimed plants belong nor the characteristics which are relevant to assess homogeneity and stability of varieties within a given species.[1195]

It came, thus, to the conclusion that "In the absence of the identification of specific varieties in the product claims, the subject-matter of the claimed invention neither limited nor even directed to a variety or varieties".[1196]

The EBA considered the wording of Article 53(b) EPC, which refers to "plant varieties" showing that plants, *as such*, are not excluded from patentable inventions under the EPC system.

[1193] ibid 16.

[1194] The botanical taxonomy is based on the International Code of botanical nomenclature (Tokyo Code). The Tokyo Code was adopted by the Fifteen International Botanical Congress held in Yokohama, August-September 2003. Article 3.1, Chapter1, International Code of botanical nomenclature, sets out the principal ranks of taxa in descending sequence, which are: "kingdom *(regnum),* division or phylum *(divisio, phylum),* class *(classis),* order *(ordo),* family *(familia),* genus *(genus),* and species *(species)*". A taxon, according to Article 1, Chapter 1 of the Tokyo Code, is a taxonomic group of any rank.

[1195] G 1/98 (n 1242) 16-18.

[1196] ibid 18.

It reconsidered the historical background of the article and pinpointed that its wording is basically due to avoid the so-called ban of dual protection for plant varieties under the original UPOV Convention 1961 and then eliminated in the UPOV Convention 1991, which imposed member Sates of the Council of Europe to exclude patent protection for varieties for which plant breeders' rights were obtainable.[1197]

Moreover, the EBA highlighted that at the time processes for the production of higher life forms and the products thereof entailed problems related to the fulfillment of the criteria of patentability, in particular as far as reproducibility was concerned. Nevertheless, some European countries at the time granted patents over plant varieties, for example Germany.[1198]

According to this historical re-construction the purpose of Article 53 (b) EPC corresponds to the purpose of Article 2(b) SPC. Article 53 (b) EPC differs from its SPC counterpart therefore inventions which were not eligible for protection under the plant breeders' rights system were supposed to be patentable under the EPC, if they fulfilled the other patent requirements.[1199]

The IP scholar Sven Bostyn, in his thorough analysis of *Novartis II,* illustrated several arguments where he asserted the conclusions of EBA should be supported from a legal perspective. In particular, as far as the definition of "plant varieties" is concerned, he pinpointed that a claim embracing a plant variety is different from a claim to a variety: "Every claim to plants will embrace plant varieties, since a plant variety is a plant grouping of the lowest possible rank. When claiming a species, or even a higher rank, it will always embrace plant varieties: all Golden Delicious apples (variety) are apples (species), but not all the apples are Golden Delicious".[1200] He, therefore, concluded that "it is perfectly plausible to claim a plant grouping, which totally lacks homogeneity (group of different plants), except for one characteristic which all the plants of the plant grouping have in common".[1201] According to his argument, this plant grouping, instead of consisting of specific taxonomic units of plants, "may consists of a taxonomically non-specific plant grouping, which can lead to the development of a great number of plant varieties".[1202]

[1197] ibid 22.
[1198] ibid.
[1199] ibid 18.
[1200] Sven J R Bostyn, 'The Unbearable Complications of Patenting Plants' in Fernando Leonini, Mariachiara Tallacchini and Matteo Ferrari (eds) *Innovating Food, Innovating the Law* (Libellula 2014) 301, 307.
[1201] ibid 308.
[1202] ibid.

However, the EBA stated that Novartis' plant product claims were directed to a transgenic plant, which lacked the *homogeneity* and *stability*[1203] of a plant variety, but did not engage in showing how and why transgenic plants had been deemed lacking these characteristics. As this decision marked a departure from the long-established way of interpreting the practice of not granting claims directed to plant varieties and from the Decision of the Technical Board of Appeal 3.3.4 of 21 February 1995 *Plant cells/Plant Genetic Systems*, which concerned Greeenpeace' opposition to a patent on "Plant cells resistant to glutamine synthetase inhibitors, made by genetic engineering", in which the TBA clarified that a claim encompassing plant varieties is not allowable if it is conducive to the evasion of the exclusions under Article 53 (b) EPC, but it can be allowed if the subject-matter of the claim is to be regarded as the product of microbiological process.[1204]

In conclusion, the narrative of the novelty of genetic engineering within the field of plant breeding technologies, carried out by the EBA, allowed the Board to decouple the technology from the product in which it is embedded, the plant, and it largely supported and settled the taxonomical non-specific status of transgenic plants and seeds. This decision elicits, however, several questions about the uncertain scientific ontology of GM plants as a kind, linked to this decoupling, which supported their patent eligibility. In particular, it questions and challenges the premises of the settled botanical classification[1205] on the face of genetic engineering and the more recent gene editing technologies[1206] and on which grounds botanists establish the threshold of genetic modification that entail the creation of a new plant variety.

Moreover, as it has been noted,[1207] the "higher taxonomic level approach" has resulted in inconsistencies with earlier and later decisions on the exclusions set out in Article 53 EPC by the EBA and made redundant the public policy exclusions that it embeds.

5.4.1 The "Nature" of the Process: the Broccoli I and Tomato I cases

Sigrid Sterckx and Julian Cockbain have illustrated that the history of patent exclusions under the EPC is marked by the erosion of their scope, which largely resulted from the jurisprudence of the EPO's Boards of Appeal.[1208]

[1203] Gert Würtenberger, 'Protection of Plant Innovations' in Duncan Matthews and Herbert Zech (eds) *Research Handbook on Intellectual Property and the Life Sciences* (Edward Elgar 2017) 121, 123-126.

[1204] Stephan C Fritz, Elisabeth K Grünbeck and Ali Hijazi, *Key to the European Patent Convention*, (Verlag E. Grünbeck 2012) 5, 108-109.

[1205] In particular the taxonomy based on the so called Tokyo Code, the International Code of Botanical Nomenclature, which was adopted by the 15th International Botanical Congress, August-September 1993.

[1206] Trevor Cook, 'Gene Editing and the Regulation of Genetic Modification in Europe' (2017) 16(1) BSLR 11.

[1207] Sterckx and Cockbain (n 739) 241.

[1208] Sterckx and Cockbain (n 739) vii.

In this chapter, it is argued that this erosion ensued from the *boundary work* that the Boards carried out, namely settling and re-settling the boundaries of what is natural and artificial by interpreting and applying the EPC and its implementing rules, as Novartis II points out.

The Broccoli I (G2/07) and Tomato I (G1/08) case offer an insightful example of how the *boundary work* of these Boards operates with regard to biotech products and processes in order to settle their patentability.

The case regarded patent EP1211926 granted to the Ministry of Agriculture of Israel on 26 November 2003 by the EPO on a "method for breeding tomatoes having reduced water content and product of the method" and patent EP1069819 granted on a "method for selective increase of the anticarcinogenic glucosinolates in *Brassica* species" to Plant Bioscience Limited. Both patents were opposed. Whereas the Tomato patent was challenged by multinational consumer goods company Unilever N.V., the Broccoli patent was challenged by two agricultural groups Syngenta Participation AG and Groupe Limagrain Holding.

As a consequence of the first referral decision of both consolidated cases to the EBA, the process claims were expunged from the patents and occasioned further quandaries concerning the interpretation of Article 53(b) EPC, namely whether the products obtained from non-patentable methods should be considered unpatentable. A second consolidated referral to the EBA followed, as the opponents argued that the product and product-by-process claims of the patents ought to be revoked.

Although both referrals to the EBA provide several insights on how the boundaries of patentability are drawn and accounted for, this section will focus on the EBA' s decision on the first referral dated 9 December 2010, as it set out what is an unpatentable essentially biological process under Article 53(b) EPC. In particular the EBA had to settle whether a process embedding one technical step should be considered an essentially biological process or not.[1209]

This first referral decision, in fact, addressed an issue that Novartis II did not settle, namely *what is the technological threshold that makes a biological process patentable*.[1210]

The EBA considered the two referrals in case G 2/07 (Broccoli) and G 1/08 (Tomato) together and provided an answer to the points of law raised by TBA in T 83/05 and, in particular, whether "a non-microbiological process for the production of plants which contains the steps of crossing and selecting plants escape the exclusion of Article 53(b) EPC

[1209] Albrecht von Menges, 'European Patents for Plant-Related Inventions' (2015) 18 The Patent Lawyer 37.
[1210] Decision of the Enlarged Board of Appeal dated 9 December 2010 G 2/07, (2012) 3 OJ EPO 130, 167.

merely because it contains, as a further step or as a part of any of the steps of crossing and selection, an additional feature of a technical nature".[1211]

Both proceedings regarded appeals against the decisions of the opposition division to maintain the patents amended. Both Broccoli and Tomato cases did not concern a transgenic process and products (seeds, plants, fruits). Whereas the Broccoli patent involved a biotechnological step, as it referred to marker assisted selection in step (b) and (c) of method claim 1, the Tomato one consisted of a more conventional process of crossing and selecting.

The EBA deemed the referral admissible and Rule 26(5) applicable to both cases, even though the referral of case G 2/07 was made before the EPC 2000 entered into force,[1212] as it did not considered it in conflict with Article 53(b) and undermining the legitimate expectations of the parties. The Rule was interpreted as not changing the scope of process exclusion established by Article 53(b) EPC.

The EBA's referral focused on defining the boundaries of "essentially biological processes for the production of plants" under Article 53(b) EPC, by relying on the relevant case law, Articles 31 and 32 of the Vienna Convention and tracing back the history of Rule 26(5) and Article 2(2) of the Biotech Directive in relationship to the UPOV.

It pointed out that whether a process (non-microbiological) is an "essentially biological process" was clarified in T320/87, as the Board argued that it "has 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".[1213] According to the Board, "the necessity of human intervention alone"[1214] was not considered "a sufficient criterion for its not being 'essentially biological'", since a human intervention may simply entail that the process is not "purely biological",[1215] but the human contribution maybe merely trivial regardless of its qualitative or quantitative character. Moreover, the Board pinpointed that the essence of the claimed process "lies in the particular manner of the combination of specific steps",[1216] as "The totality and specific operations do not occur in nature or not correspond to classical breeders' processes".[1217] Accordingly, the Board specified as relevant: the feature of the process, the special sequence of the process steps and the result of the process.[1218]

[1211] ibid 135.
[1212] ibid 161-165.
[1213] ibid 166.
[1214] ibid.
[1215] ibid.
[1216] ibid.
[1217] ibid.
[1218] ibid 167.

However, the EBA highlighted that in T 356/93 the Board held that a process for the production of plants, which involves "one essential technical step, which cannot be carried out without human intervention and which has a decisive impact on the final result" does not fall under the patent exclusion of Article 53(b) first sentence.[1219]

The EBA drew on Rule 26(5) EPC, which states that "a process for the production of plants and animals is essentially biological if it consists *entirely* of natural phenomena such as crossing or selection".[1220] The wording of the Rule corresponds to Article 2(2) of the Biotech Directive and under Rule 26(1) the Directive shall be drawn upon as a supplementary means of interpretation.[1221] However, it then, had to address whether the Rule offered an exhaustive definition or merely an illustrative example.[1222]

The EBA, using the references to Article 2(2), argued that the definition was meant to be exhaustive as Recital 33 suggested together with the Statement of Council's Reasons for the Common Position of 26 February 1998.[1223]

The EBA endorsed an historical narrative which reconstructed the use of the terms "crossing" and "selection" within the European governance of IPRs.

It recalled the criteria of legal interpretation for international treaties set forth in the Vienna Convention, namely that "a treaty shall be interpreted in *good faith* in accordance within the *ordinary meaning to be given to the terms* of the treaty in their *context* and in the light of its *object* and *purpose*" (Article 31(1).[1224]

Referring to these criteria, the EBA rejected a pure semantic interpretation of the terms, pointing out that in the context they concern "acts performed by a breeder", not merely acts that take place in nature, but refer to a human intervention to obtain a result and therefore are not intended as natural phenomena.[1225] It observed that T 1242/06, point 10 of the Reasons, backed this interpretation, by arguing that if the terms referred to purely natural events, the exception would be redundant by excluding processes which would be anyway not patentable for lack of technical character.[1226]

However, this result was not considered satisfactory as it highlighted the ambiguity of the rule. Hence, the EBA resorted to the legislative history of the Directive in order to understand

[1219] ibid.
[1220] ibid.
[1221] ibid 170.
[1222] ibid.
[1223] ibid.
[1224] ibid 170-171.
[1225] ibid 171.
[1226] ibid 172.

the meaning of the rule. The history of Article 2(2) showed a contrast between the European Parliament's approach and the Council's and Commission's stance, which marked the troubled history of the Biotech Directive and its highly contested draft. Article 7 of the first Proposal of the Council,[1227] submitted on 20 October 1988 set out: "A process in which human intervention consists in more than selecting an available biological material and letting it perform an inherent biological function under natural conditions shall be considered patentable subject-matter".[1228]

Moreover, Recital 17 buttressed the text of the proposed draft of the article and the explanatory memorandum of the Commission clarified that, in contrast with the EPO' s Examination Guidelines that required that human intervention had a "significant part" in achieving the result, Article 7 was simply excluding "only traditional biological breeding activities based upon selection".[1229] The draft of Article 7 entailed, therefore a more liberal interpretation of the processes that fell outside this patent exclusion. The Board, however, highlighted that this narrow approach to the exclusion was overruled by Parliament that approved the text of Article 7 amending it in the following way: "Essentially biological procedures shall not be patentable. Whether or not a procedure is to be so classified shall be determined on the basis of the nature of the invention, having regard to the extent of human intervention and its impact on the result achieved".[1230]

The Commission, on 16 December 1992, then drafted an amended proposal and the Common Position endorsed by the Council, however, pointed out that "In determining this exclusion, human intervention and its effects on the result obtained should be taken into account"[1231] and the Recital 27 was shaped accordingly. Since, the official text of the first Common Position was rejected by Parliament, a new draft of the article was submitted.[1232] Its wording expressed the narrower approach to the exclusion, whereas the broader version was moved to the Recital. In the following parliamentary debate, several amendments were voted, which mirrored a wider perspective of the scope of the exclusion. However, finally these amendments were not incorporated by the Council in the drafting Article 2(2) and Recital 33.[1233]

[1227] ibid 174.
[1228] COM(88) 496 final – SYN 159, 13.1.1989, OJ C 10, 3.
[1229] G 2/07 (n 1210) 174.
[1230] ibid 175.
[1231] ibid.
[1232] ibid 176.
[1233] ibid 177-178.

The analysis of the EBA pinpointed that the final definition embedded two different elements of different concepts endorsed by the Council and Parliament: the first part of the article, by referring to processes consisting entirely of natural phenomena, sustained by the former and the second part, concerning crossing and selection, taking on the latter's view.[1234] This inner contradiction could not be clarified, but since Rule 26(5) did not have its own legal history, this historical interpretation was considered applicable to the rule and served to interpret Article 53(b).[1235]

As a consequence of the contradiction embedded in Article 2(2), the EBA claimed its authority in interpreting the exclusion. It, therefore, engaged in the interpretation of the terms: 1. plant v. plant variety; 2. "production" v. "Züchtung" and "obtention"; 3. "essentially biological".[1236] On the first quandary, the EBA recalled that the term "plants" replaced "plant varieties", which was originally embedded in the Preliminary Draft Convention of the EC working group of March 1961, and ruled out interpreting it as signifying "plant varieties".[1237] As to the second point, it argued that "production" has a broader meaning than the terms "Züchtung" and "obtention"; however, the difference did not matter for deciding on the referred questions.[1238]

In order to define the locution "essentially biological", the EBA drew on the existing jurisprudence, which established the standard of interpretation for the exclusion. In particular, it distinguished three possible approaches to the exclusionary clause. Two of the approaches were proposed in referring decision T 83/05: the first hinging on the analogy between the clause and Article 52(4) EPC 1973, as far as methods of treatment by surgery and therapy are concerned; the second based on the analogy with the principles elaborated in order to determine the technical character of computer-related inventions.[1239] The third approach was devised in T 320/87 and entered on several criteria whose fulfillment largely hinges on the state of the art. Since all the approaches were considered inadequate,[1240] the EBA resorted to the legislative history of the SPC and EPC 1973 in order to infer the object and purpose of the exclusion. This history is related to the background provided by the draft of the UPOV Convention at the time and, in particular the ban on dual protection that it embedded. Article 12 of the Preliminary Draft Convention of the EC Working group of 14 March 1961, in

[1234] ibid 182.
[1235] ibid 183.
[1236] ibid 184-186.
[1237] ibid 185-186.
[1238] ibid 186.
[1239] ibid 187.
[1240] ibid 189.

paragraph 2 set out a patentability exception concerning "inventions relating to the production of or a process for producing a new plant variety or a new animal species" and clarified that the provision should not be applied to processes whose nature was technical.[1241]

In the Preliminary Draft Convention of the Council of Europe (SPC), furthermore, the exception from patentability for new plants was devised in Article 2 which pertained to industrial character.[1242]

In a subsequent meeting of the Committee of Experts of the Council of Europe, the EBA pointed out, the wording of the article was changed by adding "or purely biological, horticultural or agricultural (agronomic) processes" and the exclusion was introduced as several national laws excluded these classes from patentability.[1243] However, after a long discussion in a committee meeting on 7-10 November 1961, these categories were eliminated from article 2 and inserted in article 6 and the locution "purely biological processes" was substituted with the present reference to "essentially biological processes".[1244]

The EBA, finally concluded that the exchange of the word "purely" for "essentially" implied a deliberate legislative intention of excluding that the mere recourse to a technical device in a breeding process could be sufficient to characterize it as technical and, therefore, make it fall out of the exclusion.[1245] Although the Board acknowledged that present technical means of achieving crossing and selection have expanded and reached high level of sophistication, the intention of the legislator could be ignored since the wording had never been revised or altered.[1246]

The EBA, accordingly, deemed that a non-microbiological process for the production of plants, which consists in crossing and selection, was in principle excluded from patentability as it was essentially biological (answer to question 1) and it did not dodge the exclusionary clause merely because it entailed a step of technical nature which enabled crossing and selecting (answer to question 2).[1247] Nevertheless, if the process claimed embeds a step of a technical nature, which "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 mixing of the genes of the plants chosen for sexually crossing",[1248] it is not excluded

[1241] G 2/07 (n 1210) 195.
[1242] ibid.
[1243] ibid.
[1244] ibid 197.
[1245] ibid 200.
[1246] ibid 201.
[1247] ibid 204.
[1248] ibid 205.

from patentability (answer to question 3). In establishing whether the process is patentable under Article 53(b) EPC it does not matter whether the technical step is known or not, it is trivial or it involves a fundamental alteration of a known process, if it is naturally occurring or is the essence of the invention.[1249]

The interpretation of the terms of the definition shifted, hence, from a narrower to a broader construction of the exclusion. This sedimentation resulted from the different position of Parliament and Council and the questioned first drafts of the Directive, which came to the forefront of a European debate about biotechnology, IP and the related issues.

The complex historical narrative of the decision showed awareness of the significant issues involved in settling the boundaries of Article 53(b) EPC and, in particular, of the impact that the decision could have on plants with the native traits,[1250] namely "plants exclusively consisting of naturally occurring plant genetics, which is combined in the plant by sexual crossing".[1251] The Broccoli patent, as Kock illustrated, is an example of plant with native trait.[1252] In patents on native traits, the claims on the plants and plants component "comprising the native traits, the trait is often 'characterized by a marker'" that can be phenotypical of genetic.[1253] Consequently, this decision could have a significant impact on marker-assisted selection and, new non-transgenic breeding technologies.[1254]

After the decision the process claims were withdrawn, but there was a second joint referral to the EBA, which made clear that the scope and boundaries of the exclusion were not settled. On 25 March 2015, in the G 2/12 *Broccoli II* and G 2/13 *Tomato II* [1255] decisions, the EBA concluded that "the exclusion of essentially biological processes for the production of plants in Article 53(b) EPC does not have a negative effect on the allowability of a product claim directed to plants or plants material such as fruit" and that also product-by-process claims had to be deemed allowable. The EBA ruling drew on Articles 31 and 32 of the 1969 Vienna Convention on the Law of Treaties, which set out the rules of interpretation for international treaties, and concluded that the exception should be construed narrowly. It should be noted that some Member States of the EPC, such as Germany[1256] and the Netherlands,[1257] exclude

[1249] ibid 205.
[1250] Axel Metzger, 'Patents on Tomatoes and Broccoli: Legal Positivists at Work' (2016) 47 IIC 515.
[1251] Michael A Kock, 'Patenting Non-Transgenic Plants in the EU' in Duncan Matthews and Herbert Zech (eds), *Research Handbook on Intellectual Property and the Life Sciences* (Edward Elgar 2017)132, 133.
[1252] ibid.
[1253] ibid 136-137
[1254] Michael A Kock, 'Broccoli and Tomato: Free or Not Free? Decisions G2/12 and G/13 of the Enlarged Board of Appeal' 14(4) Bio-Science Law Review 167, 176.
[1255] EPO Enlarged Board of Appeal, 25 March 2015, G 2/12 and G2/13, OJ EPO 2016, A27 and A28.
[1256] §2a(1) No 1 German Patent Act §2a(1). Footnote (70), Kock (n 1254) 175.

from patentability the products resulting from an essentially biological process.[1258] The consequence could have entailed, as the opponent in the Tomato II case pointed out that allowing claims to plants resulting from an essentially biological process would allow eluding the patent exclusion by changing the wording of the claims and would undermine the exclusion tout court.[1259]

This case showed the political dimension of patent breeding exclusions.[1260]

Although the EBA upheld the exclusion of process claims as not patentable, it allowed the product claims, creating a tension in the interpretation of the exclusion. In the aftermath of this decision, the European Commission expressed its dissent about the EBA's interpretation of this exclusion In the EU Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions,[1261] the Commission pointed out that it "takes the view that the EU legislator's intention when adopting Directive 98/44/EC was to exclude from patentability products (plants/animals and plant/animal parts) that are obtained by means of essentially biological processes".[1262]

In this respect, both the European Commission and Parliament[1263] have expressed the same view about the scope of the patent exclusion concerning essentially biological processes and the resulting plants. It has been highlighted that only non-technical processes are covered by the exclusion under Article 53(b) EPC and 4(3) of the Directive.[1264]

Consequently, on 29 June 2017, the Administrative Council of the EPO decided[1265] to amend Rules 27 and 28 of the Implementing Regulations to the EPC and the new rules entered into force on 1 July 2017.[1266] These amendments, which provide a statutory interpretation of Article 53(b) EPC in order to harmonise EPO's interpretation and rules with the Biotech Directive. New Rule 28(2) is, in particular fundamental for the interpretation of the article as

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[1257] Article 3(1)(d) Dutch Patent Act of 15 December 1994. Footnote 43, Kock (n 1254) 141.
[1258] Kock (n 1254) 175.
[1259] Interlocutory Decision T 1242/06 dated 31 May 2012 (2013) OJ EPO 42, at 33-39. Timo Minssen and Ana Nordberg, 'The Impact of Broccoli II & Tomato II on European Patents in Conventional Breeding, GMO's and Synthetic Biology: The Grand Finale of a Juicy Patent Tale?' (2015) 34(3) Biotechnology Law Report 81, 86-87.
[1260] Kock (n 1254) 167.
[1261] Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, (8.11.2016) OJ EU C 411/3.
[1262] ibid.
[1263] European Parliament resolution of 17 December 2015 on patents and plant breeders' rights.
[1264] Michael A Kock and Gareth Morgan, 'Broccoli and Tomato: A Never Ending Story?' (2017) 16(3) Bio-Science Law Review 123.
[1265] Decision of the Administrative Council of 29 June 2017 amending Rule 27 and 28 of the Implementing Regulations of the European Patent Convention (CA/D 6/17) (2017) OJ EPO A56.
[1266] Mike Snodin, 'Patentability of Plants under the EPC: Act in Haste, Repent at Leisure?' (2017) 16(3) Bio-Science Law Review 115.

it clarifies that: "(2) Under Article 53(b), European patents shall not be granted in respect of plants and animals exclusively obtained by means of an essentially biological process".[1267]
These amendments are related to Article 4(1)(b) of the Biotech Directive. However, it has been noted that, as the Commission Notice is not binding since it has been issued by a non-judicial body,[1268] it is not clear whether the amendments will be effective or not.[1269]
The Broccoli and Tomato cases show how the EBA construes that boundaries and thresholds of the natural and artificial/technical, as far as biological processes and products are concerned. Some scholars[1270] have pointed out that in most cases this construction has been brought about according to the expectations of industry. However, the prologue and epilogue of these cases highlight that a step back has been taken by EU institutions and, partially, the EBA in order to preserve the patent exclusion under Article 53(b) and also to consider the concerns and interests of other stakeholders and civil society at large.

5.5 Conclusions

The analysis of these landmark cases involving mostly transgenic plants and seeds shows to what extent the use of specific narratives of continuity or novelty, as well as frames and conceptual metaphors, shaped the boundaries and scope of patentable subject matter in different patent systems.
The shifting of these boundaries was sustained by specific views about what kind of artificiality inventions covering plants and seeds embed. Transgenic plants and seeds have been defined like mechanical and chemical technological products, whose reproductive capacity was totally overlooked in judicial reasoning.
In the U.S., judges and the USPTO largely acted as the *gatekeepers* of the definition of patent eligible matter and favored a metaphorical-analogical and dynamic interpretation of its scope. Drawing on the narrative of progress set out in *Chakrabarty* and on the metaphor of the machine, they characterized transgenic plants and seeds as "reproductive technologies" and, therefore, assimilated them to other kinds of patent eligible products. This imaginary of biotech products has been endorsed by the scientific community and the public, which largely shares the view that IPRs over GM seeds and plants are beneficial to U.S. progress and economic growth.

[1267] Decision of the Administrative Council (n 1265).
[1268] Snodin (1266) 119.
[1269] ibid 119-120.
[1270] Sigrid Sterckx and Julian Cockbain, 'The Patentability in Europe of Plants Produced by Conventional Plant Breeding Processes: The European Patent Office Enlarged Board of Appeal Cases G-2/12 Tomatoes II/State of Israel and G-2/13 Broccoli II/Plant Bioscience' (2015) 37(4) EIPR 193, 195-196.

In Canada, although the SCC held that higher life forms were not patentable inventions because it rejected their definition in terms of bio-artefacts or chemical molecules, in *Schmeiser* it sustained the mechanistic nature of chimeric genes and cells. As a consequence, fundamental inconsistencies in the definition of patent eligible matter emerged between judgements and this decision is questionable for its tenets and uncertain implications.

Furthermore, this decision points out that the Canadian sociotechnical imaginary of biotechnology oscillated between fully backing a *semantic of artificiality* of life and nature and censuring its use for higher life forms and DNA sequences. It supported an artificial view of life especially in those sectors in which the country had made large R&D and industrial investments and where the benefits for Canadian society were more discernible. However, this semantic was partially rejected because of its possible consequences in terms of the protection of fundamental human rights and, in particular, the right to health of citizens.

In Europe, the EPO's Boards did not rely on metaphors to address these issues, but resorted to a technical re-framing of what is a plant variety, expanding the scope of patent eligible matter, in order to accommodate transgenic plants and seeds.

In Novartis II, the narrative of novelty and control of genetic engineering, as a plant breeding technology, allowed the EBA to characterize the claimed product not as a variety, but as a plant, and supported the taxonomical non-specific status of transgenic plants and seeds. This decision has elicited, however, several questions about the uncertain scientific ontology of GM plants as a kind, which supported their patent eligibility.

Moreover, the EBA resorted to an historical narrative to confirm that essentially biological processes for the production of plants were still deemed excluded from patent protection. The Broccoli I and Tomato I case shows that, after backing a long-standing erosion of patent exceptions (and exclusions), the EBA opted for partially safeguarding the scope of the patent exception under Article 53(b), as far as essentially biological processes were concerned, but then weakened its holding by allowing the patentability of the products derived from them. However, in this case, the common position on the interpretation of the Biotech Directive expressed by the European Commission and Parliament proved to be crucial in making the EPO's Administrative Council embrace a broader interpretation of the exception.

Under the EPC, the *technical* definition of invention has proved pivotal in establishing the patent eligibility of plants and seeds and the nature of the process for their production.

The legal scholar Sheila Jasanoff illustrated that "Institutions of governance, such as legislatures, courts, and administrative agencies, create order by sorting the complexity of

human experience into categories that can be rationally dealt with".[1271] She pinpointed that these institutions, by providing their opinions, which result in settlements, "do metaphysical work, because they express binding, collective judgements about the nature of things in the world". [1272] In that respect, biotechnology and its inventions elicited a substantial metaphysical endeavor from patent examiners and judges, as it constantly questions the boundaries between the natural and artificial.[1273] However, in the three compared patent systems, these boundaries have been re-framed according to specific narratives and views about the nature of transgenic plants and seeds.

[1271] Sheila Jasanoff, 'The Life Sciences and the Rule of Law' (2002) 319(4) Journal of Molecular Biology 891, 895.
[1272] ibid.
[1273] ibid.

Chapter Six
Imagining Bodies

6.1 Narrating Bodies: Making Nature, Governing Property

The human body is the crossroads in the construction of meanings about individual and collective identities and devising imaginaries of future health and life. Technoscience and law are the expert domains in which the boundaries of bodily identities are largely designed and inscribed, as they represent, define, produce and govern the body, as a whole and its parts (organs, blood, breast milk, tissues and cells). They both act as "the prime custodians of the *is* and *ought*"[1274] of the body in shaping the ontological definition of the body and backing and maintaining specific ethical and legal views about whether and how individuals and society should own, use and transfer it. The narratives of the body that these expert domains bolster are influential in settling and establishing dominant views about *what* or *who* the whole or molecular body is and justifying normative choices about it.

The legal status of the human body is largely ambiguous and unsettled across national, regional and international regulations, as this chapter will point out.

This kind of ambiguity is also embodied in the Council of Europe's *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine* open to signature in Oviedo on 4 April 1997 ("Oviedo Convention"), which is the only international binding instrument in order to protect human rights in the biomedical field.[1275]

The Convention aims at protecting the *dignity* and *identity* of all human beings,[1276] including their bodies, together with their *integrity*, and affirms the principle of *autonomy* of the individual in making choices on his own health. Moreover, it states the primacy of the interests and welfare of the human being over the sole interest of science or society.[1277] It sets out the principle of *informed consent* as a general principle regarding any intervention in the health field, including organ and tissue removal from living donors for transplantation purposes and the disposal of a removed part of the body.[1278] The Convention, however, embeds relevant limits to some of these stated principles.

[1274] Jasanoff (n 138) 767.

[1275] *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, Oviedo 4.4.1997, ETS 164.

[1276] Article1, Oviedo Convention.

[1277] Article 2, Oviedo Convention.

[1278] Article 22, Oviedo Convention.

Mariachiara Tallacchini and Fabio Terragni illustrated that the human body is at the core of three unsettled legal, ontological and moral dichotomies,[1279] which account for most issues related to its governance and the implementation of the Oviedo Convention.

The first dichotomy concerns its definition of the body either as "subject" or "object".[1280] Although most national constitutions and international human right conventions acknowledge that human beings are full "subjects" and therefore entitled to basic human rights and confer them autonomy over their bodies, namely freedoms grounded on the complex relationship of *habeas corpus* and *habeas mentem*, this full "subjectivity" is far from being actually implemented and granted across different jurisdictions. Moreover, the autonomy over the body is limited by several specific legal provisions.

Since the 1950s and 1960s, the technoscientific means of intervening, transforming, preserving and altering the body have expanded and resulted in the production of new body entities and bodily hybrids, such as cell lines,[1281] transplantable organs, chimeras, GMOs, whose legal and ontological framework as "subjects" or "objects" is only partially settled within jurisdictions, as much as their status. These entities challenge the boundaries between the natural and the artificial body and whether and to what extent these bodies should be framed as "subjects" or "objects".

The body, moreover, is concerned by a second dichotomy, which regards the autonomy or heteronomy of legal regimes over it.[1282] Although a large degree of autonomy of the individual over his own body is recognized, nationally and internationally, the different parts of it – organs, tissues, cells, discarded materials – are subject to heterogeneous legal regimes, which frame and curtail the human autonomy and the forms in which it could be exercised under the aegis of the human dignity of the body and its integrity. Significantly the Oviedo Convention endorses this frame by setting out a prohibition of financial gain from the human body and its parts which regards the individual human being to whom they belong. However, the Explanatory Report to the Oviedo Convention clarifies that "the provision does not refer to such products as hair and nails, which are discarded tissues, and the sale of which is not an affront to human dignity".[1283] The sale of these body materials is, in fact, well-established, culturally accepted and legally allowed in several countries worldwide. Nevertheless, the

[1279] Mariachiara Tallacchini and Fabio Terragni, *Le biotecnologie. Aspetti etici, sociali e ambientali* (Bruno Mondadori 2004) v, 37-40.
[1280] Muireann Quigley, 'Property in Human Biomaterials-Separating Persons and Things?' (2012) 32(4) Oxford Journal of Legal Studies 659.
[1281] Rebecca Skloot, *The Immortal Life of Henrietta Lacks* (Macmillan 2010) x.
[1282] Tallacchini and Terragni (n 1279) 37.
[1283] Article 21, Oviedo Convention.

Explanatory Report, whose interpretative force is not compulsory, does not provide any rationale to justify the distinction between different kinds of body materials and the regulatory frameworks according to which they are governed.

In different jurisdictions, human biological materials (HBMs) are subject to different lawful property transfer regimes, mainly gift and/or sale, which are backed and justified under different views of what is the nature of these materials and cultural narratives about their individual and social value. Although gift systems and commodity systems, as suitable legal frameworks in order to govern human tissues, are often considered "mutually exclusive and morally incompatible",[1284] they co-exist in the global political economy of biotechnological HBMs.[1285] Anthropological studies have highlighted that these systems, which establish particular patterns of relations between persons and persons and things, have been largely envisioned and socially promoted in terms of opposition.[1286]

These dominant narratives on the body are locally and culturally embedded and mark how HBMs are devised and framed by states. They, however, also affect the governance of these materials in the regional and international arena, as they back and sustain specific legal frameworks which are possibly endorsed in these political contexts.

It has been noticed[1287] that the body in the Oviedo Convention has been considered as *res extra commercium*, something which is outside the market, because its dignity does not allow to put a price on it.[1288] As Article 21 states, "The human body and its parts shall not, as such, give rise to financial gain". However, Article 22 of the Convention opens the way to secondary uses of human biological materials, as it sets forth that: "When in the course of an intervention any part of the human body is removed, *it may be stored and used for a purpose other than that for which it was removed*, only if this is done in conformity with appropriate information and consent procedures". The storage and use of HBMs for a purpose other than that for which they were removed, can give rise to financial gain and on an invention involving these materials a patent could be granted. The Explanatory Report, nevertheless, clarifies that "the question of patents was not considered in connection with this

[1284] Catherine Waldby and Robert Mitchell, *Tissue Economies. Blood, Organs, and Cell Lines in Late Capitalism* (Duke University Press 2006) 2, 9.
[1285] ibid.
[1286] John Frow, *Time & Commodity Culture: Essays in Cultural Theory of Postmodernity* (Clarendon Press 1997) viii, 102.
[1287] Mariachiara Tallacchini 'Habeas Corpus? Il corpo umano tra non-commerciabilità e brevettabilità' (1998) 4 *Bioetica* 531, 534; Marie-Angèle Hermitte, 'Le corps hors du commerce, hors du marché' (1988) 33 Archives de Philosophie du Droit 323, 325-329.
[1288] Tallacchini (n 1287) 534.

provision"[1289] and the article is not intended to apply to the question of the patentability of biotechnological inventions, which should be addressed in a future study.

Finally, whereas some human biological materials are specifically and thoroughly regulated, others apparently fall within the "no man's land" of the *anomy* of the body.[1290] In this case, the scientific community, patent offices and judges have contextually defined their biological, ontological, moral and legal status, drawing on metaphors, frames and narratives about their nature, which entail specific entitlements, modes of property transfer and evaluation, but mostly handled them as *commodities*.

The molecular view of body and life which biotechnology conveys, as chapter two has clarified (section 2.2.1), contributed to the design and production of materials whose very ontology and legal status suit this anomic land. In this land, as Tallacchini illustrated, the discourse of *dignity* and *autonomy* is opposed to *property* matters.[1291] As a result, a certain allocation of property rights emerged in different cultural contexts, which impinged on alternative ways of representing, framing and governing bodies.

In the last decades, intellectual property has been at the core of the process of regarding, defining and framing the body, its parts and materials and establishing the governance of it. This process is focused on representing and defining the nature of the body and drawing the boundaries between the natural body, which is owned by the individual, and the artificial and molecular one, namely human cells, tissues, materials, which are dealt with as "raw materials", resources in the production of patentable products to which others are entitled.

However, as it has been illustrated in chapter one, the STS scholar Bruno Latour explained, in his seminal work "Science in Action", that "the settlement of a controversy is the *cause* of Nature's representation, not the consequence".[1292] In that respect, all the IP controversies on HBMs are controversies on their *nature*, in which the courts offer an authoritative settlement of nature and how it should be governed within the patent system. In making sense of the *nature* of the molecular body, the courts have relied on technoscientific practices and representations of the body, which back and justify particular ways of framing and governing it. At present, these representations result from an artificial imaginary of the body that they contribute to support and maintain. In these representations, isolation and purification as

[1289] Article 21 – Prohibition of financial gain, 134, Explanatory Report to the *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, Oviedo 4.4.1997.
[1290] Tallacchini and Terragni (n 1279) 37.
[1291] Tallacchini (n 841) 87.
[1292] Bruno Latour, *Science in Action. How to Follow Scientists and Engineers through Society* (Harvard University Press 2003) 99.

criteria for patentability play a fundamental role in defining the molecular body as an *artificial* product to be regarded as totally separate and distinct from the natural body from which it was detached.

As a consequence of the hiatus constructed between dignity and property, the body and HBMs are at the crossroads of competing and alternative legal narratives about their nature and regime, unfolded according to a *human rights'* or *property rights'* perspective, which are drawn upon in judicial controversies over intellectual property.

Whereas the previous chapter illustrated how the use of metaphors on biotech micro-organisms, organisms and genes have shaped the boundaries of what is natural and artificial, as far as the interpretation of patent eligible matter is concerned, this chapter will address how these boundaries have been settled and shaped by patent offices' practices and courts'/patent boards' judgements to accommodate or dismiss other biotechnological products related to the molecular body, namely cell lines, embryonic stem cells and HBMs at large.

6.2. IPRs on HBMs in the United States: *Moore v. Regents of the University of California*

This section will examine how some of the issues concerning the ambiguous ontological, moral and legal statute of the body and its parts have been settled in the United States, when the judges decided a landmark case on the IP over human biological materials (HBMs) and how a well-established national biotech narrative and frame, together with the use of metaphors in defining the nature of materials, accounted for the arguments and holding of the majority of the court.

In the United States, the intellectual property over human biological materials ("HBMs"), in particular as far as their secondary uses are concerned, has been ambiguous and formally legally unsettled until the Supreme Court of California decided in *Moore v. Regents of the University of California* ("*Moore*") on 9 July 1990. Prior to *Moore*, at least three disputes over the property of cell-lines in the United States arose, but they were all settled out of court.[1293]

The Moore case concerned a lawsuit started by John Moore, a patient who underwent treatment for hairy-cell leukemia in 1976 at the Medical Center of the University of California (UCLA Medical Center) in Los Angeles, against Dr David W. Golde, his physician at UCLA Medical Center, the Regents of the University of California, Shirley G

[1293] U.S. Office of Technology Assessment, *New Developments in Biotechnology: Ownership of Human Tissues and* Cells, U.S. Cong., PUB. No. OTA-BA-337 (U.S. Government Printing Office, March 1987) iii, 24-26.

Quan, an employed researcher by Regents, Genetics Institute, Inc., and Sandoz Pharmaceuticals Corporation.[1294]

Moore was confirmed as having developed hairy-cell leukemia by Dr Golde on 8 October 1976 and underwent, as recommended by the doctor, a splenectomy operation to slow down the progress of his disease.[1295] Although, at the time, Moore signed an informed consent authorizing the splenectomy, he was not informed that Dr Golde and Shirley Quant made arrangements to obtain parts of his spleen after the removal to conduct research on the removed materials.

In the following years, between November 1976 and September 1983, Moore returned to UCLA Medical Center several times and samples of blood, blood serum, skin, bone marrow aspirate and sperm were taken, that he understood were necessary for his health treatment under the care of Dr Golde.[1296] He, later, discovered that Dr Golde and Shirley Quant were undertaking research on his cells with the aim of benefitting financially from them.[1297]

In 1979, Dr Golde obtained a cell line from Moore's T-lymphocytes ("the MO-Cell line") and, on 30 January 1981, the Regents of the University of California applied for a patent on the cell line, which was granted on 20 March 1984.[1298] The patent covered also several methods to use the cell lines to produce lymphokines. Moore's T-lymphocytes, which are a type of white blood cells that produce lymphokines (proteins regulating the immune system), were scientifically and commercially interesting as they overproduced a specific kind of lymphokines.[1299]

Dr Golde, then, entered together with Regents into commercial development agreements of the cell line and its derivative products with Genetics Institute and, in 1982, with Sandoz Pharmaceuticals Corporation.[1300]

Once Moore became aware of Dr Golde's undisclosed activities and use of his cells and materials, he attempted to state 13 causes of action before the Superior Court, which considered only the first cause of action, namely *conversion*.[1301]

[1294] Supreme Court of California, *Moore v. Regents of University of California*, July 9, 1990, 51 Cal. 3d 120, 15 USPQ2d 1753, 1754.
[1295] ibid.
[1296] ibid.
[1297] bid.
[1298] U.S. Patent No. 4,438,032, March 20, 1984, "Unique T-ymphocyte Line and Products Derived Therefrom".
[1299] *Moore* (n 1294) 1755.
[1300] ibid.
[1301] Angela A Staunton, 'Forfeited Consent: Body Parts in Eminent Domain' in Johanna Gibson (ed), *Patenting Lives: Life Patents, Culture and Development* (Ashgate 2008) 94.

The opinion of the majority of the Supreme Court of California, which was delivered by Justice Panelli, addressed briefly the issues concerning breach of fiduciary duty and lack of informed consent and, then, discussed and rejected Moore's action as conversion, a tort which safeguards parties against interference with possessory and ownership interests in personal property.

The majority agreed with the Court of Appeal that Moore had cause of action for lack of informed consent against Dr Golde, as a "physician who is seeking a patient's consent for medical procedure must in order to satisfy his fiduciary duty and to obtain the patient's informed consent, disclose personal interests unrelated to the patient's health, whether research or economic, that may affect medical judgment".[1302] The majority, therefore, acknowledged that the allegations against Dr Golde were sufficient, because of the physician's nondisclosures prior to the medical procedure and the postoperative taking of blood and other samples.

The court, however, deemed that, since the other defendants were not physicians and did not stand in a fiduciary relationship with Moore and did not have to obtain his consent to medical procedures, they could not be held primary liable, but possibly considered secondary-liable, provided that Moore offered sufficient allegations.[1303] The Supreme Court, nevertheless, did not engage in examining these issues, since the superior court had to address them on remand.[1304]

The opinion focused on the cause of action as *conversion*, which was admitted by the Court of Appeal. The majority allowed that case law lacked on the matter, but it refused to engage in considering conversion liability for the use of human cells in medical research in the name of the safeguard of scientific research against individual proprietary claims.[1305]

Justice Panelli recalled that conversion sprung from the common law action of trover, which was almost certainly used in cases of casual loss of goods, in which "the finder of lost goods did not return them, but used them himself, or disposed of them to someone else", so he *converted* them to his own use.[1306]

[1302] *Moore* (n 1294) 1757.
[1303] ibid 1758-1759.
[1304] ibid 1759.
[1305] ibid.
[1306] ibid.

The majority rejected the tort of conversion as a cause of action under the existing law, as an extension of the theory which could not be considered advisable to the context of human biological materials.[1307]

The judges endorsed a restrictive interpretation of the tort of conversion hinging on the same narrative of scientific and social progress set out in *Chakrabarty*, by examining, first, Moore's claims under the existing law and, second, whether the conversion liability should be extended.

In addressing the first issue, Justice Panelli pointed out, that, in order to establish conversion, the plaintiff must prove "an actual interference with his *ownership* or *right of possession*".[1308]

The court framed the laws governing human tissues, such as transplantable organs, blood, fetuses, pituitary glands, corneal tissues and dead bodies, as *lex specialis*, which dealt with them as objects *sui generis*, "regulating their disposition to achieve policy goals rather them abandoning them to the general law of personal property".[1309]

In contrast with the Court of Appeal's opinion, which affirmed that a patient has a continuing right to control the use of his excised cells, of what becomes of his own tissues, as holding otherwise "could open the door to a massive invasion of human privacy and dignity in the name of medical progress",[1310] the majority argued that:

> "Yet one may earnestly wish to protect privacy and dignity without accepting the extremely problematic conclusion that interference with those interests amounts to a conversion of personal property. *Nor is it necessary to force the round pegs of "privacy" and 'dignity' into the square hole of 'property' in order to protect the patient, since the fiduciary-duty and informed consent theories protect these interests directly by requiring full disclosure*".[1311]

Tallacchini pinpointed that the court, as it would occur in subsequent U.S. legal analysis regarding the property of HBMs, framed the issues of the case in terms of a dichotomy between the protection of *autonomy*, conceived as *privacy*, and *property tout court*.[1312] According to it, HBMs "belong to the sphere of 'private autonomy' as far as they remain in the body"[1313] and "the body-subject is only legally entitled either to abandon or to donate

[1307] ibid 1760.
[1308] ibid.
[1309] ibid 1761.
[1310] Court of Appeal, Second District, Division 4, California, *Moore v. Regents of the University of California*, 21 July 1988.
[1311] *Moore* (n 1294) 1762.
[1312] Tallacchini (n 841) 90.
[1313] ibid.

them".[1314] Once HBMs are detached, "they become abandoned things (*res derelictae*) that some legally entitled subject or entity (research institutions, corporations) may acquire as *res nullius* (things that nobody owns)". [1315] This divide provides, thus, the suitable legal background to transform HBMs into potential patentable subject matter covered by IP.

She has, moreover, noticed[1316] that this legal framework for HBMs as *res nullius* has been also supported by the U.S. Office of Technology Assessment, which used the metaphor of "wild animals" with reference to HBMs, claiming that:

> "It could be argued the patient and his tissues stand in a relationship similar to that between a landowner and *wild animals* on his land. If tissues were removed without consent, the wrongful possessor would be like a poacher of wild animals, and would have rights inferior to those of the patient. If, however, the tissues were removed without the removal itself being wrongful, their status would be that of wild animals in a state of nature and the possessor could attempt to exercise dominion over them. Not having exercised dominion or control over the tissues, the patient's rights therein would be like those of a landowner who had made no attempt to capture wild animals passing over his land. The argument seems strongest in the case of tumors because these are not normal, healthy parts of the body. A defendant/researcher could contend that it was he, not the patient, who isolated and cultured the abnormal bodily constituents and thereby reduced them to 'possession'".[1317]

This qualification as "*res nullius*" enabled to transform and allocate detached human materials, which inhabit an anomic zone, into objects of property and IPRs.

The doctrine of abandonment in common law countries, however, significantly differs from civil law ones. Abandonment, as the OTA acknowledged in its report, could be used as a defense in order to preclude a claim of conversion, but the defendant must prove "an intention to abandon or relinquish accompanied by some actor omission to act by which such an intention is manifested".[1318]

[1314] ibid.
[1315] ibid.
[1316] Mariachiara Tallacchini, 'Rhetoric of Anonymity and Property Rights in Human Biological Materials (HBMs)' (2005) 22 La w and the Human Genome Review 153.
[1317] U.S. Office of Technology Assessment, *New Developments in Biotechnology: Ownership of Human Tissues and* Cells, U.S. Cong., PUB. No. OTA-BA-337 (U.S. Government Printing Office, March 1987) iii, available at < https://www.princeton.edu/~ota/disk2/1987/8719/8719.PDF>. 82.
[1318] *Sanchez v. Fortuy's Texaco Service, Inc.*, 499 A.2d 436 (Corm. App.1985). ibid.

OTA's remark is consistent with the common law tradition, according to which abandonment is a *purposeful* act, which cannot be merely implied by discarding.[1319] Consequently, property cannot be considered abandoned without a *clear* display of this intention by the owner. It is, furthermore, questioned in common law countries whether property could be abandoned at all.[1320] Both case law and statutory law highlight this feature of property in several common law systems such as the U.K.[1321] and Australia.[1322]

It has been noted that, in the U.K., the English courts largely refrained from holding property abandoned[1323] and dead human bodies have not been qualified,[1324] according to a long tradition, in terms of property.[1325] Moreover, it has been illustrated that the authority in favour of the doctrine of divesting abandonment is slender and case law is limited only to wreck and theft.[1326]

Conversely, in the U.S., case law[1327] upheld that it is possible to abandon personal property, even though in most cases the property has been qualified abandoned when there was "an intention to abandon and a physical act supporting this intent".[1328]

Imogen Goold has explained how the doctrine of abandonment take on a pivotal role in the "tissue property model", as it is the step which enables the possible subsequent transfer of property, under the three requirements set out by the relevant case law: "an original owner of the tissue, a physical relinquishment of the tissue, and a clear, unequivocal intention on the part of the owner to divest herself of all rights in relation to the tissue".[1329]

In 1995, the Nuffield Council on Bioethics issued the report *Human Tissue: Ethical and Legal Issues* and addressed the issues of abandonment and pinpointed that, in the U.S. *Venner v. State of Maryland*, decided by the Court of Special Appeals in Maryland, clarified that: "By the force of social custom (…) when a person does nothing and says nothing to indicate

[1319] Imogen Goold, 'Abandonment and Human Tissue' in Imogen Goold, Kate Greasley, Jonathan Herring, Loane Skene (eds), (Hart Publishing 2014) 125, 126.
[1320] ibid. 129-137.
[1321] ibid. 134-135.
[1322] ibid 136-137.
[1323] ibid 134-135.
[1324] Muireann Quigley, *Self-Ownership, Property Rights, and the Human Body* (Cambridge University Press 2018), vii, 55-60.
[1325] Imogen Goold and Muireann Quigley, 'Human Biomaterials: The Case for a Property Approach' in Imogen Goold, Kate Greasley, Jonathan Herring, Loane Skene (eds), (Hart Publishing 2014) 232, 237-244.
[1326] Goold (n 1319) 130-134.
[1327] Supreme Court of Arkansas, *Eads v Brazelton*, 22 Ark 499 (1861) 509. Ibid 137.
[1328] Goold (n 1319) 137.
[1329] ibid 149.

an intent to assert his right of ownership, possession, or control over [bodily] material, the only rational inference is that he intends to abandon the material".[1330]

The Report, therefore, concluded that in the U.S. the doctrine of abandonment entails that: "1. The legal presumption is in favour of abandonment. 2. Abandonment may be prospective. 3. Where, however, the circumstances are such that abandonment may not be presumed, it must follow that if no consent were given, or a consent expressed to be 'on terms', were given, property rights over the tissue would not necessarily pass but would be retained by the person from whom the tissue was removed".[1331]

In comparison to the U.K., the U.S. courts backed a long-standing doctrine of divesting abandonment[1332] which supported the circulation of commodities, including HBMs. This approach has marked the civic epistemology of U.S. legal system on the face of the majority of other common law national jurisdictions.

In the U.S., the different doctrine of abandonment has proved pivotal, in the *Moore* case, in order to affirm a particular narrative and support a specific metaphor to provide a legal framework and allocate property rights on HBMs.

The necessary ontological and legal cleavage between the natural and the artificial body, between privacy and property, which the majority of the Court maintained, rested on the characterization of Moore's excised cells as "hazardous waste". The definition of *biowaste* has supported the conclusion that Moore could not retain any proprietary interest on his spleen cells and their genetic information, since they were hazardous unusable materials to be properly disposed by the safe hands of professionals.[1333]

This definition of Moore's HBMs as *hazardous waste* is metaphorical. According to the Oxford Dictionary "waste" is "unwanted or unusable material, substances, or by-products",[1334] which should be disposed of according to statutory regulation as "hazardous", namely "fraught with hazard or risk".[1335] "Hazardous waste" is defined, consequently, as "waste, esp. industrial waste, that is potentially harmful to human health or to the

[1330] *Venner v State of Maryland* 30 Md App 599, 354 A2d 483 Md App 1976, 627.
Nuffield Council on Bioethics, *Human Tissue. Ethical and Legal* Issues, April 1995. The case is cited and commented by Goold (n 1319)140.
[1331] Nuffield Council on Bioethics (n 1330) 69-70.
[1332] *Eads v Brazleton* 22 Ark 499 (1861), 509; *US v Wiederkehr* 33 MJ 539 (AFCMR) 541; *Ex parte Szyzcgiel*; and also, as regards seizure of property without a warrant because it does not fall within the Fourth Amendment of the U.S. Constitution, *US v Veach* 674 F2d 1217, 1220 (9th Cir. 1981) and *State v Walker* 119 Ariz 121, 126, 579 P2d 1091, 1096 (1978), cited in footnote 62, Goold (n 1319) 137.
[1333] Waldby and Mitchell (n 1284) 91-99.
[1334] Headword "waste", Oxford English Dictionary.
[1335] Headword "hazardous", Oxford English Dictionary: "1. Fraught with hazards or risks; dangerous; risky".

environment and which requires special facilities for its disposal".[1336] It, therefore, refers to anything which is considered devoid of value of use and need to be disposed of, in order not to create significant hazards.

Yet, Moore's HBMs failed to be subsumed under "unusable materials, substances or byproducts", as lymphokines which are products of the same kind of the MO-Cell line have been deemed worth $3billion in the market of HBMs.[1337] As Lori Andrews and Dorothy Nelkin pointed out, "characterizing something as 'waste' signifies that it is valueless – and human tissue in the biotechnology age is anything but valueless".[1338] Human tissues and materials, as several scholars explained, turned out to be crucial for the "knowledge-based genomics revolution"[1339] and the development of stem-cell technology.

Catherine Waldby and Robert Mitchell illustrated how, in the U.S., previously established discourses of "waste" used in the debates on human tissues played a pivotal role in fostering the use of the idea of waste in relationship to Moore's excised spleen cells.[1340] In particular, they illustrated that the idea of *waste* accounted for bringing about the process of what the STS scholar Michel Callon named "disentanglement".

Callon, addressing how technological markets are built and stabilized, pinpointed that the economies of organ transplantation are "entangled in the body of a potential donor",[1341] as the movement of organs is limited by their material and social embodiment. Making human organs circulate into the market mandates efforts of disentanglement. The transfer of the organ, therefore, hinges on a successful process of disentanglement, which "transform it into a good free of all attachments".[1342] This process, as Hogle explained,[1343] is carried out by setting up a market of organs which can circulate better because of the donor protocols, which aim at supplying "consistent materials that could be used in any appropriate recipient and to produce prime quality organs".[1344] In order to achieve this goal, obtaining informed consent together with setting up a standardized file on the donor, which embeds all the salient

[1336] Headword "waste" (n 1236) 4.
[1337] Lori Andrews and Dorothy Nelkin, *Body Bazar: The Market for Human Tissue in the Biotechnology Age* (Crown Publishers 2001) 2, 25.
[1338] ibid 29.
[1339] Dianne Nicol, Don Chalmers, Rebekah McWhirter and Joanne Dickinson, 'Impression on the Body, Property and Research' in Imogen Goold, Kate Greasley, Jonathan Herring, Loane Skene (eds), (Hart Publishing 2014) 9, 11.
[1340] Waldby and Mitchell (n 1284) 90.
[1341] Michel Callon, 'Introduction: The Embeddedness of Economic Markets in Economics' in Michel Callon (ed) *The Laws of the Markets* (Blackwell Publishers1998) 2, 36.
[1342] ibid 37.
[1343] Linda F Hogle, 'Standardization across Non-Standard Domains: The Case of Organ Procurement' (1995) 20(4) Science, Technology & Human Values 482.
[1344] ibid 585.

information about him and his relations in order to make decisions about transplantation, initiate the disentangling process of the organ.[1345] The moves of disentanglement convert the organ, which was previously attached materially and socially to a human being, into a half-good, though they are designed and carried out in view of the re-entanglement of the organ into the recipient.[1346]

Examining in depth the entanglement and disentanglement process which involves different kinds of HBMs, Waldby and Mitchell pointed out that embryos and human biological materials, like organs, are entangled entities embedded in material and social relationships, which can be *technically* and *legally* disentangled. As far as the embryo is concerned, informed consent is a legal means which detaches it from "the network of family relations that produced it, and positions it as a technical entity whose productivity is at the disposal of the laboratory".[1347] The process of separation of human biological materials from individuals is, therefore, carried out by informed consent, which enables the production of a cell line.

The next stage is technoscientific, but has also legal relevance, and consists in deriving from the embryo a cell line, which can be "standardized, stored, divided, multiplied and transported throughout the world".[1348] The transformation that the embryo undergoes, in fact, support either the existence of the "inventive step"[1349] and its "patent eligibility" as an invention and not a mere natural discovery. Stem cell lines, for example, derived from embryos can be banked, copied, and made to circulate[1350]. Moreover, they can be constituted as the IP of the researcher.[1351]

In this section, it is argued that both these technical and legal moves of disentanglement co-produce the ontology and moral and legal status of HBMs. However, as Waldby and Mitchell remarked patent protection, in particular, acts as a very powerful form of disentanglement, as it "involves a profound transmutation in value, as the ontological significance of the embryo and the social value of its donation give way to the investment value of the patented cell line"[1352] and convert cell lines into negotiable assets.

They noted that, in *Moore*, the Supreme Court of California largely drew selectively on the early debates about blood and organs transplantation hearings and legislation held in the

[1345] Callon (n 1341) 37.
[1346] ibid.
[1347] Waldby and Mitchell (n 1284) 73.
[1348] ibid.
[1349] ibid.
[1350] ibid.
[1351] ibid.
[1352] ibid 69.

1960s and 1980s, in which witnesses argued that tissue donation would assure a free flow of information which was necessary to protect human health and avoid the *waste* of these materials.[1353] Moreover, they observed that the metaphor of "waste" was also evoked by Senator Birch Bayh in the opening hearings of the Bayh-Dole Act, when he declared that "talent responsible for the development of numerous innovative scientific breakthroughs each year [was] going to waste as a result of bureaucratic red tape and illogical government regulations". [1354] The metaphor of waste, in his speech, concerned the government's appropriation of IP on the inventions which were publicly funded[1355] and has proved influential in backing a specific patent policy in the U.S.

In addressing whether the conversion liability should be extended, Justice Panelli underscored that Moore's ownership claim was problematic because California statutory law limited a patient's control over excised cells. He referred to Health and Safety Code section 7054.4, which mandated that "[n]otwithstanding any other provision of law, recognizable anatomical parts, human tissues, anatomical human remains, or infectious waste following conclusion of scientific use shall be disposed of by internment, or any other method determined by the state department [of health services] to protect the public health and safety".[1356]

Justice Panelli acknowledged that section 7054.4 occurred in a division of the Health and Safety Code entitled "Dead Bodies", but he considered the terms "recognized anatomical parts" and "human tissues" as not limited to dead bodies.[1357]

Despite the opinion conceded that the statute did not address whether a patient was entitled to compensation for the use of his excised cells without his consent, but aimed at ensuring "the safe handling of potentially hazardous biological waste materials",[1358] the drastic limits to a patient's control over excised cells qualified as "waste" were deemed sufficient to deprive the patient of any property right and control over his HBMs.

The conclusion drawn by the Court was that "By restricting how excised cells may be used and requiring their eventual destruction, the statutes eliminates so many of the rights

[1353] ibid 99 and 101.
[1354] Ashley J Stevens, 'The Enactment of the Bayh-Dole' (2004) 29 Journal of Technology Transfer 95, in Catherine Waldby and Robert Mitchell, *Tissue Economies. Blood, Organs, and Cell Lines in Late Capitalism* (Duke University Press 2006) 2, 102.
[1355] Ashley J Stevens, 'The Enactment of the Bayh-Dole' (2004) 29 Journal of Technology Transfer 93-99. This point was made by Simon Douglas, 'Property Rights in Human Biological Materials' in Waldby and Mitchell (n 1284) 102.
[1356] *Moore* (n 1294) 1762-1763.
[1357] Footnote 32, ibid 1763.
[1358] ibid.

ordinarily attached to property that one cannot simply assume that what is left amounts to 'property' or 'ownership' for purposes of conversion law".[1359]

The majority's argument, first, framed the issues of IP over HBMs as a strict alternative between *privacy rights* and *property rights*, and then, by applying the metaphor of biowaste to Moore's excised cells, emptied his proprietary interest over them. This double move, allowed the court to protect the interests of research, which were affirmed within the same narrative of progress, endorsed by SCOTUS in *Chakrabarty*, according to which promoting scientific research and the market would foster social progress.

Justice Panelli argued that access to human cells was pivotal for medical research, because researchers were increasingly able to "to isolate naturally occurring, medically useful biological substances and to produce useful quantities of such substances through genetic engineering".[1360] The extension of conversion law in the area of HBMs was, therefore, deemed to "hinder research by restricting access to the necessary *raw materials*"[1361] and "destroy the economic incentive to conduct important medical research".[1362]

The opinion largely confirmed the well-established U.S. frame for biotechnology as a set of valuable *products*, which was supported by the U.S. OTA in the Report entitled "New Developments in Biotechnology: Ownership of Human Tissues and Cells", largely used in the argument of the majority,[1363] which pointed out that the biotech efforts to isolate HBMs were beginning to bear fruit: "*Products* developed through biotechnology that have been approved for marketing in this country include treatments and test for leukemia, cancer, diabetes, dwarfism, hepatitis-B, kidney transplant rejection, emphysema, osteoporosis, ulcers, anemia, infertility and gynecological tumors, to name but a few".[1364]

In contrast with the majority, Justice Mosk, who dissented, highlighted the "inherent capacity of the common law for growth and change is its most significant feature"[1365] and that the law of conversion as a common law creature underwent several extensions, because of the advances in science and technology that could not be foreseen when the traditional tort doctrine was formulated.

[1359] ibid.
[1360] ibid 1765.
[1361] ibid 1765.
[1362] ibid 1766.
[1363] U.S. Office of Technology Assessment, *New Developments in Biotechnology: Ownership of Human Tissues and* Cells, U.S. Cong., PUB. No. OTA-BA-337 (U.S. Government Printing Office, March 1987) iii, available at < https://www.princeton.edu/~ota/disk2/1987/8719/8719.PDF>.
[1364] *Moore* (n 1294) 1765.
[1365] ibid 1776.

Moreover, he challenged the interpretation of Section 7054.4, which refers and permits only "scientific use", not commercial exploitation. Highlighting that in interpreting the statute judges should give them their usual, ordinary meaning, he deemed that the expression "scientific use" could encompass routine postoperative examination of excised tissue conducted by a pathologist for diagnostic or prognostic reasons or, possibly, purely scientific study by a disinterested researcher. However, he clarified that it could not be stretched to encompass commercial exploitation of the kind alleged before the court.[1366] However, the locution did not cover the entrepreneurial activities of Dr Golde and Quan and the support they had from UCLA in order to apply for IPRs and negotiating with bioengineering and pharmaceutical companies.[1367]

He disagreed, moreover, that the limits set out in the section could leave Moore without property or ownership rights.[1368] He observed that property consists of a bundle of rights that could be disposed of by sale or gift.[1369] Although both law and contract may be subject to restriction on the time, place and manner of use of their property, still what is left is a protectable property interest, which is retained by the individual.[1370]

This property interest, according to him, extended to the patented cell line and the products derived from it, as it not *factually* and legally distinct from the cells taken from his body. He highlighted that Moore could not be considered a "joint inventor", because he did not contribute to substantial development of the product, but as a patient who unknowingly provided his unique raw materials and, in that respect, part of the legal doctrine supported the analogy between providing raw materials and contributing in an essential way to create a patented product.[1371]

He, then, challenged the majority's policy considerations and the narrative of progress, according to which research on human tissues could be hindered by recognizing patients' property rights over their materials. Overturning the narrative and pointing to the limitations that allocating IPRs over the invention derived from HBMs could entail, he pinpointed the limits to free exchange of material among researchers, which could impinge on scientific research.[1372]

[1366] ibid 1777.
[1367] ibid.
[1368] ibid 1777-1778.
[1369] ibid 1778.
[1370] ibid.
[1371] Danfort, 'Cells, Sales, & Royalties: The Patient's Right to a Portion of the Profits' (1988) Yale Law and Policy Review 179, 197. *Moore* (n 1294) 1780.
[1372] *Moore* (n 1294) 1780-1781.

He, therefore, concluded that, as research on human cells handles the body as a commodity, "a means to a profitable end", the owner of the HBMs should benefit from them.[1373]

Jasanoff illustrated that this decision, like several other U.S. biotech patent judgements, makes sense within "the specificity-circulation framework".[1374] According to this framework, "the property claim has to involve *both* taking a specific, characterizable, and reproducible bite (and, today, perhaps as much byte as bites) out of nature *and* a capacity to make the excised element circulate widely in commerce".[1375] The judges endorsed this framework and, on its premises, deemed that property was allocated best to who was able to generate greater economic value by taking and making the natural HBMs specific and reproducible and able to make them commercially viable, namely the researchers and the pharmaceutical companies. As the majority argued, the patented cell line was "factually and legally distinct from the cells taken from Moore's body",[1376] since Moore's natural spleen cells have been made *artificial* enough to deserve patent protection and, thus, to be allocated to whom made them viable for commercial use.

As the IP scholar Gold noticed, in a large number of cases regarding property and IP in the last decades, the U.S. courts privileged mainly the economic mode of evaluating goods, either in cases regarding the protection of computer programs and algorithms, personas, genetically modified microorganisms and HBMs, and recognized property interests only to claimants who proved the economic value of the good at stake, notwithstanding the relevance of other modes of evaluation could prove to be more fundamental for them.[1377] The expansion of this approach to HBMs, which has been questioned by Gold, is fully consistent with the specification-circulation framework explained by Jasanoff.

In that respect, all the U.S. biotech patent cases that have been analysed in this work show how technoscience, patent judgments, as well as USPTO's practices, have acted in removing the natural and legal hurdles to the commodification of microorganisms, organisms, seeds, HBMs and genetic sequences: biotechnology by developing new ways of overcoming interspecific barriers to the genetic modification of organisms and making them artificial enough to fall into the framework, the case law by extending the scope of patent eligible

[1373] ibid 1783.
[1374] Sheila Jasanoff, 'Taking Life. Private Rights in Public Nature' in Kaushik Sunder Rajan (ed), *Lively Capital. Biotechnologies, Ethics, and Governance in Global* Markets (Duke University Press 2012) 155, 168.
[1375] ibid 158.
[1376] *Moore* (n 1294) 1763.
[1377] See Chapters 3-6, E Richard Gold, *Body Parts: Property Rights and the Ownership of Human Biological Materials* (Georgetown University Press 1996) vii.

matter and allocating IP rights to research institutions and companies, who are able to carry out the specificity-circulation path.

This work argues, as other scholars have thoroughly illustrated,[1378] that this trend is largely supported by U.S. political regulatory culture, which is "product-centered", as it regards and endorses the "product" as the main way to conceptualize all the issues related to biotechnology, since the 1970s: from the risks related to rDNA technology to the patentability of GM microorganisms and organisms.

As Parthasarathy has illustrated, in her comparative study of the IP policy of biotech inventions in the US and Europe, this cultural way of dealing with the issues related to biotechnology also marked how the U.S. patent system addressed the main patent cases in the last four decades, which was oriented "to market making".[1379]

In conclusion, *Moore* has settled the issues of ownership over HBMs and the patented cell lines derived from them, allocating IPRs to the researcher and the pharmaceutical companies who could best specify and transform the HBMs and make them commercially viable.

The arguments of the majority show that between corporeal and incorporeal claims, excised cells as bodily chattel and incorporeal ones over the Mo-Cell line, the latter should prevail, as they promote best the specificity-circulation framework and the creation of markets for products.

6.2.1 Stabilizing Ontologies and Allocating IP over HBMs in the United States: *Greenberg v. Miami Hospital* and *Washington University v. William J. Catalona*

In *Moore*, the Supreme Court of California set out the rationale to allocate the property and IPRs over HBMs in the United States in favour of researchers and biotech pharmaceutical companies. As these actors were able, in fact, to commodify HBMs and the information they embed more efficiently under the specification-circulation framework, they have been entitled to use and have control over these materials.

More than ten years later, *Greenberg v. Miami Children's Hospital Research Institute* ("*Greenberg*") and *Washington University v. William J. Catalona* ("*Catalona*") settled, furthermore, the issues concerning who ought to be considered the legal owner of HBMs, in controversies opposing medical researchers to academic, medical and clinical institutions or patients' families.

[1378] Jasanoff (n 568) 23; Parthasarathy (n 888) 1.
[1379] Parthasarathy (n 888) 1.

Although these two cases concerned the property over HBMs, they were pivotal in paving the way and backing the allocation of IPRs over inventions arising from HBMs to the institutions employing medical researchers and clinicians in place of the employees.

In the last forty years, the market value of different human and non-human biological materials has emerged, because of the extension of the technoscientific possibilities of extracting, isolating and using them (together with the genetic information they embed) and the ability of turning them into commercial products. Sperm, oocytes, embryos, blood, cells have increasingly been devised, since the 1970s, as valuable products that could boost both research and the economy.

Moreover, emerging patent policies in the United States, Canada and Europe (EPC system and European Union), centered on the criteria of isolation and purification as the techno-legal rationale to support the patentability of products derived from biomaterials as different from the materials in their "native" natural and embodied state, have provided the legal conditions in order to attract capital and investments and bring about their commercialization into the market.

Settling the property issues over HBMs and vesting property rights on who has the knowledge and economic means to transform these materials into circulating commodities is the first move to exclude any legal claim over IPRs on patented inventions granted on them, as well as on the earned profits, which could encroach on the use of IP.

Catalona significantly shows the bond between making and allocating property over HBMs and establishing IPRs on inventions obtained from them.

Catalona was decided by the United States Court of Appeals for the Eight Circuit on 20 June 2007 and concerned the ownership of human biological materials in their "natural state" housed on campus of WU for the purpose of genetic cancer research. Washington University ("WU") filed, on 4 August 2003, a declaratory judgment action against Dr Catalona, a renowned urologist and prostate cancer surgeon employed at WU from 1976 to 2003,[1380] aiming at establishing WU's ownership over biological materials. Dr. Catalona had focused consistently his research on the genetic basis of prostate cancer and, since 1983, started to collect samples of HBMs, together with his colleagues at WU, such as blood and tissues removed during patients' surgery, in order to study prostate cancer.[1381]

[1380] *Washington University v. William J. Catalona*, 490 F.3d 667 (8th Cir. 2007), 670.
[1381] ibid.

Moreover, he had promoted the creation of the Genito-Urinary Biorepository which, at the time of the lawsuit, was the world's largest storage facility for biological samples for prostate cancer research.[1382]

In 2001, Catalona began to negotiate with a biotech company in order to develop a genetic prostate cancer test,[1383] but the university's technology management office interposed and tried to negotiate a more beneficial agreement for the university.[1384] As Lori Andrews pointed out, WU throughout the years began to consider these collected and stored tissue samples not just a "resource for prostate cancer research advances, but as a capital resource for the university".[1385]

Afterwards, in 2003, Catalona accepted a faculty position at Northwestern University and sent, in February 2003, to his former patients and their relatives, as well as other research participants, a letter informing them that he was leaving and asking for the transfer of their biological materials to him at Northwestern University. Approximately 6,000 research participants agreed and returned the signed form[1386] to Catalona.

The main issue of the lawsuit on which the United States Court of Appeals for the Eight Circuit had to rule on was: "whether individuals who make an informed decision to contribute their biological materials voluntarily to a particular research institution for the purpose of medical research retain ownership interest allowing the individuals to direct or authorize the transfer of such materials to a third party".[1387]

The Court of Appeals, like the District Court for the Eastern District of Missouri previously, found that WU owned the biological samples, as the research participants donated their HBMs as *inter vivos* gifts, to the University, namely as a kind of "voluntary transfer of property by the owner to another, without any consideration or compensation as an incentive or motive of the transaction".[1388]

The existence of an *inter vivos* gift entails the proof of the existence of "a present intent of the donor to make a gift", "the delivery of the property by the donor to the donee" and the

[1382] ibid.
[1383] Sheila Jasanoff, 'Whose Knowledge, Whose Property?' in Sheila Jasanoff, *The Ethics of Invention: Technology and the Human Future* (Norton 2016) 177, 187.
[1384] ibid 187.
[1385] Lori Andrews, 'Who Owns Your Body? A Patient's Perspective on *Washington v. Catalona*' (2006) 34(2) Journal of Law, Medicine & Ethics 398.
[1386] *Catalona* (n 1380) 672.
[1387] ibid 673.
[1388] ibid 674.

acceptance of the gift by the donee.[1389] Since the research participants delivered their biological materials to WU, the court only dealt with the first and third elements.[1390]

By relying on the language of the brochure given to the research participants and the informed consent form, the Court of Appeals concluded that all the elements of an *inter vivos* gift occurred and that the donation of the HBMs was absolute.[1391] The research participants, therefore, did not retain any proprietary interest on their HBMs that could authorize them to transfer the biomaterials to Dr. Catalona.[1392]

In this judgment, allocating property over HBMs to WU constituted the anticipatory move in order to confirm and sustain the allocation of IPRs on inventions originated from the isolation of these materials to the research and clinical institution which stored them.

Under U.S. patent law, an employee is deemed the owner of the "patent rights to his or her inventions conceived or reduced to practice during the course of employment",[1393] however, he has to "assign patent rights to his employer if he was initially hired or later directed to solve a specific problem or to exercise inventive skill"[1394] or "if signed an assignment contract".[1395] These two exceptions are significant as, in most patent cases involving employees-inventors, the relationship with the employer falls within these exceptions.

Catalona is consistent with the policy of allocating IPRs to the employer, who is supposed to have the expertise to negotiate more efficient economic deals with biotech companies in order to bring patented products into the market, as it ruled on the property of the HMBs, which are the source of possible future inventions, in favor of the clinical and research institution-employer.

In the aftermath of these judicial decisions, in the U.S., the courts favoured this approach, which allocated property over HBMs and IPRs on the invention derived from them to the actors who could best foster innovation for market purposes. In this regard, the Bayh-Dole Act has carved out a clear role in the neoliberal agenda for academic institutions, as far as IP and patents in particular are concerned.

[1389] ibid.
[1390] ibid.
[1391] ibid 675.
[1392] ibid 676.
[1393] Donald S Chisum, Tyler T Ochoa, Shubba Gosh, Mary LaFrance, Understanding *Intellectual Property Law*(1st edn 1992, LexisNexis 2011) iii, 193.
[1394] ibid.
[1395] ibid.

Greenberg v. Miami Hospital ("Greenberg")[1396] was decided in 2003 and concerned the donation of HBMs to Dr. Reuben Matalon, a medical researcher employed at Miami Children's Hospital Research Institute, by Mr. and Mrs. Greenberg and other patients' families in order to advance the study and cure of Canavan disease, a degenerative gene-linked neurological birth disorder, which affects most frequently Askenazi Jewish families.[1397] The Greenbergs brought action for damages and equitable and injunctive relief against Dr. Matalon and the Hospital on counts of lack of informed consent, breach of fiduciary duty, unjust enrichment, fraudulent concealment, conversion and misappropriation of trade secrets.[1398]

Greenberg, just like *Moore*, concerned the *product* of research on HBMs and, in particular, the patent resulting from it.

However, in this case, as Judge Moreno pointed out, the families of children affected by the disease asserted their legal rights challenging "the commercialization of the fruits of their Canavan disease research".[1399]

Dr. Matalon and his research group isolated the gene linked to Canavan disease and applied for a patent, which was granted in 1994, unbeknown to the Greenbergs and the families who provided the HBMs and information.[1400] He, then, attempted to license his patent on the gene sequences.[1401]

In *Greenberg* the District Court clarified that the duties of researchers differ from those of physicians, whose relationship with patients is built on trust, and the law on medical consent "does not apply to medical researchers".[1402] Whereas physicians have to fully disclose their interests to patients agreeing to provide their HBMs, researchers do not have to communicate their commercial interests.[1403]

The Court drawing on *Moore* pointed out that, once the biomaterials were donated to Dr. Matalon, the patients and their families did not retain any ownership right over them and,

[1396] Debra L Greenfield, 'Greenberg v. Miami Children's Hospital: Unjust Enrichment and the Patenting of Human Genetic Material' (2006) 15(2) Annals of Health Law 213.
[1397] *Daniel Greenberg, et al. v. Miami Children Hospital Research Institute, Inc., et al.*, U.S. District Court, S.D. Florida, 264 Fed. Suppl. 2d Series 1064 (2003).
[1398] ibid.
[1399] ibid 1066.
[1400] ibid 1067. Scott F Gibson, '*The Washington University v. Catalona*: Determining Ownership of Genetic Samples' (2008) 48 Jurimetrics 167, 175.
[1401] *Greenberg* (n 1397) 1067.
[1402] ibid 1069.
[1403] ibid 1070-1071; Tallacchini (n 841) 91.

since he was granted IPRs over the isolated gene, he was also the indisputable owner of the HBMs.[1404]

In conclusion, these cases show that allocating property of the materials and IPRs rights are strictly dependent and the US courts, through judicial decisions, created a stable and coherent link between how property rights on HBMs and IPRs on inventions derived from them are allocated.

Both cases show U.S. courts' proclivity to consider informed consent as legal means to exclude that patients and research participants have any proprietary rights and interest on their HBMs, once they have agreed and signed the informed consent form, and to vest proprietary rights to the research institutions and the biotech companies, which are more able to foster "the specificity-circulation framework".[1405]

6.3 IP over HBMs in Canada

In this chapter, it will be explained that governance of HBMs has been marked by significant differences across countries that impinged on national patent policies.

In Canada, inventions on different HBMs, as well as their property, have not been challenged before the courts. The focus of bioethical, social and legal concerns has largely been the patenting of higher life forms.

In June 2002, the Canadian Biotechnology Advisory Committee ("CBAC") issued a report entitled "Patenting of Higher Life Forms and Related Issues",[1406] in which it addressed the problems raised by the *Harvard mouse* case and the *Schmeiser* case, namely whether "Canada should permit the patenting of plants, seeds and animals",[1407] which was later addressed and decided by the SCC, and the social and ethical concerns raised by biotechnology. The Report was the result of a research and consultation program started in 2000, since the government officials and the CBAC members had pinpointed the patenting of higher life forms as area of growing concerns[1408] and the *Harvard mouse* case was proving highly divisive for Canadian society. The report aimed at exploring the different positions of the groups and individuals involved in the consultation process and making normative recommendations on future biotech patent policy. These recommendations also focused on the patentability of the human body and HBMs.

[1404] ibid 1074-1076.
[1405] Jasanoff (n 1383) 168.
[1406] Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues. Report to the Government of Canada Biotechnology Ministerial Coordinating Committee*, June 2002, iii.
[1407] ibid ix.
[1408] ibid 1.

The first recommendation suggested by the CBAC was to amend the Patent Act, in order to exclude human bodies, at any stage of development, from patentable inventions.[1409]

The CBAC, nevertheless, drew a line that shielded the molecular human body from this patent exclusion. It pointed out that the human body should not be included in the scope of the recommendation, which therefore "would not, however, prevent patent claims from being granted with respect to DNA sequences, cell lines or stem cells of human origin".[1410]

The CBAC proposed a narrow definition of the locution "human bodies at all stages of development", which encompassed the "human bodies of infants, children and adults within the exclusion, but also all precursor of the human body from zygotes to fetuses",[1411] but agreed with the need to support economic investments in order to research cell lines and to safeguard IPRs over HBMs-based inventions.

By arguing that stem cell research ought not to be discouraged, the CBAC clarified that, notwithstanding the recommendation, DNA sequences, gametes (ova or sperm cells), stem and other cells or organs would remain patentable, in conformity with the provisions of the *Assisted Human Reproduction Act*, introduced in Parliament on 9 May 2002, which allowed research on gametes, cells (as well as stem cells), DNA sequences and embryos under certain conditions, but embedded a ban on the creation and use of human clones.[1412]

CBAC emphasized the relevance of biotechnology for the Canadian economy, as one of the world's fastest growing industries whose revenues amounted to nearly $2 billion, in 1999, and were expected to reach $5 billion in 2005.[1413]

Although the CBAC cautioned against some human, animal and environmental risks in biotechnology, it argued that higher life forms should be patentable in Canada, in order to promote "economic and social benefits in areas such as health, agriculture, the environment and industry".[1414]

The Committee proposed a general definition of the principle of non-patentability of the human body, criticizing some of the detailed recitals and provisions of the Biotech Directive. It pinpointed that they engendered confusion about which elements of the human body could be patentable or not (e.g. genes of human origin) and the interpretation of Article 5(3),

[1409] ibid x; Timothy A Caulfield, 'From Human Genes to Stem Cells: New Challenges to Patent Law' (2003) 21(3) TRENDS in Biotechnology 101, 102.
[1410] ibid 8.
[1411] ibid 9.
[1412] ibid.
[1413] ibid 2.
[1414] ibid.

namely whether patent applications were required to specify the function of the gene only if it's human or also if it's non-human.[1415]

According to CBAC, the choice between a general or detailed formulation of the concept of non-patentability of the human body had taken into account three main issues, which backed a general exclusion: 1. The concept must be flexible and clear enough to be applied to all future technologies; 2. It should avoid making unnecessary distinctions between discoveries and inventions, as Canadian patent law already excludes natural occurring substances, in their natural state, from patentability; 3. It ought to highlight that assessing what is patentable is different from addressing the issues of its novelty, non-obviousness and usefulness.[1416]

From the consultation emerged that a segment of public opinion deemed that patents on animals, plants, or any biological material (DNA sequences, genes and cells) should not be patented on moral grounds,[1417] but, at the time, CIPO had already established genetic material (DNA, RNA and genes) of plant, animal and human origin, as well as on microorganisms,[1418] as falling within the scope of patentable "invention".

Furthermore, the CBAC argued that administration of the Canadian patent system ought to be improved, by developing specific guidelines for patents on biological materials, which had to be regularly updated by CIPO. The guidelines should aim for more transparency (and certainty) about the interpretation of the criteria for issuing patents in the biotech sector and "the process to be followed by patent applicants and the benchmark time frames for each step, to the extent (if any) that these may differ from other patent applications".[1419]

In the same year, the majority of SCC clearly rejected CBAC's recommendation in favour of the patentability of higher life forms and, conversely, ruled, in the *Oncomouse* case that they were not patentable, deeming Parliament, not the courts or CIPO, the most appropriate forum to discuss and decide granting IPRs over complex organisms. However, this line judicially drawn, between higher life forms and the molecular dimension of life, has become murkier after the SCC's decision in *Schmeiser*.

Litman and Robertson illustrated that the legal status of genetic and human biological materials in Canadian common law was largely unsettled,[1420] when the CBAC's report was

[1415] ibid 9.
[1416] ibid 8.
[1417] ibid 1.
[1418] ibid 2.
[1419] Recommendation 10, ibid 21.
[1420] Moe Litiman and Gerald Robertson, 'The Common Law Status of Genetic Material, in Bartha Maria Knoppers, Timothy Caulfield and T Douglas Kinsella (eds), *Legal Rights and Human Genetic Material* (Edmond Montgomery Publications 1996) 51.

issued, and it is still at present. Canadian legal scholars drew on and commented the U.S. case law, which has been in part analysed in this chapter, in order to devise whether and to what extent the human body and its parts could be considered subject/person or object of property and IPRs. Moreover, in Canada, any research involving the status of these materials have to take into account that Quebec's civil law system co-exists and frames the status of the body differently,[1421] overall making sense and co-producing an order which rests on the hybrid Canadian civic epistemology.

Canada launched, in 1983, the National Biotechnology Strategy (NBS), whose goal was to exploit and facilitate the potential of rDNA techniques in order promote Canadian biotechnology. According to the strategy, biotechnology was framed as *products*. After the strategy was set forth and successfully implemented, the rhetoric of its development was centered on maintaining Canadian advantage in biotechnology. As far as IPRs on HBMs and life forms, the Canadian Supreme Court did not endorse the narrative of progress, that in the U.S. led the judges in *Chakrabarty* to open up to the patentability of biotech products. Although the Canadian Patent Act embeds a definition of invention, which is almost identical to the U.S. definition of patentable subject matter, the Supreme Court's judges refrained from endorsing a deterministic vision of progress and relied on a different constitutional view of how to settle the boundaries between the judiciary and legislative power, where patent policy is concerned.

However, under the National Biotechnology Strategy, named since 1998 Canadian Biotechnology Strategy, the preferred "product" frame for biotechnology has largely supported CIPO's long-standing practice of allowing the patentability of HBMs, provided that they fulfill a certain threshold of artificiality.

Following the holding of *Oncomouse*, CIPO refused patents claiming animals at any stage of development, from fertilized eggs on. Moreover, also totipotent stem cells, which can potentially develop into an entire animal are considered equivalent to a fertilized egg and, therefore are not patentable inventions.

At present, adult stem cells are patentable in Canada. Patent claims directed to human embryonic stem cells have been rejected by CIPO, but in 2006 CIPO issued a notice, which

[1421] Marie Hirtle, 'Civil Law and the Status of Human Genetic Material' in Bartha Maria Knoppers, Timothy Caulfield and T Douglas Kinsella (eds), *Legal Rights and Human Genetic Material* (Edmond Montgomery Publications 1996) 85, 89-116.

clarified that "Embryonic multipotent and pluripotent stem cells, which do not have the potential to develop into an entire animal, are patentable subject matter".[1422]

Blanchard has pointed out that, since CIPO did not make any distinction concerning the source of the stem cells, this part of the notice encompasses any kind of source and include human embryonic stem cells, and that the Notice conformed to the position adopted by the U.K. IPO, which allowed since 2003 claims to embryonic stem cells as long as they were non-totipotent.[1423]

At present, CIPO's Manual of Patent Office Practice (MPOP), in Chapter 17.02.02, regarding organs and tissues sets out that : "Organs and tissues (whether of plant or animal origin) are generally not considered to be manufactures or compositions of matter for the purposes of section 2 of the *Patent Act*. Organs and tissues are in general created by complex processes, elements of which require no human intervention, and do not consist of ingredients or substances that have been combined or mixed together. In view of this, the Office considers that a genetically-modified organ or tissue is not statutory subject-matter".[1424] Nevertheless, it states that "Artificial organ-like or tissue-like structures that are distinct from true tissues and organs and that have been generated by human intervention through the combination of various cellular and/or inert components may be considered, on a case-by-case basis, to be manufactures or compositions of matter within the scope of section 2 of the *Patent Act*. For example, functional and anatomical differences may be indicators that serve to distinguish an organ-like or tissue-like structure from a true organ or tissue".[1425] This guideline mirrors what CIPO's Notice settled on organs and tissues in 2006, namely that these kinds of biological materials, which fulfill a threshold of artificiality are possibly patented, on a case-by-case basis.[1426]

6.4 A Matter of Europe

In Europe, the patentability of HBMs has been questioned in the last two decades and the debate has focused mostly on embryonic stem cell lines, which have been challenged on morality grounds.

The European Convention on the Grant of European Patents in 1973 set out, first, a morality and *ordre public* clause in Article 53, which regards the exceptions to patentability, by

[1422] CIPO Notice, *Office of Practice Regarding Fertilized Eggs, Stem Cells, Organs and Tissues* (June 20, 2006).
[1423] Adrienne Blanchard, *Life Sciences in Canada*, available online at Thomson Reuters Westlaw, at 2.7.
[1424] CIPO, MPOP (n 1492) 17.02.02.
[1425] ibid.
[1426] CIPO Notice, *Office of Practice Regarding Fertilized Eggs, Stem Cells, Organs and Tissues* (June 20, 2006), available at < https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr00295.html>.

establishing in Article 53(a) that "European patents shall not be granted in respect of: (a) inventions the publication or exploitation of which would be contrary to 'ordre public' or morality, provided that the 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".

The clause has been partially modified by the Act revising the Convention on the Grant of European Patents, signed in Munich on 29 November 2000 and entered into force on 13 December 2007, and in the text of EPC 2000 the reference to publication disappeared, so that, at present, under Article 53(a) the morality and contrariety to the *ordre public* of an invention is only assessed as regards the commercial exploitation of it.

Article 53 sets out also at (b) and (c) several categories of products, processes and methods that shall not be deemed patentable.

The presence of this clause marks the EPC patent system from U.S. and Canadian patent law and in the last decades, when IPRs in biotechnology have increasingly been at the forefront of social and political debates and legal challenges, its interpretation in patent decisions is shaping the epistemic development of the European governance of IP in comparison to other jurisdictions.

The EPC is not the only patent system which set forth a morality exception clause. Section (3) of Article 4 of the Patent Law of the Russian Federation, which sets forth the conditions of patentability of inventions, embeds an *ordre public* and morality exception, by stating that "proposals that are contrary to public interest, humanitarian principles or morality"[1427] shall not be deemed patentable.

In New Zealand, both the 1953 Patents Act, s 17(1),[1428] and Section 15[1429] of the Patents Act 2013 include morality exclusion. Whereas the former exclusion was more general, as it referred to "the use of the invention in respect of which the application is made would be contrary to morality", Section 15 of Patents Act 2013 offers examples of invention, which are contrary to morality: "an invention that is a process for cloning human beings; an invention that is a process for modifying the germ line genetic identity of human beings; an invention

[1427] Article 4(3), Patent Law of Russian Federation No 3517-1 of September 23, 1992, as amended by the federal law 22-FZ of February 7, 2003, sets out: "(3) The following shall not be deemed patentable under the present Law: - plant varieties and animal breeds; - topographies of integrated circuits; - proposals that are contrary to public interest, humanitarian principles or morality".

[1428] Section 17(1), held that "(1) If it appears to the Commissioner in the case of any application for a patent that the use of the invention in respect of which the application is made would be contrary to morality, the Commissioner may refuse the application".

[1429] Section 15 *Inventions contrary to public order or morality non patentable inventions*, Patents Act 2013, Public Act 2013 No 68, sets out that: "(1) An invention is not a patentable invention if the commercial exploitation of the invention, so far as claimed in a claim, is contrary to—(a) public order (which in this section has the same meaning as the term *ordre public* as used in Article 27.2 of the TRIPS agreement); or (b) morality".

that involves the use of human embryos for industrial or commercial purposes; an invention that is a process for modifying the genetic identity of animals that is likely to cause them suffering without any substantial medical benefit to human beings or animals, or an invention that is an animal resulting from such a process".[1430]

Furthermore, under the Patent Law of People's Republic of China (PRC) Article 5 states that "Patent rights shall not be granted for invention-creations that violate the law or social ethics, or harm public interests"[1431] and for inventions "that are accomplished by relying on genetic resources which are obtained or used in violation of the provisions of laws and administrative regulations".[1432] The SIPO's (at present re-named CNIPA) Patent Examination Guidelines explain accurately the meaning of the locution "social morality" and "public interest" and provide a list of examples of inventions which could be deemed contrary to "social morality", such as "an artificial sexual organ or its substitute not designed for medical use, a process for modifying the genetic identity of the human being's germ line or use of human embryos for industrial or commercial purposes, a process for cloning human beings, a process for modifying the genetic identity of animals which is apt to cause suffering to the animals, as long as it has no substantial value for the treatment of human beings or animals".[1433]

It has been noted that general exclusions related to the granting of IPRs because of contrariety to *ordre public* or morality were included in the Paris Convention for the protection of Intellectual Property adopted in 1883, in the 1963 Strasburg Convention and in several national laws.[1434] However, the adoption of the EPC has been considered as a turning point, since it established a "pan-European institutional framework for the unified examination and grant of European patents alongside and legally separate from the institutions of the European Union".[1435]

The relevance of this clause, in the significant shift to a pan-European patent framework, lies in the formal acknowledgement of national ethical and legal pluralism concerning particular subject matter as a ground for patent exceptions, as the *travaux preparatoires* show.

[1430] Section 15 *Inventions contrary to public order or morality non patentable inventions*, Patents Act 2013, Public Act 2013 No 68.

[1431] Article 5, Patent Law of the People's Republic of China (as amended up to the Decision of December 27, 2008, regarding the Revision of the Patent Law of the People's Republic of China).

[1432] ibid.

[1433] Second Part, First Chapter, Section 3.1.2 SIPO's Patent Examonation Guidelines in Bu Yuanishi, 'Prerequisites for Protection' in Stefan Luginbuehl and Peter Ganea (eds), *Patent Law in China* (Edward Elgar 2014) 43, 44.

[1434] Aurora Plomer, 'Towards Systemic Legal Conflict: Article 6(2)(c) of the EU Directive on Biotechnological Inventions' in Aurora Plomer and Paul Torremans (eds), *Embryonic Stem Cell Patents: European Law and Ethics* (Oxford University Press 2009) 173, 175-176.

[1435] ibid 176.

In the last two decades, this clause has turned out to be the test bed of patent eligibility of HBMs and, in particular, hESCs.

The meaning of *ordre public* and morality as grounds for patent exceptions has been dealt with by the EPO Boards of Appeal in several patent cases. As chapter three has illustrated, the *Onco-mouse* has been one of the main cases addressing the meaning of the clause and devising an institutional approach to morality based on an utilitarian balance of interests.

EPO Boards of Appeal, as well as the examining divisions, use to refrain from engaging in defining morality, as they mainly construe their expertise as *technical*, dealing with patent claims and law. Moreover, as Isasi and Knoppers illustrated, the heterogeneity of legal and constitutional provisions makes the definition of European moral standards an arduous task.[1436] In *Onco-mouse*, this inclination has been openly professed, as the TBA declared its willingness to avoid delving into the meaning of morality.

However, in *Plant Genetic Systems*, the TBA acknowledged that the EPC Working Party was aware that "there was no European definition of morality",[1437] but the Member States of the EPC agreed that the "interpretation of the concept of morality should be matter for European institutions",[1438] as much as the concept of *ordre public*.[1439] It, therefore, took upon itself the task of interpreting these concepts.

According to the TBA, "It is generally accepted that the concept of '*ordre public'* covers the protection of public security and the physical integrity of individuals as part of society"[1440] including the protection of the environment.[1441] It, therefore, elucidated that "inventions the exploitation of which is likely to breach public peace or social order (for example, acts of terrorisms) or to seriously prejudice the environment"[1442] shall be considered contrary to *ordre public*, under Article 53(a) EPC, and excluded from patentability. The TBA, thus, separated the protection of the environment from morality, even though bioethics as discipline include it as field of moral collective choices, and subsumed its protection under the *ordre public* clause.

The TBA, moreover, explained that "The concept of morality is related to the belief that some behavior is right and acceptable whereas other behavior is wrong, this belief being

[1436] Rosario M Isasi and Bartha M Knoppers, 'Towards Commonality? Policy Approaches to Human Embryonic Stem Cell Research in Europe' in Aurora Plomer and Paul Torremans (eds), *Embryonic Stem Cell* Patents (Oxford University Press 2009) 29
[1437] T 356/93 (n 747) 15.
[1438] ibid. See Document IV/2767/61-E, 7.
[1439] ibid. See Document IV/2767/61-E, 8.
[1440] ibid 15-16.
[1441] ibid 16.
[1442] ibid.

founded on the totality of the accepted norms which are deeply rooted in a particular culture"[1443] and that the EPC refers to "the culture inherent in the European society and civilization".[1444] In its account of what is contrary to morality and thus excluded from patentability, the TBA points out that Article 53(a) EPC refers to "inventions the exploitation of which is not in conformity with the conventionally-accepted standards of conducts pertaining to this culture".[1445] However, it did not offer any examples of inventions contrary to European standards of conduct.

Article 53(b) EPC 1973 embedded also a specific exception concerning "(b) plant or animal varieties or essentially biological processes for the production of plants or animals", which did not apply to microbiological processes or the products thereof.

EPC 2000 expanded the scope of exceptions by adding a new exception to Article 53: "(c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced 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".

Article 6(1) of Directive 98/44/EC states that: "Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation".

Article 6(2) sets forth particular exceptions to patentability in biotechnology: "On the basis of paragraph 1, the following, in particular, shall be considered unpatentable: (a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; (c) uses of human embryos for industrial or commercial purposes; (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes". However, this list is not exclusive.

Whereas the wording of Article 6(1) replicates most of the text of Article 53(a) EPC 1973, Article 6(2)(d) resulted from the legal balancing test developed in the Oncomouse I case.[1446]

In particular the exception embedded in Article 6(2)(c) has been the ground to several patent oppositions regarding embryonic stem cell lines, as this chapter shows.

[1443] ibid.
[1444] ibid.
[1445] ibid.
[1446] Gerard Porter, 'The Drafting History of the European Biotechnology Directive' in Aurora Plomer and Paul Torremans (eds), *Embryonic Stem Cell Patents: European Law and Ethics* (Oxford University Press 2009) 3, 15.

Jasanoff and other scholars explained why the Biotech Directive has proved a democratic benchmark for the EC. The first draft of the Directive, which conveyed the Commission intent to further harmonize European patent law in order to boost European biotech industry confronting U.S and Japanese dominance, was rejected in 1995. In the aftermath of the rejection, the new draft reflected more ethical concerns, expressed in recitals and embedded in articles.

As Porter illustrated, the draft included "a clearer formulation of discovery/invention distinction in patent law, and again merged this distinction with the moral prohibition of the ownership of the human body".[1447] Nevertheless, embryos were not mentioned in the articles of the proposal until 1996.[1448]

The first explicit reference to human embryos, he explained, was introduced by the Opinion adopted by the Economic and Social Committee on 11 July 1996, which pinpointed that the former drafts of the Directive lacked any reference to embryos and suggested that "the human embryo, which is a special case, should be excluded from patentability".[1449]

The remarks and concerns expressed by the Economic and Social Committee were taken into consideration in all the subsequent drafts. However, the Common position adopted by the European Council on 26 February 1998, affected the wording of the final draft of Article 6(2)(c), by limiting the patent exception to "uses of human embryos *for industrial or commercial purposes*".[1450]

It has been observed,[1451] furthermore, that the Parliamentary debates before the adoption of the Directive show that this limitation was introduced because the U.K. was undertaking a public consultation regarding the possibility of extending the research scope on human embryos under the Human Fertilisation and Embryology Act (HFEA), as also PSE's rapporteur Rothley pointed out.[1452]

As far as the interpretation and application of the morality exceptions in articles 53 EPC and Article 6 of the Biotech Directive, Sterckx and Cockbain pointed out that a fundamental shift has taken place in EPO's approach to morality, namely the EPO has abandoned the consequentialist and balancing approach that it has validated for years in favour of a deontological principle-based approach which has emerged in the G-2/06 Use of embryos/WARF, "according to which certain things may be morally impermissible, even if

[1447] ibid 17.
[1448] ibid 18.
[1449] ibid.
[1450] ibid 21.
[1451] ibid. 22.
[1452] ibid.

they would produce more benefits than disadvantages".[1453] The next section will illustrate how the EBA endorsed this approach, re-shaping the boundaries of what was deemed patentable under the EPC.

6.4.1 A Matter of Morality: The Morality of the Embryo Stem Cells Patent in the "*WARF* Case"

In the last two decades, the morality of embryonic stem cells patents has become the test bed of European identity, which EPC conveys in Article 53(a) EPC.

As Drahos pinpointed, the EPO has embraced, in its guidelines, a "narrow approach to Article 53 (a)"[1454] affirming that it could be resorted to only in "rare and extreme cases"[1455] and that also in the *Relaxin* case the Board of Appeal emphasized that such exceptions to patentability under Article 53(a) "are to be narrowly construed".[1456]

Although the morality clause was embedded in the EPC1973, the EPC Boards of Appeal have only occasionally engaged in addressing morality issues regarding patents. As it was pointed out in chapter three, in the *Onco-mouse* case the Board of Appeal did not deal with the moral issues that the opponents to the patent brought up, but handled the morality clause formally,[1457] namely as a means to assess and balance conflicting interests which involved moral problems, which could be sorted out, nevertheless, in a technical way.

However, the EPO had to face constant challenges to granted patents by NGOs and research groups, after the *Onco-mouse* case, which made clear that intellectual property was considered by European citizens a sensitive political institution, no longer entrusted only to the legal and technical professionals working in the field, but a highly ethical and political area of the law.

The *WARF* case, in particular, shows how the ethical dimension of IPRs could not be dismissed and solved by recurring to a formal balance of interests, but had to be taken on, as several member states were developing national frameworks on embryonic stem cell research, which questions the possible next steps of the research: the patentability of embryonic stem cell lines.

Moreover, it pinpoints that, although the Boards of Appeal have decided most sensitive biotech patent cases under the aegis of the criteria of isolation and purification, these criteria

[1453] Sterckx and Cockbain (n 739) 243.
[1454] Drahos (n 760) 444.
[1455] EPO Guidelines C-IV, 3.1.
[1456] *Hormone Relaxin,* (1995) 6 OJ EPO 398.
[1457] Amanda Warren, 'A Mouse in Sheep's Clothing: The Challenge to the Patent Morality Criterion Posed by 'Dolly'', (1998) 20(2) European Intellectual Property Review 445, 447. Drahos (n 760) 444.

fell short in providing an acceptable answer to the ethical questions regarding human embryonic stem cells ("hESCs"). hESCs were not considered as mere chemical molecules by many European citizens and several national legal frameworks. This case pinpoints that, under the EPC and in the European Union, different sociotechnical imaginaries of the biotech molecular body have emerged and that a unified European moral vision failed to emerge.

The *WARF* case G 2/06 was decided by the EBA on 25 November 2008 and involved a European patent application of the Wisconsin Alumni Research Foundation (WARF), the technology transfer office of the University of Wisconsin, for James Thomson' invention, namely primate embryonic stem cells.[1458]

The invention involved the kind of embryonic stem cells, which are *pluripotent*, namely cells "which are derived from the inner cell mass of the mammalian blastocyst"[1459] and "can self-renew indefinitely and differentiate into all cell types of the three germ layers (ectoderm, endoderm, and mesoderm)".[1460]

On 13 July 2004, EPO examiners refused to grant a patent application No. 96 903 521.1 on this subject matter, as it was considered excluded from patentability under Rule 28(c). However, WARF appealed the decision before the TBA,[1461] which referred the issues relating to patentability of the invention to the EBA. The decision of the Examining Division related to claims 1 to 10 of the European patent application.

Rule 28, which implements the regulations to the EPC, concerns *Exceptions to patentability* and sets out that: "Under Article 53 (a) EPC Europeans patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following: (…) *(c) uses of human embryos for industrial or commercial purposes*; ".[1462]

The EBA had to decide on four points referred and, in particular, on whether Rule 23d(c), at present 28(c) EPC, forbade the patenting of claims directed to products (here: human embryonic stem cell cultures) which – as described in the application – at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, if the said method is not part of the claim.[1463] The EBA did not draw on metaphors in order to assess the patentability of the claimed invention under Rule 28, but on technoscientific and legal distinction between

[1458] James Thomson, *Primate embryonic stem cells* (1996), International patent application number WO96/22362, WIPO, Geneva.
[1459] Tropp (n 844) 818.
[1460] ibid.
[1461] T 1374/04, 7 April 2006.
[1462] Rule 28 Implementing Regulations to the EPC.
[1463] EPO Enlarged Board of Appeal, Decision G 2/06 (Use of embryos/WARF) of 25.11.2008, 1.

"embryo" and "pre-embryo" (a fertilized ovum less than 14 days after fertilization, according to the usage in medical field) which in some member states, such as the U.K., have been endorsed and justify morally and legally their use for research purposes.[1464] The EBA, therefore, clarified that, since this distinction was endorsed in the legal framework of some member states, inventions derived from stem cell research on pre-embryos could not be deemed immoral under Rule 28(c) EPC.[1465] Moreover, it was pointed out that a claim to an embryonic stem cell does not constitute a monopoly to the use of an embryo or the use of an embryo "for an industrial or commercial purpose".[1466]

In order to answer and provide guidance on the main issue raised by the TBA, namely question two, the EBA resorted to the *travaux préparatoire* of the Directive, pointing out that the first draft of the Directive did not embed any specific prohibition concerning the use of human embryos, whereas in the amended proposal only "methods in which human embryos are used"[1467] are set out as unpatentable. However, in the Common position EC No 19/98 adopted by the Council in February 1998, Article 6(2)c of the Directive was amended in its present form.[1468] The EBA highlighted that Directive 98/44/EC aims at preventing the commodification of human embryos and protecting human dignity, as argued in the decision of the German Bundespatentgerich of 5 December 2006.[1469]

The EBA, however, did not clarify the meaning of "commodification". According to the Oxford English Dictionary, the term commodification refers "the action of process of treating a person or thing as property which can be traded or whose value is purely monetary; the treatment of a person or thing as a commodity: commercialization".[1470] The EBA, by linking the prevention of commodification to the protection of human dignity as two of the main goals of Directive 98/44/EC, contended that human embryos should not be treated as property that could be commercialized, because of their dignity.[1471]

The EBA affirmed that the correct approach to Rule 28(c) consisted of pinpointing the claimed monopoly and determining whether that monopoly embraced the "use of an embryo for industrial and commercial purpose".[1472] The EBA acknowledged the different settled

[1464] The so called "Warnock Report" (Report of the Commission of Inquiry into Human Fertilisation and Embryology, Cmdd 9114, Lonson, HMSO 1984.
[1465] *WARF* (n 1463) 6.
[1466] ibid.
[1467] ibid 7.
[1468] ibid 21.
[1469] ibid 22. See German Bundespatentgerich (BPatG) of 5 December 2006, 3 Ni 42/04, point IV 2.2 i.f.
[1470] Headword "commodification", Oxford English Dictionary.
[1471] *WARF* (n 1463) 21-22.
[1472] ibid 6.

national legal definitions of "embryo", for example in the German[1473] and the UK[1474] laws, but argued that, since "neither the EU legislator nor the EPC legislator have chosen to define the term 'embryo', as used in the Directive or now in Rule 28 (formerly 23(d) of the EPC)",[1475] the term should not be interpreted in a restrictive way in Rule 28. A restrictive interpretation of the term "embryo" would undermine the intention of the legislator, in terms of the protection of human dignity and prevent the commercialization of embryos.[1476]

The EBA rejected the argument of WARF, that in order to fall within the prohibition of Rule 28(c) the use of human embryos must be formally claimed.[1477] Conversely, it pinpointed that, as the rule refers to "invention" in the context of its exploitation, the technical teaching of the application, as a whole should be considered.[1478] From the technical teaching, it is clear that the use of the hESCs involved the destruction of human embryos.[1479]

The EBA concluded, therefore, that Rule 28(c) EPC forbids the patenting of claims, which at the filing date could be prepared only by destroying human embryos from which the products were derived and that it was not relevant that after the filing date these products could be obtained by applying a method which does not entail the destruction of embryos.[1480]

In the United States, conversely, embryo stem cell research has not been challenged on moral grounds as far as the patentability of stem cell lines is concerned.

After James A. Thomson and his research team were able to obtain the first hESC line in 1998, the USPTO granted to WARF three patents, which covered the hESC line and the method for isolating it.[1481] The scope of these patents was very broad and they have been disputed because they hindered other scientists' research in the field.[1482] Moreover WARF licensed exclusively most of the cell lines to Geron. As the U.S. patent system does not embed a morality clause, these have been challenged for lack of novelty and they have been

[1473] Gesetz zum Schutz von Embryonen of 13 December 1990, §8, which defines the embryo as encompassing "a fertilized egg". ibid 23.
[1474] Human Fertilisation and Embryology Act 1990, section 1(1), which defines the embryo as including "the two cell zygote and an egg in the process of fertilization". Ibid
[1475] *WARF* (n 1463) 22.
[1476] ibid.
[1477] ibid.
[1478] ibid.
[1479] ibid 24.
[1480] ibid 30.
[1481] U.S. Patent No. 5,843,780 granted in 1998; U.S. Patent No. 6,200,806 granted in 2001; U.S. Patent No. 7,029,913 granted in 2006.
[1482] Elodie Petit, 'An Ethics Committee for Patent Offices' in Aurora Plomer and Paul Torremans (eds), *Embryonic Stem Cell Patents: European Law and Ethics* (Oxford University Press 2009) 305, 340.

ruled invalid by USPTO in a preliminary ruling, but in 2014 the standing of CW has been denied and then the patents have been upheld.[1483]

6.4.2 The Morality Clause in the Brüstle Case

The meaning and scope of the morality clause has been interpreted in a more expansive way by the Grand Chamber of the Court of Justice of the European Union (CJEU) in *Oliver Brüstle v. Greenpeace e.V.* ("*Brüstle*"), Case C-34/10, which was decided on 18 October 2011 and concerned the patentability of isolated and purified neural precursor cells and the processes of their production from embryonic stem cells, which comprise human embryonic stem cells.

The case was referred to the CJEU for preliminary ruling regarding the interpretation of Article 6(2)(c) of Directive 98/44/EC by the Bundesgerichtshof (the German Federal Court of Justice) in its decision of 17 December 2009.

The Bundesgerichtshof required the CJEU to answer what is the meaning of the terms 'human embryos', in Article 6(2)(c) of Directive 98/44/EC, and 'uses of human embryos for industrial or commercial purposes' and whether the technical teaching was relevant in assessing the patent eligibility of the invention pursuant to Article 6(2)(c).[1484]

In particular, as regards the first question, the Bundesgerichtshof demanded clarifications on whether the expression "human embryos" included all stages of the development of human life, from fertilisation, or only certain stages of development. Moreover, it enquired whether the locution encompassed "unfertilized human ova into which a cell nucleus from a mature human cell has been transplanted"[1485] and "unfertilized human ova whose division and further development have been stimulated by parthenogenesis".[1486]

The case arose when Greenpeace brought proceeding against Brüstle and requested the Bundespatentgericht (the German Federal Patent Court) annul the German patent granted to Brüstle on isolated and purified neural precursor cells.

The Bundespatentgericht held the patent invalid, under Paragraph 22(1) of the PatG, as it covered "precursor cells obtained from human embryonic stem cells and processes for the production of those precursor cells".[1487] However, Brüstle appealed against the judgment to the Bundesgerichtshof. According to the Bundesgerichtshof, the focus of the case rested on

[1483] ibid.
[1484] C-34/10, *Prof. Dr. Oliver Brüstle v. Greenpeace e. V.*,OJ C 100 of 17 April 2010, 19.
[1485] ibid.
[1486] ibid.
[1487] *Brüstle* (n 1484) 19.

whether the technical teaching of the challenged patent, since it regarded precursor cells obtained from hESCs, was excluded from patentability under Paragraph 2(2), first sentence, point 3 of the PatG, which, in turn, relied on the interpretation of Article 6(2)(c) of Directive 98/44/EC.[1488]

Paragraph 2(2), first sentence, point 3 of the PatG provides that patents shall not be awarded for "(3) uses of human embryos for industrial or commercial purposes".[1489] The application of patent exclusions set forth in Paragraph 2(2) is governed by the relevant provisions of the Embryonenschutzgesetz (ESchG, German Law on the protection of embryos).

Addressing the first question, the CJEU acknowledged that the Directive does not offer any definition of "human embryo" and does not refer to national laws in order to define this locution. As a consequence, it argued that it must be considered as "designating an autonomous concept of European Union law which must be interpreted in a uniform manner throughout the territory of the Union".[1490]

Recalling Recitals 3 and 5 to 7 of the Directive and *Netherlands v. Parliament and Council*,[1491] namely the CJEU's judgement which dismissed the Kingdom of the Netherlands application to annulment of Directive 98/44/EC also on moral grounds,[1492] the Court highlighted that the main aim of the Directive was the harmonization of the rules on the legal protection of biotech invention across Europe, in order to remove hurdles to trade and promote the smooth and efficient functioning of the internal market of the European Union.[1493]

It affirmed the need for a *uniform definition* of the concept of "human embryo", in order to prevent the risk of patent applicants trying to seek patent protection for their biotechnological inventions in Member States, which endorse the narrowest definition of the concept and have a liberal policy on human embryonic stem cells research.[1494] A uniform definition of "human embryo", according to the CJEU, would contribute to a smooth functioning of the internal market by averting this kind of "patentability shopping" in Member States and contribute to patent law harmonization.[1495]

[1488] ibid 20.
[1489] German Patentgesetz (PatG).
[1490] *Brüstle* (n 1484) 26.
[1491] *Netherlands v. Parliament and Council*, C-377/98, 9 October 2001.
[1492] See fifth plea, ibid 69.
[1493] C-34/10 (n) 27.
[1494] *Brüstle* (n 1484) 28.
[1495] ibid.

This conclusion – the CJEU pointed out – was also backed by the scope of the listing set forth in Article 6(2), which is to "delimit the exclusion laid down in Article 6(1), and does not allow the Member States to have any discretion with regard to the unpatentability of the processes and uses set out".[1496] In this respect, the Court explained that, whereas Article 6(1) of the Directive "allows the administrative authorities and courts of the Member States a wide discretion in applying the exclusion from patentability of inventions whose commercial exploitation would be contrary to *ordre public* or morality",[1497] Article 6(2) does not permit any margin of discretion in applying the exclusion.[1498]

Although the CJEU admitted that "the definition of human embryo is a *very sensitive social issue in many Member States*, marked by their *multiple traditions and value systems*",[1499] it purported not to carry out an interpretative task involving questions of medical or ethical nature.[1500] Conversely, the Court claimed to limit its interpretive duty to the relevant legal provisions of the Directive.

Since the Directive provides no definition of "human embryo", the *context* and *scope* have been deemed fundamental for interpretation purposes.

In interpreting the concept, the CJEU gave prominence to Recital 16 of the Directive 98/44/EC, which highlights that "patent law must be applied so as to respect the fundamental principles safeguarding the *dignity and integrity of the person*",[1501] dismissing implicitly all other recitals, which could have suggested conflicting interpretations of Article 6(2)(c). The meaning of Recital 16 has been construed in conjunction with Article 5(1) and Article 6(1) of the Directive and Recital 38, in order to pinpoint the concept of human embryo "must be understood in a wide sense".[1502] It included in definition any fertilized ovum, at any stage of development, but also the non-fertilized ovum obtained through different techniques, such as cloning and parthenogenesis, as the written observations submitted to the court pointed out that also these ova are capable of developing into a human being,[1503] concluding that : "any human ovum after fertilization, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted, and any non-fertilised human ovum whose

[1496] *Brüstle* (n 1484) 29.
[1497] ibid.
[1498] See CJEU, *Commission v. Italy*, Case C-456/03, 16 June 2005, at para 78 and 79.
[1499] *Brüstle* (n 1484) at 30.
[1500] ibid.
[1501] Recital 16 of Directive 98/44/EC, L 213/14.
[1502] *Brüstle* (n 1484) 34.
[1503] ibid 36.

division and further development have been stimulated by parthenogenesis constitute a 'human embryo'"[1504] for the purpose of interpreting Article 6(2)(c) of Directive 98/44/EC.

The CJEU, nevertheless, did not address whether stem cells derived from a human embryo at the *blastocyst* stage, should be encompassed, but left this decision to the referring court on the basis of advancement of science.[1505]

As far as the second question was concerned, the CJEU embraced a very broad definition of the term "industrial or commercial purposes", clarifying that the purpose of the Directive was to regulate the patentability of biotech inventions and it did not consider the use of human embryos for scientific research.[1506] By drawing on Recital 14 of the Directive, which sets out that a patent "entitles [its holder] to prohibit third parties from exploiting it for industrial and commercial purposes",[1507] the Court pinpointed that the act of being granted a patent, in principle, is related to and implies an industrial and commercial purpose. This interpretation was supported also by the EBA in the *WARF* case, pinpointing that a patent is connected to and implies, in principle, industrial and commercial acts.[1508]

It concluded, therefore, that the exclusion from patentability regarding the use of human embryos for industrial and commercial purposes "also covers the use of human embryos for purposes of scientific research, only use for therapeutic or diagnostic purposes which is applied to the human embryo and is useful to it being patentable".[1509]

The CJEU, finally, pointed out the significance of the technical teaching as the subject matter of the patent application, by pointing out that if it involves the destruction of human embryos or their use as base material, regardless of the fact that the technical teaching does not refer to the use of human embryos and whatever the stage at which it takes place, the invention is excluded from patentability under Article 6(2)(c).[1510] The Court argued that not including the technical teaching in the scope of the exclusion under Article 6(2)(c) would make the provision redundant, since patent applicants could easily elude it through drafting the claims in a skillful way.[1511]

In *Brüstle*, the destruction of the human embryos emerged as the fundamental issue in applying the morality clause, set forth in Article 6(2)(c).

[1504] ibid 38.
[1505] ibid.
[1506] ibid 40.
[1507] ibid 42.
[1508] ibid.
[1509] ibid 46.
[1510] ibid 52.
[1511] ibid 50.

The ruling has been criticized[1512] for its potential implications for stem cell researchers and the biotech industry, as it undermined the chances of filing successfully patent applications involving hESCs before a national patent office of countries, which are part of the EPC, or before the EPO. Moreover, it could hinder investments in stem cell projects.

The CJEU, on 18 December 2014, in *International Stem Cell Corporation v. Comptroller General of Patents, Designs and Trademarks*,[1513] partially overturned its own ruling in *Brüstle* as regards the parthenogenesis process,[1514] by holding that "Article 6(2)(c) of Directive 98/44/EC must be interpreted as meaning that an unfertilised human ovum whose division and further development have been stimulated by parthenogenesis does not constitute a 'human embryo', within the meaning of that provision".[1515] However, it left national courts to determine whether "in the light of current scientific knowledge, that ovum does not, in itself, have the inherent capacity of developing into a human being".[1516] The Court, therefore, ultimately referred to the national court the decision about the moral and legal status of human parthenotes, considering science and the legal and moral national framework.

The emerging of morality as an actual patent issue within EPC shows that, although the morality clause marks the EPC patent system in comparison to the U.S. and Canadian ones, the EPO and the Boards of Appeal have struggled to find a unified European approach to ethical patent challenges.

It has been questioned by several scholars whether common European principles of morality do exist.[1517] Although *Plant Genetic Systems*[1518] and *Relaxin*[1519] cases refer to a common European frame for morality, this frame fell short when confronting with concrete patent cases.

In *Brüstle*, the CJEU deemed that human dignity ought to be ascribed to the embryo under the Biotech Directive. However, this kind of interpretation of the morality clause, which is consistent with the definition of "the embryos" in the national German debate on hESC

[1512] Sven J R Bostyn, 'A Decade after the Birth of the Biotech Directive: Was It Worth the Trouble?' in Emanuela Arezzo and Gustavo Ghidini (eds), *Biotechnology and Software Patent Law: A Comparative Review of New Developments* (Edward Elgar, 2011) 221.
[1513] CJEU, *International Stem Cell Corporation v. Comptroller General of Patents, Designs and Trademarks*, Case C-364/13, 18 December 2014.
[1514] Ewen Callaway and Alison Abbott, 'European Court Clears Way for Stem-Cell Patents' (18/12/2014) Nature.
[1515] *International Stem Cell Corporation* (n 1513) 38.
[1516] ibid.
[1517] Enrico Bonadio, 'Biotech Patents and Morality After Brüstle' (2012) 34(7) EIPR 433, 438-441.
[1518] T 0356/93, *Plant Genetic Systems v. Greenpeace Ltd*.
[1519] T 0272/95, *Howard Florey Institute of Experimental Physiology and Medicine v. Aglietta, Amendola et al*.

research, is creating, as Plomer has illustrated, several tensions within the EPC patent system.[1520]

The German stem cell debate has largely focused on Oliver Brüstle, as he formally was the first researcher to apply for funding in order to import human embryonic stem cells to DFG, the German Research Society.[1521] Brüstle's request was granted, but the ZES accurately clarified the boundaries and the conditions of the permitted research, not allowing him to develop heart cells, but only neuronal ones.[1522] Since he had his request granted and, later, when he obtained his patent, his research became the focus of the German debate on the moral and legal status of the embryo and of the kind of protection that the Embryonenschutzgesetz ought to provide.

The protection of human dignity has been fundamental in order to provide moral legitimacy to the German state after World War II and is embedded in Article 1 of the German Basic Law, which states that "Human dignity is inviolable".[1523] Although the German Basic Law proclaims to protect also scientists' freedom of research, these two basic rights have been drawn upon in German stem cell debate and seemed to conflict.[1524] Stefan Sperling, illustrating the German stem policy debate, explained that "many Germans saw stem cell research as a threat not merely to human embryos and, by extension, to society's weakest, most defenceless members, but to humanity itself".[1525] Ethics, according to his analysis, in this debate became pivotal in order to legitimize choices on stem cell research. The German stem cell debate has been inscribed in the nexus *memory-conscience-ethics* which marks German civic epistemology and how, at present, German society makes sense and order of challenging technoscientific products and processes, in order to justify policy frameworks.

Some scholars have pointed out that it has been "the overarching role of the embryo in framing and structuring discourses in many countries"[1526] which has made stem cell science such a contested domain, but most of the public controversies regarding human embryonic

[1520] Aurora Plomer, 'The European Union's IP Policy and Funding of Stem Cell Research', in Duncan Matthews and Herbert Zech (eds), *Research Handbook on Intellectual Property and the Life Sciences* (Edward Elgar 2017) 229.
[1521] Stefan Sperling, *Reasons of Conscience: The Bioethics Debate in Germany* (The University of Chicago Press 2013) 2, 269.
[1522] ibid 364.
[1523] Article 1 German Basic Law: Die Würde des Menschen ist unantastbar". On the meaning of "human dignity" set forth in Article 1 and its implications within this constitutional clause of German Basic Law, see Christoph Enders, 'A Right to Have Rights – The German Constitutional Concept of Human Dignity' (2010) 3 NUJS Law Review 253.
[1524] Sperling (n 1521) 364.
[1525] ibid 364.
[1526] Barbara Prainsack, Ingrid Geesink and Sarah Franklin, 'Stem Cell Technologies 1998-2008: Controversies and Silences', (2008) 17(4) Science as Culture 351, 355.

stem cells did not concern stem cells directly. Conversely, they concerned, in specific national contexts, older controversies on whether the embryo had the right to life and who was entitled to make decisions on life. Nevertheless, how these controversies have been dealt with depends on the national civic epistemologies, namely "institutionalized practices by which members of a given society test and deploy knowledge claims used as a basis for making collective choices".[1527]

Although the CJEU in *Brüstle*, as well as the EBA in *WARF*, referred to the need for a uniform definition of the concept of "human embryo" and a common European clue of morality which should result from the implementation of Directive 98/44/EC, the member states of the European Union and the EPC have settled the meaning of these terms nationally. The settlement of when life begins and what an embryo is result from a complex process of co-production between science and society that contribute to define and decide what an acceptable balance within that political context is.

The national settlements (and unsettlements) are hard to reconcile with a uniform European view and definition, as they are grounded on particular civic epistemologies through which particular collectivities make sense and order of new technologies and their implications.

Even the European Court of Human Rights had to acknowledge that, to a certain extent, legal and ethical pluralism marks the definition and scope of protection of the human rights set out in the European Convention on Human Rights ("ECHR").[1528]

In *Vo v. France*,[1529] a case involving the unintentional abortion that Ms Thi-Nho Vo underwent in 1991, because of a series of mistakes made by medical personnel, the European Court of Human Rights had addressed whether France failed to protect the right to life set forth in Article 2 and whether Ms Vo's foetus was the victim of unintentional homicide.

Article 2.1 ECHR states that: "Everyone's right to life shall be protected by law. No one shall be deprived of his life intentionally save in the execution of a sentence of a court following his conviction of a crime for which this penalty is provided by law".[1530]

The Court had, therefore, to judge which were the boundaries of the term "everyone" (in French "toute personne") and if a foetus fell within this definition.

[1527] Jasanoff (n 44) 255.

[1528] Council of Europe, European Convention on Human Rights (ECHR), available at <https://www.echr.coe.int/Documents/Convention_ENG.pdf > 3.

[1529] European Court of Human Rights, *Vo v. France*, 8 July 2004, 1, available at <https://hudoc.echr.coe.int/eng#{"docname":["\"CASE OF VO v. FRANCE\""],"documentcollectionid2":["GRANDCHAMBER","CHAMBER"],"kpdate":["2004-07-08T00:00:00.0Z",""],"itemid":["001-61887"]}>.

[1530] Article 2.1, Council of Europe, European Convention on Human Rights (ECHR), 6.

In dealing with this quandary, the majority of the Court pinpointed that the interpretation of Article 2 "has been informed by a clear desire to strike a balance"[1531] and take into account "the moral and philosophical differences, reflected by the extreme diversity of legal rules applicable to human embryo research … It is not only legally difficult to seek harmonization of national laws at Community level, but because of lack of consensus, it would be inappropriate to impose one exclusive moral code'".[1532]

Consequently, the majority avowed that "the issue when the right to life begins comes within the margin of appreciation which the Court generally considers that States should enjoy in this sphere"[1533] and that there is "no European consensus on the scientific and legal definition of the beginning of life".[1534]

Furthermore, the judges noted also that the Oviedo Convention has been careful in not defining the term "everyone", because, as its Explanatory Report clarified, there is no unanimous agreement on its meaning and hence the member States intended "to allow domestic law to provide clarification",[1535] in order to apply the Convention.

The Court, accordingly, deemed that, in the absence of a European consensus on the nature and status of the embryo and/or foetus, Article 2 was meant to cover human beings (with legal personality) and there was no violation of it.[1536]

Notwithstanding the claims of patent harmonization in the biotechnology field, these kinds of settlements which result from the co-production at the national level impinge on the harmonization attempts performed by technocratic institutions like the EPO.

According to some scientists, involved in stem cell research, the *technological* solution could close this ethical conundrum affecting the patentability of hESC.

In 2006, Irving Weissman, a Stanford biologist who has been involved in the U.S. stem cell debate, published on *Nature* an article[1537] which pinpointed that researchers had already developed methods to "bypass" religious and ethical objections to hESC research.

The STS scholar Giuseppe Testa,[1538] examining one of these methods (ANT) e and the proposal of a definition of "embryo death", in analogy with the definition of human brain death, in order to overcome the ethical *impasse*, highlighted that these are construction of

[1531] *Vo* (n 1529) 36-37.
[1532] ibid.
[1533] ibid 37.
[1534] ibid 37.
[1535] ibid 38.
[1536] ibid 42.
[1537] Irving L Weissman, 'Politic Stem Cells' (12 January 2006) 439 Nature 145.
[1538] Giuseppe Testa, 'Stem Cells through Stem Beliefs: The Co-Production of Biotechnological Pluralism' (2008) 17 (4) Science as Culture 435.

pretended "neutral" solutions, based on science. These solutions, he points out,[1539] mainly aim at de-politicizing the ethical issues by shifting from the more political question, "when a normal embryo is a normal being with moral worth",[1540] to a more epistemic one, namely "what component parts and organized structure constitute the minimal criteria for considering an entity a living human organism".[1541]

These kinds of solutions which result from the co-production of science and patent law are, however, preferred by patent examiners and EPO's Boards, as they sustain the neutrality of the patent system and allow dodging significant ethical and policy issues concerning patenting hESCs.

It has been noted that Armitage and Davies, who were engaged in the preparatory works of the Strasburg Convention, pointed out that "the morality provision did not feature in the early drafts of the Convention" and "morality was not meant to be concerned with the essentials of patent law but added to permit the continuation of powers existing in national laws to refuse patents where the granting of them would be unacceptable on moral or public order grounds".[1542] They referred to Article 2 of the Convention, which has been the model for Article 53 EPC.

Although the EPO has relied on isolation and purification as legal and ontological criteria supporting the patent eligibility of HBMs, the *Brüstle* case has pinpointed that the national civic epistemology which impinge on framing hESCs cannot be overlooked within the EPC system. The moral clause has been drawn upon by NGOs and civil society in order to let the national dimension in defining hESCs emerge.

However, more significantly, the morality clause has been relied on by Member States of the EPC as offering the flexibility to maintain different sociotechnical imaginaries of the molecular biotech body and to decide whether and to what extent it could be an object of IPRs.

6.5 Conclusions

The analysis of the issues concerning the patentability of HBMs in U.S., Canada and under the EPC shows how the different civic epistemologies impinged on addressing and framing

[1539] ibid 442.
[1540] U.S. President's Council on Bioethics (2005), *Alternative Sources of Human Pluripotent Stem Cells. A White Paper*, 85 in Testa (n 1538) 442.
[1541] ibid.
[1542] Oliver Mills, *Biotechnological Inventions: Moral Restraints and Patent Law* (Ashgate 2005) viii, 26; see Shane Burke, 'Interpretive Clarification of the Concept of 'Human Embryo' in the Context of the Biotechnology Directive and the Implications for Patentability: *Brüstle v Greenpeace e V* (C-34/10' (2012) 34 EIPR 346, 348.

whether and how they can be "objects" of property and IPRs and who ought to be considered their legitimate owner.

In the U.S., the courts drew upon the metaphor of "hazardous biowaste" in order to settle the question of who is the owner of HBMs, in favor of researchers and biotech companies. This metaphor proved to be pivotal to maintain that patients were not entitled to property rights and IPRs on their detached HBMs, as they are valueless for those that do not have the knowledge and economic resources to transform them into commodities. Moreover, the *Catalona* and *Greenberg* cases illustrated that, once patients/research participants have given their informed consent and made an *inter vivos* gift of their biomaterials, it is the clinical institution which retains control over the HBMs and the IPRs on the inventions obtained from them.

In Canada, the legal status of genetic and HBMs under Canadian common law, as well as under Canadian civil law, is mostly unsettled. However, the patentability of inventions based on HBMs and human stem cells has not been debated extensively. The CBAC has broached some of the social and moral problems related to the IP over HBMs, but implicitly pointed out that the normalization of these kinds of inventions had already occurred within the Canadian patent system. Since no substantial social opposition to these kinds of patents has emerged, the molecular body has been imagined as socially beneficial biotech product, which did not entail relevant moral and legal challenges.

In Europe, the issues concerning the patentability of inventions related to HBMs seemed to be solved by setting forth, in Article 3(2) of the Biotech Directive, the criteria of isolation and purification, but as far as hESCs patents were concerned, the national civic epistemologies and related legal frameworks which defined "the embryo" emerged as relevant in shaping the boundaries of what is patentable or not. Especially the German bioethical debate[1543] over whether and how research on human embryonic stem cell should be allowed has proved pivotal in interpreting the morality clause embedded in the EPC and the Biotech Directive in order to rule out the patentability of hESC lines which involve the destruction of embryos. On the face of different national frameworks concerning the "human embryo", EPO's *policy of isolation and purification* of HBMs fell short of providing an adequate answer to the moral issues related to patenting hESCs, which were raised by civil society.

These jurisdictions have all settled the ontological and legal status of the "molecular body" as an artificial technoscientific object, which has fostered its circulation and commodification,

[1543] Sperling (n 1521) 2.

though in different ways. The cases that have been analysed in this chapter show that the biotechnological body has been framed as an artificial chattel, which can be patented, as it is detached and isolated from its owner, provided that privacy is protected and informed consent obtained. In all these jurisdictions the human body, as a whole, has been recognized full subjectivity and considered not patentable, because of the human dignity of which it is endowed. The need for the protection of human dignity, which is set forth in Article 1 of the Oviedo Convention, and the related prohibition of financial gain from the human body and its parts prove to be, however, in tension with the process of commodification and circulation that the molecular body underwent in the last forty years and its partial anomy.

Conclusions

7.1 The Co-Production of Patent Eligible Matter: Technoscientific Metaphors, Narratives and Law

This work has showed that metaphors are not transient theoretical scaffoldings, but rather recurring and solid conceptual means to "make sense and order" of the world, by co-producing it cognitively, materially and practically, at once. Likewise, it has pointed out that narratives are not just fickle, provisional modes of constructing consistent accounts of the technoscientific human experience, which is dealt with in the judicial and administrative context of patent law.

This work has illustrated that some metaphors, namely *machine*, *molecule* and *code*, have shaped new scientific fields and the scope of patentable subject matter in different jurisdictions. These metaphors are the conceptual tools which oriented the definition of the *nature* and *ontology* of biotech products and processes. Their use impinged on "the is" and "the ought" of the claimed inventions before the courts, because their endorsement entailed a series of analogies or differences between them and the kinds of inventions which case law had already established as patentable. As a consequence, the choice in favor of or against a metaphor made the claimed invention fall or not within the statutory categories of patentable subject matter.

These metaphors, as chapter two has explained, have been epistemically influential in the construction, establishment and development of specific fields of research, such as molecular biology and genetics, which have been pivotal in fostering contemporary biotechnology and its commercial potential in terms of patenting innovative products. Moreover, they have sustained an enduring reductionist vision of life (in molecular terms) and DNA sequences (in terms of information) which still inform these fields and, partially, account for the assimilation of biotech products to bio-artefacts and chemical molecules.

The thesis has explained that metaphors are not just *heuristic* devices, which are discarded once a thorough and accurate scientific knowledge is attained, nor just figures of speech that judges, patent lawyers and examiners resort to in order to argue more persuasively.

Conversely, as cognitive linguistics clarified, they are cognitive means that orient perception (Gestalt), thought and action, in everyday life as much as in specific areas of knowledge and practice. The analysis carried out in this work on how these metaphors have been employed in specific technoscientific disciplines and patent law pinpoints that metaphors are conceptual

tools endowed with epistemic and explanatory powers, which involve particular interpretative and prescriptive views.

The metaphors of the *machine* and *chemical molecule* have proved pivotal in informing the *model* and *kinds* of patentable inventions in the United States and Canada. In both countries, the definition of invention, set out in 35 U.S.C. § 101 and Section 2 of the Canadian Patent Act, dates back to the 18th century and is alike. It draws on the same kinds of products: "machine", "manufacture" and "composition of matter". As chapter three and four have illustrated, the case law related to biotech genetically engineered microorganisms, organisms and gene sequences relied on these metaphors to assess the nature of these technoscientific products: whether they were *natural* or *artificial* and their *liveliness* mattered or not to decide on their patentability.

Whereas the metaphor of the *machine* steered the judgment of the majority of U.S. Supreme Court in *Diamond v. Chakrabarty*, as the majority argued that the microorganisms at issue were *bio-artefacts*, not different from other kinds of artefacts made by man, the metaphor of the *chemical molecule* has oriented the arguments of the judges and patent applicants in *In re Bergy* and in *In re Chakrabarty* and was also resorted to by the U.S. Court of Appeals for the Federal Circuit in *AMP v. Myriad Genetics* to define DNA sequences (as well as the Australian Full Court of the Federal Court in *D'Arcy*).

These metaphors have been nurtured and settled in specific scientific disciplinary contexts, however the authority of the scientific language and expertise, which shifted into the judicial patent discourse, validated them as appropriate and accurate descriptions of "the nature of the thing" that was claimed.

For example, in *In re Bergy*, the use of the metaphor of the chemical molecule to define genetically modified microorganisms has been supported by the expertise of Upjohn's biologists, who argued for the patent applicants, and the analogies that it entailed with patentable chemical compounds were fully endorsed by Justice Rich.

In Canada, the CIPO and the judges relied on the *chemical molecul*e metaphor to expand the boundaries of the definition of "invention". This move allowed them to accommodate genetically modified microorganisms (and also HBMs) within patent eligible matter. However, in 2002, the Supreme Court of Canada in the *Harvard mouse* drew a line between lower and higher life forms, by rejecting the mechanistic and chemical metaphors of life applied to transgenic organisms. Accordingly, the Court judged higher life forms not falling within the definition of invention and pinpointed that, in the absence of a provision clearly encompassing this kind of products, Parliament was the appropriate democratic forum to

decide the relevant scientific, legal and moral issues that patenting organisms involved. Nevetheless, in *Schmeiser*, the Court endorsed a mechanistic metaphor of chimeric genes and cells, which was inconsistent with the holding in the *Harvard mouse* case, but mirrored the Canadian biotech interests in fostering GM plant breeding.

In Europe, although the EPO's Boards of Appeal employed some metaphorical expressions related to the *code* and the *chemical molecule*, they usually refrained from relating them openly to the conceptual metaphors. The kind of discourse of their legal narratives has been mainly *technical*. Just in the *Relaxin/Howard Florey Institute* case the TBA drew on and elaborated on the metaphor of the *chemical molecule* and *code* addressing the patent eligibility of gene sequences.

This work has pinpointed that the U.S. definition of "inventions patentable" and the Canadian definition of "invention" embed an epistemic *mechanistic model* of patent eligible matter, which has impinged on how its scope has been expanded by patent offices and courts in these countries. In that respect, it has been illustrated that, in order to subsume some biotech products, such as microorganisms and organisms, under these definitions, the courts had to implicitly embrace forms of methodological and ontological reductionism, which was conveyed by the metaphors that they endorsed.

Conversely, the EPC does not set out categories of patentable inventions in Article 52(1), but refers to "any inventions", "in all fields of technology", provided that they fulfill the requirements of novelty, inventive step and industrial applicability. This article was drafted centuries after the 1793 U.S. definition of patentable subject matter and it does not embed a mechanistic model of invention. Article 52(2) sets out, however, kinds of products and methods which are not considered inventions and, notably, establishes an epistemic distinction between invention and discovery under Article 52(2)(a).

This legal epistemic distinction is absent in 35 U.S.C. § 101, under which "whoever invents or discovers" may be entitled to a patent. This significant difference entailed that in the U.S. the courts had to face the problem of elaborating a doctrine in order to distinguish mere products of nature from inventions *tout court*, namely the product of nature doctrine.

Although the recourse to certain metaphors in legal argumentations results to be contingent, as they do not have an enduring impact on the process of decision-making and its outcome, this work explained that some metaphors had a *conceptual* role in defining patent eligible matter.

In particular, the thesis showed that the conceptual metaphors of the *machine* and the *molecule* informed the *epistemic model* of patentable subject matter and invention in the

United States and in Canada, statutorily, administratively (as far as the decisions of patent examiners were concerned) and judicially.

The metaphors of the machine, molecule and code, it has been argued, are *ontological* and structural, namely metaphors which "specify kinds of objects" and provide different models for what life (microorganisms and organisms, embryos, plants and seeds), genes, HBMs are. This kind of conceptual metaphors served to define the model of patentable subject matter in U.S. and Canada, but also partially impinged on the definition of patentable inventions offered by the technical narratives of the EPO Boards of Appeals.

From an STS point of view, whereas the metaphor of the *machine*, which is often drawn upon in everyday language as well as in the scientific one, to make sense of several kinds of abstract objects, such as the *mind*, could be linked to the direct human physical experience, others, such as the *molecule*, have been mediated by the technoscientific experience of the scientists working in laboratories. In technoscientific societies, people do believe that microorganisms or genes can be viewed as chemical molecules (or information) not because they directly experience them, but because they trust the experience and knowledge of molecular biologists and geneticists, who describe them as such.

The use of some ontological metaphors, which have been largely drawn upon in patent litigation and everyday language, therefore, is related to the mediated *virtual experience* that professionals and in general human beings gain from the experience, material knowledge and action that scientists have of molecules and the genome. This sort of mediated and virtual metaphorical experience has been at the core of the co-production of metaphors among science, patent law and society.

In that respect, this STS analysis shows that the authority of the scientific language and experience of scientists have credited the use of these metaphors in the patent legal discourse and contributed to a shifting of meanings in the definition of patent eligible matter in all the jurisdictions which have been compared. In turn, the jurisprudential re-definition of patentable inventions has partially impinged on how different communities of scientists and researchers view these metaphors.

As chapter four and five have illustrated as far as genes and transgenic seeds are concerned, individuals and groups sometimes propose alternative metaphors of life and nature. However, as *AMP v. Myriad Genetics* pointed out, in order to undermine dominant narratives, the plaintiffs had to reframe the narrative of progress, origins and the social contract between citizens, the inventor and the state in order to be successful.

Likewise, this work has explained that patent judicial and administrative narratives result from the co-production of technoscientific and legal discourses. Although some of these narratives prove to be provisional, others prove to be stable ways of "making sense and order" of technology in specific national and supranational contexts.

The narrative of the origins and progress devised and told by the Supreme Court in *Chakrabarty* turned out to be constantly drawn upon by the USPTO, judges and parties in order to justify a specific view of innovation, IP and the public interest in the United States. It has become a *master narrative* in the product-centered U.S. policy of science and technology, which could not easily be undermined. It has been drawn upon to affirm the patent eligibility of transgenic plants, seeds and isolated/purified HBMs.

In *AMP v. Myriad Genetics* the plaintiffs posited a successfull counter-narrative of it, while still drawing on it. They offered an alternative metaphor of the genes centered on the *code* (DNA sequences as information), recalled the significance of the doctrine of the product of nature re-affirmed in *Chakrabarty* and, then, showed how the narrative of progress and origins of the United States was undermined by Myriad's patents. These patents, according to them, impaired the social contract between inventors and society embedded in the U.S. Constitution, as they impinged on citizens' and researchers' freedom of ideas and right to health as they were directed to products of nature. They challenged, therefore, that IPRs on DNA sequences could foster the progress that IP, in the U.S., is supposed to bring about.

In Canada, the narratives concerning the patent eligibility of biotech products have been cautious in not stretching the boundaries of administrative or judicial powers to encompass potentially divisive patentable subject matter, such as transgenic organisms, that could raise scientific, ethical and legal concerns.

The Canadian courts did not draw on a narrative of the origins. They fostered the expansion of IPRs, but have been very careful in expanding it to organisms for the kind of uncertain justification of this legal expansion. Notwithstanding this choice, the Supreme Court of Canada has been more reluctant to maintain this patent restriction, as far as transgenic seeds and plants are concerned, as the *Schmeiser* case has pointed out.

In Europe, the EPO Boards of Appeal drew on a *technical* kind of discourse in order to justify their patent decisions. As the analysis of the *Myriad* cases pinpointed, the Boards made clear that, whenever patent claims should not have been granted because they did not fulfill patent requirements, the EPC patent system embed adequate judicial procedures to oppose and review patents.

Moreover, the Boards have privileged *historical legal narratives* to construct the meaning of the EPC, which also were used to handle the morality and *ordre public* patent exclusions under Article 53(a) EPC and the other exclusions under Article 53(b).

However, as the *WARF* and *Brüstle* cases pointed out, the patent eligibility of hESCs has proved to be the test bench of the morality clause embedded in Article 53(a) and of the European identity.

7.2 Why Metaphors and Narratives Matter: Technoscientific Imaginaries of Life and Future

On 28 November 2014 Jennifer Doudna and Emmanuelle Charpentier published an article in Science entitled "The new frontier of genome engineering with CRISPR-Cas9"[1544] in which they explained how they developed the groundbreaking technology CRISPR-Cas9 that purports to be more effective, cheaper and simpler than any other existing technology of "gene editing". Moreover, they described some of its possible applications in biology, biomedicine and biotechnology, spanning from human gene therapy and the modification of the germ line to the development of crops in agriculture and the creation of new animal models for research purposes.[1545] This article followed the publication of their research paper on CRISPR-Cas9.[1546] A little over two years this technology had been applied to a broad range of microorganisms and organisms, for manifold purposes.

Just a year later, in 2015, a whole volume of the American Journal of Bioethics has been devoted to CRISPR and focused, in particular, on the metaphors and metaphorical expressions used to describe it.

In particular, several scholars illustrated that "gene editing" and "targeting"[1547] are the dominant metaphors used to describe CRISPR technology in Anglo-American journals[1548] and are also largely employed in other languages.[1549] Some scholars viewed these metaphors as troublesome for what they implied in terms of the description of the physical mechanisms of CRISPR-Cas9 techniques, the risks they involve and the reductionist view that they imply.

[1544] Jennifer A Doudna and Emmanuelle Charpentier, 'The New Frontier of Genome Engineering with CRISPR-Cas9' (2014) 346(6213) Science 1076.
[1545] ibid 1082-1083.
[1546] Martin Jinek, Krzysztof Chylinski, Ines Fonfara, Michael Hauer, Jennifer A Doudna, Emmanuelle Charpentier, 'A Programmable Dual-RNA-Guided DNA Endonuclease in Adaptive Bacterial Immunity' (17 August 2012) 337(6069) Science 816.
[1547] Meaghan O'Keefe, et al., ''Editing' Genes: A Case Study About How Language Matters in Bioethics' (2015) 15(12) The American Journal of Bioethics 3.
[1548] ibid 3.
[1549] Alessandro Blasimme, et al., 'Genome Etiring and Dialogic Responsibility: 'What is in a Name?'' (2015) 15(12) The American Journal of Bioethics 54.

They questioned the use of these specific metaphors because their endorsement affects the bioethical debate, public deliberation and policymaking. In particular, O'Keefe et al. remarked that probing the words used with reference to a technology is pivotal for "sound policymaking",[1550] as the terms should convey: "(1) the ethical complexity of the technology; (2) an accurate description of the technology, how it works, and how it can be used; (3) what is known and unknown about its potential consequences".[1551]

The most frequent metaphorical expressions related to gene "editing" are "cutting and pasting", "copy and paste", "read" and "write", "the first draft".[1552] These expressions, as much as "editing", are linked to the conceptual metaphor of the genome as a *code*, which has been drawn upon in the patent controversies concerning DNA sequences.

They suggest a high degree of *control* over the genome, as they imply that it can be cut *precisely* and the exact location of off-target effects can be envisaged and handled. However, it has been illustrated[1553] that the predictions of specific locations of possible off-target effects, which are based on the use of algorithms, turn out to be not as precise as expected and unintentional "cuts" can take place anywhere in the genome.

The ballistic metaphorical expression "target", likewise, entails precision, but also conveys the idea that hazards can result from missing the target.[1554]

Ben Merriman pointed out that "regulation is a metaphorical practice",[1555] since a new regulatory framework is rarely devised and set out for the latest technology and "in most cases, regulation involves drawing an analogy between something new in science and something that is already regulated, thereby extending an existing framework".[1556]

Regulation is a matter of envisioning futures and metaphors are at the core of the process of devising technoscientific imaginaries of what a technology and its products are and entail in terms of hopes, possibilities, cure and risks, uncertainty, distributive problems.

The metaphor of "editing", he noted, implies that CRISPR is like an information technology and the metaphorical expression of "editing" is grounded on the metaphor of the *code* that has oriented how genes have been devised in molecular genetics, as information. However, as he points out, by applying the metaphor of editing, it should be taken into consideration that

[1550] O'Keefe, et al. (n 1547) 4.
[1551] ibid.
[1552] ibid 7.
[1553] ibid.
[1554] ibid 8.
[1555] Ben Merriman, ''Editing': A Productive Metaphor for Regulating CRISPR' (2015) 15(12) The American Journal of Bioethics 62.
[1556] ibid.

"the technology physically modifies cells rather than manipulating symbolic representations".[1557]

As chapter three highlighted about the regulation of rDNA in the 1970s, metaphors and the analogies they entail had a pivotal role in deciding whether and how that technology should be regulated and which could be the most appropriate frame for its governance. The choices that were made in specific national contexts on rDNA regulation impinged on the patent eligibility of biotech products related to this technology.

On 15 February 2017, the U.S. Patent Trial and Appeal Board issued a decision in the *The Broad Institute, Inc., MIT and Presidents and Fellows of Harvard College v. The Regents of the University of California, University of Vienna, and Emmanuelle Charpentier*, concerning the patent interference between patents and patent applications of the parties involved. All the claims challenged are related to CRISPR-Cas9 systems and methods of using them. The PTAB judged the parties' patent claims not interfering.[1558] The Regents of the University of California appealed against the decision in October 2017[1559] and this will probably be one the most important case of patent interference on a new technology. However, this is just the dawn of a new wave of patent controversies related to CRISPR-Cas9.

In the aftermath of this, a group of interested stakeholders organised a meeting in Napa to debate the scientific, medical, ethical and legal implication of this technology.[1560] The meeting and the reaction of the scientific community, to a certain extent, resembles the "responsible" answer prompted by the first experiments on rDNA in the 1970s that led to the Asilomar Conference in 1975 and the approval of the NIH Guidelines (which has been explained in chapter 4). Some of the promoters of the meeting, David Baltimore and Paul Berg, are still the same prominent biologists who drew up the agenda of Asilomar. Furthermore, the narratives of progress regarding CRISPR-Cas9 are not surprisingly similar to the ones concerning rDNA.[1561] The accounts on CRISPR-Cas9 are narratives of novelty and progress. Although the scientific community has pointed out the ethical issues arising

[1557] ibid 62.

[1558] USPTO, Patent Trial and Appeal Board, *The Broad Institute, Inc., MIT and Presidents and Fellows of Harvard College v. The Regents of the University of California, University of Vienna, and Emmanuelle Charpentier*, 15 February 2017.

[1559] United States Court of Appeals for the Federal Circuit, *The Regents of the University of California, University of Vienna, and Emmanuelle Charpentier v. The Broad Institute, Inc., MIT and Presidents and Fellows of Harvard College*, Brief for Appellees, 25 October 2017.

[1560] David Baltimore, et al., 'A Prudent Path Forward for Genomic Engineering and Germline Modification. A Framework for Open Discourse on the Use of CRISPR-Cas9 Technology to Manipulate the Human Genome Is Urgently Needed' (2015) 348(6230) Science 36.

[1561] Sheila Jasanoff, J Benjamin Hurlbut and Krishanu Saha, 'CRISPR Democracy: Gene Editing and the Need for Inclusive Deliberation' (2015) 32(1) Issues in Science &Technology 25, 26.

from the manifold uses of it, it has however expressed confidence that the potential risks and controversial applications can be addressed in a process of public discussion of science policy analogous to the legacy and still dominant laudatory and exemplary narrative of the Asilomar Conference.

Following the meeting, the participants formulated a series of recommendations, among which figures a temporary moratorium on experiments on germline genome modification for clinical application in humans.[1562] Moreover, the U.S. National Academy of Sciences and the National Academy of Medicine promoted an international summit to discuss the scientific, ethical, legal and policy problems related to CRISPR-Cas9 and gene editing.[1563]

The present narratives regarding CRISPR-Cas9, as well as some of the metaphors used to describe it, are like the ones employed in the rDNA debate. They are centered on progress and hope and the responsibility of the scientific community, in the legacy of Asilomar.

For example, the metaphorical expression of "genome engineering" has been applied to CRISPR-Cas9. As Jennifer Doudna and Samuel Sternberg pointed out in their recent account of the development of this technology, this locution suggests a higher degree of command and control over inserting, editing or deleting genes: "But with CRISPR, gene editing was now so powerful and multifaceted that it was also referred to as *genome engineering*, a reflection of the supreme mastery that scientists held over genetic material inside the living cells".[1564]

Genome editing seems to be a step ahead of rDNA in terms of control and reproducibility, which had been claimed, likewise, in the patent specification and drawings of highly divisive patent applications, such as the *Oncomouse*® one, in the past. Not surprisingly Rudolf Jaenisch, who was the first researcher to develop a transgenic mouse in 1974,[1565] published with his MIT research group an article on the creation of gene-edited mice through CRISPR, in 2013.[1566]

The Asilomar Conference has been praised as a model of responsible debate promoted by the scientific community on a disruptive and uncertain technology (rDNA),[1567] which can be

[1562] Baltimore, et al. (n 1560) 37.
[1563] The National Academies of Sciences, Engineering, Medicine, International Summit on Human Gene Editing. A Global Discussion, 1-3 December 2015 Washington (DC).
[1564] Jennifer Doudna and Samuel Sternberg, *A Crack in Creation: The New Power to Control Evolution* (The Bodley Head 2017) xii, 100.
[1565] ibid 97.
[1566] Haoyi Wang, Hui Yang, Chikdu S Shivalila, Meelad M Dawlaty, Albert W Cheng, Feng Zhang and Rudolf Jaenisch, 'One-Step Generation of Mice Carrying Mutations in Multiple Genes by CRISPR/Cas-Mediated Genome Engineering' (9 May 2013) 153 Cell 910.
[1567] Paul Berg, 'Asilomar 1975: DNA Modification Secured' (18 September 2008) 455(7211) Nature 290-291.

replicated with regard to CRISPR-Cas9. However, several STS scholars pinpointed the limits of that debate and deliberation in terms of the limited view about containment, imaginaries of risk, modes of deliberation, exclusions of relevant voices and relevant issues regarding biosecurity and ethics.[1568] Moreover, they highlighted how many of the legal issues, in particular concerning intellectual property, had been overlooked.

Doudna and Sternberg highlighted the *democratic* nature of this technology, which is cheap and simple, as it "has made gene editing available to the masses and is poised to turn this once-esoteric practice into a hobby or a craft, just like home-brewing beer".[1569] Nonetheless, others observed that "A therapeutic as complex as CRISPR gene therapy with multiple macromolecular components (protein, RNA, and delivery agents) is likely to be engineered and reformulated for decades to come to maximize safety and efficacy".[1570] Consequently, it may result in a chain of evergreening patents.[1571]

Furthermore, the present patent interference proceeding controversy[1572] in the U.S and the breadth of the patent claims involved suggest that maybe IPRs so much upstream might impinge on future research on this technology and limit access to patented products and methods. The IP scholars and attorneys Jacob Sherkow and Jorge Contreras, commenting on the interference patent case, cautioned against the parties' patent strategy, as it "could rapidly bottleneck the use of CRISPR technology to discover and develop useful human therapeutics".[1573]

This work pinpointed the need for a certain degree of reflexivity towards performative metaphors and narratives which shape national and supranational collective imaginaries of technoscience. Without this kind of reflexivity IP and, in particular patent law, cannot offer an adequate collective answer to what is an acceptable contract between inventors and society, in the name of the public interest.

[1568] Jasanoff, Hurlbut and Saha (n 1561) 27-28.
[1569] Doudna and Sternberg (n 1564) 113.
[1570] Jasanoff, Hurlbut and Saha (n 1561) 28.
[1571] ibid.
[1572] Jon Cohen, 'The Birth of CRISPRINC. How a Community Fractured as a Revolutionary Genome-Editing Tool Become a Business' (17 February 2017) 335(6326) Science 682, 683.
[1573] ibid 684.

Appendix

Science and Technology Studies (S&TS): Origins and Development

1.1 **Science and Technology Studies (S&TS)**

Tracing the origins of Science and Technology Studies is complex and burdensome for several reasons, but is however crucial for defining a field whose development depends on the historical, theoretical and political context where it arose.

Science and Technology Studies or "S&TS" emerged in the late 1980s from the rich and multidisciplinary work carried out across vast and different areas of research, such as history and sociology of science and technology, anthropology, science policy, legal sciences and economics (to name only the major areas of research), [1574] by scholars guided by heterogeneous theoretical and practical interests.[1575] The history of S&TS, however, spans a longer period, approximately five decades, as S&TS are marked by the rise, in the 1960s, of two traditions which both regarded science as a social activity: the constructivist tradition in sociology and ethnography of science and the critical analysis undertaken in "Science, Technology and Society" (STS)[1576] by an international group of scholars, who directed their work at the social and policy dimensions of science and technology.[1577]

The convergence and intertwining of these traditions contributed to the gradual establishment of S&TS as a research field grown out of distinct disciplines and heterogeneous methodologies, but sharing the view that science and technology are *social* enterprises to be accounted for. In order to explain the "inherent diversity" [1578] of S&TS, its theoretical perspective and analytical tools, I will try to illustrate how the field emerged, thrived and became institutionalized since the 1960s.

[1574] David Edge, the astrophysicist who started the Science Unit at Edinburgh University in 1966, pointed out that the converging disciplinary streams arose from a number of well-established specialties, embedded in history and philosophy (of science), in anthropology, in economics and political and legal sciences. He recognizes, however, that the list is not complete and suggests a series of influential works, in chronological order of publication. See David Edge, 'Reinventing the Wheel' in Sheila Jasanoff, Gerald E Markle, James C Petersen and Trevor Pinch (eds), *Handbook of Science and Technology Studies* (rev edn, Sage Publications 1995) 3, 4.

[1575] David Edge remarks that "some scholars had 'pure' epistemological and sociological aims; others were teaching students in the sciences and engineering; some were active as policy advisers". David Edge, 'Reinventing the Wheel' in Sheila Jasanoff, Gerald E Markle, James C Petersen and Trevor Pinch (eds), *Handbook of Science and Technology Studies* (rev edn, Sage Publications 1995) 3, 4.

[1576] Mariachiara Tallacchini, 'Scienza e diritto. Verso una nuova disciplina' in Sheila Jasanoff, *La scienza davanti ai giudici* (Giuffrè Editore 2001) VII, X.

[1577] See Ina Spiegel-Rösing and Derek de Solla Price, 'Preface' in Ina Spiegel-Rösing and Derek de Solla Price (eds), *Science, Technology and Society* (Sage Publications 1977) 1.

[1578] David Edge, 'Reinventing the Wheel' in Sheila Jasanoff, Gerald E Markle, James C Petersen and Trevor Pinch (eds), *Handbook of Science and Technology Studies* (rev edn, Sage Publications 1995) 3, 4.

1.2 **S&TS: Origins and Development**

As David Edge recalled, in the first edition of the *Handbook of Science and Technology Studies*, when on March 1, 1966, he arrived at Edinburgh University to start the Science Studies Unit, he was tempted to think that there could be "no subject" corresponding to S&TS initials. It was only a passing thought, since he was fully aware that scholars, in some well-established disciplines, had already focused their analysis on science in its social context and these research streams were gathering in the mid-1960s.[1579]

History and sociology of science were at the forefront of this disciplinary and epistemic shift. In 1962, Thomas Kuhn published his influential essay *The Structure of Scientific Revolutions*. Kuhn, a theoretical physicist who turned his interests and career towards the history of science,[1580] challenged the dominant view of science as a continuous incremental and cumulative enterprise, centered on the concept of "development-by-accumulation".[1581] According to the cumulative view, science is portrayed as a collection of facts, theories and methods and historians of science are assigned the task to chronicle the "successive increments and the obstacles that have inhibited their accumulation".[1582] Kuhn proposed a new picture of scientific development, characterized instead "as a succession of tradition bound periods punctuated by non-cumulative breaks".[1583]

He defined the tradition bound periods as "normal science", which is the "research firmly based upon one or more past scientific achievements, achievements that some particular scientific community acknowledges for a time as supplying the foundation for its further practice".[1584] Normal science is related to particular achievements[1585] named by Kuhn "paradigms", whose meaning refers to "some accepted examples of actual scientific practice – examples which include law, theory, application, and instrumentation together – [that]

[1579] David Edge, 'Reinventing the Wheel' in Sheila Jasanoff, Gerald E Markle, James C Petersen and Trevor Pinch (eds), *Handbook of Science and Technology Studies* (rev edn, Sage Publications 1995) 3, 3-4.
[1580] Thomas S Kuhn, *The Structure of Scientific Revolutions* (1st edn 1962, 4th edn, The University of Chicago Press 2012) v, xxxix.
[1581] Thomas S Kuhn, *The Structure of Scientific Revolutions* (1st edn 1962, 4th edn, The University of Chicago Press 2012) 1, 2.
[1582] Thomas S Kuhn, *The Structure of Scientific Revolutions* (1st edn 1962, 4th edn, The University of Chicago Press 2012) 1, 2.
[1583] Thomas S Kuhn, 'Postscript-1969' in *The Structure of Scientific Revolutions* (1st edn 1962, 4th edn, The University of Chicago Press 2012) 173, 207.
[1584] Thomas S Kuhn, *The Structure of Scientific Revolutions* (1st edn 1962, 4th edn, The University of Chicago Press 2012) 1, 10.
[1585] Kuhn explains that paradigms are achievements which share two essential characteristics: 1. the achievement is "sufficiently unprecedented to attract an enduring group of adherents away from competing modes of scientific activity"; 2. it is "sufficiently open-ended to leave all sorts of problems for the redefined group of practitioners to resolve". Thomas S Kuhn, *The Structure of Scientific Revolutions* (1st edn 1962, 4th edn, The University of Chicago Press 2012) 1, 9-10.

provide models from which spring particular coherent traditions of scientific research".[1586] Although the word "paradigm"[1587] recalls, in the established language, an accepted model or pattern which is applied to replicate examples,[1588] Kuhn points out that in science a paradigm is rarely an object for replication, but only for further research articulation and specification, and that its status is due to its success in solving problems that practitioners recognize as acute.[1589]

Normal research does not pursue major fundamental scientific novelties, but is directed to "puzzle-solving": it is, namely, an activity devoted to problems that test solving ingenuity or skill, where more than a solution is assured and "rules that limit both the nature of acceptable solutions and the steps by which they are obtained"[1590] do exist. A paradigm provides, therefore, the scientific community with a framework, which is taken for granted, within trying to address problems that have a solution.

If one or more anomalies result from normal science and cannot be reconciled with the established paradigm, they may create a crisis and induce a paradigm change. These anomalies consist in discoveries (novelties of fact) and/or in inventions (novelties of theory). Profound awareness of the anomaly in the scientific community, however, plays a fundamental role in paradigm change.

Kuhn illustrates the prevailing of the Copernican heliocentric astronomic system, in the 16th century, against the Ptolemaic geocentric astronomy as one of the main examples of paradigm change in the history of science. Since the Ptolemaic system, that was developed

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[1586] Thomas S Kuhn, *The Structure of Scientific Revolutions* (1st edn 1962, 4th edn, The University of Chicago Press 2012) 1, 11.

[1587] Since some scholars, such as Margaret Masterman and Dudley Shapere, criticized Kuhn's use of the concept of "paradigm", in his 1969 Postscript to *The Structure of Scientific Revolutions* he explained the different senses in which he used the word in the essay: "On one hand, it stands for the entire constellation of beliefs, values, techniques, and so on shared by the members of a given community. On the other, it denotes one sort of element in that constellation, the concrete puzzle-solutions which, employed as models or examples, can replace explicit rules as a basis for the solution of the remaining puzzles of normal science". The first sense of its meaning is, therefore, sociological, whereas in the second sense "paradigm" stands for an exemplary scientific past achievement. Thomas S Kuhn, 'Postscript-1969' in *The Structure of Scientific Revolutions* (1st edn 1962, 4th edn, The University of Chicago Press 2012) 173, 174.

[1588] Kuhn illustrates the difference of meaning of the word "paradigm" in the established usage and in science, clarifying that: "In its established usage, a paradigm is an accepted model or pattern, and that aspect of its meaning has enabled me, lacking a better word, to appropriate 'paradigm' here. But it will shortly be clear that the sense of 'model' and 'pattern' that permit the appropriation is not quite the one usual in defining 'paradigm'. In grammar, for example, '*amo*, *amas*, *amat*' is a paradigm because it displays the pattern to be used in conjugating a large number of latin verbs, e.g., '*laudo*, *laudas*, *laudat*'. In this standard application, the paradigm functions by permitting the replication of examples any one of which could in principle serve to replace it". Thomas S Kuhn, *The Structure of Scientific Revolutions* (1st edn 1962, 4th edn, The University of Chicago Press 2012) 1, 23.

[1589] Thomas S Kuhn, *The Structure of Scientific Revolutions* (1st edn 1962, 4th edn, The University of Chicago Press 2012) 1, 24.

[1590] Thomas S Kuhn, *The Structure of Scientific Revolutions* (1st edn 1962, 4th edn, The University of Chicago Press 2012) 1, 38.

between the last two centuries before Christ and the first two after, was "admirably successful"[1591] in predicting the changing positions of stars and planets in comparison to all other ancient systems, it was widely adopted in the following centuries. Nevertheless, it was not completely successful in predicting the planetary positions and the procession of equinoxes. Astronomers, thus, tried to reduce the discrepancies of the system, but they increasingly became aware of its failure in solving some problems. This significant awareness, achieved in the Renaissance, gave the Copernican competing system a chance to be embraced. Yet, Kuhn notices that this system was not more accurate than Ptolemy's one and the available observational tests did not proved decisive to support the choice between them. The Renaissance astronomers turned to the former mainly because they significantly recognized the crisis due to the latter. An anticipation of the heliocentric system, however, existed since antiquity and was elaborated by the Greek mathematician, physicist and astronomer Aristarchus of Samos in the 3rd century B.C., [1592] but his contemporary astronomers did not subscribe to his theory, as they did not consider the Ptolemaic system failing in solving most of the problems they were dealing with.

The transition from a paradigm in crisis to a new one entails the reconstruction of a whole scientific field from new fundamentals – namely, theoretical generalizations, methods and applications – and, therefore, results in what Kuhn calls "scientific revolution".[1593] Whilst normal science is deemed cumulative, as it is directed to the "steady extension of the scope and precision of scientific knowledge", [1594] scientific revolutions are described as "non-cumulative developmental episodes" that replace a normal scientific tradition with another.[1595] The new normal tradition is incommensurable with the previous one, since it induces a "displacement of the conceptual network through which scientists view the world".[1596]

[1591] Thomas S Kuhn, *The Structure of Scientific Revolutions* (1st edn 1962, 4th edn, The University of Chicago Press 2012) 1, 68.

[1592] See Thomas L Heath, *Aristarchus of Samos: The Ancient Copernicus* (Clarendon Press 1913). Although Aristarchus (about 310-250 BC) was the first ancient Greek astronomer to develop the heliocentric doctrine, Heraclides Ponticus (4th century BC) was the first philosopher and astronomer who advanced the heliocentric thesis.

[1593] Thomas S Kuhn, *The Structure of Scientific Revolutions* (1st edn 1962, 4th edn, The University of Chicago Press 2012) 1, 90.

[1594] Thomas S Kuhn, *The Structure of Scientific Revolutions* (1st edn 1962, 4th edn, The University of Chicago Press 2012) 1, 52.

[1595] Thomas S Kuhn, *The Structure of Scientific Revolutions* (1st edn 1962, 4th edn, The University of Chicago Press 2012) 1, 103.

[1596] Thomas S Kuhn, *The Structure of Scientific Revolutions* (1st edn 1962, 4th edn, The University of Chicago Press 2012) 1, 102.

In his concluding chapter, Kuhn portrays science as a field significantly marked by progress, generally defined as "the result of successful creative work",[1597] in comparison to other areas of knowledge. Although he acknowledges that scientific progress is not different in kind from progress in other fields, he ascribes it to the unparalleled *insulation* of the scientific community from society, which allows each scientist to concentrate his attention on a specific problem. This *insulation* is gained by a specific educational initiation and professional activity. Scientists' education relies heavily on the study of textbooks rather than in the early exposure to a variety of creative scientific literature, so that students become confident and familiar only with the paradigms that will direct their future research. Their further individual activity, then, will undergo a very exclusive scrutiny and evaluation by the other members of the community,[1598] which has no equal in other professional groups. *Insulation* is regarded as the condition for scientists' successfulness as producers and validators of knowledge.

Kuhn's essay concurred to a historiographic change in the study of science, outside strict linear cumulative lines,[1599] and to shift the theoretical interests[1600] from scientific facts, theories and data towards the pivotal role of scientific communities,[1601] their ideas and practices.[1602] His view of science and scientific community received thorough criticism[1603] by philosophers, sociologists and historians of science,[1604] who challenged the nature of the

[1597] Thomas S Kuhn, *The Structure of Scientific Revolutions* (1st edn 1962, 4th edn, The University of Chicago Press 2012) 1, 161.

[1598] Thomas S Kuhn, *The Structure of Scientific Revolutions* (1st edn 1962, 4th edn, The University of Chicago Press 2012) 1, 163.

[1599] Thomas S Kuhn, *The Structure of Scientific Revolutions* (1st edn 1962, 4th edn, The University of Chicago Press 2012) 1, 3.

[1600] The philosopher of science Ian Hacking suggests that Kuhn's essay had "more enduring effects" upon philosophy of science and public culture than on history of science. Although Kuhn considered himself an historian of science, he repeatedly admitted his interests were primarily philosophical. See Ian Hacking, 'Introductory Essay' in Thomas S Kuhn, *The Structure of Scientific Revolutions* (1st edn 1962, 4th edn, The University of Chicago Press 2012) vii, x.

[1601] Kuhn acknowledged that it was his acquaintance with the work of the Polish Hebrew bacteriologist Ludwik Fleck, *Genesis and Development of a Scientific Fact* (text published in German in 1935, but practically unknown before Kuhn promoted its translation and publication in English, in 1979), that helped him "to realize that the problems which concerned" his research had fundamentally a sociological dimension. See Thomas S Kuhn, 'Foreword' in Ludwik Fleck, *Genesis and Development of a Scientific Fact* (1st edn 1935, The University of Chicago Press 1981) vii, viii; Thomas S Kuhn, *The Structure of Scientific Revolutions* (1st edn 1962, 4th edn, The University of Chicago Press 2012) v, xli.

[1602] Sergio Sismondo, *An Introduction to Science and Technology Studies* (Blackwell Publishing 2004) 1, 18.

[1603] See Imre Lakatos and Alan Musgrave (eds), *Criticism and the Growth of Knowledge* (Cambridge University Press 1970), 1.

[1604] Kuhn, in the years that followed the publishing of *The Structure of Scientific Revolutions* replied to some of his critics. See, for example, Thomas S Kuhn, 'Reflections on My Critics' in James Conant and John Haugeland (eds) *The Road Since Structure: Philosophical Essays, 1970-1973, with an Autobiographical Interview* (1st edn 2000, The University of Chicago Press 2002), 123; Thomas S Kuhn, 'Afterwords' in James Conant and John Haugeland (eds) *The Road Since Structure: Philosophical Essays, 1970-1973, with an Autobiographical Interview* (1st edn 2000, The University of Chicago Press 2002), 224.

concept of "paradigm" and its incommensurability and found his essay marked by subjectivity, irrationality and relativism.

Kuhn's work has been influential in the development of Science and Technology Studies, as it has nurtured new streams of research. Nonetheless, as Sismondo points out, "few of Kuhn's specific ideas have survived S&TS intact".[1605] The sociologist Steve Fuller provocatively remarks that *The Structure* has been turned in a paradigm for further research [1606] by historians and sociologists of science and explicitly refers to "the research program known as the 'sociology of scientific knowledge' (SSK)" and "the interdisciplinary field of 'science and technology studies' (STS)". Fuller deems that Kuhn showed these scholars "to look beyond the positivist jargon that scientists use to justify their activities and to focus instead on what scientists actually do in their workplaces".[1607] He thinks, therefore, that Kuhn's example accounts for the post-Kuhnian methodologies that became largely imbued with "histories and ethnographies of research environment and deconstruction of disciplinary discourse".[1608]

Gieryn showed, however, that the inherent diversity of STS, in comparison to other perspectives such as Kuhn's one, lies in its *constructivist* way of dealing with the "boundary problem", namely how to demarcate society from science, science from non-science and the scientific community from other communities. According to him, the constructivist view is centered on the claim that "no demarcation principles work universally and that the separation of science from other knowledge-producing activities is (…) a contextually contingent and interests-driven pragmatic accomplishment drawing selectively on inconsistent and ambiguous attributes".[1609] Kuhn's picture differs from STS' constructivist view, since it is "essentialist".[1610] It is actually focused on identifying a demarcation principle

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One of his early critics, the historian of science Leslie Pearce Williams, can be numbered among STS scholars. He is, in fact, one of the founders, in the 1980s, of Cornell's Program in the History and Philosophy of Science and Technology that, then, became part of the Department of Science & Technology Studies.

[1605] Sergio Sismondo, *An Introduction to Science and Technology Studies* (Blackwell Publishing 2004) 1, 19.

[1606] Steve Fuller, *Thomas Kuhn: A Philosophical History for Our Time* (The University of Chicago Press 2000) 1, 3.

[1607] Steve Fuller, *Thomas Kuhn: A Philosophical History for Our Time* (The University of Chicago Press 2000) 1, 3.

[1608] Steve Fuller, *Thomas Kuhn: A Philosophical History for Our Time* (The University of Chicago Press 2000) 1, 3.

[1609] Thomas F Gieryn, 'Boundaries of Science' in Sheila Jasanoff, Gerald E Markle, James C Petersen and Trevor Pinch (eds), *Handbook of Science and Technology Studies* (rev edn, Sage Publications 1995) 393.

[1610] Gieryn explains that "essentialists argue for the possibility and analytic desirability of identifying unique, necessary and invariant qualities that set science apart from other cultural practices and products and that explain its singular achievement". Thomas F Gieryn, "Boundaries of Science" in Sheila Jasanoff, Gerald E Markle, James C Petersen and Trevor Pinch (eds), *Handbook of Science and Technology Studies* (rev edn, Sage Publications 1995) 393.

that sets science apart from other cultural practices, which Kuhn places in scientists' consensus on a paradigm.[1611]

Constructivism turns out to be a pivotal key in understanding how STS diverges theoretically and methodologically from other relevant traditions, which STS confronted with in its "formative years".

Another influential tradition with which STS confronted with, though in a very critical way, is Merton's social theory of science. In 1949, the sociologist Robert K. Merton published a book entitled *Social Theory and Social Structure*, that included the paper 'Science and Democratic Social Structure', written during World War II, in 1942. In this paper Merton defends, against the attacks on the integrity of science launched by the Nazis and their ideology, the social structure of science. Merton's portrayal of science is embedded in his functionalist theory, where science is seen as an institution that, together with other institutions such as government and religion, fulfills a necessary function and, thus, concurs to the stability and order of society.[1612] "The extension of certified knowledge"[1613] is the institutional goal of science, which consists of "empirically confirmed and logically consistent predictions".[1614]

Merton analyzes only on one aspect of science,[1615] its cultural structure as an institution, what he terms "the *ethos* of science", excluding all the methodological and cognitive issues. The *ethos* of science is "that affectively toned complex of values and norms which is held to be binding on the man of science".[1616] The norms consist of prescriptions, proscriptions, preferences and permissions that "are legitimized in terms of institutional values" and are transmitted by precept and example by the scientific community and reinforced by sanctions.

[1611] Thomas F Gieryn, "Boundaries of Science" in Sheila Jasanoff, Gerald E Markle, James C Petersen and Trevor Pinch (eds), *Handbook of Science and Technology Studies* (rev edn, Sage Publications 1995) 393, 402-403. Kuhn notices: "Once a first paradigm through which to view nature has been found, there is no such thing as research in the absence of any paradigm. To reject one paradigm without simultaneously substituting another is to reject science itself". Thomas S Kuhn, *The Structure of Scientific Revolutions* (1st edn 1962, 4th edn, The University of Chicago Press 2012) 1, 79.

[1612] Sergio Sismondo, *An Introduction to Science and Technology Studies* (Blackwell Publishing 2004) 1, 20.

[1613] Robert K Merton, 'Science and Democratic Social Structure' in *Social Theory and Social Structure* (1st edn 1949, enl edn, The Free Press 1968) 604, 606.

[1614] Robert K Merton, 'Science and Democratic Social Structure' in *Social Theory and Social Structure* (1st edn 1949, enl edn, The Free Press 1968) 604, 606.
Thomas F Gieryn, 'Boundaries of Science' in Sheila Jasanoff, Gerald E Markle, James C Petersen and Trevor Pinch (eds), *Handbook of Science and Technology Studies* (rev edn, Sage Publications 1995) 393.

[1615] Merton points out that the word "science" denotes a variety of items that are interrelated: "(1) a set of characteristic methods by means of which knowledge is certified; (2) a stock of accumulated knowledge stemming from the application of these methods; (3) a set of cultural values and mores governing the activities termed scientific or (4) any combination of the foregoing". Robert K Merton, 'Science and Democratic Social Structure' in *Social Theory and Social Structure* (1st edn 1949, enl edn, The Free Press 1968) 604, 605.

[1616] Robert K Merton, 'Science and Democratic Social Structure' in *Social Theory and Social Structure* (1st edn 1949, enl edn, The Free Press 1968) 604, 605.

Although the *ethos* of science is not codified, it can be inferred from the moral consensus of scientists. The institutional imperatives (*mores*) of science are drawn from its goal and methods. Merton identifies four sets of institutional norms:[1617] *universalism, communism, disinterestedness* and *organized scepticism*.

Universalism is based on the purported impersonality of science and lies in the idea that "truth claims, whatever their source, are to be subjected to *preestablished impersonal criteria*".[1618] According to this norm, in assessing scientific claims, the scientific community is not influenced by personal or social attributes, such as race, nationality, religion, class and personal qualifications. Merton notices however that, as science is part of a larger social structure, this imperative may be in conflict with other cultural particularistic norms. He refers to ethnocentrism and nationalism as potential threats to scientific universal standards, as well as to the potential influence of caste-standards in excluding individuals from scientific pursuit. Nevertheless, he argues, scientists are able to react to these kinds of counter-pressures and reassert their commitment to universalism. Merton considers *universalism* also a dominant guiding principle of the *ethos* democracy, since "impersonal criteria of accomplishment and not fixation of status characterize the democratic society".[1619] He suggests, therefore, that the democratic society is the best environment for assuring and promoting "the exercise of universalistic criteria in science".[1620]

C*ommunism* is the second norm embedded in the *ethos* of science. Merton uses this term in its extended meaning to denote "common ownership of goods".[1621] As he deems the

[1617] In a later paper, Merton added to these four sets of norms a 5th one, *originality*: "On every side, the scientist is reminded that it is his role, to advance knowledge greatly. This is only to say, of course, that in the institution of science originality is a premium. For it is through originality, in greater or smaller increments, that knowledge advances". Robert K Merton, 'Priorities in Scientific Discoveries' in Bernard Barber and Walter Hirsch (eds), *The Sociology of Science* (Free Press 1962) 447, 454. The sociologist of science Michael Mulkay, however, points out that, although Merton did not explicitly set out *individualism-independence* as institutional norms of science, they must be included in the functionalist account of science, since reference to them became widespread in the literature. Mulkay, particularly, refers to the following authors and works: Bernard Barber, *Science and the Social Order* (Collier Books 1962) 1; and Warren O Hagstrom, *The Scientific Community* (Basic Books 1965) 1. Moreover, he clarifies that "individualism-independence refers to the belief on the part of scientists that the individual scientist should be free to select his own research problems and techniques, and free to evaluate results without interference from those in positions of formal authority". Michael Mulkay, 'Some Aspects of Cultural Growth in the Natural Sciences' (1969) 36 Social Research 1, 25.

[1618] Robert K Merton, 'Science and Democratic Social Structure' in *Social Theory and Social Structure* (1st edn 1949, enl edn, The Free Press 1968) 604, 607. Emphasis in the original.

[1619] Robert K Merton, 'Science and Democratic Social Structure' in *Social Theory and Social Structure* (1st edn 1949, enl edn, The Free Press 1968) 604, 609.

[1620] Merton observes: "The political apparatus designed to put democratic values into practice may thus vary, but universalistic standards are maintained. To the extent that a society is democratic, it provides scope for the exercise of universalistic criteria in science". Robert K Merton, 'Science and Democratic Social Structure' in *Social Theory and Social Structure* (1st edn 1949, enl edn, The Free Press 1968) 604, 610.

[1621] Robert K Merton, 'Science and Democratic Social Structure' in *Social Theory and Social Structure* (1st edn 1949, enl edn, The Free Press 1968) 604, 610.

substantive findings of science "a product of social collaboration", he holds they belong to the community. Recognition and esteem are the only property rights scientists are granted over their discoveries. Eponyms, such as "Boyle's law" and "Copernican system", epitomize the highest recognition of scientific work.[1622] Scientific knowledge is, thus, assigned the status of common heritage. Nevertheless, this imperative is linked to scientists' implicit duty to communicate their findings to foster the advancement of knowledge and obtain, by publishing scientific achievements, due recognition. A scientist, who does not share his findings, is regarded with suspicion and surrounded by a certain kind of disapproval by his colleagues.

Merton explains that *communism*, as an institutional norm, entails that the scientific community has to face conflict-situations in a capitalistic economy,[1623] since this imperative is irreconcilable with conceiving technology as private property. He points out that the exclusive rights, conferred by patents, raised different responses by scientists aiming at solving this conflict: some scientists, such as Einstein, for example, took out their patents, others were directed towards becoming entrepreneurs or urged socialism.[1624]

The third moral imperative, *disinterestedness*, refers to "*a distinctive pattern of institutional control of a wide range of motives which characterizes the behavior of scientists*".[1625] It does not correspond to altruism, but is a means to detach scientists' motives from contingent self-interested behavior. Merton invokes the virtual absence of fraud in the annals of science as evidence of the special qualities of scientists in comparison with other communities of professionals and ascribes it to the close scrutiny that scientific work undergoes: scientists are constantly under the judgment of their peers and cannot exploit, therefore, credulity and

[1622] Robert K Merton, 'Science and Democratic Social Structure' in *Social Theory and Social Structure* (1st edn 1949, enl edn, The Free Press 1968) 604, 610.

[1623] See also Robert K Merton, 'Puritanism, Pietism and Science' in *Social Theory and Social Structure* (1st edn 1949, enl edn, The Free Press 1968) 628.

[1624] Merton remarks: "Current writings on the 'frustration of science' reflect this conflict. Patents proclaim exclusive rights of use and, often, nonuse. The suppression of invention denies the rationale of scientific production and diffusion, as maybe seen from the court's decision in the case of *U.S. v. American Bell Telephone Co.*: 'The inventor is one who has discovered something of value. It is his absolute property. He may withhold the knowledge of it from the public …'. Responses to this conflict-situation have varied. As a defensive measure, some scientists have come to patent their work to ensure its being made available for public use. Einstein, Millikan, Compton, Langmuir have taken out patents. Scientists have been urged to become promoters of new economic enterprises. Others seek to resolve the conflict by advocating socialism. These proposals – both those which demand economic returns for scientific discoveries and those which demand a change in the social system to let science get on with the job – reflect discrepancies in the conception of intellectual property". Robert K Merton, 'Science and Democratic Social Structure' in *Social Theory and Social Structure* (1st edn 1949, enl edn, The Free Press 1968) 604, 612.

[1625] Robert K Merton, 'Science and Democratic Social Structure' in *Social Theory and Social Structure* (1st edn 1949, enl edn, The Free Press 1968) 604, 613. Emphasis in the original.

ignorance in their profession. As Tallacchini notices,[1626] validity and ethicalness of scientific knowledge constitute an indissoluble combination in Merton's science structure, where "validity is part of that ethos, that, (…) while expressing the reliability of scientific method, also shapes scientists' moral integrity".[1627]

The last institutional element, *organized scepticism*, is defined as the "suspension of judgment until the facts are at hand"[1628] and sufficient evidence exists. It is a methodological and institutional kind of scrutiny that conflicts with more dogmatic attitudes that prevail in other institutional areas.

Several features of Merton's *ethos* of science underwent criticism by STS scholars, who spotted some basic flaws in his functionalist analysis. Most of them are thoroughly explained by the sociologist of science Michael Mulkay in his article "Some Aspects of Cultural Growth in the Natural Sciences", where he shows that there are no empirical studies demonstrating that Merton's norms are characteristic of the scientific community and that, conversely, according to the few available empirical studies, scientists do not conform to these norms.[1629] Moreover, many examples pinpoint that resistance to innovation by groups of scientists seems more the rule than the exception.[1630] He has, then, proved that an open and general violation of Merton's moral norms by the scientific community occurred in the "Velikovsky case".[1631]

Immanuel Velikovsky in his work *Worlds in Collision*, published in 1950, purported that historical catastrophes were the result of the near-collision between Earth and planet-sized objects breaking off from other planets, such as Mars and Venus. Most of his contemporary scientists refused to read his manuscript, before it was published, and judged his work pseudo-scientific. The rejection of Velikovsky's claims rested on their clear violation of the

[1626] Mariachiara Tallacchini, 'Before and Beyond the Precautionary Principle: Epistemology of Uncertainty in Science and the Law' (2005) 207 Toxicology and Applied Pharmacology 645, 647; Mariachiara Tallacchini, 'Scienza, politica e diritto: il linguaggio della co-produzione' (2005) 1 Sociologia del diritto 1, 11.

[1627] Merton remarks: "The virtual absence of fraud in the annals of science, which appears exceptional when compared with the records of other spheres of activity, has at times been attributed to the personal qualities of scientists (…); a more plausible explanation may be found in certain distinctive characteristics of science itself. Involving as it does, the verifiability of results, scientific research is under the exacting scrutiny of fellow-experts". Robert K Merton, 'Science and Democratic Social Structure' in *Social Theory and Social Structure* (1st edn 1949, enl edn, The Free Press 1968) 604, 613.

[1628] Robert K Merton, 'Science and Democratic Social Structure' in *Social Theory and Social Structure* (1st edn 1949, enl edn, The Free Press 1968) 604, 614.

[1629] Michael Mulkay, 'Some Aspects of Cultural Growth in the Natural Sciences' (1969) 36 Social Research 1, 27.

[1630] Michael Mulkay, 'Some Aspects of Cultural Growth in the Natural Sciences' (1969) 36 Social Research 1, 28.

[1631] See Michael Mulkay, 'Some Aspects of Cultural Growth in the Natural Sciences' (1969) 36 Social Research 1, 22.

law of mechanics and other fundamental assumptions of astronomy, geology and historical biology. As Velikovsky did not conform to most of the rules of the scientific community, scientists responded in vehement ways, contrary the institutional norms of universalism, organized skepticism and communism or communality, as well as originality. Mulkay, therefore, concludes that the reception of Velikovsky's work suggests that Merton's moral norms do not govern scientists' behaviour and "theoretical and methodological norms [namely, cognitive norms] are more central to the structure of the scientific community than are the Mertonian social norms".[1632]

Merton's ideal vision of science, however, became established in the 1960s and early 1970s, when some of his papers were re-published, in 1973,[1633] and is still the informing model of the relationship between science and society in the United States. As the historian of science Steven Shapin remarks, "it is overwhelmingly Merton's framework for a sociology of science that is turned to by U.S. government agencies on the occasions when they have asked sociologists to advise them how the social system of science works and whether it is working well".[1634] The Mertonian thesis has been called by Restivo "the hypothesis that wouldn't die", [1635] since it is still a very influential rhetorical means to legitimize science policy in the United States.

Merton's portrayal of the scientific community is ambiguous. He envisions an ideal community of peers that embeds intrinsically democratic norms, such as universalism, and therefore should be considered an inspiring model for democratic societies. However, preserving the community's autonomy from social influences entails that science is not legally and politically accountable. In Merton's view, the *ethos* of science serves to demarcate science from ideology, whose pressures over the autonomy of science Merton examined and dismissed, [1636] but it also makes science "exempt from legal and political guarantees constructed against other powers".[1637]

[1632] Michael Mulkay, 'Some Aspects of Cultural Growth in the Natural Sciences' (1969) 36 Social Research 1, 29.

[1633] Robert K Merton, *The Sociology of Science: Theoretical and Empirical Investigations* (University of Chicago Press 1973).

[1634] Steven Shapin, 'Mertonian Concessions' (5 February 1993) 259 Science 839.

[1635] Sal Restivo, 'The Theory Landscape in Science Studies' in Sheila Jasanoff, Gerald E Markle, James C Petersen and Trevor Pinch (eds), *Handbook of Science and Technology Studies* (rev edn, Sage Publications 1995) 95, 97.

[1636] Robert K Merton, 'Science and the Social Order' in *Social Theory and Social Structure* (1st edn 1949, enl edn, The Free Press 1968) 591-603.

[1637] Mariachiara Tallacchini, 'Before and Beyond the Precautionary Principle: Epistemology of Uncertainty in Science and the Law' (2005) 207 Toxicology and Applied Pharmacology 645, 647.

Whilst Merton's structure of science impinged on American modern sociology of science, Kuhnian vision inspired a number of sociologists who started, in the 1970s, a new field named "sociology of scientific knowledge" (SSK). The philosopher of science David Bloor and other historians and sociologists of science, mostly based at Edinburgh University's Science Unit, addressed the implications of Kuhn's perspective.[1638] In their work, scientific knowledge is regarded as "embodied collective practice", where social and cognitive factors are deeply entangled and, therefore, cannot be contrasted.[1639] In SSK the analysis of the context of collective practices is also theoretically relevant to understand how scientific knowledge gains social credit.

This group[1640] devised the so called "strong programme" in the sociology knowledge, epitomized by the four tenets for the sociology of scientific knowledge, which Bloor illustrated in *Knowledge and Social Imagery*:

> *1. It [SSK] would be causal, that is, concerned with the conditions which bring about belief or states of knowledge (...). 2. It would be impartial with respect to truth and falsity, rationality or irrationality, success or failure. Both sides of these dichotomies will require explanation. 3. It would be symmetrical in its style of explanation. The same types of cause would explain, say, true and false beliefs. 4. It would be reflexive. In principle its patterns of explanation would have to be applicable to sociology itself.*[1641]

The program claims no *a priori* distinction between what is rational or irrational, belief or knowledge, truth or falsity, as SSK aims at understanding and exploring the causes of both these dichotomies, by using the same kind of intellectual resources. Moreover, it entails that sociology of scientific knowledge must undergo the same analytical work of explanation applied to its object.

[1638] Three are the main implications SSK drew from Kuhn's work: "First, the 'social order' of science was likely to be not one but many orders, as many as there were 'paradigms' that structured researchers' epistemic judgments. Second, the appropriate methodological posture for an historian or sociologist concerned to interpret scientists' behavior was 'relativistic', since epistemic judgment was relative to the local culture of scientific groups. Third, a sociology of scientific knowledge appeared not only possible but necessary if one wants to give an account of social order in science". Steven Shapin, 'Mertonian Concessions' (5 February 1993) 259 Science 839.

[1639] Steven Shapin notices: "Indeed, the 'neo-Kuhnian framework, with its stress upon scientific knowledge as embodied collective practice, raised serious questions about the analytic legitimacy of traditional speech of 'social versus cognitive factors' in science. If scientists were institutionally socialized into their stock of knowledge and associated evaluations, and if that very stock of knowledge constituted the normative structure of science, then how was it proper to distinguish the social and the cognitive?". Steven Shapin, 'Mertonian Concessions' (5 February 1993) 259 Science 839.

[1640] The group was composed by the philosopher of science David Bloor, the sociologist of science Barry Barnes, the historian and sociologist of science Steven Shapin, the sociologist of science Donald Angus MacKenzie, the historian of science John Henry, and the sociologist of science Harry Collins, who developed what is named "the Bath School approach" to SSK.

[1641] David Bloor, *Knowledge and Social Imagery* (1st edn 1976, University of Chicago Press 1991) 1, 7.

Sismondo explained that SSK's engagement in methodological symmetry and impartiality constitutes "a reaction against an unsymmetrical pattern or style of explanation, in which true beliefs require internal, rationalist explanations, whereas false beliefs require external or social explanations",[1642] such as ideologies, social and political interests.

The process of "explanatory symmetrization" started off by SSK has become part of STS theoretical agenda, at large, and has been regarded as a methodological goal. However, the way in which symmetry is pursued and achieved differs largely among the group of researchers named "social constructivists", which includes SSK's and STS's scholars. SSK's academics are critical, for example, towards the symmetric mode of explanation of the Actor-Network Theory (ANT) and, conversely, ANT expresses a negative evaluation of SSK's principle of simmetry.

The Actor-Network Theory (ANT) or "*acteur reseau*" theory is a materialist[1643] frame elaborated in the mid-1980s by the French philosopher and anthropologist Bruno Latour, the sociologist Michel Callon and the British sociologist John Law. ANT addresses "science and technology in the making"[1644] rather than "ready-made science and technology".[1645] As Law explained, 'actor'-'network' is "an intentionally oxymoronic term that combines – and elides the distinction between – structure and agency",[1646] nature and society, subject and object. The term entails the "performative character of relations and the objects constituted in those relations",[1647] namely that entities "achieve their form as a consequence of the relations in which they are located"[1648] and "are *performed* in, by, and through those relations".[1649] ANT explores how networks are established as a whole. As ANT's scholars have shown that non-humans – such as machines, hybrids, animals – have agency,[1650] they describe networks as "a

[1642] Sergio Sismondo, *An Introduction to Science and Technology Studies* (Blackwell Publishing 2004) 1, 43.

[1643] ANT is interpreted as a "semiotics of materiality", since "[i]t takes the semiotic insight, that of the relationality of entities, the notion that they are produced in relations, and applies this ruthlessly to all materials – and not simply to those that are linguistic". John Law, 'After ANT: Complexity, Naming and Topology' in John Law and John Hassard (eds), *Actor Network Theory and After* (Blackwell Publishers 1999) 1, 4.

[1644] Bruno Latour, *Science in Action: How to Follow Scientists and Engineers Through Society* (Harvard University Press 1987) 1, 4.

[1645] Bruno Latour, *Science in Action: How to Follow Scientists and Engineers Through Society* (Harvard University Press 1987) 1, 4.

[1646] John Law, 'After ANT: Complexity, Naming and Topology' in John Law and John Hassard (eds), *Actor Network Theory and After* (Blackwell Publishers 1999) 1.

[1647] John Law, 'After ANT: Complexity, Naming and Topology' in John Law and John Hassard (eds), *Actor Network Theory and After* (Blackwell Publishers 1999) 1, 7.

[1648] John Law, 'After ANT: Complexity, Naming and Topology' in John Law and John Hassard (eds), *Actor Network Theory and After* (Blackwell Publishers 1999) 1, 4.

[1649] John Law, 'After ANT: Complexity, Naming and Topology' in John Law and John Hassard (eds), *Actor Network Theory and After* (Blackwell Publishers 1999) 1, 4.

[1650] Latour explains that "actantiality is not what an actor does – with its consequence for the demiurgic version of ANT – but what *provides* actants with their actions, with their subjectivity, with their intentionality, with their

heterogeneous amalgamation of textual, conceptual, social and technical actors".[1651] "Actant" is the term used by Latour to denote any agent in a network, collective or individual, human or non-human. The word has been applied by ANT's scholars to "stress that material causes as well as human actors may be determinants of social interactions and outcomes".[1652]

Actor-network theory endorses a specific methodological approach, based on three principles: 1. "*agnosticism*, which advocates abandoning any a priori assumptions of the nature of networks, causal conditions, or the accuracy of actant's accounts";[1653] 2. "*generalized symmetry*, employing a single explanatory frame when interpreting actants, human and nonhuman";[1654] 3. "*free association*, which advocates abandoning any distinction between natural and social phenomenon".[1655]

ANT has extended the application of the principle of symmetry to non-human "actants"[1656] and treated both the social and material worlds as products of networks and has, therefore, been described as "supersymmetric":[1657] "representing both human and non-human actors, and treating them in the same relational terms, is one way of prompting full analyses, analyses that do not discriminate against any part of the ecologies of scientific facts and technological objects".[1658]

ANT scholars, such as Latour, pointed out that the symmetry postulate, embedded in the Strong Program for the sociology of knowledge, is *asymmetrical*, since it does not "give proper weight to non-social things and processes, or acknowledge their contribution to our social arrangements".[1659] According to Latour, society and nature should be seen as *co-*

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morality". Bruno Latour, 'On Recalling ANT' in John Law and John Hassard (eds), *Actor Network Theory and After* (Blackwell Publishers 1999) 15, 18; see also Bruno Latour, *Reassembling the Social. An Introduction to Actor-Network-Theory* (Oxford University Press 2005) 1, 10.

[1651] Cassandra S Crawford, 'Actor Network Theory' (2005) *Encyclopedia of Social Theory* 1.

[1652] Bruno Latour, 'Actant', *Actor-Network Theory: Terms and Concepts* (2014) <http://latourbugblog.blogspot.co.uk/2009/01/actor-network-theory-terms-and-concepts.html> accessed 25 June 2014.

[1653] Cassandra S Crawford, 'Actor Network Theory' (2005) *Encyclopedia of Social Theory* 1, 2.

[1654] Cassandra S Crawford, 'Actor Network Theory' (2005) *Encyclopedia of Social Theory* 1, 2.

[1655] Cassandra S Crawford, 'Actor Network Theory' (2005) *Encyclopedia of Social Theory* 1, 2.

[1656] As Callon and Latour explain, "An actor in ANT is a semiotic definition – an actant – that is something that acts or to which activity is granted by another (…) an actant can literally be anything, provided it is granted to be the source of action". Bruno Latour, 'On Actor-Network Theory: A Few Clarifications', 369 *Soziale Welt* 373. Michel Callon & Bruno Latour, 'Unscrewing the Big Leviathan: How Actors Macro-Structure Reality and How Sociologists Help Them to Do So' in Karin Knorr-Cetina & Aaron Victor Cicourel (eds), *Advances in Social Theory and Methodology: Toward an Integration of Micro- and Macro-Sociologies* (Routledge & Keagan Paul 1981), 286.

[1657] Michel Callon and Bruno Latour, 'Don't Throw the Baby Out with the Bath School! A Reply to Collins and Yearley' in Andrew Pickering (ed), *Science as Practice and Culture* (The University of Chicago Press 1992) 343.

[1658] Sergio Sismondo, *An Introduction to Science and Technology Studies* (Blackwell Publishing 2004) 1, 69.

[1659] David Bloor, 'Anti-Latour' (1999) 30 Studies in History and Philosophy of Science 81, 84.

produced [1660] and, therefore, he proposes a new *generalized* symmetry principle, in comparison to SSK, where the agency to things is recognized.

Although ANT mode of explanation can be considered symmetrical around the human/non-human actants, it has been noted that,[1661] according to the theory, non-humans act in the same way as humans in a network. It has been noted that this implies that non-humans' agency is the effect of a network and does not exist before it.[1662] Moreover, ANT scholars tend to focus their work more on human actants, as their range of strategies is more complex than non-humans. Generalized symmetry is, thus, a methodological principle that has lost much of its significance in the actual analytic work. Nonetheless, the idea that the natural and social orders are *co-produced* has become a fundamental part of STS's theoretical framework and fostered a new methodological approach.

In conclusion, Science and Technology Studies emerged out of the critical confrontation with the influential epistemic traditions in history and sociology of science. These encounters directed the theoretical focus of the field towards the concrete dynamics that complement science and social practices, in order to understand how science builds up its social credibility.[1663] STS' approach, in comparison to other disciplinary areas is marked by the theoretical role assigned to practices and context, a constructivist approach to the boundary problem and methodological commitment to symmetry.

1.3 **Science, Technology and Society (STS)**

Whilst in the previous section I addressed how the development of Science and Technology Studies (S&TS) is related to the emergence of a constructivist tradition in sociology and ethnography of science, in this paragraph I will show how S&TS' analytical agenda has been shaped by the field of research named "Science, Technology and Society" (STS).

Science, Technology and Society is a cross-disciplinary perspective concerned with the social and policy dimensions of science and technology, which became institutionalized in the mid-1960's.[1664] As Ina Spiegel-Rösing recalls in the first handbook of Science, Technology and

[1660] Bruno Latour, 'One More Turn After the Social Turn …' in E McMullin (ed), *The Social Dimension of Science* (University of Notre Dame Press 1992) 272, 287.
[1661] See on the point Sergio Sismondo, *An Introduction to Science and Technology Studies* (Blackwell Publishing 2004) 1, 72.
[1662] Sergio Sismondo, *An Introduction to Science and Technology Studies* (Blackwell Publishing 2004) 1, 72.
[1663] Mariachiara Tallacchini, 'Scienza, politica e diritto: il linguaggio della co-produzione' (2005) 1 Sociologia del diritto 1, 7.
[1664] Ina Spiegel-Rösing, "The Study of Science, Technology and Society (SSTS): Recent Trends and Future Challenges" in Ina Spiegel-Rösing and Derek de Solla Price (eds), *Science, Technology and Society* (Sage Publications 1977) 1, 9.

Society, the genesis of that volume is linked to a series of initiatives undertaken by an international organization of scholars in different social sciences. Although STS movement dates back to the 1960's,[1665] the establishment of the International Congress (then Commission) for Science Policy Studies at the 13th International Congress of the History of Science in the summer of 1971, in Moscow, constituted a decisive moment in the development of the field.

The first meeting of the group was held at Schloss Reisesburg, in Southern Germany, in 1972, and in the same year a project to promote a cross-disciplinary mode of access to the whole range of STS scholarship, by publishing a handbook, was proposed. After a second extended and improved outline of the work was presented in the following meeting in Delhi, in 1973, in a four day conference of the authors, held in Paris in 1975, the group discussed the punctual and extensive critique of the drafts addressed by the editors. The aim of the volume was "primarily to contribute to the intellectual integration of a field",[1666] but with the hope that it could serve "some purposes in teaching and for science policy makers in the field of science and the government".[1667] *Science, Technology and Society. A Cross-Disciplinary Perspective*, was finally published in 1977, edited by the psychologist and sociologist of science Ina Spiegel-Rösing and the physicist and historian of science Derek de Solla Price, under the aegis of the Council for Science Policy Studies. The volume was organized in three main sections: whereas the first section was devoted to "the contextual values of science and technology in society, particularly the evolving critical attitudes to science and technology and the interplay between the making of science policy"[1668] and the understanding of all these processes by STS scholars, the second section focused on the different disciplinary perspectives of the social study of science and technology and the third one dealt with specific kinds of issues in science policy.

[1665] Roy MacLeod, 'The Historical Context of the International Commission for Science Policy Studies', in Jean-Jacques Salomon and Ina Spiegel-Rösing (eds), *Science Policy Studies Contributions* (ICSPS, International Union for the History and Philosophy of Science 1974) 202, 202-210.

[1666] She listed the following special journals: *Naulovedonie i Informatika* in U.S.S.R., *Zagadnienia Naukoznawstwa* and the annual or biannual review *Problems of the Science of Science* published by the Committee of Science of Science in Poland. In other countries, journals that included STS contributions were: DGRST Progrès Scientifique in France and the Stifterverband für die Deutsche Wissenshaft that published *Wirtschaft und Wissenshaft* (Economy and Science). See Ina Spiegel-Rösing, "The Study of Science, Technology and Society (SSTS): Recent Trends and Future Challenges" in Ina Spiegel-Rösing and Derek de Solla Price (eds), *Science, Technology and Society* (Sage Publications 1977) 1, 11.

[1667] Ina Spiegel-Rösing, "The Study of Science, Technology and Society (SSTS): Recent Trends and Future Challenges" in Ina Spiegel-Rösing and Derek de Solla Price (eds), *Science, Technology and Society* (Sage Publications 1977) 1, 11.

[1668] Ina Spiegel-Rösing and Derek de Solla Price, "Preface" in Ina Spiegel-Rösing and Derek de Solla Price (eds), *Science, Technology and Society* (Sage Publications 1977) 1, 2.

At the time, the study of science, technology and society (SSTS) was already an established and institutionalized field, nationally and internationally, with its own research institutions, teaching programs, journals and formal or informal organizations.[1669] Ina Spiegel-Rösing listed, as significant examples of its expansion, 14 programs and institutions across the U.S., Canada, U.K., France, Sweden, U.S.S.R., the Federal Republic of Germany and the German Democratic Republic.[1670]

Moreover, she noticed that in the 1960s and 1970s several STS international journals, that had a significant role in the definition and development of the field, were founded, as well as specialized national research journals,[1671] publication series[1672] and newsletters.[1673] "Social

[1669] At the international level the 'Sociology of Science Research Committee' of the International Sociological Association; the 'Parex Group' and the 'International Science Policy Studies'. At the national level: the 'Society for the Social Studies of Science' in the U.S.; in the UK, the British Sociological Association's 'Sociology of Science Study Group'; the 'Club de Gif' in France; in the Federal Republic of Germany, the 'Section for Science Studies' (Wissenshaftsforschung) within the German Sociological Association; in Poland, the 'Committee of the Science of Science' at the Polish Academy of Science. Ina Spiegel-Rösing and Derek de Solla Price, "Preface" in Ina Spiegel-Rösing and Derek de Solla Price (eds), *Science, Technology and Society* (Sage Publications 1977) 1, 10.

[1670] Ina Spiegel-Rösing referred to the following programs and institutions: the 'Program on Science, Technology and Society' at Cornell University and the 'Program on Public Conceptions of Science' at Harvard University in the U.S.; the 'Institut d'Histoire et de Socio-Politique des Sciences' at the University of Montreal in Canada; the 'Institute for the History of Science and Technology' at the Academy of Science in Moscow and the 'Department of Interdisciplinary Problems of Science Studies and Information Science' in Kiev, U.S.S.R.; in the UK, the 'Science Policy Research Unit' at Sussex University and the 'Science Studies Unit' At Edinburgh University; in France, the Centre de Recherche 'Science, Technologie et Société' of the Conservatoire National des Arts et Métiers and the 'Groupe d'Etudes et de Recherche sur la Science'of the Ecole Pratiques de Hautes Etudes, in Paris; the 'Research Policy Program' at Lund University and the 'Institute for Science Theory' at Göteborg University in Sweden; the 'Science Studies Unit' at the University of Bielefeld and the 'Institute for Science Policy Studies' at the University of Ulm, in the Federal Republic of Germany; the 'Institute for Theory, History and Organization of Science' at the Academy of Sciences in Berlin, in the German Democratic Republic. See Ina Spiegel-Rösing, "The Study of Science, Technology and Society (SSTS): Recent Trends and Future Challenges" in Ina Spiegel-Rösing and Derek de Solla Price (eds), *Science, Technology and Society* (Sage Publications 1977) 1, 10.

[1671] She listed the following journals: *Naulovedonie i Informatika* in USSR, the journal *Zagadnienia Naukoznawstwa* and the annual or biannual review Problems of the Science of Science published by the Committee of Science of Science in Poland. In other countries, included STS contributions: DGRST Progrès Scientifique in France and the Stifterverband für die Deutsche Wissenshaft that published *Wirtschaft und Wissenshaft* (Economy and Science). Ina Spiegel-Rösing, "The Study of Science, Technology and Society (SSTS): Recent Trends and Future Challenges" in Ina Spiegel-Rösing and Derek de Solla Price (eds), *Science, Technology and Society* (Sage Publications 1977) 1, 11.

[1672] For example, the two series Studies and Research Reports and Science and Society (Akademie-Verlag) of the German Democratic Republic's Institute for Theory, History and Organization of Science, and the series Science Studies Reports of the Sciences Unit of the Federal Republic of Germany's University of Bielefeld. Ina Spiegel-Rösing, "The Study of Science, Technology and Society (SSTS): Recent Trends and Future Challenges" in Ina Spiegel-Rösing and Derek de Solla Price (eds), *Science, Technology and Society* (Sage Publications 1977) 1, 11.

[1673] The SSSS Newsletter, published by the Society for the Social Studies of Science (SSSS or 4S), the Stopnews: Interdisciplinary Newsletter on Science, Technology, Public Policy and Sociology, Published by the Science, Technology, Public Policy and Sociology Program of the Purdue University and the Newsletter published by the Harvard University Program on the Public Conceptions of Science. Moreover, she counted several special public programs funding research in STS, such as Science Resources and policy studies at the national Science Foundation in the United States, the Action Thématique Programmée (ATP) Recherche sur la Recherche at the CNRS in France and the Science Studies of the Volkswagen Foundation in Germany. See Ina

Studies of Science. An International Review of Research in the Social Dimensions of Science and Technology", "Minerva. A Review of Science, Learning and Policy" and "Research Policy. A Journal Devoted to Research Policy, Research Management and Planning"[1674] were some of the well-established international publications in the field, already in 1977.

The origins of Science, Technology and Society are, however, embedded in the rise of science policy after World War II. As Jean-Jacques Salomon, one of the handbook's contributors and, at the time, head of Science Policy Unit of the Organisation for Economic Cooperation and Development (OECD), pointed out, World War II represented the watershed in the relationship between science and the state, as it "established science as a national asset". [1675] During World War II, the belligerent countries involved a large number of scientists and engineers in military and non-military projects, which led to significant scientific and technological contributions. The creation of the radar, the industrial development and production of new drugs such as penicillin,[1676] that improved the medical treatment of injured soldiers, and the manufacturing of synthetics to compensate for the shortage of raw materials during the war[1677] are only some of the most widely mentioned scientific and technological wartime achievements. In the United States, as in other countries committed to the war effort, thousands of scientists and engineers were diverted from their research projects and involved in war related projects funded by the U.S. government, as military or civilian personnel.[1678] They were required to work in teams under governmental control and according to the sets of research goals fixed by Office of Scientific Research and Development (OSRD).[1679] The "Manhattan Project", which Salomon significantly refers to, epitomizes most of the novel features of these wartime government's oriented projects, which

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Spiegel-Rösing, "The Study of Science, Technology and Society (SSTS): Recent Trends and Future Challenges" in Ina Spiegel-Rösing and Derek de Solla Price (eds), *Science, Technology and Society* (Sage Publications 1977) 1, 11-12.

[1674] See Ina Spiegel-Rösing, "The Study of Science, Technology and Society (SSTS): Recent Trends and Future Challenges" in Ina Spiegel-Rösing and Derek de Solla Price (eds), *Science, Technology and Society* (Sage Publications 1977) 1, 11.

[1675] Jean-Jacques Salomon, 'Science Policy Studies and the Development of Science Policy' in Ina Spiegel-Rösing and Derek de Solla Price (eds), *Science, Technology and Society* (Sage Publications 1977) 43.

[1676] See P Handler (ed), *Biology and the Future of Man* (Oxford University Press 1970), 1.

[1677] Sanford A Lakoff, 'Scientists, Technologists and Political Power' in Ina Spiegel-Rösing and Derek de Solla Price (eds), *Science, Technology and Society* (Sage Publications 1977) 355, 361. However, Lakoff points out that, although scientific and technological research, during World War II, involved military and non-military aspects, most of it was focused on gunnery, explosives, targeting devices, aeronautical engineering and telecommunications.

[1678] U.S. Congress, Office of Technology Assessment, *The Regulatory Environment for Science* – A Technical Memorandum, OTA-TM-SET-34 (Washington, DC: U.S. Government Printing Office, February 1986), available at <https://www.princeton.edu/~ota/disk2/1986/8621/8621.PDF > iii, 13.

[1679] U.S. Congress, Office of Technology Assessment, *The Regulatory Environment for Science* – A Technical Memorandum, OTA-TM-SET-34 (Washington, DC: U.S. Government Printing Office, February 1986), available at <https://www.princeton.edu/~ota/disk2/1986/8621/8621.PDF > iii, 13.

would inspire U.S. science policy in the aftermath of World War II.[1680] The code-named "Manhattan Project" was a secret military-controlled atomic research plan, set out by the U.S. government in 1939 with the support of the United Kingdom and Canada, that required a considerable amount of funding – as its cost reached two billion dollars – in comparison to the total expenditure for research and development, which the U.S. spent in the last peacetime budget, which amounted to 1.5 billion dollars.[1681] The project rested on several decades of basic research, but had an immediate practical utility, namely the development of the first atomic bombs, which were later dropped on Hiroshima and Nagasaki at the end of the war. Moreover, it required a broad cooperation of scientists and engineers from different countries, who were sometimes refugees.[1682]

This kind of wartime research experience was unprecedented for scientists. Before World War II, most of the scientific research and development, in the United States, was funded by industry and, to a lesser extent, in some universities by professors themselves.[1683] Scientists deemed the attempt to fund basic research in universities, through Federal research grants, "inappropriate if not unconstitutional" [1684] and they opposed private universities from accepting government funds.[1685] Federal government funding was regarded as a form of intrusive intervention in scientists' work. The negative attitude of the scientific community rested partially on concerns of losing autonomy and undergoing restrictions: for example on the communication and publication of the outcomes of research, which scientists experienced during World War I.[1686]

Interventions on scientific research by the states occurred, before World War II, but in Europe and U.S. a "laissez-faire" approach, that left scientific research relatively immune from systematic intervention over its organization and financial support, prevailed. Although

[1680] As Lakoff notices: "The pattern set in the Manhattan Project […] was to become the basis for the vast growth in support for research and development activities, especially in pursuit of military objectives, which occurred after the war". Sanford A Lakoff, 'Scientists, Technologists and Political Power' in Ina Spiegel-Rösing and Derek de Solla Price (eds), *Science, Technology and Society* (Sage Publications 1977) 355, 362.

[1681] Sanford A Lakoff, 'Scientists, Technologists and Political Power' in Ina Spiegel-Rösing and Derek de Solla Price (eds), *Science, Technology and Society* (Sage Publications 1977) 355, 361.

[1682] See Sanford A Lakoff, 'Scientists, Technologists and Political Power' in Ina Spiegel-Rösing and Derek de Solla Price (eds), *Science, Technology and Society* (Sage Publications 1977) 355, 362.

[1683] U.S. Congress, Office of Technology Assessment, *The Regulatory Environment for Science* – A Technical Memorandum, OTA-TM-SET-34 (Washington, DC: U.S. Government Printing Office, February 1986), available at <https://www.princeton.edu/~ota/disk2/1986/8621/8621.PDF > iii, 11.

[1684] Don K Price, 'Endless Frontier or Bureaucratic Morass?' in Gerald Holton and Robert S Morison, *Limits of Scientific Inquiry* (WW Norton & Company 1979), 75, 76.

[1685] See Lewis E Auerbach, ' Scientists in the New Deal: A Pre-War Episode in the Relations Between Science and the Government in the United States' 3 *Minerva* 1965, 457.

[1686] U.S. Congress, Office of Technology Assessment, *The Regulatory Environment for Science* – A Technical Memorandum, OTA-TM-SET-34 (Washington, DC: U.S. Government Printing Office, February 1986), available at <https://www.princeton.edu/~ota/disk2/1986/8621/8621.PDF > iii, 11.

World War I was marked by the consistent contribution of scientists, especially chemists, in war-related projects,[1687] military research was mostly focused on adapting civil technology to the needs of war. Wartime research organizations were, therefore, dismantled after the end of the conflict.[1688]

According to Salomon, "the doctrine of *laissez-faire* prevailed all the more naturally, because the lapse of time between scientific research and its application remained long, and consequently the involvement of the state in scientific matters remained limited to sectors which could guarantee relatively quick results".[1689] As a consequence, the institutionalization of science policy only started "when scientific activities began to have a direct effect on the course of world affairs".[1690]

However, cultural differences in the mode of legitimazing political action through science matter and the institutionalization of science policy in western democracies took place, as the political scientist Yaron Ezrahi showed, chiefly in countries like the U.S., which largely relied on an instrumental view of policy and were, therefore, more receptive towards "scientific and technological paradigms of public action".[1691] A different political culture, therefore, consistently accounts for the fact that, after the end of World War II, the U.S. was the political context whereby science policy was firstly devised and envisaged, in a liberal-democratic state, as a planned, organized and institutionalized attempt to direct scientific research.[1692]

The document that laid the foundations of science policy in the U.S., in the aftermath of World War II, was the Report entitled "Science. The Endless Frontier" (1945),[1693] authored by Vannevar Bush, an engineer and MIT professor who was the Director of the Office of

[1687] Sanford A Lakoff, 'Scientists, Technologists and Political Power' in Ina Spiegel-Rösing and Derek de Solla Price (eds), *Science, Technology and Society* (Sage Publications 1977) 355, 359.

[1688] Jean-Jacques Salomon, 'Science Policy Studies and the Development of Science Policy' in Ina Spiegel-Rösing and Derek de Solla Price (eds), *Science, Technology and Society* (Sage Publications 1977) 43, 47.

[1689] Jean-Jacques Salomon, 'Science Policy Studies and the Development of Science Policy' in Ina Spiegel-Rösing and Derek de Solla Price (eds), *Science, Technology and Society* (Sage Publications 1977) 43, 46-47.

[1690] Jean-Jacques Salomon, 'Science Policy Studies and the Development of Science Policy' in Ina Spiegel-Rösing and Derek de Solla Price (eds), *Science, Technology and Society* (Sage Publications 1977) 43, 47.

[1691] Ezrahi notices: "My study concerns the foundations, as well as the later decline, of the role of science and technology in upholding modern forms of liberal-democratic politics. I shall advance the argument that an 'instrumental concept of politics', which encouraged the receptivity in America – and some other liberal democracies – to scientific and technological paradigms of public action, especially between the closing decades of the nineteenth century and the late 1960s, has been discredited toward the end of this century with profound consequences for the role of science and technology in the modern liberal-democratic state". Yaron Ezrahi, *The Descent of Icarus. Science and the Transformation of Contemporary Democracy* (Harvard University Press 1990), vii, 15.

[1692] Jean-Jacques Salomon, 'Science Policy Studies and the Development of Science Policy' in Ina Spiegel-Rösing and Derek de Solla Price (eds), *Science, Technology and Society* (Sage Publications 1977) 1, 45.

[1693] Vannevar Bush, *Science – The Endless Frontier: A Report to the President on a Program for Postwar Scientific Research*, July 1945, Reprinted by the National Science Foundation (Washington, DC, 1990).

Scientific Research and Development during the war and largely endorsed the Manhattan Project. The Report was drafted to comply with President Roosevelt's request of the 17th November, 1944, for recommendations on how to employ "the information, the techniques and the research experience developed by the Office of Research and Development and by the thousands of scientists in the university and in private industry",[1694] gained during the war, in times of peace.

The Report was grounded on the premise that "scientific progress" is essential to defend the U.S. nation against military aggression,[1695] to fight diseases and improve public welfare. Bush significantly evoked the metaphor of the "endless frontier", in the title and throughout the Report, and exploited its rhetorical power within the American imaginary to support the assumption that scientific research could undergo a possible boundless growth, if it was properly funded by the U.S. government. The metaphor of "endless frontier" recalls the conquest of the Far West territories and the pioneer's spirit, which accompanied and supported the foundation and expansion of the United States. In his Letter of transmittal of the Report to the President, Bush emphasized that: "The Pioneer spirit is still vigorous within this nation. Science offers a largely unexplored hinterland for the pioneer who has the tools for his task. The rewards of such exploration both for the Nation and the individual are great. Scientific progress is one of the essential keys to our security as a nation, to our better health, to more jobs, to a higher standard of living, and to our cultural progress".[1696] Furthermore, explaining and justifying why science should be a proper concern of the government, he added that "It has been basic United States policy that Government should foster the opening of new frontiers. It has opened the seas to clipper ships and furnished land for pioneers:

[1694] See President Roosevelt's Letter to Vannevar Bush, 17th November, 1944, where he points out: "Dear Dr. Bush: The Office of Scientific Research and Development, of which you are the Director, represents a unique experiment of team-work and cooperation in coordinating scientific research and in applying existing scientific knowledge to the solution of technical problems paramount in the war. Its work has been conducted in the outmost secrecy and carried on without public recognition of any kind; but its tangible results can be found in the communiques coming in from the battlefront all over the world. Some days the full story of its achievements can be told.

There is, however, no reason why the lessons to be found in this experiment cannot be profitably employed in times of peace. The information, the techniques, and the research experience developed by the Office of Research and Development and by the thousands of scientists in the universities and in private industry, should be used in the days of peace ahead for the improvement of the national health, the creation of new enterprises bringing new jobs, and the betterment of the national standard of living". Vannevar Bush, *Science – The Endless Frontier: A Report to the President on a Program for Postwar Scientific Research*, July 1945, Reprinted by the National Science Foundation (Washington DC 1990) 1, 3-4.

[1695] Vannevar Bush, *Science – The Endless Frontier: A Report to the President on a Program for Postwar Scientific Research*, July 1945, Reprinted by the National Science Foundation (Washington, DC, 1990) 1, 15.

[1696] Vannevar Bush, *Letter of Transmittal*, *Science – The Endless Frontier: A Report to the President on a Program for Postwar Scientific Research*, July 1945, Reprinted by the National Science Foundation (Washington, DC, 1990) 1, 3.

Although these frontiers have more or less disappeared, the frontier of science remains. It is in keeping with the American tradition – one which made the United States great – that new frontiers shall be made accessible for development by all American citizens".[1697]

His proposal was centered on funding basic scientific research – namely, research "performed without thought of practical ends"[1698] that "results in general knowledge and understanding of nature and its laws" –[1699] within universities, colleges and research institutes, preserving, however, the traditional autonomy that the scientific community used to enjoy.[1700]

By increasing "the flow of new scientific knowledge through the support of basic research"[1701] and aiding the flourishing of scientific talent, he argued, the U.S. Government would promote industrial research as well. In order to attain these goals, he suggested setting up a new independent[1702] agency, "composed of persons of broad interest and experience, having an understanding of the peculiarities of scientific research and scientific education".[1703] The agency ought to be granted stability of funds to undertake long-range programs. The agency, though, had to recognize freedom of inquiry to the institutions in which research was carried on and leave them "internal control of policy, personnel, and the method and scope of research".[1704] Preservation of freedom of inquiry and choices within the funded research institutions and the funding agency was regarded as the main condition[1705] to foster science progress and fulfill the promises adumbrated in the Report.[1706]

[1697] Vannevar Bush, *Science – The Endless Frontier: A Report to the President on a Program for Postwar Scientific Research*, July 1945, Reprinted by the National Science Foundation (Washington, DC, 1990) 1, 10.
[1698] Vannevar Bush, *Science – The Endless Frontier: A Report to the President on a Program for Postwar Scientific Research*, July 1945, Reprinted by the National Science Foundation (Washington, DC, 1990) 1, 15.
[1699] Vannevar Bush, *Science – The Endless Frontier: A Report to the President on a Program for Postwar Scientific Research*, July 1945, Reprinted by the National Science Foundation (Washington, DC, 1990) 1, 16.
[1700] Mariachiara Tallacchini, 'Politiche della scienza contemporanea: le origini' in Stefano Rodotà and Mariachiara Tallacchini (eds) Trattato di biodiritto. Ambito e fonti del biodiritto (Giuffrè Editore, 2010) 53, 63.
[1701] Vannevar Bush, *Science – The Endless Frontier: A Report to the President on a Program for Postwar Scientific Research*, July 1945, Reprinted by the National Science Foundation (Washington, DC, 1990) 1, 7.
[1702] Vannevar Bush, *Science – The Endless Frontier: A Report to the President on a Program for Postwar Scientific Research*, July 1945, Reprinted by the National Science Foundation (Washington, DC, 1990) 1, 26.
[1703] Vannevar Bush, *Science – The Endless Frontier: A Report to the President on a Program for Postwar Scientific Research*, July 1945, Reprinted by the National Science Foundation (Washington, DC, 1990) 1, 8.
[1704] Vannevar Bush, *Science – The Endless Frontier: A Report to the President on a Program for Postwar Scientific Research*, July 1945, Reprinted by the National Science Foundation (Washington, DC, 1990) 1, 8.
[1705] U.S. Congress, Office of Technology Assessment, *The Regulatory Environment for Science* – A Technical Memorandum, OTA-TM-SET-34 (Washington, DC: U.S. Government Printing Office, February 1986), available at <https://www.princeton.edu/~ota/disk2/1986/8621/8621.PDF > iii, 15.
[1706] Bush pointed out that: "Scientific progress on a broad front results from the free play of free intellects, working on subjects of their own choice, in the manner dictated by their curiosity for exploration of the unknown. Freedom of inquiry must be preserved under any for the Government support of science in accordance with the Five Fundamentals listed on page 26". Vannevar Bush, *Science – The Endless Frontier: A Report to the President on a Program for Postwar Scientific Research*, July 1945, Reprinted by the National Science Foundation (Washington, DC, 1990) 1, 11.

His recommendation led, eventually, to the creation of the National Science Foundation (NSF) in 1950,[1707] although its establishment proved to be difficult.

Bush's view had its opponents. Notably Senator Harley Kilgore (D-WV), joined by the scientists Harold C. Urey, Edward U. Condon and Harlow Shapley and a group within the executive branch, headed by Presidential Assistant John R. Steelman.[1708] Kilgore and Steelman both favored the foundation of an agency more "politically responsible to the President" than the one envisaged in the Bush Report. Steelman, who was commissioned by President Truman to draft an alternative report, which was published on 27th August 1947, with the title *Science and Public Policy. A Program for the Nation*, remarked in the report that "[…] it is vital that funds for the support of basic research be administered with the advice and counsel of an imaginative group of scientists. But this necessity should not blind us to the relations of a grant program for basic research to the total science program of the Government or to the other national programs in support of education. Nor it can justify a departure from our traditions of democratic government or from tested principles of administrative organization".[1709]

Although Steelman and Kilgore agreed, as Tallacchini illustrated, that any kind of restriction to science should be confined to extraordinary actions and scientific knowledge should be fostered, notwithstanding the fact that society could be unprepared to cope with it, they convened that all these different timing issues should be addressed in political and institutional settings.[1710] Relevant critics came also from the National Patent Council, which raised concerns about the possible state control over patents related to research funded by the National Science Foundation, in the future.[1711] The Bush Report featured specific recommendations concerning patent policy.

The Report, first of all, made clear that "there should be no obligation on the research institution to patent discoveries made as a result of support from the Foundation". Moreover, whilst it suggested that the "public interest" would be adequately protected if the Government

[1707] National Science Foundation Act, May 10, 1950, 64 Stat. 149.

[1708] U.S. Congress, Office of Technology Assessment, *The Regulatory Environment for Science* – A Technical Memorandum, OTA-TM-SET-34 (Washington, DC: U.S. Government Printing Office, February 1986), available at <https://www.princeton.edu/~ota/disk2/1986/8621/8621.PDF > iii, 14.

[1709] John R Steelman Chairman of the President's Scientific Research Board, *Science and Public Policy. A Program for the* Nation, August 27, 1947, Vol. 1, III, 31.

[1710] Mariachiara Tallacchini, 'Politiche della scienza contemporanea: le origini' in Stefano Rodotà and Mariachiara Tallacchini (eds) Trattato di biodiritto. Ambito e fonti del biodiritto (Giuffrè Editore, 2010) 53, 64.

[1711] National Patent Council, *The Case Against National Science Foundation and Its Pending Bill* H.R. 4846, Gary IN, National Patent Council, January 3, 1950. See Mariachiara Tallacchini, 'Politiche della scienza contemporanea: le origini' in Stefano Rodotà and Mariachiara Tallacchini (eds) Trattato di biodiritto. Ambito e fonti del biodiritto (Giuffrè Editore, 2010) 53, 64.

receives a royalty-free license for governmental purposes, it also insisted that "there should certainly not be any absolute requirement that all rights in such discoveries be assigned to the Government, but it should be left to the discretion of the director and the interested Division whether, in special cases the public interest requires such an assignment".[1712] It, then, concluded that "legislation on this point should leave the Members of the Foundation discretion as to its patent policy in order that patent arrangements may be adjusted as circumstances and the public interest require".[1713] The discretion left to the Members of the Foundation casted some doubts about what the future legislative choices and their impact on the patent system would have been and accounts for the fears of state control over inventions, whose development could be related to NSF grants, voiced by the National Patent Council.

Bush's perspective, nevertheless, sponsored a research and market environment free from state intervention. He recognized that patent laws fostered new inventions and contributed to the flourishing of new industries and the national wealth. However, he pointed out that some uncertainties, which in the past had impaired the ability of small industries to translate new ideas into processes and products of value to the nation, should be eliminated, but not at the expense of the free market.[1714] Kilgore substantially dissented from the patent policy recommendations in the Bush Report, as he deemed that patents, obtained through publicly funded research, should be assigned to the government.[1715]

Although on 22nd July, 1947, the U.S. Congress passed the legislation establishing the National Science Foundation, President Truman opposed his veto to the act; since he considers that the Act did not provide an adequate political control over NSF governing structure and activities. Three years later, in 1950, after a long debate, the Congress passed a new bill on the establishment of NSF, which President Truman finally signed. The Bill represented a compromise between the opposing views, as it provided that the director of the NSF would be appointed by the President and for a mandate to assess and coordinate the Federal research activities. The National Science Board, which had to share NSF

[1712] Vannevar Bush, *Science – The Endless Frontier: A Report to the President on a Program for Postwar Scientific Research*, July 1945, Reprinted by the National Science Foundation (Washington, DC, 1990) 1, 32.
[1713] Vannevar Bush, *Science – The Endless Frontier: A Report to the President on a Program for Postwar Scientific Research*, July 1945, Reprinted by the National Science Foundation (Washington, DC, 1990) 1, 32.
[1714] Vannevar Bush, *Science – The Endless Frontier: A Report to the President on a Program for Postwar Scientific Research*, July 1945, Reprinted by the National Science Foundation (Washington, DC, 1990) 1, 18.
[1715] See Mariachiara Tallacchini, 'Politiche della scienza contemporanea: le origini' in Stefano Rodotà and Mariachiara Tallacchini (eds) Trattato di biodiritto. Ambito e fonti del biodiritto (Giuffrè Editore, 2010) 53, 66.

responsibilities, was organized, however, according Bush's plan and no intervention to change the patent granting procedures was included.[1716]

President Truman's choice of vetoing the first NSF Act signals that the differences between the two proposals were not confined to "political disagreements about the administration of a new agency",[1717] but on large divergences on how the relationship between science and the U.S. government ought to be set up in the aftermath of World War II. According to Steelman and Kilgore, science represented just another policy area to be addressed, not different enough to deserve a special status. Bush, conversely, treated science as a special policy area to be dealt with, since he considered that the scientific community should enjoy freedom of inquiry and autonomy in order to be able to promote scientific progress.

Bush's Report contained several relevant omissions. The social sciences, as well as the humanities, were kept outside his devised mechanism to support research and he clearly interpreted his mandate concerning only the natural sciences: "It is clear from President Roosevelt's letter that in speaking of science he had in mind the natural sciences, including biology and medicine".[1718] Although he admitted that "progress in other fields, such as the social sciences and the humanities, is likewise important" and warned against setting up "a program under which research in the natural sciences and medicine was expanded at the cost of the social sciences, humanities and other studies",[1719] he deemed "the program for science presented" in his report to deserve *immediate* attention. In his view, the progress of scientific research clearly involved and corresponded to the progress of American society *tout court*. He did not consider any grey areas that could be addressed by other kinds of knowledge. This significant exclusion may be due to his personal intellectual disregard for the social sciences, judged as a means of political propaganda, as well as to the suspicion associated with the social sciences throughout the Cold War period in the U.S. In the 1950s, the U.S. Congressman Carroll Reece, from Tennessee, headed a congressional investigation to prove that private foundations which supported the social sciences should be excluded from tax

[1716] U.S. Congress, Office of Technology Assessment, *The Regulatory Environment for Science* – A Technical Memorandum, OTA-TM-SET-34 (Washington, DC: U.S. Government Printing Office, February 1986), available at <https://www.princeton.edu/~ota/disk2/1986/8621/8621.PDF > iii, 17.

[1717] U.S. Congress, Office of Technology Assessment, *The Regulatory Environment for Science* – A Technical Memorandum, OTA-TM-SET-34 (Washington, DC: U.S. Government Printing Office, February 1986), available at <https://www.princeton.edu/~ota/disk2/1986/8621/8621.PDF > iii, 16.

[1718] Vannevar Bush, *Letter of Transmittal*, *Science – The Endless Frontier: A Report to the President on a Program for Postwar Scientific Research*, July 1945, Reprinted by the National Science Foundation (Washington, DC, 1990) 1, 3.

[1719] Vannevar Bush, *Science – The Endless Frontier: A Report to the President on a Program for Postwar Scientific Research*, July 1945, Reprinted by the National Science Foundation (Washington, DC, 1990) 1, 20.

exemption, as social sciences were fostering socialism within the United States.[1720] However, Don K. Price noted that natural scientists, who lobbied for the creation of the National Science Foundation, exercised considerable pressure to keep the social sciences outside this proposal,[1721] and afterwards social sciences were relegated among the "other sciences", which were assigned a "severely limited" amount of funds .[1722]

The Bush Report and its implementation are often referred to as the "social contract" between science and society, as it set out the underpinnings of this relationship in the aftermath of World War II. This contract however, as Tallacchini pointed out, did not involve enforceable rules and guarantees, because of the special epistemic and moral statute that was accorded to the scientific community by politics and the law, which made scientific research immune from political oversight.[1723]

Science, Technology and Society (STS) emerged in the 1960's, when several fissures and flaws in this contract became apparent and citizens, as well as scientists, began to question in the U.S. and in Europe its basic assumption: that, by funding and fostering scientific research, social progress would follow.

Science policy was implemented and was supposed to fulfill its promises in the Cold War context, a "context of strategic competition as a consequence of the impossibility of establishing real peace at the end of World War II".[1724] The intensification of the Cold War between the communist and non-communist nations of Europe and North America and the technological and weapon escalation, which marked the decades following World War II, cast some doubts on the criteria applied to established research priorities, as far as public funding was concerned. Priority was mostly accorded to costly[1725] large scale research related to the "competitive confrontation of the two blocs", namely military, nuclear and space projects. Notwithstanding European R&D projects could not confront the scale of expenditures undertaken by the emerging super-powers (the U.S. and U.S.S.R.), significant

[1720] Tax-Exempt Foundations, Report of the Special Committee to Investigate Tax-Exempt Foundations and Comparable Organizations, House of Representatives, 83rd Cong. 2nd Sess., H. Rep. 2681 (1984), pp. 17-19, 56, 60, 67, 73, 200. See on the point Don K Price, 'Endless Frontier or Bureaucratic Morass?' in Gerald Holton and Robert S Morison (eds), *Limits of Scientific Inquiry* (WW Norton & Company 1979) 75, 84.

[1721] Don K Price, 'Endless Frontier or Bureaucratic Morass?' in Gerald Holton and Robert S Morison (eds), *Limits of Scientific Inquiry* (WW Norton & Company 1979) 75, 84.

[1722] Don K Price, 'Endless Frontier or Bureaucratic Morass?' in Gerald Holton and Robert S Morison (eds), *Limits of Scientific Inquiry* (WW Norton & Company 1979) 75, 84.

[1723] Mariachiara Tallacchini, 'Politiche della scienza contemporanea: le origini' in Stefano Rodotà and Mariachiara Tallacchini (eds) Trattato di biodiritto. Ambito e fonti del biodiritto (Giuffrè Editore, 2010) 53, 55.

[1724] Jean-Jacques Salomon, 'Science Policy Studies and the Development of Science Policy' in Ina Spiegel-Rösing and Derek de Solla Price (eds), *Science, Technology and Society* (Sage Publications 1977) 43, 44.

[1725] See Harvey M Sapolsky, 'Science, Technology and Military Policy' in in Ina Spiegel-Rösing and Derek de Solla Price (eds), *Science, Technology and Society* (Sage Publications 1977) 443, 449.

atomic energy programs were set up for military and economic purposes in countries such as France, that was facing post-war reconstruction.[1726]

Moreover, the Vietnam War protests that spread in the U.S. campuses, in the late 1960s, contributed to increased public awareness about the universities' involvement in scientific research funded by the Department of Defense. The demand for social accountability of publicly funded science was consistently backed by the researchers' community. Many scientists and engineers urged action against what was called "the military-industrial complex", which they claimed had corrupted science with its political, industrial and military interests.[1727] "Scientists and Engineers for Social and Political Action", later named "Science for the People", is one of the main researchers' organizations that promoted actions to stop scientists' involvement in military projects.[1728]

On March 4, 1969, scientists at over 30 U.S. schools, including Harvard University and M.I.T., interrupted their research to protest against the use of science for military purposes in Vietnam.[1729] Following this protest, the U.S. Congress passed the so-called Mansfield Amendment, the aim of which was "to reduce the research community's dependence on the Defense Department when it appears that the investigation under consideration could be sponsored more reasonably by a civilian agency".[1730]

Also within the American Association for the Advancement of Science (AAAS), during the Cold War, scientists debated about their social responsibility.[1731] In the 1970s, AAAS funded a project to assess the impact of the use of herbicides in the Vietnam War, which showed the negative long-lasting effects of these products on human health and the environment.[1732] As a

[1726] Sanford A Lakoff, 'Scientists, Technologists and Political Power' in Ina Spiegel-Rösing and Derek de Solla Price (eds), *Science, Technology and Society* (Sage Publications 1977) 355, 364.

[1727] U.S. Congress, Office of Technology Assessment, *The Regulatory Environment for Science* – A Technical Memorandum, OTA-TM-SET-34 (Washington, DC: U.S. Government Printing Office, February 1986), available at <https://www.princeton.edu/~ota/disk2/1986/8621/8621.PDF > iii, 20.

[1728] U.S. Congress, Office of Technology Assessment, *The Regulatory Environment for Science* – A Technical Memorandum, OTA-TM-SET-34 (Washington, DC: U.S. Government Printing Office, February 1986), available at <https://www.princeton.edu/~ota/disk2/1986/8621/8621.PDF > iii, 20.

[1729] U.S. Congress, Office of Technology Assessment, *The Regulatory Environment for Science* – A Technical Memorandum, OTA-TM-SET-34 (Washington, DC: U.S. Government Printing Office, February 1986), available at <https://www.princeton.edu/~ota/disk2/1986/8621/8621.PDF > iii, 20.

[1730] U.S. Congress, House Committee on Science and Astronautics, Subcommittee on Science, Research and Development, 'National Science Policy', Hearings on H. Con. Res. 666, U.S. House of Representatives, 91st Cong., 2nd sess, 1970.

[1731] Mariachiara Tallacchini, 'Politiche della scienza contemporanea: le origini' in Stefano Rodotà and Mariachiara Tallacchini (eds) Trattato di biodiritto. Ambito e fonti del biodiritto (Giuffrè Editore, 2010) 53, 61.

[1732] Mariachiara Tallacchini, 'Politiche della scienza contemporanea: le origini' in Stefano Rodotà and Mariachiara Tallacchini (eds) Trattato di biodiritto. Ambito e fonti del biodiritto (Giuffrè Editore, 2010) 53, 61.

consequence, AAAS formulated two resolutions commending U.S. Government to phase-out of herbicides[1733] and appealing for cessation of hostilities in Vietnam.[1734]

The public attitude towards science and scientific progress was changing: they were regarded with increasing disillusion and suspicion, as a number of public opinion surveys showed.[1735]

In 1971, the OECD Report entitled *Science, Growth and Society* (also named "the Brooks Report") pointed out that "scientific research became associated in the minds of many with war, and with environmental and social deterioration resulting from the large scale application of technology".[1736]

Most of the problems arising from the implementation of the social contract between science and society were ascribable to the linear model that informed the Bush Report. According to the STS scholar Sheila Jasanoff, the Report proposed a linear model of how science is converted into technology, where discovery, invention and commercialization are regarded as "discrete, sequential activities following each other as if by natural law".[1737] Within this model, the process of scientific research and product development, she points out, "were imagined as naturally self-regulating enterprises", where the state and the law intervene, eventually, at the end of the pipeline, if some risks and damages emerge.[1738]

Although the implementation of this contract fell short in engaging with environmental, health and safety issues related to scientific research, its premises and the linear model were still applied to the life sciences, in the 1970's, when the debate over the risks of recombinant DNA technology and genetic manipulation spread.

Throughout these years, Science, Technology and Society scholars critically addressed and tried to understand, from different theoretical perspectives, the social dimensions of science policy and the problems it engendered in order to improve science policies. Although Ina Spiegel-Rösing remarked, in the handbook, that STS needed to improve the integration of several discipline perspectives, she also pointed out which were some of the main

[1733] AAAS, *Resolution: Commending U.S. Government Phase-Out of Herbicides in Vietnam*, Adopted by the AAAS Council, December 30, 1970.

[1734] AAAS, *Resolution: Appeal for Cessation of Hostilities in Vietnam*, Adopted by the AAAS Council, December 39, 1972.

[1735] See U.S. Congress, Office of Technology Assessment, *The Regulatory Environment for Science* – A Technical Memorandum, OTA-TM-SET-34 (Washington, DC: U.S. Government Printing Office, February 1986), available at <https://www.princeton.edu/~ota/disk2/1986/8621/8621.PDF > iii, 132-135.

[1736] OECD, *Science, Growth and Society. A New Perspective*, Report of the Secretary-General's Ad Hoc Group on New Concepts of Science (Paris 1971) 5.

[1737] Sheila Jasanoff, 'A Social Contract for the Life Sciences: The US Case' in in Stefano Rodotà and Mariachiara Tallacchini (eds) Trattato di biodiritto. Ambito e fonti del biodiritto (Giuffrè Editore, 2010) 103, 106.

[1738] Sheila Jasanoff, 'A Social Contract for the Life Sciences: The US Case' in in Stefano Rodotà and Mariachiara Tallacchini (eds) Trattato di biodiritto. Ambito e fonti del biodiritto (Giuffrè Editore, 2010) 103, 108.

contributions of the field. STS theoretical efforts, by showing the subjective side of science, namely that the scientist is not a dispassionate truth seeker, got "the actor back in the picture, not as an abstract unit". Moreover, STS studies, by analyzing the historical and cultural context where the functioning of science takes place, fostered a less conceptual and abstract approach to the sociology of science and technology. In addition, STS research showed the normative aspects of science and technology.

Science, Technology and Society (STS) impinged on Science and Technology Studies (S&TS) and converged with it. In the second STS handbook, published in 1995 and entitled the *Handbook of Science and Technology Studies*, the editors described STS "as a still emerging field" and they wondered what "STS" stood for in the volume, whether for "science, technology and society", as in the first handbook, or for the newer guise "S&TS", "science and technology studies".[1739] They preferred to use the newer guise in the title, although most of the contributors employed indifferently both acronyms in their essays. In the third handbook, published in 2008 and entitled *The Handbook of Science and Technology Studies*, the editors clearly considered the newer guise already established and implicitly endorsed the conflation of STS with S&TS. The editors acknowledged, nevertheless, STS' heredity in terms of theoretical and practical commitment.

The acronym "STS" and the expression "Science, Technology and Society" are, however, still used to refer to the field. A handbook entitled *Routledge Handbook of Science, Technology and Society* had been published in May 2014[1740] and this choice clearly signals that both acronyms (STS and S&TS) are currently widely used to refer to the same tradition.

STS theoretical work, however, fostered another important stream of research. This stream arose from the work of one of the editors of the first STS handbook, the historian of science Derek de Solla Price, who is deemed to be the founder of modern "scientometrics," namely the "quantitative mathematical study of science and technology".[1741] "Scientometrics", in comparison to S&TS qualitative approach, is focused on a specific methodology, which is based on "the use of quantitative indicators of the structure and development of science in

[1739] Sheila Jasanoff, Gerald E Markle, James C Petersen and Trevor Pinch (eds), *Handbook of Science and Technology Studies* (Sage Publications 1995) ix, xi.

[1740] Daniel Lee Kleinman and Kelly Moore (ed), Routledge Handbook of Science, Technology and Society (Routledge 2014), vii.

[1741] Ina Spiegel-Rösing, "The Study of Science, Technology and Society (SSTS): Recent Trends and Future Challenges" in Ina Spiegel-Rösing and Derek de Solla Price (eds), *Science, Technology and Society* (Sage Publications 1977) 1, 18.

order to decide the basic regularities of their functioning and direction".[1742] In the 1980s and 1990s, researchers committed to this kind of quantitative approach to STS gradually became part of a sub-community ("Science, Technology and Innovation" or STI) with its own handbooks,[1743] journals[1744] and conferences.[1745] Although the dialogue between the two streams seemed possible, in the early 1970s, in the following years they diverged. The STI scholars Martin, Nightingale and Yegros-Yegros, pointed out that the main reason for this split was related to methodological issues: quantitative sociology and scientometrics "focus on the products of science, an approach that, for the qualitative philosopher-historian, only captures a 'frozen' and potentially misleading snap-shot of something 'in the process of becoming', or, worse still, attempts to impose order and therefore social difference on people, their worlds and the dynamic connections that gave them their properties".[1746]

1.4 **Conclusions: Defining S&TS**

Science and Technology Studies (S&TS) is a field largely marked by inter-disciplinarity, which "is creating an integrative understanding of the origins, dynamics and consequences of science and technology".[1747] Most of S&TS scholars' work is concerned with the implications of scientific practices and policies to improve the process of democratic decision-making.

The two traditions I referred to at the beginning of this appendix – the constructivist tradition in sociology and ethnography of science and the analysis undertaken in "Science, Technology and Society" (STS) – both shaped the way in which S&TS, as a field, looks at the social and policy dimensions of science and technology and try to understand them.

[1742] Ina Spiegel-Rösing, "The Study of Science, Technology and Society (SSTS): Recent Trends and Future Challenges" in Ina Spiegel-Rösing and Derek de Solla Price (eds), *Science, Technology and Society* (Sage Publications 1977) 1, 18.

[1743] The first handbook entitled " Handbook of Quantitative Studies of Science and Technology" was edited by Antony van Raan (the Director of CWTS at Leiden, one of the most relevant academic groups in the field) and published in 1988. The second handbook entitled "Handbook of Quantitative Science and Technology Research" was edited by Henk F Moed, Wolfgang Glänzel and Ulrich Schmoch and published in 2004. Ben R Martin, Paul Nightingale and Alfredo Yegros-Yegros, 'Science and Technology Studies: Exploring the Knowledge Base' (2012) 41 *Research Policy* 1182, 1184.

[1744] The main journals in the field are "Scientometrics", that was established in 1978, and "Research Policy", that was founded in 1972.

[1745] For example, the "Leiden" conferences on S&T indicators, held for the first time in 1988. Ben R Martin, Paul Nightingale and Alfredo Yegros-Yegros, 'Science and Technology Studies: Exploring the Knowledge Base' (2012) 41 *Research Policy* 1182, 1193.

[1746] Ben R Martin, Paul Nightingale and Alfredo Yegros-Yegros, 'Science and Technology Studies: Exploring the Knowledge Base' (2012) 41 *Research Policy* 1182, 1193.

[1747] Edward J Hackett, Olga Amsterdamska, Michael Lynch and Judy Wajcman (eds), *The Handbook of Science and Technology Studies* (The MIT Press 2007) viii.

These two streams, that are also two different intellectual and cognitive regions, are densely intertwined in most of S&TS analytical work, as they both have enriched the field of theoretical tools and methodologies, which resulted from their meeting.

S&TS, in comparison to other fields, is characterized by conceptual and methodological contamination among the different areas of research and by linguistic hybridization across the disciplines, which marked its epistemic perspective in addressing the issues at the interface of technoscience and society.

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