UNIVERSITY
OF TRENTO - Italy
Faculty of Law
Department of Legal Sciences

lawtech

Trento Law and Technology
Research Group
Student Paper n. 13

The Intellectual Property and Open Source Approaches to Biological Material

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ISBN: 978-88-8443-459-3

KEYWORDS

Intellectual Property, Open Source, Biological Material, Scientific Research

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THE INTELLECTUAL PROPERTY AND OPEN SOURCE APPROACHES TO BIOLOGICAL MATERIAL

ABSTRACT

The fragmentation of scientific knowledge and the *enclosure* of living organisms are serious threats to science. Stricter proprietary approaches to biological material at the level of basic scientific research may hamper, rather than spur innovative activities. Such problems as blocking patents and patent thickets demand apposite solutions, but the one-size-fits-all character of patent law can hardly address them.

This thesis will present a profound analysis of current intellectual property systems and related problems, providing an overview of the general theories and of the main legal and economic concepts of intellectual property rights. Subsequently, it will focus on the particular problems that intellectual property rights pose to biotechnology, in particular the question of ownership over nonhuman biological materials. Afterwards we will present the open source approach as an alternative to conventional intellectual property protection. The foundational concepts of the open model will be described, in addition to the empirical cases presented to conceptualize it. In conclusion, we will demonstrate that the open source model can coexist and balance the proprietary approach to intellectual property, contributing to eliminating some f its inefficiencies in terms of flexibility and accessibility.

LA PROPRIETÀ INTELLETTUALE E GLI APPROCCI OPEN SOURCE NEI MATERIALI BIOLOGICI

ABSTRACT

La progressiva parcellizzazione della conoscenza e la tendenza verso l' "enclosure" degli organismi viventi rappresentano un serio pericolo per lo sviluppo scientifico. Un approccio proprietario nella configurazione del regime di appartenenza dei campioni biologici, ancora nella fase precompetitiva, può danneggiare anzicché promuovere l'innovazione. Problematiche come i "blocking patents" o i "patent tickets" richiedono l'elaborazione di soluzioni ad hoc, non risultando efficienti le risposte standardizzate finora fornite in materia di brevetti.

La tesi, dopo aver compiuto un'analisi dell'attuale sistema dei diritti di proprietà intellettuale e dei maggiori profili di criticità che al momento esso presenta – tanto dal punto di vista giuridico che economico – affronterà i problemi specifici che si profilano nella gestione delle biotecnologie, soffermandosi, in particolare, sulla natura proprietaria delle risorse biologiche. In seconda battuta, la tesi si concentrerà sulle soluzioni offerte dall'approccio *open source* come alternativa alla tradizionale protezione offerta dagli strumenti di proprietà intellettuale. La filosofia dei modelli aperti sarà descritta congiuntamente all'esposizione di alcuni *case studies* che ne permetteranno una più approfondita comprensione.

In conclusione, si dimostrerà che il modello *open source* può non solo coesistere ma anche bilanciare, in termini di accessibilità e flessibilità, gli squilibri e le inefficienze dell'approccio puramente proprietario ai diritti sui beni immateriali.

TABLE OF CONTENTS

List of Abbreviations

AIA	America Inventions Act
BiOS	Biological Open Source Initiative
CBD	Convention on Biological Diversity
CC	Creative Commons
COO	Country of Origin
DNA	Deoxyribonucleic Acid
DRM	Digital Rights Management
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
FAO	Food and Agriculture Organization
FSF	Free Software Foundation
G.M.	Genetically modified
G.M.O.	Genetically Modified Organisms
GPL	General Public License
IOI	Initiative for Open Innovation
IP	Intellectual Property
IPR	Intellectual Property Rights
LDC	Least-Developed Countries
MIT	Massachusetts Institute of Technology
OS	Open Source
OSI	Open Source Initiative
PBR	Plant Breeders' Rights
PIPA	Protect Intellectual Property Act
PTO	Patent and Trademark Office
R&D	Research and Development
RNA	Ribonucleic Acid
SC	Science Commons
SOPA	Stop Online Piracy Act
TRIPS	Agreement on Trade Related Intellectual Property Rights
U.S.	United States
U.S.A.	United States Of America
UPOV	International Union for the Protection of New Varieties of Plants
WIPO	World Intellectual Property

	Organization
WTO	World Trade Organization

LIST OF FIGURES

We build too many walls and not enough bridges.

Sir Isaac Newton

INTRODUCTION

Society has an obvious interest in fostering innovation. Historically, there has been a prevalent conviction that encouraging innovation could be better accomplished through the implementation of strong intellectual property rights. This concept is well rooted in western societies, and scientific research is not an exception to the phenomenon of «creeping proprietization».[1] Several scholars point out the problems inherent to the paradox between the intrinsic individualism of intellectual property rights and the aspirational communalism of scientific research.[2]

The aim of this thesis is exploring the latent consequences of enclosing biological materials. Ever since the patenting of living organisms became a common-place in some major patent systems around the world, basic living matter has been subtracted from the commons, where it was available to everyone, into the sphere of private rights. This change entails a right of exclusion from public goods, hence a negative impact on access to such goods in the name of incentivizing their creation and a constraint in the direction of science. Protection of intellectual property has often been presented as a necessary and balanced trade-off between social sacrifice and incentives to innovation. Our work challenges both assumptions (necessity and balance) from various angles.

Moreover, this thesis explores the rather recent open source phenomenon in the biological sciences in this context of strict intellectual property rights – and

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[1] Merges, R. (1996). Property rights theory and the commons: the case of scientific research. *Social Philosophy and Policy , 13* (2), pp. 145-167.

[2] See for instance Eisenberg, R. S. (1987). Proprietary rights and the norms of science in biotechnology research. *The Yale Law Journal , 97* (2), pp. 177-231..

a growing demand for stricter protections around the world. The roots of and motives for the open source movement are indentified, in order to provide a better understanding of its viability in the life sciences and the benefits and drawbacks of its implementation within the intellectual property ecosystem. In particular, the focus is on nonhuman biological resources, namely plant, animal and microorganism genetic material, even though punctual examples may embrace human genetic material as well.

The approach is intrinsically interdisciplinary, with the purpose of providing a broad and comprehensive picture of the relationship and intersection between the intellectual property and the open source models for biological material. The main legal sources are the American and European jurisprudences, as well as the international system of intellectual property rights enforcement. Developing and least-developed countries are included in the focus of this work to the extent international legislation and North-South relationships are assessed. While directly related to economic and legal disciplines, issues regarding intellectual property also allude to biodiversity, public health, food security, bioethics, social dilemmas, cultural diversity and international relations. This multidisciplinary nature is taken into consideration given its significance for understanding the quest for and rises of open source proposals for science.

This thesis is divided into four main chapters. The first chapter provides a view of the general theories and concepts of intellectual property rights. The second chapter narrows down the focus of our study to intellectual property rights over nonhuman biological material. The third chapter presents the alternative open source model, explaining the main concepts behind it, as well as the viability and limits of an open source approach to biological material. To conclude, the fourth chapter concentrates on the relationship and intersection between proprietary and open collaborative models for biological material.

1 INTELLECTUAL PROPERTY: GENERAL THEORIES AND CONCEPTS

1.1 Introduction to the theories of intellectual property

Intellectual property law embraces many protection regimes, including patents, copyright, trademarks and trade secrecy. The term intellectual property, as defined by the World Intellectual Property Organization, refers broadly to the creations of the human mind. This body of law deals fundamentally with the protection of the interests of the creators. The latter are granted exclusionary privileges over their creations.[3] This definition may be enriched with three exclusive attributes to intellectual property law.

i. Firstly, intellectual property is property *created and recognized* by existing legal systems.[4] In essence, the fear of one's idea being stolen after publishing it pushed towards a system whereby writers could be given assurances. Fear of intellectual pirates was partially nourished by the invention of the printer, and it resulted in the creation of registration systems – take the example of the Stationer's Hall in London – which ensured backing for authors in case of fraud. Printing one's title would then be subject to her approval. This system established a code of conduct which, in turn, laid down the legal bases for copyright law.[5] Patent law and copyright law clearly share some common grounds in this sense. In order to incentive the production of intellectual works which would benefit the general commonwealth, the fear from appropriation by others (we can call it intellectual piracy) had to be wiped out. States understood that intervention was needed, and by the fifteenth century most

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[3] World Intellectual Property Organization. (2004). *WIPO Intellectual Property Handbook: Policy, Law and Use* (Vol. NO. 489(E)). Geneva: WIPO.
[4] Hughes, J. (1988). The Philosophy of Intellectual Property. *Georgetown Law Journal , 77* (287).
[5] Johns, A. (2009). *Piracy: the intellectual property wars from Gutenberg to Gates.* Chicago: The University of Chicago Press.

European states were conceding privileges or patents to initiatives of all sorts, rewarding indiscriminately creators of new ideas in a quite paternalistic manner.[6] Importantly enough, patents were not seen as *rights*, but as privileges. Trademarks and trade-secrets, on the other hand, have accompanied the development of economic activity and trade from their origins.

With the maturation of legal systems and the proliferation of trade, innovation (technological progress, total factor productivity and other concepts incorporated in the economic theories of growth) started being recognized as the major factor for productivity growth for many modern economies.[7] With a bigger share of the economic activities in the developed countries dependent on innovation, new ideas and original contributions, policy measures for the protection of intellectual property turned out to be widely accepted as logic. Several cross-country empirical studies give evidence of the positive effects of strong intellectual property rights on technological change.[8]

ii. Secondly, intellectual property is *limited* in many aspects, specifically limits of duration and breadth. These limitations depend on the branch of law one is referring to. Since dealing with intellectual rights may render the discourse somewhat oversimplified, we try as much as possible to address the legal regimes under this umbrella separately. Patents, copyrights, trademarks and trade secrets, for instance, obey to legal rules designed to protect different sorts of works, and as a result they work along different mechanisms which consecutively may instigate diverse legal and economic responses.[9] This chapter will, however, stress their various commonalities as well.

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[6] *Id.*

[7] See Solow, R. M. (1957). Technical change and the aggregate production function. *Review of Economics and Statistics , 39* (3), pp. 312-320; and Varsakelis, N. C. (2001). The impact of patent protection, economy openness and national culture in R&D investment: a cross-country empirical investigation. *Research policy , 30* (7), pp. 1059-1068.

[8] Kunwar, S., & Evenson, R. (2003). Does intellectual property protection spur technological change? *Oxford Economic Papers* , pp. 235-264.

[9] Cole argues that the recent discussions on intellectual property may have blurred some important practical distinctions among the legal branches entailed in Intellectual Property Law. He refers in particular to the differences between trademarks and patents, given that the first does not have the same monopolistic character of the latter, and therefore cannot be seen

iii. Last but not least, we focus on the *intellectual* part of the concept. Information and knowledge enclose features similar to those of *public goods*. "Information" in the context of intellectual property «can be incorporated in tangible objects at the same time in an unlimited number of copies at different locations anywhere in the world».[10] Being a public good makes information (a) non-rival and (b) non-excludable, for the fact that it is immaterial.[11] Thus legal protection seems indeed to be the only effective measure to 'fence' that property, because information cannot (contrarily to physical goods) be physically fenced. The non-rival nature of information permits its use by the creator without precluding others from using it as well, so that «everyone can benefit from it once it is produced».[12] In addition, because information is hard to control (particularly now in the new technological era whereby information flows easily and cost-free on the Internet), it is also to some extent non-excludable, in the sense that the creator is «often unable to completely prevent others from using the innovation without due authorization».[13]

Merges, Menell and Lemley exemplify a world without protection for intellectual creations, where there would be at least in theory an underproduction of books. This would happen because competition in the market would push down books' prices to their marginal cost of production, offering according to the utilitarian theory no economic incentives for their authors to engage in such an activity.[14] This example illustrates the difficulty in inducing advancement for non-rival and non-excludable goods, which include some typical examples such as air, national defense, lighthouses, television broadcast signals and MP3 files shared on the Internet. Many authors refer to

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under the same light. See Cole, J. H. (2001). Patents and Copyrights: do the benefits exceed the costs? *Journal of Libertarian Studies , 15* (4), pp. 79-105.

[10] World Intellectual Property Organization. (2010, January 19). *Understanding Copyright and Related Rights*. Retrieved October 15, 2011, from World Intellectual Property Organization: http://www.wipo.int/freepublications/en/intproperty/909/wipo_pub_909.htmlhttp://www.wipo.int/freepublications/en/intproperty/909/wipo_pub_909.html.

[11] Caso, R. (2008). Proprietà intellettuale, tecnologie digitali ed accesso alla conoscenza scientifica: Digital Rights Management vs. Open Access. Milan: Creative Commons.

[12] Merges, R., Menell, P., & Lemley, M. (2006). *Intellectual Property in the New Technological Age* (4th ed.). New York: Aspen Publishers.

[13] See, for example, Kunwar and Evenson, *supra* note 8.

[14] Merges, Menell & Lemley, *supra* note 12, at p. 10-13.

public goods as a typical case of *market failure*, whereby protection by the State seems to be vital to make producers of information goods recoup their costs of production.[15] This class of goods can be contrasted with pure private goods, that is, goods that can be consumed only by those who pay its price. These include ice-cream cones, food, computers and cars and their pricing depends on the equilibrium between supply and demand.

In view of that, it is logic to think that the market will tend to undersupply public goods in the basis of insufficient gathering of returns so as to cover the incremental costs of investment of innovators. Accordingly, imperfect appropriability may lead to underinvestment in research and development. Hence protection is (at least in theory) desirable and it may positively stimulate innovative activity, at least in some industries, so as to make investment in innovative activity worthwhile. This is especially true for pharmaceutical and chemical which are highly dependent on legal protection to recoup investment expenditures.[16] Mansfield's survey revealed that respondents believed 60% of the inventions in pharmaceuticals and circa 40% in chemicals would not to have been developed in adverse legal circumstances.[17] This perspective does not go unchallenged, as we will verify in the last part of this chapter and continuously throughout this work. The following subchapters will present an overview of the theories behind intellectual property law.

1.1.1 Utilitarian Theories of Intellectual Property

In view of that, it is clear that the conventional theory applied to the protection of utilitarian works steams out of the utilitarian school.[18] According to the utilitarian economic rationale protection of inventions is required because it

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[15] Caso, *supra* note 11.

[16] It needs to be said that expenditures in research and development in the pharmaceutical and chemical industries tend to be very costly; therefore these are particularly sensitive to protection. For a more detailed view of the different reactions of different industries, see Levin, R. C., Klevorick, A. K., Nelson, R. R., Winter, S. G., Gilbert, R., & Griliches, Z. (1987). Appropriating the Returns from Industrial Research and Development. *Brookings Papers on Economic Activity , 3*, pp. 783-831.

[17] *Id.*

[18] Menell, P. S. (2007). Intellectual Property: general theories. In D. S. Clark, *Encyclopedia of Law and Society: American and Global Perspectives*. SAGE Publications.

entails an investment of resources which is endangered by the potential depreciation of value of the original idea in case it is found and explored by competitors.[19] According to this theory, without legal protection creators would have a comparative advantage so long as they could keep their idea in secret. In order to cover at least the initial costs of investment (even though expected returns are tendentiously higher than costs), creators' interests ought to be protected so as to allow for a comparative advantage towards their competitors when making commercial use of their innovative ideas. As Landes and Posner put it, «a firm is less likely to expend resources on developing a new product if competing firms that have not borne the expense of development can duplicate the product and produce it at the same marginal cost as the innovator; competition will drive the price down to marginal cost and the sunk costs of invention will not be recouped».[20]

Garret Hardin introduced the metaphor "tragedy of the commons" to explain the problematic around the over-exploitation of common physical resources[21]. Hardin observed that several individuals acting in their own self-interest would eventually deplete limited shared resources[22]. This has been generally used and accepted as justification also for the protection intellectual of property rights. Arnold Plant, however, drew attention to the differences between physical and intellectual property. In the case of physical property «the institution of private property makes for the preservation of scarce goods, tending (…) to lead us to 'make the most of them'…» given that there is generally «not a sufficient concentration of ownership of the supplies of a particular good, and of all the easily substitutable alternatives for it, to enable the owners to control the prices

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[19] See Takalo, T., & Kanniainen, V. (2000). Do patents slow down technological progress? Real options in research, patenting and market introduction. *International Journal of Industrial Organization , 18* (7), pp. 1105-1127.

[20] See Landes, W. M., & Posner, R. A. (2003). *The economic structure of intellectual property law.* Harvard: Harvard University Press.

[21] See Hardin, G. (1968, December). The Tragedy of the Commons. *Science , 162*. Hardin's theory explains that *multiple* individuals acting independently and rationally, and behaving according to their own self-interest, will ultimately deplete a shared limited resource. This will happen regardless the fact that it is in anyone's self-interest that in the long-term such depletion happens.

[22] See Heller, M. A., & Eisenberg, R. S. (1998). Can Patents Deter Innovation? The Anticommons in Biomedical Research. *Science , 280*, pp. 698-701.

of the property they own». In this sense, affecting the price of the commodity in question is not dependent on the action of the owner. Alternatively, intellectual property accomplishes «the *creation* of a scarcity of the products appropriated which could not otherwise be maintained», and through this process «the beneficiary is made the owner of the entire supply of a product for which there may be no easily obtainable substitute. »[23] Following these thoughts, we can draw one main conclusion: intellectual property recognizes property rights over immaterial goods in order to cause an artificial shortage of these goods, which would otherwise be naturally public or communal. There are major differences between physical and intellectual property and their running mechanisms are relevantly different. This point is of paramount importance for the discussion of intellectual property rights and for the understanding of the particularities behind the monopolies granted to patent and copyright holders.

In 1957, Solow developed a model demonstrating that technological advancement and increased human capital of the labor force were the main engines of the American economy between 1909 and 1949[24]. This model has been expanded to other industrialized countries by Scherer and Ross, whose conclusions underline the need for «a subtle blend of competition and monopoly, with more emphasis in general on the former than the latter (…) » in order to sustain technological progress[25]. By 1969, Nordhaus proposed a formal model for a better understanding of how optimal duration of patent protection balanced the incentives for innovation against the deadweight loss generated by a monopolistic exploitation of the outcome of innovative inventions[26]. Nordhaus came to the conclusion that each increase in the duration of a patent stimulates an increase in inventive activity. However, this model fails to explain fully how this trade-off functions because it pretty much

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[23] Plant, A. (1934). The economic theory concerning patents for innovation. *Economica New Series , 1*, pp. 30-51.
[24] Solow, *supra* note 7.
[25] Scherer, F. M., & Ross, D. (1990). *Industrial Market Structure and Economic Performance* (3 ed.). Houghton-Mifflin.
[26] See Nordhaus, W. D. (1969). *Innovation, growth and welfare.* MIT Press.

oversimplifies the complexity of the topic. Firstly, Nordhaus presupposed patent duration to be the only policy instrument to be considered, largely ignoring for instance patent breadth as a variable.[27] Secondly, this model works in situations where inventions result in an end product, ignoring than that most inventions are in reality cumulative[28]. The extent to which economic agents may collaborate, for instance through licensing or joint-ventures, is an issue of paramount importance in patent law.[29]

Other studies from economic historians and industrial organization economists during the 1970s and 1980s evaluated the importance of intellectual property law in spurring technological advancement, coming to the consensual conclusion that patents were only «rarely the principal means of appropriating returns in most industries (outside of pharmaceuticals and chemicals)». [30] This seemed to apply not only to the case of the United States[31], but also to the case of Japan[32] and Germany. Note that the case of pharmaceutical and chemical industries is exceptional. What these studies suggest is that protecting intellectual property confers «a real, but limited, incentive to innovate in some industrial sectors», provided that «the importance of such rights vary significantly across industries and fields of innovation».[33]

As decades pass by, utilitarian studies on intellectual property have become refined so as to comprise the complexity of the intellectual property scenario. Predictably some authors developed alternative hypothesis to traditional utilitarian perspectives. These alternatives include rewarding systems based on

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[27] Recent literature has been incorporating the implications of variation in patent scope/breadth in the study of patent law. For a general perspective, see Gilbert, R., & Shapiro, C. (1990). Optimal Patent Length and Breadth. *RAND Journal of Economics , 21* (1), pp. 106-112; and also Gallini, N. (1992). Patent Policy and Costly Imitation. *RAND Journal of Economics , 23* (1), pp. 52-63.

[28] For further reading on the issue, see Scotchmer, S. (2004). *Innovation and incentives*. Cambridge: MIT Press.

[29] For an overview of the open source model (the collaborative model we will deal with in this work) see chapter 3 and 4.

[30] Menell, *supra* note 18.

[31] See the results of the study carried out by Levin et al., *supra* note 16.

[32] For specific reading on Japan, see Sakakibara, M., & Branstetter, L. (1998). Do stronger patents induce more innovation?: evidence from the 1998 Japanese patent law reforms. *National Bureau of Economic Research* (2).

[33] Menell, *supra* note 18, at p. 136.

prizes and tournaments, particular business strategies[34], social norms, government subsidies and government regulatory programs. Clearly, all these options have positive as well as negative aspects.

1.1.2 Non-utilitarian theories of Intellectual Property

The utilitarian theory is, however, not the only attempt by scholars to grasp the mechanisms of intellectual property law. Non-utilitarian theorists commonly give emphasis to other sorts of arguments, in particular by providing philosophical frameworks to explain intellectual property rights. Copyright law in European states is particularly sensitive to non-utilitarian theories of rights.[35] John Locke and Immanuel Kant gave rise to a philosophical current which became known as Labor theory or Natural Rights theory. Locke claimed that property was something inherent to all humans as a fruit of their labor, that is, the « Labour of his body and the Work of his hands, we may say, are properly his».[36] He goes on arguing that «it being by him removed from the common state Nature placed it in, it hath by this Labour something annexed to it that excludes the common right of other men. For this Labour being the unquestionable property of the Labourer, no man but he can have the right to what that is once joined to, at least where there is enough and as good left in common for others».[37] Kant, for his part, focuses on the 'natural obligation' to honor the author's ownership of his works. Both authors develop the common idea that a creator ought to have rights over her creation. Several questions were raised concerning the assumptions out forward by Locke and Kant, mainly because of the differences between private physical property and intellectual property. Ideas are immaterial, public goods. Can anyone, even their creator, claim their ownership? Should the claimed rights be absolute?

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[34] Business strategies consist of a range of managerial channels through which companies may better appropriate the returns for their investments. Some examples are trade secrecy, intra-firm competition, the use of stock options and other incentive-based compensation systems, suggestion boxes, marketing and licensing, strategic partnering, among others. See Menell, *supra* note 18, at p. 143.

[35] *Id.* at pp. 156.

[36] Locke, J. (1988). *Two Treatises of government* (3 ed.). Cambridge: Cambridge University Press.

[37] *Id.*

How can these rights be interpreted in the patent law and copyright law frameworks? These matters are open to debate.

Alternatively, the personhood theory steams chiefly from Hegel's *Philosophy of Right*. In particular it draws on the premise of control over external property as a necessity of the individual in order to achieve proper development[38]. As Merges, Menell &Lemley put it, «Hegel concludes that the person becomes a real self only by engaging in a property relationship with something external. Such a relationship is the goal of the person».[39] Individuals shall therefore detain a certain level of control over these resources. From this point of view private property is fundamental for our flourishing as individuals. However, while Kant considered the literary work as part of the author's person, and thus not alienable, Hegel made a distinction between the inalienability of an individual's mental ability and the acts through which he channels that ability (the expression).[40] In sum, the personhood perspective proposes the view that the personality interest of individuals ought to be protected, whether through authors' "moral rights", inventors' "reverse shop rights" or even individuals' "right of publicity".[41] Then again, this view raises many questions, for example concerning the subjectivity of the personhood argument[42] and its applicability to intellectual property.[43]

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[38] «The premise underlying the personhood perspective is that to achieve proper development – to be a person – an individual needs some control over resources in the external environment. » *in* Radin, M. J. (1982). Property and Personhood. *Stanford Law Review , 34* (5), pp. 957-1015.

[39] Merges, Menell & Lemley, *supra* note 12.

[40] Menell, *supra* 18, at p. 158-159

[41] Hughes, J. (1988). The Philosophy of Intellectual Property. *Georgetown Law Journal , 77* (287); at p. 81.

[42] Radin for instance brings to discussion the issue of where to draw the line between *good* and *bad* personal connections with physical property. Private property, for the effects of her argument, must be detached from fungible property. Fungible property is instrumental, such as money. Private property is different in nature, for it cannot easily be replaced given that it is closely bound up with the individual (for example, a wedding ring, a portrait or a family home). See Radin, *supra* note 38.

[43] How could this theory be applied to the context of intellectual property? Do different works relate differently with their creators? Should the law take account of that, by providing higher protection to more personal works? Hughes discusses the influences of the personhood theory in copyright law, mainly in the concepts of originality of creative works, but also intentionality and sourcehood. See Hughes, *supra* note 41.

Furthermore, several philosophers focus on issues related to the distributive justice of intellectual property rights. This theoretical interpretation of intellectual property seeks to «distribute society's resources on the basis of just principles».[44] For the purposes of our analysis we will bring these arguments into discussion throughout the work. Along our examination of some pieces of international legislation[45] a clear manifestation of greater concern for issues of social justice was obvious. Clearly, the advances in the life sciences have raised concerns over the potential risks of bioprospecting and international authorities have become aware of these. Thus, international principles and legal texts currently ensure the protection of farmers' rights, the conservation and sustainable use of biodiversity and also the equitable share of benefits rising from biodiversity. Moreover there has been a vivid debate on the necessity to safeguard and make equitable use of traditional, indigenous and local knowledge in the international forums.

These concerns are shared by ecological theorists, who sustain a more naturalist ethics approach building up on broader theoretical frameworks relating humans to the environment. This view is suspicious about some of the canons in intellectual property theory, mainly by attacking the idea of technological advance as the aim of developed societies and by exposing its high costs to the environment.[46] Environmentalists are not necessarily contrary to the use of intellectual property. What they seek is the use of such a mechanism, as well as other sorts of incentive measures, to induce the invention of novel green technologies which reduce the impact of human activity on the environment.

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[44] Menell, *supra* note 18, at p.160

[45] See chapter 2 of the this work, where we discuss in particular the Convention on Biological Diversity and FAO's International Undertaking on Plant Genetic Resources.

[46] An example might be the adverse opinion developed by environmental activists, ecologists and others of the results of biotechnology advancements, particularly the risks posed by the release of genetically modified organisms in the environment and the lack of ethics behind the re-engineering of living organisms. These critiques follow the line of thought behind the non-anthropocentric view of the world. See Nash, R. F. (1989). *The rights of nature: a history of environmental ethics*. Madison: University of Wisconsin Press.

In view of this introduction, we will continue with an examination the most significant branches of intellectual property law.

1.2 Patent law

The World Intellectual Property Organization (WIPO) defines a patent as a «document, issued, upon application, by a government office (or a regional office acting for several countries) which describes an invention and creates a legal situation in which the patented invention can normally only be exploited (manufactured, used, sold, imported) with the authorization of the owner of the patent».[47] In other words, a patentee earns the right of excluding others of making, using, selling or importing his invention. Thus, a *legal monopoly* is granted over the invention and the right to take legal action against whoever commits an infringement, even the act of duplicating the protected innovation independently.[48]

In general terms patents are limited in time and breadth. The Trade Related Aspects of Intellectual Property Rights (TRIPS) set the time limit of 20 years as a minimum standard for its parties. However, patent rights may cease before the limit if renewal fees are not paid.[49] The breadth of a patent is legally established by its claims.

Patents protect ideas as such against their use by others without the authorization of the patentee[50]. In accordance, what actually is object of protection is the template for producing and using a product rather than the product as such.[51]

Inventions can be patented in a large number of countries as long as they fulfill the requirements set on their own patent law. An invention is commonly defined as a solution to a technical problem in a specific field of technology,

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[47] World Intellectual Property Organization, *supra* note 3.
[48] Scotchmer, *supra* note 28.
[49] *Id.*
[50] World Intellectual Property Organization, *supra* note 3. For a better insight of the dichotomy idea/expression, see 2.2.
[51] Scotchmer, *supra* note 28.

either by the creation of an entirely new product or process, or by an improvement to a product or process which provides a unique solution to a technical problem.[52] In more general terms, inventing is adding up to the stock of valuable knowledge.[53]

National patent laws do have shared common grounds which are reflected in the international legislation on the matter. For a subject matter to be considered patentable it must be new, non-obvious and useful. Additionally, the patentee must reveal the invention to the public. We will briefly describe each of these requirements in the following pages.

1.2.1 Patentable subject matter

Noticeably not everything is a patentable subject matter. To be precise, generally states share a number of subject matters which are undesirable to be patented. The following list is put forward by the World Intellectual Property Organization:

- Discoveries and scientific theories; aesthetic creations; schemes, rules and methods for performing mental acts;
- Newly discovered substances as they naturally occur in the world; inventions whose exploitation is contrary to the "public moral" or morality;
- Diagnostic, therapeutic and surgical methods of treatment for humans and animals;
- Plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

Due to the fact that patent law is a matter of national jurisdiction, this list is not exhaustive as only some countries include the above subject matters as legally non patentable. A good example of the variation of exceptions in

[52] World Intellectual Property Organization, *supra* note 3.
[53] Landes & Posner, *supra* note 20.

national legislations is the pharmaceutical industry, whose activity might contravene common public morals.[54]

Patent applications are submitted to a national, regional or international authority which is in charge of verifying whether the application meets the conditions for patentability. As a general rule basic requirements include novelty, non-obviousness, industrial application and disclosure of the subject matter. These requirements are broadly established in patent law (a) at the national level, as in sections 101, 102, 103 and 112 of the Title 35 of the United States Code[55], (b) at the regional level, as in Article 52(1) of the European Patent Convention[56], and (c) at the international level, as in the Patent Cooperation Treaty.[57]

1.2.2 The novelty requirement

The first condition requires for an invention to be something new, in the sense that it must not be something belonging to prior knowledge, or *prior art*. Prior art is knowledge which has been made available to the public before the case is brought before a Patent Office or in the case of the United States of America even before the invention is created.[58] The novelty test involves figuring out if the claimed invention was made before, therefore incorporated in the prior art.[59]

Secrecy plays a very important role in the patenting process, precisely because if the invention is made public, even outside the national jurisdiction, before

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[54] World Intellectual Property Organization, supra note 3.
[55] Patent Laws, 35 U.S.C. § 101-103, 112 governs all aspects of patent law. Sections 101, 102 and 103 govern eligibility of the subject matter, novelty and non-obviousness respectively. Section 112 governs the form and content of the specification and of the patent application claims.
[56] European Patent Convention, *art.* 52. 1, Oct. 5, 1973. The EPC states the following: «European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application».
[57] Patent Cooperation Treaty, *art.* 33, Jan. 24, 1978. It reads that the admission for patent requires the claimed invention to be novel, non-obvious and industrially applicable. It specifies, nevertheless, that «any contracting party may apply additional or different criteria for the purpose of deciding whether, in that State, the claimed invention is patentable or not».
[58] World Intellectual Property Organization, *supra* note 3.
[59] Merges, Menell & Lemley, *supra* note 12.

patenting, in that case it is no longer something new.[60] Consequently, it fails to fulfill the novelty requirement.

While some patent systems give the right to patent to the first inventor, others give the right to patent to the first filer of a patent application.[61] The United States followed a policy of recognition of the first inventor until September 2011, when President Obama signed the Leahy-Smith America Invents Act (AIA), altering the system from "first to invent" to "first-to-file".

1.2.3 The inventive step or non-obviousness requirement

This requirement is to ensure that there is some degree of non-obviousness in the invention, that the invention is not just a simple deduction or a mere step forward over the prior art.[62] This is the «ultimate condition for patentability», as it measures the degree of technical accomplishment in the claimed invention.[63] In a word, an invention is non-obvious when it is sufficiently different from the prior art. Thus, alternatively to the novelty requirement, a certain level of difference is required. The invention shall be significantly different from the prior art and not just different – that would make it just novel. Some scholars investigate whether the preservation of the concept of novelty is really necessary given the existence of a higher degree of examination. Franzosi argues that the difference between novelty and non-obviousness in the context of European Patent Law is not merely in degree; they rather entail different examination procedures, and therefore there is a reason why novelty and non-obviousness different, though strictly related.[64]

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[60] World Intellectual Property Organization, *supra* note 3.
[61] Landes & Posner, *supra* note 20.
[62] World Intellectual Property Organization, *supra* note 3.
[63] Merges, Menell & Lemley, *supra* note 12.
[64] The examination for the novelty requirement takes into consideration the information contained in the common general knowledge, the enhanced knowledge, the hidden knowledge and prior applications. On the other hand, for the examination for non-obviousness the expert considers the information in the general knowledge, what he finds reasonable to look for in the enhanced knowledge and he does not consider neither the hidden knowledge nor prior applications. For a deeper argumentation, see Franzosi, M. (2002). Novelty and non-obviousness - the relevant prior art. *CASRIP Symposium Publication Series*.

1.2.4 The industrial applicability or utility requirement

The utility requirement alludes to the need for the invention to be of practical use. In other words, the invention must be useful for industrial purposes. The requirement for utility excludes any purely theoretical or aesthetic activity. Given the somewhat unclear industrial applications of genetic sequences in biotechnology, this requirement has become increasingly important to disclose whether the invention has an effective value from a practical point of view[65]. However, in the United States this requirement has become in a way trivial, meaning that only in the case of total lack of practical utility will the patent be denied. The exception is again on pharmaceuticals, due to the unclear links between laboratory promise and real utility of the subject matter.[66]

1.2.5 The disclosure requirement

In most patent jurisprudence, patentees are required to reveal the patented product to the public. This requirement involves the inclusion of detailed information about the invention in the claims of the patent. The description should be sufficiently clear so as to allow other people "skilled in the art" to repeat the process and achieve a similar result.[67]

Even though one can say that patent rights are rather harmonized, the truth is that some important matters differ in different national patent regimes. For instance, relating to disclosure, the European Patent Convention rejects the application of patents which were previously made publicly available.[68] Contrarily, the United States of America law provides for a grace period of one year which allows the inventor to freely publish his invention without losing his patent rights.[69] The consequence for one who exploits the grace period

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[65] World Intellectual Property Organization, *supra* note 3.
[66] Merges, Menell & Lemley, *supra* note 12.
[67] *Id.*
[68] See European Patent Convention, *art.* 54. 1, Oct. 5, 1973. This article explores the novelty requirement, stating as follows: «an invention shall be considered to be new if it does not form part of the state of the art». Hence, «the state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way before the date of filling of the European Patent application».
[69] 35 U.S.C. § 102. The section, Conditions for Patentability, states that «a person shall be entitled to a patent unless (…)(b) the invention was patented or described in a printed

granted in the US Code is the loss of potential patent rights in the signatory countries of the European Patent Office, which is an intergovernmental organization which includes thirty-eight signatory states and two states – Bosnia and Montenegro – recognizing European patents upon request. Other differences include the first-to-file system in Europe contrasting the unique first-to-invent system practiced in the United States as well as the requirement in the US patent law for the inventor to specify the best mode to practice the invention in the patent application.[70] The European patent law, on the other hand, does not entail such specification, for it states that at least one way of using the invention must be described, while it is not provide that this way must be the best way[71]. Nonetheless, some procedures provided for in the American law have recently been amended along the lines of the reform in its national patent law.[72]

1.2.6 A critical approach to patent law

Both costs and benefits of protecting intellectual property are recognized in the literature. The problems are no longer limited to the possible unbalanced trade-off between benefits from incentives to innovate on the one hand and deadweight social loss on the other. There are other issues in question. The long-run net effects on inventing of stronger and broader patents are unknown. Even though this question remains unanswered, there seems to be a solid belief that strong patent rights are the right path.[73]

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publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States».

[70] 35 U.S.C. § 112.

[71] See European Patent Convention, *art.* 83, Oct. 5, 1973.

[72] Leahy-Smith America Invents Act, 35 U.S.C. § 257. The Leahy-Smith America Invents Act was passed by the Congress and signed by President Obama in September 2011. It significantly altered American patent law, particularly in what concerns the grace period, the first-to-invent system and the best mode requirement. In this way, American patent law is a step closer to the rest of the world. For an opinion article on this matter, see Takenaka, T. (2011). Harmony with the rest of the world? The America Invents Act. *Journal of Intellectual Property Law and Practice , 7* (1), pp. 4-7.

[73] «Through negotiations regarding GATT, and now the proceedings of the WTO, the United States has been pushing on other countries its beliefs about the economic value of strong patents. The U.S. position here is heavily freighted with national interest, but there also is a honest belief in the rightness of the position. And other countries have been going along, not always simply as a reaction to the pressure, but also because of the honest belief, on the part of

The fundamental argument in favor of patent rights is that inventors of innovative products/processes may find it hard to recover their fixed costs of research and development when marketing it without any sort of legal protection. Perfect competition may harm and discourage innovative activities.[74] In other terms, inventors may incur in costs of product development, while their competitors become capable of reproducing the same results nearly effortlessly and without incurring in such costs to obtain and commercialize the final product or process.[75] This marginal advantage may lead the final price of the product to fall, causing a capital loss for the original author. On the other hand, this phenomenon can be seen from the perspective of the final consumer. In the absence of legal protection, innovators would probably have to find alternative ways to appropriate their initial investment. In reality, these alternative means are much diffused. As we have seen previously, some studies demonstrate that, on the overall, patent law plays a limited role in the protection of intellectual property in firms. Trade secrecy, lead time, movement down the learning curve and marketing seem to be regarded as more effective means to appropriate the returns for firms' inventions.[76]

By and large, mainstream utilitarian literature stresses the idea that innovation is indeed positively stimulated by stronger patent rights because it allows for higher degrees of *appropriability* of the returns to innovations.[77] Legal systems which are protective of intellectual property allow, in doing so, firms to exploit monopolistically the product of their innovative activity. We use the term monopoly when referring to patents and copyrights because holders of these

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many parties, that in the long run strong patent protection will be good for their economic development». See Mazzoleni, R., & Nelson, R. R. (1998). The benefits and costs of strong patent protection: a contribution to the current debate. *Research Policy , 27*, pp. 273-284.

[74] Merges, Menell, & Lemley, *supra* note 12.

[75] Landes & Posner, *supra* note 20.

[76] See Levin et al., *supra* note 16. The most famous case in this regard is Coca-Cola. The formula of the American drink is not protected under patent law, but under trade secret.

[77] Allred, B. B., & Park, W. G. (2007). Patent rights and innovative activity: evidence from national and firm-level data. *Journal of International Business Studies , 38* (6), pp. 878-900.

powers become the sole supplier of a particular good.[78] Other agents have the possibility to arrange collaborative licensing agreements. However, this argument can easily be deconstructed if one assumes that collaborative enterprises depend almost entirely on the will of the patent holder to provide for it.

Therefore, by providing exclusive rights over an invention, policy-makers are indeed promoting imperfect competition on the market. This trend has been challenged by some authors who emphasize that intellectual property law lures creators to disclose, thereby preventing intellectual monopolies. It can be seen as a sort of advertising of the invention, attracting others to make use of it.[79] This mechanism renders it easier for competitors to reinvent around the patent claims, avoiding infringement.[80] Disclosure may for that reason have a positive effect on general knowledge because it allows for knowledge spillovers, opening the way for others to innovate as well.[81] The nonexistence of patent protection would, from this point of view, result in the attempt by the inventor to keeping the invention secret as an alternative protective measure, thus negatively affecting the stock of knowledge available to society as a whole.[82] Yet, reinventing around the patent, as well as patent races are responsible for the intrinsic rent-seeking nature of the system. This characteristic can be seen as economic wasteful, in the sense that it wastes resources by fostering duplicative, uncoordinated innovative activity. In addition, disclosure does not always ensure the diffusion of inventions in competitive terms, because markets for access to information do not work as well in practice as they seem to work in theory.[83] The brand name of a patented product may outlive the life

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[78] Yet patent law provides for the possibility of reinventing around a patent, which can offer a viable substitute thereby granting competition on the market.
[79] See Mazzoleni & Nelson, *supra* note 73.
[80] Landes & Posner, *supra* note 20.
[81] Allred & Park, *supra* note 77.
[82] Landes & Posner, *supra* note 20.
[83] «The premise that stronger protection will always improve the incentives to innovate is also open to challenge. Unimpeded diffusion of existing technology is immediately beneficial not only for consumers but also for those who would improve that technology. Because technological advance is often an interactive, cumulative process, strong protection of individual achievements may slow the general advance. This would not occur in a hypothetical

of the patent, as it happens quite often in the market for pharmaceuticals where there seems to exist a higher brand loyalty. Then again, even though disclosure assures the diffusion of knowledge, the fact that the patent holder can deny the licensing of his product or process negates the purpose disclosure.

Landes and Posner view the phenomena of patent law from a different perspective. Fundamentally they sustain four economic arguments supporting patent law, concluding that patent law is a response to trade secrecy and monopoly.[84] Firstly, without patent law trade secrecy becomes a costly activity, while automatically the incentives on inventive activity would be «biased toward inventions that can be kept secret». Secondly, efficiency is may be higher in a situation where patents are preferred to secrecy, in the sense that the possessor of a secret may not be the most competent carry out a product or process execution. Thirdly, patent law seems to be the second-best solution to the problems created by trade secrecy, namely the difficulties related to licensing. Tendentiously, the more people know a secret the most probable it is that it is disclose. This renders licensing under trade secret law very expensive. Valuable processes or products which might be significant for knowledge spillovers tend to be kept undisclosed or within the sphere of knowledge of a few people. Last but not least, without a patent system, it is probable that markets organize through «along monopolistic rather than competitive lines». Monopolist production can discharge patent protection given that it has advantages such as lead time, secrecy, moving quickly down the learning curve or business strategies (such as sales and services efforts).[85] On the other hand, competitive firms depend heavily on legal protection of their achievements in order to benefit from opportunities for cost reduction and product development.

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world without transaction costs, in which efficient contracts to share information would be made. In reality, however, markets for rights to information are subject to major transactional hazards, and strong protection of a key innovation may preclude competitors from making socially beneficial innovations». *In* Levin et al., *supra* note 16.

[84] Landes & Posner, *supra* note 20. See also subchapter 1.6 for details on trade secret law.

[85] Levin et al., *supra* note 16.

This point of view roughly illustrates the utilitarian justification for intellectual property in general and patent law in particular. Many authors consider this justification for patent law flawed, arguing alternatively that patent law suffers from lack of incentives. In general terms, because patents confer monopoly powers over a product or a process to the first person to come up with it (or the first person to fill up the patent application), they exclude competitors from its direct usufruct, delaying the diffusion of new knowledge. As argued by Joan Robinson, the utilitarian justification for patent law is an innate contradiction, for its justification «is that by slowing down the diffusion of technical progress it ensures that there will be more progress to diffuse»[86]. Stronger intellectual property, one might find in the literature, is not always synonymous with incrementally improved innovative activity. Superior prizes may simply result in duplicative efforts by private parties to reach it, thus wasting social resources which could have been channeled to other economic sectors.[87]

[86] Robinson, J. (1956). *The accumulation of capital*. London: Macmillan.
[87] Levin et al., *supra* note 16.

1.3 Copyright law

Even though the bases from which copyright and patent law stem from are shared, they feature different elements and rights and, at the same time, they focus on the incentive of different fields of creativity. Copyright is a branch of intellectual property which protects literary and artistic creations which include books, paintings, dance, dramatic works and music. Monopoly over original works of authorship seem to be granted not only on the basis of a utilitarian logic (to foster creation), but also because of society's will to reward authors for their effort.

Since monopoly over ideas in imaginative works brings about an enormous welfare loss[88], copyright law protects only the *form of expression* of creative ideas, unlike patent law which protects the ideas themselves. Given that it doesn't protect the ideas, but only their expression, the duration of the protection can be longer than that of a patent without damage to the public interest.[89] The reason why ideas are not protected under copyright is because they might be either commonplaces, as for instance literary techniques or familiar subject matters or places, or they might be "original" ideas in a broader sense. Some examples of the latter are cubism or the twelve-tone music.[90]

The concept of damages to the public interest is personified in the idea/expression dichotomy. This doctrine limits the copyrightability of works on the basis of their function and expression. Making use of a certain art does not confer upon its user the right of exclusivity over that particular idea, even if that general idea is completely novel. One might have exclusivity over a particular expression of that idea, though, exactly because that idea might be

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[88] *Id.*
[89] World Intellectual Property Organization, *supra* note 10.
[90] Landes and Posner, *supra* note 20.

expressed in many ways.[91] Not only does the literal text fall under protection, but also non-literal elements such as text structure, sequence and organization, so that paraphrasing is not enough to circumvent copyright law.[92] The economic reasoning behind this doctrine puts emphasis on the welfare losses of the monopoly over an idea but also the increase in the cost of creating works and consequent reduction in the overall production of works[93], which would be contrary to the fundaments of copyright.

Given the large range of protectable works and the lower standard for originality (only a minimum originality is required), copyrights are more limited than patent law. Protection is conferred only against illegal copying and distribution (extended only to the first sale) and against the unauthorized preparation of derivative works and performance or display by others[94]. The legal texts in the Europe treat separately the reproduction right, the right of communication to the public of works and right of making available to the public other subject-matter and the distribution right[95]. At the same time, given the limit in breadth the life span of copyrights tend to be longer. In the United States, copyrights extend for 70 years after the author's death, or in the case of entity authors, for a total time limit of 95 years from the year of publication or 120 from the year of creation, whichever occurs first.[96] In the European Union, the duration of copyrights was agreed among European countries to be of 70 years from the death of the author with the Council Directive 93/98/EEC of 20 October 1993 harmonizing the term of protection of copyright and certain related rights. This directive extended the previous duration of 50 years *post mortem auctoris*, laid down in the Berne Convention for

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[91] Copyright does not extend to ideas, procedures, processes, systems, methods of operation, concepts, principles or discoveries.
[92] Merges, Menell & Lemley, *supra* note 12, at p. 367. Clearly it may be sometimes hard to draw the line between idea and expression, given the possibility that both are closely aligned. In the case where the idea is merged with its expression, courts usually apply the "merger" doctrine. This doctrine states that where there are very few ways of expressing an idea, copyright law does not apply.
[93] Landes & Posner, *supra* note 20, at p. 93.
[94] Merges, Menell & Lemley, *supra* note 12, at p. 323-324
[95] Directive 2001/29/EC, OJ L 167, p. 10 of 22.05.2001. See respectively Articles (2), (3) and (4).
[96] Merges, Menell & Lemley, *supra* note 12, at p. 323.

the Protection of Literary and Artistic Works. It is worth to note that in the particular case of copyright law an extension in the duration of rights shrinks the public domain considerably in the short-run, while bringing little innovative effects.[97]

As we underlined previously, copyright offers the «exclusive right to copy, reproduce, distribute, adapt, perform or display their works»[98], so as to protect their originality. The term copyright derives from the philosophy of the United Kingdom's regime which focuses on the *rights to make copies* for the sake of promoting advancement in the arts and literature. In Europe, the corresponding body of law is known as *droit d'auteur*, which has its origins in a different philosophical approach to the issue: the natural and the personhood rationale grant intrinsic rights to the authors for their original works. This evolution from the French concept *droit d'auteur* underlines the moral rights of the authors over their work and it is almost unrecognized in the United States.[99]

Hence, copyright law can be said to evolve from two distinct categories rights. Firstly, it protects the *economic right* of the owner over their creation. This means that the creators have exclusive rights of exploiting financially their work. Secondly, the creator has a *moral right* over their work, that is, the right to claim authorship of the work and the right to object any distortion or modification of the work. Therefore, given the economic and moral rights of the creator, these may either prohibit or authorize the reproduction, distribution, public performance, broadcasting, translation or adaptation of their creation. These rights are, in the American system, not dependent upon the registration of the

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[97] See Landes & Posner, *supra* note 20. Chapter 8 in Landes and Posner's book (Optimal Duration of Copyrights and Trademarks) deals with this issue in detail.
[98] Scotchmer, *supra* note 28.
[99] See Izzo, U. (2010). *Alle origini del copyright e del diritto d'autore. Tecnologia, interessi e cambiamento giuridico.* Rome: Carocci.

copyrighted work. On the other hand, registration is useful in terms of evidence.[100] Copyright attaches as soon as a work is fixed.[101]

According to the second article in the Berne Convention for the Protection of Literary and Artistic Works states that «the expression 'literary and artistic works' shall include every production in the literary, scientific and artistic domain, whatever may be the mode or form of its expression». The following list provided in the Berne Convention includes:

- books, pamphlets and other writings;
- lectures, addresses, sermons;
- dramatic or dramaco-musical works;
- choreographic works and entertainments in dumb show;
- musical compositions with or without words;
- cinematographic works to which are assimilated works expressed by a process analogous to cinematography;
- works of drawing, painting, architecture, sculpture, engraving and lithography;
- photographic works, to which are assimilated works expressed by a process analogous to photography;
- works of applied art, illustrations, maps, plans, sketches and three-dimensional works relative to geography, topography, architecture or science;
- translations, adaptations, arrangements of music and other alterations of a literary or artistic work, which are to be protected as original works without prejudice to the copyright in the original work;
- collections of literary or artistic works such as encyclopedias and anthologies which, by reason of the selections and arrangement of their contents, constitute intellectual creations are to be protected

[100] In fact, if registration on the Copyright Office in Washington takes place within 5 years after publication, the author will obtain undisputable evidence of copyright's existence.
[101] See Merges, Menell & Lemley, *supra* note 12.

as such, without prejudice to the copyright in each of the works forming part of such collections.

However, this list is not exhaustive, in the sense that it is up to national legislation to include other items in it. For instance, computer programs are not included on the Berne Convention's list but these are widely protected under American copyright law. For that reason, computer programs were included in the WIPO Copyright Treaty established in 1996.[102] European countries are less liberal regarding the patentability of computer programs.[103]

Copyright protects against deliberate copying, thus unintended duplication of the copyrighted work is not considered to be infringement. This does not happen in patent law. Duplication is unlawful in patent law because issuing a patent involves an intense research of prior inventions. As stated previously, copyrights are simply asserted by the author or the publisher, mainly because it is fairly infeasible for the author or the responsible authority to read all the copyrighted material to make sure no duplication has been inadvertently done.[104] Accordingly, courts must have a mechanism to know whether a work as been copied illegally or not. Merges, Menell and Lemley comment on this: «While in rare cases direct proof of copying may be available, usually it is not. In its place, courts infer copying from proof that the defendant has had access to the plaintiff's work combined with evidence that the two works are similar. Even if copying is established, it must be further shown that the defendant's work is substantially similar to protected elements (e.g. excluding ideas) of the plaintiff's work».[105]

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[102] World Intellectual Property Organization, *supra* note 3.
[103] European Patent Convention, *art.* 53, Oct. 5, 1973 excludes computer programs from patentability. Namely paragraph (3) reads as follows: «The provisions of paragraph 2 shall exclude patentability of the subject-matter or activities referred to in that provision only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such. »
[104] Landes & Posner, *supra* note 20.
[105] Merges, Menell & Lemley, *supra* note 12, at p. 25.

1.3.1 Limitations on Copyrights

Some limitations on the use of copyrights are recognized by the American and European legal systems. The fair use doctrine, for instance, provides for a number of situations in which quoting is to be considered within legal parameters. In the United States the fair use doctrine covers criticism, comment, news reporting, teaching, scholarship, and research in the list of *fair* purposes. This list is not exhaustive, neither are these examples to be considered fair use in all circumstances – it will depend on such issues as the purpose and character of the use (including whether such use is of a commercial nature or is for nonprofit educational purposes), the nature of the copyrighted work, the amount and substantiality of the portion used in relation to the copyrighted work as a whole, as well as the effect of use upon the potential market for or value of the copyrighted work.[106] Other limitations include inequitable conduct, that is, when the copyright is obtained through fraud or other deceptive conduct. The European legislation on copyright also includes a list of numerous exemptions[107]. Clearly, these limitations are applicable in special occasions as long as they «do not conflict with a normal exploitation of the work or other subject-matter and do not unreasonably prejudice the legitimate interests of the rightholder».[108]

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[106] Copyright Act, 17 U.S.C. § 107 (1992).

[107] Directive 2001/29/EC, *supra* note 95. Article 5(3) includes reproductions by public libraries, educational institutions or archives for non-commercial use; preservation of recordings of broadcasts in official archives; use for illustration for teaching or scientific research, to the extent justified by the non-commercial purpose; uses directly related to a disability, to the extent justified by the disability; press reviews and news reporting; quotations for the purposes of criticism or review; uses for the purposes of public security or in administrative, parliamentary or judicial proceedings; uses of political speeches and extracts of public lectures, to the extent justified by public information; uses during religious or official celebrations; uses of works, such as architecture or sculpture, which are located permanently in public places; incidental inclusion in another work; use for the advertisement of the public exhibition or sale of art; caricature, parody or pastiche; use in connection with the demonstration or repair of equipment; use of a protected work for the reconstruction of a building; and finally communication of works to the public within the premises of public libraries, educational institutions, museums or archives

[108] *Id.* See Article 5(5) of Directive 2001/29/EC.

1.3.2 The Digital Menace to Copyright Law

Improvements in technology have been affecting the way scholars conceive copyright law. Most industries that rely on copyrights to sell are now facing a deep structural change. Publishing houses, the music record industry and the like can no longer trust conventional business models to face this issue, even though they have proven to be «quite adaptable in the early generations of computer technology».[109] In particular the World Wide Web has been rendering the sharing of information and files cheap (or entirely free) and fast. Access to broadband Internet is nowadays proliferated and access to digital files has become an uncomplicated task. A common example might be the simple distribution of *.mp3* downloadable files on the web. The *public good* nature of information might help explaining this phenomenon: the small or non-existing costs of transaction of information through the Internet facilitate its flow and, in particular, it makes it harder for the original producer of such information to lose track of it. From this perspective, consumers of information goods may grow to be a competitor of the original producer.[110]

For the reasons mentioned above, the place of property in the digital era is a very debatable issue in our days. The preoccupation of protecting rights in the technological age has shaped a number of legal acts against hacking and illegal distribution of copyrighted contents, the most noteworthy of which perhaps the United States Digital Millennium Copyright Act (1998) and the very recent *Stop Online Piracy Act* (SOPA) and the *Protect Intellectual Property Act* (PIPA), two extremely controversial anti-piracy bills introduced to the US Senate in 2011.

The Digital Rights Management Act responded to the greater concerns of copyright holders about digital piracy in the international arena by ensuring anti-circumvention and anti-trafficking provisions with a very narrow list of exemptions.[111] Not only was circumvention outlawed, but also the circulation of material facilitating circumvention. Adrian Johns comments: «Hollywood

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[109] Merges, Menell & Lemley, *supra* note 12, at p. 496
[110] See Caso, *supra* note 11.
[111] See the Digital Millenium Copyright Act.

executives make front-page headlines when their companies join forces to sell movies online, having been spurred into rare cooperation by their mutual fear of losing control of their intellectual property. So serious has the prospect of piracy become for them that in the United States the Digital Millennium Copyright Act has even outlawed the promulgation of algorithms that *might* be used to disable or circumvent copy-protection devices. A graduate student coming to Nevada to present a technical paper can be arrested, not for pirating anything himself, but for divulging principles that might allow others to do so».[112]

The SOPA/PIPA acts[113] embody more recent attempts to reinforce intellectual property within the web domain. It has been causing much controversy amongst advocates of the need to provide the state with stronger enforcement tools on the Internet, and its opponents, who firmly highlight the negative impact of such a legal framework mainly on online freedom of expression and on websites that host user content.[114] Massive blackouts of host websites took place recently as a form of protest against these two bills.

The European Copyright Directive, on the other hand, confers on the Member States the responsibility to undertake «adequate legal protection» for copyrights in the digital realm. Article 6(1) reads that legal protection shall be pursued «against the manufacture, import, distribution, sale, rental, advertisement for sale or rental, or possession for commercial purposes of devices, products or components or the provision of services which: (a) are promoted, advertised or marketed for the purpose of circumvention of, or (b) have only a limited commercially significant purpose or use other than to circumvent, or (c) are primarily designed, produced, adapted or performed for the purpose of enabling or facilitating the circumvention of, any effective technological

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[112] Johns, *supra* note 5, at p. 3-4.
[113] Stop Piracy Online Act of 2011, H.R. 3261, 112 Cong., 1st Sess. (2011); and Protect Intellectual Property Act of 2011, S.B. 968, 112 Cong., 1st Sess. (2011).
[114] SOPA has a weakening effect on the "safe harbor" for websites that host user content included in the Digital Rights Management Act (the Online Copyright Infringement Liability Limitation Act).

measures».[115] These two legal sources reflect one side of the literature: the conviction that protection must come in more rigorous forms (for example, in the form of Digital Rights Management), that strengthening and enlarging copyright protection is the answer to the perils of digital progress.

The path substantiated by these two legal sources involves a continuation of the model for intellectual property described in this chapter so as to fight infringement and ensure revenues. It does so by making enforcement more inflexible than ever. Technological protection measures (TPM) – a number of tools that guide the proper use of copyrighted material – illustrate our case. These measures use techniques such as cryptography, watermarking and digital fingerprinting. However, the extent to which Digital Rights Management (DRM) enforce rights should be a matter of concern as far as it goes beyond the levels of protection laid down in copyright law. Digital locks facilitate the prevention both of illegal sharing (from casual copying to piracy) as well as of perfectly legal uses of digital goods, such as making personal backup copies of owned DVDs and software to protect against loss or damage, or using copyrighted materials for didactic purposes under the fair use doctrine. On the other hand, these measures are seen by industry (including software and entertainment in general) as an inevitable form of protection of copyrighted content. They may be compared to physical locks used to prevent a store from being robbed – just that information is a public good, so its leakage is more likely. DRM is, however, in accordance with the general trend at least in the developed countries to underpin control over intellectual property and its monopolistic revenues in an increasingly digitally-advanced world. For the purposes of our work it is worth noting that similar restrictions can be created on genetic technology.[116]

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[115] Copyright Directive, Art 6(1). *Technological measures* is defined in the directive as follows: «any technology, device or component that, in the normal course of its operation, is designed to prevent or restrict acts, in respect of works or other subject-matter, which are not authorised by the rightholder of any copyright or any right related to copyright as provided for by law».

[116] See Burk, D. L. (2007). Intellectual property in the context of e-science. *Journal of Computer-Mediated Communication , 12* (2), pp. 600-617.

Notwithstanding many attempts to shape copyright law in accordance with the most recent technological advancement (because Internet revolutionized copyrights law more than any previous technological improvement did), many believe copyrights are by now an anachronism and that will only lose effect with time. This negativism is associated with the relative impotence of policy-makers to enforce legal measures on the Internet, in particular the inability to control copies and charge royalties on them – a reflect of the immaterial nature of the digital world[117]. This view does largely correlate to the movement of Open Access and free licensing proposed in opposition to the movement of DRM. Some examples are projects like the GNU General Public Licenses and the Creative Commons (CC).[118]

This approach is based, contrarily to DRM, on the opening of information, that is, a flexible and decentralized attitude towards intellectual property rights. The Open Access movement assures special contractual arrangements for those who wish to make their material accessible to others. It has proven to be considerably successful in software projects, whereby the source codes are provided openly (open source) and ensured to be kept publicly available. Naturally, it is of primary significance in the case of publicly financed research. The details and questions arising from the open source movement will be handled in our chapters three and four.

In a nutshell, there seem to be two pathways developing hand-in-hand in copyright theory and law which are purely contradictory. Digital Rights Management, embodied in legislation and in accordance with later trends promoted by rights holders, presents strict digital protection measures. Digital Rights Management involves a stricter control over copyrighted material. On the other hand, there has been a development of a contrasting line of thought

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[117] Cole, *supra* note 9.

[118] Creative Commons. Retrieved February 10, 2012, from Creative Commons: http://www.creativecommons.org; and GNU. *General Public License (GPL)*. Retrieved February 10, 2012, from GNU: http://www.gnu.org/licenses/gpl.html

which is based on the freedom of access to knowledge contents.[119] Are we somehow approaching a moment of transformation in the way society conceives intellectual property? How do these two pathways interact? Do these lines of thought apply to other intellectual property branches, such as patent law? Could the Open Access approach bring benefits to other industries, for instance pharmaceutical and chemical industries or biotechnology industries? We will explore the open source movement in chapter three specifically applying to the case of plant and animal material.

[119] For a detailed contraposition of these two movements, see Caso, *supra* note 11.

1.4 Trademark Law

Trademarks are distinctive symbols that allow customers to relate a certain product or service to its source of origin, helping in making a distinction among goods in the market place. Nearly all marks can be registered as trademarks: names, symbols, logos but also slogans and phrases. Even a particular design of a product or its packaging may be protected under *trade dress*.[120] The existence of particular marks to identify the manufacturer of products has been a constant throughout the development of trade. In our days these marks serve particular informative functions.[121] Given that markets are characterized by quality uncertainty (it may be hard to tell whether one product is good and another is bad), trademark may serve as a vehicle of information so that consumers are able to associate the mark with its provenance. It is a matter of creating trust and a reputation. Brand names are particularly effective in counteracting the quality uncertainty effect.[122]

Thus, the informative aspect of trademarks reduces the costs consumers would have to incur in to test all concurrent products in order to make up their minds. This is true especially for very costly products such as cars. By associating it to the source of origin, the mark may supply the consumer with some background information. Trademarks may carry a certain level of value added by investments on the part of owners, for instance in higher quality of materials, advertising the product associated with the mark and so on. For that reason, trademark law protects them against counterfeiting, that is, the use by competitors of particular marks in order to take the advantage of that mark in

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[120] Merges, Menell & Lemley, *supra* note 12.
[121] *Id.*
[122] «Brand names not only indicate quality but also give the consumer a means of retaliation if the quality does not meet expectations. For the consumer will then curtail future purchases. Often too, new products are associated with old brand names. This ensures the prospective consumer of the quality of the product». *In* Akerlof, G. A. (1970). The market for "lemons": quality uncertainty and the market mechanisms. *The Quarterly Journal of Economics , 84* (3).

the market for particular products or services (consumers prefer that product because it is associated with that mark), thus avoiding incurring in additional investment costs.

It can be said that there are two main theories behind trademark. The first one is consumer protection, focusing on the informative function of trademarks and the second is producer incentive, highlighting instead the incentive for the producer to invest in the mark in order to being able to reap benefits in terms of reputation.[123] Yet, contrarily to other branches of intellectual property rights, trademark law does not serve the purpose of rewarding inventive and innovative activity or creations of the mind. Even though it may promote inter-brand competition, trademark law does not transmit the economic incentive argument. Trademark simply awards the first one to make commercial use of that particular mark.[124]

In the USA, trademark law is protected under the Lanham Act, enacted in 1946 and its development (with some exceptions) has been towards an expansion of the rights of trademarks holders.[125] The Lanham Act divides trademarks into four categories: a) generic, b) suggestive, c) fanciful and d) arbitrary. Fanciful and arbitrary trademarks are the strongest, because of their particular uniqueness. Generic marks are, on the other hand, not protectable under American trademark law. This is rather important to grant that competitors can use the most appropriate terms to describe their products without infringement. Bayer's Aspirin was held generic for acetylsalicylic acid and therefore unprotectable.[126]

The European Union provides for a Community Trade Marks system facilitating registration for the Union. This system is governed by the Council Regulation (EC) No 207/2009 of 26 February 2009 on the Community trade

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[123] Ramello, G. B. (2006). What's in a sign? Trademark law and economic theory. *POLIS Working Papers* (73).

[124] «In trademark parlance, the senior (that is, the first) user of a mark may prevent junior (subsequent) users from employing the same or similar mark, where there is a "likelihood of confusion" between the two marks». *In* Merges, Menell & Lemley, *supra* note 12, at p. 530.

[125] *Id.*

[126] Bayer Co. v. United Drug Co., 272 F. 505, S.D.N.Y., 1921.

mark and it is one of the tools in the Office for Harmonization in the Internal Market (OHIM). Trademark law continues to be, however, a matter of national legislation and therefore it is possible to register a trademark in the single member states. European trademark law does also recognize the right of seniority. Registered Community trademarks have the duration of 10 years, renewable for further period of 10 years as long as fees have been paid.[127] The Directive 2008/95/EC of the European Parliament and of the Council of 22 October 2008 updated existing legislation on the approximation of the trademark laws of the several member states to the Union.

Trademarks are important for our discussion because they tend to capture the loyalty of consumers specifically in what concerns pharmaceutical products. Brand-names tend to outlive patents in drugs, thus generic equivalents generally enter market where competition becomes a very hard task. Even though generic and original drugs are identical in their composition, brand loyalty reduces consumer price sensitivity. It might be therefore argued that in some specific cases trademark fails to perform its informative function in a more general framework.

[127] Council Regulation (EC) No. 207/2009, OJ L 78, of 24.03.2009. See specifically Articles (46) and (47).

1.5 Trade secrets law

Trade secret law protects individuals and businesses against the misappropriation of trade secrets by improper means. Improper means include criminal acts such as theft, bribery, espionage and fraud, as well as torts and noncriminal acts such as breaching contracts, violating confidential information and the like. Trade secrets may be defined as any valuable information (a chemical compound or a process of manufacturing, for instance) which is eligible for protection, that is, it must not be commonly known to the industry.[128] Clearly there are also legitimate means of learning of a secret, for instance discovery by independent invention or by reverse engineering.[129]

Unless secrets leak out, in theory they can be kept infinitely. A good example of that is the formula for Coca-Cola. Thus, the duration of protection is dependent upon the public disclosure of the secret. In practice much secret information is unveiled after some years.[130] By consenting information to be kept undisclosed, trade secrets law contravenes all other forms of intellectual property where disclosure is either an obligation (patent law) or something inevitable (trademark law). The absence of disclosure compromises is the reason why some industries tend to prefer trade secrets to intellectual property protection in the case of processes.[131]

Theories of trade secrecy highlight its utilitarian and tort functions. The incentive theory focuses on the inducement for creation of protectable

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[128] Merges, Menell & Lemley, *supra* note 12, at p. 31.
[129] *Id.*, at p. 67.
[130] Scotchmer, *supra* note 28.
[131] Levin et al., *supra* note 16.

information while the tort theory emphasizes the deterrence of wrongful acts through legal punishment of illicit behavior.[132]

The American trade secrets law defines trade secret as «any information that 1) derives economic value from not being readily known to, or ascertainable by, others, 2) whose owner has taken reasonable steps to keep it secret, and 3) is not publicly available».[133] The second point highlights the need to take reasonable precautions against misappropriation of secrets. This means that the owner of the secret must adopt precautions such as nondisclosure agreements and other security means and of being able to demonstrate in court that she took appropriate measures of protection. Which level of protection is appropriate is a matter open to discussion. It is common that trade secrets cases stem from a particular contractual obligation (for instance, the breach of a confidentiality duty under an employment contract).

[132] Merges, Menell & Lemley, *supra* note 12.
[133] Scotchmer, *supra* note 28.

1.6 General problems at the intersection between conventional models of intellectual property protection and biological material

Both costs and benefits are recognized in the literature on intellectual property rights. In the present chapter we have focused on the mechanisms of specific branches of intellectual property. We will now summarize the main ideas of the chapter according to the corrosive character of intellectual property over scientific research on biological material.

1.6.1 Intellectual property protection models tend to favor commercially-oriented research.

Genetic resources are highly valuable in particular for the biotechnology, chemical and pharmaceutical industries. This does not only nourish "patent races" but it may also result in an overinvestment in patentable intellectual property, and consequently in an underinvestment in basic research and education. Given that basic research does not tendentiously enter the patent mechanism, a great part of the basic research done in developed countries is funded by the state, particularly in universities and public laboratories.[134] However, most of the basic research performed in the public sphere is the pillar of commercial research and development.

In the United States, however, the Bayh-Dole Act of 1980 authorized universities to seek for patents on federally funded innovations.[135] This act contributed greatly to a diverse allocation of resources also within universities,

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[134] See Caso, *supra* note 11.
[135] Runge, F. (2004). Enclosure, intellectual property and life sciences research. *Journal of World Intellectual Property , 7* (6), pp. 807 -827.

typically favoring research with commercial application. It did also contribute greatly to fencing information which was previously exchanged without barriers. Another aspect of this is that successful innovators are rewarded twice, first through government sponsoring and again through patents.[136] This distortion of incentives does not only divert inventive activity towards research that may be more commercial, but also towards products that may be easily patentable.[137]

Another problem associated with the commercial value of scientific discoveries deals with the direction towards which research and development is driven. Even though a certain number of diseases deplete the third world, research of development in pharmaceutical companies has been deviating from those and concentrating on diseases in the developed countries. The reason for this is the market for pharmaceuticals is bigger in the latter: people living beyond the line of poverty can hardly afford drugs at monopolistic price levels. In sum, pharmaceuticals are being developed according the power of market demand rather than according to the number of people in need of the drugs.

1.6.2 Intellectual property fosters strategic patenting and delays the introduction of innovative products in the market.

The main feature of patenting in the life sciences is uncertainty. What has no commercial value today may be a "jackpot" in a few years, but it can also have no marketable value at all. This intrinsic nature of life sciences gives an incentive for companies (and universities in the United States) to patent resources before they know their actual commercial value.[138] Technological uncertainty and the prospect of changes in demand call for early patenting, reducing thereby the threat of competition. This strategic, non-cooperative use of patents in the life sciences (defensive and suppressive patenting) is a means

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[136] Scotchmer, S. (1991). Standing on the shoulders of giants: cumulative research and the patent law. *The Journal of Economic Perspectives , 5* (1), pp. 29-41.
[137] Cole, *supra* note 9.
[138] Takalo and Kanniainen, *supra* note 19.

to «keeping competitors away from the market for a new product or service».[139] By blocking economic rivals from accessing important information, patent holders may be slowing down market introduction of innovative medicines, chemicals and the like. This happens mainly because reduced rivalry may result in a reduction of the incentives for the patent holder to innovate.[140]

1.6.3 Patent systems are not sensitive to the cumulative nature of innovative activity.

Most literature on the patent system focuses on isolated innovation. However, innovation tends to be cumulative, that is, technologies may be upgraded or simply incorporated in further technology.[141] For that reason, second generation developers must access first generation technologies. While facilitating the disclosure of information (the disclosure requirement demands detailed information on the to-be patented invention), patents create real obstacle in the flow of information among the scientific community (or scientific communities). When patent breadth is large, the probability of infringement by second-generation scientists is more likely. This was the case of the patents on genetically modified soybeans and cotton which are owned by *Agracetus*, and their duplication is unlawful under the Plant Variety Protection Act, regardless of the process used to achieve the result or the traits engineered.[142] In contrast, narrow patent rights incentive further innovation, by reducing the probability of infringement by second-generation products. Narrow patents may, however, hinder first-step innovative activity (by reducing

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[139] These are sometimes called "sleeping patents", for owners use them strategically to avoid the entrance of the technology in the market. This may happen for several reasons including the acknowledgement that competitors will come out benefited with the invention (they can make better use of it than the inventor itself) or simply to give the owner time to understand the market value of the technology. Some of these patents are never used in the practical sense; they may however be used to "mark the territory" of the patent in an aggressive way (seeking royalties even if that involves costly litigation). This strategic use of patents became well-known in the information technology market as "patent trolls". See Landes & Posner, *supra* note 20, at p. 320-322. For a deeper look at the effects of sleeping patents and royalty stacking on the market for information technology, see: Lemley, M., & Shapiro, C. (2007). Patent hold-up and royalty stacking. *Texas Law Review , 85*, pp. 1991-2049.

[140] Takalo and Kanniainen, *supra* note 19.

[141] Scotchmer, *supra* note 28.

[142] Svatos, M. (1996). Biotechnology and the utilitarian argument for patents. *Social Philosophy and Policy , 13* (2), at p. 113.

the breadth of protection). The problem becomes even more complex when first-step innovation has little value standing alone. Scotchmer explains: «The problem of cumulative research is especially acute when the first technology has very little value on its own, but is a foundation for valuable second generation technologies. Even with licensing, the first innovator might not capture the full social value that it facilitates and may have deficient incentive to invest. This is presumably why governments fund basic research. The branches of government which fund research are not those that set patent policy, and the decision to support basic research might be interpreted as recognition that patents and licensing are inadequate».[143]

1.6.4 Intellectual property rights increase transaction costs.

Applying for patents and trademarks is a costly venture. The same must be said about trade secret: maintaining secrecy may entail large expenses in protecting the information (physical protection, guarding, and so on). However, those are not the only costs to bear when protecting intellectual property. Yearly fees are often required for the maintenance of the protection. Litigation costs, however, are very significant. It is important to note that the absence of power to enforce one's patent renders that protection worthless. This undertakes important distribution issues. Take the case of two hospitals, one in Boston and one in Toronto, which were working on the same gene. At some point the Toronto hospital had to drop the application for the patent because it could not afford the $20,000-plus cost for pursuing the patent.[144] Unless the power to exclude exists, the incentive to create intellectual property may be harmed.

In addition, because most scientific research builds on previous knowledge, multiple holders of complementary components of a single technology bump the costs of transaction of that technology up in the market for technological exchange.[145] Transactions costs incorporate both the sale and the transfer of

[143] Scotchmer, *supra* note 136.
[144] Svatos. *supra* note 142.
[145] Heller & Eisenberg, *supra* note 22.

interests from patent holders to second generation developers. It may be the case that total costs exceed the benefits from technological progress.

1.6.5 Trademarks outlive patents, retarding competition in the market for drugs.

Patents have in general a minimal duration of 25 years, but trademarks can be kept potentially forever. Loyalty of to pharmaceutical products tends to be quite high; therefore when patent rights come to an end the brand-name extends in a sense the life of the patent. While generic pharmaceuticals enter the market, prices of trademarked pharmaceuticals tend to be high at least for some time. Generic and trademarked drugs are chemically equivalent, but the initial differentiation in price does not express this equivalence in quality. Therefore, generic drugs may not find a perfectly competitive market at the end of the life of patents for drugs.

1.6.6 Legal monopoly is a dangerous policy.

Among other doctrines, the patent misuse doctrine analyzes the difficulties at the intersection between intellectual property and antitrust. Intellectual protection creates a limited exception to antitrust laws, but these two bodies of law are intertwined. The possibility that a patent holder could discourage further research in the field covered by the patent or seek to cartelize an industry through licensing agreements that foster collusion are a real risk society has to take in order to protect intellectual.[146] Monopolists become *price makers* at the costs of less availability of the product in the market. They are able to do so thanks to their right to regulate the use ideas, that is, to have powers that go beyond first sale.[147]

The consequences of monopoly may be measured in terms of social costs. Competition pushes market prices closer to their marginal cost of production. Monopoly has the contrary effect: it allows prices to surmount and output to

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[146] Menell, *supra* note 18; see also Lemley, M. (1990). Economic rationality of patent misuse. *California Law Review , 78* (6), pp. 1599-1632.
[147] Boldrin, M., & Levine, D. K. (2002). The case against intellectual property. *The American Law Review , 92* (2).

fall below the competitive level.[148] This question of access is particularly important when dealing with biological material and their application in industry. The case of the pharmaceutical industry is typical, because the question of access to drugs is intertwined with fundamental human rights widely recognized in the international scenario, for instance the right to health. By reducing the threat of competitors, patents on genetic lines and the like may permit pharmaceutical patent owners to delay the use of important discoveries. This policy choice may result in a prevalence of patentees' rights over widely recognized human rights.

1.6.7 Strengthening of patent rights does not always translate in higher overall benefits.

Several studies test the extent to which stronger intellectual property affect innovative activity. There seems to be uncertainty among scholars about the effects of stronger patent rights on innovative activity. For instance, Kanwar and Evanson's study encourage the strengthening of patent rights as a means to spur R&D investments in terms of GDP and to incentive foreign direct investment[149]. Nonetheless the results in Kanwar and Evanson are not shared by other scholars. Building on results of previous studies, Landes and Posner conclude that «incremental increases in patent protection are unlikely to influence inventive activity significantly and incremental reductions might actually enhance economic welfare».[150] However, they affirm that it is not possible with our current knowledge to judge whether patent protection should be narrowed or broadened. Branstetter and Sakakibara corroborate these findings by concluding that the Japanese expansion in patent rights in 1988 had no effects on the country's innovation rate or research and development

[148] See Posner, R. A. (1975). Social costs of monopoly and regulation. *National Bureau of Economic Research , 83* (4), pp. 807-828.
[149] Kanwar and Evanson conclude that an increase in patent protection leads to higher R&D investments as fraction of the GDP in the 31 countries approached for the study. However, these results have been criticized by several authors, including Boldrin and Levine, who pointed out that the market size as measured by GDP was undermined in this approach to intellectual property protection. In this sense, the study by Kanwar and Evanson may also suggest that large and rich countries will invest a larger share of their GDP in R&D when compared with smaller, poorer countries. Boldrin & Levine, *supra* note 147, at p. 209.
[150] Landes & Posner, *supra* note 20, at p. 327.

expenditures.[151] On the other hand, Qian argues that intellectual property alone does not stimulate domestic innovation. The capacity to innovate depends heavily in other factors such as the level of development, the level of education and the economic freedom in a country.[152] Allred and Park stress this point as well when analyzing that the effects of stronger patents undermine the difference economic responses of economies at different development stages.[153] Boldrin and Levine highlight the fact that the right of patent and copyright holders to regulate the *use* of their ideas – what they call "intellectual monopoly" – heavily affects general societal freedoms.[154] Johns argues that the strengthening of digital rights management tools poses a serious threat to the ideals of a democratic information society, including questions of privacy.[155] In favor of the opposite thesis, it is argued by Clark that in spite of all the criticism around the patent system, in what concerns biomedical research and intellectual property rights there have been a beneficial coexistence. According to the author, this holds true as long as there is respect for rights, recognition of contributions and a belief in advancing knowledge for the benefit of all.[156]

1.6.8 Harmonization of Intellectual Property Regimes attempted by the WIPO may profoundly harm the bargaining power of developing countries.

While developed countries may benefit from stronger intellectual property rights, developing countries may not.[157] Economic activity in developing countries tends to start off from an existing technological basis and works on an imitative basis in order to being able to compete in the international markets. By setting the minimum standards for the implementation of stronger

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[151] Sakakibara, M., & Branstetter, L. (1998). Do stronger patents induce more innovation?: evidence from the 1998 Japanese patent law reforms. *National Bureau of Economic Research* (2).
[152] Qian, Y. (2007). Do national patent laws stimulate domestic innovation in a global patenting environment? A cross-country analysis of pharmaceutical patent protection, 1978-2002. *The Review of Economics and Statistics , 89* (3), pp. 436-453.
[153] Allred & Park, *supra* note 77.
[154] *In* Boldrin & Levine, *supra* note 147.
[155] Johns, *supra* note 5, at p.507.
[156] Clark, J. (2011). Do patents and IP protection hinder biomedical research? A practical perspective. *The Australian Economic Review , 44* (1), pp. 79-87.
[157] Qian, *supra* note 152; and Allred & Park, *supra* note 77.

protection regimes, the TRIPS agreement left developing countries with two options: learn by doing [158] or rely on technological transfer from developed countries. While in "the North" the existing system of protection of property rights might provide an efficient system of equilibrium between access and incentives to innovation through an optimal duration and scope of protection, the same may not happen in "the South" of the world, given the size of their markets and the level of development of their economy in the whole.

This North-South conflict on intellectual property is particularly interesting in our discussion around biological materials. While developing countries tend to be very rich in genetic material (given to more extensive fauna and flora), but very poor in terms of technological advancement, the opposite happens in the developed part of the world. Therefore, the commercial value of genes appreciated by industries in developed countries exists within the borders of others countries. The latter, though, ignore this potential and often do not take measures to protect genetic resources, because they have no incentives to do so. This is mainly for the reason that the financial benefits from genetic exploration are reaped off only by technologically advanced parties.[159]

1.6.9 Patent law may not be socially justified.

There is no solid study proving that the economic benefits of intellectual property protection outweigh the deadweight loss caused by a legal monopoly. The reduction of access to an intellectual good is achieved by the artificial scarcity created – this is a social cost. On the other hand, the possibility to reap off consistent gains from their innovative ideas increases the incentive for creation in the first place – this is a social benefit.[160] The idea is that the consumers who will purchase a good at the monopoly price will suffer a loss,

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[158] *Id.* This entails however an effort of resources which may not be available in the developing world.

[159] There is no intellectual property claim to genetic resources, for these are common heritage of mankind. However, if those resources are incorporated in commercial products, patent rights may be conferred. This favors technologically advanced countries, creating disequilibrium in the distribution of financial benefits between North and South. See Sedjo, R. A. (1992). Property rights, genetic resources and biotechnological change. *Journal of Law and Economics , 35* (1), pp. 199-213.

[160] Landes & Posner, *supra* note 20.

but that loss corresponds to the additional revenue to the hands of the inventor. This is not generally seen as a loss, but as a transfer from consumers to the owner. However, the consumers who will be excluded from access to the good will suffer a loss which is not offset by gains to the patentee. The deadweight loss of the patent system rests here.[161]

In addition, the rent-seeking nature of patent law, in particular in the pharmaceutical industry, provokes a lure of investment in research in that area, even though those resources could be socially more productive in other industries. Capital allocation is, thus, based on the prospect of acquiring a patent[162], as we argued before. Is the weight worth its overall benefits? There is a need to reach for the right balance between costs and benefits.[163]

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[161] Posner, *supra* note 148.
[162] *Id.*
[163] Merges, Menell & Lemley, *supra* note 12.

2 PROPERTY RIGHTS OVER NONHUMAN BIOLOGICAL MATERIALS

The present chapter, in the light of the knowledge basis explored in the previous one, will examine the relationship between intellectual property rights, other sorts of property rights and genetic resources from nonhuman sources. Recent progresses in the life sciences, particularly in the fields of biotechnology, biomedicine, pharmacology, pharmacogenomics, and the like have increased the magnitude and complexity of that relationship. Even though historically there were doubts about the patentability of biological inventions, one way or another, life forms have been accommodating within numerous legal systems around the world. What began with Pasteur in 1873 in the United States as a patent on single-celled organisms has overtime been extended to higher forms of life namely transgenic animals and genetically modified plants.[164]

Debates around the issue of ownership over biological resources have increased accordingly. In international forums, the subject seems to be dividing nations around the world. Political compromises leading to several multilateral agreements built up a complex international regime – with clear legal and economic spillovers in national legislations – which has become somewhat confusing and perhaps even paradoxical in specific cases. In order to better deconstruct these debates, we have divided the present chapter in two main parts. The first part will provide an overview of the international governance on matters of biological materials, intellectual property rights and sovereignty-based rights. The second part will address the key issues and main debates

[164] For a general view of issues related to the legal development concerning patenting living organisms, see Rimmer, M. (Ed.). (2006). After the Gold Rush: Patent Law and Biological Inventions. *Law in Context Special Issue , 24* (1).

around these issues. The following chapter presents the opposite viewpoint, the open access model, which provides an alternative view to patent rights, sovereignty/community rights.

2.1 International governance of biodiversity and intellectual property rights – an overview of the legal sources

International treaties as well as national laws coexist in matters of intellectual property. As discussed in Chapter 2, patent law started out as a form of reward from governments to relatively innovative industrial endeavors. Rights over biological material instigated only with superior developments in science, taking place mainly in developed countries. Patent right claims over genetic information from plants, animals and microorganisms, and even plants and animals as such, do not go unchallenged. Indeed, these same patent rights recognized in international treaties and forums contradict the recognition of other sorts of rights in the international scene, for instance, farmers' right. Clearly, biological patents should not be perceived as any other purely utilitarian patent: there is more to it than clear-cut incentive policies. In fact, dealing with living organisms raises pertinent ethical, socio-economical and political questions. From the perspective of international relations, this issue enhances the technological gap between developed and developing nations. In an effort to gain bargaining power, countries of origin (especially least-developed countries, LDC) of genetically important organisms were recognized rights of ownership over those resources. Let us examine the major developments in the international scene which aggravated the privatization of biological materials.

2.1.1 Plant Breeders' Rights

Plant Breeders' Rights (PBR) have firstly been recognized with the International Convention for the Protection of New Varieties of Plants of 1961 (latest revision in 1991), known as the UPOV Convention. The basic

concept was providing a *sui generis* form of intellectual property protection for plant varieties[165], designed to support the specific plant breeding industry and which was effective in encouraging the development of new varieties of plants. Rights are only granted so far as varieties are new, distinct, uniform and stable.[166] A sui generis system was created especially because patent law was seen as highly unsuited for this purpose. Not only was plant material regarded as incapable of meeting the basic requirements of patent law, but also there was a common sense that extensive monopoly rights over plant varieties could be somehow harmful, thus the need to facilitate, as far as possible and differently from patents, the traditional free exchange of plant material.[167]

To meet these special features of plant breeding, the plant breeders' rights system contained, among other features, special exemptions from infringement which are not recognized under patent law. Commonly, there are exemptions for farm-saved seed (that is, farmers may save part of the production for seed), for experimentation use of plant varieties and there is a further provision on compulsory licensing to assure public access to protected varieties in case of national interest or impossibility by the breeder to meet demand. Evidently the frontiers between PBR and the patent system may be blurred in some cases.[168]

The International Treaty on Plant Genetic Resources for Food and Agriculture was signed in 2004, in the framework of the Food and Agriculture Organization (FAO), in order to guarantee food security through the conservation, exchange and sustainable use of plant genetic resources, as well as the equitable sharing of benefits arising from the use of genetic resources. [169]

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[165] International Convention for the Protection of New Varieties of Plants, Dec. 2, 1961. (UPOV Convention). Plant variety is defined in the Convention as «a plant grouping within a single botanical taxon of the lowest known 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.»

[166] *Id.* International Convention for the Protection of New Varieties of Plants, *art.* 5, 1.

[167] Llewelyn, M. (1997). The legal protection of biotechnological inventions: an alternative approach. *European Intellectual Property Review , 19* (3), pp. 115–127.

[168] Some countries, such as the United States of America, allow dual protection.

[169] International Convention for the Protection of New Varieties of Plants, *supra* note 166.

Through the Treaty, countries agree to establish an efficient, effective and transparent Multilateral System to facilitate access to plant genetic resources for food and agriculture, and to share the benefits in a fair and equitable way. The Multilateral System applies to over 64 major crops and forages and these are annexed to the Treaty. [170] Most importantly, the treaty recognizes farmers' rights[171] to access genetic resources regardless of intellectual property rights. In this regard, the international treaty promotes: a) the protection of traditional knowledge relevant to plant genetic resources for food and agriculture; b) the right to benefit sharing; and c) the right of farmers to participate in decision-making, at the national level, in relevant matters.

The aim was providing a system whereby 'basic needs' in terms of genetic resources are granted. In these same lines, Article 12 (3) of said treaty outlaws any claim of intellectual property rights or other rights that somehow limit the access to resources within the multilateral system on the part of the recipients. To what extent will these obligations be respected by sovereign nations and which enforcement mechanisms are to be utilized for that purpose are issues opened to debate.

2.1.2 Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) is under the 'umbrella' of the World Trade Organization. It was signed following the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in 1994. It is regarded as the most comprehensive agreement on intellectual property to the date. The TRIPS agreement is a package deal inside the WTO, for whatever country wishes to join the organization must comply with the obligations enshrined in the TRIPS.

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[170] *Id.*, Annex 1

[171] *Id.*, *art.* 9 recognizes the great contribution that local and indigenous communities and farmers have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world.

As globalization expands, and exchanges of goods and knowledge are carried out at the global level, it becomes more important for developed countries to ensure the harmonization of intellectual property rights systems worldwide. Also, intellectual property as such, represented by the technological progress, has overtime become fundamental in trade relations. [172]On this point, the TRIPS may be considered as a mechanism to narrow the gaps in the way intellectual property rights are protected in different nations around the world, hoping to bring them under common international rules.

In what concerns biological material in particular, the TRIPS Agreement establishes minimum levels of protection that each government has to give to the intellectual property of fellow WTO members. The minimum protection period for patents under the agreement is 20 years. Under Article 27 (3), the following *may* be excluded from patentability: «plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement. » The article also requires member states to provide protection for plant varieties either by patents or by an effective *sui generis* system, or a combination of the two, therefore making a reference to the FAO's International Treaty and to the CBD to the extent these relate closely.

Many criticize the TRIPS agreement on grounds of economic protectionism on the part of developed countries, of unfairness to developing countries[173], of

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[172] This is true to the extent that developed countries may be living out of knowledge economies, or knowledge-based economies. See Drucker, P. (1969). *The age of discontinuity: guidelines to our changing society*. New York: Harper and Row.

[173] It has been argued that the TRIPS agreement in reality hampers the access to medicines in the LDCs.

neo-colonialism and "biopiracy"[174], and even of obstruction of knowledge dissemination and production[175].

2.1.3 Convention on Biological Diversity (CBD)

Pressure from developing countries, generally suspicious that intellectual property rights give a considerable advantage to developed countries, led to a political compromise whereby *sovereign rights* over wild genetic resources were ensured. The Convention on Biological Diversity was signed in 1992 in Rio de Janeiro by 168 nations under the auspices of the United Nations, and entered into force the following year.

For the first time in international law, the *in situ* conservation of biological diversity[176] (including genetic resources and ecosystem species), its sustainable use and the fair and equitable sharing of its benefits were affirmed as a common *concern* of mankind. [177] These goals were also recognized as an important part of development policies, distinguishing the sovereignty of parties in matters concerning the use of wild genetic resources, underlying the necessity to sustainable use and conservation of habitats. The Nagoya Protocol on Access and Benefit Sharing[178], incorporated in the CBD, regulates the

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[174] This argument is constructed on the imperative that economic forces driving globalization push developing countries and local communities to accept conditions set by "the North" because of their own lack of bargaining power or rights. In this regard, corporations continue the colonialist tradition of 'appropriation' of indigenous knowledge and resources. See Merson, J. (2001). Bio-prospecting and bio-piracy: intellectual property rights and biodiversity in a colonial and postcolonial context. *Osiris , 5*, pp. 282-296.

[175] Henry, C., & Stiglitz, J. (2010). Intellectual property, dissimination of innovation and sustainable development. *Global Policy , 1* (3), pp. 237-251.

[176] It is important to make a distinction at this point between in situ and ex situ conservation.

[176]It is clear that banks are a good way to storage the information contained in genes. However useful they may be in collecting information, making it easily accessible and avoid total informational loss, ex situ collections are not the same as in situ wildlife. Whereas the latter allows for organisms to continue adapting to new stresses, the first "freezes" this natural evolution at some specific point in time. This is the reason why it is so significant to incentive countries to maintain their wild habitats instead of using that acreage for other purposes.

[177] Threats to biodiversity include climate change, deforestation, inadequate farming practices, overexploitation of stocks, environmental degradation, and poor crop planning. These issues are regarded as a common concern of mankind for they are not confined solely to particular countries. It is believed that the best way to tackle these threats is through mechanisms provided by international organizations.

[178] The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity was open to signature until the 1st February 2012.

access to and sharing of benefits arising from genetic resources. In a nutshell, the Nagoya Protocol establishes more predictable and transparent conditions for the access to genetic resources and helps ensuring benefit-sharing between COO and the parties making use out of such resources. Sharing is subject to mutually agreed terms and benefits may be monetary such as royalties or non-monetary such as the sharing of research results[179]. For that matter, the equitable sharing of benefits is one of the key concepts of the CBD as well as an important international legal principle.

Seeing it from another viewpoint, by focusing on sovereignty-based rights over genetic resources, the CBD fails to incorporate some important points. For instance, oceans amount to circa 70% of the world's surface, and their genetic resources are uncountable, many of which still unknown. The particularity of these resources is that in some cases they are situated in "no man's land", that is, on the international waters. [180]These resources fall under the scope of the Law of the Sea and have been labeled "common heritage of mankind". Why should these genetic resources be subject to a different treatment than those which happen to be on the face of the earth? It is rather unclear whether it is reasonable to make such distinction.

2.1.4 Sovereignty-based rights versus patent rights

Three distinct lines of thought can be recognized in the development of the international governance concerning nonhuman genetic resources. Whereas, on the one hand, some multilateral agreements recognize intellectual property rights over scientific inventions, other agreements emphasize rights of exclusive ownership at other levels, namely sovereign rights and farmers' rights. A third view is attached to the concept of open science, which will be dealt with separately in chapter three.

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[179] See *art.* 5 of the Nagoya Protocol.

[180] Deep sea genetic resources are commercially attractive for their immense genetic diversity, especially of species which live in tremendously adverse habitats, such as in hypothermal vents in the ocean floor. These resources are sometimes coined 'blue gold'. See Ruth, L. (2006). Gambling in the deep sea. *European Molecular Biology Organization Journal , 7* (1), pp. 17-21.

The enclosure of genetic material has been ensured both by patent protection of intellectual property and by sovereignty-based rights to countries of origin of genetic resources (COO). Patent law, as a response to higher pressure from developed countries, has extended both to more countries around the world (through the TRIPS agreement), and also to a vaster range of mainly biological inventions, genetic lines, gene codes and the like. The fear of developing countries that these exclusive rights would have been taken too far, as well as the acknowledgment of the need for LDCs to engage in conservation of their genetic diversity, has led international authorities to recognize their rights of sovereignty over these resources[181].

There was additionally a clear sense of inequity, since COOs did not have a share of the profits of the commercial exploitation of genetic resources originating within their borders. A typical example is the one of *vincristine* and *vinblastine*, two compounds from Madagascar's wild rosy periwinkle. The company which (accidently) discovered them, Eli Lilly & Company, made profits of millions of dollars and thanks to these discoveries, a cure for diseases such as pediatric lymphocytic leukemia was found. Conversely, Madagascar did not benefit in any sense from this discovery, even though the plant was found in its land.[182] Clearly this inequity raised distrust among developed and developing countries, leading the latter to increasingly demand rights for compensation as a consequence of use of their countries genetic heritage.

On these same lines emerged the debate about protection of traditional and indigenous knowledge. Rarely do intellectual property rights take due account of traditional and indigenous knowledge, and this is particularly true of genetic resources. Because tendentiously indigenous people and local communities have a better knowledge of the local fauna and flora and its properties, and perhaps have traditionally used them for medical care, they provide important

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[181] For a discussion about the relationship of these rights, see Safrin, S. (2004). Hyperownership in a time of biotechnological promise: the international conflict to control the building blocks of life. *The American Journal of International Law , 98* (4), pp. 641-685.
[182] Kadidal, S. (1993). Plants, poverty and pharmaceutical patents. *The Yale Law Journal , 13* (1), pp. 223-258.

informational inputs to the biotechnological and pharmaceutical industries. Incorporating these pieces of information in a product or process may earn the industries elevated profits and it may be very probable that such inventions are rewarded with a patent for their novelty, usefulness and utility. One may question how novel can something be when it is used commonly for centuries in an indigenous tribe. The United States of America features in the most controversial cases related to appropriation of indigenous knowledge and resources. The cases include: a US patent granted in 1995 for the healing properties of turmeric, incidentally known and used for the same purposes in India for centuries; a US patent on the ayahuasca plant used for medical purposes by Amazon's indigenous peoples; a US patent on a herbal combination with anti-diabetic properties commonly used and well-documented in the Indian scientific literature as well as ancient texts for this same medical purposes. [183] Note that the United States of America have declined the ratification of the CBD after signing it in 1992. Traditional knowledge rights have been also embraced by the WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.

The question is essentially whether nonhuman genetic resources should be accessible to all, with no restrictions, or whether property rights must be granted (either in the form of patent rights or sovereignty/collective ownership over these resources) in order to grant the conservation and rightful use of the "genetic gold". Our view is that the advancements in legislation and policy at the international level have promoted a «spiral of increased enclosure of genetic material»[184]. Developed and developing countries have been measuring their strength in the international arena, exercising pressure over international organizations to move towards a system of enclosure of materials which were once in the public domain. While patent rights are ensured by the Agreement on TRIPS and WIPO's Patent Cooperation Treaty, other legal sources, namely

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[183] Díaz, C. L. (2005). Intellectual property rights and biological material - an overview of key issues and current debates. *Wuppertal Papers*.
[184] Safrin, *supra* note 181, at p. 685.

the Convention on Biological Diversity and FAO's International Treaty on Plant Genetic Resources for Food and Agriculture, may be conflicting.[185]

2.2 Debates over ownership of genetic resources

2.2.1 Invention or discovery

There is debate around the issue of whether or not plants, animals and parts thereof fulfill the requirements for patentability under patent law as we know it. Historically discoveries have been excluded from patentability in Europe. On the other hand, under the U.S. statute, discoveries fall within patent protection, but products of nature are excluded.

However important it may seem to define *invention* in legal terms, one can hardly find such definition in legal texts. The exceptions of that include the United States Patent Act, which states that «Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement therefore may obtain a patent therefore». [186] The TRIPS Agreement does not provide a positive definition of invention, the same holds true for the Biotechnology Directive (Directive 98/44/EC). [187] In both cases, invention is defined negatively as opposed to *discovery*.

Discovery is generally defined as something that 'already exists in nature'. Products of nature and natural biological processes are not dependent on human input; they are simply waiting to be found out.[188] Even though the European patent law excludes discoveries and the American patent law excludes products of nature from patentability, both patent law systems cover

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[185] It may be relevant at this point to underline the likelihood of clash between developed and developing countries' points of view. On the assumption that patent law is largely designed upon Western values (supposing again that Western countries share the same values) it is only natural that they may not fit the values and the economic framework of developing countries. For a better explanation of the argument for property rights to countries of origin, see subchapter 2.2.5.

[186] 35 U.S.C. § 101

[187] As we have seen in chapter 1, Article 52 of the European Patent Convention lists a number of issues which shall not be regarded as inventions, including, among others, discoveries and scientific theories.

[188] Westerlund, L. (2002). *Biotech patents: equivalency and exclusions under European and U.S. patent law*. New York: Kluwer Law International.

products or processes that could be found also in nature. Natural and man-made, discoveries and inventions, imply at least in theory a quite clear distinction, even though in practice the state of affairs has increased in complexity. [189]

Let us examine in detail the scientific practice and the evolution of these concepts throughout time to incorporate the advancements of science.

2.2.1.1 Genetic engineering common techniques

In order to better understand the technical input in patents over living organisms, we will provide a simplified snapshot of how genetic engineering is normally performed. A genetic modification, or transgenesis, is the process through which an organism genome is modified artificially (in the laboratory). The genome of an organism is the totality of its genetic material (that is the DNA or, in the case of viruses, the RNA). Artificial or genetically modified biological material may be inserted into an organism's genome or into an embryo.

In the case of animals, scientists may introduce extraneous genetic material into a fertilized mammalian ovum through a microinjection, and then insert it into a pseudo pregnant female, whose offspring will contain the inserted genetic material incorporated in its genome. According to the laws of Mendelian genetics, by combining this technique with classical breeding processes it is nowadays possible to transmit that genetic incorporation to the generations to come.[190] Plenty of useful applications can be foreseen for transgenic animals. For instance, by using the oncomouse[191] in the laboratory scientists may better perceive the effects of certain drugs on mammals,

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[189] *Id.*, at p. 24-27

[190] Grubb, P. W. (2004). *Patents for chemicals, pharmaceuticals and biotechnology: fundamentals of global law, practice and strategy* (4 ed.). Oxford: Oxford University Press, at p. 272-274.

[191] The oncomouse case caused a real legal odyssey, because different jurisdictions dealt with the case in different ways. The Harvard University patented the oncomouse in the United States, but it turned out to be a battle in Europe (because of ordre public and morality concerns and because the EPC explicitly excludes animal varieties from patentability). Canada, on the other hand, rejected the patentability of the oncomouse on grounds of unpatentability of animals as such.

reducing at the same time the use of more sentient species such as nonhuman primates.[192] Furthermore, transgenic animals may be a source of human organs for transplantation.[193]

Modifying the genetic composition of a plant may turn out to be harder than with an animal, for the simple fact that plant cells typically have a hard external cell wall, consisting of a barrier to scientists. Once this barrier was surpassed, the interior of the cell posed further challenges. However, advances in science permitted the access to plant cells and modifying their genome is nowadays feasible through similar process as that used in the case of animals.

2.2.1.2Patentable subject-matter – concept evolution

Genetic information was historically excluded from patentability, mostly because higher live forms such as plants and animals were not envisaged as something scientifically attainable within the confines of the laboratory until the last few decades. For instance, the 1973 European Patent Convention excludes plants and animals from patentability. Nonetheless, due to important progresses in genetic engineering, a different interpretation of this EPC provision led to a broader construction of the 1998 Biotechnology Directive.[194] The latter recognized that plant and animal varieties were not totally exempted from patentability since biological material isolated from its natural environment or produced by a technical process «may be the subject of an invention even if it previously occurred in nature». [195] Great part of this leap in the eligibility of living organisms steams out of the Red Dove case. [196] The German Supreme Court ruled not only that biological processes were eligible for patents, but also that the product derived from that process (in this case, the animal as such) was eligible as well. This case profoundly challenged the

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[192] Dennis Jr, M. B. (2002). Welfare issues of genetically modified animals. *International Law and Regulation , 43* (2), pp. 100-109.

[193] Even though no organs from transgenic animals have been transplanted into humans, xenotransplants may be a reality soon if the legal paradigms consent it. See the European Xenome Project. Retrieved February 13, 2012, from Xenome: http://http://www.xenome.eu/.

[194] Directive 98/44/EC, OJ L 213, p. 13-21, 30.7.1998.

[195] *Id., art.* 4 (1). This provision was very criticized by several scholars and NGOs.

[196] Rote Taube, IIC 01/1970, 1967.

previous concept that living organisms and their parts were non-patentable products of nature, which were and should stay in the public domain to be «equally for the use of all men». [197] Behind this decision is basically the acknowledgement that without the interference of man through particular breeding methods or genetic engineering, certain natural products and processes could not be accomplished.[198]

U.S. interpretation may perhaps provide us with more concrete insights of the matter. The U.S. Patent Act explicitly excludes 'products of nature' from patentability. The distinction between products of nature and man-made ones have been shaped by case law. In the famous *Diamond v Chakrabarty* case[199], the U.S. Supreme Court ruled that this distinction should not be thought of in terms of living and inanimate things, but rather in terms of products of nature and man-made inventions. The idea is that the fact that the subject matter is in fact a living organism (a microorganism in this case) does not rule out that fact that it is a 'manufacture' or 'composition of matter' within the statute. Therefore, an invention entails a creation by man, who confers new properties to a product that perhaps existed in nature, but would not have the said properties unless technical inputs were performed.

In light of these historical developments, it can be claimed that case law has accommodated the inclusion of living organisms under patent law. As examined in the previous chapter, eligibility does not depend solely on the subject matter; indeed, other legal steps must be accomplished. Whether process and product patents on living organisms satisfy the requirements of patent law (novelty, non-obviousness, utility and industrial application) is still open to question.[200] In actual fact, which level of novelty should be required for genetic modification driven in naturally occurring substances and products? How 'new' is a gene or genetic sequence from the perspective of patent law?

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[197] Westerlund, *supra* note 188, at p. 29.
[198] Note however that under the European Patent Convention essentially biological processes are not patentable. See Article 53(b), exceptions to patentability.
[199] The court ruled in favor of the eligibility of a bacterium capable of destroying crude oil, useful for oil spills. Diamond v. Chakrabarty, 447 U.S. 303 S. Ct. 2204, 1980
[200] Westerlund, *supra* note 188, at p. 31.

Furthermore, the problems posed by chemistry and biotechnology in applying the non-obviousness requirement are unique. On the one hand, «a newly-synthesized compound may be very similar in structure to known and existing compounds and yet exhibit very different properties. »[201] In order to apply for a patent on a gene or a genetic sequence, scientists must isolate or purify the substance, in other words removing all the non-coding segments present on the sample. Regardless of the difficulty of this process, it has in effect become the standard procedure for new discoveries in the genetic field. Should this level of technical input suffice to eligibility under patent law? The process of cell line isolation and its purification are typical steps any competent chemist could potentially elaborate, hence the difficulty in distinguishing in the application of such requirement. Some authors fear biological patents are being awarded to «straightforward arrangements of factual data»[202], which may cause an anti-commons effect in terms of access to basic information.

Patents are a mechanism to reward inventive solutions to technical problems. Chemical compounds are often developed without any particular purpose. Uncertainty is the main feature of bioprospecting; discovering a pertinent compound may be a jackpot as well as a waste of resources. [203] Hence, gene patents are often filled without a clear knowledge as to what problems they solve and to what purpose they serve. [204] This suggests that the utility requirement may not always be present or perceived in the moment of patent filling.[205] In this regard, Michael Polyani states «Invention, and particularly modern invention which relies more and more on a systematic process of trials and error, is a drama enacted on a crowded stage. It may be possible to analyze its various scenes and acts, and to ascribe different degrees of merit to participants; but it is not possible, in general, to attribute to any one of them

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[201] R. Merges citing D. Chisum, Patent § 5.04 [**6**] (1978 & Supp. 1996), at p. 590. See Merges, R. (2002). *Patent Law and Policy: Cases and Materials* (3 ed.). Newark: Lexis Nexis.
[202] Boyle, J. (2003). The second enclosure movement and the construction of the public domain. *Law and Contemporary Problems , 66*, pp. 33-74.
[203] See Merges, *supra* note 201.
[204] Boyle, *supra* note 202.
[205] Perhaps the utility of a compound has no application in the moment of patent filling but is provides important inputs for future solutions.

one decisive self-contained mental operation which can be formulated in a definite claim». [206]

Additionally, genes and genetic lines provide informational contents which are unique in kind. Given the fundamental nature of the subject matter it may prove unfeasible to "invent around" a gene patent.[207] This boosts the power of excludability of patent holders. Also, considering that some of these patents are on living organisms and parts thereof, there is a certain fear that «as transgenic organisms become commonplace, the possibility increases that a patented organism will accidentally become either the 'building block' of the patentable transgenic organism or a component of a breeding program.»[208] This becomes a serious problem in terms of infringement of basilar patents. For example, the application in front of the EPO for the Harvard oncomouse included a claim covering the insertion of an activated onco-gene into all nonhuman mammalians. The scope of protection, in case this patent would have been granted[209], would have reached far beyond the actual performed genetic alteration, but it is in fact possible to obtain a patent covering all known applications of information relating to gene sequences and their interactions.[210] This problem is enhanced by the fact that most crops are wind pollinated, which may make it impossible to control the spread of genetically modified plants into the environment. The same holds for animals, which could spread into the environment.[211]

2.2.2 Genetic resources as public goods and the problem of enforcement

As perceived by international legal texts, there seems to be the idea that genetic resources share the properties of other tangible goods, such as oil or minerals. To be precise, the CBD recognizes the sovereign rights of States «over their

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[206] Polyani, quoted *in* Merges *supra* note 201.
[207] Matthijs, G. (2004). Patenting genes. *British Medical Journal* (329), pp. 1358-1360.
[208] Westerlund, *supra* note 188, at p. 31.
[209] After 20 years of court dispute between patent holders and activists, the oncomouse patent was revoked in 2006 for lack of fees payment.
[210] Westerlund, *supra* note 188, at p. 30-31.
[211] *Id.*

natural resources» and therefore «the authority to determine access to genetic resources rests with the national governments and is subject to national legislation».[212] One might question whether this interpretation is accurate.

As a matter of fact, genetic resources share most features of public goods, even though they have a tangible component.[213] To begin with, what industries seek in genetic resources are their informational inputs rather than their physical properties. In addition, this information is reproducible in laboratory in vast quantities.[214]

This feature of genetic goods – the public goods layer[215] – causes the phenomenon of *market failure*. Market failure expresses the problem of inefficient allocation of certain goods in a free market, often requiring the state regulation to efficiently allocate them. The situation may explain as follows: the inability of a seller to exclude non-buyers from making use of public goods/common pool resources leads, in a free market, to underinvestment, given that it may be impossible for the seller to cover the costs of researching and making such goods. This is particularly important in the case where markets may bear high transition costs.

An ultimate problem with genes and genetic lines is that they provide a unique informational content. Such features make it impossible for competitors to "invent around" the patented gene or sequence. This particular characteristic of genetic information confers on the patent holder a "double" monopoly.[216] In other words, since competitors are not free to develop technologies that come close to the boundaries of the patent, without infringing its claims, the bargaining position of the patent holder is reinforced.

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[212] Convention on Biological Diversity, *art.* 15. 1, Dec. 29, 1993.
[213] After all, cells and gene lines are minuscule combinations of chemicals.
[214] We may say that from this point of view genetic resources are similar to books, in the sense that they can be rather easily reproduced, as books can be photocopied.
[215] Stone, C. D. (1995). What to do about biodiversity: property rights, public goods, and the earth's biological riches. *Southern California Law Review , 68* (577).
[216] Matthijs, *supra* note 207.

We may certainly assume that biological resources are non-rival – one's benefit or consumption does not impede everyone else's and does not require incurring in additional costs.[217] Moreover, nonhuman biological material is hardly excludable given that it can be found in natural habitats. It is tough, if not unfeasible, to set physical boundaries around these materials so as to exclude their appropriation by others. Migratory species illustrate entirely the point. From another perspective, it might be also hard to set boundaries at the level of information exchange. Markedly, John Daly, a scientist at the National Institutes of Health (NIH - United States of America) isolated a chemical from an Ecuadoran frog with properties similar to morphine, without damaging side effects. Ecuador demanded rights over the properties of the frog's chemical, even though the scientist never saw or even touched the frog; according to the NIH he had just read a scientific paper about it.[218] In sum, it seems rather difficult to "fence" genetic information, impede that it flows without authorization and charge some sort of royalties on their use, unless sovereignty-based rights are effectively ensured by every single government all over the world. [219]

Even though genetic information can be made available to all with no cost, because it is a public good, the physical land where this information exists (say, the forest) is in clear competition with other uses of such land. To be precise, the more forest is conserved, the less acreage is available for agriculture and housing. [220] The challenge is in finding a way to make conservation more economically attractive than other uses of the land.

In spite of these aspects, many developing countries have passed laws to restrict access of third parties to their genetic riches as a consequence of the CBD. Given its nature of public good, it might prove hard to control flows of biological materials across borders. In this sense, sovereignty-based rights seem

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[217] See the private/public goods dichotomy discussed in the introduction of chapter 1.
[218] Pollack, A. (1999, November). Patenting life: a special report; biological products raise genetic ownership problems. *The New York Times*.
[219] All in all it might be unfeasible to police borders, forests, seas and the like to impede leakage of unauthorized genetic materials.
[220] See Stone, *supra* note 215.

to be difficult to implement and enforce. Differently from typical private goods, like oil, there are no physical infrastructures for the extraction of genetic material. Prospecting for oil requires stable physical equipment and therefore the activity may be well supervised.[221] Instead, wild plants and animals may be easily smuggled or appropriated. On the other hand the physical aspect of these resources (land use policies) must be taken into consideration in order find a solution to the problem of incentives to conservation.

2.2.3 The value of biological material

From the viewpoint of the industries involved, the information contained in the genetic history of plants and animals is one of the basic pillars at the bottom of R&D. The use of such information might have immediate direct commercial application or, on the contrary, prove not to be useful to solve any problem R&D labs are facing. These resources may, nevertheless, be important in future problems and that is the reason why the utility of genetic resources may be not immediately perceived[222].

The informational input can be brought into commercial products «either in the incorporation of the explicit information that specific genetic resources represent (the observed characteristic or phenotype) or alternatively by the use of the implicit, biological coding of that information (its genotype). »[223] In other words, these industries can develop products which incorporate the explicit information of the resources (without translocating the biological material) or it can employ the actual genetic material by transplanting it into the desired purpose.[224] Hence, biological materials provide very important informational inputs to research and development in the fields of biotechnology, agriculture and pharmaceuticals.

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[221] *Id.*
[222] Some compounds may not have an immediate utility when they are discovered, but they may prove essential for resolving future problems. See Merges, *supra* note 203.
[223] See Swanson, T., & Gölsch, T. (2000). Property rights issues involving plant genetic resources: implications of ownership for economic efficiency. *Ecological Economics , 32* (1), pp. 75–92; at p. 78.
[224] *Id.*

However understandable, sovereign rights over genetic resources may be overestimating their value to the industry. An additional cost at the first stage of scientific innovation may discourage the use of such materials or a more intensive research for alternative solutions to the natural ones. Genetic resources are undoubtedly very valuable to the industry, and clearly they are capable of solving important biological problems, but a restriction of access to this genetic pool may discourage the use of this biological diversity. A direct consequence is the search for alternative materials, such as synthetic materials, which may require less economic efforts to obtain. Whether this happens or not will depend only on the goodwill of COOs to respect the obligation under Article 15 of the CBD to facilitate access to genetic resources.[225]

Processes to obtain genetic resources from developing countries are usually quite long and expensive which, adding up to the natural uncertainty inherent to the industries[226], may be responsible for a disincentive for companies to prospect for materials in their territories. In fact, this seems to be happening already.[227] Colombia, Bolivia, Ecuador, Peru and Venezuela (these countries have a common set of regulation for biological diversity preservation, the Andean Pact) adding to Costa Rica, India and Brazil are just some of the countries which have enacted legislation to regulate sampling of biological materials. In this regard, certain scientific undertakings «that might lead to breakthroughs in medicine and agriculture (…) are being impeded or abandoned»[228]. When bioprospecting is not encouraged, there are hardly any benefits to be shared or compensation flowing to countries of origin. It is clear that the CBD may be, in this sense, a double-edged sword. Lastly, if developing countries reject to encumber intellectual property rights, giving no actual

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[225] Convention on Biological Diversity, *supra* note 212, *art.* 15. 2: «Each Contracting Party shall endeavor to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention».
[226] Consider, for instance, that the great majority of compounds for drugs fail clinical trials. «It is estimated that approximately 5,000 compounds are found to have activity in early testing for every one which finally is marketed». Grubb, *supra* note 190, at p. 402.
[227] Andrew Pollack, *supra* note 218.
[228] *Id.*

assurances to investors, the most likely scenario is non-collaborative. In other words, if developing countries restrict access to genetic resources and developed countries refuse to share the benefits from technological advancement, the international collaborative agreements will eventually fail their purpose.

2.2.4 Bioethical questions and the precautionary principle

Ownership over higher living organisms, such as animals, plants or fragments of their composition is a controversial issue in the public sphere. Many have opposed these advances in science invoking ethical, economic and even religious arguments. Perhaps the most contentious cases on genetic engineering involve genetically modified and cloned animals, such as the *Harvard oncomouse*[229], the famous sheep *Dolly*[230] and, more recently, the first chimera monkeys *Roku* and *Hex*[231]. These are milestones in the history of science and they came as a confirmation of the massive potential of biotechnology. Nevertheless, the potential environmental and health risks seem not to be ignored by the public opinion and some green activist groups.

In the overall, genetic resources are a fundamental pillar in the many industries which directly affect important policy issues such as public health, food security and environment sustainability. These issues are clearly controversial, because they touch upon fundamental human rights. [232] Biotechnology, pharmacology and biomedicine aim at serving some basic needs of mankind such as increased food security and improved healthcare, but there is great

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[229] The oncomouse is a transgenic mouse, genetically modified to increase the mouse's susceptibility to cancer, thus more suitable to cancer research. Scientists Phillip Leder and Timothy Steward from the Harvard University achieve these results by designing the mouse genome to carry a specific gene (the oncogene).

[230] Dolly was the first cloned mammal in history. Dolly's death led to many controversies in the public sphere, also because it was a very explored issue by the media. Scientists were asked to rethink their attitude towards cloning and stem cell research.

[231] Roku and Hex were the first successful result of genetic modification on monkeys, born in the US in January 2012.

[232] On this matter, the UN Sub-Commission for the Protection and Promotion of Human Rights adopted in 2000 a resolution on «Intellectual Property Rights and Human Rights» arguing that the TRIPS agreement could infringe the rights of poor people around the world to access seeds and pharmaceutical solutions. The document perceives a clash between private interests and public concerns. UN Resolution E/CN.4/Sub.2/2000/L.20.

apprehension about unexpected secondary effects of such activities on the part of communities and governments around the world.

The functioning of these industries has habitually raised concerns about the equitable access to health and benefits from scientific progress. It might be questioned whether research on certain life sciences' fields should even be permitted (say, for instance, cloning human beings). On the other hand there are ethical questions regarding the granting of patents over biological material as such (both human and nonhuman). For that reason some particular technologies are purposely kept outside the scope of patent law in many countries (for example, genetically modified organisms). [233] Then again, these issues are highly controversial precisely because it is hard to reconcile plural ethical views about particular technologies.

Particularly in the European Union, where this point is clearly made in legal sources, patents can be denied on grounds of morality or *ordre public*: Article 53 of the European Patent Convention reads that, among others, patents *shall not* (emphasis added) be granted in respect of « inventions the commercial exploitation of which would be contrary to *ordre public* or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States». This means that where there are reasons to believe that public interest is contrary to the request for property rights, the latter shall simply be denied. This may be explained by the fact that European states are very asymmetrical, hence the difficulty in reaching a compromise on sensitive issues. The morality-based legal restrictions in the European Union on genetically engineer actions often clash with the (almost) inexistent moral constraints under the U.S. Code. [234]

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[233] World Intellectual Property Organization. (2007). *Intellectual Property and Bioethics - An Overview*. Life Sciences Series 1. New York: World Intellectual Property Organization Press.

[234] The repetitive use of the expansive term "any" in the language of the US Code was interpreted as an intention not to place further restrictions on the patentability of an invention beyond those specifically stated in 35 U.S.C. § 101. Therefore, the policy regarding biological materials is included in the famous sentence «everything under the sun made by man». Nevertheless, some events in the United States challenged this approach, showing perhaps a shift in the public perception of the patentability of certain biotechnology-related inventions.

The problem of pluralism in ethical perspectives is latent also in the TRIPS agreement. [235] The moral and philosophical debate about whether forms of life should be patented is still a hot debate in the international arena. Skeptical views may argue that reconciling the value systems of all the parties to the TRIPS agreement might be simply unattainable. Whereas using animals for scientific research may be acceptable for some, it may be simply outrageous for others. The TRIPS Agreement recognizes the morality and "ordre public" exception, which explicitly includes inventions dangerous to human, animal or plant life or health or seriously prejudicial to the environment.

An important ethical issue regards the freedom of IP rights owners to actively restrict access of others to their technology. When these freedoms defy the public interest, legal safeguards tend to be created. This applies in general to competition law, to rules against abusive licensing practices and of specific remedies under patent law, such as compulsary licensing. [236]At this point it is interesting to note the mushrooming of open access projects in recent years.[237]

Many have also raised concerns about the threats to the environment posed by the release of genetically modified plants. Environmentalists fear that GM crops could "*contaminate*" non-GM crops through cross-polarization, the natural reproductive biological process of some plants, and even the possibility of mutant animals to get in contact escape and breed with feral populations.[238] In this sense, European legislation is deeply shaped by the precautionary principle and its legislators have become risk-avert, as opposed to the United

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See Dunleavy, K. J., & Vinnola, M. M. (2000). A comparative review of the patenting of biotechnological inventions in the United States and Europe. *Journal of World Intellectual Property , 3* (1), pp. 65-76.

[235] Agreement on Trade-Related Aspects of Intellectual Property Rights, *art.* 27. 2, Jan. 1, 1995: «Members *may* exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law».

[236] World Intellectual Property Organization, *supra* note 233.

[237] See chapters 3 and 4 of the present thesis.

[238] Dennis Jr., *supra* note 192.

States of America, which has become less precautionary overtime. [239] However, environmental issues are not the only concern arising from the release of genetically modified organisms into the environment. For instance, health risks posed by GM food contributed heavily to the European precautionary approach latent in European legislation on the matter. [240]

In addition, there are issues regarding the secondary effects caused by the approval of such organisms. Let us take the example of the famous *golden rice*[241]. The enablement of this GM rice aimed at the alleviation of nutritive deficiencies in developing countries and it is frequently presented as a successful case of green biotechnology. However, some have argued that the use of golden rice in developing countries may have unexpected negative collateral effects. For instance, the existence of a superior rice variety may lead to a diversity loss in rice varieties. There may be deep social costs as well, for instance royalties over genetically modified seeds may be too expensive for small farmers in the third world. Also, patents inhibit farmers that were highly dependent on saving seed for the future to do so with these new seeds. [242] The opponents of the golden rice (and of G.M. crops in general) argue that other policies, like the introduction of new vitamin-A-rich elements in developing

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[239] Vogel referred to the opposing trends in the EU and the USA as «ships passing in the night». Vogel, D. (2001). Ships passing in the night: GMOs and the contemporary policy of risk regulation in Europe. *RSC Working Papers* (2001/16).

[240] Risk regulation, in the context of EU law, refers, in principle, to the need by regulators to ascertain the potential harm and the probability of such harm when faced with a novel product or process, before making a definite decision about the legality or not of the said product or process. The trend in the Union had been to take precautionary measures regarding biotechnology, either by «regulating strictly or even banning products or activities, in the absence of complete information about the risks posed». *In* Pollack, M. A., & Shaffer, G. C. (2004). Biotechnology policy - between national fears and global disciplines. *Jean Monnet Working Papers* (2004/10).

[241] The golden rice is a transgenic variety of rice, to which scientists have added pro-vitamin A through a combination of transgenes enabling its biosynthesis in the endosperm of standard rice (*oryza sativa*). This project envisaged the introduction of vitamin A in the diet of countries, predominantly in Southeast Asia, Africa and Latin America, where its absence was causing serious public health problems. Ye, X. S., Al-Babili, S., Klöti, A., Zhang, J., Lucca, P., Beyer, P., et al. (2000). Engineering the provitamin A (β-Carotene) Biosynthetic Pathway into (Carotenoid-Free) Rice Endosperm. *Science , 287* (5451), pp. 303-305.

[242] Vandana Shiva is an Indian activist against genetically modified organisms, with a particular insight of the developing countries problematic. See Shiva, V. (2000). *Genetically engineered vitamin 'A' rice: a blind approach to blindness prevention.* Retrieved February 15, 2012, from http://www.biotech-info.net/blind_rice.html.

countries' diets, would be more effective means to fight vitamin A deficiencies.[243]

Finally, along these same lines, there is a clear opposition to the use of genetically engineered animals in scientific research. In the case of scientific research, the main issue is related to animal welfare. Animals are used for a great variety of purposes, incidentally for disease models, gene discovery and therapy, and xenotransplantation. The majority of these scientific areas have started being fully explored in recent years, consequently an increased number of animals have been employed in research. In view of these preoccupations, the EPO ensures that there is an exception to patentability where animal suffering is likely but medical benefits are not likely to be substantial. [244] The European view is in contrast with the policy of the US Patent and Trademark Office (PTO), which has performed a broader construction of patent scope concerning transgenic animals. [245]

2.2.5 Property rights at the base of the industrial chain

A closer look at the mechanisms through which some of the industries involved work may help us understanding how intellectual property rights affect them and their reaction to property rights at other stages of the industry chain. Numerous studies have highlighted the importance of intellectual property rights in those industries where the primary product is informational[246]. This is the case of industries dealing with genetic resources,

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[243] Enserink, M. (2008). Tough lessons from golden rice. *Science , 320* (5875), pp. 468-471.

[244] European Patent Convention, *art.* 28d, *supra* note 56, excludes from patentability the «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».

[245] Nonpatentability may be asserted in America based on lack of *beneficial utility*. This requirement applies where society frowns upon the use of an innovative creation. However, according to scholars and to the patents granted by the PTO in recent years, the beneficial utility requirement has not restricted patentability on transgenic animals. See Koopman, J. (2002). The patentability of transgenic animals in the United States of America and the European Union. *Forham Intellectual Property, Media and Entertainment Law Journal , 13* (1), pp. 102-204.

[246] *Id.;* see also Swanson, T. (1995). *Intellectual Property Rights and Biodiversity Conservation.* Cambridge: Cambridge University Press.

which solve specific problems at the interface between human technology and the biological world.

These industries are R&D intensive, hence the need to incentive large investments by ensuring ownership rights over the products created[247]. In the words of Swanson and Gölsch, «When R&D is a significant part of the production process within an industry, it is not always possible to obtain a reasonable rate of return on the product without an extended right of control over its subsequent use and marketing. This is because the end result of the R&D process is an idea, and this idea is then embodied in the products in which it is sold, and potentially lost on first sale. (…) In industries in which a substantial amount of the value produced is attributable to the information it contains (generated through R&D), there would be no incentive to invest in this R&D in the absence of the capacity to control the marketing of its goods even after their transfer to others.»[248]

Let us consider the pharmaceutical industry. Fixed costs[249] of research and development are particularly high for pharmaceutical innovators[250], mainly due to the many regulatory requirements the industry is subject to. Yet marginal costs are quite low both for the inventors and for competitors. Therefore, imitators may attain products at low costs and that makes pharmaceutical

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[247] This obeys to IP mainstream economic theory, extensively debated in chapter 1.
[248] Swanson & Gölsch, *supra* note 223, at p.79.
[249] Fixed costs of research and development are, in the frame of conventional patent economics, costs which do not vary according to production or to sales levels. In open access economics most scholars consider that these costs are actually sunk, that is, costs which are in any case irrecoverable.
[250] Pharmaceutical innovative companies spend in average 15-20% of their total sales revenue on research and development. In contrast, industry in the overall spends less than 4% in R&D. However, it is perhaps convenient to make a differentiation of the types of companies generally operating within this industry. Protection is important where companies have no alternatives (that is, where trade secrecy is not a feasible option). Therefore, patents are perceived as tremendously important for innovative pharmaceutical companies. Other kinds of companies coexist in the market, though. Generic companies specialize in manufacturing and selling pharmaceutical products whose patent protection is terminated. "Imitators" specialize in producing those products during their patent lives, in markets where patent protection is not assured to pharmaceutical products, such as India. Parallel importers simply trade drugs, buying them at low prices in certain countries and selling them at higher prices in other markets. Counterfeiters produce and sell pharmaceutical products as genuine goods of the originator. These differences may punctually overlap (for instance, an innovative company may also produce generics).

companies particularly reliant on intellectual property as an appropriability means rather than alternative means to protect their initial investment.[251] Furthermore, the effective term of a pharmaceutical product is shortened due to the structure of the industry. Consider the fact that it takes typically seven to fourteen years from first patent filling to marketing of a drug. [252] Hence, pharmaceutical innovators invest intensively on R&D and are highly dependent on new genetic information inputs for commercial purposes. These two aspects render the drug industry extremely sensitive to intellectual property policies and dependent on patent law as an incentive to develop new products.

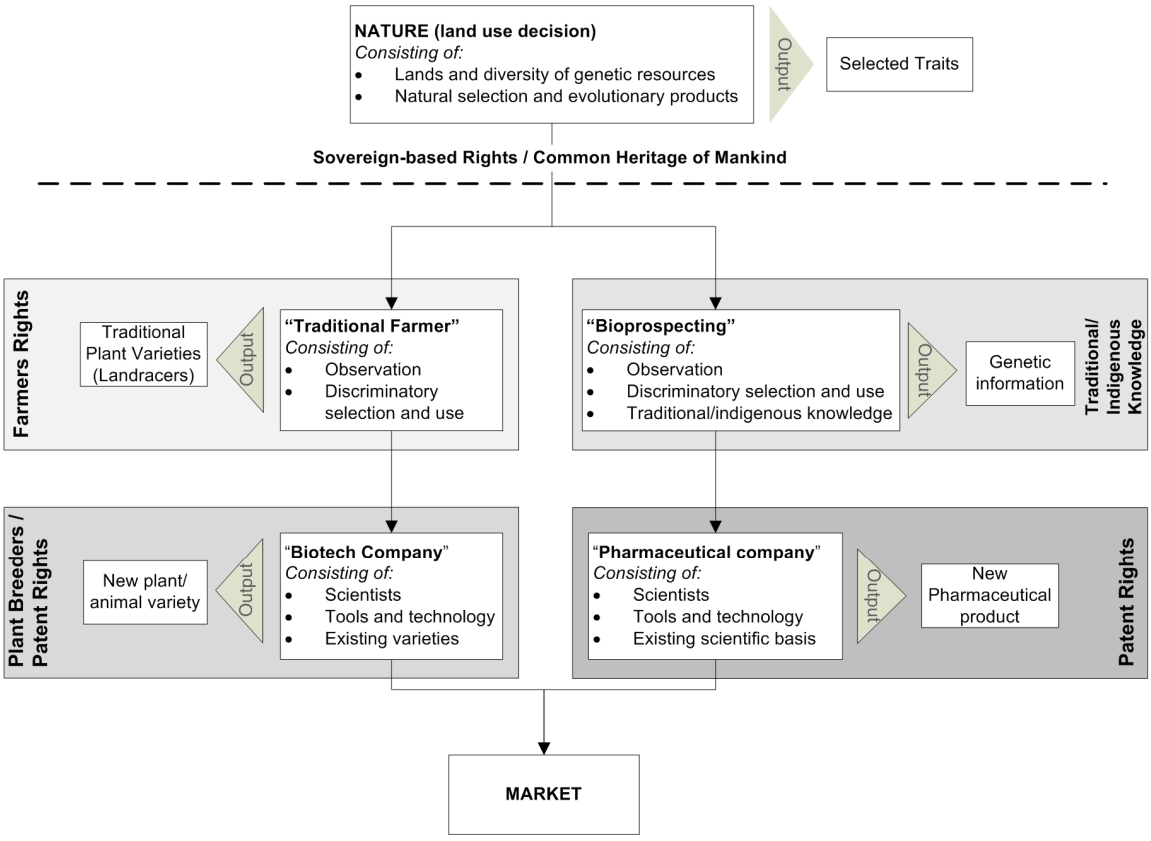

Figure 1 Property rights in the context of biological-related industries

[251] See Landes & Posner, *supra* note 20, at p. 313.

[252] Compounds have to go through many stages in order to confirm their utility to the industry. It may take up to ten years just to surpass pre-clinical and clinical trials. See Grubb, *supra* note 190, at p. 402.

Figure 1 shows the vertical frame of the biotechnological and pharmaceutical industries, from initial stage to final product in the market. [253] The several layers of rights predict a system of 'hyperownership' over wild genetic resources.[254] Throughout time, property rights have been recognized at the national and international levels. Products of nature, that is animals, plant and microorganisms which may be found in the wild, were seen as common heritage of mankind, therefore the access to them was open to all men. However, the CBD conceded the power of single nations to exclude third parties from making use of genetic resources within their national jurisdiction. At the first level – that is between nature and its use by men – a sovereignty-based right was included, while other resources fall under the category of Common Heritage of Mankind.

At a second level, the recognition of farmers' rights became an obligation under the FAO's International Treaty, while Traditional Knowledge and Indigenous Knowledge have been under discussion in international forums since the CBD recognized the value of traditional knowledge in protecting species, ecosystems and landscapes. The WIPO established in 1999 the established the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, in order to deepen the relationship between IP and TK rights.[255]

At the third layer, the industry layer, intellectual property rights are granted either through patents, through a *sui generis* system (Plant Breeders Rights) or a combination of both. These rights are tendentiously more effectively enforced, because institutions have been created for the purpose of harmonizing national laws and resolving disputes even at the international level (TRIPS and WIPO).

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[253] This graphic is largely constructed on the basis of the graph presented by Swanson and Gölsch, altered here to incorporate the pharmaceutical industry and further information about the distribution of property rights.
[254] Safrin, *supra* note 181.
[255] In addition to this, the UN adopted the United Nations Declaration on the Rights of Indigenous Peoples, Sept. 7, 2007.

According to Swanson and Gölsch, if at the very base of the industry property rights are not recognized, then there are no incentives for preserving genetic diversity. At that point, other economic incentives overwhelm these IP-based incentives. In other words, whether or not a country will conserve its forest area will depend on some factors, including: a) the opportunity costs of keeping the land rather than investing alternatively; b) the costs of deforestation; c) The asset value of the goods and services deriving from the forest conserved as such (timber, fruits, etc.); d) the costs of managing the area and protecting it from natural catastrophes; and d) the supply of compatible forests elsewhere in the world. [256] Therefore, with the international recognition of sovereignty-based rights, policy-makers hope to positively influence the very first layer in Figure 1 (land use decision), that is, to create a strong economic incentive for the conservation of nature.

We can conclude that, sovereignty-based rights over genetic resources are put out in the CBD as the solution to the problem of conservation. However, such rights may disincentive the industries to prospect for biological material in COO with very restrictive access policies. What was thought to be a benefit to countries of origin may carry some less obvious risks. Restricting access to resources that were by and large in the public domain may add up to the heavy burden on the back of scientific researchers.

2.3 Conclusions

Access to wild biological resources has historically been in the public domain, accessible to all without legal restrictions. Nevertheless, the extension of the legal concept of invention to include living organisms and biological processes, as well as the recognition at the international level of sovereign and community rights over genetic resources and their use contributed to an undergoing «spiral of increased enclosure of genetic material». [257]

[256] Stone, *supra* note 215.
[257] Safrin, *supra* note 181.

While the liberalization and globalization of markets have raised demands for higher IP protection systems around the world for (private) knowledge goods[258], at the same time there has been an obvious recognition of the right of 'countries of origin' to impose sovereignty restrictions for the access to genetic riches found within their territories. Such an enclosure movement may have a negative impact on the exploitation and circulation of valuable genetic information, thereby adding up to the current dysfunctional nature of incentives to innovation and to the disequilibrium in terms of access to crucial information. [259] A strong exploitation of property rights (intellectual, sovereign or of any other sort) may indeed slow down scientific progress.

As discussed in Chapter 1, intellectual property rights may create a problem in the trade-off between incentive and the social loss caused by the power of exclusion of patent owners. The patent system might be as well responsible for some of the problems discussed during this chapter, to the extent that, by design, is restricting the access to intellectual property, by allowing patent holders to directly control the supply of innovative goods to the market. The question of accessibility is particularly significant for research with biological materials, and has been dealt with through many mechanisms. The Open Source/Open Access movement has been pioneer in creating structures that better address the problem of access to data, thus reducing the negative effect of patent rights. Chapter 4 will examine the theoretical features and the practicability of open source initiatives in a world evermore ruled by private property.

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[258] Maskus, K., & Reichman, J. (2004). The globalization of private knowledge goods and the privatization of global public goods. *Journal of International Economic Law , 7* (2), pp. 279-320.
[259] Henry & Stiglitz, *supra* note 175.

3 THEORIES AND VIABILITY OF AN OPEN SOURCE APPROACH TO BIOLOGICAL MATERIALS

Increasing property rights over biological material are at the origin of restrictive access to informational inputs that play an important role in solving technical problems at the interface between mankind and the biological world. As we discussed in Chapter 2, scientific research, as well as any other technological field, is a cumulative process. Science is like a snowball: additional developments are built upon previous research and knowledge, and researchers in the scientific community are inspired and influenced by one another. That cumulativeness requires secondary developers to be motivated to work in a given technology. Yet intellectual property rights, as currently designed, tend to exacerbate the rights of initial innovators, perhaps in detriment of follow-on innovators.[260]

Access to previous research and the possibility of endorsing follow-on research projects is often deficient among scientific communities, either because instruments for sharing such results are ineffective (even though collaborative networks are becoming increasingly important in the process of data sharing) or because patent owners retain enough power to prevent useful results to be explored by third parties. The latter is one of the social burdens inherent to intellectual property rights and to other property rights granting exclusivity over biological material.

Such problems are precisely the target of open source licensing. The present chapter serves at shedding some light on the other side of the moon compared to intellectual property rights. After putting forward an analysis of the general theories behind the open source model, as applied to the software industry, we

[260] Scotchmer, *supra* note 136.

will discuss whether this model could by any means function if applied to scientific research in the biological sciences. The second part of the chapter is dedicated to some prominent cases where this model was somehow adapted to meet the needs of scientific researchers.

3.1 General Open Source Theories

3.1.1 Open Source in the software industry – history and original characteristics

The open source movement was born in the software industry sphere as a response to propagating intellectual property rights from which restrictions on freedom to use and operate derived. With minimum levels of intellectual property protection being constantly pushed higher, follow-on development becomes increasingly inhibited. In other words, the balance between the interest of initial innovators and those that come afterwards is affected and this translates into a reduced scope for downward adjustment. Since software development, similarly to scientific development, is a cumulative process, deficient access to basilar tools may be responsible for a retarded entry of innovative products in the market.[261]

The software industry has a tradition of cooperation and sharing for code development.[262] In fact, in the early days of computer programming there was hardly any commercial off-the-shelf software – one had to write the code herself or hire someone to do it.[263] It was by then fundamental that source code was open and freely exchangeable, and often open source software projects were taken ahead by academic and corporate laboratories. In 1969, the development of U.S. Defense Advanced Research Project (ARPA) gave life to the ARPANET, a computer network which for the first time allowed for transcontinental and high speed information exchange and therefore

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[261] Takalo & Kanniainen, *supra* note 19; and Mazzoleni & Nelson, *supra* note 73.

[262] This behavior towards software may reflect the misconception that software alone was not a profitable market. Lerner, J., & Tirole, J. (2004). Economic perspectives on open source. In G. D. Libecap, *Intellectual Property and Entrepreneurship* (pp. 33-69). Emerald Group Publishing Limited.

[263] Von Hippel, E., & Von Krogh, G. (2003). Open source software and the "private-collective" innovation model: issues for organization science. *Organization Science , 14* (2), pp. 209-223.

reinforced the spirit of the *hacker culture*. [264] In sum, software development was a cooperative undertaking, under very informal rules, whereby generally no source code was claimed under intellectual property rights.

However, in the 1970s and 1980s this paradigm started changing, when increasing property rights were claimed on source code or parts thereof. Proprietary claims contributed to impeding the free access and sharing of such code, eroding the communal behavior of Internet-based hacker communities. The most (in) famous case is that of the Massachusetts Institute of Technology (MIT), when some of the source code created at the Artificial Intelligence Laboratory was licensed to a commercial company. This situation rendered it impossible for the own developers of such code to continue accessing it, developing it and using it as a learning tool.[265] Software vendors generally restrict access by providing only the machine-readable code (the object code) to the consumers. Source code is made through high level programming languages, and then compiled into machine readable code. This procedure makes it extremely hard to translate it back into human-readable code. Open source, on the other hand, provides the source code.[266]

In response to litigation threats to communally created software, Richard Stallman, one of the most brilliant developers within the MIT, decided to elaborate formal rules to ensure the continuity of communal software development.[267] By 1984 Stallman designed a formal licensing procedure, the General Public License (GPL), commonly known as copyleft. The GPL was planned to match copyright law, allowing interested developers to make their work widely available. In 1985 the Free Software Foundation (FSF) was created to develop and disseminate software without proprietary restrictions and costs.

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[264] *Id.* Von Hippel and von Krogh explain that the term hacker has a positive connotation in these circles, for it describes very talented and dedicated programmers.
[265] *Id.*
[266] Madison, M. J. (2004). Reconstructing the software license. *Loyola University Chicago Law Review , 35* (275), pp. 275-340.
[267] This license was designed for the GNU Project (GNU stands for "GNU's not Unix"). See Lerner & Tirole, *supra* note 262.

The GPL is a viral license, that is, the obligations extended to all code compiled under the software, because users have to agree not to impose IP restrictions on follow-on users, in the same manner these had not been imposed on them.[268] The FSF requires that each author of code incorporated in their projects provide a copyright assignment, and, where appropriate, a disclaimer of any work-for-hire ownership claims by the programmer's employer.

The terms of the license basically emphasize the rights of software users rather than those of software owners or vendors, thus inverting the rules of the knowledge game. More concretely, a copyright owner granted users the rights to use, study, modify and distribute modified or the original version of the source code to others (or simply keep them and use them for private purposes). The copyright owner basically renounces his proprietary rights for the sake of freedom to use and operate.

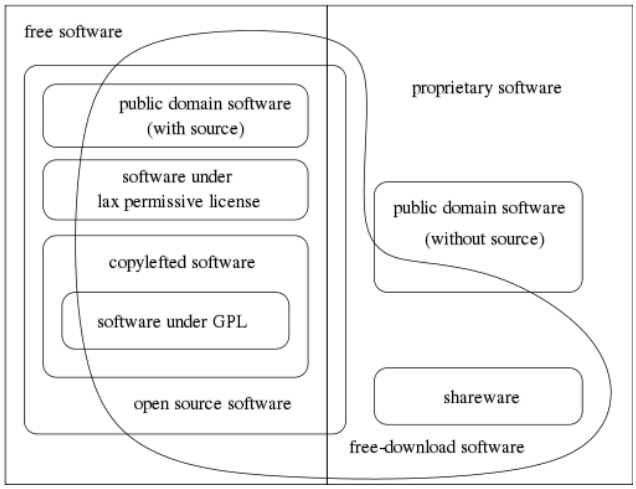

Figure 2 Categories of free and non free software according to the General Public License[269]

In 1997, fruit of the Debian Free Software Guidelines[270], the concept of free licensing was altered to increase the flexibility of the GPL. To achieve this

[268] *Id.*

[269] This diagram was originally designed by Chao-Kuei and updated by several other contributors.

purpose, the "Open Source Definition" consented open-source licenses to abandon the viral requirement.[271] In 1998, the Open Source Initiative (OSI) was established, aiming at encouraging decipher the development of open software as a mainstream commercial strategy.[272] This may have become important with the stricter collaboration between open source projects and commercial companies happening in the 1990s.[273] More recently, the GPL has given attention to issues such as the Digital Rights Management threat, tivoization[274], globalization and the compliance of the license with other licenses.[275]

The Open Source Institute was created to diffuse the usage of open source technology through legally enforceable terms of contract. The definition of open source licenses released by the OSI incorporates all licenses that allow anyone, anywhere, for any purpose, to copy, modify and distribute (through payment of a fee or not) without the obligation to pay royalties to the copyright owner. [276] It is therefore an institution that encapsulates the rightful use of licensing (not only through the GPL) as a means of protecting the rights of follow-on software users.

Open licenses differentiate from placing work in the public domain. If a work is in the public domain it means it is not copyrighted. If a piece of software is available freely in the public domain, some copies or modified version may not

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[270] Debian was an organization set up to disseminate Linux, possibly one of the most famous cases of open source software.
[271] The Open Source Initiative (1999) stated that «the license must not place restrictions on other software that is distributed along with the licensed software. For example, the license must not insist that all other programs distributed on the same medium must be open-source software».
[272] Hope, J. (2009). Open source genetics - general frameworks. In G. van Overwalle (Ed.), *Gene patents and collaborative licensing models* (pp. 171-193). Cambridge: Cambridge University Press.
[273] Lerner & Tirole, *supra* note 262.
[274] Tivoization is a term coined by Richard Stallman which refers to the system that incorporates software protected under 'copyleft' licenses, but prevents the running of modified versions of the software through hardware restrictions. It came into use after the case of TiVo, a brand of digital video recorders, which included GNU/GPL licensed software but actively blocked users from running modified software versions on their machines.
[275] See Stallman, R. (2007). *Why upgrade to GPLv3*. Retrieved January 15, 2012, from GNU: http://www.gnu.org/licenses/rms-why-gplv3.html.
[276] Hope, *supra* note 272.

be free at all, because there is no contractual obligation to make them available.[277] This is the point where free revealing and open source distinguish.

3.1.2 Economics of Open Collaboration

The open source licensing institution was born in this context of growing property rights.[278] It is a contract-based approach, established within the software community in order to address this emergent proprietary approach of commercial companies to software products and basic tools.[279] As we have seen previously, the community of software developers has historically engaged in informal cooperative exchange of software code. Therefore, open source licenses are an adaptation of existing legal frameworks (copyright law) to specific conditions. Rather than a top-down intervention from state actors through legislation, these licenses take place among private actors who are not satisfied with the conditions imposed legally, without infringing such laws. To the extent these are private endeavors, licenses play the role of contract-based *modelling*[280]*,* or private-driven adjustment of a suboptimal situation.

The utilitarian school of open source advocates that such a method of production is evidently superior to closed, restrictive models because, contrarily to hierarchical firms, open source products display higher quality, take shorter to develop and decrease production costs substantially.[281] As

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[277] See GNU. (n.d.). *GNU Philosophy*. Retrieved January 15, 2012, from http://www.gnu.org/philosophy/categories.en.html.

[278] Open source is not the only institution created to solve problems arising from stricter property rights. Patent pools and clearinghouses are two examples of applicable collaborative licensing models. A patent pool consists of a consortium of enterprises with patents related to a particular technology, which establishes a platform enabling cross-licensing agreements, in order to avoid blocking patents. Clearinghouses are mechanisms whereby providers and users of goods, services and information are matched, through networks that facilitate the exchange of information and technical and scientific cooperation. An example of such mechanisms is the Clearing-House Mechanism of the Convention on Biological Diversity. For a complete understanding of collaborative licensing models see Van Overwalle, G. (Ed.). (2009). *Gene Patents and Collaborative Licensing Models*. Cambridge: Cambridge University Press.

[279] Hope, *supra* note 272.

[280] For a deeper view of "modelling" in the institutional context see Braithwaite, J. (1994). A sociology of modelling and the politics of empowerment. *The British Journal of Sociology , 45* (3), pp. 445-448.

[281] Boettinger, S., & Burk, D. (2004). Open source patenting. *Journal of International Biotechnology Law , 1* (6), pp. 221-231.

Raymond puts it «given enough eyeballs, all bugs are shallow»[282], expressing the superior mechanism of open source peer reviewing. The more widely available the source is, the more rapidly bugs will be discovered.

Most economic literature around open source has examined the sort of incentives behind collaborative projects and the role played by collaborative endeavors in a market dominated by property rights, for example regarding the business models applicable to open collaborative undertakings. Such literature has been particularly, although not exclusively, focused on the software phenomenon of open source. The next sections will be dedicated to these issues.

3.1.2.1 A paradigm shift

The producers' model is conventionally perceived as superior in providing the market with innovative inputs and outputs. The reasoning has been that profit for producers would incentive them to engage in innovative activity and, by the same token, given the profits, producers can afford to invest more in further innovative activities. This reasoning is behind the design of producer incentives theory.[283] Nevertheless, empirical studies show that open collaborative innovation may be competing and even displacing the producers' model in many sectors of the economy.[284]

The theories of producers incentive, upon which intellectual property policies build, support the idea that granting monopolies over innovative ideas and products will eventually turn out to be valuable to society, even though it generates clear losses expressed through the restriction in accessing, using and reproducing such ideas and products. As explained in Chapter 2, the idea is that preventing the misappropriation of one's ideas/products incentives innovators to invest. Accordingly, spillovers of protected information reduce

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[282] Raymond, E. S. (2000). *The Cathedral and the Bazaar*. Retrieved January 15, 2012, from http://www.catb.org/~esr/writings/homesteading/cathedral-bazaar/.
[283] Baldwin, C., & von Hippel, E. (2009). Modelling a paradigm shift: from producer innovation to user and open collaborative innovation. *Harvard Business School Working Papers* (10-038).
[284] *Id.*

the profits to the innovator, therefore reducing the willingness of innovators to spend additional resources in further innovative actions. What society has to gain with this model is the fact that information which was previously kept secret (trade secrets) becomes fully available, in addition to the benefit in itself represented by better or more effective product and processes.

The conventional producers' model defines strict roles to suppliers and receivers in the market. In this framework, producers develop their goods and services in a closed fashion, protecting their creation through intellectual property rights, say by patenting innovative outputs or enforcing trade secrecy to prevent imitation or free-riding. The role of the users in this ecosystem is reduced to demand, or having needs, which would ideally be identified by manufacturers. The latter would then supply the goods and services so as to meet such demand.[285]

Open collaboration models have clearly challenged these assumptions, so that, accompanied by alternative models of user-based innovation, the user or consumer (firms or individuals) leave the typical static role of "demanders" to assume a role of knowledge producers.[286] Indeed, studies have shown that 10 to nearly 40 percent of users engage in developing or modifying products.[287]

As a driver of innovation, open collaboration has been grabbing particular parts in the economy given the increasingly «digitalized and modularized design and production practices, coupled with the availability of very low-cost, Internet-based communication».[288] Ultimately, the costs of information dissemination have been tremendously reducing overtime due to the Internet and other advanced information and network technologies.

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[285] See Von Hippel, E. (2005). *Democratizing Innovation.* Cambridge: MIT Press.
[286] *Id.*
[287] *Id.*
[288] *Id.*, at p. 3. Modularity refers to systems in which elements are decomposable into smaller subsets called modules. The elements may be decisions, tasks, or components. Software is modular to the extent that it may be composed by different, interchangeable components, which put together will function as a whole. Digitalization refers to the trend of information and physical products to be represented through binary language.

Contrary to the conventional view, these new perspectives on innovation refuse the concept that profits are the only incentive to innovate. In fact some empirical cases illustrate the range of monetary, social and learning motivations that must be dragged into the economic models for a complete insight of the phenomenon.

In addition, the model of open collaborative innovation[289] also challenges the idea that all information outside IP protection tends to be kept secret. In reality, though, free-revealing has been reported as a relatively diffuse phenomenon especially among users (firms or individuals), also outside the framework of software development.[290] Free-revealing may be the new paradigm for the exchange and transfer of information amongst users who may be found in self-organizing collectives outside traditional firm boundaries.[291] These new ways of producing knowledge may be complementary to their commercial counterparts or may somehow feed the industry.[292] At the same time users' knowledge production may directly compete with traditional firms in particular markets.[293]

Novel and more efficient systems of propagating knowledge predict a widespread participation in knowledge production, for it may be done at very low costs. Therefore, the Internet and other facilitating tools have been fundamental to the democratization of knowledge creation.[294]

Widespread networking technologies revolutionized the way communication and knowledge production is done. Perhaps the deepest arrangement change

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[289] Open collaborative innovation projects as defined by Baldwin and von Hippel involve «users and others who share the work of generating a design and also reveal the outputs from their individual and collective design efforts openly for anyone to use». In Baldwin & von Hippel, *supra* note 283, at p. 16.
[290] *Id.*, at p. 5.
[291] Lakhani, K. R., & Tushman, M. L. (2012). Open innovation and organizational boundaries: the impact of task decomposition and knowledge distribution on the locus of innovation. *Harvard Business School Working Papers* (12-057).
[292] Von Hippel, *supra* note 282.
[293] See Lakhani & Tushman, *supra* note 291.
[294] See von Hippel, *supra* note 282. The author perceives the democratization of knowledge as the increasing ability of users of products and services (both firms and individual consumers) to innovate for themselves.

derived from it is that it «connect[s] people around interests rather than through geographical location or company affiliation».[295] This has profound consequences in the way innovation is carried out and perceived, posing challenges to the classical innovation logic.[296]

Open source software and its particular model of user/peer innovation go beyond traditional concepts of firm-based innovation (or the "private investment" model). New sources of knowledge inputs arise outside the firm. These unconventional sources of knowledge «push the locus of innovation outside traditional firm boundaries»[297] while often competing directly with firms in the markets.[298]

A further economic perspective highlights both the private and the collective features of open source projects. There are essentially two models used for rewarding innovation, one relying on private investment and the other one in collective action. On the one hand, the "private investment" model assumes that private investment is the driver of innovative activities, because private investors will be rewarded by returns on their investment. From this perspective, encouraging innovation will be more effectively done if society grants private actors such returns on investment, in this particular case through property rights mechanisms. This view is well entrenched in current intellectual property law.

On the other hand, the "collective action" model, applies to the provision of public goods, which are by design non excludable and non-rival, and it requires that contributors make their work available in a common pool. Von Hippel and von Krogh affirm that the case of open source software development provides an interesting blend of both models, with a private investment layer as well as a collective action layer, explained solely through a novel "private-

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[295] O'Reilly, T. (2005). The open source paradigm shift. In J. Feller, B. Fitzgerald, S. A. Hissam, & K. Lakhani (Eds.), *Making sense of the bazaar: perspectives on free and open source software.* Cambridge: MIT Press.
[296] Lakhani & Tushman, *supra* note 291.
[297] *Id.*
[298] Baldwin, *supra* note 283.

collective" model. In the authors' words «this behavior appears to offer society the best of both worlds – new knowledge is created by public funding and then offered freely to all».[299]

3.1.2.2 Why do users engage in open collaboration and peer assessment?

In order to examine the motivations behind collaboration in open projects one has to count for their heaviest costs. Collaborators have a time opportunity cost because OS activities are generally not remunerated or in any case retarded when compared to IPR activities. Time spent in OS activities could be dedicated to remunerated tasks. They also invest physical resources, even though in the case of software it is generally material that the user already possesses (the personal computer and other hardware).[300] So why do software developers engage in open collaborative projects, considering that collaborators are often highly skilled and had perhaps more direct economic benefits if engaging in proprietary software development? Why would anyone – against the entire logic of property rights theory – embark in complex activities with high requirements of time and technical knowledge whose fruits do not fall under property rights protection?

Scholars have put forward several justifications in this regard. Von Hippel considers that what motivates collaboration by users is their need to solve their own unique problems.[301] For instance, developing open source software may contribute to the performance improvement in remunerated jobs. Customization falls under this description, to the extent that users convert solutions that are general into solutions adapted to one's personal needs. In

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[299] Von Hippel & von Krogh, supra note 263.
[300] Lerner, J., & Tirole, J. (2005). The economics of technology sharing: open source and beyond. *Journal of Economic Perspectives , 19* (2), pp. 99-120.
[301] See Von Hippel, E. (1998). Economics of product development by users: impact of "sticky" local information. *Management Science , 44* (5), pp. 629-644.

other words, where users have unique needs and solution information, they will exploit this advantage to solve them on their own.[302]

On the other hand, Haruvy, Wu and Chakravarty conclude that the main determinant of collaboration is a combination of social considerations and potential future financial rewards accruing from open collaborative endeavors.[303] Monetary rewards may be inclusive of the possibility of future job offers, shares in commercial open-source based companies and access to market capital ventures.[304]

Another viewpoint suggests that intellectual curiosity is in fact the true driver of collaboration. This perspective identifies motivations of personal, educational or social nature, which can entail such justifications as the simple pleasure of learning, gratification from peer recognition and to some extent expected reciprocity.[305] Interestingly enough, by sharing information, collaborators may enhance their reputation and benefit from positive network effects.[306]

We may as well add that private collaborators to open projects avoid incurring in private costs related to intellectual property protection, which tend to be quite expensive. These costs, which include for instance patenting and maintenance fees and potential court trials, may be too high for developers to bear, especially considering that most open source projects are of personal character. On the whole, costs of disclosure, which include the loss or adjustment of intellectual property rights and the costs of diffusion, have to be counterbalanced with the private benefits to receive in return. Users and peers incur in private costs associated with the development, review and extension of

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[302] *Id.* Von Hippel describes thoroughly how users rather than suppliers are the real designers of many products and solutions. Additionally, von Hippel offers evidence of this pattern in the industries of application-specific integrated circuits and computer telephony integration system.

[303] Chakravarty, S., Haruvy, E., & Wu, F. (2007). The link between incentives and product performance in open source development: an empirical investigation. *Global Business and Economic Review , 9* (2), pp. 152-169.

[304] Hope, *supra* note 272.

[305] *Id.*

[306] Von Hippel & von Krogh, *supra* note 263.

work, but in compensation they acquire the value of the entire design, including improvements made by peers.

Harhoff, Henkel and von Hippel collect incentives for free revealing in the context of open source software development in four main categories.[307] Firstly, reputational incentives may influence users to freely release quality code in order to increase their reputation as programmers with the peers, as well as the value in the job market.[308] Secondly, there are incentives associated with the low level of damage to the innovator associated with the decision to freely reveal. Generally it can be said that programmers contribute as a learning or hobby activity, out of which they may gain more than what they actually lose. Thirdly, users may be compelled to abide to communal norms, as it happens within the hacker community. For instance, there is a generalized reciprocity expectation to freely reveal code when one has benefited from the existent code at disposition. Lastly, the authors highlight the incentives correlated with the increased diffusion of knowledge products, such as network effects, reputational gains and related innovations induced among and revealed by other users. However, in general terms, it may be said that benefits tend to be delayed in comparison to commercial projects (under proprietary settings).[309]

Even though the nature of incentives towards collaboration in knowledge creation is a rather complex issue, there seems to be one basic imperative. It is that collaboration dependents almost entirely on whether benefits overtake the costs of disclosure. In other words, users contribute freely to the provision of public goods because they garner private benefits from doing so and such benefits may be varied. Yet when costs of engaging in collaborative actions are higher than the benefits to be harvested, then it is rather clear that there are no

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[307] See Harhoff, D., Henkel, J., & Von Hippel, E. (2003). Profiting from voluntary spillovers: how users benefit from revealing their innovations. *MIT Sloan School of Management Working Papers* (4749-09). The authors sustain that even though the GPL is not truly free revealing, because it imposes obligations on users to maintain the software non-proprietary, they agree that given the impact of the license, it may be included in this description.

[308] These two arguments are supported by Raymond, *supra* note 282, as well as by Lerner & Tirole, *supra* note 262.

[309] Lerner & Tirole, *supra* note 262.

incentives to engage in the provision of public goods. This imperative will help us better understanding the strengths and weaknesses of open collaboration in the knowledge game.

3.1.2.3 Open Business Models or "where does the money come from"?

By freely revealing potential or real proprietary information, innovator users (firms or consumers) sacrifice their IP monopoly rights. This phenomenon has been propagating in determined sectors of the economy, namely software development and biotechnology. Freely revealing entails that information is «voluntarily given up by innovator and all interested parties are given access to it».[310] Thus it becomes a public good, and whoever receives and uses such information is not liable to pay royalties to the innovator, even though the latter may have incurred in costs to come up with such information.

Free provision of complex public goods has come to dispute the market presence of commercial proprietary firms. It requires a transformation of the rules of the knowledge game and adaptation on the part of firms to these novel channels of knowledge. The mechanism through which firms, collaborative communities and other similar knowledge production entities interact and relate has been influenced by such changes. The locus of knowledge production has moved beyond the traditional boundaries of the firm, facilitated by more efficient means of communication and information exchange.[311]

One of the core dilemmas of open collaboration is connected with the lack of incentives to invest, given that reduced or even absent returns on initial investment are assured. How exactly can a company make profit and pay off their nonproprietary ventures? This is particularly puzzling for the fact that the outcomes of such ventures are exposed to extremely competitive settings, whereby potentially anyone can become a competitor. The most important feature of open collaboration is precisely that competition is very intense and

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[310] Harhoff, Henkel & von Hippel, *supra* note 307.
[311] See Lakhani & Tushman, *supra* note 291.

unpredictable, because the figures of the producer and the consumer to a certain extent merge.

For what reason would profit-seeking firms invest robust resources in cooperative projects of product development? Merges affirms that the massive growth in private contributions to the expansion of the public domain may be explained from a strategic perspective. Private actors may behave so in order to preempt or undermine the potential property rights of economic adversaries.[312] In other words, firms and individuals may be compelled to invest in public goods information as a defense mechanism against rival proprietary behavior.

Another important aspect is related to the *value* for the firm of the information revealed. To be precise, firms may be less likely to reveal core business information and less reluctant in giving up IP rights for products whose value is not recognized or known.[313] Sharing proprietary information owes mainly to the lack of recognition of real value in such information, that is, in the perception (or misperception) that such information is complementary to other products developed by the firm. From this perspective, making these information goods available to a wider number of users will enhance their value. In addition, every input attached by single collaborators will further enhance the value of the goods. It may be assumed, thus, that the cooperative model is based on value enhancement of public goods.

What business models function when intellectual property rights do not grant monopolist returns on investments? This question has been explored in the context of open source software, and empirical cases demonstrate the viability of the commercial exploitation of software which is freely available to all. Eric Raymond predicted the dominant business model in open source would have been software-as-a-service.[314] O'Reilly explains in addition that software has

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[312] Merges, R. (2004). A new dynamism in the public domain. *The University of Chicago Law Review , 71* (1), pp. 183-203.
[313] See, for instance, O'Reilly, T. (2005). The open source paradigm shift. In J. Feller, B. Fitzgerald, S. A. Hissam, & K. Lakhani (Eds.), *Making sense of the bazaar: perspectives on free and open source software*. Cambridge: MIT Press.
[314] Raymond, *supra* note 282.

been commoditized, that is, it is «found to be a building block for many different purposes».[315] So, by placing software on the market at reduced costs, open source is somehow pressing the software industry. Competition generally drives prices down, and may end up eliminating firms which cannot correct their inefficiencies. This process has been repeatedly coined as «creative destruction», highlighting the fact that the loss in value of a product (its commoditization) is replaced with higher productivity, a higher wealth level and new business opportunities. These new opportunities are essentially what new business models for open source software explore.

There are essentially three recognized manners of reaping profits from open source software. The first business model relates to the distribution of open software. Certain firms specialize in providing the software on CD (rather the user downloading it directly from an accredited website), in providing related support (such as installation, training, technical support) and upgrading services. The distributor model is very much appreciated by firms, which generally worry about accountability, high-quality services and flawless performance.[316]

The second business model involves the production of software per se. In this case, it should be noted that the type of license is fundamental in the design of business strategies. When the license of the software is not the GPL, that is not viral, software producers may incorporate open source code to create a new product. This will allow the producer to benefit from lower production costs, while only obliged to acknowledge that it benefited from the open source code.[317] Under the GPL the rules of the game change substantially, because the producer is forced to release any source code of the derived product. This

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315 O'Reilly, *supra* note 313, at p. 464.

316 Krishnamurthy, S. (2005). An analysis of open source business models. In J. Feller, B. Fitzgerald, S. Hissam, & K. Lakhani (Eds.), *Making sense of the bazaar: perspectives on open source and free software*. Cambridge: MIT Press.

317 *Id.* Krishnamurthy explains how Microsoft utilized software under the Berkeley Software Distribution (BSD), a non-viral license, without granting access to the source code back to the BSD community. The software giant had simply to acknowledge that it had benefited from open source code.

might be explained by different expectations on users: GPL licensors expect users to be empowered and willing to modify and tinker with the source code.[318]

The last business model is the third-party service provider, and it relates to onsite/local assistance to firms or individual users. This service is typically coupled with the distribution model.[319]

Clearly the success of these business models is mainly dependent on the quality of the product proposed and it is highly affected by factors such as the fierce competition among open source products, the presence of competitive proprietary software products, the competitive position of the product and brand awareness. In the overall, we may conclude by highlighting that profit attractiveness has moved forward in the value chain, to the services related to software rather than software itself.[320]

3.1.3 Conclusions

The open source movement, originated in the communities of software developers, has revealed a hidden side of innovation models: the one where users contribute actively to innovative processes. This movement does also highlight that there are alternative paths to the IPR mainstream road and which may lead to a more reasonable use of property rights and common pool resources. Similar problems arising within the biological sciences make us wonder whether such a model could be transported to the lab.

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[318] *Id.*

[319] *Id.*

[320] See Christensen, C. (1995). *The innovator's dilemma: when new technologies cause great firms to fail.* Harvard: Harvard Business Review Press.

3.2 Open Collaborative Models in Biology – concept extension

Collaborative behavior within the software industry has brought about the discussion around the open source model and its applicability to other sectors of the economy, namely the biological sciences, so as to conduct consumer friendly policies while ensuring that innovation and advancement were taking place in a sustainable manner. While the applicability of these mechanisms to biological material are still rather theoretical, some initiatives of collaborative character have taken place in recent years in the field. These cases have attracted much attention for their ground-breaking characteristics, and for the success of some of its initiatives.

In practice these institutions are a prototype for a radically different approach in a field of science that is perceived as more dependent on patent rights than any other.[321] The idea is that patents rights need not be exploited through exclusive licenses in view of financial returns. Instead, patentees may make their core technologies available for wide use in a "protected commons", where patentees retain their patent rights, but have obligations vis-à-vis the users of the common pool. An open approach to the sciences will mainly depend on how it is molded to the particularities of the biological industries. [322]

Throughout this subchapter we will provide an overall assessment, as far as possible, of the viability of an open science approach applied to biogenetic research, an industry which is strongly governed by patents. We will also analyze and discuss the most important open source initiatives regarding biological material.

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[321] Levin et al., *supra* note 16.

[322] Rai, A. K. (2009). Critical commentary on 'open source' in the life sciences. In G. Van Overwalle (Ed.), *Gene Patents and Collaborative Licensing Models*. Cambridge: Cambridge University Press.

3.2.1 Extension to fields other than software development

The open source movement is noticeably still quite unexplored outside the software industry framework, although the feasibility of exporting the open source system to other industries, namely to biogenetic research, has also been questioned by many.

Indeed, the open source software movement was inspirational to many projects beyond the boundaries of that industry. Perhaps the most successful application of the ideas of freedom in knowledge goods is Creative Commons, an institution founded in 2001 devoted to «the idea of universal access to research, education, and culture».[323] Largely based on copyright law, the founders of the institution designed several copyleft licenses (Creative Commons licenses, or CC licenses), which allow creators to define the terms of access to follow-on creators and users. In the same way as the GPL, CC licenses consent a standardized approach on the part of interested copyright owners, generally to assert that instead of «all rights reserved», only some rights are. Creative Commons uses copyright law to mitigate infringement on the Internet – of unauthorized copying and distribution of copyrighted material – similarly to the function of digital tools and legal action.[324]

However distinctive CC licenses and the GPL might be both share the same legal ground. Copyright law protects against unauthorized copy, distribution and the preparation of derivative works, as well as performance and display by unauthorized third parties. However, the monopoly rewarded to authors of original works protects only the particular *form of expression*.[325] Designers of copyleft licenses used such tenets to turn the game of knowledge around, stressing the freedom of users, especially given the distributive opportunities offered by the Internet and analogous networks.

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[323] Creative Commons, *supra* note 118.
[324] Broussard, S. L. (2007). The copyleft movement: creative commons licensing. *Communications Research trends*.
[325] On this matter, see subchapter 2.2.3.

This is precisely the point where they differ from gene patents. Genes are protected under patent law after isolation, and often the claims of the patent include their chemical composition and the processes to obtaining such gene. Genes may as well be integrated in innovative products, say genetically modified plants or animals. In view of such conditions, there are three topics we must highlight. Firstly, the fact that patents offer exclusive rights on building blocks spreads the seeds for abusive behavior on the part of the patent holder. Secondly, genetic information is unique and thus cannot be invented around, which is commonly perceived as the "safety valve" of patent monopolies. For this motive, we can assert that gene patents are more firmly enforceable and the blocking effects of such patents more hazardous. Finally, even though patent law and copyrights have a common philosophical foundation, there are fundamental structural differences between the two which cannot be overlooked. We attempt at exploring the viability of an open source approach to the biological sciences, with all its particularities, problems and opportunities, in this last sections of the present Chapter.

3.2.2 Open source and biological materials

Similarly to source code, proprietary rights over raw genetic information may become burdensome to follow-on technological development. Patent thickets are a common concern to open source programmers and scientists alike. A patent thicket is «overlapping set of patent rights requiring that those seeking to commercialize new technology obtain licenses from multiple patentees».[326] Transaction costs are negatively affected by such fragmentation in fundamental building blocks of technology.

More specifically, patent thickets may be partly liable for the late introduction of innovative products in the market. Developing a critical pharmaceutical product, for instance, may depend heavily on the availability of several stakeholders to license their personal patents, and the company willing to

[326] Shapiro, C. (2001). Navigating the patent thicket: cross-licenses, patent pools and standard setting. In A. J. Jaffe, J. Lerner, & S. Stern (Eds.), *Innovation policy and the economy* (Vol. 1, pp. 119-150). MIT Press.

invest in R&D may be caught up in an overlapping web of proprietary rights. Patent thickets are more problematic where the number of licenses involved is high. In fact, «the number of licenses required of users may be too costly and inefficient for users to negotiate. (…) By increasing uncertainty and conflict and restricting freedom of movement surrounding use of a technology, a patent thicket may impede its adoption, interoperability and use».[327]

The cumulative nature of technology development renders it extremely sensitive to intellectual property rights. Isaac Newton recognized that he has reached new heights only by standing in the shoulders of giants. Shapiro completed the analogy with the acknowledgement that scientific researchers today are effectively on top of a gigantic pyramid, built up by multiple patent holders.[328] Heller and Eisenberg discuss this issue applied to biotechnology, claiming that a tragedy of the anti-commons was in place where excessive intellectual property protection may cause a resource to be underused. This may be the case of the fragmentation in the market caused by multiple patentees holding essential patent rights.[329]

Moreover, complementary patent rights and capabilities may cause much inefficiency and raise dangerous transaction costs for those seeking to commercialize new technologies.[330] These problems require coordination measures, but antitrust law is very much unsympathetic to cooperative agreements between horizontal competitors. Scotchmer argues that even though prior agreements between prior and later generation innovation would lead to optimal results and more efficient investment in follow-on products, the truth is that antitrust authorities do not allow collusive agreements among firms. The author concludes that given the instruments of patent law are

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[327]Horn, L. A. (2009). Case 1. The MPEG LA® licensing model. What problem does it solve in biopharma and genetics? In G. Van Overwalle (Ed.), *Gene Patents and Collaborative Licensing Models*. Cambridge: Cambridge University Press, at p. 33.
[328] Shapiro, *supra* note 326.
[329] Heller and Eisenberg, *supra* note 22.
[330] Shapiro, *supra* note 326.

limited to breadth and length it may be actually a very blunt instrument to respond to such sensitive problems.[331]

Given that the fundamental problem which Stallman aimed at solving with the GPL can noticeably relate to the fundamental problem in research and development in the biological sciences – the anti-commons problem – there has been substantial excitement as to the viability of similar rules applied to genetic research. In the overall, scientists may be willing to protect basic biological discoveries through patents when their significance to commercial applications is enhanced. Where value is perceived for essential building blocks, scientists and their sponsors will try to hold on to intellectual property rights. [332] This is true for both for software and biogenetics, causing common pools of information to diminish in size and value. In other words, it is possible to provide a negative definition of intellectual property rights to the extent they translate into structured, systematic exclusions from the public domain.[333]

On this aspect the movement for biological open source shares the transformational basis behind software open source, as well as its democratic character. Beyond these generic topics, genetic research and software development share other similarities. For example, the scientific and the hacker communities do, in broad lines, share some ethical views and behavioral standards. In this regard, informal rules play an important role within the scientific community, as well as within the hacker community, thus making these communities rather responsive to incentives of reputation and social recognition – what Benkler called the social-psychological reward.[334] Informal rules may be defined as the behavior of a community given the existence of

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[331] Scotchmer, *supra* note 136.
[332] Eisenberg, *supra* note 2.
[333] Taubman, A. S. (2009). Several kinds of should - the ethics of open source in the biological sciences innovation. In G. Van Overwalle (Ed.), *Gene patents and collaborative licensing models.* Cambridge: Cambridge University Press.
[334] Benkler, Y. (2002). Coase's penguin, or Linux and the nature of the firm. *The Yale Journal , 112* (3).

certain shared norms, even though sanctions on free-riders has been formally agreed upon.[335]

However, Raymond observed that the hacker culture was a "gift culture", where competition is measured by the level of reputation, in other words by the quality and quantity of "gifts" conveyed to the rest of the community.[336] Raymond goes on arguing that such a gift community arises in a context where there is no scarcity of resources, which is the case of software communities. Resources for open source software development (computer power, network bandwidth and so on) are rather cheap, abundant and widely spread.[337]

Interestingly enough, Lerner and Tirole found that where the community of users was relatively specialized strong copyleft licenses were not so common.[338] Strong copyleft licenses are those which require the code modified under the license to be made generally available (the copyleft provision). The fact that specialized communities within the software realm do not rely on strong legal obligations proves the point. Non-legal social norms may indeed have a particular magnitude in the biological sciences. This does not mean, of course, that there is no other incentive to which the scientific communities respond to. It is important to note that scientists often answer to corporative management or university departments and their quests for proprietization.

There are unique features in terms of context and industry structure which must be discussed when considering a translation of an open source arrangement similar to the one happening in the software industry. Firstly, genetic resources and software code represent two completely different realities, mainly from the point of view of industry organization. Secondly, structural differences between patent and copyright law call for a better

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[335] Dedeurwaerdere, T. (2009). The role of law, institution and governance in facilitating access to the scientific research commons - a philosopher's perspective. In G. Van Overwalle (Ed.), *Gene patents and collaborative licensing models*. Cambridge: Cambridge University Press.

[336] Raymond, E. (2000). *Homesteading the Noosphere*. Retrieved January 16, 2012, from http://catb.org/~esr/writings/homesteading/homesteading/.

[337] *Id.*

[338] Lerner, J., & Tirole, J. (2005). The scope of open source licensing. *Journal of Law, Economics and Organization , 21* (1), pp. 20-56.

analysis of legal barriers to collaborative contracts. Lastly, complex ethical issues and protocols in genetic research must be included in the debate around the convenience, effectiveness and efficiency of open and collaborative models in biology.

3.2.2.1Industrial organization and open collaborative projects

As Janet Hope puts it open source is an approach to technology development, IP licensing and commercialization which has its seeds in the software industry, and addressed conditions shared with the field of genetic research, in particular the freedom to use and operate due to proliferating property rights.[339] Even though the basic problem to be addressed is the same, the open source movement has to be contextualized and understood in its many forms and shapes within the software realm.[340] We have made reference to restrictive licenses, such as the General Public License with its *share-alike* requirement, as well as non-GPL licenses which tend to be more tolerant towards follow-on usage of the source code.[341] In the same line, open collaboration in scientific research must have a rather malleable design. Indeed, many aspects inherent to the functioning of the industry decline any one-size-fits-all expectations, even though the criticism to existent open source projects have been based on their detachment from pure open source features.[342]

Genetic research and software development encompass essential differences. Objectively, breeding plants may have little comparison with writing software code. For example, as we have repeated often throughout our argumentation, there is no option for inventing around a gene. Making an analogy to software, there is one and only operating system when it comes to genes; in genetic

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[339] Hope, *supra* note 272.
[340] Arti K. Rai. Critical commentary on "open source" in the life sciences. In *Perspectives on Free and Open Source Software*. Edited by Joseph Feller, Brian Fitzgerald, Scott A. Hissam and Kiram Lakhani. MIT Press: Cambridge, 2005.
[341] It must be noted however that norm-based obligations of reciprocity do play an important role in the construction of a source public domain.
[342] We will address the implementation in real world projects and their characteristics further on this chapter. See subchapter 1.2.3.

research there is neither the possibility of inventing around DNA nor developing a functional alternative to it.[343]

In addition to that, products derived from biological material are often subject to extremely high regulatory requirements, like in the case of drug development, cosmetics or genetically modified food and feed. These risk management measures are necessary because they concern sensitive issues such as public health and food security. Differently from software development as we know it today, biotechnology and pharmaceutical products are expensive to bring all the way through to commercialization.

Perhaps the major difference between software and biological sciences is the capital costs of the latter. Capital costs of development tend to be much higher for the biological sciences. Computer software can be done from the programmer's own house, while biotechnology is done in laboratories. Software is done in a computer, which is normally owned by the programmer. Conversely, biologists and chemists need access to highly specialized and often costly equipment, which somehow has to be paid for. In addition, patents present high costs of registering, of maintenance fees and require often the services of patent attorneys.

This aspect might be responsible for a more commercially-oriented behavior on the part of scientists or their sponsors (public or private entities). In effect, Robert Merges claims that the more expensive it is to create biological material, the less likely it is shared. A related contour of practice asserts that material and information flow more easily among unrelated fields than actually among competitors.[344]

Business models in science seem to be shaped accordingly. Given the requirement of covering investment costs (fixed costs) of R&D in industries such as biotech or chemical and pharmaceutical, scientists and sponsors adopt a protectionist posture towards competitive scientific communities. They do so

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[343] Taubman, *supra* note 333.
[344] Merges, *supra* note 1.

by making aggressive use of IPR (trade secrecy or patents), and this position is partially responsible for an inefficient employment and management of resources. This trend is a reality in public sector research establishments, where funding is perhaps more contingent. Public sector researchers engage often in proprietary research as a solution to budget constraints and urge towards financing from industrial sources, especially in the life sciences.[345] Eisenberg asserts that changes in the intellectual property rights rules have instigated the strategic behavior by researchers, who tend to be more secretive and more oriented to the calculated patenting of their discoveries.[346] In this trend we should include such intellectual property reforms as the growing *proprietization* by university departments[347] and public laboratories of their upstream technologies.

Congruent with this line of thought, the biology *open source* movement provides a different approach to IP management by trying to combine the lacking freedom to use, operate and distribute with the ability to generate revenue for investors through alternative business models.[348] This model builds necessarily on top of a proprietary foundation, as we will observe when we present our case studies.

Whether biology will become open may depend heavily on the overtime fall of operational costs, in the same manner software development became easily accessible and something feasible from a personal computer, rather than in complex and expensive machines.[349] Open access to basic resources in biology

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345 David estimates that industrial sources fund 25 per cent of the life sciences R&D programs at the leading public sector institutions. See David, P. A. (2004). Can "open science" be protected? *Journal of Institutional and Theoretical Economics , 160*, pp. 9-34.

346 Eisenberg states that informal scientific norms prevailed among the scientific community and that the trend toward private rights in scientific research should be reversed for the sake of the biotechnology commons. See Eisenberg, *supra* note 2.

347 The Bayh-Dole Act mirrors the growing request for intellectual property protection by American universities.

348 Editorial: open sesame. (2006). *Nature Biotechnology , 23* (6), p. 633.

349 Bains, W. (2005). Open source and biotech. *Nature Biotechnology , 23* (9), p. 1046.

may assist in the reduction of transaction costs by making such high expenditures more efficiently and effectively managed.[350]

3.2.2.2Patent law vs. Copyright law

Software and biological material are different subject-matters for intellectual property law. The fact that life sciences are thought to be less proprietary is related to the higher investments and higher regulatory frameworks to which biological material and products derived thereof are subject.

The open source movement in the software arena applies within the specific framework of copyright law. Patents have quite a different legal structure, therefore a translation of the movement must adapt to the different rules of the game, especially when we are referring to a field of science that seems to be tremendously dependent on patent rights to appropriate the returns on high initial investments. It should also be noted that in particular the biotechnology and pharmaceutical industries rely also in other forms of intellectual property protection. For instance, trademark law plays a relevant role in pharmaceutical products' marketing. This is to say that while software development might be quite homogeneous in terms of legal protection, biological materials are not.[351]

For instance, copyright protection instigates from the moment an original work is created. On the other hand, applications to patent protection generally undergo a lengthy, meticulous process of understanding whether the invention satisfies the requirements for being awarded a patent. It is clearly a case-by-case analysis, which is regulated through precise commands and has important implications on the continuation of the patent system's credibility. For that reason, drafting licenses that encompass this complexity is certainly a very hard task.[352]

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[350] See Berthels, N. (2009). Case 8. CAMBIA's Biological Open Source Initiative (BiOS). In G. Van Overwalle, *Gene patents and collaborative licensing models*. Cambridge: Cambridge University Press.

[351] See Hope, J. (2008). *Biobazaar: the open source revolution and biotechnology*. Cambridge: Harvard University Press, at p. 142-145.

[352] Andrés Guadamuz González. 2006. Open Science: open source licenses in scientific research. *North Carolina Journal of Law and Technology*. Vol. 7 (2), pp. 321-366.

Patents are a social compromise whereby innovators make the information about their invention publicly available in exchange for a right to exclude others from exploiting it without an apposite license.[353] Hence, patents already granted the disclosure of information to the public domain, unlike the case of software which is compiled into machine-readable code. The information is indeed made widely available, so why should society foster openness to something that is already public? In filling a patent, patent owners have an obligation to disclose the invention, either through written claims or, often in the case of biological materials, through deposit in a publicly accessible repository. Repositories became a practice because biological materials and natural phenomena are difficult to describe with words.[354]

The patent mechanism already encompasses a disclosure of the invention. However, the patent itself may block the public use of such invention; ultimately it is a question of «accessibility rather than disclosure».[355] Similarly to copyright, label licenses have been used in the context of patents in the form of "seedwrap" licenses[356], and repositories generally impose specific terms of access.[357] Therefore, public repositories or universities material transfer agreements may at least in theory impose or notify an open source license.

However, as Boettinger and Burk eloquently put it, it is not clear whether single patent holders can make a claimed patented invention widely available under broad terms of use. The reason behind this is connected to the condition of *privity*, that is, the nexus of contact that confers validity to a contractual arrangement between an offeror and the offeree. Because the

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353 See the description of the disclosure requirement for patents in chapter 1.
354 Boettinger & Burk, *supra* note 281.
355 *Id.*, at p. 225.
356 "Seedwrap" licenses may be compared to "clickwrap" licenses in software. Seedwraps are commonly used forms of contracts, whereby the terms of such contract (normally ascertaining exclusive rights) are printed or attached to the seed bags sold to farmers. By using the seed, the farmers implicitly agree on the terms of such contract. See Aoki, K. (2003). Weeds, seeds & deeds: recent skirmishes in the seed wars. *Cardozo Journal of International and Comparative Law , 11* (2), pp. 246-331.
357 Boettinger & Burk, *supra* note 281. Material Transfer Agreements (MTAs) among universities and research labs are a practical example of label licenses under current patent law practice.

world is not in privity with an offeror, and there is no specific context so as to define meaningful terms of a license, hardly any obligation arises from sufficiently general licensing terms.[358]

Unlike copyright, there seems to be no mechanism within patent law to dedicate an invention to the public without having to renounce the patent.[359] Indeed, patent owners have an obligation to enforce their patent rights, otherwise not suing in case of infringement could result in an approval of such infringement. This is quite different than asserting one's patent rights to ensure wide accessibility to one's invention. In fact, in practical terms, not asserting one's rights has the same effect as not patenting in the first place, thus leaving the invention to potential capturing in proprietary improvements of such technology.[360]

Instead, patent rights must be enforced to ensure the protection of common resources, of building blocks of scientific advancement. For that matter, open source patenting, that is, licensing patented inventions through particularly permissive terms, can be very effective in precluding the commercial exploitation of protected essential biological materials, as well as promoting their non-commercial creative exchange and adaptation.[361] Certainly this view demands a clear differentiation between upstream inputs and downstream outputs, as well as a clear definition of improvements to basic tools of research and novel derived products. In sum, securing property rights is vital to avoid that raw data and basic tools are enclosed in proprietary rights by anyone who performs any incremental improvement to such data or tools. This is a real risk for the open source approach to the life sciences, and that is the reason why patent rights must be enforced as a defensive strategy.

In reality, this view does not exclude patent rights as such; it rather reinforces the idea that patentees should be encouraged to deploy their patent rights so as

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[358] *Id.*
[359] *Id.* Even though Boettinger and Burk refer specifically to US patent law we actually verify that the statement holds true within the European patent ecosystem.
[360] *Id.*
[361] Taubman, *supra* note 333.

to preserve a widespread access to basic units of information in the biological sciences. Similarly to copyleft licenses, an open model for basic biological materials would emphasize the right of patentees to distribute their knowledge and garner the positive network externalities appended to such openness. An appropriate structure in this direction could balance the trade-off between access and incentives - the eternal dilemma of intellectual property law.

3.2.2.3 Funding open source projects

Open source scientific consortiums experience typical problems associated with collaborative action. The projects are not only highly dependent on third-party financing (public or private), but there is also the problem of free-riding. The first problem, which we will call patronage, entails the dependency from public and private funding. Because the public budget is generally constrained, the public grants for open source projects may not suffice.

On the other hand, private financing may be involved with the particular agendas of corporations, and this generally encompasses some level of expectation of returns on investment for shareholders.[362] In addition to the public/private funding schemes, according to the approach licensing fees may be charged in view of cost recovering and/or subsidizing equitable sharing.[363]

With biology becoming more computer-intensive, there is an opportunity for novel forms of research institutions and the abatement of data sharing costs, by bringing communities together on the basis of research interest rather than geographical/institutional proximity. Projects such as BiOS and Science Commons tend to underline the novel uses society can make out of current technological capabilities. However, these projects require investments, and they generally rely on public moneys or private benefactors.

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[362] Nicol, D. (2007). Cooperative intellectual property in biotechnology. *Script-ed , 4* (1)

[363] This is the case of BiOS, which requires the payment of some of the costs related to the maintenance to for-profit licensees at rates which are relative to the size of the firm. Firms which cannot afford the fee may contribute in other non-monetary forms, like by offering traineeships.

The second problem, free-riding, is very much related to the investments and it typically applies to collaborative ventures. It is particularly important in open source patenting because the essence of open projects is creating something that becomes freely available to all. The idea is that each contributor gives out a block and all of them get a complete house in return. However, public goods may be under-produced or even not produced at all in cases where licensing is not adequate. While the greatest benefit of open source is that potentially anyone can contribute, loose licensing brings about its greatest drawback: the situation in which the resource is widely exploited but hardly anyone contributes to its improvement.[364]

3.3 Practical open source approaches to biological material

There are several empirical exploitations of the concepts of open source applied to biological sciences. This section is dedicated to an overall analysis of the most pertinent cases based on the open source structure and licensing schemes to the management of nonhuman genetic data – CAMBIA's Biological Open Source Initiative (BiOS) and the ScienceCommons (SC).

3.3.1 Biological Open Source Initiative

The BiOS initiative was established in September 2004 within CAMBIA[365], a non-profit research institute based in Canberra, Australia. The initiative, originally supported by the Rockefeller foundation and the IBM[366], is generally perceived as a successful implementation in biological innovation of the principles of the open source movement even though some scholars believe it is not pure open source.[367] BiOS is but an international research network

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[364] Clearly this problem extends beyond software. For instance, Wikipedia (an online encyclopedia whose articles are count on the contribution of volunteers) had to change its policy of openness to contradict other forms of free-riding, like vandalism, prejudice and inaccuracy. See The Economist. (2006, March 16). Open-source business: open, but not as usual.

[365] CAMBIA. Retrieved February 4, 2012, from CAMBIA: http://www.cambia.org/.

[366] See Berthels, *supra* note 350.

[367] Hope believes that BiOS licenses give too much power to the licensors and insufficient freedom to "fork the code", in addition to the fact that the initiative is financially sponsored by

providing a platform where open access to a basic biological toolkit takes place, and is especially targeted to addressing the critical human challenges of the twenty-first century: poverty, hunger, decaying natural resources and third world medical treatment.[368] BiOS products and tools noticeably concentrate on developing countries' troubles which generally attract less attention from market-oriented firms.

Essentially, BiOS develops and promotes platforms and tools which assist innovators on their path to invent, improve and deliver new technologies in the field of the biological sciences, with a special focus on agriculture and medicine.[369] Deeply inspired by the open software case, this initiative aims at democratizing problem solving to enable solutions through decentralized innovation as a response to inequities in food security, nutrition, health, natural resource management and energy.[370]

BiOS licenses are tailored to the biological context and wisely distinguish tools of innovation from the products derived thereof, allowing innovators to retain their ownership rights while coupling these with responsibilities to foster efficient development, improvement, sharing and use of underlying technologies. Licensors agree not to hinder anyone from developing consequential products or technology improvements based on the core information, even if this means that both licensor and licensee may develop similar end products. Licensees, on their part, must agree to a set of legally binding conditions.

In essence, those making use of BiOS licensing schemes agree to share technology, materials and methods with other parties to the initiative,

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private parties. Project fork happens when take source code from one software package and start independent development, therefore giving life to a new project. See Hope, *supra* note 351. Rai argues contrarily that such a distinction is actually not so important in practical terms, because forking the code is not such a common phenomenon in the hacker community. See Rai, *supra* note 322.

[368] Jefferson, R. (2008). Science as a social enterprise: the CAMBIA BiOS initiative. *Innovation, Technology, Governance, Globalization , 1* (4), pp. 12-44.

[369] BiOS. Retrieved February 14, 2012, from BiOS: http://www.bios.net

[370] *Id.*

refraining to assert IP rights against them or any derived products from the common technologies, in an effort to create a "protected commons"[371] and foster dynamic synergies among its members. Users are free to make use of the technology to pursue research or to develop commercial or non-commercial products, as long as the core technology is kept outside the proprietary ventures of the parties. Hence, while demanding that improvements to IP protected enabling technology are shared among other BiOS licensees, there is no such obligation for products or materials made, created or obtained by using an enabling technology.[372] So, all licenses non-exclusive and moreover viral to the extent improvements to enabling technology are concerned, ensuring the enhancement of the core toolkit for the community.

In order to defend the common pool, the Initiative and the patent owners are required a certain enforcement power, so as to litigate against infringers of the rights involved. In order to cover these and other costs, as well as maintenance costs and not-for-profit research costs, members pay a fee fixed by the "Technology Support Services Subscription Agreement". Fees differentiate academic and non-profit organizations, whose applied fee serves «solely to cover for the costs of production and distribution».[373] For-profit firms pay a fee in accordance to their size, although companies that cannot afford such costs may contribute in other forms, such as by offering traineeships.

As an example, CAMBIA was the crib for a transformation method called TransBacter, which came as an alternative to Agrobacterium. The latter is a basic tool for performing plant genetic engineering which was intensively used for more than three decades. Because it was a preferred tool, Agrobacterium-

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[371] Hess and Ostrom define the commons as «a resource shared by a group of people that is subject to social dilemmas». Some of the dilemmas inherent to a commons include congestion, free-riding, conflict, overuse, and 'pollution'. Typical threats, on the other hand, consist of commodification, enclosure, degradation and non-sustainability. Knowledge or information commons are included in the group of commons without boundaries; a complex and variable set of resources, which have been typically seen as non-subtractive (the more it is shared, the bigger the common good). See Hess, C., & Ostrom, E. (Eds.). (2007). *Understanding Knowledge as a Commons*. Cambridge: MIT Press, p. 3-26.

[372] Berthels *supra* note 350.

[373] *Id.*

derived and related technologies were extensively patented. The legal complexity around the tool clearly presents an obstacle to its use.[374] CAMBIA's TransBacter not only created an alternative to such tool, but also made it available to all interested in using it. This and other technologies were made available under BiOS licenses and have subsisted

3.3.2 Science Commons

Science Commons is an organization launched in 2005 as a sort of mirror project from Creative Commons, on the basic concept that scientific data should be shared openly.[375] Applying the philosophical basis of Creative Commons, Science Commons designs strategies for lowering the legal barriers to scientific research using information technologies to make research data and material available to a wider range of individuals. In this manner, SC collaborators hope to contradict the present trend of secrecy within the scientific communities, intellectual property enclosure and suboptimal use of scientific data.

The Science Commons initiative relies on various tools to achieve its goals of spurring scientific advancement through open distribution of scientific data. In the overall, the three channels through which it most effectively does so are licensing, publishing and integrating data.

Similarly to the BiOS initiative, Science Commons deploys a series of licenses under its flexible and modular *Biological Material Transfer Agreement* which aims at lowering the costs of transferring physical biological material (such as DNA, cell lines or model animals).[376] This tool is generally very problematic for scientists, who often see their projects delayed or discarded for being denied access to needed research tools to MTAs.[377] The licenses collection

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374 Chung, S.-M., Tzfira, T., & Vaidya, M. (2006). Agrobacterium is not alone: gene transfer to plants by viruses and other bacteria. *TRENDS in Plant Science , 11* (1), pp. 1-4.
375 Creative Commons, *supra* note 118.
376 *Science Commons*. Retrieved February 14, 2012, from Creative Commons: http://sciencecommons.org/.
377 See Lei, Z., Juneja, R., & Wright, B. D. (2009). Patent versus patenting: implications of intellectual property protection for biological research. *Nature Biotechnology , 27* (1), pp. 36-40.

incorporated several agreements on university-industry transfer as well as two university-university transfer agreements – the Uniform Biological Material Transfer Agreement[378] and the Simple Letter Agreement[379]. Moreover, these licenses are deployed on the web, through the Creative Commons software infrastructure, a "one click" system for research in biological materials and for tracking materials propagation and reuse. Standardized SC agreements are sufficiently flexible to be made "unstandard" according to the use individuals want to make of them.[380]

Science Commons also supports and assists in the development of open-access publishing. For instance, it supports the Public Library of Science (PLoS), a non-profit scientific and medical publishing venture launched in 2003, and the BioMed Central, a publisher pioneer in open access publishing. Both ventures provide freely accessible and immediately available articles online. This is, of course, not an extensive list of the projects endorsed by Science Commons.

Lastly, Science Commons is working towards a better integration of data spread across organizational boundaries. For instance, the Neurocommons project, launched in 2007, uses an open source knowledge management platform to bring together all relevant scientific research materials, like articles, knowledge bases, research data and physical materials.[381] In order to do that, a sort of digital library was created, where it is possible to combine knowledge sources in an easy and meaningful manner using the Semantic Web tools.[382] The project is protected under an Open Source Initiative license and for the

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[378] National Institute of Health. (n.d.). *Uniform Biological Material Transfer Agreement*. Retrieved February 25, 2012, from http://www.ott.nih.gov/NewPages/UBMTA.pdf.
[379] National Institute of Health. (n.d.). *Simple Letter Agreement*. Retrieved February 25, 2012, from http://www.ott.nih/pdfs/slaform.pdf.
[380] iBridge Network. (n.d.). Retrieved February 25, 2012, from iBridge Network: http://www.ibridgenetwork.org/.
[381] NeuroCommons. (n.d.). Retrieved February 26, 2012, from NeuroCommons: http://neurocommons.org/.
[382] The semantic web is a new form of web content building of a web of data. In other words, common formats for data coming from different sources are created, therefore allowing for the integration of such data, making it easily available and traceable. See W3. *Semantic web*. Retrieved March 1, 2012, from http://www.w3.org/standards/semanticweb/.

moment it focuses on neuroscience, because it is being developed with neurodegenerative disease funders.

To conclude, Science Commons is working towards educating the scientific community to sharing, by making it easier from a technical and legal perspective, so as to reverse the fragmentation of data and the erosion of communal knowledge-sharing in the sciences and academia. It uses the theoretical and practical bases of Creative Commons, and expands it to the sciences using original and revolutionary channels. Whether or not the project will be successful will depend on the Science Commons' capacity of enforcing its licenses and on the devotion of the community to these new ways of doing and interacting with science.

3.4 Conclusions

The open source model has its seeds within the intellectual property rights system and it sheds light in the problems related to the enclosure of ideas and the misuse of IPR so as to obstruct rather than disseminating knowledge. In particular, the movement of open source in the context of software development was a breath of fresh air in a system that seems to repudiate the countless new opportunities arising from technological advancement.

The translation of this democratic philosophy into the framework of sciences, and in particular into biology, has been shaped by the particularities of patent law and has not violated intellectual property rights. This adjustment to basic legal principles of patent law may be inevitable given the profound differences between software development and scientific research. Projects like BiOS and Science Commons are «no more than a tiny drop in the ocean of the Research and Development conducted in what is now the traditional manner for commercial companies and research centers».[383] Yet, they are undoubtedly a symptom of discomfort with the current state-of-affairs, above all to what concerns the basic building blocks and tools in the bottom of the Shapiro's scientific pyramid.

Open-source biology obviously faces many problems: free-riding[384], potential financing difficulties, the wobbly legal ground in which they are planted, the incompatibility with mainstream firm business models and so on. Nevertheless, they do move beyond rhetoric in an attempt to construct something viable, sustained, modernized and economically feasible. In addition, it is a movement sensitive to the problems of developing countries, potentially those who are

[383] De Beer, D. (2005). Is open-source biotechnology possible? In M. Wynants, & J. Cornelis (Eds.), *How open is the future? Economic, social & cultural scenarios inspired by free and open-source software*. Brussels: Brussels University Press.

[384] Free-riding is a typical problem related with collective action. In particular, free-riding expresses the basic problem with incentives to contribute to collective endeavors, especially when the collective action involves multiple contributors. It is a matter of concentrated benefits versus diffuse costs: one reaps the benefits arising from the commons, but does not contribute to its maintenance. On this matter, see Olson Jr., M. (1965). *The Logic of Collective Action: Public Goods and the Theory of Groups*. Cambridge: Harvard University Press.

most affected by the current IPR environment. Let us now confront both intellectual property and the open source models from the point of view of current technological capabilities.

4 INTELLECTUAL PROPERTY AND BIOLOGICAL MATERIAL: PROPRIETARY VERSUS OPEN MODELS

4.1 Proprietary and open models in biology

Scientific communities' conduct has been studied by numerous scholars in different disciplines. Robert Merton provided a fundamental contribution to the theorization of the normative structure of science. Mertonian norms of science incorporate communalism, universalism, disinterestedness and organized skepticism.[385] This aspirational view, endorsed by numerous scholars, entails the concepts of public and fundamentally open science, which has been damaged by the encroachment of intellectual property rules.[386]

Nevertheless, numerous scholars reject this straightforward description of science as a purely cooperative enterprise. Such line of thought highlights, conversely, that competitive and strategic behavior have historically been a reality for scientists and scientific institutions.[387] According to some of these authors, competition may fundamentally constrain the applicability of open-source methods of social-psychological rewards to scientific research.[388] In

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[385] Merton, R. (1973). The normative structure of science. In R. Merton, *The Sociology of Science: Theoretical and Empirical Investigations* (Vol. III). Chicago: University of Chicago Press.
[386] See for instance Eisenberg, *supra* note 2; and also Eisenberg, R. S., & Kai, A. R. (2003). *Bayh-Dole reform and the progress of biomedicine*. Retrieved March 1, 2012, from Duke Law: http://www.law.duke.edu/shell/cite.pl?66+Law+&+Contemp.+Probs.+289+(WinterSpring+2003).
[387] See, for example, Harry Collins and Trevor Pinch. 1993. The Golem: what everyone should know about science.; Merges states as well that «science is a highly competitive enterprise regulated by a complex set of professional rules». See Merges, *supra* note 1, at p. 148.
[388] David, *supra* note 345.

other words, conflict views of scientific research recognize proprietary impulses under the Mertonian aspirational wrap.[389]

Therefore, there are rather generalist norms which may influence, and even favor, the sharing of information within the biological sciences, although these norms may better suit academic and basic research than commercially-oriented science. Reichmann and Uhlir have noted that where scientific research is funded by governments, contractual clauses and informal norms have typically encouraged the disclosure of the results.[390] However, scientists do not to publish everything they produce. This might be either a strategic behavior, or there is an underlying impossibility to capture all scientific input. In other words, much of the input in scientific knowledge is not written, but rather «embodied in the craft-knowledge of the researchers, about such things as the procedures for culturing specific cell lines, or building a new kind of laser that has yet to become a standard part of laboratory repertoire».[391] Some of these features may possibly not be reported.

Alternatively, Eisenberg and Rai note that current legal mechanisms in the United States permit government-sponsored research and development to be patented, rendering such institutions as universities and public laboratories «inadequately motivated to take the social costs of their proprietary claims into account in deciding what to patent».[392]

Robert Merges observes that implicit pairings such as public/open and private/closed are misleading to the extent the boundaries of the public and the private sphere in science have become blurred.[393] Moreover, the author notes that, in practice, there is growing reluctance in sharing biological

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[389] See Hagstrom, W. O. (1965). *The scientific community*. New York: Basic Books. Hagstrom notes that there is a tendency for scientists to be secretive when concerned with the possibility of being anticipated and having their ideas "stolen".

[390] Reichmann, J. H., & Uhlir, P. F. (2003). A Contractuallt reconstructed research commons for scientific data in a highly protectionist intellectual property environment. *Law and Contemporary Problems , 66*, p. 315. However, the authors recognize that such disclosure is weakened by legal decisions such as the Bayh-Dole Act in the United States.

[391] David, *supra* note 345.

[392] Eisenberg & Kai, *supra* note 386.

[393] Merges, *supra* note 1.

materials among researchers. Failing to share materials may come even as an assertion of informal property rights – in particular scientists strive to holding on to their material as much as possible.[394] Rothen and Powell confirm the increasing interconnection between the public and private spheres of science.[395]

Researchers and other scientific communities interact in a rather complex manner among themselves. Such relationships are defined not only in terms of its informal rules within and beyond scientific communities, but also in terms of income source, nature of the project and applicable formal rules of intellectual property. Weakening intellectual property protection could result in some important players quitting the game or attempting at keeping information in strategic secrecy, both of which we see as detrimental to scientific innovation, as well as harmful to the commons.[396]

Additionally, even though we argued that both the hacker and the scientific communities are particularly sensitive to rewards other than monetary, such rewards are quite different in their essence. Socio-psychological rewards in the biological sciences are generally related to publications in prestigious journals, invitations for collaborating with important institutions or to participate in conferences, titles and promotions and ultimately the prospect of prestigious prizes (for instance, the Nobel Prize).[397] This prestige system is rather suited to the fundamentals of the open source model, but they do nevertheless require a certain level of adaptation from their original rules. In other words, the situation in science differs from the hacker culture since it is not a "gift culture", but rather a prestige culture.

Hence, the biological sciences are shaped by an interesting blend of formal and informal rules. While some informal norms often contain an «unwritten and often unspoken agreement among researchers that the materials shared will not

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[394] See also Cohen, J. (1995). Share and share-alike isn't always the rule in science. *Science , 268*, pp. 1715-1718..
[395] See Rhoten, D., & Powell, W. W. (2007). The frontiers of intellectual property: expanded versus new models of open science. *Annual Review of Law and Social Science , 3*, pp. 345-373.
[396] See Opberdeck, D. W. (2004). The penguin's genome, or Coase and open source biotechnology. *Harvard Journal of Law and Technology , 18* (1), pp. 168-227.
[397] *Id.*

be used for commercial gain and will not be passed on without permission from the original owner»[398], researchers may actually avoid entering in such agreements in the first place, given the current push to claim intellectual property rights. With the claim of such formal rights over biological materials, the problem of misappropriation is solved, yet researchers often choose to protect their materials even after publication, by means of restrictive licensing or no licensing at all.[399]

In this regard, formal rules of intellectual property protection largely determine transaction costs, access to scientific outcomes and the incentive to engage in scientific activities. Based on the premise that a proprietary approach to intellectual property is the most effective means to inducing innovation, the producers' innovation model relies on protective measures which in effect spur producers to create innovative products. In order to do so, this proprietary model grants producers rents over their creations for determined periods of time (the standard twenty years), by means of a legal right of excluding third parties from making, using, selling or importing the invention. Fundamentally, such authoritative rights stress the significance of ensuring progress. However, the deadweight loss it causes is significant enough to make us wonder whether there are socially desirable alternatives.[400]

The issue demands reconciliation between private ownership and the public domain. In other words, existing systems of intellectual property rights encourage private parties to claim ownership rights over biological material. However significant such property rights are in ensuring public disclosure, the point is that such disclosure is not equivalent to a factual diffusion of knowledge, because accessing such material for practical uses may be curtailed by the rights holder. The problem of diffusion versus incentive is a crucial

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[398] Burk, D. (1994). Misappropriation of trade secrets in biotechnology licensing. *Science , 4* (2), pp. 121-154.
[399] Cohen, *supra* note 394.
[400] Scotchmer concludes that research outputs directed to the public domain involve less deadweight loss than the protection of intellectual property rights. However, public domain differs from open source to the extent the first is not covered by intellectual property rights. Scotchmer, *supra* note 28, at p. 58.

social dilemma, because it involves the balance between the rights of individual innovators versus the rights of access for a widespread, unidentified mass of individuals (including follow-on innovators). In a sense, one developing a product cannot freely use the ideas incorporated in the patented invention of someone else.[401]

Proprietary models somehow fail to recognize the cumulative nature of scientific research by treating individual innovators in their singularity, rather than as part of a more complex process of innovation. In contrast, open source collaboration builds on the premise that innovators are «standing on the shoulders of giants», and therefore accessing previous research outcomes is crucial for the development of further research. Access cannot simply be hypothetical.

In particular, access to biological materials often involves the transfer of basic tools. Without such physical transfer, much of these materials have limited value. To be precise, if a researcher creates a genetically modified mouse which is particularly valuable for, say, immunology studies, but refuses to share such creation with immunology researchers or research labs, she is actually cutting off a tremendous amount of potential contributions, namely the improvement of basic tools and the development of significant end-products. Instead, if the initial inventor would opt to license the GM mouse without limitations, more researchers would be able to access the material, thus being able to experiment, manipulate and alter such materials.

Nonetheless, such a non-exclusive approach requires high levels of collaborative effort. Given the current IP protection environment, collaborative efforts are difficult to accomplish. Even though it is widely perceived that collaboration is the optimal behavior for basic scientific research, there is a strong incentive for individual researchers to defect.[402] One of the aspects inherent to the incentive to defect is the employed business

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401 Some legal systems ensure a "research exemption" to patent law; however this exemption does not apply to product development.
402 Merges, *supra* note 1.

models for scientific research. There are fundamentally two options for funding basic scientific research: either it is government-funded or research institutions must find other ways to finance their activities. The latter include charging royalties to licensees and refusing to license in order to have monopoly over the development of end-products arising from basic tools.

Open source approaches to biological materials provide systems for facilitating the exchange of basic tools, and they do often assist in funding basic research. However, they present further troubles in motivating private investment. On the bright side, these systems bring about different sorts of incentives to share, namely the promise that other members of the community will share-alike. In this manner, by contributing to a "protected commons", the researcher or institute benefit by having direct access not only to the common pool of valuable tools, but also to the feedback and improvements made by other members of the community to the initial tool. The worst case scenario would be the one in which all participants defect from the community and encumber basic tools with proprietary claims.[403]

In order to make open source models in biology work, property rights of initial innovators should be asserted, by means of contractual agreements. Rather than purely proprietary, the open source mechanism attempts at creating a communal pool for whoever is interested in participating. The negative side of such a model is the lack of incentives to contributing to the commons where no obligations to do so exist. For instance, BiOS and Science Commons rely predominantly in informal rules and in the moral obligations of community members to contribute. There is no actual formal obligation to contribute to the protected commons.

In a nutshell, property rights provide social benefits by ensuring private investment in product development.[404] These rights function as an institutional guarantee to private parties conferring assurance in the highly unpredictable

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[403] See Burk, *supra* note 166.
[404] Eisenberg & Kai, *supra* note 386.

process of R&D.[405] Nevertheless this institution places burdensome transaction costs on R&D activities. On the other hand, open source models applied to the biological sciences resolve the questions involving transaction costs, accessibility to basic tools and lowers overall costs of production. Open models are more sensitive to the cumulative nature of scientific research and attempt at balancing the rights of initial developers with the rights of follow-on developers. However, such approaches may have adverse effects in the incentive to invest and are mainly dependent on the willingness of private parties to engage in open source patenting.

[405] Runge, *supra* note 135.

4.2 Open source as a complement to current intellectual property standards

Open source is not the only collaborative model for technological inducement, but it may be the one that provides the most drastic amendments to current intellectual property systems.[406] As we argued before, open source differs from placing inventions in the public domain. Moreover, the open model also differs from the proprietary model, for it gives innovators the possibility to adopt a position of non-exclusiveness in licensing agreements.

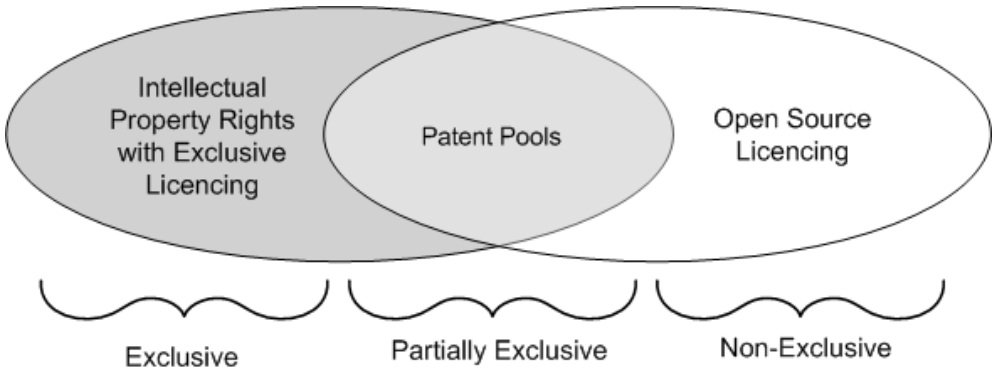

Figure 3 The relationship between proprietary and open models in scientific research[407]

Even though it is largely based upon formal proprietary rights, open source licensing assumes a non-exclusive character. This non-exclusiveness is ensured through contract-based initiatives among private parties. The growing number of initiatives with a non-exclusive character indicates that rather than relying on

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[406] The spectrum of collaborative models for gene patenting includes, for instance, patent pools and clearinghouse mechanisms. For an overview of other models for wider access to gene patents, see Van Overwalle, G., von Zimmeren, E., Verbeure, B., & Matthijs, G. (2006). Models for facilitating access to patents on genetic inventions. *Nature Reviews Genetics , 7*, pp. 143-147.

[407] This figure is largely based on Dedeurwaerdere's, *supra* note 335, at p. 371.

legal environment adjustments (top-down measures), private actors shape those rules according to their private requirements.[408] There are several positive aspects to this approach, one of them being that it allows for a certain degree of *modelling* instead of the typical one-size-fits-all intellectual property policies.[409]

Hence, private parties engage in sharing and sharing-alike endeavors regardless of the legal IP settings. This trend is portrayed by Merges as «order despite law».[410] In a way, behind open source ventures there is an informal recognition that, in some cases, intellectual property rules are wholly inappropriate.[411] For instance, why would the pharmaceutical industry, often portrayed as dependent on IP protection, present growing numbers of open source projects in recent years?

The answer to this question may be rather logical. The pharmaceutical industry bares high costs of product development – to name some, the costs of uncertainty in compound discovery and the rigid regulatory burden for drug development. In order to cut development costs, firms may decide to «deemphasize intellectual property rights at least on early biology and be more open about sharing negative results so that knowledge advances faster in drug discovery research».[412] Adopting such a posture allows firms to extract value from precompetitive information, therefore effectively using and managing commonly shared information and refocusing on subsequent stages of drug development.

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[408] Merges, *supra* note 312; and also Hope, *supra* note 272.
[409] Such a case-by-case approach may fit the particular requirements of the biological industries, because these are typically "mined" with many sensitive areas (public health, food security, etc.).
[410] Merges, *supra* note 312, in reference to Ellickson's theory of institutional formation ("order without law"). See Robert Ellickson. 1994. *Order without law*. Cambridge: Harvard University Press, 1994.
[411] For instance, as paradoxical as it may seem from current perspectives on intellectual property, one of the fundamental goals of IP rights in their design was precisely the protection of the commons. See Boyle, *supra* note 202.
[412] Strauss, S. (2010, July). Pharma embraces open source models. *Nature Biotechnology , 28* (7), pp. 631-634.

This willingness to collaborate is indeed an indication that, even in fundamentally patent-oriented industries like biotechnology and pharmaceuticals, commercially-oriented entities are preoccupied with the consequences of strict intellectual enclosure of basic materials and tools.[413] Open source may be a rather effective strategy to address scientific research bottlenecks, such as patent thickets and blocking patents.[414]

This approach may be even more rational when considering neglected diseases or market niches.[415] Such markets are a problem because they do not fit current IP systems – to be sure, patents pay off as long as enough patented products are sold, so that R&D costs may be covered. In these markets needs tend to be great while funds are scarce. Open source will probably not gather greater investments for such markets, but it could surely present a more efficient management method for such scarce funds.[416]

Most open-source activities occur at the pre-commercial R&D stage. This exploratory stage has been increasingly assaulted by intellectual property claims and secrecy, even though most problems at this level are common to most research endeavors and most of the times common to whole industries. For this reason, research at initial stages may be more efficiently carried out in an "open science" mode. By adopting a non-exclusive policy, firms may reduce the wasteful resources in the early stages of R&D, therefore leveraging their capacities to tackle some of the problems addressed in our work.

Despite the disparity in organizational and institutional networks between open source and current scientific research settings, there seems to be room for open source to complement the inefficiencies of intellectual property rights.

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[413] Rhoten & Powell, *supra* note 395; moreover, endorsing open projects may be a strategy for big corporations to gain sympathy in developing countries.

[414] Feldman, R., & Nelson, K. (2008). Open source, open access and open transfer: market approaches to research bottlenecks. *Northwestern Journal of Technology and Intellectual Property , 14* (7).

[415] This is, in part, the mission of BiOS.

[416] Munos, B. (2006). Can open-source R&D reinvigorate drug research? *Nature Reviews Drug Discovery , 5* (9), pp. 723-729. In this article, Munos specifies that only 10% of R&D resources are spent on illnesses that affect circa 90% of the world population.

Such inefficiencies are evidently holding back innovation and stifling a widespread distribution of important biological tools. This is not to say that there is a perfect equilibrium between intellectual property regimes and open source complementary projects. Indeed, there are fundamental technical obstacles to surpass.[417] Be that as it may, open source approaches to biological materials create pathways towards a better use of resources to meet more widespread needs.[418]

[417] For example, there is a clear need to find open science licenses that substitute the strong informal norms found among open source programmers.
[418] Taubman, *supra* note 333.

4.3 Conclusions

Scientific research is shaped by a particular blend of formal and informal norms, although in recent decades the legal, proprietary approach has been the main driver of the relationship among researchers and research labs. Formal rights to exclude have, nevertheless, brought about problems of access and high transaction costs, which are disturbing also to private actors in biological sciences. The open source approach permits a position of non-exclusiveness – a right to include rather than a right to exclude.[419] A rebalance between these two approaches aims at reconstructing a commons, and it seems fundamental for a sustainable and more efficient management of existing knowledge resources and shared problems associated with such knowledge. At the end, it is a matter of efficient management.

Open source consents the extraction of value in precompetitive stages, thereby avoiding proprietary claims on basic blocks of knowledge and on basic biological tools. Even though open source is not a magic pixie powder[420], it has potential to meet some of the inefficiencies in the IP regimes, provided that concurrent business models are deployed.

[419] Runge, *supra* note 135.
[420] Taubman, *supra* note 333.

CONCLUSION

In the last three decades, intellectual property protection has assumed an exclusionist character, particularly within the scientific domain. This phenomenon is supported by the prevalent conviction that stimulating innovation is contingent on the effective implementation of intellectual property rights coupled with exclusive licensing. This work demonstrates that, when pushed too far, intellectual property rights actually hamper innovation, instead of encouraging it.

Strict intellectual property rights may also damage the bargaining power of developing countries in North-South relations. We portray the growing enforcement of sovereign-based rights over genetic resources in various developing countries as a defensive measure against such IP protection impositions. Nevertheless, this work demonstrates that sovereign-based rights over genetic resources add up to the complex and often conflicting web of rights as regards biological material.

Given its cumulative nature and the *public goods* feature of biological materials, scientific research is very sensitive to intellectual property policies. While it is clearly in the interest of society to spur innovation in science, there has been a constant preoccupation in the literature about the trade-off between the social benefits and the drawbacks of monopolistic rewards to innovators. Even though inventors need some degree of protection, there are doubts regarding the one-size-fits-all design of patent rights.

In the specific case of basic research, encumbering basic living organisms and biological tools with patent claims may cause knowledge fragmentation. Such fragmentation – often referred to as the "tragedy of the anti-commons" – results in burdensome transactions costs, which are in turn partially responsible for the delayed development and market introduction of end-products. Hence,

accessibility to basic blocks of life is fundamental to the sustainability of scientific research in the life sciences. To some extent the design of patent law undermines the prospect of blocking patents and patent thickets.

Since several researchers, and often even whole industries, share the same problems when dealing with basic biological tools, we reckoned that a collaborative approach would be useful in eliminating some of the inefficiencies of formal intellectual property rules. In light of this, this thesis proposes an open source adaptation to biological materials in order to provide solutions to fragmentation and access problems. Our examination includes two particularly relevant empirical cases, CAMBIA's Biological Open Source Initiative (BiOS) and ScienceCommons, an initiative from Creative Commons.

Despite the predictable technical obstacles and organizational disparities, we argue that, combined with equitable intellectual property protection, knowledge commons may rebalance exclusive rights with inclusive needs. Also, given its contract-based approach, open source biology concedes some freedom for *modelling* formal rules to particular cases. Moreover, its non-exclusiveness character plays an important role in providing extensive access to fundamental tools for scientific research.

Deemphasizing intellectual property rights at the initial stage of scientific research may be an effective strategy on the part of private parties to resolve resource mismanagement. For policy-makers, incentivizing open source structures may compensate the social loss created by strong IP protection. This collaborative approach might even favor research in neglected diseases and market niches, especially because it allows a more widespread use of basic tools and it facilitates biological material transfer. Therefore, rather than an alternative to the proprietary model, open source is a plausible complement to it. Additionally it is a rather effective strategy to address scientific research bottlenecks.

However, open source is no end in itself. There are several associated problematic issues – for instance, project financing arrangements or additional

revenue sources, and the potential encumbering of common tools in derived products' patent claims. Further exploration of these issues would be desirable in order to accurately assess the viability and impact of open source approaches to biological materials.

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