UNDERSTANDING GENETIC INFORMATION AS A COMMONS: FROM BIOPROSPECTING TO PERSONALIZED MEDICINE

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1 Introduction

In the Anglo-American legal tradition the concept of commons is linked to goods that are owned by a community and of which the same community can freely dispose. In this sense, the notion of commons identifies all the tangible and intangible resources that constitute a collective heritage of a specific community. The analysis of knowledge as a commons "has its roots in the broad, interdisciplinary study of shared natural resources, such as water resources, forests, fisheries, and wildlife".[1] The exploitation of these collective resources must be regulated to prevent the overuse, depletion or extinction. This phenomenon is known as "the tragedy of the commons" - a key metaphor coined by Garret Hardin - where individuals overuse resources because they are completely detached from the real cost .[2] The "tragedy of the commons" is also an allegory used to exemplify the potential struggle between the benefits of producers and consumers and the common or public good. However, contrary to the Hardin's thesis, common resources can be sustainable and successfully managed by the people who use them rather than by private companies.[3] Commons may in fact be vital resources for communities and nations as long as those subjects involved in their exploitation are able to define and share rules for their sustainability. So the tragedy can be avoided.

Starting from these considerations, the paper tries to expand this approach to the realm of genetic resources: in particular it illustrates the progressive development of the new forms of enclosure in the domain of the "intangible commons of the mind," through several waves of expansion of

* The author is beneficiary of a Marie Curie FSR Incoming Post-doctoral Fellowship of the Académie universitaire Louvain, funded by the Marie Curie Actions of the European Commission.

1 See Understanding Knowledge as a Commons: From Theory to Practice 4 (Charlotte Hess & Elinor Ostrom eds., 2007).

2 See Garrett Hardin, The Tragedy of the Commons: The Population Has No Technical Solution; It Requires a Fundamental Extension in Morality, 162 SCIENCE 1243, 1244 (1968).

3 See Charlotte Hess and Elinor Ostrom, Introduction: An Overview of the Knowledge Commons, in UNDERSTANDING KNOWLEDGE AS A COMMONS: FROM THEORY TO PRACTICE 11 (Charlotte Hess & Elinor Ostrom eds., 2007) (arguing that there may be situations where the Hardin's model can be applied, "but many groups can effectively manage and sustain common resources if they have suitable conditions, such as appropriate rules, good conflict-resolution mechanisms, and well-defined group boundaries").

intellectual property rights in the area of genetic materials.[4] It then discusses how such proliferation of new enclosures is proportional to reduction of genetic materials in the public realm and can lead to a consequent decrease of the public domain and also of new innovation.[5]

Finally, the paper suggests a new way of framing discussions between genetic information and all attempts to abridge the full access to it. In particular it proposes to understand the human information and genetic information on an equal footing with the "free code": an intangible resource of public utility, which must be acknowledged paternity but not ownership, whose exploitation is subject to transparency, not opposed to but distinct from the market. Scientific knowledge is supposed to be open and free. It also should benefit the general public and with a twofold purpose: on the one hand it should be available to the scientific community; on the other hand, it should be used for further research. Basically, the paper wants to look over the increasingly central role of information putting the attention on how knowledge is replacing physical inputs as factors of production.

In the following pages, it will be investigated the impact of emerging aspects of patent law on the access to public natural resources and human genetic material. On this footing, the paper goes on to pose a series of questions related to the rapidly growing field of "bioprospecting" and personalized medicine. In both cases we are in front of a process that consists in a mechanical separation of natural elements from their original environment. What are the ethical, social and legal consequences of patenting in the area of diagnostic methods and bioprospecting? In particular, what are the implications of the particular application of genetic patenting for the right to health care, access to medication and to genetic resources? What are the consequences of commercial activity involving public resources?

In this framework the paper aims to explore a number of issues that stand at the intersection of intellectual property law, biotechnology and public interests. The purpose is to explore the relationship between two apparently different phenomena establishing connections and drawing possible parallels through a critical analysis of case studies.

2 Patents *versus* Information Commons

[4] See James Boyle, The Second Enclosure Movement and the Construction of the Public Domain, 66 Law & Contemp. Probs. 33, 33 (2003) (referring to a second enclosure movement).

[5] On this, see e.g. Michael A. Heller & Rebecca Eisenberg, Can Patents Deter Innovation? The Anticommons in Biomedical Research, 280 Science 698, 699 (1998); Jessica Litman, The Public Domain, 39 Emory L.J. 965, 1023 (1990); Arti K. Rai & Rebecca S. Eisenberg, Bayh-Dole Reform and the Progress of Biomedicine, 66 Law & Contemp. Probs. 289, 295 (2003); Pamela Samuelson, Mapping the Digital Public Domain: Threats and Opportunities, 66 Law & Contemp. Probs. 147, 155 (2003).

The spirit of intellectual property legislation is primarily intended to encourage creation and dissemination of knowledge. Intellectual property rights define property interests in inventions and expressions that would otherwise be directly available for all to share without paying the appropriate charge. As properly observed, "in market terms, information has significant "public good" qualities; it is often expensive to create or generate but cheap to copy."[6] Consequently, economic theory tells us that "public goods will be under produced because there will be too little incentive to create them".[7] In his thoughtful book "Shamans, Software, And Spleens", James Boyle points out that "[w]e have already reached the point where genetic information is thought of primarily as information. We look at the informational message—the sequence of As, Gs, Cs, and Ts—not the biological medium."[8] In other words, we are assisting to a gradual dematerialization of biologic and genetic information implemented by new forms of colonization operated by science, markets and the law.

Supporters of enclosure argued that only in this way it is possible to guarantee the kind of investment of time and capital necessary to produce new drugs, new pharmaceuticals, gene therapies and other commercial products. On the other hands, the opponents of enclosure claimed that our common genome as well as the natural resources "belongs to everyone" because they are "the common heritage of humankind". It means that these resources should not be owned and that the effects of turning over these common goods to private property rights be real troublesome in the near future, because market logic led to a gradual and inexorable extension of this approach to areas which should be the remotest from the market.

Within this new paradigm "the tendency is toward the economic and conceptual separation of the informational message from the medium-cells, diskettes, telephone directories, or whatever-and of the progressive devaluation (literally, the diminishing marginal cost) of the medium as compared with the message. As the information content is decontextualized, the location or form of the information comes to seem increasingly irrelevant-as irrelevant as the color of two books would be to a comparison of their arguments. Thus ideas originally applied to one "information area" seem to apply to another, first in metaphor and then in technological reality."[9]

Always according to Boyle, it is the advent of this new paradigm which made possible the patenting of biological materials opening a new and unexplored window into the private appropriation of

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[6] See James Boyle, Shamans, Software & Spleens xi (Harvard Univ. Press 1996).
[7] Id.
[8] See JAMES BOYLE, SHAMANS, SOFTWARE, AND SPLEENS 4 (1996)
[9] Id., at 7.

natural capitals. Information of biological materials combines with the notion of proprietary information through the tool of intellectual property rights. In this context "the author vision blinds us to the importance of the commons-to the importance of the raw material from which information products are constructed".[10] But precisely because of that blindness, "there is some space for intervention by scholars, citizens, and activists of various stripes-before the information society's assumptions about entitlement rigidify in an inegalitarian and ultimately self-defeating pattern".[11] This new vision is part due to the fact that current society is increasingly becoming knowledge-based and knowledge is replacing physical resources as the main driver of economic growth.[12] Considering this framework, it is here necessary to first discuss what are the principles and legal provisions, which deal with the patentability of genetic materials.

3 Patenting "genetic material": standard and requirements

The current approach of the Trilateral Patent Offices (i.e. the European Patent Office (EPO), the Japan Patent Office (JPO) and the United States Patent and Trademark Office (USPTO)) with respect to patents on biological materials is to grant patents only for isolated and purified gene sequences with a demonstrated specific utility.[13] The distinction between a non-patentable "product of nature" and a patentable "non-naturally occurring composition of matter" was settled for the first time by the United States Supreme Court in Diamond v. Chakrabarty.[14] This ruling in combination with the decision in Moore v. Regent of University of California[15] opened unquestionably the way for the patenting of genetic material. Subsequently, in 1998, the USPTO, EPO and JPO issued a joint policy statement asserting that "purified natural products are not regarded as products of nature

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[10] Id., at xvi.

[11] Id.

[12] See European Union, Communication from the Commission to the Council and the European Parliament - Delivering on the modernisation agenda for universities - Education, research and innovation/* COM/2006/0208 final */, available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52006DC0208:EN:HTML

[13] See Melanie J. Howlett & Andrew F. Christie, *An Analysis of the Approach of the European, Japanese and United States Patent Offices to Patenting Partial DNA Sequences (ESTs)*, 34 Int'l Rev. Indus. Prop. & Copyright L. 581 (2003); Leslie G. Restaino et al., Patenting DNA-Related Inventions in the European Union, United States and Japan: A Trilateral Approach or a Study in Contrast?, 2003 UCLA J.L. & TECH. 2 (2003). See also Anne Reese & Brian Opeskin, *Current Issues in Gene Patenting, in Disputes and Dilemmas in Health Law* 277, 280 (Ian Freckelton & Kerry Petersen eds.) (2006).

[14] Diamond v. Chakrabarty, 447 U.S. 303 (1980). In this landmark decision the United States Supreme Court held that a live and human-engineered microorganism is patentable subject matter under Section 1010 of the United States Patent Act. The rule for which the decision is commonly known is that patents can be issued on "anything under the sun that is made by man". For a detailed review of the case, see Rebecca S. Eisemberg, *The Story of Diamond v. Chakrabarty: Technological Change and the Subject Matter Boundaries of the Patent System*, in *Intellectual Property Stories* 327 (Jane C. Ginzburg & Rochelle Cooper Dreyfuss eds. Foundation Press 2006).

[15] Moore v. Regents of the University of California, 793 P.2d 479 (Cal. S. Ct) (1990).

or discoveries because they do not in fact exist in nature in an isolated form. Rather, they are regarded for patent purposes as biologically active substances or chemical compounds and eligible for patenting on the same basis as other chemical compounds".[16] Today, patents for biotechnological innovations are therefore limited only by the ability of the individuals drafting the claim.[17] In recent years, one of the most troublesome aspects for gene patents have been their novelty and, consequently, their status as patentable subject matter.[18] But still a further question comes up: "as DNA has existed well before the gene discoverer arrived, how can these molecules be novel?". The answer, as one writer has suggested, "is that the actual molecule produced and claimed by the gene discoverer is new in a strict sense of the word".[19] More precisely, "gene sequences exist naturally as part of a much bigger molecule" and "there is no doubt that this much bigger molecule would be unpatentable".[20] But the gene discoverer's thesis is that "purified and isolated gene sequences are distinct from the overall DNA molecule".[21] This view is supported by one of the first U.S. patent infringement litigations involving a gene patent. In Amgen, Inc. v. Chugai Pharm. Co. Ltd., the district court held that the patent in suit was valid because the invention "is not as plaintiff argues the DNA sequence encoding human erythropoietin since that is a nonpatentable natural phenomenon 'free to all men and reserved exclusively to none'. […] Rather, the invention as claimed in claim two of the patent is the "purified and isolated" DNA sequence encoding erythropoietin."[22]

Currently, both in EU and US, to be eligible for patent protection, an innovation must meet three basic requirements:[23] (i) novelty; (ii) inventive step (non-obviousness in the US); (iii) industrial application (utility in the US). The design of the patenting system for human genes requires not

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16 1988 Joint Statement of USPTO, EPO and JPO; see Comparative Study of Patent Practices in the Field of Biotechnology Related Mainly to Microbiological Inventions, 7 Biotechnology L. Rep. 159, 163 (1988); see footnote 9, Nuffield Council of Bioethics Discussion Paper, *The Ethics of Patenting DNA* (2002) 26, 3.14.

17 See Douglas Robinson & Nina Medlock, *Diamond v. Chakrabarty: A Retrospective on 25 Years of Biotech Patents*, 17 Intell. Prop. & Tech. J. 12, 14 (2005).

18 See e.g. John J. Doll, *The Patenting of DNA*, 280 Science 689 (1998); Daniel J. Kevles & Ari Berkowitz, *The Gene Patenting Controversy: A Convergence of Law, Economic Interests, and Ethics*, 67 Brook. L. Rev. 233 (2001). For a recent overview of the gene patenting controversies, see also Lisa Larrimore Ouellette, *Access to Bio-Knowledge: From Gene Patents to Biomedical Materials*, 2010 Stan. Tech. L. Rev. N1, http://stlr.stanford.edu/pdf/ouellette-access-to-bio-knowledge.pdf.

19 See Oskar Liivak, *Maintaining Competition in Copying: Narrowing the Scope of Gene Patents*, 41 U.C. Davis L. Rev. 177, fn 53 (2007).

20 *Id.*

21 *Id.*

22 See Amgen, Inc. v. Chugai Pharm. Co., 13 U.S.P.Q.2d (BNA) 1737, 1759 (D. Mass. 1989).

23 See Oliver Mills, *Biotechnological Inventions. Moral Restraints and Patent Law*, 2nd ed., 4 (Ashgate 2010); Lionel Bently & Brad Sherman, *Intellectual Property Law*, 3rd ed., 391 (OUP 2009).

only an understanding of the key issues related to the requirement of invetiveness, but also a careful balancing of conflicting exclusive rights. As pointed out by the U.S. Supreme Court Justice Stephen Breyer in the case of Laboratory Corp. v. Metabolite Industries, too much patent protection can impede rather than promote the objective of patent protection.[24]

The dilemma of patent proliferation in biotech is made more difficult by a confused regulatory framework. The ethical and legal issues surrounding the patenting of DNA sequences generate intense international debate, particularly in the technologically advanced United States and European Union.[25] Based on a principle of non-discrimination with regard to technology, art. 27 of TRIPs agrees that biological material should be patentable.[26] Human genes can be patented if they meet the requirements of novelty, inventive step and industrial applicability.[27] In other words, genes can be patented if the inventor meets the general requirements of a patent.[28] States may exclude patents on human genes on their territory. Up to now, a few countries have used this possibility. On the other hand, the European Directive on the Legal Protection of Biotechnological Inventions, specifies that "elements isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene" may constitute a patentable invention.[29] In particular, the Directive recognizes that biological material which is isolated from its natural environment or produced by means of a technical process is considered to be an invention even if this material previously occurred in nature.[30] In addition, the European

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[24] In his famous dissent, Justice Breyer stated that "too much patent protection can impede rather than promote the progress of science and the useful arts" that is the U.S. constitutional objective of copyright and patent protection. See Lab. Corp. of America Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 126, 79 U.S.P.Q.2d (BNA) 1065, 1066 (2006) (per curiam) (Breyer, J., dissenting) (quoting U.S. Const. art. I, § 8, cl. 8). This dissent, joined by Justices Stevens and Souter, seems to suggest that at least three of the Supreme Court Justices are becoming increasingly concerned about the quality and quantity of the patents being issued by the United States Patent and Trademark Office. See Terry Wrigh, *Patent Trends in the U.S. Supreme Court*, http://brandlaw.org/2010/01/patent-trends-in-the-u-s-supreme-court/ (last visited Apr. 22, 2011).

[25] Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. Rev. 1623, 1624 (2001).

[26] See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, art. 27, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 1125 (1994) [hereinafter TRIPS]. On this point, see also Johanna Gibson, *Patent Publics, Patent Cultures*, in *Patenting Lives: Life Patents, Culture and Development* 1,3 (Johanna Gibson ed., Ashgate 2008).

[27] According to Art. 27 of the TRIPS Agreement, "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application". See also Bently & Sherman, *Intellectual Property Law*, cit., at 393-394.

[28] Lori B. Andrews & Jordan Paradise, *Essay, Gene Patents: The Need for Bioethics Scrutiny and Legal Change*, 5 Yale J. Of Health Pol'y, L. & Ethics 403, 404 (2005).

[29] Council Directive 98/44/EC, art. 5(2), 1998 O.J. (L 213) 13 (EC).

[30] Id., at art. 3(2).

Patent Convention (EPC) prohibits the granting of patents for "methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human body".[31] On this basis, the European Patent Office concluded that "all methods practiced on the human or animal body which relate to the diagnosis or which are of value for the purposes of diagnosis" are prohibited from being patented.[32] However, Biotech inventions are considered patentable under both the EPC and the Biotechnology Directive.[33] In particular, the European Patent Convention explicitly acknowledges the patentability of biotechnological inventions in Rule 26(1) EPC.[34] In addition, Rule 27(a) EPC provides supplementary specifications about patentable subject-matter in Biotech stipulating that "Biotechnological inventions shall also be patentable if they concern biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature".[35]

As private research in biotech becomes increasingly protected by patents, concerns appear to arise from the nature and extent of protection granted to patent holders. Patents, in fact, may play multiple roles in the knowledge-based economy. In the current regulatory framework, patent holders have broad freedom in the use of their patent rights.[36] In fact, patent holders are free to choose how to exercise their exclusive rights.[37] Consequently, they are free to set royalties, to grant or refuse licensing requests, or they may choose the licensees and the licensing terms freely, as long as the arrangement complies with relevant regulations, such as competition or antitrust law.[38]

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[31] Convention on the Grant of European Patents, art. 53(c), Oct. 5, 1973, 13 I.L.M. 270 [hereinafter EPC]. The EPC provides a uniform method and standard for examining a European patent application, but reserves to members of the European Union the task of interpreting and enforcing a patent: "under the EPC, the EPO grants European patents for one or more of the contracting parties to the EPC. However, a European patent is not a uniform patent. Rather it consists of a bundle of parallel national patents granted as a result of a centralized grant by the EPO". See August Reinisch, Decisions of the European Patent Organization Before National Courts, in CHALLENGING ACTS OF INTERNATIONAL ORGANIZATIONS BEFORE NATIONAL COURTS 137, 138 (A. Reinisch ed., 2010).

[32] See decision T 964/99 (OJ EPO 2002, 4), starting from the interpretation set out in decision T 385/86, decision T 964/99.

[33] See RICHARD A. SPINELLO & MARIA BOTTIS, A DEFENSE OF INTELLECTUAL PROPERTY RIGHTS 64 (2009).

[34] Rule 26(1) of 5 October 1973 as adopted by decision of the Administrative Council of the European Patent Organisation of December 7, 2006 and as last amended by decision of the Administrative Council of the European Patent Organisation of October 26, 2010 [hereinafter Implementing Regulations]. The Rules cited are to the earlier version. On the point, see Giovanni Macchia, Patentability Requirements of Biotech Inventions at the European Patent Office: Ethical Issues, in BIOTECH INNOVATIONS & FUNDAMENTAL RIGHTS 37 (R. Bin et al. eds, 2011).

[35] Implementing Regulations, Rule 27(a).

[36] See, e.g. Bement v. Nat'l Harrow Co., 186 U.S. 70, 90-92 (1902) ("The general rule is absolute freedom in the use or sale of rights under the patent laws of the United States").

[37] A patent simply grants the patentee the right to exclude others from making, using or selling the claimed invention for a limited period of time in return for the disclosure if technical information. See Bently & Sherman, *Intellectual Property Law*, cit., at 335.

[38] See Bently & Sherman, *Intellectual Property Law*, cit. at 570. In the U.S., an intellectual property rights holder has

Unfortunately, this system, even though designed to encourage private research, could also bring negative results. When patents are licensed too restrictively or when patents are used excessively to protect information "this could hamper research and development, clinical access, and availability of high-quality tests for patients".[39] In other words, it may have a chilling effect on research.[40]

4 Human Genetics, Biomedical Science and Natural Resources

Biotechnology is a recognized research area that has increasingly advanced into new technologies and modern practices raising several legal, ethical and regulatory issues. Broadly speaking, biotechnology comprises "any technique that uses living organisms or substances from those organisms to make or modify a product, to improve plants or animals, or to develop microorganisms for specific uses".[41] Biotechnology - especially genetics and genomics - has also had substantial influence on the development of new pharmaceuticals and the methods used to study, predict and treat human disease.[42] At the same time, this revolution has also resulted in a new set of challenges for lawyers. In particular, the revolutionary speed of biotech innovations has had a significant impact on the protection of the rights of the individual and collectivity. The legal regulation of scientific research and scientific investigations impact more and more directly on the freedom of research and therapies as well as on the broad diffusion of knowledge commons. Closely related is also the much debated question of the technological manipulation of life and the boundary of scientific knowledge with regard to the topical question of genetic invention patents and their effects on access to scientific information and health care opportunities. Today, interests antagonistic to freedom of scientific research and access to scientific knowledge are emerging distinctly, requiring a careful balance between public and private domain. As pointed out by other scholars, "the uniquely open-ended nature of biomedical science requires a reassessment of how patenting affects biotech research and innovation".[43] A few questions may arise in this regard: Do new biotech innovations affect fundamental rights? How does the protection of genetic inventions and natural resources change the conditions of access to knowledge? Looking at different aspect of the legal and scientific issues involved in regulation of biological resources, it is necessary to

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no obligation to either use or license its property rights. On the point, see Herbert Hovenkamp, Mark D. Janis & Mark A. Lemely, *Unilateral Refusals to License in the US*, 2 J. Competition L. & Econ. 1, 13 (2006).

39 Geertrui Van Overwalle, *Turning Patent Swords into Shares*, 330 Science 1630 (2010).

40 See David B. Resnik, *Owning the Genome: A Moral Analysis of DNA Patenting* 141 (SUNY Press 2004).

41 Office of Technology Assessment, U.S. Congress, Biotechnology in a Global Economy, app. f, at 268 (1991).

42 See e.g. John Travis, Frontiers in Biotechnology: Biotech Gets a Grip on Cell Adhesion, 260 SCIENCE 906 (1993); See DAVID B. RESNIK, OWNING THE GENOME: A MORAL ANALYSIS OF DNA PATENTING 7 (2004).

43 See David E. Adelman, A Fallacy of the Commons in Biotech Patent Policy, 20 Berkeley Tech. L.J. 985, 986 (2005)

investigate the impact that modern technology can have on the production and dissemination of knowledge. In particular the focus of attention must be on the access to genetic information, to the protection of natural collective resources and the role of biotech patents. It is also important to highlight challenges, opportunities and contradictions regarding the revolutionary technological developments in the life sciences and their consequences for the protection of individual and collective rights.

5 Bioprospecting and Personalized Medicine

Over the past several years, the genomic, bioinformatic and biotech research has been successful in discovering of genetic and biochemical data that have been employed to create linkages between genes and health disorders or genes and new commercial products. In this way, biotech and pharmaceutical companies have tried to profit from sickness and natural resources. In this framework, personalized medicine and bioprospecting are considered as emerging research fields that will bring new opportunities but also new risks.

The term "personalized medicine" refers to the tailoring of medical treatment to the individual characteristics of each patients based on their genetic background.[44] It is essentially centered on the connection between genetic inheritance and susceptibility to a disease. Patents directed to personalized medicine are instruments for the development and commercialization of treatments or predictive tests in the area of medical diagnostics. From a more practical point of view, personalized medicine applies new methods in molecular analysis to improve the patient's disease status, or susceptibility toward a specific disease. As defined by the Personalized Medicine Coalition, it consists in

> the use of new methods of molecular analysis to better manage a patient's disease or predisposition toward a disease. It aims to achieve optimal medical outcomes by helping physicians and patients choose the disease management approaches likely to work best in the context of the patient's unique genetic and environmental profile. Such approaches may include genetic screening programs that more precisely diagnose diseases and their sub-types, or help physicians select the type and dose of medication best suited to a certain group of patients.[45]

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[44] See Committee on a Framework for Development a New Taxonomy of Disease; National Research Council, Toward Precision Medicine: Building a Knowledge Network for Biomedical Research and a New Taxonomy of Disease, 125 (2011).

[45] See Personalized Med. Coal., Personalized Medicine 101, available at http://www.personalizedmedicinecoalition.org/abou t-personalized-medicine/personalized-medicine-101. For an overview of developments in personalized medicine see the two reports issued by the United States Department of Health and Human Services: Dep't Of Health & Human Servs., Personalized Health Care: Opportunities, Pathways, Resources (2007), available at www.hhs.gov/myhealthcare/news/phc-report.pdf and Dep't Of Health & Human Servs.,

According to some optimistic approaches, personalized medicine promises many medical innovations increasing the quality of clinical care. In this context, it lays down the foundation for a new healthcare paradigm and it is considered a priority for the biotechnology and pharmaceutical sectors seeking to develop new diagnostics and products targeted to specific populations.[46] But the pathway to success and achievement is paved of a range of public policy issues. Some of the most troubling ethical and legal questions are essentially related to intellectual property rights, effective access to diagnostic or prognostic tests and patient privacy and confidentiality.[47]

On the other hand, the term "bioprospecting" refers to the exploration of biocultural diversity for commercially valuable genetic, biochemical, and cultural resources.[48] From a concrete point of view, bioprospecting is the process of searching and exploring (from wild plants, animals and microorganisms) genetic or biochemical information for potentially beneficial biological substances.[49] In particular, it focuses on microscopic resources at the genetic and biochemical level.[50]

Bioprospecting encompasses a large variety of concerns and problems essentially related to the grant of patents on specific chemicals isolated or developed from wild plants, animals, microorganism or from other natural genetic resources used to develop commercial products. In particular, it is argued that the most significant problem could arise from bioprospecting on public lands and biotechnological innovation from the resources found there.[51] Among the more troublesome risks in this category are those arising from commercial extractive uses of public natural resources. As observed by other authors, bioprospecting is a relatively new type of natural resource use, but it has already raised interesting legal questions.[52] The debate over the legitimacy of this activity brings to mind an excellent question: "should the government controlling land

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Personalized Health Care Pioneers, Partnerships, Progress (2008), available at www.hhs.gov/myhealthcare/news/phc_2008_report.pdf. See also Huntington F. Willard, Geoffrey S. Ginsburg (eds.), Essentials of Genomic and Personalized Medicine (2009); Shubha Ghosh, Identity, Invention, and the Culture of Personalized Medicine Patenting (2012).

[46] See Jennifer S. Geetter, Another Man's Treasure: The Promise and Pitfalls of Leveraging Existing Biomedical Assets for Future Use, Vol. 4, No. 3, J. Health & Life Sci. L. 1 (2011).

[47] See Personalized Med. Coal., cit.

[48] Katy Moran et al., Biodiversity Prospecting: Lessons and Prospects, Ann. Rev. Anthropology 508, 508 (2001).

[49] See John R. Adair, The Bioprospecting Question: Should the United States Charge Biotechnology Companies for the Commercial Use of Public Wild Genetic Resources, 24 Ecology L. Q. 131, 132 (1997).

[50] Id.

[51] See Dennis Michaels, Bioprospecting Agreements: Forging a Comprehensive Strategy for Managing Genetic Resources on Public Lands, 22 Environs Envtl. L. & Pol'y J. 3, 4 (1999)

[52] See John R. Adair, The Bioprospecting Question: Should the United States Charge Biotechnology Companies for the Commercial Use of Public Wild Genetic Resources, 24 Ecology L. Q. 131, 141 (1997).

containing potentially valuable wild genetic resources profit when bioprospectors remove these resources?"[53] Traditionally, wild genetic resources were considered a "common heritage of humankind" that should be available without restriction.[54] In the past, collection rights were mostly conceded for free by the country in which the wild genetic resources were found.[55] Biotechnology companies supported this free access by arguing that the use of these resources provide some benefits on behalf of all the people of the world. In reality, such use has mainly been devoted to generate great profits just for private companies. Indeed, the only possibility for profit lies in intellectual property law. Bioprospectors try to patent the products they extract from genetic material in order to own these exclusive property rights and thus achieve a market control on these products.[56]

In the subsequent pages we will observe the real nature of personalized medicine and bioprospecting activities and certain problematic issues surrounding the use of natural biological resources analyzing two concrete case studies: the Myriad Genetics controversy and the Yellowstone's Park Bioprospecting case.

6 The Yellowstone National Park bioprospecting controversy

The paragraph briefly outlines how Diversa Corporation, a biotech company founded in San Diego, California in 1994, set out to create a new approach to bioprospecting.[57] In fact, in 1997 Diversa signed a benefit-sharing agreement known as Cooperative Research and Development Agreement ("CRADA") with the Yellowstone National Park. Under this agreement Diversa agrees to pay the Park for the right to collect biological samples offering in exchange some royalties for any products, services or other commercial exploitation derived from biological materials collected in the Park.[58] As explained in the Statement of Work incorporated in the CRADA, Yellowstone and Diversa "cooperate to research and catalog the Park's biological diversity, primarily in the Park's thermal features such as geysers, hot springs, fumaroles, and mud pots, but also in the Park's alpine tundra ecosystems, subalpine forests; riparian habitats, sedge marshes, bogs, swamps, streams and

[53] Id.

[54] See Roger A. Sedjo, Property Rights, Genetic Resources, and Biotechnological Change, 35 J.L. & Econ. 199, 202 (1992).

[55] Id., at 209.

[56] See Andrea Aseff, First Federal Prohibition on Bioprospecting within a Place of Protection: Time to Spur the Legislative Dialogue, 22 Colo. J. Int'l Envtl. L. & Pol'y 189, 199 (2011).

[57] See David L. Finegold et al., Bioindustry Ethics 127 e seq. (2005).

[58] See David L. Finegold et al., Bioindustry Ethics 128 (2005).

lakes".[59] Diversa was essentially interested to search for unknown biochemical forms from which to develop commercially useful enzymes and other biomolecules.[60] The Diversa-Yellowstone partnership rapidly developed into broader protests against the possibility to establish a commercial activity involving public natural resources.[61] Thus, just after the public announcement of the agreement, opponents brought a lawsuit. The principal plaintiff was the Edmonds Institute, a non-profit, public interest organization dedicated to education about environment, technology, and intellectual property rights.[62] It filed a lawsuit against the Department of the Interior and the National Park Service asserting in the complaint that the defendants had infringed the public trust doctrine, common sense, and their responsibilities of stewardship in Yellowstone National Park by signing agreements with private corporations to access and commercialize the public natural resourced of the park.[63] The key aspect of the case was essentially about whether the National Park Service had engaged in public consultation and taken in consideration the necessary environmental impact assessment as required by the National Environmental Policy Act.[64]

The judge ordered the National Park Service to complete a National Environmental Protection Act review of the effects and potential risks of the partnership.[65] The judge also ordered the postponement of the agreement until the conclusion of this review.[66] In December 2009, the National Park Service issued a Final Environmental Impact Statement on bioprospecting and "benefits-sharing" in the US national parks, officially accomplishing its requirements per the court's order. However, in the final judgment, the Court held that the agreement was proper and did not conflict with the conservation mandate.

In basic terms, the case offers a critical question concerning the authentic purposes of national parks and how the National Park Service should realize those objectives. It means to understand if public lands and their resources can be available for extraction by private commercial firms.[67]

Although, bioprospecting seems conflicting with public land and wildlife law, current regulations does not explicitly allow or exclude bioprospecting on public land.[68] In this uncertain setting,

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[59] Edmonds Institute v. Babbitt, 42 F. Supp. 2d, 5 (D.D.C. 1999).
[60] See David L. Finegold et al., Bioindustry Ethics 130 (2005).
[61] Id., at 128.
[62] *See* The Edmonds Inst., http://www.edmonds-institute.org.
[63] See Edmond Inst. V. Babbit civ. Action 98-561 (RCL) Memorandum Opinion of Apr. 12, 2000.
[64] See Edmond Inst. V. Babbit civ. Action 98-561 (RCL) Memorandum Opinion of Apr. 12, 2000.
[65] Edmonds Institute v. Babbitt, 42 F. Supp. 2d, 20 (D.D.C. 1999).
[66] Id.
[67] See Mike Wood, Are National Park Resources for Sale?, 21 Pub. Land & Resources L. Rev. 201, 221 (2000).

bioprospecting - despite the adoption of the Convention on Biological Diversity[69] - remains a an unfairly regulated activity across the world.[70] Before the entry into force of the Convention genetic resources were freely available and held as a common public good.[71] On this ground, the Convention addresses the issue of access to genetic resources and the consequent distribution of benefits generated. In particular, article 15 stipulates that "Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation." Within this framework, States have the right to regulate access to genetic resources, controlling them according to their national guidelines and designing the appropriate settings to enable access to other member States.[72] The purpose of the access is to be able to use these resources - specifically in their genetic and biochemical expressions - for industrial purposes and economic profit. In addition, another key function is related to the extraction of genetic information potentially applicable to commercial uses (i.e. bioprospecting). Undoubtedly the advent of the biotechnological revolution has underlined not only the economic potential of genetic resources, but also the lack of proper legislation and balanced regulatory instruments for a rational and sustainable use of genetic resources. Up to now, the most advanced legislations concerning sustainable exploitation of genetic resources, are essentially those which are implemented in developing countries.[73] In particular, they have adopted a series of instruments of regulation directed to control unauthorized or inappropriate bioprospecting activities. However, intellectual property rights granted with inadequate or improper information concerning the genetic resources used for the purposes of the invention could make such efforts completely worthless.[74]

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68 See See Andrea Aseff, First Federal Prohibition on Bioprospecting within a Place of Protection: Time to Spur the Legislative Dialogue, 22 Colo. J. Int'l Envtl. L. & Pol'y 189, 216 (2011) (arguining that "there is no specific law that directly addresses or clarifies some of the myriad issues of private, commercial bioprospecting".)

69 Convention on Biological Diversity, 31 I.L.M. 818 (1992).

70 See David L. Finegold et al., Bioindustry Ethics 140 (2005).

71 See Calvin O. Qualset and Robert K. Webster, Biotechnology: New benefits, New Questions, 52 Cal. Agricolture 2 (1998). See also Michael Bowman, The Nature, Development and Philosophical Foundations of the Biodiversity Concept in International law, in INTERNATIONAL LAW AND CONSERVATION OF BIOLOGICAL DIVERSITY 5, 31 (Michael Bowman & Catherine Redgwell eds., 1996) (discussing the key trends in the international environmental legal system).

72 The United States has signed the Convention on June 4th, 1994, but they have not ratified it yet. See http://www.cbd.int/information/parties.shtml

73 See See Andrea Crescenzi, Access to Genetic Resources in the Practices of States, in BIOTECH INNOVATIONS & FUNDAMENTAL RIGHTS 345, 353 (Roberto Bin et al. Eds., 2012).

74 Id., at 353.

7. The Myriad Genetics controversy and its ramifications

The second case study chosen for this analysis is a landmark and recent litigation filed by the American Civil Liberties Union (ACLU) alleging violation of constitutional rights and the legitimacy of patents on two human genes used to predict breast and ovarian cancer.[75] More specifically, the controversy has centered on the validity – under § 101 of the US Patent Code – of two patents on tumor suppressor genes known as BRCA1[76] and BRCA2.[77]

The origins of Myriad controversy date back to September 1994, when the U.S. Biotech Company Myriad Genetics[78], in collaboration with the University of Utah and other research laboratories was able to identify the nucleotide sequences linked to susceptibility for breast and ovarian cancer.[79] The oncogene was identified with the acronym BRCA that stands for "breast cancer". Following the isolation of the oncogene, Myriad also developed a diagnostic test intended to identify genetic predisposition to breast and ovarian cancer.[80] After the isolation of these two genes, Myriad filed for patent protection in both the United States and Europe.[81] These patents immediately raised questions for discussion among scientists and others concerned. Their controversial nature is reflected in their negative feedback received in different countries.[82] In Europe, unlike in the

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75 *Assoc. for Molecular Pathology v US Patent and Trademark Office*, 702 F Supp 2d 181 (SDNY 2010) [hereinafter Myriad I].

76 U.S. Patent No. 5,747,282 (filed June 7, 1995). BRCA1 is a human gene expressed in the cells of breast and other tissues to repair damaged DNA and suppress tumor growth. See Tina Saladino, Seeing the Forest Through the Trees: Gene Patents & the Reality of the Commons, 26 BERKELEY TECH. L.J. 301, 302 (2011).

77 U.S. Patent No. 5,710,001 (filed Dec. 21, 1995). BRCA2 is a human gene that binds to and regulates a protein which fixes breaks in DNA. Although structurally different from BRCA1, BRCA2 serves a similar function and the two genes are often referred to collectively as "BRCA". See Saladino, Seeing the Forest Through the Trees: Gene Patents & the Reality of the Commons, cit. at 302.

78 See E. Richard Gold & Julia Carbone, Myriad Genetics: In the Eye of the Policy Storm, 12 GENETICS MED. S39, S41 (2010) (observing how the continuing debate on Myriad's patents began in October, 1994 with the publication in "Science" of an article reporting the results about BRCA1). Myriad Genetics is a healthcare company founded in May 1991 specializing in developing and marketing molecular diagnostic products to perform such tasks as assessing a person's risk of developing a disease later in life. See Myriad Genetics - About, www.myriad.com/about (last visited Oct. 20, 2011). "Myriad is a for-profit corporation located in Salt Lake City, Utah [that does] business throughout the United States. Myriad is incorporated in Delaware. Myriad is a co-owner of patent 5,747,282, and formerly was a co-owner of several of the other patents challenged [by the Association for Molecular Pathology]."

79 See Myriad I, cit., at 201-03 (S.D.N.Y. 2010); See also Yoshio Miki, et al., A Strong Candidate for the Breast and Ovarian Cancer Susceptibility Gene BRCA1, 266 Science 66-71 (1994).

80 See Myriad I, cit. at 201.

81 Id. at 202.

82 "Oppositions were filed against the European patent (EP 705902) on the isolated BRCA-1 gene by, among others, Switzerland's Social Democratic Party; Greenpeace Germany; the French *Institut Curie*; *Assistance Publique-Hôpitaux de Paris*; the Belgian Society of Human Genetics; the Netherlands, represented by the Ministry of Health; and the Austrian Federal Ministry of Social Security." See Anja von der Ropp & Tony Taubman, Bioethics and Patent Law: The Case of Myriad, WIPO MAG., Aug. 2006, at 8, available at <http://www.wipo.int/wipo_magazine/en/2006/04/article_0003.html>.

United States, the opponents contested the patent on the basis of the European Patent Convention's patentability criteria, claiming that the invention "lacked novelty, inventive step and industrial application, and that the patent failed to disclose the invention sufficiently for a person skilled in the art to carry it out."[83]

Negative reactions were particularly strong in France, where French public health organizations and genetics societies promoted opposition proceedings before the European Patent Office (EPO) against the Myriad' patents.[84] These oppositions have been mostly successfully effected in amendment of the opposed Myriad's patents.[85] In particular, the claims of the gene sequence were held invalid for lack of novelty.[86] In the United States the case was decided by the district Court (Myriad I)[87] and the Federal Circuit (Myriad II)[88] . Recently the Supreme Court sent the case back to the US Court of Appeals for the Federal Circuit for reconsideration in light of the Mayo Collaborative Services v. Prometheus decision, where the Supreme Court's justices unanimously invalidated a patent on a medical test because it covered a "law of nature".[89]

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[83] Id.

[84] See E. Richard Gold & Julia Carbone, Myriad Genetics: In the Eye of the Policy Storm, 12 GENETICS MED. S39, S45, S54 et seq. (2010); Joshua D. Sarnoff, Patent Eligible Medical and Biotechnology Inventions After Bilski, Prometheus, and Myriad, 19 TEX. INTELL. PROP. L.J. 393, 416 (2011).

[85] See von der Ropp & Taubman, Bioethics and Patent Law: The Case of Myriad, cit. (noting that the opposition proceedings led to the revocation in 2004 of European Patent 699754, which covered a method for diagnosis); See also Sarnoff, Patent Eligible Medical and Biotechnology Inventions After Bilski, Prometheus, and Myriad, cit. at 416; Gold & Carbone, Myriad Genetics: In the Eye of the Policy Storm, cit. at S45; Jordan K. Paradise, Lessons from the European Union: The Need for a Post-Grant Mechanism for Third-Party Challenge to U.S. Patents, 7 MINN. J.L. SCI. & TECH. 315, 320 (2005).

[86] The opposition procedure concerning the BRCA1 gene concluded in 2007, following an appeal procedure. European patents on the BRCA genes were partially revoked or amended for lack of conformity to the fundamental patentability requirements: novelty, inventive step, industrial application and disclosure of technical information. See Board of Appeal decision T1213/05 available at <http://www.epo.org/law-practice/case-law-appeals/pdf/t051213eu1.pdf>. For related European perspectives, *see* von der Ropp & Taubman, Bioethics and Patent Law: The Case of Myriad, cit. (arguing that "the proceedings found that errors in the original patent application had not been corrected until the gene sequences were in the public domain. This meant that, according to patentability criteria, the invention had not been fully disclosed in the application as originally filed; and was not novel by the time the invention was fully described in the amended application"). See also E. Richard Gold & Julia Carbone, Myriad Genetics: In the Eye of the Policy Storm, 12 GENETICS MED. S39, S45, S54 (2010); Nayanah Siva, Myriad Wins BRCA1 Row, (2009) 27 NATURE BIOTECHNOLOGY 8 (2009); Gert Matthijs, The European Opposition against the BRCA Gene Patents, 5 FAM. CANCER 95 (2006); Gertrui Van Overwalle, Analysing DNA patents in relation with diagnostic genetic testing, in 14 European J. Human Genetics, 26, 30 (2006).

[87] Ass'n for Molecular Pathology v US Patent and Trademark Office, 702 F Supp 2d 181 (SDNY 2010) [hereinafter Myriad I].

[88] Ass'n of Molecular Pathology v. U.S. Pat. & Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011) [hereinafter Myriad II].

[89] No. 10-1150 (U.S. Mar. 20, 2012).

In the District Court's view, "isolated DNA is not markedly different from native DNA as it exists in nature" and consequently it represents unpatentable subject matter.[90] In this regard, the case invigorated the debate on policy issues relating to diagnostic gene patenting.[91] The increasing importance of molecular biology in the prevention and diagnostics of human pathologies amplified the importance of access to genomic information for the development of drugs and therapies.[92]

The Federal Circuit overturned the District court in part. In particular, the Court ruled in favor of the patent holder, reversing the decision of the lower court. Following the motivation laid out in the Supreme Court's decisions in the Chakrabarty case,[93] the court come to a different conclusion. It argued that due to human manipulation the isolated DNA did exist in a distinct chemical form and consequently was different from DNA in the human body.[94] As a consequence, isolated and purified DNA has the "markedly different" chemical structure that makes it eligible for a patent.[95]

As previously pointed out, the Supreme Court has recently sent back the case to the Appeals Court for reconsideration in light of it recent decision that can influence or impact the case.[96] Consequently, on August 16, 2012, the Federal Circuit issued its new pronouncement reversing - for a second time - the district court's decision that isolated gene sequences are not patentable.[97] At the same time, the Court also partly confirmed the District Court's decision that some methods patents directed to "comparing" or "analyzing" gene sequences may not be patentable.[98] The

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90 Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 232 (S.D.N.Y. 2010), as amended (Apr. 5, 2010) ("Because the claimed isolated DNA is not markedly different from native DNA as it exists in nature, it constitutes unpatentable subject matter under 35 U.S.C. § 101.").

91 Geertrui Van Overwalle, *Turning Patent Swords into Shares*, cit. at 1630.

92 Brian A. Jackosn, *Innovation and Intellectual Property: The Case of Genomic Patenting*, 22 J. Pol'y Analysis & Mgmt 5, 9-12 (2003).

93 See Diamond v. Chakrabarty, 447 U.S. 303 (1980). In this landmark decision the United States Supreme Court held that a live and human-engineered microorganism is patentable subject matter under Section 101 of the United States Patent Act. The rule for which the decision is commonly known is that patents can be issued on "anything under the sun that is made by man". For a detailed review of the case, see Rebecca S. Eisenberg, *The Story of Diamond v. Chakrabarty: Technological Change and the Subject Matter Boundaries of the Patent System*, in INTELLECTUAL PROPERTY STORIES 327 (Jane C. Ginsburg & Rochelle Cooper Dreyfuss ed., 2006).

94 See Ass'n for Molecular Pathology v. USPTO (Myriad II), 653 F.3d 1329, 1351 and 1358 (Fed. Cir. 2011).

95 Id.

96 Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794, 182 L. Ed. 2d 613, 2012 U.S. LEXIS 2356, 80 U.S.L.W. 3545 (U.S. 2012).

97 See A*ssociation for Molecular Pathology, et al., v. United States Patent & Trademark Office, et al. ("Myriad III")*, ___ F.3d. ___ (Fed. Cir 2012).

98 On this point, the Court stated the following: "We turn next to Myriad's challenged method claims. This court in its now-vacated decision of July 29, 2011, had held method claims 1 of the '999, '001, and '441 patents, as well as method claims 1 and 2 of the '857 patent—all of which consist of analyzing and comparing certain DNA sequences—not to be patent-eligible subject matter on the ground that they claim only abstract mental processes. In light of the Supreme Court's decision in Mayo, we reaffirm that prior holding. The Court made clear that such diagnostic methods in that case essentially claim natural laws that are not eligible for patent."

consequence of this new interpretation means that isolated gene sequences continue to be – at least for now – patent eligible. However, given all the various ramifications of the lawsuit, there is a reasonable possibility that this case will again go before the Supreme Court for a definitive ruling.

8 Access to Knowledge, genetic-based inventions and property rights

The two mentioned cases demonstrate how role of exclusive rights in biotechnology innovation is extremely complex. Normally, we consider patents as useful instruments to promote innovation, progress and scientific discoveries, "but that is because most patents are granted for human inventions".[99] Even if patents protect inventions, they fundamentally help also innovation, in that way they promise a possible return on investment to inventors and companies spending resources in developing new products for the civil society. Here the questionable point is whether genetic material can or can not be considered a human invention because it is "features of the natural world".[100] In light of this situation, it is indispensable to recognize and discuss the possible ramifications of private control over genetic material. As a potential consequence these patents "can be used to block innovation and hurt patient care".[101] But, at the same time, genes have become a new area of research just because of their potential to cure genetic diseases, and to test new treatments and medicines. This is a very peculiar situation, since contrasting rights and interests are involved and they need to be weighted and appropriately assessed.

The protection of intellectual property rights is therefore a delicate balancing act between private economic interests, individual ownership, moral values, and public interest.[102] As a consequence, protecting intellectual property is not without risks. In fact, the protection of intellectual property can "also restricts the access to knowledge since it defines knowledge as private property and tends to facilitate monopolistic practices. The granting of monopoly control over inventions may restrict their social utilization and reduce the potential public benefits. The principle of exclusive control over the exploitation of works someone has created, can constitute an effective right to monopoly control, which restricts the free flow of ideas and knowledge."[103]

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99 See Michael Crichton, Op-Ed., Patenting Life, N.Y. Times, Feb. 13, 2007, at A23, available at http://www.nytimes.com/2007/02/13/opinion/13crichton.html.

100 Id.

101 Id. (arguing that gene patents block innovation and inhibit research as demonstrated by the postponed research of SARS due to patent concerns).

102 See Cees J. Hamelink, Human Rights for the Information Society in COMMUNICATING IN THE INFORMATION SOCIETY 121, 144 (Bruce Girard & Seán Ó Siochrú, eds., 2003).

103 Id., at 145.

The huge number of gene patents and specifically the considerable amount of patents granted on "isolated" DNA sequences generated a large controversial debate regarding the effect of these patents and subsequent licensing practices on the cost, availability, accessibility, and quality of particular genetic tests and other applications of genomic technology.[104]

During the last few years we have witnessed incredible progress and achievements of DNA related technologies. This kind of research has undoubtedly had a fundamental role in many scientific and medical advances. However, biotech research is extremely costly and requires many years to develop and implement effective products or diagnostic tools.[105] Often governments must provide grants for research and offer intellectual legal protection to original creative inventions in order to safeguard the investment in research and development of biotech industries.[106] In particular, the patent system is the instrument properly configured to allow innovators to recoup their investment in research and development.[107] For this reason, it is also considered to play a critical role in the growth of the biotechnology industry and in promoting innovation across biotech industries.[108]

However, along with some benefits, there are also adverse effects associated to some form of DNA-based inventions. For example, people begin to wonder whether it might be acceptable to patent part of the human body or elements from natural resources. Similar questions and concerns are common not only among the general public but also among scientist and legal scholars.[109] These

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104 See Sec'y's Advisory Comm. on Genetics, Health, and Soc'y, Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests, Report of the Secretary's Advisory Committee on Genetics, Health and Society 2 (2010), available at http:// oba.od.nih.gov/oba/sacghs/reports/SACGHSpatents__report_2010.pdf.

105 See DAVID B. RESNIK, OWNING THE GENOME: A MORAL ANALYSIS OF DNA PATENTING 67 (2004).

106 Id., at 81. See also Arti K. Rai, Knowledge Commons: The Case of Biopharmaceutical Industry, 12 First Monday, Jun. 4, 2007, <http://firstmonday.org/is sue12_6/rai/index.html>.

107 U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, THE EVOLVING IP MARKETPLACE: ALIGNING PATENT NOTICE AND REMEDIES WITH COMPETITION 1 (2011) [hereinafter 2011 Marketplace Report], available at <http://www.ftc.gov/os/2011/03/110307patentreport.pdf>. See Dominique Guellec & Bruno van Pottelsberghe de la Potterie, The Economics of the European Patent System: IP Policy for Innovation and Competition 123 (2007) (noting that patents constitute the main asset for biotech industries).

108 Id. See also Rebecca Eisemberg, Patenting the Human Genome, 39 EMORY L.J. 721, 736 (1990). The author argues that "A rule that limits the first inventor to process patent protection may consequently provide a considerably weaker incentive to invest in developing the first means of making an obviously desirable product than a rule that offers product patent protection. Whether the process patent alone would provide an adequate incentive to induce the necessary inventive effort is ultimately an empirical question with an answer that varies from one invention to the next. Yet the first inventor to develop a means of making an obviously desirable but previously unobtainable product has made an invention that the public may well consider worth the price of a patent monopoly on the product itself. Rather than risk losing valuable inventions by offering too little patent protection in the form of what may eventually become an unenforceable process patent, it may be preferable to offer the higher bounty of a product patent at the outset". Id., at 736.

109 See e.g. Mark J. Hanson, Patenting Genes and Life: Improper Commodification?, in WHO OWNS LIFE? 161, 168-73 (David Magnus et al. eds., 2002); John M. Conley & Roberte Makowski, Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents (Part II), 85 J. PAT. & TRADEMARK OFF. SOC'Y 371, 393 (2003) (offering a critical analysis of the so called "isolation and purification doctrine"); DAVID B. RESNIK, OWNING THE GENOME: A MORAL ANALYSIS OF DNA PATENTING 73-83 (2004) (illustrating various arguments against patents on DNA-related inventions); Matthew Albright, PROFITS PENDING: HOW LIFE PATENTS REPRESENT THE BIGGEST SWINDLE

debates are highly intense and contentious, and focus much more on ideological, ethical and economic arguments than on factual considerations. Now here the whole question is, whether a gene can be considered simply a chemical compound (like in patent law) or rather an information-carrying structure which, even if manipulated or isolated, maintains the quality or state of being produced by nature. On this topic, there are essentially two schools of thoughts.[110] There are those who believe that DNA or genetic material is simply a combinations of various chemicals.[111] Adopting this chemical approach, patent protection on genes can be allowed.[112] As we have seen, this is exactly the current approach adopted by the American, European and Japanese patent authorities.[113] The patentability of genetic information[114] was gradually recognized by a number of decisions of courts including the US Supreme Court in 1980[115] and the board of appeal of the European Patent Office[116] in the 1990s.[117] On the other hand, there are those whose view of the DNA and genetic information is strictly connected to the judicially created doctrine of "product of nature".[118] According to this theory, anything made or intervened by human hand is patentable, but things that exist in nature as it is, are not patentable.[119] However, opponents to DNA patents argue that all DNA is a non-patentable product of nature with no difference between transformation or

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OF THE 21ST CENTURY 140-43 (2004) (criticizing gene on patents and on living organisms); DAVID KOEPSELL, WHO OWNS YOU?: THE CORPORATE GOLD-RUSH TO PATENT YOUR GENES 156 (2009) (arguing that gene patents should be forbidden).

110 RESNIK, OWNING THE GENOME: A MORAL ANALYSIS OF DNA PATENTING, cit. at 73-74; Dominique Guellec & Bruno van Pottelsberghe de la Potterie, The Economics of the European Patent System: IP Policy for Innovation and Competition 122 (2007) (observing how opponents to the patentability of genetic stuff claim that living material is a discovery, not an invention, as it exists in nature before being identified by researchers).

111 See Kathrin Garforth, Life as Chemistry or Life as Biology? An Ethic of Patents on Genetically Modified Organisms", in PATENTING LIVES: LIFE PATENTS, CULTURE AND DEVELOPMENT 27 ,46 (Johanna Gibson ed., 2008).

112 Id., at 42. The authors notes that: "The legal fiction that assumes away the complexity of life to allow the patenting of organisms also suggests that these organisms are fungible with the other types of things patented under the statute". Id., at 35.

113 See Melanie J. Howlett & Andrew F. Christie, *An Analysis of the Approach of the European, Japanese and United States Patent Offices to Patenting Partial DNA Sequences (ESTs)*, 34 Int'l Rev. Indus. Prop. & Copyright L. 581 (2003); Jasmine C. Chambers, Patent Eligibility of Biotechnological Inventions in the United States, Europe, and Japan*:* How Much Patent Policy is Public Policy?, 34 Geo. Wash. Int'l L. Rev. 223 (2002); Leslie G. Restaino et al., Patenting DNA-Related Inventions in the European Union, United States and Japan: A Trilateral Approach or a Study in Contrast?, 2003 UCLA J.L. & TECH. 2 (2003). See also Anne Reese & Brian Opeskin, *Current Issues in Gene Patenting, in Disputes and Dilemmas in Health Law* 277, 280 (Ian Freckelton & Kerry Petersen eds.) (2006).

114 Here the term includes: genetic materials and gene fragments, such as expressed sequence tags (ESTs) and single nucleotide polymorphisms (SNPs).

115 Diamond v Chakrabarty 447 US 303 (1980).

116 Decision T 19/90-3.3.2, 1990 O.J. Eur. Pat. Off. 476.

117 See Dominique Guellec & Bruno van Pottelsberghe de la Potterie, The Economics of the European Patent System: IP Policy for Innovation and Competition 123 (2007).

118 Gottschalk v. Benson, 409 U.S. 63, 67 (1972).

119 For a discussion on this topic, see John M. Conley, Gene Patents and the Product of Nature Doctrine, 84 Chi.-Kent L. Rev. 109, 113 (2009); John M. Conley & Roberte Makowski, Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents, 85 J. Pat. & Trademark Off. Soc'y 301, 303-04 (2003);

isolation in the wild or in the lab.[120] Moreover, opponents of gene patents also argues that this praxis violate the freedom of speech, expression and communication - common to all Western liberal democracies - because of their potential to restrict the individual's freedom of expression.[121] Looking over both arguments, it is evident that genes are different from other things that are patented, because they are not proper inventions, and other researchers cannot invent alternative genes. As recently argued by the American Civil Liberties Union "even if patent-holders publish information about the genes they have identified, there is nothing to invent around – the genetic material contained in the gene is the information. Because this information is the foundation for future diagnostic tests and potential treatments, tying it up as intellectual property can inhibit, rather than stimulate, advances in biomedical research".[122]

9 Conclusion

In the preceding pages we have addressed the question of how the patent system has expanded its boundaries to protect matters whose protection is questionable. We have also shown how there is an increasing sensibility on the matter of fair and equitable access to information arising from the exploitation of genetic resources.

Through the analysis of some cases, we have exemplified how this particular situation can harm innovation and knowledge sharing by making the products of nature privately owned.

The main causes of this new complexity of the patent system, when applied to the genetic materials, are due to the indiscriminate granting of patents without proper regard for the real value of the invention. In addition, new technologies have completely changed how discoveries are made in genetics and genomic research.[123] These disputed patents are the results of transnational corporation strategies to ensure extensive gene patent portfolios regardless of their real function. The outcome of this methodological approach is that biological discovery has become a "work of

[120] See Resnik, Owning the Genome: A Moral Analysis of DNA Patenting, cit. at 74; see also generally Vandana Shiva, Biopiracy: The Plunder of Nature and Knowledge (1997).

[121] Complaint at 19, 22-25, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (No. 09 Civ. 4515).

[122] See American Civil Liberties Union, Legal Challenge to Human Gene Patents 8 (May 27, 2009), available at <http://www.aclu.org/pdfs/freespeech/brca _qanda.pdf >.

[123] See Rebecca S. Eisemberg, *Patents on DNA Sequences: Molecules and Information*, in *The Commodification of Information* (N. Elkin-Koren & N.W. Netanel, eds., Kluwer law 2002) at 416.

low invetorship", and much more a work of "mere cartography".[124]

The current patent trends for global technological innovations seem both inefficient and unsustainable. Monopolies or oligopolies in this sector may threaten not only the free exchange of information in the scientific community, but also in the realms of healthcare and knowledge management in general. Empirical studies support the assumption that patenting reduces rather than increases global technology diffusion.[125]

Genomics and biotechnology (as well as other technological advances) are pushing the IP system into unexplored areas, challenging the accepted rules of the game. This state of affairs suggests the need to establish new guidelines recognizing the changed landscape and the crucial role played by science and technology in modern society. Without a radical recasting of the system, no significant progress will be possible. On the contrary, if the present condition persists, it could actually hurt innovation, rather than help it. As suggested by other authors, patent law "should be assessed from a human right's perspective" also introducing certain limits on patentable subject matter in order to safeguard the rights of human being.[126]

These considerations lead to a question: do we need a specific regulatory regime for genomics particularly in its form of genomic information? The current policy attention is easily dominated by the extreme views. It is an occasion for people to develop discussion and the opportunity to engage in thoughtful discourse about the pros and cons of patenting genes and the ramifications of private control over common information.[127]

Many of these trends have begun to merge as it becomes obvious that what is needed is a major rethinking of the current processes related to the ownership of genetic material and information: a recasting of "the basic patent paradigm that would give much greater weight to the provision of public goods and "access to knowledge" in general, at the expense of private incentives to innovate".[128]

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[124] See Oskar Liivak, *Maintaining Competition in Copying: Narrowing the Scope of Gene Patents*, 41. U.C. Davis L. Rev. 177, 185 (2007).

[125] See e.g. Fiona Murray & Scott Stern, *Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis*, 63 J. Econ. Behav. & Org. 648 (2007); John P. Walsh, Ashish Arora & Wesley M. Cohen, *Working Through the Patent Problem*, 299 Science 1021 (2003).

[126] See Geertrui Van Overwalle, *Human rights' limitations in patent law,* in INTELLECTUAL PROPERTY AND HUMAN RIGHTS. A PARADOX 236, 263 (Willem Grosheide ed., 2010).

[127] For some possible and practicable solustions, see e.g. Geertrui Van Overwalle et al., *Models for Facilitating Access to Patents on Genetic Invention*, 7 Nature Review Genetics 143 (2006); Geertrui Van Overwalle, *Turning Patent Swords into Shares*, cit.

[128] See Jerome H. Reichman & Rochelle Cooper Dreyfuss, Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty, 57 DUKE L.J. 85, 105-6 (2007); EUROPEAN PATENT OFFICE (EPO), SCENARIOS FOR THE FUTURE - HOW MIGHT IP REGIMES EVOLVE BY 2025? WHAT GLOBAL LEGITIMACY MIGHT SUCH

Patent law has normalized biotechnology by endorsing the view that they do not constitute a real novelty, but they are novel in accordance with the meaning of novelty that already belongs to the semantic of patent.[129] Biotechnology would be patentable just because their innovative character is an element that qualifies the invention and that justifies legal protection. This is exactly the argument used by the Canada's Federal Court of Appeal in a decision allowing patents for genetically modified animals. Here the Court argued that "the language of patent law is broad and general and is to be given wide scope because inventions are, necessarily, unanticipated and unforeseeable."[130]

REGIMES HAVE? 72 (2007) (In the report, the EPO defines four different scenarios that could potentially arise in response to different interest groups attempting to influence national and international policymaking in this area).

[129] See Mariachiara Tallacchini, La Trappola e il Topo: la Brevettabilità della Materia Vivente, in LE TECNICHE DELLA BIOLOGIA E GLI ARNESI DEL DIRITTO 203 (A. Santosuosso et al. Eds., 2003).

[130] *Harvard College v. Canada* (Commissioner of Patents) (2000), 7 CPR (4th) 1 (F.C.A.) at para. 36.