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Understanding genetic information as a commons: from bioprospecting to personalized medicine

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Abstract: The aim of the paper is to discuss how the concept of commons can be enlarged to include genetic resources – both naturally occurring and as essential resources in research laboratories – that are increasingly considered as part of market frameworks. Looking beyond the enclosure of traditional public goods (such as land or water), the paper emphasizes the debate around the progressive commodification of genetic resources and associated genetic information operated by means of intellectual property rights or other forms of management of knowledge. The discourse around commons is used to evaluate alternative tools and strategies to the issue of private appropriation of human genetic resources and natural compounds.

Keywords: Bioprospecting, commons, genetic information, intellectual property rights, personalized medicine, public intangible goods

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1. Introduction

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" (Hess and Ostrom 2006a, 4). 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 (Hardin 1968; Ostrom 1990, 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 (Hess and Ostrom 2006a, 11). In particular it is argued 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" (Ibid). 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.

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. Starting from these considerations, the paper illustrates the progressive development of new forms of enclosure in the realm of the "intangible commons of the mind," through several waves of expansion of intellectual property rights in the area of genetic materials and intangibles goods in general (David and Foray 1995; Rai 1999; Benkler 2000b; Boyle 2003; Samuelson 2006). 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 (Litman 1990; Heller and Eisenberg 1998, 699; Rai and Eisenberg 2003, 295; Samuelson 2003, 155).

Finally, the paper suggests a new way of framing discussions between opponents of open access to genetic information associated to genetic resources freely occurring in nature and all attempts to abridge the full access to it. In particular it proposes to understand human and genetic information on an equal footing with the "free code" (Boettiger and Burk 2004, 222; Deibel 2009): 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 (Contreras 2010; Madison et al. 2010). 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. In a more general context, 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.

The following pages will investigate the impact of emerging aspects of patent law on the access to public non-human genetic resources as they occur in nature and human genetic material. On this footing, the paper goes on to pose a series of questions related to the rapidly growing fields of "bioprospecting" and personalized medicine. What are the ethical, social and legal consequences of patenting in the area of diagnostic methods and bioprospecting? What are the implications of the application of genetic patenting for the right to health care, access to medication and to genetic resources? What are the consequences of commercial activities 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 individual's or group's fundamental rights and freedoms. The purpose is to explore the relationship between two apparently different phenomena (bioprospecting and personalized medicine) establishing connections and drawing possible parallels through a critical analysis of case studies. We also try to examine if it is possible to contribute a sustainable and fair use of genetic resources and biodiversity through the commons based approach to genetic resources.

2. Intellectual property rights *versus* information commons

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." (Boyle 1996, xi) because the cost of original research is high (Andonian 1989, 51) but knowledge, is then easily 'portable'. Consequently, economic theory tells us that "public goods will be under produced because there will be too little incentive to create them" (Boyle 1996, xi). 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." (Ibid, 4). 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 enclosures 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 hand, the opponents of enclosure claimed that our common human genome as well as the non-human genetic 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 may be real troublesome in the near future. Market logic can – in fact – lead to a gradual and inexorable extension of this approach to areas which should be the remotest from the market.

Within this new paradigm, we can assist to a trend toward the economic and conceptual separation of "the informational message from the medium" and an increasing "devaluation (literally, the diminishing marginal cost) of the medium as compared with the message" (Boyle 1996, 7). As the information content is considered in isolation from its context, "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" (Ibid). Thus ideas, concepts or principles originally related "to one 'information area' seem to apply to another, first in metaphor and then in technological reality." (Ibid, 7).

Always according to Boyle, the advent of this new paradigm – which made possible the patenting of biological materials – is opening a new and unexplored window into the private appropriation of natural assets of common interest or their exclusive control by private interests. But, there are also some who argue that "the usefulness of any natural resource depends on its private appropriation as property". As a direct result, "parts of the natural environment must be removed from the 'commons' and used privately if they are to have any significant effect on the comfort and well-being of the individual humans" (Katz 1997, 226). The boundaries between the private and the public sphere as well as the relationship between the private and public domains of knowledge production are challenged particularly with respect to the protection of contemporary inventions under the intellectual property rights regime. Information of biological material and the knowledge associated with biodiversity – in fact – 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" (Boyle 1996, xvi). 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" (Ibid).

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 (European Commission 2006). Considering this framework, we will try to expand the Ostrom's approach to the realm of genetic information (Ostrom 1990) illustrating how genetic resources are not

simply biochemical compounds, but they can be reasonably considered in part as essential and limited public resources which requires a more effective institutions for governing them as commons.

To better understand the role of the governance and regulatory practices within this sector, it is necessary to first discuss what are the principles and legal provisions that deal with the private property regimes 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 (Howlett and Christie 2003; Restaino et al. 2003; Reese and Opeskin 2006, 280). 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.[1] This ruling in combination with the decision in Moore v. Regent of University of California[2] 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 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" (Joint Policy Statement 1998, 163; Crespi 2003, Crespi 2005).[3] In other terms, a purified natural substance is considered patentable if the "purification" results in a compound with such distinct characteristics that it becomes a new product commercially or therapeutically valuable. Formally, through the process of purification and isolation of genetic materials it is possible to achieve the separation of different compounds from a biological cell. However, various criticisms have been made on this point. In particular, it has been observed that even if genetic materials are isolated and purified, the main properties of such substances – which are the 'useful' and exploitable information – "are naturally occurring, not created by the person who isolates and purifies the material" (Australian Law Reform Commission 2004, 126). Furthermore, isolated and

[1] 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 Eisemberg 2006, 327.

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

[3] On this matter, see also Howlett and Christie 2003; Restaino et al. 2003; Reese and Opeskin 2006, 280.

purified genetic sequences are "structurally similar or identical to the form that exists in nature." (Ibid).

The direct result of this interpretation is that patents for biotechnological innovations are consequently limited only by the ability of the individuals drafting the claim (Robinson and Medlock 2005, 14). In recent years, one of the most troublesome aspects for gene patents has been their novelty and, therefore, their status as patentable subject matter (Doll 1998; Kevles and Berkowitz 2001; Larrimore Ouellette 2010). But still a further question comes up: "as DNA has existed well before the gene discoverer arrived, how can these molecules be novel?" (Liivak 2007, 192). 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" (Liivak 2007). 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" (Ibid). But the gene discoverer's thesis is that "purified and isolated gene sequences are distinct from the overall DNA molecule" (Ibid). 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 non-patentable 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."[4]

Currently, both in the EU and the US, to be eligible for patent protection, an innovation must meet three basic requirements (Bently and Sherman 2009, 391; Mills 2010, 4): (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 only an understanding of the key issues related to the requirement of inventiveness, 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.[5]

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 Europe (Gitter 2001, 1624).

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

[5] 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. For more on this concern, see Wright 2010.

Based on a principle of non-discrimination with regard to technology, article 27 of TRIPs agrees that biological material should be patentable (Gibson 2008, 3).[6] Human genes can be patented if they meet the requirements of novelty, inventive step and industrial applicability (Bently and Sherman 2009, 393–394).[7] In other words, genes can be patented if the invention meets the general requirements of a patent (Andrews and Paradise 2005, 404). 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.[8] In particular, the Directive recognizes that biological material 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.[9] In addition, the European 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".[10] 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.[11] However, Biotech inventions are considered patentable under both the EPC and the Biotechnology Directive (Spinello and Bottis 2009, 64). In particular, the European Patent Convention explicitly acknowledges the patentability of biotechnological inventions in Rule 26(1) EPC (Macchia 2012, 37).[12] In addition, Rule 27(a) EPC provides supplementary specifications about patentable subject-matter in Biotech stipulating that "Biotechnological inventions

[6] 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].

[7] 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".

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

[9] Ibid, at art. 3(2).

[10] 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". On this, see Reinisch 2010, 138.

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

[12] 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.

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".[13]

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.[14] In fact, patent holders are free to choose how to exercise their exclusive rights.[15] 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 (Bently and Sherman 2009, 570).[16] 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" (Van Overwalle 2010b). These factors suggest that patents may have a chilling effect on research and innovation (Resnik 2004, 141), resulting in a significant impact on other researchers' ability to conduct further research.

4. Bioprospecting, personalized medicine and the governance of access to essential genetic resources

Over the past several years, the genomic, biosciences 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 (National Research Council 2011, 125). It is essentially based 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

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

[14] 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").

[15] 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 and Sherman 2009, 335.

[16] On this matter, it is worthy to note that in the U.S., an intellectual property rights holder has no obligation to either use or license its property rights. On the point, see Hovenkamp et al. 2006, 13.

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 (Personalized Medicine Coalition).[17]

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 new products targeted to specific populations (Geetter 2011). 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 protection of intellectual property rights, effective access to diagnostic or prognostic tests and patient privacy and confidentiality (Personalized Medicine Coalition).

On the other hand, the term "bioprospecting" refers to the exploration of biocultural diversity for commercially valuable genetic, biochemical, and cultural resources (Moran et al. 2001; Dedeurwaerdere 2005; Sarr and Swanson 2012). 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 (Adair 1997, 132). In particular, it focuses on microscopic resources at the genetic and biochemical level (Ibid).

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 problems could result from bioprospecting on public lands and the subsequent biotechnological innovations from the genetic resources found there (Michaels 1999, 4). 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 (Adair 1997, 141). The debate over the legitimacy of this activity brings to mind an excellent

[17] For an overview of developments in personalized medicine see the two reports issued by the United States Department of Health and Human Services: U.S. Dep't Of Health & Human Servs. 2007; U.S. Dep't Of Health & Human Servs. (2008). See also Willard and Ginsburg 2009; Ghosh 2012.

question: "should the government controlling land containing potentially valuable wild genetic resources profit when bioprospectors remove these resources?"(Ibid). Traditionally, wild genetic resources were considered a "common heritage of humankind" that should be available without restriction (Sedjo 1992, 202). In the past, collection rights were mostly conceded for free by the country in which the wild genetic resources were found (Ibid, 209). Biotechnology companies supported this free access by arguing that the use of these resources provides 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 (Aseff 2011, 199). The issue of patentability of biodiversity is also intimately related to a derivative and more problematic form of bioprospecting. This is an activity referred as "biopiracy": it mainly consists in the unauthorized and uncompensated taking and patenting of biological resources and traditional knowledge for valuable research purposes (Shiva 1997; Mattix 1999, 529). Biopiracy can be a serious problem for developing countries rich in biodiversity, in particular when transnational corporations take unfair advantage of these resources.

In the next pages we will observe the real nature of personalized medicine and bioprospecting activities pointing out some challenging issues surrounding the use of natural biological resources. To explore more in details the increasing commercial pressure on natural and human genetic resources, the article considers two emblematic case studies: the Myriad Genetics controversy and the Yellowstone's Park Bioprospecting case.

5. The Yellowstone National Park bioprospecting controversy

This section briefly outlines how Diversa Corporation, a biotech company founded in San Diego, California in 1994, set out to create a new market oriented approach to bioprospecting on public land (Finegold et al. 2005, 127). 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 and to pay royalties for any products, services or other commercial exploitation derived from biological materials collected in the Park (Ibid, 128). 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 lakes".[18] Diversa was essentially interested to search for unknown biochemical forms from which

[18] Edmonds Institute v. Babbitt, 42 F. Supp. 2d, 5 (D.D.C. 1999).

to develop commercially useful enzymes and other biomolecules (Finegold et al. 2005, 130). The Diversa-Yellowstone partnership rapidly gave rise to broader protests against the possibility to establish a commercial activity involving public natural resources (Ibid, 128). 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.[19] 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 resources of the park.[20] 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.[21]

After hearing the parties' arguments, the judge ordered the National Park Service to complete a National Environmental Protection Act review of the effects and potential risks of the partnership.[22] The judge also ordered the postponement of the agreement until the conclusion of this review.[23] 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 of access to genetic resources in public land offers a critical discussion concerning the authentic purposes of national parks and how the National Park Service should realize those objectives (Wood 2000, 221). Although bioprospecting seems conflicting with public land law and wildlife law, current U.S. regulations does not explicitly allow or exclude bioprospecting on public land (Aseff 2011, 216). In this uncertain setting, the adoption of the Convention on Biological Diversity[24] (hereafter "the Convention") is an important landmark. Before the entry into force of the Convention genetic resources were often *de facto* freely available and held as a common public good (Bowman 1996, 31; Qualset and Webster 1998). The Convention reaffirmed the national sovereignty of states over their genetic resources. Even though the US did not ratify the Convention, it regularly has expressed its support to its basic principles, but did not clarify what specific principles would apply to access to *in situ* genetic resources on its own territory. In reaction to the re-affirmation of the principle of national

[19] *See* The Edmonds Inst., http://www.edmonds-institute.org.
[20] See Edmond Inst. V. Babbit civ. Action 98–561 (RCL) Memorandum Opinion of Apr. 12, 2000.
[21] Ibid.
[22] Edmonds Institute v. Babbitt, 42 F. Supp. 2d, 20 (D.D.C. 1999).
[23] Ibid.
[24] Convention on Biological Diversity, 31 I.L.M. 818 (1992).

sovereignty over natural resources in the Convention of Biological Diversity, the International Treaty on Plant Genetic Resources for Food and Agriculture[25] has tried to preserve an international and multilateral commons based approach for plant genetic resources. The International Treaty motivates this move as a way to stimulate greater support for the conservation and sustainable use of plant genetic resources for food and agriculture, attempting to strike a balance between overly exclusive property rights and fully unregulated open access (Frison et al. 2010).

In this debated context, access to genetic resources and the consequent sharing of benefits is regulated in article 15 of the Convention, which 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.[26] The purpose of the access regulated by the Convention includes the direct use of these resources – specifically in their genetic and biochemical expressions – for industrial purposes and economic profit. In addition, the scope of the Convention also includes the extraction of genetic information potentially applicable to commercial uses. 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 that are implemented in developing countries. In particular, the latter countries 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 (Crescenzi 2012, 353).

Despite the conclusion of the Yellowstone case in favour of Diversa, this dispute offers a well-documented case of the still problematic practice of bioprospecting on public land and its direct and indirect impacts on the conservation of biodiversity. As long as the methodical search for novel products from plants and microorganisms lacks effective regulatory measures to prevent the misuse of public resources, bioprospecting is likely to threaten sustainable and fair use of biodiversity and, consequently, fail to support conservation efforts for preserving the ecosystems health (Aseff 2011, 198). Furthermore, unclear ownership rights on bioprospected resources may lead to the risk of depletion or neglect of valuable

[25] International Treaty on Plant Genetic Resources for Food and Agriculture, Nov. 3, 2001, 2400 U.N.T.S. 303.

[26] 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.

genetic resources on public land. The key question here is how to ensure that the results of research based on scarce and common resources are not privately appropriated by scientists or corporations, but are shared with all the users of public lands. In other terms, there is a need to reach a better balance between the public investment in "protected public land and natural resources" and the "commercial exploitation" of biological materials and associated knowledge.

6. 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.[27] 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[28] and BRCA2.[29]

The origins of the Myriad controversy date back to September 1994, when the U.S. Biotech Company Myriad Genetics (Gold and Carbone 2010, S41)[30], in collaboration with the University of Utah and other research laboratories was able to identify nucleotide sequences linked to susceptibility for breast and ovarian cancer (Miki et al. 1994).[31] The oncogene was identified with the acronym BRCA that stands for "breast cancer". Following the isolation of the oncogene, Myriad developed a diagnostic test intended to identify genetic predisposition to breast and ovarian cancer.[32] After the isolation of these two genes, Myriad filed for patent protection in both the United States and Europe.[33] These patents immediately raised questions among scientists and others concerned in different countries. In particular, oppositions were filed against the European patent (EP 705902) on the isolated BRCA-1 gene by – among others – Assistance Publique-Hôpitaux de Paris, the French Institut Curie, the Switzerland's Social Democratic Party; the Belgian Society of Human Genetics; Greenpeace Germany; the public health authority of the Netherlands and the Austrian Federal Ministry of Social

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

[28] 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 Saladino 2011, 302.

[29] 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 2011.

[30] 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 Dec. 28, 2012).

[31] See Myriad I, at 201–203 (S.D.N.Y. 2010).

[32] Ibid, at 201.

[33] Ibid, at 202.

Security (von der Ropp and Taubman 2006, 8). In Europe, unlike in the 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" (von der Ropp and Taubman 2006).

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 (Gold and Carbone 2010, S54; Sarnoff 2011, 416). These oppositions have been mostly successfully effected in amendment of the opposed Myriad's patents (Paradise 2005, 320; von der Ropp and Taubman 2006; Gold and Carbone 2010, S45; Sarnoff 2011, 416). In particular, the claims of the gene sequence were held invalid for lack of novelty.[34] In the United States, the case was decided *in primis* by the district Court (Myriad I)[35] and then by the Federal Circuit (Myriad II).[36] Recently the Supreme Court granted a writ of certiorari[37] and 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. In this last mentioned case, the Supreme Court's justices unanimously invalidated a patent on a medical test because it covered a "law of nature".[38]

The Myriad lawsuit was initially decided by the District Court (Southern District of New York, Judge Robert Sweet, presiding) in favor of the plaintiffs. 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.[39] 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

[34] 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. On these points, see Board of Appeal decision T1213/05 available at: http://www.epo.org/law-practice/case-law-appeals/pdf/t051213eu1.pdf.

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

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

[37] Petition for Writ of Certiorari, Association for Molecular Pathology v. Myriad Genetics, Inc., 653 F. 3d 1329 (Fed Cir. 2011) (No. 11–725) 2011.

[38] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012) [with reference to the decision in Mayo Collaborative Services v. Prometheus Laboratories, Inc., 132 S. Ct. 1289 (2012)].

[39] 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.").

Chakrabarty,[40] the court came 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. As a consequence, isolated and purified DNA has the "markedly different" chemical structure that makes it eligible for a patent.

As previously noted, the Supreme Court sent the case back to the Appeals Court for reconsideration in light of Supreme Court's Mayo Ruling and its potential to influence or impact also the Myriad case.[41] 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.[42] At the same time, the Court also partly confirmed the District Court's decision that some method patents directed to "comparing" or "analyzing" gene sequences may not be patentable.[43] Nevertheless, the plaintiffs filed a new petition for a writ of Certiorari [44] and the Supreme Court agreed to once again hear the case limiting the question of whether human genes are patent eligible.[45] On June 13, 2013, the U.S. Supreme Court issued this long-awaited decision invalidating, *de facto*, the patents on BRCA 1 and BRCA 2 and concluding that isolated genomic DNA is not eligible for patenting under Section 101 of the US patent statute.[46] The Court's reasoning essentially rests on the difference between products as they are found in nature as opposed to those that have been transformed or altered into something man-made. Mentioning the Supreme Court's prior decision in *Diamond v. Chakrabarty*, the judges argued that: "Myriad recognizes that our decision in *Chakrabarty* is central to this inquiry. […] In *Chakrabarty*, scientists added four plasmids to a bacterium, which enabled it to break down various components of crude oil." At the same time, the Court also recognized that the *Chakrabarty* bacterium was new "with markedly different characteristics from any found in nature." The Court finally concluded that, "Myriad did not create anything", namely "it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention." As a consequence, these

[40] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[41] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794, cit.

[42] Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303 (Fed. Cir. 2012)

[43] Ibid. 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."

[44] 689 F.3d 1303 (Fed. Cir. 2012), petition for cert. filed (U.S. Sept. 25, 2012).

[45] *Ass'n for Molecular Pathology v. Myriad Genetics, et al.* (USSC Docket 12–398) (*Certiorari* granted November 30, 2012).

[46] Association for Molecular Pathology v Myriad Genetics, Inc. et al. 12–398, 569 U. S. ____ (2013) (No. 12–398. Argued April 15, 2013 – Decided June 13, 2013).

"naturally occurring, isolated DNA segments" were ruled to be patent ineligible subject matter.

This landmark decision represents a substantial shift in patent law and overturns current Patent Offices policy. However, the Court left the possibility open to patent artificially created DNA sequences, such as cDNA, because they do not occur naturally. In other words, DNA that has been modified from its naturally occurring form will still be subject to patent monopolies. On this point, the Court stated that:

> "cDNA is not a "product of nature," so it is patent eligible under §101. cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments. Its creation results in an exons-only molecule, which is not naturally occurring. Its order of the exons may be dictated by nature, but the lab technician unquestionably creates something new when introns are removed from a DNA sequence to make cDNA."[47]

Even if the full and practical consequences of this decision remain to be seen, some early commentators argued that it could increase "the uncertainty regarding the availability of effective patent protection in important areas of biotechnology and pharmaceutical research" (Holman 2013). However – at the moment – the only evident effect of this decision is that it could affect the validity of granted patents and make it harder to obtain patents protecting newly isolated products of nature and other biotechnology-based inventions. Understanding the implications of the Supreme Court's decision on the biotech field will require further analysis and consideration also in terms of its influence at global level.

7. Access to essential knowledge, genetic-based inventions and property rights

The two discussed cases demonstrate the complex role of exclusive rights in the biosciences marketplace. The crucial point here is that "the aspirational normative structure of science regards new biological discoveries as shared public resources", while "commercial biotechnology regards such discoveries as potential commodities to be patented, licensed, and marketed through the application of exclusive proprietary rights (Boettiger and Burk 2004, 221). 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" (Crichton 2007). Even if patents protect inventions, they fundamentally help also innovation, in that way that 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 materials can or can not be considered a human invention because they are "features of the natural world" (Ibid). In light of this situation,

[47] Ibid.

it is indispensable to recognize and discuss the possible ramifications of private control over genetic material.

The protection of intellectual property rights ends up turning into a delicate balancing act between private economic interests, individual ownership, moral values, and public interest (Hamelink 2003, 144). As a consequence, protecting intellectual property is not without risks. In fact, the protection of intellectual property can hinder – even just partially – the dissemination of information and the access to knowledge (Crichton 2007; Murray and Stern 2007, 670) "since it defines knowledge as private property and tends to facilitate monopolistic practices" (Hamelink, 145). The granting of a temporary monopoly of the use on inventions may also restrict their common utilization and decrease the potential public benefits associated with. 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" (Ibid).

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 exclusive rights and subsequent licensing practices on the cost, availability, accessibility, and quality of particular genetic tests and other applications of genomic technology.[48]

On the one hand, biotech research is extremely costly and requires many years to develop and implement effective products or diagnostic tools (Resnik 2004, 67). Often governments must provide grants for research or offer intellectual property protection to original creative inventions in order to safeguard the investment in research and development of biotech industries (Ibid, 81; Rai 2007). In particular, the patent system is the instrument properly configured to allow innovators to recoup their investment in research and development (Guellec and van Pottelsberghe de la Potterie 2007, 123; U.S. Department of Justice and Federal Trade Commission 2011, 1). 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 (Eisemberg 1990, 736).[49]

[48] 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.

[49] Here 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". Ibid, 736.

On the other hand, there are also adverse effects associated to intellectual property on some form of gene-based inventions. For example, people begin to wonder whether it might be acceptable to patent part of the human body. Similar questions and concerns are common not only among the general public but also among scientist and legal scholars (Hanson 2002; Conley and Makowski 2003, 393; Albright 2004; Resnik 2004; Koepsell 2009, 156). These debates are highly intense and contentious, and focus much more on ideological, ethical and economic arguments than on factual considerations.

From a legal perspective, the whole question is whether a gene can be considered simply a chemical compound 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 (Resnik 2004, 73; Guellec and van Pottelsberghe de la Potterie 2007, 122). There are those who believe that DNA or genetic material is simply a combination of various chemicals (Garforth 2008, 46). Adopting this chemical approach, patent protection on genes can be allowed (Ibid, 42). As we have seen, this is exactly the current approach adopted by the American, European and Japanese patent authorities (Chambers 2002; Howlett and Christie 2003; Restaino et al. 2003; Reese and Opeskin 2006, 280). The patentability of genetic information[50] was gradually recognized by a number of decisions of courts including the US Supreme Court in 1980[51] and the board of appeal of the European Patent Office[52] in the 1990s (Guellec and van Pottelsberghe de la Potterie 2007, 123). 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".[53] 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 (Conley and Makowski 2003, 303; Conley 2009, 113). However, opponents to DNA patents argue that all DNA is a non-patentable product of nature with no difference between transformation or isolation in the wild or in the lab (Shiva 1997; Resnik 2004, 74). Moreover, opponents of gene patents also argues that this praxis violates 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.[54]

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

[50] Here the term includes: genetic materials and gene fragments, such as expressed sequence tags (ESTs) and single nucleotide polymorphisms (SNPs).
[51] Diamond v. Chakrabarty 447 US 303 (1980).
[52] Decision T 19/90-3.3.2, 1990 O.J. Eur. Pat. Off. 476.
[53] Gottschalk v. Benson, 409 U.S. 63, 67 (1972).
[54] 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).

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" (American Civil Liberties Union 2009). The unsolved debate between these two schools of thought is reflected in turn in the uncertain legal status that was reviewed above. On the one hand, as reflected in the 1998 joint policy statement by the US, EU and Japanese patent offices discussed in Section 3, purified natural substances are considered patentable. On the other hand, the 2013 decision of the Supreme Court in the Myriad case seems to indicate a reversal in overly broad application of this criterion to genetic resources and the extraction of genetic information.

The debate over the regulation of access and use of genetic resources in the two cases that we discussed is reflecting how the balance between rewarding innovation and protecting the benefits flowing from public domain uses is an arduous task. It is in this respect that the analysis of both previous cases reveals how the development and application of new technologies play a significant role "in the robustness or vulnerability of commons" (Hess and Ostrom 2006, 10). It is exactly this ability to capture "the previously uncapturable" that is able to provide a substantial metamorphosis "in the nature of the resource" (Ibid). As argued by Hess and Ostrom, the risks inherent in the enclosure of the knowledge commons are exactly "based on the ability of new technologies to "capture" resources that were previously unowned, unmanaged, and thus, unprotected (Ibid).

8 Conclusion

In the preceding pages we have addressed the question of how to identify and measure the uncertain legal status of genetic resources, both as naturally occurring resources and as genetic code which are new immaterial goods associated to these resources. Working through an analysis of the various statutory, regulatory and judicial rules involved in governing immaterial information goods, we have attempted to identify the most critical points against a strict proprietary regime for governing these resources. In particular, from this analysis it follows that one of the most challenging aspects of litigation in this area involves the determination of the boundary line between the "domain of property" and the "domain of commons" over naturally occurring compounds and associated genetic information (Benkler 2000a, 557; Resta 2011, 68).

The appropriation and commercialization of immaterial goods is possible. However, it becomes obvious that the current strong property rights regime is based on legally untenable ground: in fact, its implementation totally depends on the design of artificial scarcity of immaterial good which is supported and maintained by a set of questionable assumptions, whether through strong intellectual property rights or through exclusive contracting over genetic resources on public lands (Boldrin and Levine 2008). The considerable increases in exclusive access regimes

and patent protections have not converted comparable increases in innovation. Furthermore – as suggested by some scholars – there is little historical evidence that supports the argument that intellectual property monopoly efficiently increases innovation and knowledge transfer activity (Bessen and Meurer 2008, 46–71; Boldrin and Levine 2008; Heller 2008; Burk and Lemley 2009, 95–100). On the contrary, too much ownership of intellectual property can have the effect of decreasing rather than increasing innovation (Walsh et al. 2003; Murray and Stern 2007). As recently observed by the US Supreme Court in the landmark case Mayo v. Prometheus, the balance between rewarding innovation and protecting the public domain is a somewhat arduous task: "Patent protection is" – in fact – "a two-edged sword".[55] On one side, "the promise of exclusive rights provides monetary incentives that lead to creation, invention, and discovery". On the other side, "that very exclusivity can impede the flow of information that might permit, indeed spur, invention".[56] In spite of the uncertain legal situation that results from these ongoing debates, this article has shown that recent court decisions seem to hint in the direction of a recognition of the unpatentable character of substances and associated information "as occurring in nature".

The dilemma in the governance of immaterial goods suggested here is a fundamental tension between the security of property and the exercise of natural liberty over genetic resources and associated information as they occur in nature. Genetic information is a public good and must be freely available to other researchers who want to use and test it in similar process. As bioscience is being transformed into an information science (Hess and Ostrom 2006b, 335), those who want to do research must have a free access to this information. It implies that users of naturally occurring genetic resources cannot appropriate the value of genetic information. The patent system has expanded its scope to protect matters whose protection is questionable. At the same time, biological discovery has become a "work of low inventorship", and much more a work of "mere cartography" (Liivak 2007, 185). The direct consequence of this new phenomenon is that courts are dealing with an increasing number of legal actions against forms of privatization of knowledge that were previously public common goods or consisting in mere reformulation of natural phenomena.

The current policy attention is still dominated by the extreme views. It is however 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 (van Overwalle et al. 2006; Ibid, 2010b). 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 access to and 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

[55] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S.Ct. 1289, 1305 (2012).
[56] Ibid.

incentives to innovate" (European Patent Office 2007, 72; Reichman and Dreyfuss 2007, 105). This suggested approach has a potential to resolve the tension between the communality of science and genetic information as well as the economic incentive purpose of patent law (Boettiger and Burk 2004, 231). At the same time – as (indirectly) resulted from the Supreme Court's Myriad decision – the standard for invention must be high enough in order to ensure adequate public access, tempering the vulnerability and uncontrolled access to common resources and their extreme exploitation.

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