

BIOTECHNOLOGICAL INVENTIONS  
AND LIMITS OF PATENTABILITY  
BETWEEN RECENT EVOLUTIONS  
IN THE US CASE LAW AND THE EU  
PERSPECTIVE OF FUNDAMENTAL RIGHTS:  
MOVING TOWARD A COMMON “WESTERN  
APPROACH”?

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*The paper analyzes the forms and limitations of patent protection recognition for biotechnological inventions. In this perspective, the paper compares the American model, traditionally based on technical evaluations, and the European model, inspired by fundamental rights.*

*Intellectual property law, and especially biotechnological patent law, in fact, often involves and/or faces off with the exercising of fundamental rights. In particular, the issues analyzed and the considerations proposed highlight how the regulation of biotechnological inventions should guarantee a fair balance between protection of investment and access to information which is essential for research and innovation.*

*In this framework, the recent US Supreme Court decision in *Myriad* and *Mayo* (and the subsequent USPTO Patent Eligibility Guidance), along with the European ECJ's decision in *Brüstle* and that of the EPO in *WARF*, appears to lead toward a common “Western approach” to the regulation of biotechnological inventions, with specific regard to the limits of patentability.*

*Such an approach could be based, indeed, on the balance of fundamental rights and public and private interests, which are relevant on a case-by-case basis, resorting to the criteria of hierarchy and proportionality in order to regulate value-based choices and functional interactions between them.*

*Finally, the same approach would be particularly relevant to the current perspective, which is aimed at enhanced transatlantic cooperation on the matter of intellectual property, specifically within the framework of the “Transatlantic Trade and Investment Partnership”(TTIP) that is presently being negotiated.*

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### 1. THE LIMITS OF PATENTABILITY OF BIOTECHNOLOGICAL INVENTIONS: FROM *CHAKRABARTY* TO *MYRLAD*.

In the US Supreme Court leading case *Chakrabarty*<sup>1</sup>, the central issue regarding the patentability of biotechnological inventions was faced in relation to the distinction between living organisms existing in nature and those produced by human ingenuity, recognizing patentability only in the latter case.

As a consequence, the subsequent case law<sup>2</sup> on both sides of the Atlantic, as well as various international agreements and declarations and European legislation<sup>3</sup>, held that DNA in its natural state may not be patented, while DNA which has been isolated and

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<sup>1</sup> US Supreme Court, *Diamond v. Chakrabarty*, 447 U.S. (1980).

<sup>2</sup> According to a broad concept of case law which includes the decisions of patent offices, in that – especially in the biotechnology field – they are the creators of law. Concerning the relevance of the analysis of the different “formants” of legal rules, see: R. Sacco, “Legal Formants: A Dynamic Approach to Comparative Law (I-II)”, 39 *American Journal of Comparative Law* 1 et seq. and 343 et seq. (1991); P.G. Monateri, “Methods in Comparative Law: An Intellectual Overview”, in: *Id.* (ed.), “Methods of Comparative Law” 7 et seq. (Edward Elgar, Cheltenham 2012). Regarding the importance of the use of comparative method with respect to intellectual property as a whole, see recently: I. Calboli, “The Role of Comparative Legal Analysis in Intellectual Property Law: From Good to Great?”, in: G.B. Dinwoodie (ed.), “Methods and Perspectives in Intellectual Property” 3 et seq. (Edward Elgar, Cheltenham 2014).

<sup>3</sup> In particular, the UNESCO “Universal Declaration on the Human Genome and Human Rights” of 1997 prohibited profiting from the human genome in its natural state, the “European Patent Convention” of 1973 stated that biological materials and processes may be patented if they are the result of an inventive step, and directive no. 98/44/EC provided that natural plant varieties, animals and processes may not be patented, while biological material which has been isolated from nature and purified may be.

purified or significantly modified may be patented, given that it is the result of human ingenuity<sup>4</sup>.

Thus, the fundamental question still asked today is in relation to the criteria on the basis of which the subject of protection may consist in a product of human ingenuity, and not instead in a product of nature<sup>5</sup>.

In this regard, it was held that DNA produced in a laboratory is *not* structurally or functionally identical to that existing in nature. According to this position, during the process of isolation and purification of natural DNA, organic mutations would take place, such that would make it differ from its natural form. Researchers, further, may introduce specific mutations, for example by removing or adding DNA sequences<sup>6</sup>. What is more, even where researchers do not make changes to isolated and purified DNA, it would not be, in its purified form, identical to natural DNA, given that in nature it exists in an impure form.

On the basis of such an assumption, according to which isolated and purified DNA constitutes a patentable invention while that occurring in nature does not, then, it shall be guaranteed that exclusive patent right claims cannot exist for DNA existing in nature, so that anyone can study it. Therefore, a patent concerning DNA shall be interpreted to guarantee the inventor exclusive rights for its isolated and purified form, but no right over the natural form<sup>7</sup>.

This reconstruction was recently brought under discussion, within the US system itself<sup>8</sup>, by recent Supreme Court interventions regarding the *Mayo* and *Myriad* cases, in

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<sup>4</sup> See D.B. Resnik, "DNA Patents and Scientific Discovery and Innovation: Assessing Benefits and Risks", 7 *Science and Engineering Ethics* 29 et seq. (2001); M. Sagoff, "DNA Patents: Making Ends Meet", in: A.R. Chapman (ed.), *Perspectives on Gene Patenting. Religion, Science, and Industry in Dialogue*, 245 et seq. (American Association for the Advancement of Science, Washington, DC 1999); J.J. Doll, "The Patenting of DNA", 280 *Science* 689 et seq. (1998).

<sup>5</sup> In this sense, see D.B. Resnik, "Owning the Genome. A Moral Analysis of DNA Patenting" 83 (State University of New York Press, New York 2004).

<sup>6</sup> In practice, on one hand, to produce cDNA sequences which do not codify for protein are removed; on the other hand, researchers can add sequences of nucleotides to the DNA in order to induce modifications in the proteins produced.

<sup>7</sup> In this regard, see *again* D.B. Resnik, "Owning the Genome. A Moral Analysis of DNA Patenting", supra note 5, at 89.

<sup>8</sup> Contrarily, in Europe "it has generally been the case that if the methods used to isolate a DNA sequence are routine and the starting materials are available, there will be no inventive step": S.A. Jameson, "A Comparison of the Patentability and Patent Scope of Biotechnological Inventions in the United States and European Union", 35 *AIPLA Quarterly Journal* 193 et seq., at 222 et seq. (2007). This, further, is with the possibility of acknowledging the patentability should isolation be particularly difficult; see: A. McCoy, "Biotechnology and Embryonic Stem Cells: A Comparative

March 2012 and in June 2013. In the ruling of the first case<sup>9</sup>, a patent concerning a method to optimize the therapeutic efficacy of a medicine for the treatment of a gastrointestinal illness was declared invalid, holding that the claims in effect concerned the “laws of nature” underlying the method itself, in particular regarding a “*well-understood, routine, conventional activity previously engaged in by scientists in the field*”. This mutation of the approach with respect to the previous one on the matter appeared immediately likely to give rise to significant implications for the patentability, not only of isolated genes, but more generally of purified natural products and other innovations based on biological matter existing in nature.

As a consequence, the Supreme Court itself intervened a few days later on the *Myriad* controversy – concerning genes used for tests related to the inheritability of breast and ovarian cancer – through the granting of a *certiorari* and by referring the case to the Federal Circuit, so that it might reconsider its decision in light of the aforementioned *Mayo* ruling. In fact, as was shown also later in an *amicus brief* filed by the Department of Justice in June 2012<sup>10</sup>, the *Mayo* sentence seemed to provide important indications with respect to the issue of whether the difference between isolated and natural DNA is significant enough to make the first considerably different from the second, for the purposes of 35 U.S.C. § 101.

According to the criteria outlined in *Mayo*, in the *Myriad* case the Federal Circuit could have held that the information codified in DNA was a “law of nature”, that DNA was a “product of nature”, and that the isolation of DNA consisted in a process which was already well known and predictable at the moment of the application; and thus, isolated DNA was not patentable, given that the claims would have concerned, in effect, a “law of nature” and a “product of nature”. On the contrary, in August 2012, the Federal Circuit Court of Appeals confirmed the validity of *Myriad*’s patents on “isolated” genes related to breast and ovarian cancer<sup>11</sup>.

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Analysis of the Laws and Policies of the United States and Other Nations”, 8 Loyola Law and Technology Annual 63 et seq., at 80 (2009).

<sup>9</sup> US Supreme Court, *Mayo Collaborative Services, DBA Mayo Medical Laboratories, et al. v. Prometheus Laboratories, Inc.*, 566 U.S. (2012).

<sup>10</sup> “Brief for the United States as *amicus curiae* in support of neither party”, No. 2010-1406, June 15, 2012.

<sup>11</sup> More specifically, the Federal Circuit upheld *Myriad*’s composition claims to isolated DNA (reversing the District court), invalidated *Myriad*’s method claims for comparing or analyzing gene sequences (affirming the District court), and upheld *Myriad*’s method claims for screening potential cancer therapeutics (reversing the District court); see M. Textor, “Gene Patents at Home

Thus, in June 2013 the Supreme Court confirmed that Myriad's DNA claim falls within the law of nature exception, and so is not patentable<sup>12</sup>. According to the Court's decision, in fact, Myriad did not create or alter either the genetic information encoded in the BCRA1 and BCRA2 genes or the genetic structure of the DNA. It found important and useful genes<sup>13</sup>, but innovative or brilliant discovery alone does not satisfy the U.S.C. § 101 requirement.

However, the Court specified that the decision does not include, on one hand, cDNA, which is not a "product of nature." Thus, it is eligible for a patent under § 101, as its creation results in a not naturally occurring exon-only molecule<sup>14</sup>. On the other hand, the decision itself does not cover method claims, patents on new applications of knowledge about the BRCA1 and BRCA2 genes, or the patentability of DNA in which the order of the naturally occurring nucleotides has been altered<sup>15</sup>.

Therefore, every patent drafted similarly to Myriad's broadest claim – an isolated DNA code for a specific protein – is now invalid. Vice versa, claims related to cDNA versions of genes continue to pass the threshold test, though they are still subject to scrutiny under all the other patentability requirements<sup>16</sup>.

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and Abroad: Should the WTO Take Action in Light of Myriad?" 9 (available at <http://ssrn.com/abstract=2282676>, May 2013).

<sup>12</sup> In this sense, the Court recalled the wording used lastly in Mayo decision, according to which: "laws of nature, natural phenomena, and abstract ideas"... "are basic tools of scientific and technological work" that lie beyond the domain of patent protection. As the Court had held there, in fact, without this exception, there would be considerable danger that the grant of patents would "tie up" the use of such tools and thereby "inhibit future innovation premised upon them"; this consequence, evidently, would be at odds with the very point of patents, which as known exist to promote creation. In this respect, it is worth noting how a recent study affirmed that sequence patents would already cover the entire human genome; see J. Rosenfeld & C.E. Mason, "Pervasive sequence patents cover the entire human genome", 5 *Genome Medicine* 27 et seq. (2013).

<sup>13</sup> In fact, Myriad's principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes within chromosomes 17 and 13.

<sup>14</sup> This distinction has its roots mainly in the decision of the case *Amgen v. Chugai* (927 F.2d 1200, 18 USPQ 2d 1016, 1991), where the Federal Circuit focused the subject matter of the claim on a purified and isolated DNA sequence encoding human erythropoietin, interpreting the term "purified" as meaning essentially only the coding regions, that is, only the novel purified and isolated sequence which coded for EPO (see, also for the other relevant precedents: M. Textor, "Gene Patents at Home and Abroad: Should the WTO Take Action in Light of Myriad?", supra note 11, at p. 23-26; D.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 *New York University Law Review* 1623 et seq., 2001).

<sup>15</sup> US Supreme Court, *Association for Molecular Pathology et al. v. Myriad Genetics Inc. et al.*, 569 U.S. (2013).

<sup>16</sup> As far as concerns Myriad, in particular, about three-quarters of its BRCA-related patents haven't been invalidated, including claims to cDNA and some of its methods. Moreover, the

In March 2014, then, the USPTO issued a memorandum titled “Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products”<sup>17</sup>. The Guidance implements a new procedure to address changes in the law relating to subject matter eligibility under 35 U.S.C. § 101 in view of the above-mentioned *Myriad* and *Mayo* decisions<sup>18</sup>.

## II. THE AMERICAN “TECHNICAL” APPROACH

Thus, in the light of the above mentioned developments in case law, a particularly interesting profile for the purposes of policy regarding biotechnological inventions<sup>19</sup>

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invalidated patents would have begun to expire in the next year. Last but not least, Myriad’s most valuable asset may be the proprietary database it has built up through its testing monopoly: this database consists of test results, i.e. DNA sequences, and associated health outcomes, and gives Myriad a relevant advantage in interpreting BRCA gene mutations, especially the lesser-known one (see: J. Conley, “Myriad, Finally: Supreme Court Surprises by not Surprising”, 2013 Genomics Law Report 1, available for consultation at <http://www.genomicslawreport.com/index.php/2013/06/18/myriad-finally-supreme-court-surprises-by-not-surprising>, 18 June 2013; and, also for an interesting analysis of the previous European decisions and related developments concerning Myriad’s patents: G. Matthijs, I. Huys, G. Van Overwalle & D. Stoppa-Lyonnet, “The European BRCA patent oppositions and appeals: coloring inside the lines”, 31 Nature Biotechnology 704 et seq., especially 709, 2013). In this respect, then, a new episode of the “Myriad saga” before antitrust authorities could be projected (regarding the profiles involved in the relationship between access to databases and antitrust, and the relative case law, see among others: D. Lim Tze Wei, “Regulating Access to Databases Through Antitrust Law: A Missing Perspective in the Database Debate”, 2006 Stanford Technology Law Review 7 et seq.; E. Derclaye, “The IMS Health decision: a triple victory”, 27 World Competition 397 et seq., 2004; D.M. Gitter, “Strong Medicine for Competition Ills: The Judgment of the European Court of Justice in the IMS Health Action and Its Implications for Microsoft Corporation”, 15 Duke Journal of Comparative & International Law 153 et seq., 2004).

<sup>17</sup> USPTO, “2014 Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products (March 2014)”, available at <http://www.uspto.gov/patents/law/exam/examguide.jsp>.

<sup>18</sup> Regarding the industry’s criticism and the ongoing debate on the Guidance, see: “Life sciences special”, 240 Managing Intellectual Property 30 et seq. (June 2014).

<sup>19</sup> Patent protection for biotechnological inventions, as known, is justified in order to guarantee adequate incentive and return on the huge investments which are necessary to do research in the field. For an overview of the economic studies in this regard, and the related acknowledgment of the patent’s incentive function, at least in the biotechnological, pharmaceutical and chemical sectors (as characterized by high risk research projects), see especially: B. Hall & D. Harhoff, “Recent Research on the Economics of Patents”, 4 Annual Review of Economics 541 et seq. (2012); E. Mansfield, “Patents and Innovation: An Empirical Study”, 32 Management Science 173 et seq. (1986). In fact, the subject matter protected by patents is basically information, as such not rivaled or easy to copy: so, without a system of protection which enables innovators to charge a price for innovative products above the marginal cost, they would not be effectively

concerns the issues – inherent to the collective well being, as well as of useful pursuit for competition – raised by them in regards to the profile of access to findings by third parties, subsequent innovators or patients, consumers, et cetera<sup>20</sup>.

In this perspective, it has been already widely highlighted how in the biotechnology sector, characterized by the cumulative effect of the innovative process, often based on the use of well known techniques or materials, there are, on one hand, the problem of anticommons<sup>21</sup>, on the other hand, that of the high transaction costs needed for negotiations with multiple patent owners for genes or other basic elements which are needed for the development of a biotechnological invention (so called patent thicket)<sup>22</sup>.

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motivated to either bear the research and development expenses and to innovate or disclose innovation, to the detriment of the public welfare; *see* T. Eger, P. Ebermann & P. Ramanujam, “Incremental Innovation and Patent Protection for Pharmaceutical Products in India”, in: P.G. Babu, T. Eger, A.V. Raja, H.B. Schäfer & T.S. Somashekar, *Economic Analysis of Law in India*, 128 et seq., especially 146 (Oxford University Press, New Delhi 2010). However, as known, patent protection also gives rise to relevant social costs, which are due basically to: a) the static welfare losses due to the above mentioned mark up on the marginal cost of producing the result of the invention; b) the possible waste of resources originating from the patent race and related litigation; c) the increased cost of secondary innovation, that is especially relevant in the biotechnology framework, where innovative activity is to a large extent a cumulative process, with present innovations which are mostly incremental, depending on past innovations; *see* V. Denicolò, “Do patents over-compensate innovators?”, 22 *Economic Policy* 679 et seq. (2007); S. Scotchmer, “Innovation and Incentives” *passim* (MIT Press, Cambridge - USA 2004); for an heterodox point of view, *see also* M. Boldrin & D. Levine, “The case against intellectual property”, 92 *American Economic Review*, 209 et seq. (2002).

<sup>20</sup> In this regard, *see especially* G. Ghidini, “Innovation, Competition and Consumer Welfare in Intellectual Property Law”, *passim* (Edward Elgar, Cheltenham - Northampton 2010). In healthcare, patients are not customers who can choose whether or not to be consumers; patients do not have the same freedom of choice as costumers do when choosing to purchase any other good, and some people in society need more healthcare than others (*see*, among others, N. Hawkins, “An Exception to Infringement for Genetic Testing - Addressing Patient Access and Divergence Between Law and Practice”, 43 *IIC* 641 et seq. (2012).

<sup>21</sup> Term used, as known, to highlight that the granting of exclusive rights for basic research risks hindering subsequent research, so called “downstream”. The main instrument through which an anticommon may arise is constituted by the Reach Through License Agreement (RTLA), clauses which are inserted into the licensing contracts through which the owners of patents for research tools are ensured rights for subsequent innovation, rights which may consist in royalties on the profits of the final product, a license on the product or in an option to buy such a license. On the theme of the “tragedy of anticommons,” and the “gridlock economy” which arises from it, *see especially* A. Musso, “Grounds of protection: how far does the incentive paradigm carry?”, in: A. Ohly (ed.), *Common principles of European intellectual property law* 33 et seq. (Mohr Siebeck, Tübingen 2012); M. Heller, “The Gridlock Economy. How Too Much Ownership Wrecks Markets, Stops Innovation, and Costs Lives” *passim* (Basic Books, New York 2008), and *Id.*, “The Tragedy of Anticommons”, 111 *Harvard Law Review* 621 et seq. (1998); M. Heller & R.S. Eisenberg, “Can Patent Deter Innovation? The Anticommons in Biomedical Research”, 280 *Science* 698 et seq. (1998).

<sup>22</sup> The concept indicates, as known, “an overlapping set of patent rights’ which require innovators to reach licensing deals for multiple patents from multiple sources”, with the possible result of obstructing entry to some markets and so impeding innovation, with effects which

In this framework, according to the traditional “technical” approach of the American model, the criteria for identification of the patentability requirements of non-obviousness and industriality are particularly significant.

The former, according to the restricted reading provided by the US Court of Appeals for the Federal Circuit in the decision *In re Kubin*<sup>23</sup>, must be held to be excluded wherever there is a wide knowledge about the protein a target gene encodes plus general knowledge of the techniques for isolating and sequencing the same gene.

The requirement of industriality needs the identification of specific methods of use for the finding, and so allows the limitation of the patent exclusive only for a specific application of the invention<sup>24</sup>.

Moreover, as far as the extension of patent protection for biotechnological inventions is concerned, according to the traditional approach of the American model, the distinction between patents for inventions of products and processes is still fundamental.

In principle, as is well known, the patent for a product is held to provide protection for the product regardless of how it is obtained and for all its possible uses.

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damage not only the producers of innovation but also the licensees of inventions and the consumers of the final product; *see* I. Hargreaves, “Digital Opportunity. A review of Intellectual Property and Growth. An independent report by Professor Ian Hargreaves”, 18 and 56 et seq. (available at <http://www.ipo.gov.uk/ipreview.htm>, 2011), who recalls C. Shapiro, “Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting”, in: A.B. Jaffe, J. Lerner & S. Stern (eds.), *Innovation Policy and the Economy* (Volume 1) 119 et seq. (MIT Press, Cambridge - USA 2001). On the theme, *see also* V. Falce, “Innovation in the new technological industries: looking for a consistent cooperative model”, in: E. Arezzo & G. Ghidini (eds.), *Biotechnology and Software Patent Law: A Comparative Review of New Developments*, 40 et seq., especially 42 et seq. (Edward Elgar, Cheltenham - Northampton 2011); F.M. Scherer, “The Economics of Human Gene Patents”, 77 *Academic Medicine* 1348 et seq. (2002); R.S. Eisenberg, “Bargaining over the Transfer of Proprietary Research Tools: Is This Market Failing or Emerging?”, in: R. Dreyfuss, H. First, & D. Zimmerman (eds.), *Expanding the Bounds of Intellectual Property: Innovation Policy for the Knowledge Society* 209 et seq. (Oxford University Press, New York 2001); with respect to the implications in terms of an antitrust, *see also* M. Ganslandt, “Intellectual Property Rights and Competition Policy”, in: K.E. Maskus (ed.), *Intellectual Property, Growth and Trade* (Frontiers of Economics and Globalization, Volume 2) 233 et seq. (Emerald Group, Bradford 2009); D.L. Rubinfeld & R. Maness, “The Strategic Use of Patents: Implications for Antitrust”, in F. Lévêque & H.A. Shelanski, *Antitrust, Patents and Copyright: EU and US Perspectives* 85 et seq. (Edward Elgar, Cheltenham - Northampton 2005).

<sup>23</sup> 561 F.3d 1351 (Fed. Cir. 2009).

<sup>24</sup> Therefore, for instance, it is held that under the Kubin standard many of the single gene patents that Myriad has foreclosed would have gone down on obviousness grounds anyway. What is more, such a standard is likely having a similar effect on cDNA patents as well, undercutting the significance of the Court allowing them to survive as patentable subject matter (*see* J. Conley, “Myriad, Finally: Supreme Court Surprises by not Surprising”, *supra* note 16, at 2).

With regard to biotechnological inventions, however, under the first profile, considering their peculiarity of being living and self replicating matter, the opinion of those who state that the patent grants exclusive production rights for the finding only when it is produced through the process described in the patent application seems convincing<sup>25</sup>.

Under the second profile, then, in the field of genetics the inventions are linked to the identification of the function of the gene, which is usually not the only function it may carry out: in this context, extending protection to all possible functions of the gene appears excessive, given that the contribution to scientific and social progress by the inventor concerns solely one specific function of the identified gene<sup>26</sup>; in this perspective, subsequent inventions regarding the same gene may be considered dependent on the first only when they are to some degree logically connected to its technical teaching.

In the patent for a process, the exclusive covers, in fact, the process, even if it does not lead directly to the product but satisfies in any case industrial interests, or, should it lead to the creation of a product, with the possibility of extension also to the product created through that process, where it is the direct and necessary result of it.

The extension of protection for the process to the product, within the limits indicated, allows third parties to be granted patent protection for an identical product as long as it was obtained through a different process, or with instruments coming from the first process unless the product is directly derived from it (that is a so called product-by-process claim).

These approaches in regards to biotechnological inventions of products or processes are based, evidently, on the desire to avoid that subsequent innovation be needlessly hindering.

As a consequence, the invention which improves the execution of the same type of use with a solution which perfects the previous invention shall be dependent on it, while the invention which – though it uses elements which are the subject of other exclusive rights – combines them in such a manner as to give rise to a new useful result which could not be obtained through the first, shall not be dependent on it. Similarly, the

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<sup>25</sup> In this sense, *see* V. Di Cataldo, “Fra tutela assoluta del prodotto brevettato e limitazione ai procedimenti descritti ed agli usi rivendicati”, 2004 *Rivista di diritto industriale* 111 et seq., at 117.

<sup>26</sup> *See* D.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”, *supra* note 14, at 1670 et seq.

invention which transfers previously existing ideas to a different and distant sector of use, producing a new useful result, shall not be dependent<sup>27</sup>.

Furthermore, another technical approach which appears useful regarding the limits of patentability of biotechnological inventions could be defined as being “technology specific”.

It is based on: a) the accurate definition of the context of the extension for innovations “upstream”; b) the cost-benefit analysis, with specific regard to the various circumstances in which they may arise – for instance, therapeutic proteins, diagnostic methods and research tools, et cetera – with different evaluations depending on their particular respective characteristics.

So, the rules on the matter should be interpreted, or detailed, in favor of or against the patentability of the findings, according to the specific category of scientific research in question<sup>28</sup>.

In the United States, however, these approaches in practice face relevant limitations, because of some peculiar aspects of patent law.

In particular, among such peculiarities, it is necessary to remember those regarding: a) the narrowness of exceptions for experimental use<sup>29</sup>; b) the failure to use the tool of the compulsory license (except for the hypothesis, till now only “on the books”, of the so called “march-in right”)<sup>30</sup>; c) the broadness with which patent protection has traditionally been granted, independently from the specific indication of the function

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<sup>27</sup> See again G. Ghidini, “Innovation, Competition and Consumer Welfare in Intellectual Property Law”, supra note 18, 69 et seq. Thus, the patent of a certain segment of DNA aimed at producing a protein covers its commercial uses which are aimed at the production of the protein, but if it later emerges that the protein can carry out other functions, or that its functions may increase when it is associated with other structures, the subsequent inventor can patent the different use or the different characteristics of the protein without the first being able to oppose it. Still, the owner of the patent on the protein obtained through a certain process may not claim an exclusive right for the production of the protein through different methods, which should be the subject of an independent patent.

<sup>28</sup> In this sense, see A. Lauer, “The Disparate Effects of Gene Patents on Different Categories of Scientific Research”, 25 Harvard Journal of Law & Technology 179 et seq., especially 183 et seq. (2011); C.J. Shiu, “Of Mice and Men: Why an Anticommons Has Not Emerged in the Biotechnological Realm”, 17 Texas Intellectual Property Law Journal 413 et seq., at 442 et seq. (2009).

<sup>29</sup> Now strictly limited to use “for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry”; see especially Federal Circuit, Roche Products, Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858, 1984, and Madey v. Duke University, 307 F.3d 1351, 2002.

<sup>30</sup> Which, according to the “Bayh-Dole Act”, would permit the federal government to require a federally-funded patentee to grant licenses under his patent to third-party applicants where the patent holder has failed to achieve sufficient practical application of the invention, or to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee or their licensees (35 U.S.C. § 203(1)(a)-(b), 1994).

concretely carried out by the molecule of DNA in the patent application (a principle which, rather, is specifically provided for in more recent European legislation on the subject, such as in German and Italian legislation)<sup>31</sup>.

### III. THE EUROPEAN (BUT WITH CORRESPONDING DEVELOPMENTS IN RECENT US CASE LAW) “VALUE-BASED” APPROACH

In order to deal with the multiple and constantly changing issues posed by biotechnological inventions, in the European model the American technical approach to the regulation of related patents appears to be complementary to one which can be defined as “value-based”, inspired to balance the interests at play.

The European approach is based, in particular, not only on tools – still of a technical nature but used, as noted, in a different perspective – such as those just recalled of the greater wideness of the exception for experimental use<sup>32</sup>, of the use of the compulsory license<sup>33</sup>, and of the limitation of the protection to the function specifically

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<sup>31</sup> According to the US “Utility Examination Guidelines”, in fact, “(a) patent on a composition gives exclusive rights to the composition for a limited time, even if the inventor disclosed only a single use for the composition” (“Guidelines”, January 2001, 66 Fed. Reg. 1092, 1095). However, US law allows an inventor who develops a new use for a patented compound to get a process patent for that new use, notwithstanding that the DNA is itself patented; *see* M. Textor, “Gene Patents at Home and Abroad: Should the WTO Take Action in Light of Myriad?”, *supra* note 11, at 28-29; D.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”, *supra* note 14, at 1666. Regarding these issues, among others, *see also* W. Lesser, “Myriad & Prometheus, Laws & Products of Nature: Are the Courts Considering an Economic Non-Statutory Subject Matter Exclusion?”, 53 IDEA - The Intellectual Property Law Review 173 et seq. (2013); H.C. Wegner, “Mayo v. Prometheus Patent-Eligibility: Whither Myriad and Gsk v. Classen” *passim* (available at [www.grayonclaims.com/hal](http://www.grayonclaims.com/hal), 2012); C.A. Fowler, “Ending Genetic Monopolies: How the TRIPS Agreement’s Failure to Exclude Gene Patents Thwarts Innovation and Hurts Consumers Worldwide”, 25 American University International Law Review 1073 et seq., especially 1091 and 1097 et seq. (2010).

<sup>32</sup> *See* S. Aymé, G. Matthijs e S. Soini, “Patenting and licensing in genetic testing – Recommendations of the European Society of Human Genetics”, in 16 European Journal of Human Genetics, 2008, p. S3 et seq., especially p. S7, and *Id.*, “Patenting and licensing in genetic testing: ethical, legal and social issues”, *ibidem*, p. S10 et seq., especially p. S27.

<sup>33</sup> *See again* S. Aymé, G. Matthijs e S. Soini, “Patenting and licensing in genetic testing: ethical, legal and social issues”, *supra* note 30, p. S27 et seq.

indicated, but also – especially – on the above mentioned balance of interests in light of the relevant fundamental rights on the matter<sup>34</sup>.

In this sense, the relation between intellectual property and the system of fundamental rights – in the current framework of technological and economic developments – is more and more evident<sup>35</sup>. There are always more frequently, in fact, cases in which the courts are called to evaluate the legitimacy of the granting or the use of intellectual property rights in regards to a fundamental principle of constitutional status considered to be antagonistic to them, such as the right to health, freedom of scientific research, human dignity, et cetera<sup>36</sup>.

In the biotechnology field, such a “dialectic of goals” has been crucial, for instance, in the EU Court of Justice rulings on the validity of directive no. 98/44/EC in light of the principles of human dignity and non-patentability of discoveries<sup>37</sup>, and in the *Brüstle* case regarding the compatibility with the principles of human dignity and integrity of processes which allowed for the obtainment of neural progenitor cells from human embryonic stem cells (given that they implied the destruction of the embryo)<sup>38</sup>.

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<sup>34</sup> See D. Wielsch, “Zugangsregeln. Die Rechtsverfassung der Wissensteilung”, 8 and 66 et seq. (Mohr Siebeck, Tübingen 2008); C. Geiger, “‘Constitutionalising’ Intellectual Property Law? The Influence of Fundamental Rights on Intellectual Property in the European Union”, 37 IIC 371 et seq. (2006).

<sup>35</sup> See especially C. Geiger, “Fundamental Rights as Common Principles of European (and International) Intellectual Property Law”, in: A. Ohly (ed.), *Common principles of European intellectual property law*, supra note 19, at 223 et seq.; L.R. Helfer & G.W. Austin, “Intellectual Property: Mapping the Global Interface” 1 et seq. (Cambridge University Press, Cambridge 2011); W. Grosheide (ed.), “Intellectual Property and Human Rights: A Paradox” *passim* (Edward Elgar, Cheltenham - Northampton 2010); P.L.C. Torremans, “Intellectual Property and Human Rights” *passim* (Kluwer Law International, Alphen aan den Rijn 2008); P. Yu, “Reconceptualizing Intellectual Property Interests in a Human Rights Framework”, 40 UC Davis Law Review 1039 et seq. (2007); L.R. Helfer, “Toward a Human Rights Framework for Intellectual Property”, *ibid.* 971 et seq., and *Id.*, “Human Rights and Intellectual Property: Conflict or Coexistence?”, 5 Minnesota Intellectual Property Review 47 et seq. (2003); A.R. Chapman, “A Human Rights Perspective on Intellectual Property, Scientific Progress, and Access to the Benefits of Science”, in: WIPO, *Intellectual Property and Human Rights - WIPO Publication No. 762(E) passim* (WIPO, Geneva 1999).

<sup>36</sup> In this regard, see C. Geiger, “‘Constitutionalising’ Intellectual Property Law? The Influence of Fundamental Rights on Intellectual Property in the European Union”, supra note 32, at 371 et seq.; T. Braegelmann, “The Constitutional Scope and Limits to Copyright Law in the United States, in Comparison with the Scope and Limits Imposed by Constitutional and European Law on Copyright Law in Germany”, 27 *Cardozo Arts & Entertainment Law Journal* 99 et seq. (2009).

<sup>37</sup> EU Court of Justice, *The Kingdom of the Netherlands v. European Parliament and Council*, case C-377/98 (2001) ECR I-07079.

<sup>38</sup> EU Court of Justice, *Oliver Brüstle v. Greenpeace eV*, 18 October 2011, case C-34/10. For comments on the decision and on the relations between biotechnological patents and bioethics, see M.I. Schuster, “The Court of Justice of the European Union's Ruling on the Patentability of

Similarly, the EPO Enlarged Board of Appeal in the *WARF* case, regarding a patent application presented by the Wisconsin Alumni Research Foundation on a method for obtaining cultures of embryonic stem cells from embryos of primates (man included), and on the cultures themselves, rejected the application because the invention could be developed only through the destruction of human embryos<sup>39</sup>.

In US case law, then, similar issues of balance of interests at play have been relevant in the recent Supreme Court decisions in the *Myriad* and *Mayo* cases, regarding the relationship between patents for genes, freedom of research and the right to health<sup>40</sup>. Thus, such Supreme Court decisions seem likely to produce significant consequences toward the introduction of a systematic and accurate evaluation of the above mentioned balance in the scrutiny of the patentability of biotechnology innovations<sup>41</sup>.

#### IV. CONCLUSION.

Intellectual property law, and especially biotechnological patent law, often involves and/or faces off with the exercising of fundamental rights.

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Human Embryonic Stem-Cell-Related Inventions (Case C-34/10)", 43 IIC 626 et seq. (2012); S. Burke, "Interpretive Clarification of the Concept of "Human Embryo" in the Context of the Biotechnology Directive and the Implications for Patentability: *Brüstle v Greenpeace eV* (C-34/10)", 34 European Intellectual Property Review 346 et seq. (2012); A. Stazi, "Innovazioni biotecnologiche e brevettabilità del vivente. Questioni giuridiche e profili bioetici nei modelli statunitense ed europeo" 230 et seq. (Giappichelli, Turin 2012, forthcoming in English).

<sup>39</sup> EPO Enlarged Board of Appeal, *Use of embryos/WARF*, 25 novembre 2008, G 2/06. The "whole content approach" adopted by the EPO, then, has been restated by the European Parliament in the "Resolution of 10 May 2012 on the patenting of essential biological processes (2012/2623(RSP)", which at point 6 "(w)elcomes the recent decision of the European Patent Office in the *WARF* case and of the European Court of Justice in the *Brüstle* case, as they appropriately interpret Directive 98/44/EC and give important indications on the so-called whole content approach", and "calls on the European Commission to draw the appropriate consequences from these decisions also in other relevant policy areas in order to bring EU policy in line with these decisions".

<sup>40</sup> See J. Rosenfeld & C.E. Mason, "Pervasive sequence patents cover the entire human genome", 5 *Genome Medicine* 27 et seq. (2013); T. Minssen & D. Nilsson, "Standing on shaky ground: US patent-eligibility of isolated DNA and genetic diagnostics after *AMP v USPTO* - Part I", 1 *Queen Mary Journal of Intellectual Property* 223 et seq. (2011), "Part II", 2 *Queen Mary Journal of Intellectual Property* 136 et seq. (2012), "Part III", 2 *Queen Mary Journal of Intellectual Property* 225 et seq. (2012), and "Part IV", 3 *Queen Mary Journal of Intellectual Property* 118 et seq. (2013); A. Lauer, "The Disparate Effects of Gene Patents on Different Categories of Scientific Research", 25 *Harvard Journal of Law & Technology* 179 et seq. (2011).

<sup>41</sup> More specifically, currently potential competitors results legitimate to enter the market affording less risks of being rightfully sued for infringement, patients seem allowed to obtain the availability of a second-opinion testing, and basic researchers are free to do research with isolated genomic DNA (while as said in the US there is no effective research exemption to patent infringement, even in the nonprofit sector); see J. Conley, "Myriad, Finally: Supreme Court Surprises by not Surprising", supra note 16, at 1.

The issues analyzed and the considerations proposed highlight how the regulation of biotechnological inventions should guarantee a fair balance between protection of investment and access to information which is essential for research and innovation. In this framework, the recent US Supreme Court decision in *Myriad* and *Mayo* (and the subsequent USPTO Patent Eligibility Guidance), along with the European ECJ's decision in *Bristle* and that of the EPO in *WARF*, appears to lead toward a common “Western approach” to the regulation of biotechnological inventions, with specific regard to the limits of patentability.

Such an approach could be based, indeed, on the balance of fundamental rights and public and private interests, which are relevant on a case-by-case basis, resorting to the criteria of hierarchy and proportionality in order to regulate value-based choices and functional interactions between them<sup>42</sup>.

Finally, the same approach would be particularly relevant to the current perspective, which is aimed at enhanced transatlantic cooperation on the matter of intellectual property, specifically within the framework of the “Transatlantic Trade and Investment Partnership”(TTIP) that is presently being negotiated.

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<sup>42</sup> In this perspective, *see amplius*: G. Ghidini, A. Stazi, “Freedom to Conduct a Business, Competition and IP”, in: C. Geiger (ed.), “Research Handbook on Human Rights and Intellectual Property” (Edward Elgar, Cheltenham forthcoming); G. Ghidini, “Exclusion and access in copyright law: the unbalanced features of the European Directive ‘on information society’”, 2013 *Rivista di diritto industriale* 5 et seq.; A. Stazi, M. Marzetti, “Synergetic Interaction Between Intellectual Property and Consumer Protection: A Pragmatic Proposal to Rebalance Incentives and Access”, in: D. Beldiman (ed.), “Access to Information and Knowledge: 21st Century Challenges in Intellectual Property and Knowledge Governance” 189 et seq. (Edward Elgar, Cheltenham 2013).