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Myriad Genetics and the BRCA Patents in Europe: The Implications of the U.S. Supreme Court Decision

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Myriad Genetics and the BRCA Patents in Europe: The Implications of the U.S. Supreme Court Decision

Jessica C. Lai*

Biotech patents are perhaps the most controversial form of property, and the U.S. Supreme Court decision in 2013 in Association for Medical Pathology v. Myriad Genetics, which held that simply isolated DNA constitutes natural products, was applauded by many, particularly civil society groups and medical practitioners. From a legal perspective, the decision itself is brief and leaves much to be desired. Nevertheless, it is interesting to question what might be its potential impact on European research, the biotech industry, and patent law. Given the fact that the Biotech Directive was in large part passed in order to keep the European Union competitive with the United States, it is possible that the European Union has gained an advantage over the United States in terms of research and local industry. However, this is far from clear. At the same time, the Myriad decision may relight the fire surrounding the Biotech Directive, which was both debated and reluctantly implemented by the Netherlands, Germany, and France. This Article looks at patent law in Europe as it pertains to biotechnology before addressing what the possible implications may be of the U.S. Supreme Court Myriad decision on research, the biotech industry, and the policy debate in Europe.

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INTRODUCTION

On June 13, 2013, the U.S. Supreme Court assessed the patentability of gene-related technologies, particularly with respect to the two genes associated with breast and ovarian cancer (BRCA1 and BRCA2). The Court handed down *Association for Medical Pathology v. Myriad Genetics*, declaring that simply isolated genes and genetic sequences (genomic DNA or gDNA) fall within the “natural product” doctrine and so are not capable of being “inventions” for the purposes of patent law—reversing part of the majority opinion of the Court of Appeals for the Federal Circuit.¹ At the same time, the Court ruled that complementary DNA (cDNA)—reverse transcribed mRNA—is not naturally occurring and so capable of being an “invention,” upholding this part of the Federal Circuit’s decision.²

The situation in Europe (as a culmination of European Union (EU) law and the European Patent Convention (EPC))³ is vastly different, making a comparison between the approach taken in the United States and that used in Europe an interesting exercise. The *Myriad* decision highlights that attempts to define concepts like “natural laws” and “natural products” in the United States are rife with difficulties and potentially ultimately futile.⁴ It is difficult not to sink into a philosophical debate about what is “natural.” In contrast, decisions handed down by the European Patent Office (EPO) regarding BRCA1 and BRCA2—while socially controversial—were doctrinally uninteresting. Before the U.S. Supreme Court’s *Myriad* decision, patents relating to BRCA1 and BRCA2 had been strongly opposed through the EPO for over ten years, resulting in Myriad Genetics having only a handful of very narrow patents in Europe.⁵ However, these decisions were

1. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2111 (2013).

2. *Id.*

3. Convention on the Grant of European Patents, Oct. 5, 1973, 1065 U.N.T.S. 254 [hereinafter European Patent Convention].

4. Dan L. Burk, *Edifying Thoughts of a Patent Watcher: The Nature of DNA*, 60 UCLA L. REV. DISCOURSE 92, 97, 101 (2013).

5. See discussion *infra* Part II.

matters of basic legal interpretation, as even before the oppositions began, Europe had already debated the patentability of biotechnologies and codified the results at the international level.⁶ The cases heard through the EPO, thus, had a very different tone. Moreover, the focus in Europe lies not in asking whether a claim is for a natural law or natural product but ultimately whether it is for a mere discovery and therefore not an “invention.” At first blush, the distinction between the two approaches may not be apparent. However, the different approaches can (at least potentially) be quite different in effect, in most part because looking at claims from the perspective of a mere discovery overcomes the need to define “natural laws” and “natural products.”

Europe is often painted as having stricter patentability standards than the United States. An interesting consequence of the *Myriad* decision is that this is clearly not the case when it comes to gene-related technologies. As discussed in depth below, the Directive on the Legal Protection of Biotechnological Inventions (hereinafter the “Biotech Directive”)⁷ and the EPC (and its Implementing Regulations and Guidelines)⁸ allow genetic sequences as patentable subject matter, so long as the industrial applicability is explicitly clear from the patent application but not necessarily in the claims themselves. In comparison, the U.S. Supreme Court has held that simply isolated genetic sequences are not patentable subject matter, regardless of their potential utility.⁹ For patentability in the United States, one would have to claim isolated genetic sequences as part of a method or process that is an invention (and not the mere application of a natural law or abstract mental process).¹⁰ The lack of harmonisation between the two biotechnology powerhouses, Europe and the United States, may prove to have unwanted effects on invention and innovation.

6. In Switzerland (which is not a part of the EU, but is a party to the EPC), whether gene-related technologies should be patentable went to referendum in 1998 (*Volksinitiative zum Schutz von Leben und Umwelt vor Genmanipulation (Gen-Schutz-Initiative) [Popular Referendum on the Protection of Life and the Environment against Gene Manipulation (Gene Protection Referendum)]*). Switzerland has direct democracy, which means that, had the referendum passed, the government would have been forced to heed it. The referendum sought to outlaw: (i) the generation, purchase, or distribution of transgenic animals; (ii) the release of genetically altered organisms into the environment; and (iii) the patenting of transgenic animals and plants, their components, and the relevant processes. The referendum was resoundingly rejected by sixty-seven percent of voters (Vote No. 440). See Gottfried Schatz, *The Swiss Vote on Gene Technology*, 281 SCIENCE 1810 (1998). Given that Switzerland was (and continues to be) a party of the EPC, which—as discussed further below—specifically states that gene-related inventions must be protected if they satisfy certain conditions, it is questionable whether Switzerland could have implemented the initiative into its national law without running afoul of the EPC.

7. Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) [hereinafter Biotech Directive].

8. European Patent Convention, *supra* note 3.

9. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2111 (2013).

10. Nevertheless, due to the biotech industry being centered in the United States and the fact that genetic sequences were per se patentable subject matter until the U.S. Supreme Court's decision in *Myriad*, the United States has more gene-related patents than most other countries. WILLIAM CORNISH ET AL., INTELLECTUAL PROPERTY: PATENTS, COPYRIGHT, TRADE MARKS AND ALLIED RIGHTS § 21-05, at 921–22 (7th ed. 2010).

This Article starts by analysing the framework for biotech inventions in Europe. It does not rehash the *Myriad* decision, which has no doubt been done aptly by other authors in this symposium issue. The discussion on the European legal framework is followed by an examination of the EPO decisions made by the Opposition Division and Board of Appeals pertaining to Myriad Genetics' BRCA1 and BRCA2 patents in the chronological order in which the decisions were made. The Article then turns to an exploration of the potential effects of the *Myriad* decision on the European context. In particular, it looks at the uncertainty raised by the decision, the possible effects on invention and innovation, and whether the decision has possibly fuelled the policy debate in Europe.

I. BIOTECHNOLOGY PATENTS IN EUROPE

A. *The Biotech Directive and EPC*

The EU has largely dealt head on with policy issues relating to biotechnology at the legislative level. After over fifteen years of discussion and debate, the Parliament passed the Biotech Directive in 1998, which specifically addresses the patentability of biotech inventions.¹¹ All EU states are also members of the European Patent Organisation and its organ, the EPO.¹² Through the administration of the EPC, its Implementing Regulations,¹³ and its detailed Guidelines,¹⁴ the EPO provides for a single grant procedure for all its member states. According to Article 2 of the EPC the EPO does not grant a unitary European or EPC patent but a European patent that has the effect of national patents in the member states selected by the applicant. Together, the Biotech Directive and the EPC—and its Implementing Regulations and Guidelines—specifically regulate whether and how gene-related inventions can be patented.

11. In 1982, the EU Commission proposed harmonising the treatment of biotechnology by patent law in order to be competitive with Japan and the United States. See *Vorschlag für eine Europäische Strategie auf dem Gebiet der Wissenschaft und der Technik: Rahmenprogramm 1984 bis 1987* [*Proposal for a European Strategy in the Field of Science and Technology: Framework Program 1984 to 1987*], KOM (82) 865 endg. This resulted in a draft Directive. *Vorschlag für eine Richtlinie des Rates über den rechtlichen Schutz biotechnologischer Erfindungen vom 2 Oktober 1988* [*Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions from 2 October 1988*], KOM (88), 496 endg, <http://aei.pitt.edu/3814>. This was rejected by the Parliament in 1995. After a lot of controversy, particularly pertaining to the patentability of biotechnology, a new draft was created by the Commission, which was accepted on July 6, 1998. Biotech Directive, *supra* note 7. Member states were to have implemented the Directive by July 20, 2000, but it took until 2005 for this to become a reality.

12. The “EU” as such is not a party to the EPO or EPC. Membership to the EPO is broader than just EU states, including Albania, Switzerland, Iceland, Liechtenstein, Monaco, Norway, Serbia, San Marino, and Turkey.

13. Implementing Regulations to the Convention on the Grant of European Patents (last amended June 2012) [hereinafter EPC Implementing Regulations].

14. European Patent Convention Guidelines for Examination in the European Patent Office (Nov. 2014) [hereinafter EPO Guidelines].

Whereas the U.S. and Canadian courts have been struggling with how to tackle biotechnology and its policy concerns in the realm of patent law, the EPC explicitly deals with certain types of biotechnology and also questions of morality. Let us take the oncomouse cases as an illustration. Section 101 of the U.S. Patent Act provides that

Whoever invents or discovers any new and useful process, machine, *manufacture, or composition of matter*, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.¹⁵

The Canadian provision for patentability is very similar.¹⁶ In the United States, the only statutory limitation to § 101 patentability is, “[n]otwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.”¹⁷ Though the oncomouse patent was never challenged in the United States,¹⁸ it was in Canada, where the Supreme Court ruled that higher life forms (including human beings) are not a “manufacture” or “composition of matter,” and therefore are not inventions.¹⁹

In comparison, Article 53(a)–(b) of the EPC specifically states that plant and animal varieties are not patentable subject matter and neither are inventions the exploitation of which would be contrary to *ordre public* or morality.²⁰ The United States has no equivalent *ordre public* or morality statutory provision.²¹ The EPC Implementing Regulations clarify that the *ordre public*/morality clause excludes from patentability “processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal and also animals resulting from such processes.”²² The approach taken by the EPO for the oncomouse patent was, thus, unsurprisingly quite different than in Canada. The EPO held that the exclusion of animal varieties was not an exclusion of animals, and the oncomouse was not an animal variety.²³ The EPO did not have to try to distinguish between lower or higher life forms, or human beings and all other life forms, as the Biotech Directive and EPC Implementing Rules clearly draw the line between human beings and everything else, stating that the human body, at the various stages of its formation and development, and its elements are not

15. 35 U.S.C. § 101 (2012) (emphasis added).

16. Patent Act, R.S.C. 1985, c. P-4, § 2 (Can.).

17. Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 33(a), 125 Stat. 284, 340. This applies for any patent application pending, filed on or after the date of enactment of the Act. It does not affect the validity of patents issued prior.

18. U.S. Patent No. 4,736,866 (filed April 12, 1988), which lapsed in 2005.

19. Harvard Coll. v. Can. Comm’r of Patents, [2002] 4 R.C.S. 45 (Can.).

20. European Patent Convention, *supra* note 3, art. 53(a)–(b).

21. As discussed in Jessica Downing, *Analyzing the Broadening Scope of Patentability in the Advancing Field of Biotechnology*, 18 J. COM. BIOTECHNOLOGY, Oct. 2012, at 27–31.

22. EPC Implementing Regulations, *supra* note 13, r. 28, implementing Article 6.2(d) of the Biotech Directive, *supra* note 7.

23. Case T 0315/03, President and Fellows of Harvard Coll. v. British Union for the Abolition of Vivisection (EPO Boards of Appeal, 2004).

patentable subject matter.²⁴ Using a utilitarian balancing approach, the oncomouse patent was held to be valid, as the potential medical benefits to humanity in cancer research outweighed the suffering of the mice.²⁵

The EPC also excludes that which is abstract or nontechnical,²⁶ specifically (but not exhaustively) delineating “discoveries, scientific theories and mathematical methods” as not “inventions.”²⁷ These terms are quite different from the terms “natural product,” “natural law,” and “abstract idea” used in the U.S. context.²⁸ Something may be simply isolated from nature, but this is not to say that it is a mere discovery. “Mathematical method” is quite specific, whereas “abstract idea” is a nebulous concept.²⁹ Perhaps most striking is the difference between “natural laws” and “scientific theories.”³⁰ This is because it is highly questionable whether we can really define what are or are not immutable “natural laws.”³¹ The examples of “natural laws” often cited by courts are Newton’s laws of motion.³² However, it has been proven that Newton’s laws only work to explain what we experience in everyday life, or “classical physics.” Newton’s laws do not work on the quantum or cosmic scale. So, we can hardly say that these “laws” were just out there waiting to be discovered or worked out. As any scientist knows, what we have are theories, often supported by empirical evidence, but nevertheless open to be disproved by opposing empirical data. Thus, the term “scientific theories” found in the EPC is far more fitting and noncontradictory.

According to the EPC, inventions must have both a concrete and technical character, dependant on the content of the claims, not the form or kind of claim.³³ Discoveries, scientific theories, and mathematical methods by themselves have no technical effect, but may be patentable subject matter if put to practical use. Finding a new property of a known material or article or a previously unrecognised substance occurring in nature is a mere discovery. However, if the new property or the substance found in nature has a technical effect, it may be patentable.³⁴ Thus, the EPO and many European States focus on the inherent quality of the subject matter, requiring that it be technical in nature.³⁵ In comparison, the U.S. approach

24. Biotech Directive, *supra* note 7, art. 5; EPC Implementing Regulations, *supra* note 13, r. 29.

25. Case T 0315/03, *President and Fellows of Harvard Coll. v. British Union for the Abolition of Vivisection* (EPO Boards of Appeal, 2004). It was narrowed from a claim for making oncorodents to oncomice, as the “substantial medical benefit” has to be demonstrated for all the animals claimed and the patentee did not do so.

26. EPO Guidelines, *supra* note 14, pt. G, ch. II-1.

27. European Patent Convention, *supra* note 3, art. 52(2)(a).

28. See EPO Guidelines, *supra* note 14, pt. G, ch. II-2.

29. *Id.*

30. *Id.*

31. This point and the following example were made by Dan L. Burk in *IP and the Two Cultures: Where Science Meets the Law*, *Lucernaivris Laboratorium*, Institute for Research in the Fundamentals of Law Lecture Series (Oct. 7, 2014) (University of Lucerne).

32. *E.g.*, *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1290 (2012).

33. EPO Guidelines, *supra* note 14, pt. G, ch. II-1.

34. *Id.* at ch. II-2.

35. For example, Germany requires that an “invention” is a “systematic teaching using

does not so much address whether certain subject matter constitutes an “invention,” but that abstract ideas, natural products, and natural laws are exceptions to patentability, as well as that which is not a process, machine, manufacture, or composition of matter. In the United States, the focus is not upon the inherent nature of the subject matter at hand and whether it is technical or not, but rather upon whether the subject matter falls into an exception to patentability or not.

The EPC, its Guidelines, and the Biotech Directive do not at any point rely on or try to define what is “natural,” such as “natural products” or “natural laws,” which are terms that tend to open a metaphysical debate. Instead, the focus is on “discovery” and its antithesis—that with a technical effect—both of which depend much more on human action than philosophical musing and are thus far more suitable for the purposes of patent law and the legal delineation between what is a mere discovery and what is an “invention.” It is undoubtedly different to ask whether something is natural or not, compared to asking whether something is a discovery or has a technical effect.

The Biotech Directive has been incorporated into EPO law through the EPC Implementing Regulations,³⁶ the combined effects of which are: (1) EU Members must protect biological materials or a process by means of which a biological material is produced, processed, or used;³⁷ (2) finding a previously unrecognised substance (including the sequence or partial sequence of a gene) occurring in nature is a mere discovery;³⁸ (3) however, “[a]n element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element”³⁹—what this means is that the mere discovery of a sequence or the location of a gene cannot be patentable subject matter, but a sequence or gene that is isolated or produced by a technical process can; (4) a substance found in nature must produce a technical

controllable natural forces to achieve a result with clear cause and effect.” GERMAN PATENT AND TRADE MARK OFFICE, GUIDELINES FOR THE EXAMINATION PROCEDURE 7 (2004). Similarly for Switzerland, see FRANÇOIS DESSEMONTET, INTELLECTUAL PROPERTY LAW IN SWITZERLAND, ¶¶ 188–92 (2012).

36. See EPC Implementing Regulations, *supra* note 13, r. 26(1), which states that the Biotech Directive is a supplementary means of interpretation of the EPC for biotech inventions. The EPO passed this through on June 16, 1999 and it came into force on September 1, 1999. Notably, much of the Biotech Directive reflects pre-existing EPO case law. Incorporation of such into the Biotech Directive forced these standards onto EU Member States at the national level.

37. Biotech Directive, *supra* note 7, art. 1(1); EPC Implementing Regulations, *supra* note 13, r. 27. “Biological material” means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system. Biotech Directive, *supra* note 7, art. 2(a); EPC Implementing Regulations, *supra* note 13, r. 26(3).

38. Biotech Directive, *supra* note 7, art. 5.1; EPO Guidelines, *supra* note 14, pt. G, ch. II-2.

39. Biotech Directive, *supra* note 7, art. 5.2; EPC Implementing Regulations, *supra* note 13, r. 29(2).

effect to be patentable,⁴⁰ and “[t]he industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.”⁴¹

Of course, every invention has to have an industrial application in order to be patentable. However, it is not always necessary that an industrial application be explicitly spelt out when it is implicitly obvious.⁴² The Biotech Directive and EPO law require that this be explicit for sequences or partial sequences of a gene.⁴³ Although the Biotech Convention and EPO Implementing Regulations state that one need only disclose an industrial application in the patent application for “a sequence or a partial sequence of a gene,” the EPO Boards of Appeal has consistently held that this includes all DNA sequences, whether they form a part of a gene or not (so-called noncoding DNA), and RNA, whether they are genomic, transcribed, or regulatory. In other words, all biological nucleic acid sequences are included.⁴⁴ Furthermore, although the title in EPO Implementing Regulations is “[t]he human body” and its elements, it has been interpreted by the EPO as extending to all biological sequences, whether from humans, other animals, plants, or microbes.⁴⁵

Polypeptide sequences and proteins are not nucleotide sequences. Nevertheless, the EPO applies the same reasoning because a polypeptide sequence is an expression of the gene sequence.⁴⁶ Thus, if a polypeptide sequence is claimed, an industrial application also needs to be disclosed in the patent application.⁴⁷

40. EPO Guidelines, *supra* note 14, pt. G, ch. II-2; *see also* Genentech, Inc.’s Patent, R.P.C. 147 (1989); CORNISH ET AL., *supra* note 10, §§ 5–54, 21–08.

41. Biotech Directive, *supra* note 7, art. 5.3; EPC Implementing Regulations, *supra* note 13, r. 29(3). According to EPC, art. 57, “[a]n invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry.”

42. EPC Implementing Regulations, *supra* note 13, r. 42(1)(f).

43. Biotech Directive, *supra* note 7, art. 3.1.

44. This is clear from the EPO Guidelines, *supra* note 14, pt. G, chs. III-1, -2, which uses the terms “nucleic acid sequence” and “nucleotide sequence.” *See also* E-mail from Berthold Rutz, Examiner Directorate, European Patent Office, to author, Postdoctoral Researcher, Univ. of Lucerne, Switz. (Oct. 20, 2014, 2:32 PM) (on file with author) [hereinafter E-mail from Berthold Rutz].

45. Article 5.1 and 5.2 of the Biotech Directive, requiring that natural occurring elements be produced through a technical process, are directed at the human body. However, Article 5.3, pertaining to genetic sequences, is not limited in this way. Despite the fact that Article 29 of the EPC Implementing Regulations places Article 5 of the EU Commission’s Biotech Directive under the heading “The human body and its elements,” the EPO Guidelines make it clear that Article 5.3 covers all genetic sequences, whether human or not; EPO Guidelines, *supra* note 14, pt. G, chs. II-13, III-1, III-2. *See also* PETER HEINRICH, PATG/EPÜ: KOMMENTAR ZUM SCHWEIZERISCHEN PATENTGESETZ UND DEN ENTSPRECHENDEN BESTIMMUNGEN DES EUROPÄISCHEN PATENTÜBEREINKOMMENS [COMMENTARY ON THE SWISS PATENTS ACT AND THE CORRESPONDING PROVISIONS OF THE EUROPEAN PATENT CONVENTION] 75 (2010); Rainer Moufang, *Menschlicher Körper/Human Body*, in PATENTGESETZ MIT EUROPÄISCHEM PATENTÜBEREINKOMMEN: KOMMENTAR AUF DER GRUNDLAGE DER DEUTSCHEN UND EUROPÄISCHEN RECHTSPRECHUNG [PATENT LAW WITH EUROPEAN PATENT CONVENTION: COMMENTARY ON THE FOUNDATIONS OF GERMAN AND EUROPEAN CASE LAW] 176, 181 (Rainer Schulte ed., 2008).

46. E-mail from Berthold Rutz, *supra* note 44.

47. Case T 0870/04, Max-Planck-Gesellschaft zur Förderung der Wissenschaften e.V. (EPO Boards of Appeal, 2005).

Notably, this is seldom an issue in practice because usually the function of a protein is known before it is sequenced, due to the difficulties in sequencing proteins.⁴⁸ This may change with advances in the field.

B. *Disclosing an Industrial Application*

It makes sense that for nucleotide sequences and polypeptide sequences that can simply be located, isolated, and sequenced we also demand that a specific industrial application be disclosed to highlight how there is or could be a technical effect. This is because patents are meant to reflect a technical teaching, such that to allow claims for such subject matter without any idea of an industrial application would be contrary to the purpose of the patent system. With respect to cDNA, the requirement is also logical. Though one might argue that cDNA is by definition man-made and not found and isolated, this is not the point according to Central European patent law. The focus is on whether the subject matter has technical effect and the patent discloses a technical teaching.⁴⁹ Simply producing cDNA from mRNA does not implicitly satisfy this.

The same can be said about nucleotide sequences and polypeptide sequences that are made from scratch. It may be that artificial sequences, with a different backbone than DNA or RNA, may be created and have a particular use, such as the ability to be used to create polypeptides, perhaps even artificial proteins.⁵⁰ However, it is entirely possible that—although made from scratch *in vitro*—a sequence is identical or analogous to something that can be found in nature. Peter Heinrich has concluded that regardless of whether a sequence is completely technically produced or derived from a naturally occurring sequence, a function of the sequence must be disclosed, or else there would be no “invention” and no industrial application.⁵¹ This is logical because it may be easy to simply string together an artificial nucleotide or polypeptide sequence (particular in the future), but such a sequence could be entirely useless and prone to patent trolling unless a specific function is disclosed.

In *BDP1 Phosphatase*, the EPO Boards of Appeal stated that the simple production of a substance, the disclosure of the method thereof, and the description of the substance do not necessarily mean that there is industrial application, as there must also be a “profitable use for which the substance can be employed.”⁵² For example, the mere statement that a nucleotide sequence codes for a protein and the characterisation of the protein may not be sufficient. The reason for this was explained in *Hematopoietic Receptor*:

48. E-mail from Berthold Rutz, *supra* note 44.

49. Biotech Directive, *supra* note 7, art. 3.2.

50. The production of proteins is extremely difficult due to the complex nature in which the polypeptide needs to fold in on itself in order to create active sites. In nature, this usually occurs with the assistance of specialised “chaperone” proteins.

51. HEINRICH, *supra* note 45, at 75.

52. Case T 0870/04, Max-Planck-Gesellschaft zur Förderung der Wissenschaften e.V., ¶ 4, at 9.

[P]atents being an incentive to innovation and economic success, the criterion of “industrial applicability” requires that a patent application describes its subject invention in sufficiently meaningful technical terms that it can be expected that the exclusive rights resulting from the grant of a patent will lead to some financial or other commercial benefit.⁵³

It is not necessary that applicants show an actual or potential economic profit or a commercial interest.⁵⁴ But the claimed use must be plausible, reasonably credible, or an “educated guess.”⁵⁵ The disclosure of industrial application needs to provide a sufficiently “sound and concrete technical basis” (not vague, hypothetical, or speculative) for the skilled person to recognise that the claimed invention could lead to practical industrial exploitation, without the skilled person having to do any further research.⁵⁶ In other words, “profitable use” should be understood as an “immediate concrete benefit”:

This conveys, in the words “concrete benefit”, the need to disclose in definite technical terms the purpose of the invention and how it can be used in industrial practice to solve a given technical problem, this being the actual benefit or advantage of exploiting the invention. The essence of the requirement is that there must be at least a prospect of a real as opposed to a purely theoretical possibility of exploitation. Further, the use of the word “immediate” conveys the need for this to be derivable directly from the description⁵⁷

The burden cannot be placed on the reader of a patent “to guess or find a way to exploit it in industry by carrying out work in search for some practical application geared to financial gain, without any confidence that any practical application exists.”⁵⁸ The EPO Boards of Appeal stated:

In cases where a substance, naturally occurring in the human body, is identified, and possibly also structurally characterised and made available through some method, but either its function is not known or it is complex and incompletely understood, and no disease or condition has yet been identified as being attributable to an excess or deficiency of the substance, and no other practical use is suggested for the substance, then industrial applicability cannot be acknowledged. While the jurisprudence has tended to be generous to applicants, there must be a borderline between what can be accepted, and what can only be categorized as an interesting research result which per se does not yet allow a practical industrial application to be identified. Even though research results may be a scientific achievement

53. Case T 0898/05, ZymoGenetics, Inc., ¶ 4, at 12–13 (EPO Boards of Appeal, 2006).

54. *Id.* ¶ 5, at 13.

55. *Id.* ¶ 21, at 23, ¶ 27, at 25–26.

56. *Id.* ¶ 5, at 13; Case T 0870/04, Max-Planck-Gesellschaft zur Förderung der Wissenschaften e.V., ¶ 21, at 20.

57. Case T 0898/05, ZymoGenetics, Inc., ¶ 6, at 13–14.

58. Case T 0870/04, Max-Planck-Gesellschaft zur Förderung der Wissenschaften e.V., ¶ 19, at 19; see also Case T 0898/05, ZymoGenetics, Inc., ¶ 6, at 13–14.

of considerable merit, they are not necessarily an invention which can be applied industrially.⁵⁹

One does not satisfy the requirement of an industrial application simply by giving a vague and speculative indication that one may possibly attain something through the performance of further research with or on the disclosed substance; the disclosed industrial application cannot simply be to find out more about the natural function of the substance claimed. This is because “[t]he purpose of granting a patent is not to reserve an unexplored field of research for an applicant.”⁶⁰ In *Human Genome Sciences, Inc. v. Eli Lilly & Co.*, the UK Supreme Court noted that the line between “plausibility” and “educated guess,” on the one hand, and “speculation,” on the other, is not an easy one to draw.⁶¹ However, it stated that EPO jurisprudence, refinement, and application of the distinction had made it “tolerably clear.”⁶²

Interestingly, the profit-orientated interpretation of “industrial applicability” means that claims for probes simply as research tools for the detection of the complementary DNA do not have industrial application, as there is no commercial application. However, the use of probes for diagnostic purposes does have industrial application.⁶³

The relevant substantive parts of both the Biotech Directive and the EPO Implementing Regulations relating to patentability only use the term “industrial

59. Case T 0870/04, Max-Planck-Gesellschaft zur Förderung der Wissenschaften e.V., ¶ 6, at 10–11.

60. *Id.* ¶ 21, at 20; see also *Case T 0898/05, ZymoGenetics, Inc.*, ¶ 5, at 13. This case also clarified that there can be industrial applicability even in the absence of actual experimental data, on the basis of the description and common general knowledge. *Case T 0898/05, ZymoGenetics, Inc.*, ¶ 20, at 22–23. In this case, an attributed function based on computer-assisted methods was accepted. In *Case T 0604/04, Genentech, Inc. v. SmithKline Beecham PLC*, ¶ 18, at 18–19 (EPO Boards of Appeal, 2006), it was held that the categorisation of structurally characterised polypeptide receptors under a specific category of receptors (in this case chemokines) was sufficient, even though the ligands of the polypeptide were not characterised, because chemokines were well known as being interesting for the pharmaceutical industry, whether their role had been clearly defined or not. Similarly, in *Case T 0018/09, Human Genome Sciences v. Eli Lilly & Co.*, ¶ 22, at 38–39 (EPO Boards of Appeal, 2009), the court stated that—where a protein family shares a specific function or specific characteristics—there may be a manifest “immediate concrete benefit” merely through stating that a protein belongs to this family. However, if members of a protein family have different functions and characteristics, then this would not suffice. The reasoning of the Board of Appeal was unanimously followed by the U.K. Supreme Court for the same patent, resulting in the same conclusion, in *Human Genome Sciences, Inc. v. Eli Lilly & Co.*, [2011] UKSC 51 (appeal taken from Eng. and Wales Court of Appeal). The U.K. Supreme Court discussed the desirability of uniformity of principle and approach between national courts and the EPO, though differences in evidence and arguments may result in different results. *Id.* ¶¶ 83–87, at 27–28. The U.K. Supreme Court summarises EPO jurisprudence on “industrial application” at paragraphs 43–68, at 12–21, and paragraph 107, at 32–34.

61. *Human Genome Sciences, Inc. v. Eli Lilly & Co.*, [2011] UKSC 51, ¶ 123, at 38.

62. *Id.*

63. *Case T 1213/05, Univ. of Utah Research Found. v. Sozialdemokratische Partei der Schweiz*, ¶ 62, at 57 (EPO Boards of Appeal, 2007); *Case T 0666/05, Univ. of Utah Research Found. v. Institut Curie*, ¶ 84, at 47 (EPO Boards of Appeal, 2008).

application.”⁶⁴ However, the preambular text of the Biotech Directive states that a mere sequence without indication of a “function” is not considered to contain any technical information, but it is a mere substance found in nature and so not patentable subject matter.⁶⁵ It further notes that, where a sequence is used to produce a protein or part of a protein, it must be specified which protein is produced (or part thereof) *and* what function it performs.⁶⁶ The introduction of the term “function” in the preambular text of the Biotech Directive is interesting because it is not a typical patent law term. The EPO Guidelines also refer to the term “function;”⁶⁷ however, it is notable that they only do so when referencing the preambular paragraphs of the Biotech Directive that also use the term.⁶⁸ Otherwise, the EPO Guidelines refer to “industrial application.”⁶⁹

C. *Absolute- or Purpose-Bound Claims*

The requirement that a concrete industrial application or function be explicitly disclosed seeks to ensure that there is a technical effect and, therefore, an “invention.”⁷⁰ According to the Biotech Directive and EPO Guidelines, the industrial application need only be disclosed in the patent application description and not necessarily specifically in the claims.⁷¹ EPO-granted product claims for nucleotide sequences and polypeptide sequences are, therefore, not per se limited to the disclosed industrial application (“purpose bound”). Claims are drafted as traditional “absolute” claims, whereby the patentee has protection over all potential future uses of the sequences.⁷²

The EPO only deals with substantive questions of patentability.⁷³ Jurisdiction over certain postgrant issues such as patentee rights and patent effects remain with

64. Biotech Directive, *supra* note 7, art. 5.3.

65. *Id.* pmb. ¶ 23, at L 213/15.

66. *Id.* pmb. ¶ 24, at L 213/15. The English version of the text actually uses the word “or” instead of “and,” and the French version uses “ou.” The author here has decided to adopt the German version—which uses “und”—because this is the most consistent with EPO case law, which, as discussed above, has always required that one do more than simply disclose how to produce a substance and describe what that substance is.

67. EPO Guidelines, *supra* note 14, pt. G, ch. III-2.

68. *Id.*

69. *Id.* On the possible consequences of the different terminology existent in Europe, see Jessica C. Lai, *Gene-Related Inventions in Europe: Purpose- vs Function-Bound Protection*, 5 Queen Mary J. Intell. Prop. 449 (2015).

70. It also touches upon the standard of the inventive step and ensuring that there is sufficient disclosure of the invention. See *Case T 0898/05, ZymoGenetics, Inc.*, ¶ 6, at 13–14 (EPO Boards of Appeal, 2006); HEINRICH, *supra* note 45, at 58, 74; Johanna Gibson, *The Discovery of Invention: Gene Patents and the Question of Patentability*, 12 J. INTELL. PROP. RTS. 38, 39 (2007); Moufang, *supra* note 45, at 176, 178.

71. Biotech Directive, *supra* note 7, art. 5.3; EPO Guidelines, *supra* note 14, pt. G, ch. III-1. This is also the case in Switzerland. See Code Civil [CC] [Civil Code] June 25, 1954, CC 232.14, art. 49.2.b, *as amended by* No. I of the Federal Act, June 22, 2007, AS 2008 2551, BB1 2006 1 (“The patent application must contain . . . a description of the invention and, where a claim is made for a sequence derived from a sequence or partial sequence of a gene, a specific description of the function it performs.”).

72. EPO Guidelines, *supra* note 14, pt. G, ch. III-1.

73. See European Patent Convention, *supra* note 3.

Member States.⁷⁴ Postgrant patent effects are to some degree regulated by the Biotech Directive.⁷⁵ However, the effect of claims for nucleotide sequences is by no means clear-cut. Due to the open wording of the Biotech Directive, there is uncertainty surrounding whether it was the intention that the disclosure of an industrial application or function consequent that product claims for nucleotide sequences be purpose bound rather than absolute.⁷⁶ One could argue that the requirement to disclose an industrial application must limit the patent scope of the claims, otherwise the requirement does nothing more than repeat the industrial application standard. Why not simply utilise the standard of “industrial application” to ensure there is industrial applicability? On the other hand, one could also reason that the requirement ensures that there is an “invention” and industrial applicability at grant, decreasing the need to initiate patent revocation proceedings later on. But, once granted, the requirement to disclose an industrial application does not limit the effect of the patent. After all, the naming of an industrial application in the patent description, such as for a classic chemical invention, never limits the scope of patent claims.

Moreover, had the intention been to create purpose-bound claims, the Biotech Directive and EPO law could simply have stopped at stating that a sequence or partial sequence of a gene is a mere discovery, thus restricting patentability to use or application claims, rather than allowing product claims. Instead, the combined effect of the Biotech Directive and EPO law is to allow for product claims covering sequences or partial sequences of a gene if produced by a technical process and so long as an industrial application is provided. The intention was clearly not to have only use or application claims. Indeed, the purpose of the Biotech Directive was to ensure that all EU Member States *do* protect gene-related technologies.⁷⁷ The Biotech Directive was intended to be propatent, such that it does not make sense to interpret it as limiting protection as purpose bound.

The postgrant effects of patents are, to some extent, regulated by Article 9 of the Biotech Directive, which stipulates that:

The protection conferred by a patent on a product containing or consisting of genetic information shall extend *to all material*, save as provided in Article

74. *Id.* art. 64.3.

75. *See* Biotech Directive, *supra* note 7, arts. 8–12.

76. Geertrui Van Overwalle, *The CJEU's Monsanto Soybean Decision and Patent Scope—as Clear as Mud*, 42 INT'L REV. INTELL. PROP. & COMPETITION L. 1, 2–3 (2011). Some commentators do not see the confusion and deem that an EPO-granted patent clearly grants absolute product claims. *E.g.*, Christoph Ann, *Patents on Human Gene Sequences in Germany: On Bad Lawmaking and Ways to Deal with It*, 7 GERMAN. L.J. 279, 286 (2006).

77. *Vorschlag für eine Europäische Strategie auf dem Gebiet der Wissenschaft und Technik: Rahmenprogramm 1984 bis 1987 [Proposal for a European Strategy in the Field of Science and Technology: Framework Program 1984 to 1987]*, *supra* note 11, at 7, 22–24; *see also* Michael A. Kock, *Purpose-Bound Protection for DNA Sequences: In Through the Back Door?*, 5 J. INTELL. PROP. L. & PRAC. 495, 499–503 (2010) (outlining in-depth how the legislative intent was clearly not for purpose-bound protection).

5(1), in which the product in [sic] incorporated and in which the genetic information is contained and *performs its function*.⁷⁸

The use of the term “genetic information” here is somewhat strange. Article 9 is the only article within the substantive part of the Biotech Directive that uses the term “genetic information.”⁷⁹ In contrast, Article 5 on patentability refers to “the sequence or partial sequence of a gene.”⁸⁰ Similarly, Article 9 contains the only reference to the term “function” in the operative text of the Biotech Directive.⁸¹ It is confusing because the part of the Biotech Directive on patentability and the requirement of disclosure refers to “industrial application.”⁸² It is unclear if the drafters intended the terms to have distinct meanings and what the consequences of this might be. However, it is interesting to note that for patentable subject matter we have the terms “the sequence or partial sequence of a gene” and “industrial application,” which sound very product orientated. Whereas for postgrant effects, we suddenly have the very information- or use-orientated terms of “genetic information” and “function.”

It has also been argued that Article 9 should mean that claims for genetic sequences be limited to the disclosed industrial application, that is, purpose bound. In 2010, the Court of Justice of the EU interpreted Article 9. From this judgement, we know that—with respect to third-party use of a patented genetic sequence—the sequence has to at least be able to perform the function indicated in order to be infringing.⁸³ The Court of Justice of the EU did not specify if the third-party use has to exploit this function in order to be infringing. It is not difficult to imagine situations where a patented sequence is placed into a cell and capable of performing the function indicated but is nevertheless being used for another purpose, or is simply in a cell and not being used at all. It is also unclear what the law is when the sequence is technically viable to undertake the disclosed function but not in an environment where it is able to do so. The Court of Justice of the EU, thus, did not take the opportunity to indicate whether the Biotech Directive requires that the effects of claims for genetic sequences be purpose bound or not.

It is highly doubtful that Article 9 can be used to find that gene-related

78. Biotech Directive, *supra* note 7, art. 9 (emphasis added).

79. It appears nonsubstantively in preambular paragraph 41 regarding the cloning of human beings with the “same nuclear genetic information,” *id.* pmb. ¶ 41, at L 213/16, and also in Article 2 under the definition of “biological material,” *id.* art II, at L213/18.

80. *Id.* art 5, at L213/18.

81. *Id.* art. 9, at L 213/19.

82. *Id.* art. 5, at L213/18; pmb. ¶ 22, at L 213/15.

83. *Case C-428/08, Monsanto Tech. LLC v. Cefetra BV*, 2010 CR I-6765 (interpreting Biotech Directive, *supra* note 7, art. 9). The opinion of the Advocate General of this case was far clearer in finding that the protection conferred on DNA sequences in the EU is “purpose bound.” *Opinion of Advocate General Mengozzi, Case C-428/08, Monsanto Tech. LLC v. Cefetra BV*, ¶¶ 29–33, at 7/16–8/16 (2010). This decision has also been interpreted as saying that protection *is* purpose bound. Caroline Pallard & Bart Swinkels, *The Role of the Function of DNA Sequence Before and After Grant*, LIFE SCI. INTELL. PROP. REV. 56, 58 (2011). This author agrees with Geertrui Van Overwalle that this is not remotely clear. Overwalle, *supra* note 76, at 2.

technologies can only have purpose-bound protection. This is because the intention behind Article 9 was to extend patent protection and ensure that patentees did not lose control of their invention as a result of the first-sale doctrine (exhaustion of patent rights) and the ability of many gene-related inventions to propagate (thereby infringing on the patentee's right to make the invention).⁸⁴ The limitation within Article 9 that the genetic information must perform its function was implemented in recognition of the fact that genetic information can be bred out or may be nonviable in harvested or produced materials.⁸⁵ Article 9 is only relevant for gene-related inventions that are used *in vivo*; it is not relevant for those used *ex vivo* or *in vitro* and which are not propagated.⁸⁶ It therefore cannot be interpreted as restricting claims for gene-related technologies to being purpose bound. Thus, the Court of Justice of the EU decision that a patentee's rights extend to materials where the genetic information is capable of performing the indicated function is logical.⁸⁷ However, it only applies to situations where there is or was propagation or multiplication.

Not limiting the patent rights to the disclosed industrial application has been argued to offer patentees rights disproportionately large compared to their contribution to the field.⁸⁸ In mid-2005, the EU Commission discussed the question but refused to take a particular position.⁸⁹ A few months later, the EU Parliament passed a Resolution, calling for the EPO and Member States to only grant patent claims covering human DNA if limited to a concrete application, so that others may use the same DNA sequences for other applications (i.e., purpose-bound protection).⁹⁰ Despite this, the issue remains unresolved.⁹¹ In any case, the limited nature of the Parliament's Resolution restricted only to human DNA is highly questionable, as there is no logical distinction between human DNA and other DNA. Nor is there any sensible reason why one should differentiate between DNA, RNAs, and polypeptide sequences.

D. Policy Concerns

With the Biotech Directive and the EPC, the policy discussion within the EU has taken place at the legislative level. The preambular text of the Biotech Directive makes this very clear. On the one hand, it mentions the increasing importance of

84. Kock, *supra* note 77, at 500.

85. *Id.* at 500, 505.

86. This is clear from reading the rest of Chapter II of the Biotech Directive on "Scope of Protection," namely Arts. 8, 10, and 11. Biotech Directive, *supra* note 7, at arts. 8, 10, 11.

87. Kock draws the same conclusion. Kock, *supra* note 77, at 512.

88. Opinion of Advocate General Mengozzi, Case C-428/08, *Monsanto Tech. LLC*, ¶ 32, at 8/16.

89. *Report from the Commission to the Council and the European Parliament: Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering*, at 3–5, COM (2005) final (July 14, 2005).

90. European Parliament Resolution on Patents on Biotechnological Inventions, EUR. PARL. DOC. P6 TA-PROV (2005) 0407, point 5.

91. Because the Court of Justice failed to clarify the situation in *Case C-428/08, Monsanto Tech. LLC*.

the biotech industry for development, the environment, healthcare, and agriculture in developing countries as well as the high-risk investment involved.⁹² This reflects the concerns raised by the EU Commission in 1982 that differences in patent law and the way it treated biotechnology in EU Member States were hindering the EU's ability to compete with the United States and Japan with respect to biotechnology.⁹³ On the other hand, the preambular text addresses the fact that there are competing interests, such as the dignity and integrity of human beings and animal suffering,⁹⁴ and that the exceptions to patentability under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)⁹⁵ for *ordre public* or morality are relevant and a matter for Member States to assess (though some inventions are explicitly—but not exclusively—listed in the Directive as being contrary to *ordre public* or morality, such as processes that offend human dignity, including processes to produce chimeras from germ cells or totipotent cells of human and animals, otherwise modifying the human germ line or cloning human beings, and using human embryos for industrial or commercial purposes).⁹⁶ The Biotech Directive further explicitly discusses why isolated genetic sequences are patentable subject matter, stating that:

[S]uch an element isolated from the human body or otherwise produced is not excluded from patentability since it is, for example, the result of technical processes used to identify, purify and classify it and to reproduce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself.⁹⁷

There is patentable subject matter in isolated DNA, RNA, and cDNA sequences

92. Biotech Directive, *supra* note 7, pmb. ¶¶ 1–3, at L 213/13, ¶¶ 10–11, 17, at L 213/14.

93. *Vorschlag für eine Europäische Strategie auf dem Gebiet der Wissenschaft und Technik: Rahmenprogramm 1984 bis 1987* [Proposal for a European Strategy in the Field of Science and Technology: Framework Program 1984 to 1987], *supra* note 11.

94. Biotech Directive, *supra* note 7, pmb. ¶ 16, at L 213/14, ¶ 45, at L 213/16.

95. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27.2, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.

96. Biotech Directive, *supra* note 7, pmb. ¶¶ 36–42, at L 213/16 & art. 6.2; see also EPC Implementing Regulations, *supra* note 13, r. 28 (outlining certain biotechnological inventions that are not patentable subject matter because their commercial exploitation would be contrary to *ordre public* or morality under Article 53(a) of the European Patent Convention). Regarding the definition of “human embryos” and “use for industrial or commercial purposes” as per the directive, see *Case C-34/10, Brüstle v. Greenpeace e.V.*, 2011 E.C.R. I-9821, ¶ 23, at I-9867–68. This decision held that “human embryos” is to be understood in a wide sense and courts are to ask whether the cells are capable of commencing the process of development of a human being. *Id.* ¶¶ 34–37, I-9871–72. It further held that the grant of a patent implies “use for industrial or commercial purposes,” *id.* ¶ 41, I-9873, and that use for the purposes of scientific research is included under “use for industrial or commercial purposes.” *Id.* ¶¶ 43–46, I-9873–74. The Court of Justice further held that skillful drafting—leaving out of the claims the nonpatentable use of human embryos, such as the destruction of the embryos or use as a base material—cannot be used to patent something that must use human embryos in a nonpatentable way in order to be implemented, regardless of the stage at which the use takes place. *Id.* ¶¶ 49–52, I-9875–76.

97. Biotech Directive, *supra* note 7, pmb. ¶ 21, at L 213/15.

because a laboratory process is involved in either the translation and/or isolation of the sequences.⁹⁸ The Biotech Directive (and the EPC) does not require that the claimed sequences be chemically different than their in-cell counterparts.⁹⁹

Unlike in U.S. courts, which are left with quite a lot of room for policy-informed decision-making, it is not the role of the EPO to make policy decisions. Indeed, the EPO Guidelines specifically state that the EPO has not been vested with the task of assessing the economic effects of the grant of certain types of technology and deciding patentable subject matter accordingly.¹⁰⁰ There are undoubtedly advantages of the approach in the EU, specifically that there is more certainty, as illustrated by the EPO BRCA decisions discussed in Part II. Governments often push the decision-making onto the courts, which are in turn often reluctant to make policy decisions. In the EU, at least someone is making policy decisions. At the same time, the Biotech Directive and EPC remove a lot of flexibility, which is dangerous in an area of law that deals specifically with new technologies. For example, perhaps the Biotech Directive and EPC work now with the biotechnology of today, but how will these instruments deal with the biotechnology of tomorrow?

II. BRCA PATENTS IN EUROPE

As a consequence of the Biotech Directive and EPC, the oppositions heard against Myriad Genetics' BRCA patents in Europe were of little legal interest. Like in the *Myriad* case, the strong contestation reflected the social unease with regard to gene-related patents. However, unlike the *Myriad* case, the EPO's role was one of strict legislative application due to the very clear nature of the pertinent parts of EPO law. The following Sections briefly outline the decisions made by the EPO.

A. EP0705902 "17q-Linked Breast and Ovarian Cancer Susceptibility Gene" (Case T 1213/05)

This case predominantly dealt with priority and whether priority could be claimed from a U.S. Patent Application (filed September 2, 1994, designated the P2 priority application) that disclosed the BRCA1 sequence with errors.¹⁰¹ Namely, fifteen nucleotides of the cDNA sequence disclosed were incorrect, nine of which led to amino acid changes and six of which were "silent deviations" not impacting on amino acid expression.¹⁰² None of the deviations were an insertion or deletion or resulted in a stop codon. The correct "open reading frame"¹⁰³ for BRCA1 was

98. CORNISH ET AL., *supra* note 10, at ¶ 21-08.

99. *Id.*

100. EPO Guidelines, *supra* note 14, pt. G, ch. II-7.

101. Case T 1213/05, Univ. of Utah Research Found. V. Sozialdemokratische Partei der Schweiz, ¶ I (EPO Boards of Appeal, 2007).

102. *Id.* ¶ 20, at 27.

103. A "reading frame" is the identification of the sets of three nucleotides that make up codons in a nucleotide sequence. An "open reading frame" contains a start and stop codon in the same frame,

disclosed in P2, which was important for the BRCA1 method patent at issue in Case T 0080/05, which is discussed below.¹⁰⁴ The Opposition Division and the Board of Appeal took a strict and structural understanding of the “the same invention” to conclude that the errors meant that there was no priority as the prior art document did not disclose “the same invention.”¹⁰⁵ As a result, Myriad Genetics only had priority from a later U.S. Patent Application (filed March 24, 1995), could not claim the BRCA1 sequence as a whole, and the patent claims were limited to probes (short strands of the BRCA1 sequence) to isolate the gene, cloning vectors, and host cells.¹⁰⁶

The Board of Appeal also addressed whether the probes were discoveries, as per Article 52(2) of the EPC. It very succinctly held that there was patentable subject matter in light of Rule 29(2) of the EPC Implementing Regulations,¹⁰⁷ which states that elements of the human body that are isolated or technically produced, including a sequence or partial sequence of a gene, can constitute inventions.¹⁰⁸ The nucleic acid probes comprising partial DNA sequences of the human BRCA1 gene were obtained by technical processes and were thereby isolated elements of the human body and thus patentable subject matter.¹⁰⁹

The opponents also argued that the claims violated *ordre public* or morality because the Applicants did not prove that they had consent to use the cells from which they identified the BRCA1 gene, or consent for the commercial exploitation of research results, as well as access and benefit sharing.¹¹⁰ The Board of Appeal stated that EPC law does not require that applicants submit evidence of prior informed consent or access and benefit sharing.¹¹¹ The Board of Appeal also rejected arguments that the socioeconomic consequences of the claims were contrary to *ordre public* or morality. It held that it is the “exploitation of the invention” that is relevant, not the “exploitation of the patent” and issues relating to increased costs for patients and the impact on diagnosis and research have to do with the latter.¹¹² Moreover, focussing on the exploitation of the patent is illogical, as “such an objection applies to the exploitation of any patent, as the nature of the consequences of the exploitation of a patent (which derive from the exclusionary nature of private property rights), are the same for all patents.”¹¹³ The Board further affirmed that the EPO does not have the competence to take into account the economic effects of granting patents and to restrict certain fields of patentable

the totality of which should translate into a protein. http://bioweb.uwlax.edu/genweb/molecular/seq_anal/translation/translation.html [<http://perma.cc/7U35-7U72>].

104. See discussion *infra* Section II.C.

105. Case T 1213/05, Univ. of Utah Research Found., at ¶¶ 22–34, at 29–41.

106. *Id.* ¶ 34, at 41.

107. Rule 23e(2) at the time the Decision was handed down. See *id.* ¶ 56, at 54.

108. EPC Implementing Regulations, *supra* note 13, r. 29(2).

109. Case T 1213/05, Univ. of Utah Research Found., at ¶¶ 43–45, at 46.

110. *Id.* ¶ 53, at 50–51.

111. *Id.* ¶¶ 46–50, at 47–49.

112. *Id.* ¶ 53, at 50–51.

113. *Id.*

subject matter accordingly.¹¹⁴ This lack of competence is very different from the potential flexibility that courts in the United States have to take policy issues into account. Finally, as a distinct legal order, the EPC does not need to be interpreted in light of national legislation of its member states—namely the ethical concerns reflected in the French and German legislation¹¹⁵—or a Resolution from the EU Parliament calling for purpose-bound protection.¹¹⁶

It was further argued that the probes had no industrial application because:

The capacity of a single stranded DNA sequence to hybridize with a complementary single-stranded sequence was a consequence of the physico-chemical properties of each single-stranded DNA molecule and was thus a universal characteristic thereof. It could not have been the intention of the legislator to accept such universal characteristic as basis for an industrial application . . . , as this would have the consequence that each and every single-stranded DNA was industrially applicable¹¹⁷

The Board of Appeal dismissed this, stating that there was industrial applicability as the probes were useful for diagnostic purposes and were thus able to be used commercially to detect the presence of BRCA1 alleles predisposing individuals to breast cancer.¹¹⁸

B. EP0705903 “Mutations in the 17q-Linked Breast and Ovarian Cancer Susceptibility Gene” (Case T 0666/05)

One of Myriad Genetics’ European patents for BRCA1 (for mutations indicating a predisposition for breast and ovarian cancer) was also narrowed, in 2008, from a method covering thirty-four mutations to only one “frame-shift” mutation (the deletion or insertion of one or two nucleotides).¹¹⁹ This was a result of the filing of the incorrect sequence (as noted above), making them lose priority. Specifically, Myriad Genetics narrowed the patent to the “185delAG → ter39” mutation, which means deletion of the nucleotides “AG” at position 185, which would result in a stop codon in codon number 39.¹²⁰ The claims relating to the one frame-shift mutation covered a method for diagnosing a predisposition for breast and ovarian cancer with respect to this mutation and a related probe.¹²¹ Myriad Genetics did not lose priority for this particular mutation and related probe, as the errors made in the priority document did not affect the detection of this particular mutation or the nucleotides of the related probe.¹²² The method simply called for

114. *Id.*

115. *See* discussion *infra* Part III.

116. *See* discussion *supra* Section I.D.

117. Case T 1213/05, Univ. of Utah Research Found., ¶ 60, at 56.

118. *Id.* ¶ 62, at 57.

119. Case T 0666/05, Univ. of Utah Research Found. v. Institut Curie, ¶ I, at 1 (EPO Boards of Appeal, 2008).

120. *Id.* ¶ VI, at 3.

121. *Id.*

122. *Id.* ¶ 40, at 27–28.

the detection of the deletion of AG at position 185 (which was nowhere near any of the errors) and not a comparison between the patient's nucleotide or amino acid sequence and a reference sequence.¹²³

Similar to the decision T 1213/05, the Board of Appeal held that the probe had been obtained by a technical process and was therefore an isolated element of the human body and patentable.¹²⁴ The Board also followed the T 1213/05 decision regarding the irrelevance of economic and ethical considerations of the patenting of diagnostic methods involving the use of human genetic materials¹²⁵ and held that nucleic acid probes have industrial applicability.¹²⁶

C. EP0699754 “Method for Diagnosing a Predisposition for Breast and Ovarian Cancer”
(Case T 0080/05)

In 2008, Myriad Genetics' patent covering methods for diagnosing a predisposition for breast and ovarian cancer regarding BRCA1 was also narrowed.¹²⁷ The patent had been fully revoked in 2004 as a result of Myriad Genetics registering the incorrect genetic sequence, meaning that full diagnosis was not possible from their application, making it lose priority.¹²⁸ The Board of Appeal reversed this decision when Myriad Genetics reduced the scope of the claims to methods for diagnosing a predisposition for breast and ovarian cancer with respect to frame-shift mutations because the exact correct sequence is not required to detect frame-shift mutations.¹²⁹ Myriad Genetics rephrased their methods to reference the open reading frame (which, as noted above, was correctly disclosed in the P2 priority application) rather than the sequence disclosed in P2.¹³⁰ The Board distinguished the case from Case T 1213/05, stating that the earlier case pertained to product claims, where the errors affected a technical feature of the invention, whereas the errors did not affect the technical feature of the diagnostic method for frame-shift mutations.¹³¹

The opponent argued that the methods at suit were “based on the discovery of a mutation in the genome of a human, on the further discovery of a relationship that exists in nature between this mutation and a disease and on the purely mental act that a human having this mutation has a predisposition for the disease,” and thereby not inventions as per EPC, Article 52(2)(a) and (c).¹³² The Board of Appeal

123. *Id.*

124. *Id.* ¶ 76, at 43.

125. *Id.* ¶ 82, at 45–46.

126. *Id.* ¶ 84, at 47.

127. Case T 0080/05, *Univ. of Utah Research Found. v. Institut Curie* (EPO Boards of Appeal, 2008).

128. *Institut Curie v. Myriad Genetics, Inc.*, European Patent Office Opposition Division, Division Revoking the European Patent EP0699754 (3 November 2004); <https://register.epo.org/application?number=EP95305602> [<https://perma.cc/N5L8-QVLV>].

129. Case T 0080/05, *Univ. of Utah Research Found.*, ¶ VI, at 3–4.

130. *Id.*

131. *Id.* ¶ 39, at 28.

132. *Id.* ¶ 57, at 36.

held that the EPC Implementing Regulation Rule stating that an element isolated from the human body or otherwise produced by technical means may constitute a patentable invention applies *a fortiori* to method claims.¹³³ The claims at issue were therefore not discoveries as per Article 52(2)(a). Regarding whether the claims were purely mental acts as per Article 52(2)(c), the Board ruled that the diagnostic method of determining the presence of frame-shift mutations requires “working steps of [a] technical nature which belong to the preceding steps which are constitutive for making a diagnosis as an intellectual exercise.”¹³⁴ The method claims to detect frame-shift mutations were also held to have industrial applicability due to the decisive connection between the BRCA1 polypeptide and breast and ovarian cancer.¹³⁵

The Board of Appeal, furthermore, upheld the long-settled understanding that only diagnostic methods performed *on* a living human or animal body are excluded from patentability under EPC Article 53(c), and not those performed on tissue samples.¹³⁶ Finally, as in Case T 0666/05, the Board followed the T 1213/05 decision to dismiss the relevance of economic and ethical consequences of patenting diagnostic methods involving the use of human genetic material.¹³⁷

D. EP0785216 “Chromosome 13–Linked Breast Cancer Susceptibility Gene BRCA2”¹³⁸

Myriad Genetics had one EPO-granted patent for BRCA2, which was initially granted for the gene, disease-associated mutations and breast cancer-predisposing mutations.¹³⁹ In 2005, the patent was narrowed to a single claim over a nucleic-acid sequence that carries the BRCA2 mutation that is associated with a predisposition to breast cancer in Ashkenazi Jewish women.¹⁴⁰ The claim specifically refers to “6174delT” or the deletion of a T at position 6174 “for diagnosing a predisposition to breast cancer in Ashkenazi-Jewish women *in vitro*.”¹⁴¹

The mutation claimed had been described before the priority date of the application, such that a distinguishing technical feature was required to overcome

133. *Id.* ¶ 59, at 37.

134. *Id.* ¶ 60, at 37.

135. *Id.* ¶ 67, at 40.

136. *Id.* ¶¶ 62–63, at 38.

137. *Id.* ¶ 65, at 39.

138. European Patent No. 0 785 216 (B2) (filed Dec. 17, 1996). In an earlier decision, the Board of Appeal revoked a patent belonging to Cancer Research UK (often called the “Stratton patent” after the lead inventor Michael Stratton), which had claimed BRCA2 as a product-by-process claim and also a method of diagnosis. Myriad Genetics successfully opposed the patent on the basis of priority and novelty. *See Case T 0902/07, Cancer Research Tech. Ltd. v. Myriad Genetics, Inc.*, (EPO Boards of Appeal, 2010).

139. European Patent No. 0 785 216 (B2), *supra* note 138.

140. In June 2005, the EPO Opposition Division determined the patent be maintained in amended form. This decision was not appealed to the Technical Board of Appeal. There was a Board of Appeal decision, however this only related to priority. *See Case T 0156/08, Univ. of Utah Research Found.*, ¶ 4, at 8 (EPO Boards of Appeal, 2011).

141. European Patent No. 0 785 216 (B2), *supra* note 138 (emphasis added).

the standards of novelty and obviousness.¹⁴² The reference to Ashkenazi-Jewish women was thus included to be the distinguishing technical feature, as the mutation had not previously been linked to this subgroup.¹⁴³ The Opposition Division sided with the applicant, deciding that the claim was not immoral in relation to Article 53(a).¹⁴⁴

E. Overall?

Overall, neither BRCA1 nor BRCA2 were strongly patented in Europe. Neither gene, nor a related nucleic acid or polypeptide sequence, was patented as a whole. Regarding BRCA1, Myriad Genetics only had product claims over probes to isolate the gene, cloning vectors, and host cells; the “185delAG → ter39” mutation and a related probe; and method claims over frame-shift mutations.¹⁴⁵ The claims covering the probe to isolate the gene would not have prevented one from sequencing in order to locate BRCA1.¹⁴⁶ One could have gotten around the “185delAG → ter39” mutation patent by simply sequencing down the gene to observe the effect of the deletion. The method patent covering frame-shift mutation was arguably the most restrictive, as most (and the most severe) cancer-causing mutations recognised in BRCA1 are caused by frame-shift mutations.¹⁴⁷ However, the narrowing of the two mutation patents has created some confusion regarding at what point in a diagnosis the patents would be infringed.¹⁴⁸ This is because they simply claim “a method” (i.e., any method), rather than a specific method for determining the presence of the mutations. Is it simply the process of sequencing? Or only if the “185delAG → ter39” mutation on BRCA1 or a frame-shift mutation on BRCA2 is found? Is then the outcome of the diagnosis determinative of whether there is infringement?¹⁴⁹

As to BRCA2, Myriad Genetics has only one claim covering mutation “6174delT” for diagnosing a predisposition to breast cancer in Ashkenazi-Jewish women *in vitro*. This is exceedingly narrow. At the same time, this claim has been stated to be discriminatory and also impractical, given that many people of Ashkenazi Jewish descent are not aware of their ancestry. Gert Matthijs noted that “there is something fundamentally wrong if one ethnic group can be singled out by patenting” and that “women coming to be tested for breast cancer will have to be

142. Gert Matthijs et al., *The European BRCA Patent Oppositions and Appeals: Coloring Inside the Lines*, 31 NAT. BIOTECHNOLOGY 704, 708–709.

143. *Id.*

144. *Id.*

145. *Id.*

146. *Id.* at 707.

147. *Id.* at 708.

148. See Alison Abbott, *Europe to Pay Royalties for Cancer Gene*, NATURE (Dec. 2, 2008), <http://www.nature.com/news/2008/081202/full/456556a.html>.

149. See Isabelle Huys et al., *Legal Uncertainty in the Area of Genetic Diagnostic Testing*, 27 NAT. BIOTECHNOLOGY 903, 908 (2009).

asked whether they are Ashkenazi Jewish or not.”¹⁵⁰ It is additionally unclear at what point the claim would be infringed, as it merely refers to the “use” of the mutation for diagnosing a predisposition for breast cancer. Does the mutation have to be found for there to be infringement? Would the claim be infringed if a diagnosis for the “6174delT” mutation were performed on a woman who did not know that she was Ashkenazi-Jewish, but found out later that she was? What if an Ashkenazi-Jewish woman had her entire BRCA2 sequenced and she happened to have the “6174delT” mutation?

III. WHAT DOES THE *MYRIAD* DECISION MEAN FOR EUROPE?

Though Myriad Genetics’ patents were controversial in Europe, and arguments were made to revoke or narrow them on the ground of “non-invention,” ultimately the EPO restricted patent claims relating to BRCA1 and BRCA2 mostly on the basis of lost priority.¹⁵¹ The Boards of Appeal showed unwillingness to entertain the idea that isolated genetic materials are not capable of being “inventions.” Quite rightly so, given the restricted nature of the EPO’s mandate and competence.¹⁵² At the time that the Biotech Directive was adopted and the BRCA cases were heard in Europe, simply isolated genetic materials were considered to be “inventions” in the United States.¹⁵³ The Biotech Directive was in most part adopted in order to harmonise the patent protection of biotechnology in Europe, as this was seen as necessary to ensure that the European biotech industry could compete with that in the United States and Japan.¹⁵⁴ In other words, it was seen as necessary to encourage research, innovation, and investment in biotechnology in Europe. After the *Myriad* decision, the landscape in Europe is arguably different. If the U.S. trend is to hold simply isolated biological materials as mere natural products, this could have a significant impact on the invention and innovation and policy debate in Europe.

A. *The Meaning of Myriad*

Before one can analyse the potential impact of the *Myriad* decision on the European context, it is important to note the uncertainty surrounding the exact scope of the decision. The *Myriad* judgement tells us that simply isolated genes and

150. *Slimmed Down Breast Cancer Gene Patent Upheld*, BIONEWS (June 30, 2005), http://www.bionews.org.uk/page_12415.asp [<http://perma.cc/6JVD-F66D>].

151. Katerina Sideri, *Practical Reasoning, Impartiality and the European Patent Office: The Legal Regulation of Biotechnology*, 18 EUR. L.J. 821, 838 (2012).

152. See *id.* at 838–42, for an argument against the merely interpretative nature of the EPO.

153. As noted in *Ass’n for Molecular Pathology v. USPTO*, 689 F.3d 1303, 1343 (Fed. Cir. 2012), *aff’d in part and rev’d in part sub nom. Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

154. *Vorschlag für eine Europäische Strategie auf dem Gebiet der Wissenschaft und Technik: Rahmenprogramm 1984 bis 1987* [*Proposal for a European Strategy in the Field of Science and Technology: Framework Program 1984 to 1987*], *supra* note 11, the entirety of which discusses the European patent situation compared to that of Japan and the United States.

genetic sequences are natural products, but this does not explicitly tell us what a natural product is.¹⁵⁵ We know from the decision that cDNA is not a natural product because it is man-made.¹⁵⁶ This is despite the evidence that cDNA in fact does exist naturally, even in humans, as a consequence of retroviruses which transcribe mRNA into cDNA.¹⁵⁷ The U.S. Supreme Court stated that “[t]he possibility that an unusual and rare phenomenon *might* randomly create a molecule similar to one created synthetically through human ingenuity does not render a composition of matter nonpatentable.”¹⁵⁸ But what does this tell us about what a natural product is?

The Supreme Court essentially held that what is “natural” is what exists with certainty without human intervention. Even if this could be taken as the *ratio decidendi* of the decision, it was arguably incorrectly applied to isolated DNA, as isolated genetic sequences and genes do not exist in isolated form in cells. Even if one were to presume that isolated genetic sequences are in all ways identical to their in-cell counterparts, the approach of the Supreme Court also does not take into account that there may be situations where there is absolute certainty that something exists in nature without the influence of man, but this is not the same as having that thing accessible for use.¹⁵⁹ In other words, that a genetic sequence exists in nature is not the same as knowing its exact location and wild-type sequence (the sequence most frequently found in nature). If patent law exists to incentivise the introduction of something of value to society, both with respect to the physical invention itself and the information behind it, patent law should award those who make something available to the public that previously was not.¹⁶⁰

The Supreme Court’s decision is further unhelpful because of its use of an informational or functional rationale for gDNA¹⁶¹ but a structural rationale for cDNA.¹⁶² It has been suggested that judging whether something is structurally and functionally distinct enough from that in nature should be done on a sliding scale, as sometimes small structural differences can result in large changes in functionality

155. Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2111 (2013).

156. *Id.*

157. See David Baltimore, *Viral RNA-dependent DNA Polymerase: RNA-dependent DNA Polymerase in Virions of RNA Tumour Viruses*, 226 NATURE 1209 (1970); Howard M. Temin & Satoshi Mizutani, *Viral RNA-dependent DNA Polymerase: RNA-dependent DNA Polymerase in Virions of Rous Sarcoma Virus*, 226 NATURE 1211 (1970).

158. *Myriad*, 133 S. Ct. at 2119 n.8 (emphasis in original).

159. Dan L. Burk, *Anticipating Patentable Subject Matter*, 65 STAN. L. REV. ONLINE 109, 112 (2013).

160. Historically, most states had local novelty standards, meaning that one could “invent” through being the first to import something. It did not matter that the invention already existed elsewhere because travelling from land to land used to be long and dangerous. Today, most states have universal novelty standards, as travel is no longer perilous and modern technology means that information travels differently.

161. The U.S. Supreme Court stated that “genes *and the information they encode*” are not patentable. *Myriad*, 133 S. Ct. at 2120 (emphasis added).

162. *Id.* at 2119 n.7.

and vice versa.¹⁶³ This is not particularly helpful with DNA, as any isolated genetic sequence or whole gene will be structurally different because it will not fold on itself as it would in-cell.¹⁶⁴ Furthermore, given that it is the informational component of nucleic acids that makes them of interest to man, their functionality (not to be confused with their utility) will often be the same as in-cell.

The failure of the U.S. Supreme Court to provide a usable test of what a natural product may be is abundantly clear when we try to apply the judgement to newer technologies. For example, what does the judgement tell us about the doctrine to help us assess DNA or DNA-like sequences made *ab initio*? Does it matter if the sequences are virtually the same as something known to exist in nature, made synthetically to make the same naturally existing proteins? Or if the sequences are completely different from those known to exist in nature, to make naturally existing proteins? Or if the sequences are completely different from those known to exist, to make non-naturally existing proteins? At what point do we have “human ingenuity”?

What about genetic materials from prokaryotes, which have no introns and thus no “cDNA”? Or genomic biomarkers, which are genetic sequences that are used to identify species or diseases? The decision also did not deal with RNA molecules. Not only did the U.S. Supreme Court fail to address the RNA analogues of DNA for polypeptide production, but it also failed to address noncoding RNA (ncRNA), transfer RNA (tRNA), ribosomal RNA (rRNA), micro RNA (miRNA), and small interfering RNAs (siRNA). It also did not refer to polypeptide sequences.

The U.S. Supreme Court decision gives us no guidance as to how these questions should be answered and whether we should take an informational or structural rationale, or both.¹⁶⁵ The U.S. Patent and Trademark Office (PTO) has added some clarification in its 2014 *Guidance for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products (Guidance)*.¹⁶⁶ Though the PTO noted that the *Myriad* decision was limited to nucleic acids (not differentiating between types of nucleic acids), it stated that the decision reminds us that “claims reciting or involving natural products should be examined for a marked difference.”¹⁶⁷ For product claims, the claim has to be “markedly different *in structure* from naturally occurring products.”¹⁶⁸ The PTO stated that “[n]ot all differences rise to the level of marked differences, for example, merely

163. Samantak Ghosh, *Gene Patents: Balancing the Myriad Issues Concerning the Patenting of Natural Products*, 27 BERKELEY TECH. L.J. 241, 262–66 (2012).

164. Burk, *supra* note 4, at 98–101.

165. A more recent preliminary injunction decision from the U.S. District Court has not helped the matter. See *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 3 F. Supp. 3d 1213 (D. Utah 2014).

166. U.S. PATENT & TRADEMARK OFFICE, *GUIDANCE FOR DETERMINING SUBJECT MATTER ELIGIBILITY OF CLAIMS RECITING OR INVOLVING LAWS OF NATURE, NATURAL PHENOMENA & NATURAL PRODUCTS* (2014).

167. *Id.* at 1.

168. *Id.* at 4 (emphasis added).

isolating a nucleic acid changes its structure (by breaking bonds) but that change does not create a marked difference in structure between the isolated nucleic acid and its naturally occurring counterpart.¹⁶⁹ The PTO focus on structural “marked differences” stems from the *Diamond v. Chakrabarty* U.S. Supreme Court decision,¹⁷⁰ which was not a major focal point in *Myriad* and instead centred on the fact that Myriad Genetics “did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes.”¹⁷¹

Despite the very structural focus that the PTO took when setting out the test to be used, they then introduced the role of function in one of the outlined examples pertaining to a pair of primers. The PTO stated that the primers were not structurally markedly different and:

Further, the first and second primers have the *same function* as their natural counterpart DNA, i.e., to hybridize to their complementary nucleotide sequences. The minor structural differences *taken together with the lack of any functional difference* between the primers and the natural DNA fail to demonstrate that the recited products are markedly different from what exists in nature.¹⁷²

The PTO thus seems to take a mixed structural-functional approach. At the end of the day, even if the U.S. approach is to be purely structural, the subjective term “marked” is by no means clear cut. The PTO stated that not all differences are “marked” differences, using the example of simply isolating nucleic acid as not “marked.”¹⁷³ But this tells us nothing more than what *Myriad* does. If an isolated nucleic acid is modified by a researcher, is this then “markedly different”? Does this depend on the modification? Does this depend on the function of the modification or if a new property is introduced?

What the PTO does make clear is that the ease with which the subject matter is obtained is irrelevant. It stated that “[t]he fact that a marked difference came about as a result of routine activity or via human manipulation of natural processes does not prevent the marked difference from weighing in favor of patent eligibility.”¹⁷⁴ The PTO used cDNA as an example of something that is markedly different from natural occurring DNA and eligible subject matter, even though making cDNA is routine in the biotechnology field.¹⁷⁵ Analogously, this should mean that the difficulty with which one has to obtain the claimed subject matter is equally as irrelevant for the determination of whether there is an “invention.”

169. *Id.* at 5.

170. *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980).

171. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013).

172. U.S. PATENT AND TRADEMARK OFFICE, *supra* note 166, at 12 (emphasis added).

173. *Id.* at 5.

174. *Id.*

175. *Id.*

B. *The Biotech Industry*

Given the uncertainty surrounding what exactly the *Myriad* decision denotes in the United States, it is difficult to gauge what it means in the European context. It is possible that the biotech industry will see Europe as a friendlier environment within which to undertake biotech research and—more to the point—to commercialise biotech inventions. Evidently, there are less granted gene-related patents in Europe than the United States, partly because many applications are not followed through.¹⁷⁶ If the European market looks more fertile for commercialisation, this may change. At the same time, European-based biotech companies may find it harder to commercialise their inventions in the United States. This largely depends on what is deemed to be “markedly different,” or, in other words, how much one has to change in order for the subject matter to no longer be a “natural product.” The easier the standard is to overcome, the smaller the trickle-down effect that will be felt in Europe as a consequence of the *Myriad* decision.

However, the analysis of the impact on the biotech industry would not be complete if we did not also consider the *Myriad* decision together with *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*¹⁷⁷ In 2012, the U.S. Supreme Court ruled that a diagnostic method using metabolite thresholds to determine correct dosage of a medicament was a mere recitation of a natural law.¹⁷⁸ At the Federal Circuit level of the *Myriad* case (in a part of the decision that was not reconsidered by the Supreme Court), the *Mayo* decision was used to rule that a method of analysing a patient’s BRCA sequence and comparing it to a normal (wild-type) sequence to identify cancer-disposing mutations was not an invention but the recitation of an abstract idea.¹⁷⁹ The claims did not apply the step of comparing two sequences in a process but rather only recited the abstract mental steps necessary to compare two different sequences.¹⁸⁰ The Federal Circuit, however, held to be valid a method for screening potential cancer therapeutics, via growing a transformed eukaryotic host cell containing an altered BRCA1 gene (which causes cancer) in the presence of a suspected cancer therapeutic, and measuring the rate of growth and comparing it to the growth when not in the presence of the therapeutic.¹⁸¹ This is because the steps of comparing cell growth rates and growing the transformed cells were “transformative.”¹⁸²

176. Huys et al., *supra* note 149, at 908.

177. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012).

178. *Id.* at 1297.

179. *Ass’n for Molecular Pathology v. USPTO*, 689 F.3d 1303, 1333–35 (Fed. Cir. 2012).

180. *Id.*

181. *Id.* at 1335–37.

182. *Id.* The transformed eukaryotic host cell containing an altered BRCA genes would potentially be patentable subject matter due to *Diamond v. Chakrabarty*, 447 U.S. 303, 309–10 (1980), which held that bacteria with extra genetic material was a “nonnaturally occurring manufacture or composition of matter—a product of human ingenuity” The intervention of man resulted in bacteria with “markedly different characteristics” from nature and “the potential for significant utility,” resulting in patentable subject matter. *Id.* at 310.

Taken together, *Myriad* and *Mayo* severely narrowed the scope of biotech patents. This is supported by the PTO's statement in its 2014 *Guidance* that "the correlation between the presence of misfolded protein ABC in blood and degenerative disease X is a natural principle."¹⁸³ As a consequence, mutations such as the "185delAG → ter39" mutation would be difficult to patent, as the mutations themselves would be mere natural products as per *Myriad*, and the fact that the mutations are cancer causing would be considered to be natural laws as per *Mayo*.¹⁸⁴ Similarly, single-nucleotide polymorphisms (SNPs) or genomic biomarkers and methods for their use to determine the presence, susceptibility and prognosis of a disease would likely fall under *Myriad* and *Mayo*. One would have to claim such mutations, SNPs, and genomic biomarkers in very specific method claims that do not foreclose other methods and that are not purely conventional or routine in the art, possibly in conjunction with something that does not exist in nature.¹⁸⁵ In contrast, the patentability of method claims in Europe is far broader, allowing claims for detecting a disease or mutation or comparing genetic sequences.¹⁸⁶ The combined effect of the two cases may, therefore, make Europe seem a far friendlier place for the biotech industry, and investment in infrastructure, research, and commercialisation may increase in biotech strongholds, such as Germany and Switzerland.

Nevertheless, where a biotech company is based and commercialises its products is determined by many factors, of which patent law is only one. The United States has many other factors that make it a good home for industry and for commercialisation. For example, the country is stable and secure and has both good infrastructure and a relatively well-educated populace. It also has a relatively large population representing a wealthy consumer base. As a consequence, it seems unlikely that the biotech companies would simply choose to move to Europe or to focus on other patent-friendlier markets for commercialisation. It is far more probable that they will seek other means to retain a competitive advantage. For example, companies may choose to keep more as trade secrets, both in the United States and in Europe. A large part of why *Myriad Genetics* had a competitive advantage did not even have to do with their BRCA patents, but rather with their immense and secret database of mutations, related clinical outcomes, and patient data relating to breast cancer.¹⁸⁷ The impact of *Myriad* could be to encourage biotech

183. U.S. PATENT AND TRADEMARK OFFICE, *supra* note 166, at 13.

184. There are those that argue that it is correct that a link between a mutation and a disease be considered "a fact derived from nature, and the activity of identifying and making this link constitutes a mental act (or even a discovery) rather than an invention." Isabelle Huys et al., *The Fate and Future of Patents on Human Genes and Genetic Diagnostic Methods*, 13 NAT. REV. GENETICS 441, 445 (2012).

185. U.S. PATENT AND TRADEMARK OFFICE, *supra* note 166, at 14.

186. See, e.g., Huys et al., *supra* note 184, at 444; Isabelle Huys et al., *Gene and Genetic Diagnostic Method Patent Claims: A Comparison Under Current European and US Patent Law*, 19 EUR. J. HUM. GENETICS 1104, 1106–07 (2011). One way in which method-claim patentability is still wider in the United States is through claims for methods of medical treatment, which are not patentable in Europe. European Patent Convention, art. 53(c), Oct. 5, 1973, 1065 U.N.T.S. 199 (as amended Nov. 29, 2000).

187. Rochelle C. Dreyfuss & James P. Evans, *From Bilski Back to Benson: Preemption, Inventing*

companies to emulate such behaviour, which could prove to be negative for both research and the healthcare systems of the United States and Europe.

One could argue that a negative aspect of the *Myriad* decision is that Europe-based companies may find it harder to recoup their costs in the United States. However, the impact of *Myriad* may be significantly cushioned by the fact that the trend in Europe and the United States had, in any case, been to move away from broad nucleic acid claims or at least to diversify the invention across many types of claims. This is in part because many genetic sequences have been published and are part of the public domain.¹⁸⁸ In Europe, claims have become narrower because of the strict way in which the inventive step standard has been policed, meaning that simply isolated genetic materials are often claimed as part of method claims rather than product claims.¹⁸⁹ The obviousness standard in the United States has similarly been construed more strictly with respect to whole-gene patents.¹⁹⁰ A potential difficulty may arise from the fact that biomarkers, including genomic biomarkers, are becoming more important and product claims over them are still sought.¹⁹¹ The difficulty is lesser in Europe, where they can be claimed within method or use claims. It is more problematic in the United States, where their method or use claims may be nonpatentable due to *Mayo*. Indeed, it seems that the largest difference between the United States and Europe may play out with method claims, not product claims.

A potential implication of the *Myriad* ruling, and the fact that the law in Europe and the United States is now different, is that patent drafters will have to take more care in their priority filings. If first filed in the United States, a patent has to be broad enough to set priority for an EPO filing that allows for wider subject matter. This means that one may have to include claims that one knows will be rejected. If first filed in through the EPO, it must be done so in a way that valuable claims can still be made in the U.S. filing. It may be that applications will simply have to have more and diverse claims. However, as noted above, the strict means by which the EPO assesses the inventive step standard may mean that the difference between what can be patented as a product through the EPO compared to in the United States is not so great. In other words, one could say that the United States narrows claims earlier through the eligible subject matter inquiry, whereas the EPO narrows later with the inventive step standard. In any case, because of the unclear interpretation

Around, and the Case of Genetic Diagnostics, 63 STAN. L. REV. 1349, 1369 (2011); E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, GENETICS MED. April 2010, at S39, S61. Of course, they were partly able to build such a large database because of the patents they held.

188. Huys et al., *supra* note 184, at 446.

189. The European inventive step standard is generally considered to be stricter than the U.S. nonobviousness standard. This is because it uses a problem-and-solution approach, whereby an examiner or court has to ask whether the invention would have been an obvious solution to an “objective technical problem” to a person skilled in the art, in light of the “closest prior art”; see EPO Guidelines, *supra* note 14, pt. G, ch. VII-3; cf. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) (reaffirming *Graham v. John Deere Co.*, 383 U.S. 1 (1966)).

190. See, e.g., *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009).

191. Matthijs et al., *supra* note 142, at 709.

of “markedly different,” patent drafters may deem it prudent to include multiple product claims with a range of alterations in order to ensure that some claims are held valid.

Overall, taken together, *Myriad* and *Mayo* have potentially broad implications for the biotech industry in Europe. However, these implications are significantly dampened by: (1) other factors that make the United States an attractive place to operate and commercialise biotech inventions; (2) the trend away from patenting simply isolated biological materials; and (3) the strict way that the EPO assesses whether there is an inventive step.

C. *Research in Europe*

The impact of the narrowing scope of patentable subject matter in the United States on research in Europe will depend on the exact facts at hand. If invented in the United States and no patent is sought anywhere because of nonpatentability in the United States, researchers from everywhere gain. If something is patented in Europe but not in the United States, researchers from the latter could have an advantage over those in the former. It is important to remember, however, that unlike the United States, which has virtually no experimental use exception,¹⁹² most European countries have an exception for research. Under the European Economic Community (EEC) Community Patent Agreement from 1989, the exception allows “acts done privately and for non-commercial purposes” and “for experimental purposes relating to the subject-matter of the patented invention,”¹⁹³ where the latter relates to determining the scope of the patent, whether the patent disclosure is adequate and to seek further knowledge about the patented invention.¹⁹⁴ It can include research to seek more scientific knowledge and technical improvement. Most EU Member States do not confine the experimental use exception to purely noncommercial use, so long as the research is really related to the subject matter of

192. Currently, there is no legislated exception in the United States; the common law (court-recognised) exception is extremely narrow in the United States and the research cannot have the slightest tinge of commercial interest. Even if there is no immediate commercial interest, it must be confined to private study “for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.” *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002). Specifically, it does not apply to actions that are “in keeping with the alleged infringer’s legitimate business, regardless of commercial implications.” *Id.* at 1362. “Legitimate business” has been defined broadly, such as to include research by nonprofit or government-funded research institutions and universities because their legitimate business is research. *Id.* at 1362–63; see also *Roche Prods. Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984); Helen M. Berman & Rochelle C. Dreyfuss, *Reflections on the Science and Law of Structural Biology, Genomics, and Drug Development*, 53 UCLA L. REV. 871, 877–88 (2006).

193. European Economic Community (EEC), Convention for the European Patent for the Common Market, Agreement Relating to Community Patents, art. 27(a)–(b), 89/695/EEC, 1989 O.J. (L 401) 1, 15. Note, however, that this agreement is not in force, as only Denmark, France, Germany, Greece, Luxembourg, Netherlands, and the United Kingdom ratified it. Switzerland has implemented similar exceptions to infringement in Art. 9.1 of the Patents Act 1954 (CH) (amended by No. I of the Federal Act of June 22, 2007, in force since July 1, 2008), despite that it is not a member of the EEC.

194. See, e.g., Patents Act, 1977, c. 37, § 60(5) (U.K.); *Monsanto Co. v. Stauffer Chem. Co.*, R.P.C. 515 (1985).

the patented invention.¹⁹⁵ The existence of the private use exception has been interpreted to mean that the experimental use exception must include commercial use.¹⁹⁶ Thus, even if something is patented in Europe but not the United States, it may not always be the case that U.S. researchers have an advantage over European researchers.

As discussed above, a likely situation is that companies will simply keep more information and knowledge in nonpublicly disclosed forms, such as trade secrets and nonpublicly disclosed databases. If they do so, they will obviously do so internationally. At the same time, we cannot presume that researchers from universities and publicly funded institutes will not also keep their information and knowledge this way, with patent trends showing that such institutes are proprietising their research results more and more.¹⁹⁷ Because of the cumulative nature of biotechnology,¹⁹⁸ the locking up of information and knowledge in such regimes could prove to be a detriment to research in the field, whether in the United States or Europe.

On the other hand, this very much depends on the strategy chosen by the keepers of the information/knowledge. It may well be that patents, even in restricted form, are a necessary component of a business model, perhaps together with trade secrecy and nonpublicly disclosed databases. This is not new, as illustrated by Myriad Genetics' approach to their BRCA research. This is strengthened by the fact that not all types of information or knowledge can be kept secret or in databases, such that patents have an integral role in incentivising invention and innovation. In such situations, the *Myriad* decision has the effect of encouraging better invention, or perhaps less fundamental research, in the United States (as simply isolating biological materials is becoming more and more standard) and restricting patentability to what inventors actually contribute, leaving the rest open for future research.

What may prove to benefit Europe is the perception of investors that Europe is more biotech friendly, as noted above. It may be that U.S. researchers have more freedom to research with less proprietary red tape (though arguably they will just encounter different red tape related to trade secrets); however, it is a separate question whether anyone would be willing to bring a product to market in the absence of patent protection. Within modern patent systems, patents are not only necessary to incentivise invention, but also innovation. The incentive is not only for the patentees themselves, but also for potential investors or venture capitalists, who require property as collateral and something well-defined to contract around, and

195. *Monsanto*, R.P.C. 515, at 538; see also AUSTRALIAN LAW REFORM COMMISSION (ALRC), GENES AND INGENUITY REPORT: GENE PATENTING AND HUMAN HEALTH, 339–41 (2004).

196. CORNISH ET AL., *supra* note 10, at ¶ 21–21.

197. See, e.g., Nicolas van Zeebroeck et al., *Patents and Academic Research: A State of the Art*, 9 J. INTELL. CAPITAL 246, 249–51 (2008).

198. James Boyle, *Open Source Innovation, Patent Injunctions, and the Public Interest*, 11 DUKE L. & TECH. REV. 30, 55–56 (2012); Bronwyn H. Hall & Dietmar Harhoff, *Recent Research on the Economics of Patents*, 4 ANN. REV. ECON. 541, 542 (2012).

also a “signal” or evidence as to the potential of the invention and the competence of the patentees.¹⁹⁹ Of course, whether Europe is seen to be better for commercialisation depends on the invention and if it could be claimed in a way such that a strong proprietary right is obtained covering the commercially valuable use in the United States or if a commercial advantage could be maintained through secrecy. However, it could be that the United States becomes a fertile ground for invention (i.e., research) but that Europe seen as more fruitful place for innovation (i.e., commercialisation).

D. *The Policy Discussion in Europe*

Perhaps even more interesting is the effect that the *Myriad* decision will have on the policy discussion in Europe. Of course, the EU and the U.S. legal systems are separate and do not set precedents for one another. However, it is not unheard of that important or revolutionary U.S. Supreme Court decisions influence patent law and practice around the world.²⁰⁰ Harmonisation between different nations is also desirable, as it smoothens the international application process. Moreover, if the Biotech Directive was largely adopted in order to ensure that the EU could compete with the United States and Japan, the decision has arguably given Directive naysayers some arsenal. From a logical perspective, the scope and effect of the *Myriad* decision on the Biotech Directive can only be narrow because the Directive is far broader in scope than just nucleic acids and materials isolated from biological specimens. However, the subject matter of the decision, gDNA, is so controversial for the average person, or even the average politician, who may not understand other biotech inventions, that the decision could have strong political force.

Countries such as the Netherlands, France, and Germany were already strongly opposed to the Biotech Directive, particularly with respect to human genes.²⁰¹ As a Member State of the EU, Germany was obliged to implement the Biotech Directive by July 30, 2000.²⁰² However, as a consequence of heated debate within the Federal Parliament regarding the patentability of biotechnology and particularly absolute gene-related claims, Germany missed this deadline.²⁰³ It was not until after a ruling by the Court of Justice of the EU that Germany was in violation of its EU obligations that Germany implemented the Biotech Directive,²⁰⁴

199. Hall & Harhoff, *supra* note 198, at 542; Dietmar Harhoff, *The Role of Patents and Licenses in Securing External Finance for Innovation*, 14 EIB PAPERS 74, 80–82 (2009).

200. See, e.g., *Diamond v. Chakrabarty*, 447 U.S. 303, 309–10 (1980) (holding that genetically modified organisms are capable of being a “manufacture” or “composition of matter,” and opening the door for biotech patents, is such a decision); Huys et al., *supra* note 184, at 1106.

201. See, e.g., Case C-377/98, *Kingdom of the Netherlands v. European Parliament and Council of the European Union*, 2001 E.C.R. I-07079; Case C-126/03, *Comm’n of the European Cmty. v. Fed. Republic of Germany*, 2004 E.C.R. I-11197.

202. Biotech Directive, *supra* note 7, art. 15.

203. JOSEPH STRAUS, *Product Patents on Human DNA Sequences: An Obstacle for Implementing the EU Biotech Directive?*, in PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT 65, 69 (F.Scott Kieff ed., 2003).

204. Case C-126/03, *Comm’n of the European Cmty.*, 2004 E.C.R. I-11197.

which came into force on March 1, 2005.²⁰⁵ However, the German legislature chose to specifically delineate that claims for human genetic sequences can only be purpose bound, stipulating that:

Where the subject matter of an invention is a sequence or a partial sequence of a gene, the structure of which is *identical* to the structure of a natural sequence or partial sequence of a human gene, *the use thereof, for which industrial application is specifically described in subsection (3), shall have to be included in the patent claim.*²⁰⁶

Similarly, the law in France states that the discovery of a sequence or partial sequence of a gene cannot constitute patentable inventions nor can the total or partial sequences of a gene as such.²⁰⁷ However, technical applications of a function of isolated human genetic sequences are patentable subject matter, but the protection only extends to the implementation and operation of the particular application.²⁰⁸ Article L611.18 of the Intellectual Property Code states:

Only an invention constituting a technical application of a function of an element of the human body may be protected by a patent. This protection shall cover the element of the human body only to the extent necessary to the realization and the exploitation of this particular use. Such use must be disclosed in the patent application in a concrete and precise manner. The following, in particular, shall be considered unpatentable:

....

d) total or partial sequences of a gene as such.²⁰⁹

The *Myriad* decision may highlight and pronounce the reservations already existent in Europe. Whether this will lead to any legislative change in EU law is difficult to say. This is for several reasons. Firstly, the Directive was not only implemented in reaction to broad patentability in the United States but also in the tech giant Japan, which still allows for patentability of isolated biological materials.²¹⁰ Secondly, as noted above, exactly what the *Myriad* decision entails is far from clear, and until it has been settled by the PTO and the U.S. courts (especially the Court of Appeals for the Federal Circuit), it would seem rash for the EU to react. It may be that *Myriad* is read very narrowly, for example, only to exclude simply isolated human genetic sequences from patentability—“human” because in the writ of certiorari that the U.S. Supreme Court granted to hear the appeal, the

205. Gesetz zur Umsetzung der Richtlinie über den rechtlichen Schutz biotechnologischer Erfindungen [Act Implementing the Directive on the Legal Protection of Biotechnological Inventions], Jan. 21, 2005, BGB-I 6, 146.

206. Patent Act 1980 (DE), sec. 1a(4) (as amended July 31, 2009) (emphasis added).

207. Code de la propriété intellectuelle [Intellectual Property Code] (FR), art. L611-18 (inserted by Act No. 2004-800 of August 6, 2004, art. 17a II, Official Journal of Aug. 7, 2004).

208. *Id.*

209. *Id.*

210. That the United States has stepped away from the law in Europe and Japan may prove challenging for the trilateral cooperation set up in 1983 among the USPTO, EPO and Japan Patent Office (JPO).

Court limited the inquiry to the question of whether human genes are patentable.²¹¹ Furthermore, the standard of “marked difference” may prove to be a very easy one to surpass. Thirdly, as a consequence of a challenge against the Directive from the Netherlands, the Court of Justice of the EU ruled in 2001 that the patenting of genetic and other materials isolated from the human body as per the Biotech Directive does not contravene human dignity.²¹² Taken together with the fact that the Biotech Directive took an opposition-filled fifteen years to pass, it may very well be that the EU legislature has no wish to revisit the matter.

CONCLUSION

What may or may not constitute an “invention” in the United States is by no means clear. This is in large part because of the sparseness of legislative guidance on the matter, forcing courts to interpret the court-made exception for “natural products,” which has proven to be challenging with the advent of the life sciences. Despite the wait and the hype, the U.S. Supreme Court’s *Myriad* decision was disappointing. In contrast, the EU passed the Biotech Directive in 1998, which was quickly adopted by the EPO. As a consequence, the patentability of certain types of biotechnologies is far clearer in Europe. Perhaps more importantly, the policy discussion attached to the Directive is indicative of the legislative intent, which is useful for analysing the patentability of new technologies.

Though *Myriad* did not set out a robust test for determining what is an “invention” as opposed to a “natural product,” it did make it clear that simply isolated genetic sequences do not constitute inventions. It remains to be seen whether this decision will be read narrowly or broadly by other courts, particularly the Federal Circuit, making it difficult to say what the consequences of the decision may be in the European context. Generally, the potential narrowness of the decision, along with the strength of the biotech industry in the United States and the fact that fewer patents were being granted for simply isolated sequences, suggest that the impact of the decision on the biotech industry will not be colossal. However, taken together with *Mayo*, it is possible that Europe will be viewed as more biotech-patent friendly. With respect to research, it is possible that U.S. researchers will have more freedom to operate; however, Europe will be seen by potential investors as a more favourable place to commercialise inventions than the United States. This is very much dependent on the particular facts at hand, as many information or knowledge holders may decide to lock this up as trade secrets or in nonpublicly disclosed databases, which would impact negatively on research in Europe and the United States.

It remains to be seen whether the *Myriad* decision will enter into the European policy discussion on patent law. Notwithstanding the Biotech Directive and EPO

211. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 694 (2012).

212. *Case C-377/98, Kingdom of the Netherlands v. European Parliament and Council of the European Union*, 2001 E.C.R. I-07079.

law, biotech patents are still considered to be controversial, particularly those pertaining to genes. When we consider that the Directive was largely adopted in order to ensure that the EU could compete with the United States, the *Myriad* decision seems to be a ready weapon for opponents of the Biotech Directive. However, until the exact implications of *Myriad* are clarified in the United States, any move for change would be imprudent.

