



**WORKING DOCUMENT**

**From The International Expert Group On Biotechnology, Innovation and Intellectual Property**

**MYRIAD GENETICS  
In the Eye of the Policy Storm**

**APPENDIX B: DETAILED LEGAL ANALYSIS OF GENE PATENTS, COMPETITION LAW AND PRIVACY LAW**

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In this appendix, we examine in greater detail the three legal arguments about Myriad and show that, despite the force of arguments put forward, there is very little uncertainty about the law and Myriad's legal position. There is, in fact, little doubt that human genes can be patented, that anti-trust and competition law does not prevent actors such as Myriad from exclusively licensing their inventions and that privacy law permits the citizens of one country to send blood samples, if they so choose, outside their country, even if the destination country has lower privacy standards. While one can object to the wisdom of the law in each of these three cases, our central point is that the law as it stood at the time was not in serious dispute and that Myriad seemingly was in compliance with the law. This indicates that the conflict over Myriad was not truly one of law but of policy.

## i) Patent law

Many criticisms relating to Myriad's patents over the BRCA1 and BRCA2 genes as well as over the diagnostic procedure to determine whether a mutation in those genes exists focused on their patentability. As noted above, current law does not seem to support any of these criticisms. Rather, it is a scientific understanding, and not the rules of patent law, that motivate each criticism.

Most countries now provide patent protection over genes and associated technologies. Genes are the physical units of heredity that parents pass down to children.<sup>1</sup> They are made up of a molecule called deoxyribonucleic acid (DNA). DNA itself is made up of sequences of components – called nucleotides.<sup>2</sup> Genes are fundamental as they contain the blueprint for the body to make proteins. It is the proteins that do the actual work in our bodies.<sup>3</sup> According to the Organisation for Economic Cooperation and Development,<sup>4</sup> gene patent claims relate to one of the following four categories: 1) whole genes or parts of them<sup>5</sup>, 2) proteins that the genes encode as well as their function in organisms, 3) vectors used for the transfer of genes from one organism to another, or 4) genetically modified cells or organisms, processes used for the making of genetically modified products and the uses of genetic sequences or proteins for genetic tests. Myriad's patent claims relate to categories (1) and (4) above, covering whole and partial gene sequences as well as a method of diagnosing breast and ovarian cancer through a genetic test.

According to both national laws and international agreements,<sup>6</sup> only *inventions* can be patented. Inventions must be things or processes that owe their existence to human intervention and must also be new, involve an inventive step (that is, not be obvious to someone with expertise in the field) and must be useful or have an industrial application. Any invention that fails to meet all three criteria will either not be patentable or, if it is, the patent will be ruled invalid by a court.

To understand the particular criticisms leveled against Myriad's patents over the BRCA1 and BRCA2 genes, it is necessary to briefly review the history of their identification. Over a number of years, scientists both within and outside of Myriad found out that the BRCA1 and BRCA2 genes lead the body to produce tumor suppressing proteins. (Genes themselves do not have a direct function on the body; rather, they produce proteins that do the work necessary to carry on life.) When present, these proteins reduce the chances that an individual will develop cancer. When there is a mutation in one of these genes, however, the body cannot produce the protein, thus increasing the risk of contracting breast or ovarian cancer.

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<sup>1</sup> See National Institutes of Health, online at: <http://www.genome.gov/glossary.cfm?key=gene> (last accessed September 1, 2008).

<sup>2</sup> See National Institutes of Health, online at: [http://www.genome.gov/glossary.cfm?key=deoxyribonucleic%20acid%20\(dna\)](http://www.genome.gov/glossary.cfm?key=deoxyribonucleic%20acid%20(dna)), last accessed September 1, 2008.

<sup>3</sup> See National Institutes of Health, online at: <http://www.genome.gov/glossary.cfm?key=protein> (last accessed September 1, 2008).

<sup>4</sup> Organisation for Economic and Cooperative Development, *Genetic Inventions, IPR and Licensing Practices: Evidence and Policies* (Paris: OECD, 2002) (OECD, *Genetic Inventions*).

<sup>5</sup> For example, cDNAs, ESTs, and SNPs.

<sup>6</sup> See for example, article 27 of the *Agreement on Trade-Related Aspects of Intellectual Property Rights*.

Based on this knowledge, Myriad and others applied for and obtained patents over the genes and associated diagnostic test.

The criticisms against Myriad's patents are fivefold. First, some claim that what Myriad did was simply to identify the function and sequence of two preexisting genes. This, they claimed, was a discovery and not an invention as no human intervention was required for the genes to possess this function.<sup>7</sup> Second, even if the act of sequencing a gene could be considered an invention in the abstract, the process of sequencing genes has now become so routine that that act alone can no longer be considered to be inventive.<sup>8</sup> Thus, if all the scientists did was sequence a gene, the 'invention' would be considered obvious and not patentable. Third, some argued that the problem with Myriad's patents is that they cover all possible functions – even those unknown at the time of application – of the genes and covered virtually all forms of diagnostic testing, even those not contemplated by the inventors. That is, the scope of the patent claims was too broad and should have been restricted to a specific, known function.<sup>9</sup> Fourth, arguments were made that Myriad's patent over the diagnostic test should be disallowed as it should fall within certain national exemptions that hold that methods of medical diagnosis and treatment cannot be patented.<sup>10</sup> Fifth, there was argument about whether Myriad's patent actually could be used to prevent certain activity, most prominently, research aimed at developing or improving diagnostic tests in the clinical setting.<sup>11</sup>

In the following subsections, we examine these arguments in turn.

- *Patenting Genes*

The argument that genes in general, and the BRCA1/2 genes in particular, do not meet the criteria for patentability is wanting in several respects. First, national patent law in OECD countries (including the US, Canada, Europe, Australia and Japan) clearly holds that genes can be patented.<sup>12</sup> It is even arguable that international trade agreements such as the *Agreement on Trade-Related Aspects of Intellectual Property Rights* requires this conclusion. The result is that, by and large, the steps required to isolate and purify genes in order to sequence them are collectively considered to be a sufficient intervention as to qualify the genes as inventions.

Patent law in the United States provides that any new and useful process, machine, manufacture, composition of matter or any new and useful improvement to any of the above, qualifies for patent protection.<sup>13</sup> While the law does not explicitly make a distinction between the concepts of invention and discovery, courts have held that certain categories of activity cannot be patented because they are 'products of nature'.<sup>14</sup> Included in this category are scientific principles such as the law of gravity and pure mathematical formulae. Genes, however, do not fall within these exclusions. Beginning in the 1980s, with the United States Supreme Court decision in *Diamond v. Chakrabarty*,<sup>15</sup> in which the Court held that a

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<sup>7</sup> See for example, Nuffield Council on Bioethics, *The Ethics of patenting DNA*, A Discussion Paper, online at: [www.nuffieldbioethics.org/fileLibrary/pdf/theethicsofpatentingdna.pdf](http://www.nuffieldbioethics.org/fileLibrary/pdf/theethicsofpatentingdna.pdf), at 56 (Nuffield, *Ethics of patenting DNA*). See also Gert Matthijs and Dicky Halley, "European-wide opposition against the breast cancer gene patents" (2002) 10 *European Journal of Human Genetics* 783.

<sup>8</sup> See for example, Richard Binns, "Gene patents: are they socially acceptable monopolies, essential for drug discovery? – reply" (15 January 2002) 7(2) *Drug Discovery Today* 102; , Gert Matthijs, "The European opposition against the BRCA gene patents" (2006) 5(1) *Familial Cancer* 95 (Matthijs, "European opposition").

<sup>9</sup> See, for example, Lori Andrews, "Genes and patent policy: rethinking intellectual property right" (October 2002) 3 *Nature Reviews: Genetics* 80 (Andrews, "Genes and patent policy").

<sup>10</sup> See, for example, Matthijs, "European opposition", *supra* note 8.

<sup>11</sup> Andrews, "Genes and patent policy", *supra* note 9; Matthew Rimmer. "Myriad Genetics: Patent Law and Genetic Testing" *European Intellectual Property Review* Jan. 2003: 20-33.

<sup>12</sup> See patent law charts at [www.cipp.mcgill.ca](http://www.cipp.mcgill.ca).

<sup>13</sup> 35 U.S.C. 101.

<sup>14</sup> See for example *Diamond v. Diehr*, *Parker v. Flook* 437 U.S. 584.

<sup>15</sup> 447 US 303.

genetically altered organism (a bacterium that cleaned oil spills) qualified for patent protection, the patent office has been granting patents over genes, animals, plants and other products of biotechnology. Essentially, the court held that the bacterium was altered to a sufficient extent to qualify as an invention. While raw products of nature – things that exist in exactly the same form in nature – are not patentable in the United States, the steps involved in isolating, purifying or modifying genes and gene sequences are sufficient to render the resulting product (i.e., genes in an artificial setting) an invention as opposed to a discovery. According to a statistic that the OECD cites, taken from the World Survey of Genomics Research website, the USPTO granted over 5,000 DNA patents in 2002.<sup>16</sup> In a more recent article (2005), Kyle Jenson and Fiona Murray identified 4,270 US patents containing claims on human DNA sequences.<sup>17</sup>

In addition to being in principle patentable, genes also satisfy the US criteria of non-obviousness (inventiveness), novelty and utility (industrial application). Under US law, a genetic sequence will not meet the test for non-obviousness if both the structure of the protein resulting from the gene is known as well as the procedure to determine the sequence of a gene that results in a protein with that function.<sup>18</sup> In other words, if the protein is known and we know how to find the gene that corresponds to that protein, then the gene itself cannot be patented.<sup>19</sup> Further, the US Patent Office's utility guidelines,<sup>20</sup> released in 2001, state that the utility of an invention must be substantial, specific and credible. Genes satisfy this test if an organism produces a protein, with a clear function, from the gene.<sup>21</sup>

Canadian patent law is similar in result to that of the United States. The Canadian *Patent Act*<sup>22</sup> defines inventions as any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter. The Canadian Intellectual Property Office and the courts include genes within this definition.<sup>23</sup> A patent claim meets the criterion of non-obviousness (inventive step) if someone who works in the field – the so-called 'skilled reader' – would not have directly and without difficulty come up with the invention. An invention meets the utility requirement if it is directed to a practical use and means. As of January 2002, there were over 2200 issued Canadian patents and over 15,000 applications that made reference to genes or "nucleic acids" in their claims.<sup>24</sup> It is worth noting that, although Canada is the only OECD country that does not grant patents directly over entire animals or plants, in practice this makes little difference. The Supreme Court of Canada has ruled that an inventor with a patent claim over a gene (or partial gene) has *de facto* exclusive rights over the entire animal or plant containing that gene.<sup>25</sup>

The European Patent Office (EPO), applying the European Patent Convention (EPC), adopts substantially the same criteria for patentability as in the US and Canada. It too grants patents over isolated genes with a known function. The EPO treats DNA sequences as analogous to chemical compounds: they are therefore considered inventions and not discoveries. In 1995, the EPO Opposition Division approved the grant of a

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<sup>16</sup> OECD, *Genetic Inventions*, *supra* note 4.

<sup>17</sup> K. Jenson and F. Murray. "The intellectual property landscape of the human genome" (2005) 310 *Science* 239.

<sup>18</sup> See recent case of *KSR Int'l Co. v. Teleflex 127 US 1727* (2007) ("*KSR*"), adopting a more flexible approach towards obviousness.

<sup>19</sup> D Nicol and J Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347 at 365. See also D. Keays, "Patenting DNA and Amino Acid Sequences: An Australian Perspective" (1999) 7 *Health Law Journal* 69 at 83; see 51 F.3d 1552 (Fed. Cir. 1995) and 991 F.2d 781 (1993) although see also *KSR*, *ibid*.

<sup>20</sup> United States Patent and Trademark Office, *Utility Examination Guidelines* (Washington, 2001), online at: <http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf> (last accessed September 1, 2008)

<sup>21</sup> See Julie Grisham, "New rules for gene patents" (2000) 18 *Nature Biotechnology* 921.

<sup>22</sup> *Patent Act*, R.S.C. 1985, c. P-4.

<sup>23</sup> For example, in both *Harvard College* and *Monsanto*, the Supreme Court of Canada held that genes were patentable.

<sup>24</sup> See Bereskin Parr, online at: <http://www.bereskinparr.com/English/publications/pdf/Bio-Patent-Genes-Nador.pdf>, last accessed September 1, 2008.

<sup>25</sup> See the Supreme Court of Canada in *Monsanto*.

patent for a gene that provided the code for a human protein that pregnant women produce, which had useful applications during the childbirth process. The Opposition Division held that scientists can patent a process to isolate a naturally occurring protein. In addition, if the protein so produced can be identified by its structure – for example, by identifying the sequence of DNA of the corresponding gene or the way the protein folds up – and was not previously known, the scientists can also patent the protein.<sup>26</sup> Later legislation by the European Union, and adopted as part of the European Patent Convention, confirmed this.<sup>27</sup>

One difference between European patent law and that in the US is that in Europe, the standard for inventiveness is slightly higher. The EPO will not grant a patent over a gene involving an isolated DNA sequence unless the process to identify the sequence involved ingenuity or if the sequence had surprising characteristics identified by the inventor.<sup>28</sup>

It should be noted that, while the EPO grants patents over genes, French law does not.<sup>29</sup> Nevertheless, since French law runs counter to European Union law on this matter, it is likely invalid.<sup>30</sup> Until a court rules on this, however, the French patent office will not award patents over human genes. Nevertheless, anyone wishing to obtain patent protection over a human gene in France need only apply for a patent through the EPC since this avoids French law.

Following the same pattern as in the US, Canada and Europe, Australia also grants patents over genes. The Australian *Patents Act*<sup>31</sup> provides that an invention is patentable if it is a 'manner of manufacture,' novel, involves an inventive or innovative step, is useful and has not already been used within Australia

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<sup>26</sup>Howard Florey/Relaxin 1995 O.J. E.P.O. 388 [Opp. Division]. See also in Steven Hildebrand, "Patenting of Human Genes in Europe: Prerequisites and Consequences" (2001) MAS-IP Diploma Papers & Research Reports, Paper 11, footnote 28 available online at: <http://www.bepress.com/cgi/viewcontent.cgi?article=1014&context=ndsip#search=%221995%20oj%20epo%20388%22> (last accessed August 8, 2008).

<sup>27</sup> In 1998, the European Parliament and Council passed the Directive 98/44 on the legal protection of biotechnological inventions that specifically stated that natural substances can be patented if isolated. Following on this Directive, the member countries of the European Patent Convention added Rule 23 to its implementing regulation that stated that an 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 the element is identical to that of a natural element.

<sup>28</sup> United States National Research Council of the National Academies, *A Patent System for the 21st Century* (Washington, D.C.: National Academies Press, 2004) online at: [http://www.nap.edu/catalog.php?record\\_id=10976](http://www.nap.edu/catalog.php?record_id=10976) (last accessed August 6, 2008) at 93 [National Academies, *Patent System for the 21st Century*]; European Patent Office, Japan Patent Office and United States Patent and Trademark Office, Trilateral Project B3b: Mutual Understanding in Search and Examination: Report on Comparative Study on Biotechnology Patent Practices (2001), Annex 2, 43. The Nuffield Council has agreed with this approach: Nuffield, *Ethics of patenting DNA*, *supra* note 7 at pp. 30, 50. In April 2004, the EPO upheld a challenge to Myriad Genetics Inc's patent on the BRCA1 on the basis that, among other matters, it did not involve an inventive step: European Patent Office, "'Myriad/Breast Cancer' Patent Revoked after Public Hearing", Press Release (Munich), 18 May 2004. In December 2003, the EPO issued revised examination guidelines that dealt with the 'industrial applicability' requirement for patenting genes. These guidelines now state that: "A mere nucleic acid sequence without an indication of a function is not a patentable invention ... In cases where a sequence or partial sequence of a gene is used to produce a protein or a part of a protein, it is necessary to specify which protein or part of a protein is produced and what function this protein or part of a protein performs. Alternatively, when a nucleotide sequence is not used to produce a protein or part of a protein, the function to be indicated could [for example] be that the sequence exhibits a certain transcription promoter activity."

<sup>29</sup> See France's bioethics law of 1994 which provides that "[t]he human body, its elements and products along with the partial or total knowledge of a human gene cannot as such be patented." Law No. 94-654 of July 29, 1994, J.O., July 30, 1994, p. 11,062; D.S.L. 1994, 29, 411

<sup>30</sup> E. Richard Gold and Alain Gallochat. "The European *Biotech Directive*: Past as Prologue" (2001) 7:3 *European Law Journal* 328.

<sup>31</sup> *Patents Act 1990* [Cth].

before the priority date of the patent application.<sup>32</sup> Australia has adopted the same distinction as in other countries between DNA sequences in their natural state and those that have been isolated and purified. So, as the Australian patent office (IP Australia) indicates in its patent manual, it will grant patents over DNA sequences and genes identified and copied from their natural source but artificially created if there is a clear function to the gene.<sup>33</sup>

Similarly, Japan provides patents over genes. Japanese law defines inventions as “the highly advanced creation of technical ideas by which a law of nature is utilized.” (s.2(1) Japan Patent Law). This is broad enough to include isolated genes that derive from nature, provided that the inventor is able to disclose the function of the gene.

In 1988, the Japanese Patent Office, European Patent Office and the United States Patent and Trademark Office issued a joint statement explaining the distinction between natural and man-made substances for the purposes of patent law in all of those jurisdictions: “Purified natural products are not regarded as products of nature or discoveries because they do not in fact exist in nature in an isolated form. Rather, they are regarded for patent purposes as biologically active substances or chemical compounds and eligible for patenting on the same basis as other chemical compounds”.<sup>34</sup>

So, while the exact standards may vary between countries, the US, Canada, Europe, Australia and Japan have clearly rejected the argument that genes cannot be patented because they are found in nature. They have all determined that isolating a gene, purifying a gene for the purpose of identifying its function and identifying mutations in a gene involves sufficient human intervention to justify calling the result an invention and granting a patent over it.

- *Scope of Gene Patents*

One of the most contentious issues relating to gene patents in general, and Myriad’s patents in particular, has been the setting of their appropriate scope. Critics argue that the scope of a gene patent should be limited to the particular function that the inventor describes in the patent application.<sup>35</sup> If this had been the case, Myriad’s patents would have been restricted to those mutations that it knew about at the time and the very particular form of genetic test that it utilized. Instead, the patents were broad patents covering the entire gene and any diagnostic procedures.

The scope of a patent right refers to how much activity falls within the rights of the patent-holder. That is, it refers to how many different things and ways of doing things are subject to the approval of the patent-holder. Patent offices make decisions as to patent scope when they grant patent rights and courts, when they interpret those rights. The broader the wording of the patent claim – the part of the patent application that describes what the patent covers – the greater the ability of the patent-holder to stop others from making and doing things in the same area.<sup>36</sup>

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<sup>32</sup> *Ibid* at s.18.

<sup>33</sup> See IP Australia, Australian Patents for: Microorganisms; Cell Lines; Hybridomas; Related Biological Materials and their Use; & Genetically Manipulated Organisms, online at: [www.ipaustralia.gov.au/pdfs/patents/specific/biotech.pdf](http://www.ipaustralia.gov.au/pdfs/patents/specific/biotech.pdf)→ at 16 June 2004. To date, Australia has provided patent protection over synthetic genetic or DNA sequences; mutant forms and fragments of genetic sequences (including polymorphisms); isolated or recombinant DNA coding for a sequence of a gene; proteins expressed by a gene; vectors containing a gene; probes for a gene; methods of transformation using a gene; host cells, higher plants or animals carrying a gene; and recombinant DNA methods—such as polymerase chain reaction (PCR) and novel expression systems. *Ibid*.

<sup>34</sup> Joint Policy Statement, US, Japan and European Patent Offices, 1988.

<sup>35</sup> OECD, *Genetic Inventions*, *supra* note 4 at 28.

<sup>36</sup> Centre for Intellectual Property Policy, “Genetic patents and health care in Canada: an international comparison of patent regimes of Canada and its major trading partners,” (2005) report prepared for the Canadian Biotechnology

Patent offices initially screen the patent claim. These offices review existing patents, technical journals and general knowledge in the relevant scientific field to determine exactly what the inventor has come up with that is new, is inventive (or, in some countries, non-obvious) and has an industrial use (or, in some countries, is useful). Patent examiners, working in these offices, negotiate the exact language of the patent claim with the inventor or, more often, a specialist patent agent representing the inventor. To the extent possible, given time and other constraints, when making decisions, patent examiners follow guidelines and manuals that the patent offices issue.

Once a patent is issued, however, it is for the courts to interpret the claims. This comes about usually when the patent-holder sues someone else for using a thing or a process that the patent-holder believes falls within the scope of the patent. Often, there is a slight difference between what the patent-holder described in the patent application and what the other person is doing. The court must decide whether the patent scope is sufficiently broad as to include that slightly different thing or process.

When it comes to how courts interpret patent claims – that is, how they go about making decisions about patent scope – countries fall into three basic camps. The first consist, at least until recently, of such countries as France and Germany which historically have tried to get to the essence of what the inventor invented. While, at a strictly technical level,<sup>37</sup> courts ask how someone with technical skill in the particular discipline would understand the words of the claims, in practice, courts read the language of the claims sympathetically to the inventor so as to give the inventor what he or she invented rather than what a strict reading of the claim language would give.<sup>38</sup> Recent cases in Germany indicate that the country may have moved into the second camp of countries below. Further decisions are necessary to determine whether this is the case.<sup>39</sup>

The second camp of countries includes Canada, the United Kingdom and Australia.<sup>40</sup> In these countries, courts undertake what they call a 'purposive analysis' of the claims. Similar to the first camp, courts ask how someone with technical skill in the particular discipline would understand the words of the claims. Instead of giving the claims a sympathetic construction, however, courts limit the claim scope to the strict language used to define the claims. This ends up meaning that courts in this second camp of countries read the patent claims more restrictively, thus diminishing patent scope.

Courts in the third camp of countries – which includes the United States and Japan – use a nearly literal approach to interpreting patent claims.<sup>41</sup> Their first step in interpreting claims is to break them down into their constituent components. They then give each component a literal interpretation (based on the language of the claim) and ask whether the equivalent component in the thing or process that the patent-holder claims is infringing is identical or almost identical. The court will only find that the second thing or process falls within the scope of the patent if the answer to this questions is 'yes' for each and every component. In addition, courts in the United States will limit a claim to the absolute literal terms – that is, without asking whether a component is almost identical – if the patent holder had asked for a broader

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[CIPP, *Genetic patents and health care in Canada*]; E.R. Gold and K. Durell. "Innovating the Skilled Reader: Tailoring Patents to New Technologies" [2005] 19[1] Intellectual Property Journal 189.

<sup>37</sup> Due, in large measure, to the adoption of the Protocol to Article 69 of the EPC that attempts to set out a harmonized set of rules for patent claim construction for all Member States of the EPC.

<sup>38</sup> See CIPP, *Genetic patents and health care in Canada*, *supra* note 36.

<sup>39</sup> See Bundesgerichtshof, GRUR 2002, 515 - *Schneidmesser I*; 519 - *Schneidmesser II*; 523 - *Custodiol I*; 527 - *Custodiol II*. See also Philippe Mueller, "Scope of Protection of Patents in the UK and Germany" [2005] MAS-IP Diploma Papers and Research Reports, Paper 1, online at: <http://www.bepress.com/cgi/viewcontent.cgi?article=1017&context=ndsip#search=%22Improver%20Corporation%20Remington%20Products%20german%22> (last accessed August 8, 2008).

<sup>40</sup> See CIPP, *Genetic patents and health care in Canada*, *supra* note 36.

<sup>41</sup> *Ibid.*

scope to his or her patent but had given this up during the negotiation process with the patent examiner.<sup>42</sup> However, in *Festo*, the United States Supreme Court rejected drew an exception for those cases where an amendment to a claim cannot reasonably be viewed as surrendering a particular equivalent – that is “ where the equivalent was unforeseeable at the time of the application or the rationale underlying the amendment bears but a tangential relation to the equivalent—the patentee can rebut the presumption that prosecution history estoppel bars a finding of equivalence by showing that at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent”.<sup>43</sup>

What is common to all three camps of countries is that the language of the claims circumscribes the patent-holder’s rights to a greater or lesser degree. If a claim covering a gene or a genetic test is written in broad and general language, then under the test in all countries, the scope will include all functions of the gene and test. The only limiting factor, then, is whether the law specifically requires – which it does not in general – the language of a claim over gene patents to be drafted restrictively.

So far, few countries have implemented rules that would specifically restrict the scope of a patent claim over genes. Germany provides one exception. German law requires that patents over gene sequences be restricted to the particular function associated with the protein that the gene produces.<sup>44</sup> French law provides, as we saw above, a second example by simply forbidding patents that cover human genes.<sup>45</sup> However, it is easy to avoid both sets of law by simply applying for a patent at the EPO rather than national patent offices.

We can thus conclude that, in almost all countries, the law has been clear on the question of patent scope for some time. Despite differences in interpretation between the three camps discussed above, the patenting of a gene covers all uses of that gene without limitation to any particular process of purification or isolation and without any limitation as to its function or intended use. While each country has its own way of interpreting patent scope, the scope of the patent can be quite broad and can extend to areas that the inventor neither described nor contemplated.<sup>46</sup>

Illustrative of the current position is the European Commission’s 2005 report on Directive 98/44 on the legal protection of biotechnological inventions in which the Commission specifically addressed the issue of the scope of gene patents.<sup>47</sup> The Commission noted that the majority of a group of experts called upon to examine the Directive concluded that there was no reason to restrict the scope of gene patents. In particular, legal and technical experts felt there were no differences between DNA sequences and chemical substances that could justify different treatment as regards the scope of patent protection. Thus, despite arguments that have been raised to limit patent scope – and that have led to legislation in Germany – in general there is no inherent limit to the scope of patent claims over genes or genetic tests.<sup>48</sup>

- *Patenting Genetic Tests*

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<sup>42</sup> See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., et al.* [2002] 535 U. S. 722 (“*Festo*”).

<sup>43</sup> *Ibid.* at 725.

<sup>44</sup> German Patent Statute (PatG), paragraph 1a Sec. 4 PatG.

<sup>45</sup> Law No. 94-654 of July 29, 1994, J.O., July 30, 1994, p. 11,062; D.S.L. 1994, 29, 411, article 7.

<sup>46</sup> OECD, *Genetic Inventions*, *supra* note 4 at 36.

<sup>47</sup> 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*, online at: <http://register.consilium.eu.int/pdf/en/05/st11/st11341.en05.pdf> (last accessed September 1, 2008).

<sup>48</sup> Australian Law Reform Commission, *Genes and Ingenuity: Gene patenting and human health (ALRC 99)* (Government of Australia, June 2004), online at: <http://www.austlii.edu.au/au/other/alrc/publications/reports/99/> (last accessed August 6, 2008). See also B Cain, *Legal Aspects of Gene Technology* [2003], 121–122.

A third argument that framed the conflict revolved around the question of whether Myriad's diagnostic genetic test was properly patented.<sup>49</sup> Specifically, did Myriad's claims over genetic tests constitute a medical procedure – the diagnosis of a possible medical condition – that properly fell outside the scope of patent law.<sup>50</sup>

The exemption of diagnostic methods exists in article 52(4) of the EPC as well as in Japanese law.<sup>51</sup> On the other hand, Canada (excluding methods of medical treatment),<sup>52</sup> the United States<sup>53</sup> and Australia<sup>54</sup> do grant patent protection over diagnostic procedures. Those countries with this form of exception justify it on the basis that any patents on how physicians diagnose or treat patients restricts the physicians ability to provide medical care and thus unduly impinges on the physician-patient relationship.

The exemption, even where it exists, does not cover genetic tests. Even in Europe, where the exemption is broadest, the EPO's Boards of Appeals has stated that the exemption is restricted to medical activities on the human body.<sup>55</sup> As genetic testing takes place outside the body – in the laboratory – these tests do not fall within the exemption. Further, it is a laboratory and not a physician that conducts the test, undermining the argument that the physician-patient relationship is at risk. The physician is only involved at the stage of providing counseling about the meaning of the test, an area generally untouched by gene or diagnostic patents.<sup>56</sup>

#### ▪ *Other Arguments*

Additional arguments concerned not the validity or appropriate scope of Myriad's patents, but whether patent law provided countervailing rules that could be used to limit Myriad's activities. In particular, some suggested<sup>57</sup> that two mechanisms, compulsory licensing<sup>58</sup> and research exemptions<sup>59</sup> could be used to

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<sup>49</sup> Article 27(3)(a) of the TRIPs Agreement permits, for example, countries to exclude methods of medical treatment, diagnosis and surgery from patent protection.

<sup>50</sup> See, for example, Matthijs, "European opposition", *supra* note 8

<sup>51</sup> Itsuki Shimbo, Andrew Cobden and Koichi Sumikura, "The Patentability of Medical Inventions related to personalized medicine in Japan" (2005) 11 *Nature Biotechnology* 1367.

<sup>52</sup> *Tennessee Eastman Co. et al. v. Commissioner of Patents* (1972), 8 C.P.R. (2d) 202 first established the unpatentability of methods of medical treatment.

<sup>53</sup> U.S. law includes a medical use exception at 35 U.S.C. § 287 (c).

<sup>54</sup> See *Anaesthetic Supplies Pty Ltd v Rescare Ltd* [1994] IPR 383 at 421.

<sup>55</sup> See G 5/83, OJ EPO 1985, 64.

<sup>56</sup> Although this may not prove to be true in the long term. In *Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc., et al.*, 548 U.S. XXX (2006), the United States Supreme Court avoided determining whether the mere mental process of associating a disease condition – in that case a vitamin deficiency – with a test result could fall within a patent claim.

<sup>57</sup> See, for example, discussion in Ontario Ministry of Health and Long-Term Care, *Genetics, testing & gene patenting: charting new territory in healthcare* (2002), online at: <http://www.gov.on.ca/health/english/pub/ministry/geneticsrep02/genetics.html> (accessed August 6, 2008).

<sup>58</sup> Most countries have provisions through which the State can use an invention without the permission of the patent holder in order to address these concerns. In most countries, this takes the form of a compulsory license or a license of right, as well as a government use provision. Most countries also provide compulsory licenses as a remedy for anti-competitive conduct. Canada, where legislation allows for the issuance of a compulsory license (section 19 of the *Patent Act*), could have invoked this provision to allow other labs to continue providing genetic tests. None of the federal or provincial governments ultimately decided to do so, however. See also, for example, section 83 of the Japan Patent Law, section 163 and section 133 of the Australian Patent Act.

<sup>59</sup> A research exemption permits researchers and the institutions to which they belong to make certain uses of a patented invention without paying a fee or risking patent infringement. The purpose of the exemption is to allow certain useful activities, such as research and testing, to be carried out without the need to obtain the patent holder's permission. For example, experimentation to satisfy regulatory requirements, experimentation in the context of clinical trials and general research aimed at improving the invention (whether or not commercial) can be undertaken, at least some countries, without the patent holder's permission. While the issue was never litigated in the context of the dispute with Myriad, it is arguable that research laboratories offering BRCA1/BRCA2 tests may have been able to

either exempt certain activities from Myriad's patents or could override Myriad's patents. Since both of these arguments have more to do with possible policy solutions than legal rights, this is discussed within the main text of the case study.

## ii) Competition law

Apart from the issues related to whether Myriad should ever have been issued its patents, criticism also centered on how Myriad exercised its patents rights. Specifically, there was considerable argument<sup>60</sup> about whether Myriad's business strategy of not licensing the genetic tests where the company had a virtual lock on the entire market for those tests violated competition or anti-trust law. In particular, commentators argued that Myriad's licensing practices constituted an abuse of its dominant position in the marketplace, contrary to competition law. Once again, however, on an examination of current law, Myriad's conduct did not seem to violate competition rules.

The interaction between patent law and competition law has not always been easy.<sup>61</sup> To understand it, one must first understand how patent licensing works. A patent license is a contract between the holder of a patent and another person – called a licensee – who wishes to make, use or sell the invention that the patent covered. Typically, the licensee agrees to pay the patent holder a fee or royalty (usually calculated as a fixed percentage of the licensee's revenues) in exchange for the ability to make, use or sell the invention. While patent law generally governs if a patent is awarded and the scope of that patent, competition/antitrust law determines whether those rights are used fairly in the marketplace<sup>62</sup> and, in particular, how the patent holder licenses the invention. Patent law and competition/antitrust law are therefore complementary in the sense that one deals with the nature and grant of the right and the other deals with how that right is actually used. As the Federal Trade Commission in the United States explains, the mere fact of having a statutory monopoly – that is, a patent right – does not necessarily lead to a violation of competition law.<sup>63</sup> Since the very nature of patent rights is that they provide exclusive rights in the marketplace, something more than merely exercising those rights is required before there is a violation of competition law. What this something more is, we examine next.

In Canada, the *Competition Act*<sup>64</sup> provides a remedy against "abuse of a dominant position." In particular, section 32 of the *Competition Act* prohibits the use of a patent right where that use lessens competition. Section 75 of the Act states that nobody can refuse to supply the market with a product on normal terms where there is a lack of competition for that product. In either case, the mere exercise of a patent right to exclude others from entering the market is not considered, by itself, to be anti-competitive. According to

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rely on research exemption to allow them to carry out their work in at least some countries. It should be noted that European countries, such as Germany, France and the United Kingdom, have all adopted legislation that tracks Article 31 of the *Community Patent Convention* (even though that convention is not in force) that states that patent rights do not extend to acts done for experimental purposes relating to the subject matter of the patent invention. Although the United States has not adopted a general research exemption (reinforced by, the Federal Court of Appeal for the Federal Circuit's decision in *Madey v. Duke University*, 307 F.3d 1351 ), the United States does have the most generous right to conduct research aimed at meeting regulatory requirements (see *Merck KGaA v. Integra Lifesciences Ltd., et al.*, 545 U.S. 193 [2005]).

<sup>60</sup> Nikolaus Thumm, "Patents for genetic inventions: a tool to promote technological advance or a limitation for upstream inventions?" [December 2005] 25(12) *Technovation* 1410 at 1414.

<sup>61</sup> See, for example, F. Scott Kieff & Troy A. Paredes, "The Basics Matter: At the Periphery of Intellectual Property" [2004] 73 *The George Washington Law Review* 174.

<sup>62</sup> The situation is a bit more complicated as patent law contains so-called 'abuse' provisions that prevent the patent holder from engaging in certain conduct. Generally, however, competition law and not patent law provides the regulatory framework for determining whether a patent holder's conduct undermines the fairness of the market.

<sup>63</sup> See Federal Trade Commission, "Promote Innovation: The Property Balance of Competition and Patent Law and Policy", online at: <http://www.ftc.gov/os/2003/10/innovationrptsummary.pdf> [last accessed September 1, 2008].

<sup>64</sup> *Competition Act*, R.S.C., 1985, c. C-34.

the Competition Bureau's Intellectual Property Guidelines,<sup>65</sup> the patent holder must engage in conduct that goes beyond what the patent right awarded. In other words, it is anti-competitive for a patent holder to use a patent right to obtain exclusivity in areas not covered by the patent right. For example, a patent holder that forces licensees to buy all their products from the patent holder – even where the patents do not touch on those other products – would be anti-competitive. In this context, licenses will only be considered anti-competitive if they reduce competition in other products that would not have been limited in the absence of the license. Therefore, the grant or withholding of an exclusive license to a patent product does not itself reduce competition as, even in the absence of the license, nobody would be able to make, use or sell the invention. However, if the license effectively limited competition with respect to other products or services not covered by the patent, it would violate competition law. Given that Myriad did not go beyond providing a license to market the BRCA1/BRCA2 tests in Canada, there was no reduction in competition beyond that which would have existed due to the patent alone.

The US has adopted a similar approach, as reflected in the Department of Justice's anti-trust guidelines for the licensing of intellectual property.<sup>66</sup> The approach in the United States is to examine whether licenses act as restraints on trade, for example, through naked price-fixing, output restraints, and market division among horizontal competitors, as well as certain group boycotts and resale price maintenance. The basic test tenet of anti-trust law in this area is whether the license's negative impact outweighs its pro-competitive impact in making the invention available to others. Given that exclusive licensing of the diagnostic test is no different, in principle, from any form of exclusive patent licensing and given the premise that patents are necessary for innovation to occur, there is nothing wrong with Myriad's licensing strategy from an anti-trust point of view (s.2 of the *Sherman Act*<sup>67</sup>).

In Australia, the *Trade Practices Act 1974*<sup>68</sup> (TPA) describes a range of anticompetitive conduct and the *Patents Act 1990* also contains provisions that seek to give effect to competition principles. In particular, s. 45 of the TPA forbids agreements that substantially lessen competition (collusive conduct) and s. 46 of the TPA provides that a corporation with a substantial degree of power in a market cannot take advantage of that power for the purpose of eliminating or substantially damaging existing competitors, or preventing the entry of potential competitors. Section 46 of the TPA is particularly relevant to the issue of patents and licenses.<sup>69</sup> According to Jane Neilsen,<sup>70</sup> current court decisions imply that it will only be in rare circumstances that a refusal to license will contravene s. 46 of the TPA. Generally, this will only occur where a patent holder stifles competition by refusing to license its invention to another party that either uses the invention in making its product or delivering its service or which sells a product in a completely different market.

In Japan, section 21 of the *Antimonopoly Act* provides that the Act does not apply to the exercise of rights under the Copyright Act, the Patent Act, the Utility Model Act, the Design Act, or the Trademark Act." However, the Japan Fair Trade Commission recognizes the tension between the IP rights and competition law. In 2007, the Japan Fair Trade Commission adopted new guidelines - *Guidelines for the Use of*

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<sup>65</sup> See Canadian Competition Bureau, *Intellectual Property Guidelines*, online at: <http://strategis.ic.gc.ca/pics/ct/ipege.pdf> (last accessed August 8, 2008).

<sup>66</sup> United States Department of Justice, *Antitrust Guidelines for the Licensing of Intellectual Property*, April 6, 1995, online at: <http://www.usdoj.gov/atr/public/guidelines/0558.htm> (last accessed August 8, 2008).

<sup>67</sup> *Sherman Act*, July 2, 1890, ch. 647, 26 Stat. 209, 15 U.S.C. § 1-7.

<sup>68</sup> *Trade Practices Act*, 1974, C2008C00305.

<sup>69</sup> Australian Law Reform Commission, "Issue Paper 2:7 Gene Patenting and Human Health" (Government of Australia, 2003), online at: <http://www.austlii.edu.au/au/other/alrc/publications/issues/27/> (last accessed August 8, 2008) at chapter 17.

<sup>70</sup> J Nielsen, 'Biotechnology Patent Licensing Agreements and Anti-Competitive Conduct', [2002] *Centre for Law and Genetics Occasional Paper No. 4*, online at: [www.lawgenecentre.org/fsvr/symposium2001/neilsen/pdf](http://www.lawgenecentre.org/fsvr/symposium2001/neilsen/pdf) (last accessed August 8, 2008).

*Intellectual Property under the Antimonopoly Act*<sup>71</sup> - dealing with the relationship between IP and competition law. According to these guidelines, the exercise of intellectual property rights is not subject to antitrust laws except when "...business activity that may seem to be an exercise of a right cannot be "recognizable as the exercise of the right" under aforesaid Section 21, provided that it is found to deviate from or run counter to the purposes of the intellectual property system, which is namely to motivate firms to realize their creative efforts and make use of technology, in view of the purpose and manner of the conduct and the scale of its impact on competition. The Antimonopoly Act is applicable to this kind of conduct".

As this summary of competition/anti-trust law indicates, different countries have slightly different understandings of the interaction between patent and competition law. Nonetheless, none of them would find that Myriad's practices in only providing exclusive licenses to market the BRCA1/BRCA2 tests amounted to a violation of the law. In general, countries have adopted the position that so long as a license does not prevent competition that would have existed in absence of the license, there is no violation of competition law. Since Myriad's exclusive license agreements essentially involves a transfer of the exclusive right to market the test from Myriad (the patent owner) to licensees, there was no 'extra' exclusivity created through those licenses.

### iii) Privacy Law

A third area of concern related to Myriad's practice of requiring patients to send blood sample to Myriad's laboratories in the United States. This was of particular concern to those living in countries with high levels of privacy protection (e.g. Europe) since the US has significantly lower levels of privacy protection.<sup>72</sup> Given that one can extract much private health information from a blood sample, there was a real worry that this information would not be adequately protected.<sup>73</sup>

While sending of samples abroad may undermine a country's ability to protect the privacy of its residents, there is nothing illegal (with the exception of in France<sup>74</sup>) about a patient agreeing to have a sample of blood sent abroad for analysis. In doing so, the patient voluntarily gives up – providing there was adequate informed consent – the right to benefit from his or her country's privacy laws. While this may be a policy concern, it is not a legal concern.

Based on the above analysis, whether one agrees with how the law is designed, it is quite clear that there was nothing inherently illegal in the granting of Myriad's patents or in its business strategy.

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<sup>71</sup> Japan Fair Trade Commission, *Guidelines for the Use of Intellectual Property under the Antimonopoly Act* (September 28, 2007), online at: [www.jftc.go.jp/e-page/pressreleases/2007/May/IPguideline.pdf](http://www.jftc.go.jp/e-page/pressreleases/2007/May/IPguideline.pdf) (last accessed September 1, 2008).

<sup>72</sup> For a discussion of the varying standards see W. J. Long and M.P. Long, "Personal data privacy protection in an age of globalization: the US-EU safe harbor compromise" [June 1, 2002] 9[3] *Journal of European Public Policy* 325 at 331. See also Gerhard Steinke, "Data privacy approaches from US and EU perspectives" (May 2002) 19[2] *Telematics and Informatics* 192.

<sup>73</sup> See, for example, Adam J. Wolfberg, "Genes on the Web — Direct-to-Consumer Marketing of Genetic Testing" (August 10, 2006) 355 *The New England Journal of Medicine* 543; Patricia A. Kaufert, "Health policy and the new genetics" [2000] 51 *Social Science & Medicine* 821 at 826.

<sup>74</sup> LOI n° 2004-800 du 6 août 2004 relative à la bioéthique, J.O n° 182 du 7 août 2004 page 14040, art. 8 modifying article L. 1221-12 of the code de la santé publique.