COMMENT

The Harold G. Fox Moot Lecture*

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"Keep your greedy hands off my genes!"
The U.S. Supreme Court's invalidation of gene patents is a victory for basic principles of patent law, but public policy concerns remain unresolved

The face of the biotechnology industry changed dramatically this summer when the United States Supreme Court held in *Association for Molecular Pathology v. Myriad Genetics Inc.* that naturally occurring DNA segments[1] are "products of nature" and therefore not patentable subject matter.[2]

In so doing, the Supreme Court's brief opinion overturned more than 30 years of U.S. Patent and Trademark Office practice and outraged the thousands of patent holders and their lawyers who had staked their careers on the presumed validity of issued gene patents.

Commercial empires have been built around biotechnology patents, of which gene patents are historically an important constituent. Between 1971 and 2006, ap-

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* Delivered by Ian Binnie on February 21, 2014.

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1 Genes guide the production of polypeptide chains that form proteins, which in turn make up living matter. Each gene is made up of a string of repeating paired subunits, or "nucleotides," which are referred to collectively as a "genetic sequence." In humans, genes are comprised of deoxyribonucleic acid (DNA) and are found packaged together into cells in units called "chromosomes." Complementary DNA or "cDNA" is genetic material in which only the protein-coding portions are conserved.

A helpful explanation of the relevant science is found in the trial level judgment of District Judge Sweet in *Association for Molecular Pathology v. Myriad Genetics Inc.*, 702 F.Supp.2d 181 at paras. 25–55 (S.D.N.Y., 2010) [*Myriad Dist. Ct.*].

2 *Association for Molecular Pathology v. Myriad Genetics Inc.*, 133 S.Ct. 2107 (Sup. Ct., 2013) [*Myriad USSC*].

proximately 33,000 nucleic acid patents were issued in the U.S. alone.[3] It is said that about 20 per cent of the human genome is now subject to patents, or at least it was until the *Myriad Genetics* decision sounded a death knell.[4]

While the fight in Canada over gene patents has played out in the political sphere, it has largely bypassed Canadian courts. Even the Myriad Genetics firm, despite a generally aggressive policy of patent enforcement, backed off the Canadian market. The national and provincial health ministries apparently proved too intransigent and the Canadian market too small for it to be worth "taking on the system." Today, several provinces including Ontario continue to administer and fund BRCA testing in flagrant disregard for Myriad's property rights.[5]

1. SOME BACKGROUND TO MYRIAD'S GENE PATENTS

In the 1980s, it was discovered that some women inherited a predisposition to breast and ovarian cancers. A researcher by the name of Mary-Claire King lead a team that identified one of the major players as the so-called BRCA1 gene on chromosome 17. In 1995, a second culprit, the BRCA2 gene, was identified on chromosome 13.

Scientists at Myriad used this pioneering research to identify the precise location and genetic sequence of the two BRCA genes, which increase a woman's risk of developing breast cancer from 12-13 per cent in the average population to up to 80 per cent. Some idea of the magnitude of this scientific achievement can be measured by the fact we are talking of two genes amongst the 24,000 genes spread over 23 chromosomesin the human body.

When the *Myriad Genetics* case reached the U.S. Court of Appeals for the Federal Circuit, Dr. James Watson, the co-discoverer with Dr. Francis Crick of DNA's double helical structure, despaired of the apparent judicial misunderstanding of the relevant science. His *amicus* brief to the U.S. Supreme Court included the following *cri de coeur*:[6]

> [W]hat the Court misses, I fear, is the fundamentally unique nature of the human gene. Simply put, no other molecule can store the information necessary to create and propagate life the way DNA does. It is a chemical entity, but DNA's importance flows from its ability to encode and transmit the instructions for creating humans. *Life's instructions ought not to be controlled*

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3 Stephen A. Merrill & Anne-Marie Mazza, eds., *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health* (Washington D.C.: National Academies Press, 2006). In 2013, a study in *Nature Biotechnology* reported that the number of U.S. patents currently in force and containing claims to simple nucleic acid molecules with natural sequences was closer to 8,000: Gregory D. Graff *et al.*, "Not quite a myriad of gene patents" *Nat. Biotech.* 31:5 (2013) 404.

4 Kyle Jensen & Fiona Murray, "Intellectual Property Landscape of the Human Genome" *Science* 310:5746 (2005) 239-240.

5 R. Gold & J. Carbone, "Myriad Genetics: In the eye of the policy storm" *Genetics in Medicine* 12:4 (April 2010 Supplement) S39 at S51 and S54.

6 Brief of *amicus curiae* James D. Watson, Ph.D. in support of neither party, filed with the Supreme Court on January 31, 2013, at p. 2 [*Watson brief*].

> *by legal monopolies created at the whim of Congress or the Courts*. (emphasis added)

In other words, DNA fragments are important not as compositions of matter, but as carriers of information. The attempt to patent "the messenger" is bad science as well as bad public policy.

The concern of Dr. Watson and other scientists is easy to appreciate. Isolation of the BRCA genes is a fundamental step in any diagnostic test for BRCA mutations. The plaintiffs in the *Myriad Genetics* case maintained that Myriad's aggressive enforcement tactics discouraged other scientific researchers from improving on the Myriad work and perhaps developing more accurate diagnostic tools.

While Myriad claims not to have impeded follow-on research, a chilling effect is broadly feared in the scientific community. John Sulston, head of the British effort in the Human Genome Project and joint winner of the 2002 Nobel Prize in Medicine, publicly cautioned that "many human genes have patent rights on them and this is going to get in the way of treatment unless you have a lot of money."[7]

Our view is that the U.S. Supreme Court was quite right in the application of traditional patent law to deny the patent. We expect that when the issue of gene patenting finally comes to Canada, the Canadian Supreme Court will likely reach the same conclusion, although perhaps for slightly different reasons (as will be discussed).

However, we also recognize that patents are blunt instruments. The innovator either gets a 20-year monopoly or it may get nothing. If one accepts that Myriad's work with the BRCA1 and BRCA2 genes was a major contribution to women's health, it seems unjust, and potentially inimical to the adequate funding of future research, to deny such innovators some reward.

In our view, if the proper balance is to be struck, it will be necessary to look to Parliament or the provincial legislatures to craft a scheme that assures continued funding of biotech research through some sort of "user-pay" system.

This solution may or may not involve property rights. But it must ensure that innovators' efforts are justly rewarded. The current attitude of our provincial health schemes, as described below, to rip off Myriad's discovery while refusing to pay any compensation at all to the innovator or to obtain statutory authority for their usurpation, is an unpromising foundation on which to assure the long-term future of healthcare.

2. SOME BASIC PRINCIPLES OF PATENT LAW

We now turn to five basic principles of patent law implicated by gene patents.

(a) Myriad Attempted to Patent a "Discovery" and not an "Invention"

Since their origins in the 17th century, patents (or "monopolies" as they were known in 1623) have distinguished between things that exist in nature and are only

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7 Alok Jha, "Human Genome Project leader warns against attempts to patent genes," *The Guardian* (24 Jun 2010), online: <http://www.theguardian.com/science/2010/jun/24/human-genome-project-patent-genes>.

"discovered" by research, and actual "inventions" which manipulate the natural world to create something "new" and "useful."[8]

In this respect, Myriad's "discovery" may be contrasted with the Harvard University researchers' "invention" of the oncomouse — the genetically engineered rodent with a heightened susceptibility to cancer.[9] In the *Harvard Mouse* case, every gene in the oncomouse's body had been modified. The majority of judges on the Supreme Court of Canada concluded that the oncomouse was an unpatentable "product of nature" because although the oncogene was patentable and injecting that gene into a fertilized egg was the "but-for cause" of a mouse predisposed to cancer, the adult mouse developed through the natural process of gestation.[10]

In the case of *Myriad Genetics*, neither the physical structure nor function of the BRCA1 and BRCA2 genes was modified. Even Myriad claimed no more than that these genes had been extracted from their natural setting and purified of any other cellular material. That perfect replication of nature was what enabled the alleged invention to be useful in diagnostic testing.

(b) Genetic Material, as a "Product of Nature", Belongs to All Humanity and Cannot be Reduced to a Form of Private Property

The "product of nature" rule is one facet of the prohibition on patenting discoveries. It arises from a sense that such things belong to everyone and are to be used for the common good.

Of course, "product of nature" is a somewhat elusive concept. Rocket ships can also be considered an aggregate of "products of nature", albeit the constituent elements have been reorganized and reconstructed with the benefit of human intervention. Nevertheless, the invalidation of gene patents was a rather straightforward application of the traditional rule, even though it was argued that isolated gene fragments of the sort claimed by Myriad do not exist "in nature".[11]

(c) In Canada, Biotech Companies Face the Additional Hurdle of the "Harvard Mouse Exception"

In 2002, the Supreme Court of Canada upheld the Commissioner of Patents' refusal to grant a patent to the Harvard researchers who had created (with nature's help) the oncomouse. The majority of the court appeared to acknowledge that the oncomouse egg itself could be the valid subject of a patent. It also concluded that

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8 *Statute of Monopolies 1623*, Ch. 3 21 Ja 1, s. 6.

9 *Harvard College v. Canada (Commissioner of Patents)*, [2002] 4 S.C.R. 45 [*Harvard Mouse*].

10 *Ibid. per* Bastarache J. for the majority, at para. 162.

11 In contrast to the E.U., Australian, District Court and Court of Appeals for the Federal Circuit cases, the record before the U.S. Supreme Court contained evidence that in fact isolated DNA fragments, including BRCA1 and BRCA2 genes, *are* routinely found in nature. While not explicitly referred to in the decision, this evidence was the subject of much questioning at the Supreme Court hearing and likely had a large impact on the result. See Brief for *amicus curiae* Eric S. Lander in support of neither party, filed with the Supreme Court on January 31, 2013 [*Lander brief*].

while the oncomouse egg had developed through the natural processes of gestation into a mouse, it ceased at some point in time to be patentable because patents are not available for "higher life forms". Unless the Supreme Court changes its view, it seems likely to bar the patenting of any element of a human being, even a fragment of the human genome, whether or not it is extricated, purified or isolated.

(d) Genetic researchers who merely "discover" elements of the natural world do not deliver any *quid pro quo* in exchange for a 20-year monopoly. They fail to fulfill the "patent bargain". The public gets nothing to which it is not already entitled

Patent law is based on a notional bargain between the inventor and the public. The former discloses its invention and how it works so that the person skilled in the relevant art will be able to work it when the patent expires. In exchange, the public confers on the inventor property rights in the invention, permitting 20 years of exploitation free from direct competition.

"Bargain theory" is typically viewed from the perspective of the public: what is the *public* getting in exchange for the 20-year monopoly? But a bargain implies mutuality, and it is also appropriate to ask what researchers like Myriad are getting in exchange for the major "discovery" they contributed to medical science.

Critics observe that, while in the short term, the public might think it is getting a better "bargain" by denying a patent to the genetic researcher, in the end such denial might turn out not to be much of a bargain if biotech research stalls for lack of steady and predictable private funding.[12] To make this observation is not to doubt the correctness of the outcome of the U.S. Supreme Court in *Myriad Genetics*. The "discovery" did not meet the criteria essential to establish an intellectual property right. But "bargain theory" should perhaps cause the public to explore new and different ways of rewarding an innovator.

(e) The denial of a patent on "products of nature" is said to be consistent with good public policy, or, as it is put on the *Statute of Monopolies 1623*, it accords with the "public convenience"

The U.S. Supreme Court has taken the view that patenting gene sequences would "tie up" the use of important, basic biological tools and inhibit rather than promote future innovation. Such an outcome, it said, "would be at odds with the very point of patents, which exist to promote creation."[13]

The notion that the inventor "creates," whereas the researcher merely "discovers" what is already there and would therefore be overcompensated by the grant of a patent, is good patent law but questionable economics. The proposition that gene patents would inhibit rather than facilitate research is a hotly disputed topic on

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12 See, *e.g.*, the argument that was advanced by Myriad and accepted before the Court of Appeals for the Federal Circuit: *Association for Molecular Pathology v. Myriad Genetics Inc.*, 689 F.3d 1303 (Fed. Cir., 2012) [*Myriad CAFC*].

13 *Myriad USSC*, *supra* note 2 at 2116.

which current economic data is inconclusive.[14] On this issue, the U.S. Supreme Court has started to second guess the marketplace. (Of course, patent law has always kept a close eye on "the marketplace.")

The question is whether the court should be acting on an assumption about the economic effects of gene patents when the proposition is lacking in proof either way.

We now turn to a more detailed examination of these five "basic principles," and, more fundamentally, to whether their application in the *Myriad Genetics* case struck the correct public policy balance between private property and the entitlement of "the Commons."

3. DISCOVERY V. INVENTION

The existence of biotechnology, let alone its amazing expansion, was of course unimaginable at the time the original definition of "patentable subject matter" was drafted by Thomas Jefferson in 1793 (which is still more or less the definition we work with today).[15] Going back even further, the "privileges" granted under section 6 of the *Statute of Monopolies 1623* were limited to:

> . . . the sole working or makinge of *any manner of new manufactures* within this realme, to the true and first inventor and inventors of such manufactures, which others at the tyme of makinge such letters patents and graunts shall not use, soe as alsoe they be not contrary to the lawe or *mischievous to the state by raising prices* of commodities at home, or hurt of trade, or *generallie inconvenient*". (emphasis added)

The reference to "manner of new manufactures" is not as outdated as it may seem. It is the language still used in the definition of patentable subject matter in the Australian *Patents Act 1990*.[16]

Canadian lawmakers have since expanded upon the definition to include *art, processes, machines* and *compositions of matter*. Yet despite an abundance of par-

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14 Timothy Caulfield, "Reflections on the Gene Patent War: The Myriad Battle, Sputnik and Beyond" *Clin. Chem.* 57:7 (2011) 977–979 at 978.

15 Notably, the Canadian definition of patentable subject matter in section 2 of the *Patent Act* has been refined over the years to exclude any reference to discoveries.

16 Australian *Patents Act 1990*, s. 18(1): . . . an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim:

> (a) *is a manner of manufacture within the meaning of section 6 of the statute of Monopolies*; and
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> (b) when compared with the prior art base as it existed before the priority date of that claim:
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> (i) is novel; and
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> (ii) involves an inventive step; and
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> (c) is useful; and
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> (d) was not secretly used in the patent area before the priority date of that claim, by or on behalf of, or with the authority of, the patentee or nominated person of the patentee's or nominated person's predecessor in title to the invention.

liamentary reports and recommendations of special advisory boards like the Canadian Biotechnology Advisory Committee (created in 1999 to advise the Federal Government with respect to the patenting of biological materials), legislators have left it to the judges in most of the common law countries, and certainly in Canada, to apply dated legal terms originally intended to foster innovation in manufacturing industries like textiles, machinery, and soap,[17] to such exotica as "isolated" nucleic acid, eukaryotic cells, homologous chromosomes, and polypeptides.

Should some discoveries be patentable in some circumstances for limited purposes *pour encourager les autres*? Or should biotechnology be addressed in a different statutory framework, as is the case with industrial designs? Or, as a further alternative, should "the Commons" simply appropriate "discoveries" for its own use and benefit on the questionable basis that they were already *in situ* when extraordinarily sophisticated researchers "unveiled" their existence?

(a) Should "Anything Under the Sun" be Patentable?

When the issue of patenting genetically modified life forms first came before the U.S. Supreme Court in *Diamond v. Chakrabarty*,[18] the court footnoted the Commissioner of Patents' sublimely confident view that "anything under the sun" could, should and would be patented.

The court declined to go so far as to say that "anything under the sun" is patentable, but it opened the door to patents on a variety of life forms. The effects of the *Chakrabarty* decision quickly spread throughout the world (as did Chakrabarty's customized petroleum-eating bacteria). Gene patenting, which had begun in the 1970s, exploded as the U.S. Patent and Trademark Office granted a backlog of gene patent applications and eager patentees filed more applications in their place.[19] Australia, the U.K. and Canada followed suit and began granting patents on microorganisms and other biotech products.[20]

By the mid-90s, gene patenting was at its peak. In 1996 alone, a biotech company by the name of Incyte Pharmaceuticals filed applications for roughly 400,000 expressed sequence tags.[21] In 2006, one legal scholar observed:[22]

> A quarter-century ago it was unclear whether the subject matter boundaries of the patent system were expansive enough to embrace biotechnology and information technology. Today, it is not clear whether the patent system has any subject matter boundaries at all. (emphasis added)

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17 *Re Abitibi Co.* (1982), 62 C.P.R. (2d) 81 (Can. Pat. App. Bd.) at para. 7 [*Abitibi*].

18 *Diamond v. Chakrabarty*, 447 U.S. 303 at 309 (Sup. Ct., 1980) [*Chakrabarty*].

19 Matthew Rimmer, *Intellectual Property and Biotechnology: Biological Inventions* (Massachusetts: Edward Elgar Publishing Ltd., 2008) at 43-44.

20 See *e.g.*, *Ranks Hovis McDougall's Application*, [1976] 46 A.O.J.P. 3915 (Aus. Pat. O.); *American Cyanamid v. Berk Pharmaceuticals*, [1976] R.P.C. 231 (Ch. D.); *Abitibi*, *supra* note 17; *Re Application for Patent of Connaught Laboratories* (1982), 82 C.P.R. (2d) 32 (Can. Pat. App. Bd.).

21 Timothy Caulfield & Yann Joly, "Human Gene Patents and Genetic Testing; Chapter 36" in G. Patrinos and W. Ansorge, eds., *Molecular Diagnostics*, 2nd ed. (London: Elsevier, 2009) at 528.

22 Rimmer, *supra* note 19 at 45, quoting Rebecca Eisenberg.

In *Myriad Genetics* and a predecessor case, *Mayo Collaborative Services v. Prometheus Laboratories Inc.*, the pendulum swung back sharply.[23]

4. "PRODUCTS OF NATURE" ARE NOT PATENTABLE SUBJECT MATTER

According to the "product of nature" doctrine, if a scientist discovers what is really a "product of nature," that is, some aspect of the natural world that pre-exists its identification by human beings like "the heat of the sun, electricity or the quality of metals,"[24] any beneficial utility arising from the discovery is the result of nature's handiwork and not the patentee's. The question, in terms of patent law, is where does discovery end and invention begin? The concept was already entrenched in English law in 1902:

> Discovery adds to the amount of human knowledge, but it does so only by *lifting the veil and disclosing something which before had been unseen or dimly seen*. Invention also adds to human knowledge, but not merely by disclosing something. Invention necessarily involves also the suggestion of an act to be done, and it must be an act which results in a new product, or a new result, or a new process, or a new combination for production an old product or an old result.[25] (emphasis added)

The expression "lifting the veil" makes discovery seem easy. Sometimes this is true. In *Funk Bros. Seed Co. v. Kalo Inoculant Co.*,[26] the patentee had discovered that certain strains of naturally occurring bacteria did not inhibit each other when combined. The U.S. Supreme Court decided that the patentee could not monopolize this inherently useful property, as the bacteria "served the ends nature originally provided and act quite independently of any effort of the patentee".[27]

The theory is that the discoverer, as distinguished from an inventor, "is trying to get something for nothing."[28] Thus, regardless of whatever extraordinary exercise of skill and imagination may be required to bring a discovery to light, the fruits of the research will be retroactively characterized as "part of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none."[29]

Quite apart from patent theory, the application of the "product of nature" approach is not always predictable. What makes fruit skin treated with mold-resistant borax[30] less worthy of the grant of a patent than a purified and isolated DNA se-

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23 *Mayo Collaborative Services v. Prometheus Laboratories Inc.*, 132 S.Ct. 1289 (Sup. Ct., 2012) [*Mayo*].

24 *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 at 130 (Sup. Ct., 1948), *per* Douglas J. [*Funk Bros.*].

25 *Reynolds v. Herbert Smith & Co. Ltd.* (1902), 20 R.P.C. 123 at 126 (Ch.D.), *per* Buckley J.

26 *Funk Bros.*, *supra* note 24.

27 *Ibid.* at 131.

28 *Free World Trust v. Électro Santé Inc.*, [2000] 2 S.C.R. 1024 at para. 13.

29 *Funk Bros.*, *supra* note 24 at 130.

30 *Am. Fruit Growers v. Brogdex Co.*, 283 U.S. 1 (Sup. Ct., 1931).

quence encoding human erythropoietin?[31] Why is purified vanadium[32] not patentable, but purified adrenaline[33] and isolated prostaglandins[34] are? By what deceptively simple criteria can such lines be drawn and justified?

In the early era of biotech, the Canadian Patent Office was faced with many claims to living organisms derived through varying levels of human intervention. In *Re Abitibi*,[35] the Patent Appeal Board held that a mixture of fungal cultures was a true invention, as the fungi could only digest waste because the inventors had acclimatized the fungi to a new environment. In *Pioneer Hi-Bred Ltd. v. Canada*,[36] the Supreme Court suggested that new soybean varieties created by genetic engineering were an invention because the "intervention occurs inside the gene itself." In contrast, the court doubted the patentability of soybean varieties generated using historic Mendelian techniques of cross-breeding because in such a case, the patentee "did not in any way appear to alter the soybean reproductive process, which occurs in accordance with the laws of nature."[37]

The Supreme Court of Canada thus accepted the patentability of genetically engineered bacteria, fungi and other "lower" life forms. But in the later *Harvard Mouse* case, it rejected the patentability of "higher life forms" like animals. These contrasting judgments blur the line between discovery and invention, and illustrate the elasticity of the concept of "products of nature."

The blurred and shifting line between invention and discovery has led some to reject the distinction entirely. Addressing the validity of a patent on mixtures of bacterial strains in the 1948 *Funk Bros.* case, Justice Felix Frankfurter of the U.S. Supreme Court wrote:

> Everything that happens may be deemed "the work of nature", and any patentable composite exemplifies in its properties "the laws of nature". Arguments drawn from such terms for ascertaining patentability could fairly be employed to challenge almost any patent.[38]

The Australian Federal Court, Trial Division recently echoed these same concerns in upholding as valid Myriad's BRCA patents.[39] But the "product of nature" theory was reaffirmed in triumphant style by Justice Clarence Thomas writing for a unanimous U.S. Supreme Court in *Myriad Genetics*, overturning Myriad's attempt to patent "isolated and purified" genetic material.

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31 *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir., 1991).

32 *In re Marden*, 47 F.2d 958 (C.C.P.A. 1931).

33 *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (C.C.S.D.N.Y., 1911).

34 *In re Bergstrom*, 427 F.2d 1394 (C.C.P.A. 1970).

35 *Abitibi*, *supra* note 17 at para. 4.

36 *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623 at para. 15 [*Pioneer Hi-Bred*].

37 *Ibid.* at para. 19.

38 *Funk Bros.*, *supra* note 24 at 134-145, *per* Frankfurter J. concurring. See also *Myriad CAFC*, *supra* note 12 at 90, *per* Moore J. concurring.

39 *Cancer Voices Australia v. Myriad Genetics Inc.*, [2013] F.C.A. 65 (Aus. F.C.) at paras. 84, 91–103 [*Myriad Australia*].

Just prior to hearing the *Myriad Genetics* case, the U.S. Supreme Court had unanimously endorsed the strength of the "products of nature" doctrine in *Mayo Collaborative Services v. Prometheus Laboratories Inc.*[40] The patents at issue concerned the use of thiopurine drugs to treat autoimmune diseases such as Crohn's. Specifically, Prometheus Labs purported to patent a method for precisely identifying correlations between metabolite levels in a patient's blood and likely harm or ineffectiveness of the drug dose, thereby allowing physicians to determine the appropriate dosage for a particular patient.

Despite Justice Frankfurter's observation — almost a truism — that fundamentally everything is a "product of nature," the *Mayo* court signalled its reliance on that doctrine to help define the boundary between invention and "mere discovery." It held that the impugned method claims did not add "enough" to the naturally occurring phenomena, namely, the relationship between certain metabolites and the drug's effect, so as to satisfy the patent bargain.[41]

(a) The Myriad Genetics Controversy

And then came *Myriad Genetics*. At issue before the Supreme Court were nine "composition of matter" claims to the isolated BRCA genes and associated mutations, as well as to short fragments of the BRCA1 gene (which is thousands of nucleotides long) and BRCA1 complimentary DNA (or "cDNA").[42]

The ingenuity in Myriad's patents was that Myriad had, for the first time, identified the precise location and sequence of the BRCA1 and BRCA2 genes and their link to breast cancer and ovarian cancer.[43] Using this information, Myriad developed a diagnostic screen for mutations in the "isolated gene sequences" as opposed to the "normal" or "wild-type" sequences.

(b) U.S. Court of Appeals Says Genes are Inventions

The Court of Appeals for the Federal Circuit unanimously held that cDNA was patentable, on the basis that it cannot be directly isolated from nature but is "created" in the lab by excising the introns (DNA segments not involved in protein generation) from the native gene.[44]

At that point, the court divided on whether the isolated and "purified" BRCA genes were patentable inventions or mere unpatentable discoveries. The court was not much impressed with the "magic microscopic" test proposed by U.S. Government, which asked whether if a sophisticated instrument could be built to zero into the human body at the molecular level, could the researcher "see" the claimed gene

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40 *Mayo*, *supra* note 23.

41 *Ibid.* at 1297.

42 To put this figure in perspective, the Australian Federal Court noted that the human genome comprises approximately 3.2 billion individual nucleotides. See *Myriad Australia*, *supra* note 39 at para. 32.

43 *Myriad USSC*, *supra* note 2 at 2112-2113.

44 *Myriad CAFC*, *supra* note 12 at 65 *per* Lourie J., for the majority; at 98–100 *per* Moore J., concurring; at 143-144 *per* Bryson J., dissenting.

fragment? If so, the genetic material, isolated and purified or not, was *not* patentable subject matter.

An interesting feature of the debate amongst the judges of the Court of Appeals was the battle of more or less plausible metaphors from snapping green twigs and surgically removing kidneys, to Michelangelo extracting the statue of David from a piece of raw Carrera marble.[45] Eventually, the question that divided the court was whether the breaking of covalent bonds to isolate the gene sequences from the rest of the chromosome was an inventive act sufficient to give rise to patentable subject matter. The majority held that it was. Justice Lourie wrote:

> [T]he challenged claims are drawn to patent-eligible subject matter because the claims cover molecules that are markedly different — have a distinctive chemical structure and identity — from those found in nature.[46]

Justice Bryson, dissenting, disagreed. In his opinion, the act of isolating the genes, while difficult, added nothing "inventive" to the natural product.[47] He saw nothing remarkable about breaking a few covalent bonds.

(c) Public Policy Concerns

Justice Moore, the concurring judge, held that the genetic subject matter was probably *not* patentable as a matter of patent law. She wrote:[48]

> If I were deciding this case on a blank canvas, I might conclude that an isolated DNA sequence that includes most or all of the gene is not patentable subject matter.

However, she went on to state that as a matter of policy, the United States Patent and Trademark Office "has allowed patents on isolated DNA sequences for decades . . . we must be particularly wary of expanding the judicial exception to patentable subject matter where both subtle expectations and extensive property rights are involved."[49]

Essentially, given its long reliance on the settled practice of the U.S. PTO in issuing gene patents, the biotech industry had virtually earned squatters' rights to its intellectual property.

A similarly pragmatic argument was endorsed by the Australian Law Commission in its 2004 report on gene patenting:[50]

> 6.51 . . . legitimate concerns have been raised about the patenting of biological materials that occur in nature, but have been isolated and purified by humans. Isolated biological materials may, in some cases, replicate exactly the composition and characteristics of material that occurs in nature. Although one cannot deny the legitimacy of patenting processes for isolating

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45 *Ibid.* at 73–75, 104-105, 118-119, 134-135, 137.

46 *Ibid.* at 61.

47 *Ibid.* at 127-128.

48 *Ibid.* at 106.

49 *Ibid.* at 106-107.

50 Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health* (ALRC 99, 2004) at paras. 6.51–6.53, quoted in *Myriad Australia*, *supra* note 39 at para. 116.

> and purifying naturally occurring materials, or the legitimacy of patenting new chemical substances that are the product of human ingenuity, *there are attractive arguments for the view that such materials should not have been treated as patentable subject matter*.
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> 6.52 *However, the time for taking this approach to the patenting of products and materials has long since passed*. For decades, naturally occurring chemicals have been regarded by patent offices in many jurisdictions as patentable subject matter, when they are isolated and purified. This principle has been applied by analogy to biological materials, including genetic sequences, on the basis that they are "merely" complex organic compounds. This development was certainly not foreseen when the modern patent system was established, and a different approach might have been available when the issue first arose for consideration.
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> 6.53 Nonetheless, the ALRC considers that a new approach to the patentability of genetic materials is not warranted at this stage in the development of the patent system, for the following reasons . . . (emphasis added)

Had the swing judge on the U.S. Court of Appeals not been so concerned about the health of the biotech industry and switched her vote, the result would have been an invalidation of the patent at that stage.

(d) U.S. Supreme Court Says Genes Are Unpatentable Discoveries

The Supreme Court eventually came down on the same side as the dissenting Justice Bryson. Myriad had made an important discovery, but not an "invention." In its brief unanimous decision, the court confirmed that "[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the §101 inquiry."[51] Myriad had not created or altered the structure of the DNA or any of the genetic information encoded in the BRCA1 and BRCA2 genes.[52] It had merely discovered their precise location and genetic sequence. And this discovery, the court held, was not worth the grant of a 20-year monopoly.

In contrast, applications of Myriad's discovery, like Myriad's method claims for applying genes to treatment, or for isolating the genes, are patentable.[53] The court also agreed with the Court of Appeals that cDNA was patentable, on the basis that "the lab technician unquestionably creates something new when cDNA is made."[54]

The Supreme Court's reasoning is consistent with what many scientists have said all along about DNA's unique role as a carrier of information. Dr. Watson and Dr. Crick never applied for a patent for their identification of the helical structure

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51 *Myriad USSC*, *supra* note 2 at 2117.

52 *Ibid.* at 2116-2117.

53 *Ibid.* at 2119-2120.

54 *Ibid.* The outer limits of what constitutes an unpatentable discovery still remain muddy. For one, if isolated genes' inherent utility as information carriers is what distinguishes them from patentable subject matter, it is hard to see why cDNA is patentable. The Supreme Court also confusingly suggested that cDNA derived from very short series of DNA with no intervening introns would not be patentable, as it is indistinguishable from genomic DNA.

of DNA because "its importance flows from its ability to encode and transmit the instructions for creating humans" and, it is worth repeating, "life's instructions ought not to be controlled by legal monopolies created at the whim of Congress or the courts."[55]

Similarly, the utility of the BRCA genes in identifying women with an increased risk of breast and ovarian cancers did not arise from Myriad's work of isolation and purification, but because of the genetic information encoded therein by nature. To allow a patent on the inherent properties of a molecule naturally produced by the human body is, in the words of Dr. Watson, "lunacy."[56]

This seems to accord with the comment of Lord Hoffman in *Kirin-Amgen Inc. v. Hoechst Marion Roussel Ltd.*, addressing another biotech patent almost a decade ago:[57]

> Standing back from the detail, it is clear that Amgen have got themselves into difficulties because, having invented a perfectly good and groundbreaking process for making EPO and its analogues, they were determined to try to patent the protein itself *notwithstanding that, even when isolated, it was not new*. (emphasis added)

(e) Australia Disagrees with the U.S.

The Federal Court of Australia, Trial Division takes a different view. Making what sense it could of s. 6 of the *Statute of Monopolies 1623* and centuries of subsequent jurisprudence, and recognizing that the Australian Parliament had recently rejected proposals to amend the *Patents Act 1990* to exclude genetic materials from patent protection,[58] the trial judge concluded that *extraction* was the key to patentability. Isolated genes are patentable subject matter because, Nicholas J. said, they do not exist outside the cell,[59] but only become isolated and purified from other cellular components through human intervention.[60]

The Australian Court in effect concluded that Dr. James Watson and other scientists who argue that DNA sequences are simply carriers of information possess a poor grip of patent law. According to the trial judge:[61]

> [The] disputed claims are not to genetic information *per se*. They claim tangible materials. Much emphasis was placed by the applicants upon the informational character of DNA as a storehouse of genetic information. But the disputed claims are not to information as such. They could never be in-

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55 *Watson brief*, *supra* note 2 at p. 2.

56 *Ibid.* at p. 10.

57 *Kirin-Amgen Inc. v. Hoechst Marion Roussel Ltd.*, [2004] U.K.H.L. 46 at para. 132.

58 *Myriad Australia*, *supra* note 39 at para. 119.

59 As noted above, this may not be scientifically accurate in light of the evidence put forward before the U.S. Supreme Court in the *Lander brief*, *supra* note 11.

60 *Myriad Australia*, *supra* note 39 at para. 108. See also para. 77: "Second, because each of the claims is to an *isolated* chemical composition, naturally occurring DNA and RNA as they exist in cells are not within the scope of any of the disputed claims and could never, at least not until they had been isolated, result in the infringement of any such claim." (emphasis in original)

61 *Myriad Australia*, *supra* note 39 at para. 76.

> fringed by someone who merely reproduced a DNA sequence in written or digitised form.

Thus, basing himself on the unnatural properties of isolated and purified genetic sequences, Nicholas J. concluded:[62]

> [I]n absence of human intervention, naturally occurring nucleic acid does not exist outside the cell, and "isolated" nucleic acid does not exist inside the cell. Isolated nucleic acid is the product of human intervention involving the extraction and purification of the nucleic acid found in the cell. Extraction of nucleic acid requires human intervention that necessarily results in the rupture of the cell membrane and the physical destruction of the cell itself. And purification of the extracted nucleic acid requires human intervention that results in the removal of other materials which were also originally present in the cell. It is only after both these steps are performed that they extracted and purified product may be properly described as "isolated" in the sense that word is used in the disputed claims.

This decision is currently under appeal.

(f) Europe and the U.K. Take Their Own Approach

Europe and the U.K. have a directive from the European Parliament that explicitly allows patents on DNA sequences identical to those found in nature[63]:

> . . . inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.
>
> Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

Furthermore,

> 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 that element is identical to that of a natural element.

But Myriad has had a difficult time enforcing its BRCA patents in Europe and the U.K., despite the existence of the Biotech Directive. In the 2000s, opposition proceedings at the European Patent Office resulted in significant narrowing of Myriad's BRCA-related patents, which now cover a limited range of mutations and diagnostic methods.[64] Myriad's European patent on the isolated BRCA1 gene was revoked entirely (though not on the basis of subject matter).[65]

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62 *Ibid.* at para. 108.

63 Articles 3 and 5 of the Directive 98/44/EC of the *European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions*.

64 T 0666/05 (Mutation/UNIVERSITY OF UTAH); T 0080/05 (Method of diagnosis/UNIVERSITY OF UTAH); T 0156/08 (BRCA2/UNIVERSITY OF UTAH).

65 T 1213/05 (Breast and ovarian cancer/UNIVERSITY OF UTAH) at paras. 43–45. See also T 0666/05 (Mutation/UNIVERSITY OF UTAH) at paras. 74–76.

The European and Australian approaches to date are at odds with that of the U.S. Supreme Court.

As for Canada, we predict that the Canadian courts, if and when given the opportunity, may open up a new dimension in the public policy argument about the commodification and privatization of the higher life form, as it did in the *Harvard Mouse* decision. Then see how far Myriad gets with the patent bar's beloved legal truisms.

5. CANADA'S "HARVARD MOUSE" LIMITATION ON PATENTING "HIGHER LIFE FORMS" IS PORTRAYED AS A "COMMON SENSE" EXCEPTION

The Supreme Court of Canada split from the U.S. and most other jurisdictions in the world when it rejected Harvard University's claims to the oncomouse.[66] The majority in a 5-4 decision subscribed to the rather controversial view the adult mouse was unpatentable because it developed into a higher life form through the "natural process of gestation."[67] The majority concluded that Parliament had not intended the phrase "composition of matter" to include conscious, sentient living creatures (as opposed to bacteria and other "lower life forms") within its scope:[68]

> The fact that animal life forms have numerous unique qualities that transcend the particular [genetic material] of which they are composed makes it difficult to conceptualize higher life forms as mere "composition[s] of matter". It is a phrase that seems inadequate as a description of a higher life form.
>
> . . . . .
>
> *The distinction between lower and higher life forms, though not explicit in the Act, is nonetheless defensible on the basis of common sense differences between the two*. (emphasis added)

The dissenting judges, on the other hand, concluded that what was significant was not the "natural process of gestation" but the very unnatural product of a mouse whose every cell had been modified by human intervention for a new and medically useful purpose. The minority view was that "[t]he extraordinary scientific achievement of altering every single cell in the body of an animal which does not in this altered form exist in nature, by human modification of "the genetic material of which it is composed" was undoubtedly something that deserved patent protection.[69]

However, this unique "higher life form" limitation stands as the current state of Canadian law. The theory, likely, would be that just as the emancipation from slavery was based on the principle that one human being cannot own a "property" in another, so also the state cannot have intended to confer intellectual property rights in another human being, or parts thereof, including some or all of the human genome.

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66 *Harvard Mouse*, *supra* note 9.

67 *Ibid*. *per* Bastarache J. for the majority, at para. 162.

68 *Ibid*. *per* Bastarache J., at paras. 155, 163 and 199.

69 *Ibid. per* Binnie J., dissenting, at para. 8.

6. DOES GENE SEQUENCING PROVIDE A *QUID PRO QUO* IN EXCHANGE FOR PATENTABILITY?

The bargain theory is said to be the golden thread that weaves through patent law. A patent is based on a *quid pro quo*: in exchange for disclosing a new, useful and non-obvious invention to the public, an inventor is given the exclusive right to exploit his or her invention for 20 years. Accordingly, courts measure the validity of a patent in terms of the bargain concept: what is the public getting in return for excluding all others from the forbidden field fenced off by the claims?

But public policy would ignore at its peril the other side of the exchange. What, if anything, is the genetic researcher going to get for a very substantial contribution to the health and well-being of the country?

Gene-based diagnoses and therapies hold out great promise for the future of healthcare. There is no question that Myriad's diagnostic tools have saved countless women's lives, by helping to structure an appropriate course of treatment and to determine whether to undertake preventative options, including prophylactic surgery. Myriad has argued that its BRCAnalysis product has helped over one million patients to date.[70] Myriad did the work, made the discovery, and bargain theory suggests that it deserves a just reward.

We are all aware of one very famous client, Angelina Jolie. Myriad's stock rose to a 52-week high in the wake of Ms. Jolie's statement that genetic testing for women should be more widely available.[71]

The great unknown, and unknowable, is whether gene patents inhibit more downstream innovation than they promote.

Biotech research is costly: a 2008 study in *Nature* reported that on average, companies spend $1.24–$1.33 billion and more than a decade in bringing a new biologic to market.[72] The public purse has serious limits and private industry is not run on philanthropic lines.

Myriad says that it has invested hundreds of millions of dollars to improve upon its BRCA testing — in particular, it has built a database of genetic mutations that allows it to catch over 97 per cent of variants, as opposed to the 70–75 per cent caught using public databases.[73] Myriad has also denied that it enforced market exclusivity at the expense of basic research by other institutions. It has used its own profits to develop BRCA-related new products like its MyRisk Hereditary Cancer test, a diagnostic test covering 25 different genes in six different cancers, including the BRCA genes and, it says, has encouraged other private ventures to do the same.[74]

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70 Plaintiff's memorandum filed in respect of Case No. 2:13-cv-00640-RJS at p. 3, seeking a motion for preliminary injunctive relief against Ambry Genetics Corporation.

71 Christopher Caldwell, "Angelina Jolie and the dilemmas of genetic screening", *The Financial Times* (May 18, 2013) 7.

72 Henry Grabowski, "Follow-on biologics: data exclusivity and the balance between innovation and competition" (2008) 7 Nat. Rev. Drug Disc. 479 at 481-482.

73 Plaintiff's memorandum filed in respect of Case No. 2:13-cv-00640-RJS at p. 37, seeking a motion for preliminary injunctive relief against Ambry Genetics Corporation.

74 *Ibid.* at pp. 3-4, 37, 39.

On the other hand, the evidence that gene patents provide a necessary and sufficient reward to inventors is also slim.[75] Many also argue that the impact of the U.S.'s decision is likely to be limited, given the decline in patents on isolated and purified genes since 1999 and the corresponding rise of patents on cDNA and diagnostic tests, which will continue to receive patent protection in the U.S. based on *Myriad Genetics*.[76]

To date, Canada seems content to be a free rider in biotech: "let others do the work, and our health system will simply use the fruit of their research and refuse to pay for it." Several Canadian provinces continue to offer genetic testing in flagrant disregard for Myriad's Canadian patents.[77]

7. THE DENIAL OF SUBJECT MATTER PATENTABILITY REFLECTS SOUND PUBLIC POLICY AND "CONVENIENCE"

As noted earlier, while two of the three judges on the U.S. Court of Appeals voted to uphold Myriad's composition of matter claims, one of the judges constituting the majority did so on a sort of "squatters' rights" theory. Justice Moore agreed that as a matter of law the BRCA genes were not patentable, but that gene patents were necessary to foster biotech innovation and fulfill the underlying objectives of the patent scheme.

However, the U.S. Supreme Court was convinced that denying the patent monopoly would, on the contrary, lead to greater scientific research and development:[78]

> Laws of nature . . . are the basic tools of scientific and technological work that lie beyond the domain of patent protection. As the Court has explained, without this exception, there would be considerable danger that the grant of patents would "tie up" the use of such tools and thereby "inhibit future innovation premised upon them."

In other jurisdictions, public policy is weighed differently. The Australian trial court took a "reward for the sweat of the brow" approach:

> It would lead to very odd results if a person whose skill and effort culminated in the isolation of a micro-organism (a fortiori, an isolated DNA sequence) could not be independently rewarded by the grant of a patent because the isolated micro-organism, no matter how practically useful or economically significant, was held to be inherently non-patentable. In my view it would be a mistake, *and inconsistent with the purposes of the Act*, not to give full effect in such situations to the broad language [defining patentable subject matter]. (emphasis added)

For its part, Canada has weighed the goals of fostering innovation against other considerations like public healthcare.[79] There is concern about the long-term

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75 Caulfield, *supra* note 14 at p. 978.

76 See *e.g.*, Gregory D. Graff, *et al.*, "Not quite a myriad of gene patents" *Nat. Biotech.* 31:5 (2013) 404–410.

77 Gold & Carbone, *supra* note 5 at p. S54.

78 *Myriad USSC*, *supra* note 2 at 2116.

79 *Harvard Mouse*, *supra* note 9 *per* Bastarache J., at para. 185.

sustainability of universal healthcare when diagnostics and therapies are parcelled out to commercial suppliers like Myriad. Increasingly, for example, polygenic testing is seen to be more effective for diagnosis and treatment than testing for a single gene. The existence of many separate monopolies over each implicated gene would cause a huge impact, for example, in the diagnosis and treatment of illnesses like coronary heart disease, which is a leading cause of death worldwide and has been linked to over 300 genes to date.[80]

The collision between private reward and public healthcare is evidenced by Myriad's experience in Canada. In the 1990s, Myriad obtained broad Canadian patents on both the BRCA genes and related diagnostic tests. Nevertheless, several provinces continued to administer and fund BRCA testing — at a fraction of Myriad's cost and in some cases providing faster service.

So Myriad began in 2001 with an aggressive policy of enforcing its patents in the Canadian market. It issued several cease and desist notices to the provincial health plans, but with little result.[81] Myriad discovered that in addition to legal limits on patentability, there are practical limits. Following Myriad's letter to the Ontario Ministry of Health alleging infringement, the Ontario Government denounced Myriad's "monopoly pricing of a whole new category of diagnostics" that threatened the future of healthcare in Canada and was unacceptable.[82] In the end, the provincial governments simply told Myriad to get lost, which it did, presumably because Myriad decided the Canadian market was too small to be worth the effort of enforcing its intellectual property rights.

Myriad's American competitors now say they can offer equivalent diagnostics for less than a quarter of the price Myriad charges for BRCAnalysis.[83] For its part, Myriad continues to assert its BRCA-related patents in other jurisdictions, including the U.S. Since the U.S. Supreme Court's ruling, Myriad has initiated several suits on the basis of over 500 patent claims that it says are not affected by the ruling.[84] Many of the defendants have countersued, alleging anticompetitive behaviour.

As in Canada, the National Health Services in the U.K. continues to provide diagnostic testing without making royalty payments to Myriad.[85] As an alternative, some European countries such as France have implemented compulsory licensing schemes to avoid any question of infringement entirely.[86]

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80 Hui Liu, *et al.*, "CADgene: a comprehensive database for coronary artery disease genes" (2011) 39 Nucl. Acids Res. D991.

81 See, generally, Gold & Carbone, *supra* note 5 at p. S50–54.

82 *Ibid.* at p. S51.

83 Plaintiffs' Reply Memorandum in Support of Motion for Preliminary Injunctive Relief, filed in respect of Case No. 2:13-cv-00640-RJS at para. 46.

84 See *e.g.*, the plaintiff's Memorandum filed in respect of Case No. 2:13-cv-00640-RJS at p. 1, seeking a motion for preliminary injunctive relief against Ambry Genetics Corporation.

85 U.K. Houses of Parliament Post Note Number 401 regarding Biomedical Patents at p. 4.

86 Gold & Carbone, *supra* note 5 at p. S55.

When Canadian courts get around to dealing with the validity of gene patents, they will have the benefit of seeing, through hindsight, the effects of the U.S. Supreme Court's decision in *Myriad Genetics* on innovation (at least in the U.S.), and whether the public policy concerns about the loss of private funding for the significant development costs are borne out. If the Canadian Parliament concludes that the detrimental effects of a prohibition on isolated gene patents outweigh the benefits, it could always attempt to craft a legislative scheme to reward the innovators while avoiding the insolvency of public health care.

Whatever the outcome, Canadian courts will not be blind to Canadian public policy in terms of public healthcare and the cost of privatizing a significant and growing type of medical services. But fairness to innovators, and the need to encourage them to keep innovating, are also valid public policy objectives.

8. CONCLUSION

We started by laying out five basic tenants of patent law that are raised by the *Myriad Genetics* case:

> 1. Myriad attempted to patent a "discovery" and not an "invention."
>
> 2. Genetic material, as a "product of nature," belongs to all humanity and cannot be reduced to a form of private property.
>
> 3. In Canada, biotech companies face the additional hurdle of the "*Harvard Mouse* exception" for higher life forms.
>
> 4. The genetic researchers who merely "discover" elements of the natural are said to fail to fulfill the "patent bargain," as they do not deliver any *quid pro quo* in exchange for a 20-year monopoly.
>
> 5. The denial of a patent on "products of nature" is consistent with good public policy and the "public convenience."

Each of the five basic principles of patent law can be used to support contrary positions regarding the patenting of "naturally occurring" gene sequences.

First, it must be said that the boundary between discovery and invention is not as clear in 2013 as it was when Thomas Jefferson amended George Washington's draft bill 225 years ago. It is no doubt true today, as it was then, that the simple "discovery" of an abstract law of nature can never support a patent. Nor, according to orthodox patent law, should isolation of a naturally occurring gene sequence confer a property right. But "lifting the veil" on a hitherto unknown branch of nature understates the contribution of genetic research to the common good.

Although mapping the genome today is a much simpler exercise than it was when Myriad did its work in the 1990s, there is still no "magic microscope" with which researchers can access the secrets of our DNA. Biotech companies continue to work at the outer edge of scientific knowledge, and both economic theory and commercial fairness suggest that they should receive some reward for the intellectual capital thus contributed to "the Commons."

Second, the reliance on the "product of nature" exception to patentable subject matter does not tell the full story. Much of what is patented traces its roots to "products of nature," with varying degrees of human intervention. It is interesting that Dr. Watson did not rely on this exception when he protested the granting of gene patents. He looked at the problem functionally, and through the eyes of a

scientist, and pointed out with some vehemence that DNA's utility lies not in the "tangible materials" sought to be patented, but its role as a storehouse of genetic information. Recognizing the reality that DNA's importance lies not in its physical embodiment but in the realm of instructions to create life is, in many ways, a more satisfying approach to the denial of a patent than simply labelling the gene sequence a "product of nature."

Third, Canada's "higher forms of life" exception would likely lead to a ban on gene patenting on grounds unrelated to the *Patent Act* itself. As the majority in the *Harvard Mouse* case acknowledged, the exception for "higher life forms" is not based on the principle of patent law, but comes from the realm of "common sense."[87] It is likely that just as "common sense" proved fatal to the *Harvard Mouse* patent, a decade later "common sense" could dictate the rejection of gene patents, too.

Fourth, as to bargain theory, we ought to ask ourselves whether the public has treated genetic researchers fairly by appropriating their "discoveries" without reward on the basis that these researchers really did nothing but "reveal" to the public what the public already owned.

Fifth, public policy may require a more nuanced balance of public benefits and burdens than can be accomplished within the four corners of the *Patent Act*. Public policy presumably favours long-term solutions. In the long-term, money must be generated to fund tremendously expensive medical research. One potential solution is to reward the innovator on some sort of "user-pay" system. But the strategy of the provincial health ministries to operate as "free riders" on Myriad's valuable research is not a sound policy that should recommend itself to governments.

The bottom line is that this is one public policy decision that should be resolved by legislation. There could be a separate legislative scheme as there is for industrial designs. There might be some sort of specialized regulatory scheme, like the *Patented Medicines (Notice of Compliance) Regulations* for pharmaceuticals. Or, perhaps we need a statutorily-created and non-proprietary interest that recognizes that innovators have some rights to the fruits of their successes. Such a legislative scheme should offer a measure of limited statutory protection, plus a "compulsory licence" feature that could tailor the terms of the "bargain" to the particular circumstances.

Myriad got its "greedy hands" slapped by the U.S. Supreme Court in the American litigation. Whether this was a good idea from the perspective of public policy and bargain theory will only be evident as the financial fallout from this decision reveals itself. We hope that Canadian Parliament and the provincial governments are paying attention.

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87 *Harvard Mouse*, *supra* note 9 at para. 199.