Towards a Canadian Policy for Patenting Disease Genes

S. Jodi Gallagher
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ABSTRACT

Thousands of human genes, many associated with human disease processes and diagnosis, have been patented in Canada. The scope of these patents has restricted public access to genetic testing and raised the question of whether human genetic material should be subject to differential treatment by our patent law regime. The Canadian Intellectual Property Office (CIPO) has failed to offer guidelines on the application of patent laws to genetic material, symptomatic of the broader problem of a lack of strong federal leadership in this area.

In this paper I will engage the debate over patenting of human genes specifically as it relates to disease gene patents and will critically discuss various proposals for reform. For the purpose of my discussion I have assumed that access to genetic testing (specifically for breast cancer susceptibility) is desirable, that restricting access to testing is not ethically justifiable and that commodification of human genes can be harmful. Re-establishing an appropriate balance between private and public interests in biotechnology requires patent reform. In arguing for patent reform, I will focus on Myriad Genetics, a company that holds patent rights to breast cancer susceptibility genes [discussed infra] and is attempting to establish a worldwide monopoly on breast cancer susceptibility testing. Myriad’s claims have begun to stir a debate in the public over the application of patent law to the human genome and the potential harms of permitting commercial monopolies over genetic testing services.

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I. Introduction

Thousands of human genes, many associated with human disease processes and diagnosis, have been patented in Canada. The scope of these patents has restricted public access to genetic testing and raised the question of whether human genetic material should be subject to differential treatment by our patent law regime. The Canadian Intellectual Property Office (CIPO) has failed to offer guidelines on the application of patent laws to genetic material, symptomatic of the broader problem of a lack of strong federal leadership in this area.

In this paper I will engage the debate over patenting of human genes specifically as it relates to disease gene patents and will critically discuss various proposals for reform. For the purpose of my discussion I have assumed that access to genetic testing (specifically for breast cancer susceptibility) is desirable, that restricting access to testing is not ethically justifiable and that commodification of human genes can be harmful. Re-establishing an appropriate balance between private and public interests in biotechnology requires patent reform. In arguing for patent reform, I will focus on Myriad Genetics, a company that holds patent rights to breast cancer susceptibility genes [discussed infra] and is attempting to establish a worldwide monopoly on breast cancer susceptibility testing. Myriad’s claims have begun to stir a debate in the public over the application of patent law to the human genome and the potential harms of permitting commercial monopolies over genetic testing services.

Parts II and III of this paper present background information to genetic disease and the application of Canada’s Patent Act, infra to human genes. Part IV outlines the problem presented by companies such as Myriad who wish to explore the outer limits of their patent rights. Part V will examine the current state of patent law in Canada and conclude that the law currently exists in favor of Myriad’s claims, leaving the question of whether change is warranted. Part VI addresses the theoretical and practical implications of permitting patenting of human disease-associated genes and engages arguments in favor of and against the status quo principle of broad patentability. After concluding that patent reform is necessary to strike a better balance between legitimate private and public interests, Part VII presents a number of policy options available to decision-makers while an international consensus is given
time to develop. Part VIII concludes that further study and debate is necessary in the Canadian context. Two of the most appealing policy options are the implementation of a formal patent opposition procedure and a compulsory licencing scheme for human disease-associated genes.

II. UNDERSTANDING GENETICS & DISEASE

1. The Genetic Revolution

In the past fifty years we have witnessed a revolution in science that has spread to many unexpected areas of our existence. Since Watson and Crick first characterized the structure of DNA\(^1\), over 50 years ago, the romantic allure of genetics as the holy grail of medicine has been almost overwhelming. When the worldwide Human Genome Project was launched in the 1980s, with the goal of mapping, or sequencing the entire human genome, it was widely touted as promising a panacea of medical breakthroughs. A more sober view is emerging.

While knowing the sequence of the human genome is an impressive accomplishment, it is only a first step in a long process of scientific discovery and learning. Decoding the bare sequence of the human genome is much like having thousands of pages of text in another language without knowing where the punctuation fits, what parts are important or even how to translate the unfamiliar characters into an understandable form. Most of the human genome is junk-DNA (the unimportant parts of the foreign language text mentioned above) – non-coding sequences that normally get edited out when proteins, the building blocks of cells, are made.

In humans, DNA is organized into superstructures known as chromosomes. On each chromosome are thousands of DNA sections of particular interest. Each of these packets of DNA is known as a gene. In their natural form, genes are a raw product of nature and are not patentable.\(^2\) A geneticist who sequences a gene is not “inventing” the

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\(^1\) DNA is deoxyribonucleic acid, the form in which genetic information is stored in cells of living things. For a layperson’s review of the basic science of DNA, genes and inheritance see I. Rosenfield et al., DNA For Beginners (New York: W.W. Norton, 1983).

\(^2\) In the American case of Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 927 F.2d 1200 (Fed. Cir. 1991), cert. denied, 502 U.S. 856 (1991) [hereinafter “Amgen”], a researcher had purified
gene, since it exists in nature and was in a sense simply awaiting discovery. It is not the natural form of a gene that can be the subject of a patent claim, but rather the isolated, purified form of a gene that has been the object of considerable human intervention. Multiple manipulations are required to clone, amplify and sequence a very small portion of the genetic code that is of interest – the single gene.

2. Genetic Mutation and Genetic Disease

Purely genetic disorders are rare. Disease is more often related to complex interactions between genetics and lifestyle, accumulated exposure to toxins, environmental factors or infectious disease. Purely genetic disorders are those where a change in the DNA sequence for a specific gene (or genes) leads to a dysfunctional gene product being made by the body, which in turn causes a disorder or condition. Clinical examples include Tay Sachs syndrome, Canavan disease, spinal muscular atrophy and cystic fibrosis. The genetic laws of inheritance determine whether children of specific parents, who are affected or who are carriers, will develop the genetic condition in question.

While some gene mutations are known to cause disease, abnormalities in specific genes can be associated with increased risk for developing disease. Predictive genetic testing is designed to identify individuals with disease-associated genetic abnormalities before they develop any disease-related symptoms. Genes such as BRCA1 and BRCA2, for example, are associated with inherited susceptibility to breast cancer. Approximately 5-10% of all cases of breast cancer are thought to be genetically-linked. While the general female population’s lifetime risk for developing breast cancer is approximately 10%, those with specific mutations in genes known as BRCA1 and BRCA2 (for breast cancer genes 1 and 2), have approximately an 80% lifetime risk of developing

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breast cancer. An inherited predisposition, also called a susceptibility, to breast cancer can be detected by genetic testing for abnormalities in BRCA1/2.

While the chances of a woman in the general population having the relevant mutations in the BRCA1/2 genes is very low, access to genetic testing for breast cancer susceptibility is a key issue for women with familial histories of breast cancer. Those who discover they have inherited the BRCA1/2 mutations may consider preventative measures such as increased breast monitoring, chemotherapy, drug treatment or double mastectomy. Information gained from breast cancer susceptibility testing offers women with worrisome familial history of cancer options in the management of their own health care.

3. Disease Gene Patents

Discovering the sequence of a particular gene and the role of a gene’s protein product in the human body is the beginning of what can be a long road of application-directed research. Commercial products and services relating to genetic research can include diagnostic tests, drug development or gene-based therapies. In the eyes of private or even public institutions, patenting disease-related genes, as opposed to genes not directly related to disease processes, could offer the attraction of control over later, more profitable stages of research.

Before the gene patenting gold rush of the mid-1990s, a rich literature had begun to develop relating to the ethics of patenting human genetic material. What was merely an ethical debate has now become a matter of reality. Thousands of gene patents have been issued around the

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6 Stanford Program Report, ibid. at 534.
7 Canadian Biotechnology Advisory Committee, Patents in Genes (Background Paper) by E Richard Gold (Ottawa: CBAC, 2000) at 1, online: <http://cbac-cccb.ca> (date accessed: 20 October 2001) [hereinafter “Patents in Genes”].
world. In the United States, more than 1000 human genes have been patented with a further 10,000-20,000 human gene patents pending approval.

III. UNDERSTANDING THE BASICS OF CANADIAN PATENT LAW

A patent is a form of intellectual property that grants an inventor a limited monopoly over the practical application of a new idea. For a specified period of time, currently 20 years in Canada, a patent holder can exclude all others in the country from making, using or selling the invention without permission. The inventor must, in their patent application, make full disclosure of the patented innovation.

The federal Patent Act governs the procedure for acquiring a patent, the requirements an invention must fulfill to qualify for patent protection and the rights granted to a patent holder. The Canadian Patent Office operates as part of the Canadian Intellectual Property Office (CIPO), a branch of Industry Canada that administers laws in relation to copyright, trademarks and patents. Patent officers, under the authority of the Commissioner of Patents, are responsible for reviewing applications and granting patents on innovations that qualify for protection under the Act.

A mere discovery of something that exists in nature (which is not patentable) is legally distinguishable from inventions, which are patentable. Determining whether an innovation is a patentable invention is a two-step inquiry. First, the innovation must be patentable subject matter.

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9 Patents in Genes, supra note 7 at 3.
13 See <http://www.strategis.ic.gc.ca> for comprehensive information regarding patent application procedure and patent policy in Canada.
Scientific principles, abstract theorems, mathematical formulas, and methods of medical treatment including surgical procedures have been held not to be patentable.\textsuperscript{14} Second, it must be an "invention" within the meaning of the Act.

The definition of "invention", which has remained virtually unchanged since Confederation,\textsuperscript{15} is found in section 2 of the Act and states that an invention is

\begin{quote}
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.\textsuperscript{16}
\end{quote}

Three statutory requirements have been distilled from this definition. To be patentable, an innovation must be novel, non-obvious and have utility. Canadian patent law shares these basic requirements with patent regimes in many other countries.\textsuperscript{17}

Gene-based innovations are measured against the same patentability criteria as subject matter in other areas of innovation. Critics have suggested, apart from philosophical arguments that human genes are not an appropriate subject matter of property rights, that genes may not meet the technical requirements of novelty, inventiveness and utility.

\textbf{1. Novelty}

To be novel, the innovation must not be in the public domain anywhere in the world\textsuperscript{18} or be previously patented. The novelty requirement ensures that technology or products already in the public domain cannot be removed and monopolized by a single party. While genes themselves are not newly created, the knowledge of a gene’s sequence, function and method of its purification may be new. Some gene patent applications may fail on the grounds that knowledge of the gene se-

\textsuperscript{14} Patent Act, supra note 12 at s.27(8) [scientific principles, abstract theorems]; Tennessee Eastman v. Commissioner of Patents (1972), 8 C.P.R. (2d) 202 (S.C.C.) at 206 - 7 [methods of medical treatment including surgical procedures].

\textsuperscript{15} Intellectual Property Law, supra note 11 at 932.

\textsuperscript{16} Patent Act, supra note 12, s. 2.

\textsuperscript{17} See for e.g. 35 U.S.C. x 100-12 (1988).

\textsuperscript{18} In Canada, a one-year grace period exists pursuant to s. 28.2(1)(a) of the Act whereby inventors may publicly disclose their innovation and still qualify for a valid patent if the application in filed within one year of the disclosure. In some patent systems, absolute novelty is required such that any public disclosure of the innovation in advance of a patent application would defeat the statutory novelty requirement.
quence already existed in the public domain, but this is not a broad principled-based objection to disease susceptibility gene patenting. Given the fast-paced growth of knowledge in this area, perhaps novelty will become a significant hurdle to the patentability of human genes if the novelty requirement is interpreted differently, but currently this requirement offers little resistance to widespread gene patenting.

2. Non-Obviousness

Only inventive subject matter can be patented. If the innovation would be obvious to an "unimaginative skilled technician" in the relevant field of invention, it is unpatentable. Arguably, the isolated form of a gene meets this criterion. The value in isolating a particular DNA sequence from the vast amounts of DNA in a cell and the sequence itself are not obvious, even if DNA sequencing techniques are now standard. It is not the natural form of a gene that is patentable. The isolated and purified form of a gene, which does not occur in nature, is patentable provided the other statutory requirements are met. In the U.S., genes are viewed as complex chemical compounds that are patentable as a 'composition of matter'. Just as the purified form of a natural substance like the antibiotic penicillin are patentable, it is argued, so should genes be viewed as inventive and therefore worthy of patent protection. On this logic, it has been argued, "in chemistry, the elements would have been patented." It is difficult to construct a counterargument against this claim. Somehow, significant human intervention is seen to remove an innovation from the natural realm and make it an appropriate subject of patent protection.

3. Utility

The key criteria to meet when filing a gene patent is utility. Merely sequencing a gene offers insufficient information to warrant patent protection. CIPO requires that an innovation must have an actual, ult-

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19 The currently accepted test for obviousness was fashioned by the Federal Court of Appeal in Beecham Canada Ltd. et al. v. Proctor & Gamble Co. (1982), 61 C.P.R. (2d) i at 27.
mate utility in the traditional commercial sense in order to be patent-
able. General usefulness in basic research or treatment is insufficient. For a gene patent application to meet the utility criterion, the gene product must be known and have a useful function. Researchers cannot patent genes of unknown function or utility, hoping to later determine their importance to disease or research.

4. Scope of Patent Protection

Under current law, if a genetic sequence is isolated and is shown to be novel and have a function that is useful, that gene is patentable as a composition of matter derived from nature. Beyond the fundamental debate concerning whether human genes are properly the subject of patents, an additional issue of contention is the scope of protection that such a patent confers on its holder. Simply put, if BRCA1 and 2, the breast cancer susceptibility genes are patented, what does that mean for the holder of the patent and others members of the community? The defensible scope of patent protection is of critical importance in relation to disease gene patents. The scope of patent rights can impact the accessibility of genetic testing to the general public.

One part of any patent application is the “claim”, which defines the scope of the monopoly the applicant asserts is covered by the patent. Once the patent application is reviewed and approved, the claim defines the scope of the proprietary interest the patent holder possesses. In exchange for full disclosure of the details of an invention, a patent holder is granted a 20-year term to exclusively make, construct, use, sell or import the invention. In the case of gene patents, claims are being made for the right to exclude others from any method of using that DNA composition, including all diagnostic applications. Myriad, for example, has been granted a patent on the BRCA genes. In describing the utility of the BRCA genes, Myriad explained their testing for susceptibility to breast cancer and claimed a proprietary interest in all diagnostic and therapeutic applications of the BRCA genes. Myriad claims that patenting a gene to be used for genetic testing gives them rights over all testing

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23 Intellectual Property Law, supra note 11 at chapter 21; Patents in Genes, supra note 7 at 5-9.
24 Ibid.
of that specific gene. By stating their patent application claims broadly, Myriad has been granted patent rights in more than just their testing methodology.

As illustrated by examples in the U.S., biotechnology companies have already begun to aggressively monopolize the testing service market. Duke University holds the patent on the human Apo-E gene, which is linked to late-onset Alzheimer’s disease. Duke exclusively licensed its patent to Athena Diagnostics, a company who in 1999 demanded that all tests for Alzheimer’s be routed through its own labs. Similarly, the Miami Children’s Hospital, after patenting the gene linked to Canavan disease, attempted to enforce its patent by stopping other labs from conducting genetic testing on potential Canavan carriers.26

Many authors have accepted the view that gene patent holders can legitimately claim a monopoly over all therapeutic and diagnostic applications resulting from knowledge of their patented gene.27 This idea of the broad scope of a gene patent stems from traditional patent law principles relating to the market protection afforded inventors. When the subject of a patent is a distilled version of a naturally-occurring item, however, the relevant question becomes whether the patent protection extends to all uses of the natural form of the item as well. It seems the distinction between patenting the natural form of a gene and the isolated, purified form of a gene is illusory if the scope of patent protection is as broad as that claimed by patent holders such as Myriad Genetics, Athena Diagnostics and the Miami Children’s Hospital. I will address in a later section whether such broad patent rights are in the public’s interest and if not, whether government regulation is warranted.

IV. UNDERSTANDING THE CHALLENGE OF MYRIAD GENETICS INC.

Myriad Genetics Inc. [“Myriad”] is well on its way to acquiring a global monopoly on testing for breast cancer susceptibility. By May of 2001, the company held more than seventeen patents in Europe, the

26 Gene Blues, supra note 10; Disease Gene Patents, supra note 4.
27 See e.g. Disease Gene Patents, supra note 4; Gene Blues, supra note 10.
United States, Canada, Australia and New Zealand covering the breast cancer susceptibility genes BRCA1 and 2 and its BRACAnalysisâ testing method.\(^{28}\) Myriad’s gene patents claim a monopoly over all diagnostic and therapeutic applications of the BRCA1 and 2 gene sequences.

While Myriad was filing and processing patent applications on genes and testing methods during the 1990’s, both the public and private sectors were forced to respond to increasing demand for genetic testing for breast cancer susceptibility. Consequently, health authorities in the United Kingdom, France, Germany and various provinces in Canada developed their own genetic tests for BRCA1 and 2 mutations. Ontario, for example, began offering clinical BRCA1 and 2 testing in April 2000 through seven Regional Genetic Testing Centers.\(^{29}\) During the year 2000, approximately 1000 BRCA screening tests were conducted in Ontario at a cost of $800-$1200 per test.\(^{30}\) British Columbia, Quebec and Alberta have also been conducting BRCA screening tests in provincial laboratories. Once Myriad’s patents were finally granted in Canada,\(^{31}\) the company took aggressive steps to enforce the legal rights granted by CIPO.

In May of 2001, Myriad sent a cease-and-desist letter to all provincial governments notifying them of the company’s patents on the BRCA genes and that provincial programs testing for those genes constituted a patent violation. The letter demanded that all tests for breast cancer be routed through Myriad’s Canadian licensee MDS Laboratories\(^{32}\) or directly to Myriad’s worldwide testing center in Utah. Myriad’s screening costs $3850 per test.\(^{33}\)

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\(^{28}\) See www.myriad.com. The four Canadian patents are numbers 2,196,790, 2,196,795, 2,196,797 and 2,239,733.

\(^{29}\) From 1995-2000 BRCA testing was available in Ontario as part of clinical research projects.


\(^{31}\) Myriad’s Canadian patent on BRCA1 was finalized in October 2000 while the BRCA2 patent was issued April 2001: see www.strategis.ic.gc.ca.


Myriad’s aggressive steps to exercise its exclusive rights to perform diagnostic testing on the BRCA genes reignited a debate in the media and political circles over human gene patenting and the scope of patent protection in the public health arena. In July 2001, in response to Myriad’s warning, British Columbia’s Ministry of Health abandoned its three-year old testing program amid protests that the public could not afford private testing services. Ontario has taken a different tactic.

1. Ontario’s Response to Myriad

In the face of Myriad’s threat of patent infringement litigation, the Ontario government decided to continue funding the testing program at its provincial Regional Genetic Testing Centers. The province’s position is that:

services now provided by the Ontario hospitals do not constitute infringement of any valid claim of Myriad’s patent. The question of whether isolated genes should be patentable is still a matter of international debate.34

In recent speeches before the Ontario Advisory Committee on New Predictive Genetic Technologies, both Ontario Premier Mike Harris35 and the Minister of Health & Long-Term Care Tony Clement36 stated vehemently that Ontario would continue its testing program. Reaffirming the Ontario government’s position, the message to Myriad was clear – claiming a monopoly over all diagnostics related to the BRCA genes is not legitimate, and human genes should not be patented anyway.

Harris and Clement’s objections raised two broad arguments against Myriad’s viewpoint. First, granting exclusive monopolies over genetic testing would collapse our public health care system and make testing inaccessible to all but those who can afford to pay exorbitant private

testing fees. Since this result is unacceptable, the scope of gene patents must not be as broad as that claimed by Myriad, meaning that Ontario hospitals are not infringing any valid claim by Myriad in continuing their testing programs.

Secondly, a more fundamental argument was advanced that human genes are discoveries and not patentable inventions. Since the human genetic heritage belongs to everyone, the benefits of genetic research must not be concentrated in the hands of a select few companies or individuals. While the biotechnology industry may have a legitimate commercial interest in recouping costs and making a reasonable profit, these interests must be balanced against the public interest in having meaningful access to predictive genetic testing. I will further assess these arguments in Part VI of this paper, where I discuss whether patent reform is needed.

2. The Ontario Context: Webster

It is tempting to hypothesize that the Harris government took such a strong stand against Myriad, in part, because of a woman named Fiona Webster, an Ontario woman with a strong family history of breast cancer. Webster’s physician had recommended she undergo prophylactic double mastectomy as a preventative treatment. Webster wanted to be tested for the BRCA mutations before undergoing the surgery so that she could make a fully informed decision, but faced a two-year waiting list for access to research-based BRCA testing programs in Ontario. OHIP would pay $20,000 for the mastectomy procedure but refused to cover the $3600 cost for out-of-province genetic testing. A private donor paid the $3600 price tag for Webster to be tested by Myriad. The test was negative – Webster had not inherited the BRCA mutations that would put her at extremely high risk for breast cancer. She declined prophylactic surgery.

Webster fought for reimbursement of the cost of BRCA testing. In a precedent setting case before the Ontario Health Services Appeal and

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37 Recall that if a woman tests negative for the relevant BRCA mutations, her lifetime risk of breast cancer is approximately 10%, while women with BRCA mutations have a 70-85% lifetime risk of developing breast cancer: Stanford Program Report, supra note 5.

Review Board in 1999, Webster was prepared to argue that BRCA gene testing for women with a strong history of breast cancer was a “medically necessary” service, meaning that the Ontario Health Insurance Plan (OHIP) would be compelled to cover its cost. The case settled on consent, with the Health Ministry recognizing that BRCA gene testing was no longer experimental and that Webster’s testing was an essential medical service for which OHIP was obliged to pay.

The lesson from the Webster case seems clear. In Ontario, BRCA genetic testing for women with a strong family history of breast cancer is a medically necessary service that OHIP must fund. Testing for BRCA mutations in Ontario hospitals at $800-1200 per test is far cheaper than Myriad’s $3850 price tag for BRACAnalysis® testing. If 1000 high-risk women qualify for testing each year, the difference would be upwards of $3 million dollars to the provincial health care budget.

In the context of a constrained health care budget, an awakening debate over the ethics of human gene patenting, little federal leadership relating to biotechnology patents, a growing European backlash against Myriad’s BRCA patents, and the Webster case, Premier Harris’ government made a savvy move. They gambled that a bold response to Myriad’s demands would garner public support and precipitate action by the federal government in this arena. After all, Myriad’s expensive test is not the only one on the horizon. The health care system is being faced with potential monopoly pricing of a whole new category of diagnostics relating to human genetic research. As stated by Dr. Philip Wyatt, director of the genetic testing program at North York General Hospital:

Here is a corporation saying, ‘We own this material, here are the rules, here are the costs.’ There are hundreds of these patents coming. It’s

41 Approximately 1000 women underwent BRCA testing in 2000. If the difference in cost to medicare between Myriad’s test ($3850) and in-province testing ($800) is $3000 per test, testing 1000 women per year would mean a difference in cost of approximately $3 million dollars. If interest and awareness of breast cancer susceptibility testing creates a greater demand in future, the difference in cost could be even more staggering.
breast cancer today, prostate cancer and heart disease tomorrow. If they're all handled like this, it is the end of publicly funded health care.42

Since Myriad’s Canadian patents on the BRCA genes run until 2015 and the company seems intent on protecting its intellectual property, this is not an issue that will disappear on its own. A resolution to the Myriad challenge will set the stage for subsequent battles with other biotech giants over human gene patents.

3. Federal Leadership Needed

As Ontario Premier Harris has noted, in the arena of biotechnology and gene patenting, there has been a “troubling lack of action”43 on the part of the federal government. In 1993, the Royal Commission on New Reproductive Technologies recommended banning commercial genetic testing in Canada.44 If this recommendation had been legislated, Myriad’s exclusive Canadian licensee MDS Laboratories would be unable to perform testing, but the underlying questions relating to the breadth of patent law in relation to human genes or the legal scope of gene patent claims would have been left unresolved.

There is no policy framework at the federal level to deal with these issues and many groups are calling for a reexamination of Canadian patent law in light of the potential impact of gene patenting on the health care system. The issues and impact of human gene patenting are far broader than any single provincial jurisdiction and are constitutionally within the competence of the federal government to address. Some progress appears to be on the horizon.

In 1999, the federal government appointed the Canadian Biotechnology Advisory Committee (CBAC), “an expert, arm’s-length committee created under the renewed Canadian Biotechnology Strategy (CBS) to advise Ministers, raise public awareness and engage Canadians in an open and transparent dialogue on biotechnology matters.”45 The CBAC

42 Star article, supra note 33.
43 Harris Speech, supra note 35.
special project steering committee examining the “Protection and Exploitation of Biotechnological Intellectual Property (Including the Patenting of Higher Life Forms)” recently released an interim report which proposes a number of amendments to the Patent Act in light of current and emerging biotechnology issues. The CBAC project is still in the public consultation stage and is not scheduled to submit a final report until April 2002. However, it is not clear whether recommending sweeping reform is within the mandate of the CBAC Steering Committee or that considering the consequences of human disease-associated gene patenting is foremost on their agenda. More comprehensive federal analysis and reform in the area of gene patenting and regulation of genetic testing is required.

V. UNDERSTANDING WHY GOVERNMENT INTERVENTION IS NECESSARY

To warrant government intervention, Myriad’s monopoly over BRCA diagnostics must be contrary to the public interest. Arguments on this issue generally fall into two forms – deontological, which address the intrinsic rightness or wrongness of patenting human disease genes and consequentialist arguments that assess the consequences of the status quo approach to human gene patenting. It is not my goal to present the entire debate over whether human genes should be patented, but to engage the key arguments of specific relevance to disease gene patents such as those held by Myriad on BRCA1 and 2.

47 CBAC Interim Report, ibid. at 25.
1. The Ethics of Patent Law

The ethical and financial consequences of broad patent protection for human disease genes are currently not a consideration for those granting or refusing patents in Canada. According to Industry Canada, who is responsible for patent policy, the financial impact of human disease gene patents on Medicare has nothing to do with the Patent Act49 and is an issue for Health Canada.50 The United States Patent and Trademark Office has espoused a similar view, that their office exists to call “balls and strikes” on patent applications. Taking into account the potential effect of gene patenting on the accessibility of testing services “would be way outside the purview of the agency.”51 Some would claim this hands-off approach is appropriate. Patent law, they argue, operates for economic ends and is “entirely unsuited to arbitrate on moral and ethical questions.”52 Further, commentator C. M. Ho has opined:

A patent system is not a means of safeguarding the public interest. It is primarily a commercial and industrial tool that encourages innovation, divorced from social and ethical concerns.

Furthermore, since the Patent Act53 makes no explicit reference to ethics, it is argued, it would be inappropriate to reinterpret the neutral requirements of the Act as erecting ethical boundaries.

Unfortunately, it is beyond the scope of this paper to fully debate whether patent law legitimately incorporates ethical considerations. In constructing patent law as a social contract between an inventor and the government on behalf of society, I have implied it is appropriate to take into account broader social interests. Ethical analysis seems embedded in the normative elements of patent law. Judgements about whether an innovation has utility, for example, can be a subjective determination of what our society considers useful.54 Our patent law sets up a legal regime whose purpose is not only to create economic incentives and wealth, but to stimulate the overall level of invention in

49 Supra note 12.
53 Supra note 12.
54 Looney, supra note 8 at 251.
society. We must not ignore the ethical implications of our chosen patent law scheme.

2. The Status Quo Supports Myriad’s Claims

If federal leadership fails to materialize in relation to patenting human disease genes, legal battles such as that between Ontario and Myriad may continue to arise as patents are granted and enforced in other clinically relevant areas. Companies such as Myriad argue they have a right to recoup research and development costs and to exploit their patents to the fullest extent allowed by law. If Myriad were to bring a patent infringement suit against Ontario’s Health Ministry, it would be futile for Ontario to argue that human genes are not patentable material. The courts have stated clearly that patent law is to be interpreted broadly. In August 2000, the majority of the Federal Court of Appeal held that a genetically-modified mouse (the “Harvard oncomouse”) was patentable subject matter and that:

the provisions of the Patent Act have been cast in broad terms to fulfill Parliament’s objective — to promote invention. If anyone is of the opinion that the scope of patentability should be narrowed, it is open to that person to ask Parliament to do so.\(^5\)

The Court could easily offer the same reply to Ontario’s argument that human genes are not patentable under the Act. In addition, the Supreme Court of Canada has strongly stated that patent rights are broad in scope. Lamer J. (as he then was) for the Supreme Court of Canada in Pioneer Hi-Bred Ltd. v. Commissioner of Patents\(^5\) stated that the granting of a patent in Canada permits an inventor “exclusive right to exploit his invention for a period in exchange for complete disclosure to the public of the invention.”\(^57\) Based on these decisions, Myriad’s lawyers most likely feel quite confident that without legislative or regulatory reform, the Canadian courts would enforce broad subject matter patentability and a broad scope of exclusive rights to patent holders.


\(^{57}\) Ibid. at 265.
3. Interpretations of the Public Interest Can Vary

Human gene patents need not necessarily result in testing monopolies and outrageous prices. When researchers at the University of Michigan patented the gene associated with cystic fibrosis, a common lethal genetic disease, they prohibited exclusive licensing agreements and charged only $2 per test.⁵⁸ Arguably, Myriad’s testing is more labour intensive and high-tech than cystic fibrosis testing, but the contrast in philosophy about profiting from gene discoveries is startling. Francis Collins, one of the University of Michigan researchers who patented the cystic fibrosis gene, felt strongly that human genes are a common heritage that should not be patented.⁵⁹ While philanthropic gene patent holders will hopefully always exist, it would be naïve to assume that society can trust all patent holders to act primarily in the public interest.

In press releases and interviews, Myriad officials have attempted to justify their aggressive patent enforcement measures as being in the public interest. Myriad spokesperson Bill Hackett claims that Ontario women who are not using their lab’s sophisticated technology could be getting false results, thereby putting their health at risk. Myriad’s President Dr. Gregory Critchfield has stated that

> if you let everybody do their tests on any aspect of BRCA, we’ll end up having testing performed by mediocre labs; some have actually already been sued for not having detected mutations they should have seen.⁶⁰

By enforcing a testing monopoly, Myriad argues, they are simply establishing a standard of high quality testing that protects the public from inferior screening programs.⁶¹

The clever public relations spin Myriad has put on its monopoly position has been directly challenged by Curie Institute, a not-for-profit

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⁵⁹ Ibid.
cancer research group in Paris, France. In October 2001, the Curie Institute filed an opposition to Myriad’s European BRCA1 patent, challenging it on a number of technical grounds. The Curie Institute, having published data showing the BRACAnalysis® method fails to detect certain types of mutations in BRCA1, objected to the company’s claim of a monopoly over testing in Europe – an excessively broad scope of patent right.

Patent holders may operate in the public interest by offering unrestricted access to genetic testing or claim to be operating in the public interest by restricting testing. What constitutes the ‘public interest’ and how it is appropriately balanced against private interests must be examined more closely to determine whether current patent laws should be changed.

VI. UNDERSTANDING THE NEED FOR PATENT REFORM

1. Deontological Arguments: Human Disease Genes are Not Cell Phones

Fundamental objections to the patenting of human genetic material is fueling a rebellion against Myriad’s BRCA gene patents that extends far beyond Ontario. In addition to the Curie Institute’s opposition, testing agencies in Germany, Britain, and the Netherlands are refusing to stop testing in favour of sending samples to Myriad’s worldwide testing center in Utah. Dr. Gregory Critchfield, President of Myriad, argues that European labs cannot continue testing in the face of Myriad’s patent. He has analogized patents on human disease genes to those for consumer goods by asking, “[i]f I am a researcher that works in telecom and I want to be able to build my own cell phone, can I steal from Nokia?” In making such a comment, Dr. Critchfield has funda-

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mentally misunderstood the nature of the human genome. Genes, especially human disease genes, are not analogous to cell phones. Nor is access to cell phone technology analogous to access to predictive BRCA gene testing. Dr. Critchfield seems to have no difficulty viewing human genes as a commodity that is appropriately held as individual property and subjected to market forces. Breast cancer susceptibility screening, however, has a significant public interest and public health component that is obviously missing from the development of Nokia’s newest gadget. While Dr. Critchfield may endorse the market ethic that has enveloped the American health care system, such an ideology will not be warmly embraced in Canada.

At the heart of the growing backlash against Myriad is a principled objection to the patenting of the human genome, a position expressed by the French Minister for Research and Technology in a 1991 letter to Science:

> It would be prejudicial for scientists to adopt a generalized system of patenting knowledge about the human genome...[S]uch a development would be ethically unacceptable. A patent should not be granted for something that is part of our universal heritage.

The human genome is fundamentally different from traditional patent matter such as light bulbs, compact disc players or cell phones, thereby justifying special treatment under the law. Human biological material has unique cultural and societal meaning. Genes are inherent to our personal identity and are common to all humanity. This view was expressed in UNESCO’s *Universal Declaration on the Human Genome and Human Rights:*

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67 But see M.M. Burgess, “Whither Morality in Genetic Tests?” (2001) 9:3 Health L. Rev. 3 at 4 [hereinafter “Whither Morality”]. Professor Burgess cautions against grounding social policy regarding access to genetic testing in the “special nature of the genome” but does not address the legitimacy of gene patenting. Burgess argues that the centrality of the genome to human nature, dignity and moral status must not be overestimated and avoiding an instrumental view of the genome is not a persuasive reason to limit access to genetic testing. It does not necessarily follow, however, that the unique character of the genome (which is not denied by Burgess) is insufficient to warrant concern over gene patenting.
Article 1: The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.

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Article 4: The human genome in its natural state shall not give rise to financial gains.68

In September 2001, UNESCO’s International Bioethics Committee (IBC) recommended on ethical grounds that the human genome should be excluded from patentability.69 Similarly, the Human Genome Organization (HUGO) has stated, “the human genome is our common heritage and collective property; genetic information is...in the public domain...human DNA is not patentable, but belongs to humankind.”70 These statements are evidence of a growing awareness of the difficult issues at the intersection of genetic research and patent law.

Underlying this broad, principled objection to the patenting of human genes appears to be a cluster of five related arguments. I will discuss each in turn and critique their relevance to whether intervention in the current patent system is warranted.

(i) Universal Heritage

The human genome is inherently distinct from patentable subject matter due to its universal character and status as part of our natural heritage.71 In the sense that disease and health are foundational to our experience as human beings, disease-associated genes can be seen as central to our sense of natural heritage.


The idea that the human genome is part of humanity's universal heritage is difficult to dispute. What few authors have addressed is why the unique nature of the genome necessitates the conclusion that it is incompatible with patent rights. More than an argument in itself, the "universal heritage" claim lays the foundation for other deontological objections.

The counter argument to all objections based on the universal, sacred nature of the genome is a legalistic one. Since it is the "novel, purified and isolated"\(^7^2\) form of a gene and not the gene in its natural form that can be patented, it is argued that there is no ownership or compromising of the 'universal heritage.' William Haseltine, President of Human Genome Sciences, articulated the distinction in this way:

"Trying to patent a human gene is like trying to patent a tree. You can patent a table that you build from a tree, but you cannot patent the tree itself."\(^7^3\)

Applying the Myriad situation to this analogy, we should not be concerned about the patenting of BRCA1 and 2, because Myriad has patented the purified, manipulated form of BRCA1/2 (the "table") and not the natural form of those genes (the "tree"), which is our natural, universal heritage.

In the case of human disease gene patents, the distinction between the "tree" and the "table" is purely illusory. With exclusive rights over all diagnostic and therapeutic applications of the BRCA genes, Myriad in effect has control over the natural form of the genes. Canadian and European labs are not using Myriad's technology, testing methods or data as part of their BRCA tests but arguably have infringed Myriad's patents. Testing a patient's natural form of the BRCA genes using any technique seems to be a patent infringement. Practically speaking, Myriad is claiming what amounts to patent protection over knowledge of the BRCA genes, since it is not only the technology or processes that are protected but use of the gene sequence. Current patent law makes no allowance for the nature of human genes or draws a distinction between the scope of genetic and non-genetic patents. Consequently, the claim that patents on the purified, isolated form of a human gene have no

\(^7^2\) *Amgen, supra* note 2 at 1206.

\(^7^3\) *Universal Heritage, supra* note 71.
relation to concerns over the universal heritage of the human genome are unconvincing.

(ii) Commodification

Gene patenting may undermine human dignity and our sense of "humanness" by commodifying genetic material and treating the genome (and therefore people) as property. There are a number of elements that can be teased out of this assertion. Human dignity and 'humanness' are undermined by gene patenting because it alters our conception of the genome, which is central to our humanity, into an object that can be owned. Philosopher David Resnik has distilled part of this argument into a three step analysis:

1) patenting human genes treats person as property that can be bought, sold, traded or modified;
2) it is morally wrong to treat persons as property;
3) the practice of human gene patenting is therefore morally wrong.

In reply, Resnik maintains that as long as patents are only allowed on inventions related to manipulating, analyzing or sequencing genes, people are not being treated as property. This type of patenting would be unproblematic. However, as I have discussed using Myriad as an illustration, patents on human disease genes currently are of such a large scope so as to, in effect, grant a patent on the natural form of the gene itself. Personal property law doctrines seem incompatible with a subject matter that forms part of the evolution of humanity and is key to each of our personal identities.

As Macklin discusses, undermining our sense of 'humanness' is a difficult foundation on which to build public policy arguments for banning human gene patenting. The shifting sand of concepts such as human nature, humanness and what amounts to dehumanizing practices are difficult to capture.

74 These arguments are discussed by Macklin, supra note 8 at 132. Macklin addresses the human dignity, humanness, and commodification arguments separately. I have merged them as related concepts that are most usefully discussed in concert as they relate to human disease gene patenting.

75 D. B. Resnik, "The Morality of Human Gene Patents" (1997) 7 Kennedy Institute of Ethics J. 50 at 54 [hereinafter “Resnik”].

76 Macklin, supra note 8 at 133.
Concerns about commodification reference a more general idea that the human genome should not be subjected to the forces of the marketplace or thought of as the subject of ownership rights. Patents serve primarily an economic function and subject patented material to the marketplace. Martin Teitel, in his article *The Commercialization of Life*, comments that it is difficult to imagine a greater presumption than an individual or company asserting exclusive rights over the “fantastically intricate genetic code that represents the current end point of millions of years of biological evolution.” The universality of the human genome seems disharmonious with a pure market-driven view of genes as a commodity.

Critics of this argument would again fall back on the weak plea that the natural form of a human gene is not patentable. As discussed above, this reply is unconvincing. Patent holders like Myriad may not be the only party to blame for commodifying human genes. Our current patent law regime was a permissive participant in stretching the originating concepts of intellectual property rights to their limits. Myriad simply exploited to their advantage an economically focused system unprepared for the genetic revolution.

(iii) Collective Property

Since the genome is universal, an appropriate concept of ‘ownership’ is a collective one that is incompatible with individual monopoly rights. There are two facets to this argument and therefore two types of counter-arguments to address.

The first aspect of this argument is that the universal nature of the genome is determinative of the fact that collective, not individual rights should exist. This claim is not convincing. While it could be argued the universal character of the environment and natural resources prohibits the granting of individual property rights, this philosophy is not widely accepted in mainstream North American culture. Non-collective ownership and control over land, waterways, airspace and natural resources are ideas deeply ingrained in much of Canadian culture. Its universality is not, therefore, the critical element to a claim for a collective interest in the human genome.

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78 Macklin, *supra* note 8 at 133.
The second aspect of the common property argument against human gene patenting claims that the genome is unpatentable because it is our common heritage. The word ‘common’ incorporates the idea of universality discussed above. Arguing that the genome being humanity’s “common heritage” is inconsistent with gene patenting is more convincing than simply its shared nature. Not only is the genome shared, but it is uniquely fundamental to our existence. In a sense, it is the essence of our humanity. The genome is what we inherit from generations before us and what we pass on to generations after us. It evolves as our species evolves and sets the boundaries of our existence. As stated by HUGO, the human genome belongs to humankind, although this view is unlikely to please the biotechnology industry.

(iv) Privacy Rights

As part of the human body, genes arguably attract an expectation of privacy. Flowing from a sense of collective ‘ownership’ of the genome, gene patenting also may violate a collective privacy right. This argument has been succinctly articulated by B. Looney:

The patenting of genes and gene sequences may interfere with privacy rights in that it permits an interference with a bodily part. Genes are the building blocks of human life and a part of every cell in the human body. Moreover, genes are inextricably and intimately related not only to a person’s physical body, but also to a person’s intellectual and emotional constitution. They are thus in a zone of privacy that may be violated by assignment of gene patent rights to others.

A collective privacy right also may be violated by gene patenting. Genome research seeks a composite map of humankind’s collective genetic make-up. Critics of gene patenting cite the privacy infringement inherent in assigning ownership interests to an item in which every individual is a part-owner merely by virtue of being human [footnotes omitted].

Even if we accept the assumptions underlying Looney’s analysis, an invasion of privacy (be it individual or collective) fails to offer a persuasive justification for banning human gene patenting. Arguably, all...
scientific research using humans that sheds light on some aspect of our shared experience would constitute an invasion of privacy. Since we are all susceptible to certain diseases, much of that research could also be considered a violation of collective privacy rights, yet the value of scientific research is seen to clearly outweigh the harm of any minimal privacy violation.

Looney has drawn an analogy between collective rights in the genome and collective rights in the environment.\textsuperscript{81} Just as our collective interest in a safe environment justifies limitations on harmful polluting activities, limitations on gene patenting are justified by a comparable concern for a "well-preserved genetic history."\textsuperscript{82} It is difficult to analogize pollution and other inherently harmful activities with gene patenting, a seemingly value-neutral legal process. Patenting in and of itself does not harm the genome and thereby engage privacy rights. To the extent that patenting may interfere with collective rights to knowledge or benefits of genetic research, such effects are more appropriately analyzed as distributive justice issues than invasions of personal or collective privacy.

\textit{(v) Distributive Justice}

One version of distributive justice principles\textsuperscript{83} would demand that the benefits of genomic research not be concentrated in the hands of a patent holder. There are various ways to construct a just and moral distribution of benefits from genome research. One version, as stated in the Bilbao Declaration,\textsuperscript{84} draws on ideas of the universality of the human genome:

\begin{quote}
\textit{\textsuperscript{81} Ibid.}
\textit{\textsuperscript{82} Ibid.}
\textit{\textsuperscript{83} Distributive justice refers to "just distribution in society structured by various moral, legal, and cultural rules and principles that form the terms of cooperation for that society, that is, the implicit and explicit terms under which individuals are obligated to cooperate." Distributive justice principles require a connection between a person's characteristics and the morally correct distribution of burdens and benefits in society: T.L. Beauchamp & J.F. Childress,} \textit{Principles of Biomedical Ethics, 3\textsuperscript{rd} ed.} (New York: Oxford University Press, 1989) at 258 [hereinafter "Beauchamp & Childress"]
\textit{\textsuperscript{84} The Bilbao Declaration is an international statement by scientists and legal experts on the legal implications of the Human Genome Project. The Bilbao Declaration was adopted during the May 26, 1993 International Workshop on the Human Genome Project: Legal Aspects.}
\end{quote}
[National and international rules should be developed, having as their objectives...the just distribution to people everywhere of the benefits of the Human Genome Project whose product belongs ultimately not to individual scientists, nor to sponsoring nations but to human beings in every land: of this generations [sic] and of all generations to come [emphasis added].]85

A similar sentiment is expressed in Article 12 of UNESCO’s Universal Declaration on the Human Genome and Human Rights:

a) Benefits from advances in biology, genetics and medicine, concerning the human genome, shall be made available to all, with due regard to the dignity and human rights of each individual.

b) Freedom of research, which is necessary to the progress of knowledge, is part of the freedom of thought. The applications of research, including those in biology, genetics and medicine, concerning the human genome, shall seek to offer relief from suffering and improve the health of individuals and humankind as a whole [emphasis added].86

Both the Bilbao and UNESCO Declarations propose a model of just benefit distribution that is inconsistent with human gene patent monopolies. It is unjust for our patent regime to allow the ‘fruits of genome research’ to be monopolized by a certain segment of society (the affluent) or by developed countries, when all of the world’s citizens should enjoy such benefits. For disease-associated genes, where potential diagnostic and therapeutic applications are in question, the argument is even stronger that distributive justice principles challenge the morality of a patent law system that fails to address the distinct character of the human genome. Benefits that should belong to humankind are at stake.87

The marketplace conception of “justice as fairness”88 counters the suggestion that gene patent monopolies are unfair. Patent holders may argue that a different model of distributive justice should be applied in

86 UNESCO Declaration, supra note 68 at 338.
87 B. Healy highlights in “Special Report on Gene Patenting” (1992), 327 New. Eng. J. Med. 665 at 666 the danger that industrial nations holding monopolies on gene patents might sell end products of those patents back to developing nations at prohibitively high prices. In light of the universal heritage character of the genome, this would be an unjust distribution of benefits and burdens.
88 Macklin, supra note 8 at 134.
relation to gene patents. It may be just and proper to distribute reward to those who expend effort and money to make genome-related discoveries. Beauchamp & Childress discuss the idea of justice as fairness in this way:

[I]n general, rules and laws are unjust when they make distinctions between classes of persons that are actually similar in relevant respects, or fail to make distinctions between classes that are actually different in relevant respects.\(^89\)

Arguably, to weaken patent protection over human genes would be unjust to researchers (and the investors supporting their work, but I will use the term researcher for simplicity’s sake in discussing this argument) in two respects. First, researchers are materially distinct from the rest of the population who has not spent time and money engaged in genome research. Refusing patent protection would unfairly ‘fail to draw a distinction between classes that are actually different in relevant respects.’ Second, genetic researchers are similar to researchers in other fields of investigation. To refuse patent protection for comparable effort when patents are available in other areas of scientific endeavour would unfairly ‘draw distinctions between classes of persons that are actually similar in relevant respects’.

What is clear from articulating these counter arguments is that the validity of conclusions based on distributive justice ideals is contingent on our view of what distinctions should legitimately be taken into account.

\textbf{(vi) Effort Must be Rewarded}

The first reply to the argument that benefits of genetic research should be available to all of humanity is that researchers have expended effort in relation to genetic innovations while the rest of the population has not, so it is fair to award patents as a recognition of that distinction. The weakness of this argument is it fails to recognize that our patent system is not designed to reward effort and investment in research \textit{carte blanche} – only the first to complete the final stretch in meeting the patentability requirements succeeds.

\footnote{\textsuperscript{89} Beauchamp & Childress, supra note 83 at 257}
The Curie Institute’s opposition to Myriad’s European BRCA1 patent, for example, is in part based on the assertion that an international public consortium of researchers had completed much of the foundational investigation into BRCA1. Myriad, they claim, swept in near the finish line, conducted “routine” final sequencing of the gene and filed the patent application that granted them, in effect, monopoly rights over the gene.90 If patent law drew a distinction between those who expended effort and resources in conducting research and those that did not, then the system would not have granted Myriad exclusive rights, but would have recognized all parties who contributed to the innovation.

Patent law is not simply a meritocratic body of rules, since many who expend considerable time and money go unrewarded in the end. A claim that researchers deserve patents because they have made effort while the rest of humanity has not is an unpersuasive argument for maintaining the status quo in our system of patent law.

(vii) Discrimination Based on Field of Research is Unfair

The second objection to a universal distribution of benefits from genome-related research is that it is fundamentally unfair to refuse patents in genetic research since patents are permitted in all other similar fields of research and development. Unquestionably, drawing a distinction between genome-related patents (human disease gene patents specifically) and all other patentable material is drawing a distinction between genetics and other fields of research, and justifiably so.

It is difficult to imagine another area of research that has internationally been lauded as the “heritage of humanity”91 and an issue that is “nothing less than the future of humanity.”92 While these statements may, at first glance, seem unnecessarily dramatic, few in the scientific or legal communities are downplaying the significance of the Human Genome Project and the myriad scientific/legal/moral/ethical issues it raises. Recall that ethicists Beauchamp and Childress stated that it would be unjust to make distinctions between classes of persons that are actually similar in relevant respects.93 The overwhelming public inter-

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90 Curie Institute Press Release, supra note 60.
91 UNESCO Declaration, supra note 68.
92 Bilbao Declaration, supra note 85.
93 Beauchamp & Childress, supra note 83 at 263.
est dimension to human genome research (specifically human disease gene research since it explicitly engages public health issues) places it in a realm that is not analogous to other seemingly similar fields of research. On this basis, it is fair to draw a distinction between patents for genome-related subject matter and other innovations.

2. Consequentialist Arguments

Patent monopolies in the arena of human disease-related genes are in their infancy. Companies such as Myriad are just starting to explore the scope of the legal rights vested in them by our current patent regime. In the next decade we will be faced with the consequences of the policies we choose to implement today. In deciding whether patent reform is necessary, it is informative to address the expected consequences of allowing monopoly rights over human disease genes.

The consequentialist arguments I will address in this section are of two types. First, I will discuss the necessity of gene patents for advancement in genetic technologies and the effects of human disease gene patenting on international collaboration and the dissemination of information within the field. I will argue that many of industry’s objections to patent reform are unpersuasive and that when balanced against the public interest, offer no strong reason to maintain the legal status quo, which favours companies such as Myriad.

Secondly, I will discuss the consequences of a commercial monopoly on the development and delivery of genetic testing. I will argue that not only are monopolies in this arena per se inappropriate, the dangers of commercial monopolies offer compelling reasons to reform our current patent policy in relation to human disease-associated genes.

(i) Whether Rigorous Patent Protection is Necessary to Promote Innovation

The simplistic view of patent law is that the broader patent protection is, the greater the scope of innovation that will occur in society. Since innovation benefits society generally, the most liberal patent regime possible should be implemented. This articulation of potential patent policy is far too simplistic, near-sighted and economically oriented. The value of innovation for its own sake must be balanced against other legitimate interests and concerns. While a pure version of this argument is easily overcome, vestiges of this view underlie many other
arguments in favour of broad patent laws and must be recognized where it lurks behind other, more innocuous, claims.

The call from the biotechnology industry for greater patent protection is more than a philanthropic gesture towards increasing innovation in the name of the public good. Any effect of the patent regime on society's overall ingenuity may simply be a benefit collateral to the industry's primary objective of increasing profits.94

The desirability of public as opposed to private involvement in human genome research, development, and product delivery is a debate that raises a host of legal, ethical and policy issues that are largely beyond the scope of this paper. Whether genetic testing should be permitted at all or if private source testing should be allowed are engaging questions that are inspiring a rich academic literature.95 The reality in Canada today, however, is that private industry is significantly involved in bringing genetic tests to the public.96 How private interests, including patent rights, can best be integrated into the Canadian health care system is now the key question. To focus the issue even further, the key question is whether the harmful consequences of a commercial monopoly, such as that claimed by Myriad over breast cancer susceptibility testing, demands patent reform.

94 E. Richard Gold, in "Biomedical Patents and Ethics: A Canadian Solution" (2000), 45 McGill L.J. 413 at 423 [hereinafter "Biomedical Patents and Ethics"] has gone so far as to state:

"The argument for greater patent protection should be understood for what it is: an attempt to maximize profit, not to maximize levels of innovation. Clearly, a company would prefer to have as large a monopoly as possible. This gives it ultimate control over how and when to market its product and the ability to garner monopoly profits. But patent law is not about individual profit maximization; it is about maximizing the overall level of innovation in society."


Intellectual property rights are a major incentive for industry’s investment in the research and development of new drugs, therapies and diagnostic technologies. Without a guarantee of patent protection and the accompanying financial rewards, it is argued, private investment in research would be “seriously compromised”\(^{97}\) and tomorrow’s greatest inventions would never be realized. Private funding sources can bear the immense financial cost to bring research to a commercial product endpoint (from which society at large benefits) but must be rewarded with the potential for a return on their investment or such research would not occur.

From the point of view of the biotechnology industry, patent rights should be strengthened, not weakened or restricted. It has been suggested that to remain competitive in the global economy and to encourage innovation in the biotechnology sector, Canada’s patent laws in relation to biotechnology must be at least consistent with, if not broader than, the United States.\(^{98}\) Private sector investment in research increases when patent protection is robust,\(^{99}\) and increased investment benefits the economy and results in increased innovative output. Society, it is argued, benefits from strong patent laws because they encourage investment and innovation. To reform our approach to human gene patents could have two related effects—decrease investment in biotechnology in Canada and decrease output from that sector. Canada could lag behind its global competitors and become an unattractive place for biotechnology investors to call home.

The easy reply to this position is to take the moral “high ground”. If we accept the fundamental ethical reasons (discussed earlier in Part VI) and the consequentialist arguments (discussed later in Part VI) why


\(^{99}\) An often-quoted illustration is the pharmaceutical industry in Canada. Both Bill C-22 in 1986 and Bill C-91 in 1993 strengthened patent protection for drugs in Canada by changing the compulsory licensing provisions of the *Patent Act*, R.S.C. 1985, c. P-4. Following each of these bills becoming law, research and development expenditures by pharmaceutical companies in Canada increased. For a general discussion, see: *Brief History*, supra note 11 at 21-24.
human disease genes should not be treated like cell phones or fabric softener sheets under our patent system, then we must defend that position in the face of economic consequences. It may not be cheap or profitable to be ethical.

When compulsory licensing was first introduced for food and drugs in Canada, the public policy justifications concerning access and availability were seen to outweigh the potential economic ramifications of departing from the classic monopoly system. Similarly, I would argue, if human disease gene patenting should be reformed as a matter of public policy, we must not be terrified of potential economic consequences. Patenting human beings, nuclear weapons and methods of medical treatment may very well be profitable and foster innovation, but public policy reasons outweigh the potential rewards such expansions on our patent law would generate. The key question to be answered is whether human gene patents, granted to private companies, reach the threshold of public concern that warrants differential treatment. The deontological and consequentialist arguments presented in this paper strongly suggest that change is needed.

Aside from hiding behind a moral “high ground” position, there are two substantive counter-arguments to the claim that a reformed patent scheme for human disease-associated genes would slow innovation in the biotechnology sector. First, it has been hypothesized that patents in this field may have a deterrent effect on innovation, the so-called “tragedy of the anti-commons.” Since a number of related patents exist in this field, research may be stifled by the potential of overlapping rights or uncertainty about the scope of pre-existing patents.

A version of this “tragedy” is already unfolding in relation to human disease gene patenting. A 1999 poll indicated that half of American laboratory directors who were questioned had stopped working on developing various screening technologies because they knew a patent had been licensed or was pending in the same research area. Thus, in some

100 The 1923 Patent Act introduced a compulsory licensing scheme for patented food and drugs: see Brief History, supra note 11 at 18.
cases patents may have an effect opposite to the intended effect of promoting research and innovation.

Second, authors such as E. Richard Gold have argued that the economic incentives granted to biomedical materials are too strong and that there is little empirical proof that the patent system actually encourages innovation in the biomedical field. Without patents, other market forces may lead to a similar level of innovation in the biotechnology sector. More limited patent rights may act as a sufficient economic incentive for the private sector to undertake biomedical research. This view runs counter to industry’s demands for stronger patent protection. If public policy concerns are considered, there may be approaches to human disease-associated gene patents that more effectively balance public and private interests in genome research.

In the case of human disease genes, there is an additional reason to believe that an inability to patent human genes would not completely stifle research or financial incentives. If human genes were considered non-patentable research tools, the end products (or “true” innovations) such as genetic testing kits and pharmaceutical innovations would still be patentable and a potential source of profit. In order to develop marketable end products, gene sequencing and characterization would still be done but companies would have no basis under which to claim an exclusive monopoly over diagnostics and therapeutics more generally in relation to the gene. Other researchers would be able to design and administer their own tests without fear of patent infringement litigation. Competing genetic tests would succeed or fail on their own merits without a bubble of exclusivity artificially protecting the inventor. In sum, it is not clear that the level of incentive offered by our current patent system is necessary to promote innovation in disease-related genetic research. At the very least, concerns about decreased innovation do not offer overwhelming arguments against patent reform in this arena.

(ii) Whether Patents Promote or Inhibit Information Sharing & International Collaboration

Unraveling the mystery of the human genome is an international venture. Information sharing and collaboration are key to ensuring rapid

\[\text{See Making Room, supra note 97 at 68ff; Biomedical Patents and Ethics, supra note 94 at para. 26.}\]
and meaningful advancement of our scientific understanding of human disease diagnosis and treatment. To the extent that gene patenting promotes delayed disclosure of research findings\textsuperscript{104} and encourages competitiveness as opposed to collaboration, the underlying goals of patent law and scientific research are left unfulfilled. Researchers keen to patent their work may delay public disclosure of results until a patent application is filed on the project. This delay in information sharing is an impediment to scientific advancement.\textsuperscript{105} An opposing view is that since patent applications require full disclosure, patents offer incentive to avoid suppressing information. More information becomes part of the public domain as part of the patenting process than would be available if patents were prohibited. Without the guaranteed protection of patents, it is argued, innovators would resort to trade secrecy and the advancement of research would suffer even further than under the umbrella of the patent system.

A related argument addresses the impact of patenting human genes on international scientific collaboration efforts. Groups such as the United Kingdom Medical Research Council argue that patents stifle international collaboration and have called for an international agreement to govern rights in genomic research.\textsuperscript{106} Patenting promotes international competitive research behaviour and reduces research to a 'race to patent'. A logical counter to this argument is not to deny the stifling effect of patents in specific circumstances, but to argue that overall, patents add legitimacy to innovations and foster overall investment and interest in science.\textsuperscript{107} In the long run, the public interest is better served by allowing rather than prohibiting gene patenting.

\textsuperscript{104} Macklin, \textit{supra} note 8 at 134 quotes molecular biologist Jonathan King, "Gene Patents Retard the Protection of Human Health" (1996) 10 GeneWatch 9 at 11 as holding the view that:

\begin{quote}
"[c]ontrary to the claims of the biotech industry, gene patents retard progress in the biomedical arena, introduce secrecy where openness is essential, and slow the publication and sharing of important results. This follows from the fact that once a result is reported publicly, it cannot be patented. Thus, researchers drawn into the web of the patent process do not report their results, even informally, until they have passed through the expensive patent application and granting process."
\end{quote}

\textsuperscript{105} See Sexton, \textit{supra} note 22 at 1.

\textsuperscript{106} Reviewed in Looney, \textit{supra} note 8 at 245.

\textsuperscript{107} R. Eisenberg, "Patents and the Progress of Science: Exclusive Rights and Experimental Use" (1989) 36 U. Chi. L. Rev. 1017 at 1024-1028.
How patenting effects information sharing and collaboration is not a debate specific to human disease gene patenting. All areas of science are experiencing a collision with patent law and private interests. It is difficult to assess the impact of patenting on the scientific community because there is no “patent-free” standard against which to compare our level of progress. While patenting has changed the dynamic of science, so has the global nature of our economy and the invention of research tools and methods beyond our imagination even fifty years ago. It is difficult, if not impossible, to dissect the impact of one specific variable—patent law—on our pace of scientific progress. The true impact of gene patenting on the dissemination of information and collaboration efforts is unclear and therefore offers no clear direction on whether our patent law regime requires reform.

(iii) Whether a Commercial Monopoly over Genetic Testing Services is Desirable

A monopoly over all diagnostics and therapeutic applications of a gene, such as that being claimed by Myriad in relation to the BRCA genes, is not in the public interest. Such a monopoly being held by a commercial interest is even more worrisome. As discussed in Part V of this paper, Canada’s current legal regime likely operates in favour of Myriad’s broad claim to a testing monopoly. The consequences of permitting commercial monopolies over genetic testing services are good reasons to call for patent reform.

Three of the most persuasive arguments against maintaining the status quo are:

(A) the harmful effects of monopolization;
(B) the harmful effects of commercial monopolies in skewing the focus of genetic research;
(C) limitations on access to services and costs to the public health care system.

For the sake of clarity, I will discuss each argument using Myriad’s patent and exclusive BRCA testing rights as an illustration of potential harms.
(A) Harmful Effects of Monopolization

Many in the medical field argue that genetic testing monopolies are not in the best interests of patients. Myriad is attempting to dictate what methods can be used to test for BRCA mutations and may be able to limit the conditions under which testing can be performed. Jon F. Merz, an ethicist at the University of Pennsylvania, has expressed a concern that monopolies allow gene patent holders to dictate the medical standard of care. This power is an unacceptable outcome of patenting and highlights the fundamental incompatibility of patenting with medical care. 108

Another concern about single source testing is that refinement and optimization of testing methods may be hindered by a patent holder such as Myriad demanding exclusive rights to testing. Clinicians, no longer allowed to improve diagnostic technologies, will lose the expertise and skill in testing that will be required of them once Myriad’s patent expires.

Having a patent holder exercise exclusive rights and use a substandard test is not in the public’s best interest. Without alternate testing methods being clinically available, it may be difficult to determine which tests have superior predictive value. The reliability and accuracy of services in an industry such as genetic testing, which is not yet subject to a rigorous regulatory scheme, must be ensured.

France’s Curie Institute claims that Myriad’s BRACAnalysis test-ing method is unreliable. 109 Researchers at the Institute recently published data showing that Myriad’s technology fails to detect 10-20% of all mutations in the BRCA genes. 110 This finding contradicts Myriad’s claims that their aggressive patent enforcement protects the public from “short-cut” testing methods performed by mediocre labs. 111 Myriad’s claim that their method is the ‘gold standard’ in testing may be premature. In the face of monopoly rights, however, it may be difficult for clinical labs to make such determinations.

Monopoly rights over genetic testing also raises concerns about the use of genetic information. Discriminatory uses of genetic information

108 Disease Gene Patents, supra note 4 at 327.
109 Curie Insitute Press Release, supra note 60.
110 Supra note 62.
111 See e.g. Star article, supra note 33.
and a lack of genetic privacy are two harmful effects that could result from monopoly rights on testing.

Certain gene mutations occur more frequently in some ethnic or racial groups. Ashkenazi Jewish populations, for example, are at higher risk for Canavan disease and hereditary breast cancer than the general population.112 Potentially, genetic information (including susceptibility to cancer) or even the availability of genetic testing could be used in discriminatory ways. Professor Gold has expressed concern that as a society we should not leave in a single party’s hands “the decision about whether a patented good is used in such a fashion as to lead to the effective discrimination of a minority.”113

Regarding genetic privacy, the Curie Institute objects to the fact that if Myriad is successful in compelling labs worldwide to send samples to Utah for analysis, the company will be able to build up an extensive human genetic data bank.114 The privacy of patients’ genetic information has not been ensured.

Concerns about genetic discrimination and misgivings about potential abuses of a genetic databank are valid issues to which there has not been enough attention brought. As the vast potential of the biotechnology industry is realized, specifically in relation to the human genome, the proper use of genetic information will be debated in fora much broader than the patent law arena. It is likely that many of these concerns will be addressed by mechanisms external to patent law.

Arguments against monopoly rights over genetic testing seem ethically persuasive when grounded in the potential harmful consequences outlined above. Many of the same arguments, however, could be invoked to argue against allowing monopolies over any medical or pharmaceutical product. It is difficult to justify genetic testing being subject to a higher set of concerns than life-saving medications, medical equipment or other health-related products. On balance, the concerns over the harmful effects of monopolies in this area must be taken into account but do not by themselves strongly compel patent reform.

112 “Breast Cancer, the Genetic “Quick Fix” and the Jewish Community” (1997) 7 Health Matrix 97 at 99.
113 Making Room, supra note 97 at 73.
114 Curie Institute Press Release, supra note 60.
(B) Harmful effects of commercial monopolies

Compounding the arguments that genetic testing monopolies are inappropriate per se is an objection to private companies exercising such monopolies. Commercial interests are profit-driven and not necessarily committed to acting exclusively in the public interest. An American biotechnology corporation should not drive Canadian health policy regarding the availability of or the clinical standards for genetic testing.\(^\text{115}\)

Commercial involvement in health research raises another concern. Public health measures and advances in preventative treatments, which hold the greatest hope for improving human health, may not be commercializable. Commercial patent holders who control clinical research and potential applications of a human disease-associated gene would have no incentive to undertake less profitable types of research. As in other areas of health research, an appropriate balance must be achieved between public and private interests.

(C) Restricted Access and Exorbitant Cost to the Health Care System

The price tag associated with Myriad’s BRCA gene testing procedure puts it far beyond the financial resources of most Canadians. Women in British Columbia, where the health department abandoned its in-province testing program in response to Myriad’s cease and desist demands,\(^\text{116}\) have been left stranded. This restricted access is unjust because it negatively effects the health of women at high risk for hereditary breast cancer. If accessing testing is beyond their financial means, women are unable to make informed decisions regarding preventative interventions or future health management and cancer surveillance. Realistically, more disease-associated genes will be patented in Canada. If, like British Columbia, provinces concede the legality of the monopoly rights claimed by patent holders but deny provincial health plan coverage for the costs, access to many medical services may be restricted. Such consequences are unacceptable.

In Ontario, there is precedent for BRCA screening being ‘medically necessary’ and therefore an insured service for women at high-risk for

\(^{115}\) Making Room, supra note 97 at 74; Patents in Genes, supra note 7 at 18.

\(^{116}\) Discussed supra Part IV.
hereditary breast cancer. Assuming for a moment that commercial patent holders’ testing monopolies are legally enforceable, the financial consequences for universal health care are staggering. Provinces would be compelled to pay the testing price set by market forces or hope that patent holders would be willing to negotiate lower rates. CBAC has recognized the potential impact of biotechnology patenting on health services. A draft recommendation in CBAC’s Interim Report states that further research should be conducted into the effects of biotechnology patenting on all aspects of health care, including what approaches Canadian policymakers can use to address any harmful effects.

Concerns over restricted access to testing and the cost to the health care system are not issues specific to breast cancer susceptibility testing. Prostate cancer, late-onset Alzheimer’s, heart disease and a host of other genetic tests may be made available only through single source commercial providers at exorbitant cost unless patent reform is made a priority.

VII. OPTIONS FOR PATENT REFORM

As illustrated by Myriad’s claims over the BRCA genes, Canada’s current patent regime is not equipped to grapple with the unique issues raised by human disease gene patenting. Based on both deontological and consequentialist arguments, the status quo policy of granting human disease gene patents of broad scope is not justifiable. Government intervention is warranted to protect the public’s interest.

Barbara Looney has proposed that an international Human Genome Trust be established that would hold the human genome in trust for humanity and grant licenses as seen fit. Arguably, an international solution would be ideal since social and ethical concerns surrounding the genome are not merely a national concern. International consensus would be required to determine the appropriate relationship between

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117 Discussed supra, Part IV.
118 CBAC Interim Report, supra note 46 at 22. CBAC will be gathering input on its interim recommendations and issuing a final report of recommendations to the Government of Canada by April 30, 2002.
119 Looney, supra note 8 at 268.
120 Biomedical Patents and Ethics, supra note 94 at para. 10.
patent law and the human genome – a consensus that does not currently exist.

While we wait for an international consensus regarding the patenting of human disease genes to be negotiated, in Canada, there are a number of options for domestic policy reform. In designing domestic policy, it is important to be aware of both the practicalities of implementing a solution unilaterally within our borders and of Canada’s international obligations relating to intellectual property protection. Our domestic patent policy must be economically and ethically practical in addition to appropriately balancing public access to health care against the legitimate commercial interests of patent holders. These criteria make critical assessment of potential policy choices a complex process. I will outline a number of the options available to the federal government and highlight key factors in favour of and against each potential strategy. A combination of approaches may be most effective in addressing the ethical and practical concerns discussed earlier in Part VI that make our current patent practice unacceptable.

1. Exclude Disease Genes from Patentability

An approach that would address many of the deontological arguments against granting property rights in the genome would be to exclude human disease-associated genes from patentability altogether. Exclusion could be accomplished by adding a subject matter exclusion clause to the Patent Act, or by taking the European approach of incorporating into the Act a morality and “ordre public” clause\textsuperscript{121} that would enable CIPO to refuse patent applications based on ethical grounds.

There are a number of difficulties with the blanket exclusion option. First, it is difficult to justify a distinction in law between human disease-associated genes and other genes without much more extensive ethical analysis. Exempting only disease-associated genes may not address the universal heritage or distributive justice arguments against gene patent-
ing. At the same time, the consequentialist arguments\(^{122}\) presented in favour of patent reform do not necessarily justify a blanket prohibition on human gene patenting. It would be hasty of Canada to unilaterally ban human gene patents without further consultation and study. A patenting ban would likely have detrimental effects on our burgeoning biotechnology industry.\(^{123}\)

The second difficulty with an absolute exclusion approach is that it may not be consistent with Canada’s international obligations regarding intellectual property rights. Both the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs)\(^{124}\) and NAFTA\(^{125}\) contain anti-discrimination clauses that guarantee equal patent protection regardless of the field of technology or where an invention is produced.\(^{126}\) If Canada were to impose special standards or exclude human disease-associated genes from the patent regime, it may be in violation of TRIPs and NAFTA.

Third, patent exclusion simply may not be the best overall solution. This approach fails to strike an appropriate balance between commercial and private interests. It would be naive to deny the legitimate interests of the biotechnology industry in recouping development costs and making a (modest) profit. Cooperation and compromise are likely the better approaches than a blanket prohibition on gene patenting.

In addition, it has been argued that attempting to remove biological materials from the reach of patent law would subject them to greater commercial pressure than if they were patentable.\(^{127}\) No one would have

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\(^{122}\) Discussed *supra*, Part VI.

\(^{123}\) Grover report, *supra* note 98 at 8.


\(^{126}\) Virtually identical provisions appear in Article 27 of TRIPs and Article 1709 of NAFTA. Article 27.2 of TRIPs states:

> “Members may exclude from patentability inventions the prevention within their territory of the commercial exploitation of which is necessary to protect “ordre public or morality” including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.”

\(^{127}\) *Biomedical Patents and Ethics*, *supra* note 94 at para. 14ff.
the ability nor the incentive to control the use, development or market-
ing of biological materials, since they would not be the subjects of patent
rights. While this model imagines a market without other regulatory
forces (which does not exist), it is useful to realize that the consequences
of drastic action may not be any more ethical than our current situation.

My fourth objection to the subject matter exclusion or public moral-
ity clause approach is primarily a pragmatic one. The problems of
drafting an exclusion clause of appropriate scope,\textsuperscript{128} and designing
regulation pursuant to the \textit{Patent Act} to address questions of interpreta-
tion and application is a process that could take years and the effective-
ness of the outcome is uncertain. Other areas of invention would be
impacted. Introducing an exclusion provision is an overly broad
brushstroke in response to a specific problem.

2. Opposition Procedure

In October 2001, the Curie Institute in Paris launched an opposition
procedure against Myriad’s European patent on the BRCA1 gene, chal-
lenging the validity of the patent on several grounds. Such an opposition
mechanism is not presently available in Canada.

Under the \textit{Patent Act}, issued patents are presumed valid until chal-
lenged,\textsuperscript{129} which usually occurs in the context of infringement litigation.
The courts determine patent validity based on the rights of a patent
holder and the conduct of a potential infringer. There is no room for the
public interest or third party objections. In contrast, Europe’s legislation
incorporates a formal opposition procedure. Third parties can challenge
the validity or scope of patents within nine months of them being issued.
This mechanism is currently being used by Paris’ Curie Institute to
challenge Myriad’s European patent over BRCA1 and the diagnostics
associated with the gene.\textsuperscript{130}

\textsuperscript{128} It is not clear that without explicit guidance from Parliament that a public order exclusion
clause would apply to gene sequences: \textit{Patenting of Higher Life Forms}, supra note 48 at 17.
Europe’s public order and morality clause has only successfully been invoked to withhold
patents on a hairless mouse used to test hair growth products and an invention involving the
cloning of a fused human and pig cell. The EPC decided that patenting the “Harvard
oncomouse” did not violate the public order/morality clause, a finding that was upheld
following a challenge by Greenpeace and other public interest groups: CBAC \textit{Interim Report},
supra note 46 at 12.


\textsuperscript{130} Curie Institute Press Release, supra note 60.
Both the National Biotechnology Advisory Committee\textsuperscript{131} and the Canadian Biotechnology Advisory Committee\textsuperscript{132} have recommended to the federal government that Canadian patent law be amended to include a formal opposition procedure. Third parties could challenge CIPO’s acceptance of patent applications on grounds of invalidity or excessive breadth without the expense of a lawsuit. CIPO would be able to reconsider its decisions in light of third-party arguments and perhaps develop policies regarding if and when patents could be challenged on ethical grounds.

While I agree that an opposition process would benefit the administration of the Canadian patent system, this approach in isolation will not directly address concerns about commercial genetic testing monopolies. Challenges to the scope or validity of Myriad’s BRCA gene patents based on our current patent law would likely be decided in Myriad’s favour. More direct reform is required.


The \textit{Patent Act} historically included provisions for abuse-based compulsory licenses and government appropriation of patent rights in national emergencies. Reinvigorating these provisions is not consistent with Canada’s international obligations and would not effectively address the concern over the patenting of human disease-associated genes. The “abuse of patent provisions” of the \textit{Patent Act}\textsuperscript{133} provided a remedy against monopolistic misuses of patent rights. If a patent holder failed to meet commercial demand for the patented material within three years of the patent being issued, a compulsory license could be granted to a third party or the patent could be revoked. These provisions were deleted in 1993 as part of Canada’s commitment to NAFTA.

Attempting to reinvigorate abuse-based compulsory licenses is not a viable solution to the problem at hand. Apart from being in violation of NAFTA, it is questionable whether Myriad’s conduct falls within the interpretation of “abuse of patent”. Myriad has made their testing avail-

\textsuperscript{132} CBAC’s \textit{Interim Report}, supra note 46 at 25.
able in Canada and is able to meet commercial demand. In addition, such an approach would undermine the certainty demanded by the biotechnology industry about the meaning of their intellectual property rights. Waiting to determine whether a company’s conduct will fall within the scope of ‘abusing’ their patent and then issuing compulsory licenses is an indirect method of addressing an issue that demands a direct approach.

4. Compulsory Licensing

While we should provide financial incentive to encourage innovation and reward effort in genetic research, we must take an approach that properly takes into account the public interest in access to services. Instituting a system of compulsory licensing for human disease-associated gene patents would help recalibrate the balance between the public and private interests in this arena.

The idea of compulsory licensing for research tools such as cell line and genes has garnered widespread support in the literature. Companies such as Myriad would be unable to maintain a monopoly over genetic testing or the development of new technologies. Third parties, including provincial health authorities, would pay royalty fees to Myriad in exchange for non-exclusive licenses to do what would otherwise constitute patent infringement. This approach strikes an appropriate policy balance. Myriad still receives an advantage from holding the patent – it receives reasonable royalty fees, but is unable to restrict access to testing or future diagnostic applications of the BRCA genes.

Immediately implementing a compulsory licensing scheme would arguably violate Canada’s international patent treaty obligations. The TRIPs Agreement seriously restricts the conditions under which compulsory licensing may be used. Exceptions to the exclusive patent rights are permissible if they

\[ \ldots\text{do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties.} \]

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134 Disease Gene Patents, supra note 4 at 325; Making Room, supra note 97 at 72; Patenting Higher Life Forms, supra note 48 at 17-18.
135 TRIPs, supra note 124, art. 30-31.
Whether legislating compulsory licences for human disease-associated genes compromises the “legitimate interests” of patent holders such as Myriad is a matter of interpretation and debate.

The WTO recently adopted a Declaration on the TRIPS Agreement and Public Health clarifying that member nations “have the right to grant compulsory licences and have the freedom to determine the grounds upon which such licences are granted.” Although this TRIPS Declaration was adopted in reference to compulsory licensing of pharmaceuticals, it is recognition at the international level that patent rights are not absolute in the face of public health concerns.

Compulsory licensing solves the problem of restricted access to genetic testing in a way that would not bankrupt the public health care system and avoids the harmful effects of commercial monopolies. While we await an international consensus on the application of patent law to the human genome, implementing a system of compulsory licensing strikes a workable balance between various competing interests.

VIII. Conclusions

The conflict between Myriad and provincial health ministries across the country, against a backdrop of financial restraint in the health care system, has brought the issue of human gene patenting to the forefront of public attention. The Myriad situation, combined with the release of CBAC’s Interim Report on patenting and the Supreme Court of Canada granting leave to decide the ability of researchers to patent a genetically engineered “Harvard oncomouse” have made biotechnology patents the subject of heated debate.

Myriad’s aggressive posturing to enforce its patents worldwide has raised not only the question of what the enforceable scope of human disease-associated genes should be, but whether such genes should be patented at all. The Canadian Intellectual Property Office has offered no

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136 WTO, Declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/MIN(01)/DEC/2, online: WTO <http://www-chil.wto-ministerial.org/english/thewto_e/minist_e/min01_e/mindec1_trips_e.htm> (date accessed: 23 November 2001) [hereinafter “TRIPS Declaration”].

137 TRIPS Declaration, supra note 136 at art. 5(b).
policy guidance in relation to human disease gene patenting. Our current patent system overprotects private monopolies at the expense of the public interest. The unique character of the genome and distributive justice principles demand that genes be treated differently than other patentable material. The consequences of allowing commercial monopolies over genetic testing also offer strong reasons to recalibrate the balance between the public and private interest in relation to human disease-associated gene patenting.

While I have argued that patent reform is crucial, much more public consultation and debate must take place before it will be clear what shape such reform should take. Approaches taken by other countries may not be appropriate in a Canadian setting. Compulsory licensing of gene patents and establishing a patent opposition procedure hold great potential as policy options that can be implemented in Canada while we await an international consensus on the relationship between genes and patent law.