GENETIC INVENTION LICENSING IN HEALTHCARE:

AN ANALYSIS OF POLICY INSTRUMENTS

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ABSTRACT

While it may seem that genomic innovations recently burst upon the scene but they have actually been taking place since the early 1970s. Genomic research in microbes, animals, plants and humans have all triggered intrigue and controversy. This is perhaps best known in the field of plant sciences with the development of genetically modified plants and their resulting products. However, human genomic research, especially relating to disease research, has triggered its own share of debate.

Private firms undertaking biotechnology research on human diseases have invented a range of testing procedures and, in some cases, the patenting of these test procedures based upon individual human genes. Myriad Genetics has been involved in research on breast cancer. After the identification of two genes that coded for the presence of breast cancer in women, Myriad filled for, and received, patents in the United States and Canada for the breast cancer diagnostic test that the firm developed. Canadian provinces utilized this diagnostic test as part of the testing procedures for women and all was fine until Myriad started to enforce the patents rights on the test, which meant that all samples would need to be sent to Myriad's laboratories at much higher cost to the Canadian provinces using this test.

The enforcement of patent rights is well within the law, but it was the enforcement of patent rights on a human gene patent that triggered considerable consternation. What was revealed to those interested in genomic research and the related aspects of this research, was the apparent conflict between the *Canada Health Act* and the Canadian *Patent Act*. While the *Canada Health Act* guarantees equal treatment for all Canadians, the ability for private firms to profit from basic

health procedures, established the need for a fundamental review of this situation. Canadian health and genomic researchers were not alone in this review. Most industrial nations were part of this debate and dialogue process. The result was that the world's industrialized nations agreed to develop guidelines for the patenting of testing procedures for human diseases.

Canada faces a policy quandary with the competing objectives of a publicly funded accessible and universal healthcare system and the right to a return on private investment from intellectual property and other rights associated with patents. The Canadian healthcare system and the delivery of services are based on innovative technologies. These innovative technologies have been patented and firms and investors expect a return on their investment. This thesis examines the conflict that Myriad created within Canada when it began to enforce their patent rights. In essence, what it examines is the right to profit from an innovative discovery and technology and how to balance that against the regulatory requirement to ensure that Canadians continue to get the best healthcare service possible.

Canadian policy makers face a choice of policy instruments to resolve this quandary through the implementation of the OECD Guidelines for Licensing of Genetic Inventions. This thesis also explores the implementation issues and feasibility of the choices of policy instruments for implementation of the OECD Guidelines and concludes that the soft law policy instrument is the most optimal choice for implementation of the Guidelines.

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DEDICATION PAGE

I would like to dedicate this thesis to my parents, Adam and Beatrice. Without you, your unconditional love and support, I would not be who I am today nor would I have accomplished this task. As children we rarely say this enough … thank you.

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LIST OF ACRONYMS

BC	British Columbia
BCCA	British Columbia Cancer Agency
BRCA	Breast Cancer
CBAC	Canadian Biotechnology Advisory Committee
CHA	Canada Health Act
CIPO	Canadian Intellectual Property Office
IP	Intellectual property
IPRs	Intellectual property rights
OECD	Organisation for Economic Co-operation and Development
US	United States

CHAPTER ONE

INNOVATION AND GENOMICS

1.1 Introduction

Innovative discoveries in genetics research have fundamentally challenged the patent legislation of many, if not most, industrial jurisdictions. Patent acts in Europe and North America were written to provide protection for inanimate objects. Patents are a legal construct designed to provide incentives to create investment in research and development and knowledge-based industries. Patent owners receive a monopoly over the invention for a defined period of time and an avenue for legal recourse against those who use the invention without authority to do so. In return for those rights, patent owners agree to disclose information regarding their research or invention to the public.

Patent acts were developed prior to the genetics revolution and are thus open to broad interpretations regarding patent applications on living life forms. Opponents argued that patent acts were developed with the intention that living matter should not be patentable, while proponents argued that while there was nothing explicitly allowing life forms to be patented, the drafters of those acts did not want to prohibit innovation and thereby purposely made the legislation open to broad interpretation.

The patenting of plants began in the 1930s with the enactment of the Plant Patent Act in the United States. Patenting of living life forms involving microorganisms began in the 1970s but rapidly progressed into further applications involving plants and animals in the 1980s. The

patentability of lower life forms has evolved to the point that it now seeks to reach the pinnacle of higher life forms. This evolution began in 1980 with the United States ruling in *Diamond v. Chakrabarty*, continued into 1982 with the Canadian decision in the *Application of Abitibi Co.*, encompassing the 1999 European decision of the Enlarged Board of Appeal in *Novartis* and concluding to date with the rulings on the *Harvard/Onco-mouse* applications (Kaminski *et al*., 2005). Patents on lower life forms (single cell microorganisms) initially taxed patent offices in both North America and Europe during this period of time.

While the legal evolution of life form patenting has provided inventors with the ability to patent genetic innovations, ongoing discussions and debates regarding patent rights continue to highlight some recurring concerns. Such concerns include freedom-to-operate, research exemptions, economic return on investment analysis, timely access to information, monopolistic opportunities and whether or not future research is fostered or impeded through the use of patents. Phillips (2007) stated that concerns regarding the use of intellectual property rights (IPRs) and patents revolved around the need to review, with a potential solution to amend, the intellectual property system. However, at its workshop in Berlin in January 2002, the Organisation for Economic Co-operation and Development (OECD) concluded that the intellectual property system largely serves the purpose for which it was created when analyzing the intellectual property system specifically for the purposes of biotechnology and genetics research (OECD, 2006).

1.2 Problem Statement

The OECD has stated that the patent system serves its purpose relative to biotechnology and genetic innovations; however, the issues and concerns surrounding the commercialization of intellectual property, from which patents are a stream, remain. Commercialization of patents deals with the generation of use and therefore the value of patents. In response to these concerns, the OECD brought forward its 'Guidelines for the Licensing of Genetic Inventions' in 2006. The intent of the Guidelines was to suggest how to best generate use and enhance value of intellectual property – how to aid commercialization of patents – through the licensing of genetic inventions.

Gold (2006) presented implementation options of the Guidelines in the Canadian patent system at Health Canada's Human Genetics Licensing Symposium. These options include the following implementation approaches: hard law; soft law; institutional; and educational. The question that remains to be answered is: What implementation option or options of the Guidelines most effectively address the issues and concerns surrounding the generation and use of patents on genetic inventions?

1.3 Objective of Study

Canada faces a policy quandary with the competing objectives of a publicly funded accessible and universal healthcare system and the right to a return on private investment from intellectual property and other rights associated with patents. The Canadian healthcare system and the delivery of services are based on innovative technologies. These innovative technologies have been patented and firms and investors expect a return on their investment. Canadian policy makers face a choice of policy instruments to resolve this quandary through the implementation

of the OECD Guidelines for Licensing of Genetic Inventions. This thesis explores the implementation issues and feasibility of the choices of policy instruments for implementation of the OECD Guidelines and concludes that the soft law policy instrument is the most optimal choice for implementation of the Guidelines.

The specific objectives of the study are:

i) to review the theoretical underpinnings of the policy issues and concerns surrounding the commercialization of patents in biotechnology and genetics research;
ii) to present the case of Myriad Genetics and the enforcement of their patent rights on the BRCA1 and BRCA2 genes;
iii) to summarize the OECD Guidelines;
iv) to apply the policy framework created for implementing the OECD Guidelines and to provide a discussion regarding the choices of policy instruments for implementation of the Guidelines; and
v) to summarize the choices of policy instruments based on feasibility and to suggest best choice implementation options for the OECD Guidelines.

1.4 Organization of the Study

This study is organized into seven chapters. Chapter Two provides a literature review of the policy issues and concerns surrounding the commercialization of patents in biotechnology and genetics research. Chapter Three provides the theoretical insights regarding the health and innovation policy framework in Canada. Chapter Four provides the background to Myriad Genetics' enforcement of their intellectual property rights for the BRCA1 and BRCA2 genes and

highlights the policy issues and concerns that resulted. Chapter Five provides a detailed overview of the OECD Guidelines. Chapter Six applies the policy framework articulated in Chapter Three to analyze the potential effect the OECD Guidelines may have had on Myriad. Chapter Seven offers concluding thoughts, presenting a summary of the results, limitations and extensions to future research.

CHAPTER TWO

THEORY AND LITERATURE REVIEW

2.1 Introduction

The concept of health and health delivery has evolved. Health has come to be defined by so much more than the simple interaction between doctor and patient or contained within a hospital; it is a multi-faceted institution that encompasses citizens, doctors and researchers, governments, innovative technologies and the environment. Health delivery has the potential to be significantly affected by the role of innovative technologies upon health. The Canadian Biotechnology Advisory Committee (CBAC, 2004) suggested that a health innovation can be "… a new or improved product, service or method [that] is introduced and used in the course of providing health care to individuals, or in the course of organizing, managing and delivering health services from a population/public health perspective." This perspective of health clearly extends well beyond the conventional perception of health encompassing only the standard doctor/patient relationship.

The application of a new innovation to society must be accompanied by appropriate intellectual property protection mechanisms to provide the developers of the technology with the capacity and freedom to operate that is necessary to take new innovations forward for society's benefit. This is needed in order to serve the purpose of patent legislation by encouraging further research and development. This concept is relatively straightforward and openly accepted by societies when it comes to physical products (i.e. electronics); however, when it comes to the advancement, protection and commercialization of knowledge related to human genetics or more specifically, human genes, society gets very nervous, very quickly.

The relationship between human gene patents and the protection of intellectual property (IP) in this field of research serves to broaden the traditional concept of health. While patents in the health sector are not a new concept as it is commonplace for new drugs or diagnostic tools to be patented, what is new is that the human genes that are essential in diagnostic testing and disease treatment can be patented. Presently, human gene patents create complexity regarding freedom to operate. The lack of freedom to operate at the research level can create hold-ups for the commercialization of new technologies involved in the diagnostic testing and treatment of human diseases. As a result, researchers are uncertain over the effects that human gene patents will have on the future delivery of health services.

Considerable literature is available on the issues and concerns with the patent system. Some authors have opined that the system needs to be completely discarded or substantially revised (Scherer 2002, Siebrasse undated, Paradise *et al*., 2005). Others have argued that the system is fine (Gold *et al*., 2007) and that it is the management within the system that needs changing. Yet others have presented positions that perhaps a hybrid of a change in the legislation and a change in management is required. The OECD (2006) has determined that the patent system itself is effective for the purposes for which it was created; however, it acknowledges that there remain issues and concerns surrounding the patenting and licensing of genetic innovations.

The patenting of living life forms began in the 1970s involving microorganisms, but rapidly progressed into applications involving plants and animals in the 1980s. The patentability of lower life forms evolved to the point that it has now reached the pinnacle of higher life forms. This evolution began in 1980 with the United States ruling in *Diamond v. Chakrabarty*,

continued into 1982 with the Canadian decision in the *Application of Abitibi Co.* and concluding to date with the rulings on the *Harvard/Onco-mouse* applications. Each of these decisions builds upon its predecessor and illustrates the differing mindsets and considerations of the legal systems present in individual jurisdictions in adjudicating a patent application.

Table 2.1 shows that the various jurisdictions dealt with these initial applications in vastly differing amounts of time. This is especially evident when comparing the process of approving the Harvard mouse across the two jurisdictions.

Table 2.1: Relevant Decisions in Life Form Patenting

CASE	JURISDICTION	YEAR OF FILING	YEAR OF FINAL RULING
Chakrabarty	United States	1972	1980
Abitibi Co.	Canada	1976	1982
Harvard/Onco-mouse	United States	1984	1988
Harvard/Onco-mouse	Canada	1985	2002

The following section examines the precedent setting cases in the jurisdictions of Canada and the US. In both of these jurisdictions, the case that is presented was the initial living life form patent application case that opened the way for all subsequent life form patents. By comparing each of the two jurisdictional cases, it is possible to see the similarities and differences in each decision.

2.2 United States - *Diamond, Commissioner of Patents and Trademarks v. Chakrabarty*

In 1972, the Respondent, Chakrabarty, filed a patent application for a genetically engineered microorganism that degraded multiple components of crude oil and was therefore conceptually very valuable to the treatment of oil spills. The ability of this artificially-made bacterium to break down crude oil was not found in naturally occurring bacteria and was therefore treated as a newly created composition of matter. Within the 36 patent claims, Chakrabarty brought forward

three types of claims: the process to create the bacteria; the inocula to carry the bacteria on water; and the bacteria itself. The patent examiner accepted the claims for the process and for the inoculums but rejected the claim for the bacteria citing that microorganisms are products of nature and are living things and are therefore excluded from patentability under Title 35 U.S.C. 101.

Upon appeal, the Patent Office Board of Appeals reaffirmed the rejection on the grounds that the subject matter constitutes a living thing and that living things are not patentable subject matter under 35 U.S.C. 101. This decision was reversed by the Court of Customs and Patent Appeals who adjudged that “the fact that micro-organisms are alive is without legal significance for the purposes of patent law.”

Upon final appeal, the issue presented to the US Supreme Court was for the court to provide its perception or legal understanding of Title 35 U.S.C. 101, which states:

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

More specifically, the Court felt it was required to define the terms ‘manufacture’ and ‘composition of matter’ as they appear in the statute based on their intended purpose and their usual, common meaning. Further, the Court determined that the use of expansive terms such as 'any new and useful …. manufacture, or composition of matter …' clearly indicated that the

patent laws should be given broad scope. As such, the Respondent's microorganism was held to be patentable matter.

The Petitioner, The Commissioner of Patents and Trademarks, put forth two arguments both of which were rejected by the Supreme Court. Firstly, the Petitioner argued that the micro-organisms were excluded from patentability as they were living organisms and the presence of the 1930 *Plant Patent Act* and the 1970 *Plant Variety Protection Act* provide evidence that Congress did not intend for living things to be patentable under the *Patent Act*. This argument was not found to be persuasive. The enactment of the 1930 *Plant Patent Act* was done to address two concerns regarding the patentability of plants: that all plants were excluded from patentability as natural products; and that plants were not patentable because differentiation was difficult, if not impossible, to obtain in the written description requirement of a patent. Such concerns were addressed in the Act wherein it states that the work of a plant breeder is patentable and through the relaxing of the written description requirements for such patentable plants. The 1970 *Plant Variety Protection Act* extended the protection afforded by the 1930 Act for true-to-type reproduction of plants. Further, there is no exclusion for the patentability of bacteria in either Act. The enactment of these two Acts does not indicate that Congress intended for living organisms to be excluded from patentability under referenced patent legislation.

The second argument put forward by the Petitioner stated that the unforeseen development of genetic technology was excluded from patentability because Congress could not possibly have intended for this to be included as there was no pre-existing knowledge that such products could be created. The Court ruled that while the sociological arguments put forth in the brief filed by

the Petitioner illustrate some valuable concerns, it is not the job of the Courts to augment societal concerns into its role in determining what the law is in areas of perceived ambiguity. Further, the Court states that there is no area of ambiguity in the patent legislation; there are merely broad terms which are required to obtain the objectives of Congress which, in this case, is to allow for the patentability of unforeseeable inventions. It is the position of the Court that subject matter that is not expressly included in patent legislation as patentable is not deemed as excluded from patentability on that basis alone.

It is important to note that the ruling in *Diamond v. Chakrabarty* is very narrow and was based on the artificial content of the bacterium. The Court clearly stated that while the bacterium was a living organism it was not a natural life form and, more importantly, that the relevant distinction for patentability was between products of nature and man-made products and not living versus inanimate things. Chakrabarty received patent protection upon the ruling of the US Supreme Court in 1980, eight years from its initial filing date in 1972.

2.3 Canada - *Abitibi Co.*

Abitibi Co. applied for a patent on June 16, 1976 for its assigned microbial yeast culture created from domestic sewage. Such sewage is modified to create spent sulfite waste liquor which is then used to digest sulfite waste liquor from pulp plants thereby allowing the effluent to be disposed of without contamination of the waste system. Value to the culture is enhanced as a result of its ability to purify foaming wastes. The culture was found to be able to recreate itself on spent sulfite liquor ensuring the continued supply of the product. The process claims of creating the culture were allowed by the patent examiner; however, the examiner rejected two claims on the

basis that the culture is a living thing and is therefore excluded from patentability under Section 2 of the *Canada Patent Act*.

Relying on the ruling provided in Chakrabarty, the Applicant claimed that the culture is a man-made product and therefore falls within the realm of the definition of 'manufacture' and 'composition of matter'. Abitibi further submitted that if a process is patentable for the creation of a living organism, the creation or living organism itself should therefore be patentable as well.

Precedent setting decisions in Germany, Australia, Canada and the United States illustrate that judicial bodies have broadened the scope of the legislation for patentable subject matter to encompass new developments and emerging technologies. As such, the Patent Appeal Board could not with certainty believe that the Canadian courts would not allow the patentability of a microorganism. This is the satisfying criterion for Section 42 of the Act.

Section 36 of the Act requires that for a product to be patentable the inventor must be able to describe the creation of same such that it can be duplicated by any member of the public schooled in the art or science under which the product was invented. In this case, the Board held that such section has been satisfied given that the microorganism can reproduce itself in the described medium at a level that is sustainable to supply the public the microorganism into the future and upon expiration of the rights granted under the patent.

The Board held that the microbial yeast culture satisfied the criteria necessary to meet the test of patentability and provided its recommendation that the rejections be withdrawn. Upon review of

the findings, the Commissioner concurred and remanded the application to the examiner for execution. From the date of filing, June 16, 1976, to the date of final adjudication by the Patent Appeal Board, March 18, 1982, it took just under six years for Abitibi to secure its patent.

The significance of the ruling of the Board in Abitibi is seen in its summary review of case precedence from several jurisdictions and in its deviation from the historical practices of the Canadian Patent Office. Past practices of the Patent Office were to narrowly define patentability of lower and higher life forms such that a general ruling was that higher life forms were excluded from patentability. In its ruling, the Board provided a clear outline of the criteria for patentability of living things. Holding to Section 36, the inventor must provide a description of the method of production clearly and concisely to allow for future reproduction; this is done through the ability of the microbial yeast culture to reproduce itself upon the creation of the medium. The medium for reproduction must therefore be well articulated to be afforded patent rights and be reproducible. Further, the organism must be a new and useful invention and not merely a stepping stone for further research. Such organism must also possess traits that are significantly different from any known species to satisfy the requirement for inventive ingenuity.

2.4 Cross Jurisdictional Comparison

Harvard College applied for a patent for a ‘transgenic mouse’ whose genes had been modified by the induction of the oncogene into a fertilized mouse egg in its early stages of development. The modified egg is then planted in the female mouse whose offspring are then born and tested for the presence of the oncogene. Founder mice are created in this fashion and are categorized based on the presence of the oncogene. These mice are then mated with unchanged mice. It is the

offspring of this coupling who present the existence of the oncogene that are suitable for use in cancer research. Harvard College filed the same patent application in the US and Canada.

2.4.1 *Harvard/Onco-mouse – US Decision*

On June 22, 1984, Harvard College filed a patent application for a patent on a higher life form. The product claims of the application were for transgenic, non-human mammals whose cells contain the oncogene sequence as introduced into such mammal or any ancestor of such mammal. Specific claim was made for the 'transgenic mouse'. Process claims consisted of the method of creating the transgenic cell culture and induction into the mammal, the method of testing for the presence of carcinogens in the transgenic mammals, the method of testing matter believed to cause the formation of malignant tumors and various claims relating to the cell cultures and plasmids of the transgenic mammals (Garland and Smordin, 2003).

The 1980 ruling in *Diamond v. Chakrabarty*, as outlined above, provided the legal basis upon which Harvard College was successful in obtaining acceptance of its patent application for the transgenic mammals in the United States (Ramlall, 2003). The main premise of the Chakrabarty ruling is the distinction of man-made versus naturally developed products.

With the ruling in 1988, the patent application process concluded and afforded Harvard College their patent protection benefits four years after the initial date of filing.

2.4.2 *Harvard College v. Canada (Commissioner for Patents)*

Harvard College's Canadian patent application was filed on June 21, 1985 entitled 'Transgenic Animals' and, once again, encompassing the product and process claims as contained in the corresponding US patent application filed in 1984 and outlined above.

All of the product claims, those claims relating to the onco-mouse in and of itself, were rejected upon examination by the Patent Office based on the determination that the onco-mouse was not an 'invention' as defined by the Patent Act: "any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter". The Examiner further noted that there is a lack of precedence for the patentability of higher life forms. The 1982 ruling in *Abitibi* allows for the patenting of lower life forms; however, the Patent Appeal Board noted in its ruling in *Abitibi* that the patenting of higher life forms would require further debate and consideration. Also referenced was the ruling in *Pioneer Hi-Bred* wherein the Commissioner of Patents adjudged that the product did not fall within the definition of 'invention' pursuant to the Act (Garland and Smordin, 2003). The process claims contained in the onco-mouse application were accepted by the Examiner.

In its ruling of August 1995 on the appeal, the Commissioner of Patents noted that the Supreme Court in *Pioneer* did not rule on the definition of inventions but rejected the claim on the basis of insufficient disclosure. The Commissioner separated the subject matter into two phases and found that the inventor could control the creation of the plasmid (phase one) but not the final mouse (phase two), the offspring of the host mouse, which is produced through the laws of

nature. This finding was qualified by the position of the Commissioner that the terms ‘manufacture’ and ‘composition of matter’ are items that are controlled by the inventor (Garland and Smordin, 2003). Such findings resulted in the Commissioner for Patents reaffirming the ruling of the Patent Examiner.

Review of the case by the Federal Court Trial Division resulted in the appeal being dismissed and the decision of the reaffirmation of the decision of the Commissioner. Following in the next step of the appeal process brought the matter to the Federal Court of Appeal. Summarily, the Federal Court of Appeal reversed the decision of the Trial Division and directed the Commissioner to accept the product claims of the onco-mouse patent application. After 17 years of debate within the Canadian legal system, in 2002, the Supreme Court of Canada overturned the Federal Court of Appeal ruling with a 5-4 majority decision and with finality determined that the Harvard/Onco-mouse is not patentable in Canada. Interestingly, the Court ruled in favour of the claims for patenting the process to create the onco-mouse and the genes involved in this process, but the living life form was rejected.

The significance of the *Chakrabarty* decision lies in the ruling setting the basis for the patenting of a living organism which is considered to be a lower life form. This decision and the mindset of the Court in reaching same served to set the premise upon which the US Patent & Trademark Office granted Harvard College the patent on the onco-mouse. Of particular interest is the approach of distinguishing that the issue at hand was not that of a lower versus higher life form but was that of a man-made versus nature created subject matter. The Court surmised that it was not relevant that the invention was a living organism; what was relevant was if it was in fact an

invention pursuant to the terms of the Act requiring that an invention be manufactured and be a composition of matter. Utilizing this mindset going forward, we can see some clear distinctions that can be drawn when determining patentability. If man's intervention is required to create the product and such product could not be created without man's intervention such a product should therefore be deemed patentable, all other conditions of patentability having been met, notwithstanding the living or non-living state of such product.

While both the Federal Court of Appeal and the Supreme Court in Canada have stated that social policy debates have no place in determining the patentability of the onco-mouse, it is interesting to note that the Supreme Court makes a notation that to patent the subject matter would be akin to patenting a higher life form which would be a contentious issue and outside of the scope of traditional practice of the Canadian Patent Office.

In the US, a positive evolution has taken place in the patenting of lower and higher life forms, where there has been progression in the influential decisions as they have come forward over the past 25 years. Canada began its evolution with the *Abitibi* decision and, at first glance, appears to have ceased such progress by its final ruling on the Harvard/Onco-mouse application.

Is that truly the case though? Has the ability to protect higher life forms in Canada been circumvented by the Harvard mouse ruling? The Supreme Court ruling in the *Monsanto v. Schmeiser* case provides for what is being termed as practical patent protection (Ogilvy Renault, 2003). Monsanto claimed the chimeric gene and the plant cells that contained such gene in its patent application and did not make claim to the transgenic plant itself. The infringement ruling

against Schmeiser was valid based on the reproduction of the chimeric gene and the plant cells containing such genes as they were present in Schmeiser's crops. At the time of the filing of the Harvard mouse application and its subsequent ruling, it was not technologically possible to monitor the presence of a gene at the single cell level. This is exactly the process that has been utilized in confirming the existence of the protected product in the *Monsanto v. Schmeiser* case. When dealing with transgenic life forms, whether higher or lower, practical patent protection can be obtained by claiming the specified gene and the cells of the organism containing such gene (Ogilvy Renault, 2003).

While the US has granted the patenting of higher life forms, with the exception of human beings, Canada has not done so, per se. Canada does, however, have protective mechanisms in its present legislation to afford very practical protection with the equivalent result as is obtained in the US.

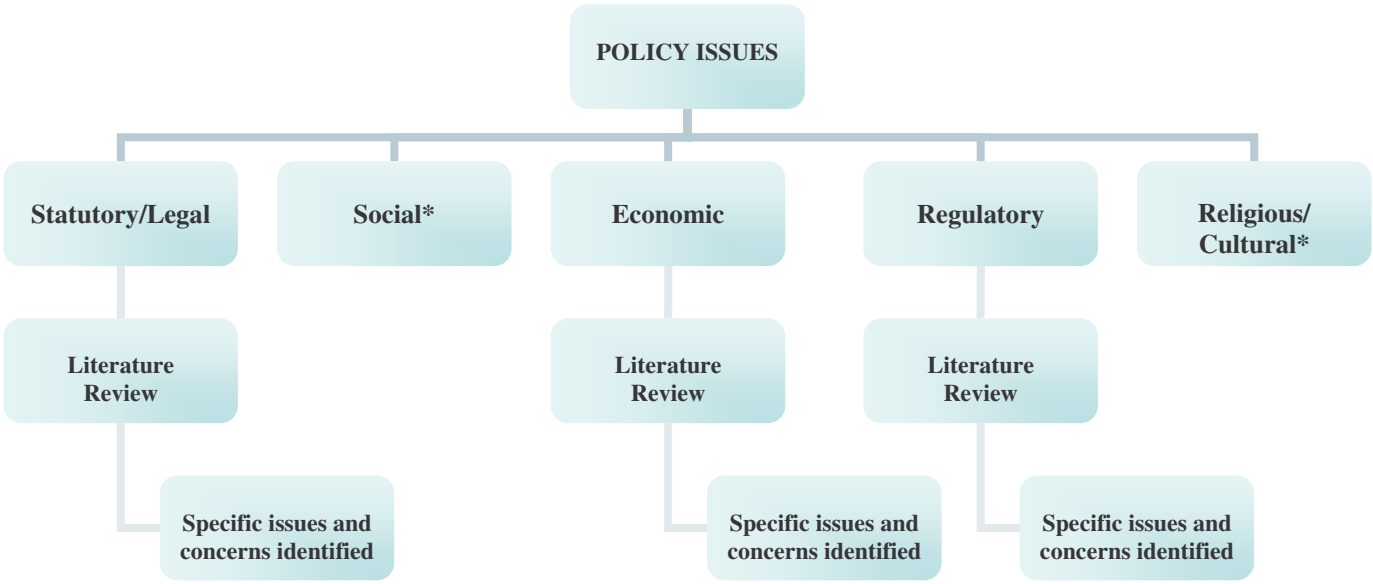
CHAPTER THREE

ANALYTICAL FRAMEWORK

3.1 Introduction

This section provides a concise contrast of the governance frameworks relating to patenting of higher life forms. The key elements of the governance framework are: statutory (legal); economic; and regulatory (Figure 3.1). These three aspects are finally contrasted with the OECD Guidelines relating to the patenting of genetic inventions.

Figure 3.1: Identifying Issues and Concerns with Present Patent System



*Not focus of topic of thesis therefore culled.

3.2 Statutory/Legal

Discussions and debates regarding IPRs, and more specifically patent rights, highlight some recurring concerns. These topics are presented above and have been discussed at length at many levels of government and within both public and private organizations. Concerns regarding the use of IPRs and patents revolved around the need to review, with a potential solution to amend,

the IP system (Phillips, 2007). While the above concerns are present in all industries within which IPRs and patents are utilized, the debate becomes more contentious when considering these matters within the context of biotechnology and genetics research. One of the objectives of an IP system is to foster research and development by providing an opportunity to earn a return on a research investment. The dollar investment in biotechnology and genetics research is extensive and it is through these research areas that a significant contribution is being made to enhancing human health and the delivery of healthcare services (OECD, 2006). As a result, it is relevant to ask and seek to determine if Canada's health policy and IP system are complimentary and if the objectives of each of these systems are being met within the confines or operations of the other. This opens up the discussions on patent rights and their effect on health and healthcare services – an ongoing, controversial discussion within the ranks of government and society in both developed and developing countries.

The following summary of the *Canada Health Act* (1984) and the *Patent Act* (1985) of Canada, highlight areas of potential conflict between the two Acts. Following this, the section will summarize the OECD's 'Guidelines for Licensing of Genetic Inventions' and proposed implementation approaches presented at the Health Canada Symposium held in Vancouver in March 2006.

3.2.1 The *Canada Health Act*

There are five criteria contained in the *Canada Health Act* that must be adhered to by the provinces in order to qualify for the full annual cash contribution that the federal government provides to each province with regard to healthcare spending. Each of these criteria has its own

level of importance within discussions surrounding biotechnology and genetic innovations and their contribution to health and the delivery of healthcare in Canada. These five criteria are: public administration; comprehensiveness; universality; portability; and accessibility. The following three are relevant to this paper.

Comprehensiveness within the *Canada Health Act* requires that the provinces "must insure all insured healthcare services provided by hospitals, medical practitioners or dentists," and where the law of a province dictates, any other such service provided by any other healthcare professional. A provincial government cannot arbitrarily refuse to pay for or insure an insured service that is defined as an insured service pursuant to the Act and any relevant provincial laws. The *Canada Health Act* defines an insured health service as "hospital services, physician services and surgical-dental services provided to insured persons." This definition does not include those health services that are provided under other forms of legislation such as workers' compensation. This criterion provides a minimum standard of insured care that is available to all residents of a province.

Universality requires that each and every person defined as a resident of a province be entitled to the same insured health services provided under the provincial insured health plan on the same terms and conditions. The goal of this criterion is to remove financial barriers to access of medical services and to assist in setting the base standard of healthcare to be provided to all residents of a province.

Accessibility deals primarily with ensuring that all insured persons are not restricted from reasonable access to insured health services for as a result of any charges for such services. Adherence to this criterion also requires that the province provide reasonable compensation to healthcare providers and hospitals for the provision of insured health services. The objective of this clause is to remove the financial barrier that may be present to residents of a province in order to obtain access to insured health services.

In summary, the *Canada Health Act* seeks to provide a uniform system of healthcare across the board to all Canadians regardless of race, gender, province of residence or socio-economic status. It seeks to provide equality and eliminate any opportunity for discrimination of any type within the healthcare system in Canada.

3.2.2 The *Patent Act*[1]

The *Patent Act* of Canada provides patentees, those entitled to the benefits of a patent, "the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used." In order to obtain these patent rights, an application for an invention must be made to the Commissioner of Patents and must contain a specification of the subject matter. Specification is a detailed description of the invention and how it is used, how the invention is created or made such that any person skilled in the art or science from which the invention is created could replicate same. Should the subject matter of a patent be a process, the specification portion of the application must include the required sequence of steps specific to the subject

[1] This review of the *Patent Act* of Canada is not exhaustive in nature but is specific to the sections of such legislation that are relevant to the discussion topic of this thesis.

matter. The specification must be completed with the statement of a claim or claims that clearly defines the subject matter of the invention for which the patent rights are being sought.

Under the Act, for an invention to be defined as patentable it must not be previously disclosed to the public and must be novel and useful. Section 28.2 of the Act states that the subject matter of a patent application must not be public information more than one year before the filing date of the application. The filing date of an application is the date upon which the Commissioner receives the patent application and any required supporting documents and fees. The novelty of an invention is defined in Section 28.3 of the Act and requires that the subject matter of a patent application not be obvious to a person skilled in the art or science of the industry in which the subject matter is contained.

Section 19 of the *Patent Act* states that the Commissioner can authorize the use of a patent by either a federal or provincial government subject under the following criteria:

i) That the subject matter of the patent be used to supply the domestic market;
ii) That the government pay for the use of such patent based on a fair and equitable economic valuation; and
iii) That efforts were made to obtain the use of such patent from the patentee on "reasonable commercial terms" and that such efforts were unsuccessful except in the case of a national emergency or urgency or where use of the patent is sought for public non-profit use.

Section 32 of the Act provides for the patentability of improvements made to existing patents. This section also requires that the researcher or inventor obtain proper authorization for the

original patent or patents and that only such improvements be the subject matter of the new patent application.

3.3 Economic

Phillips (2007) provides a discussion of four reasons for economic resistance regarding patenting and intellectual property rights: generating investment debate; freedom to operate concerns; monopolistic opportunities; and return on investment.

3.3.1 Generating Investment

Intellectual property rights were designed to provide economic incentives for private business to invest in research and development and knowledge-based industries (Jackson, 2003; Caulfield, *et al*., 2004). Patents are one form of IPRs that provide the owner of a patent a monopoly over the invention for a defined period of time and an avenue for legal recourse against those who use the invention without authority to do so (Jackson, 2003; Caulfield, *et al*., 2004). In return for those rights, patent owners in Canada agree to share their information with the public to work towards government's goal of inciting further research and development (Jackson, 2003). Phillips states that the evidence supporting the need for patents in order to generate ongoing private investment in research and development is contested, opining that a stronger argument is whether or not patenting is required for private investment in *commercialization* of products or innovations in biotechnology. He further opines that many biotechnological inventions that reach the market are pharmaceutical in nature, coming from non-commercial programs but incurring large regulatory and development costs.

The investment debate increased in intensity post the Supreme Court of Canada's ruling on the Onco-mouse patent application. Phillips posits that one side of the debate resulted from the perception that the rejection of the product claim in the patent application put Canada at a disadvantage with other competing countries in the biotechnology industry since the rejection would have a negative effect on private investment in research and development in Canada. Others have argued that the ruling would promote other forms of, and investment in, alternative methods of research. Neither of these arguments has been supported by empirical evidence to date.

Investment into research provides the financial wherewithal to conduct the research; however the next argument in the debate on patenting life forms is the restrictiveness of further research based on granted patents and the need for licenses and agreements in order to build upon protected research. This restrictiveness refers to freedom to operate concerns.

3.3.2 Freedom to Operate

Vast uses of gene sequences in biotechnology makes it exceedingly difficult to clearly determine the specific terms of a gene patent. At the time of development and patenting, it is unknown what the future uses of a gene sequence will be and, in the absence of substitutable products, it becomes virtually impossible to define the terms of a patent resulting in a greater breadth to the terms of the patent itself. The breadth of patent claims further reduces opportunity for research and development based on the initial gene sequence as it would most often result in patent infringement. This particular concern varies in degree based on the position of the owner of the patent – whether or not the owner is adverse to patent infringement litigation or not (Caulfield, *et*

al., 2004; Jackson, 2003). Such breadth of patents and the lack of explicit research exemptions in patent systems create freedom to operate concerns.

Phillips states that while research exemptions do not exist in patent systems, many public universities and institutes are undertaking their research using private IP without a license. The problem with operating without a license and conducting further research is the impediment created to commercializing that research given the unauthorized use of IP. Phillips opines further that a research exemption may not address this concern as exemptions do not provide a method for negotiating a commercialization contract and would likely lead to strategic bargaining and result in a loss of sunk costs. A more appropriate model would be the use of research licenses which would contain provisions for negotiating subsequent operational licenses (Phillips, 2007).

Research hold-ups are known to exist and with the increase in the breadth and depth of the patent pool, there is increased concern as to whether hold-ups are on the rise. Recent research from the agricultural side of the biotechnology industry examine the issue of hold-ups in some detail (Dierker and Phillips, 2003, Galushko *et al*., 2010; Smyth and Gray, 2011). The authors identify that hold-ups in agricultural biotechnology research have developed in the past 20 years, but that innovative strategies have been implemented by the various firms to address the situation. The suggestion appears to be that the hold-ups that develop in an industry are tolerated at the lower levels, but once the inability to have large degrees of freedom to operate, the industry repositions itself in such a way that it tries to resolve the barriers to innovation as best as possible.

The restricted use of a patented innovation provides patent holders with monopolistic opportunities in the market place resulting in the third reason discussed in this paper for economic resistance.

3.3.3 Monopolistic Opportunities

Patent protection provides patent holders with the right to a monopoly over the use of the patented product or innovation. This monopolistic position gives inventors the opportunity to restrict supply of their product in the market thereby resulting in higher prices to consumers and higher profits to the inventors (Phillips, 2007).

In a competitive marketplace, firms are allowed to price discriminate, but at their own peril. If a firm drastically overcharges for a product, it can serve to undermine the success of the product as consumers will decide that the perceived benefits are not justified by the pricing strategy. Additionally, if the potential for profits is substantial, other firms will discover ways and means of inventing around a specific patent and thereby providing competitive products to the market. Increased competition is the biggest economic fear that monopolistic firms have as they prefer to price such that other firms will not desire to enter the market, yet that consumers are not complaining about the price of the product and demanding the introduction of competitive products.

3.3.4 Return on Investment

Gene or life form patenting is more complex than traditional technological patents because of the hybrid of both technology and information within a gene sequence (Jackson, 2003). Information

contained in the same gene sequence can be used for pharmaceutical development, in areas of diagnostic testing for diseases, in target drug formation and a few other areas (*Ibid*.). Each area requires additional investment to pursue research post the identification of the gene sequence in and of itself. Identifying the protein content of a gene is a very costly venture and patenting is required to attract investors to empower biotech and knowledge-based industries and to elicit further investment that is required to protect the IPRs of investors (*Ibid*.).

A predominant economic reason that patenting of life forms is resisted is the cost factor involved with patenting and the inability to see the financial return of such patent in the vast majority of cases. The reasons for economic resistance to patenting life forms – generating investment, freedom to operate, monopolistic opportunities and return on investment – are open to debate and are supported based on varying perspectives of the participants in the discussion; however, the reasons are present and do create economic resistance. As contentious as the arguments on economic resistance can be, a more intense debate ensues when the reasons for social resistance are discussed.

3.4 Market

The delivery of health care is facing numerous challenges and the issue of human gene patenting and its potential to affect the delivery of health care services will continue to increase as the level of human gene research advances. As researchers apply for patents on human genetic discoveries and innovations regarding disease research, the potential exists that IPRs could impede the delivery of healthcare services or other researchers' ability to undertake research in the same or a related field. A study of patents on human genes examined 74 human gene patents and found

there were 1,167 claims resulting from those patents (Paradise *et al*., 2005). Multiple patent claims have the potential to increase the complexity and difficulty of freedom to operate related to gene disease research.

Research regarding the level of human gene patents would appear to vary, but a study by Jensen and Murray (2005) indicates that nearly 20% of human genes had been claimed by then in US patents. The authors had identified that 4,270 gene patents (containing 4,382 claims) existed within the National Center for Biotechnology Information database. The authors make an important observation in their article in that the number of gene sequences that have been explicitly claimed (4,382) is much different from the number of gene sequences that have been merely disclosed, which the authors estimate could be as high as 10 for every one patented. One important observation in this article is that nearly two-thirds (63%) of the human gene patents that have been assigned, have been assigned to private firms.

While the amount of peer reviewed research is scarce on this topic, initial studies would suggest that there is a correlation between human gene patents and the ability to overcome some challenges in the delivery of health care services. Merz *et al*., (2002) report a 30% decline in genetic testing for haemochromatosis after patents for this test were awarded. Cho *et al*., (2003) surveyed clinical laboratory directors in the US and found that 53% decided not to develop new clinical genetic tests because of patent concerns. Additionally, the survey found that clinical geneticists believed that their research was inhibited by existing human gene patents.

From both the public and private perspectives, Caulfield (1998) argues that patenting is essential to fostering continued investment in research and the development of appropriate regulations in biotechnology. In the era of health care budget cuts and under-funding, public funding has been difficult to obtain, thereby increasing the opportunity for private entities to fund research initiatives. The health care market is an inefficient system and requires regulations within the system in order to provide the benefits of commercialization to government and society.

Many have argued that Canada's system is over-regulated and can be seen as prohibiting further development in biotechnology. For example, the enactment of Bill C-47, the *Reproductive and Genetic Technologies Act* is cited by Caulfield as an example of such over-regulation by restricting commercialization of genetics. Caulfield provides the consumer position on patent choice as restrictive when consumers perceive that their choices are being restricted by regulation.

Restricted and timeliness of information flow is one concern outlined by Caulfield. In order to facilitate the novelty of a patent, the information surrounding the patent must not be common knowledge. As such, new developments or findings regarding the effects of a medication, for example, may be held back from consumers in order to protect patentability. Contrastingly, researchers may jump too quickly to share information in order to capitalize in a dynamic market. This potentially results in dependence by consumers on a product where in-depth testing of such product may not have been completed sufficiently or the societal effects of widespread use of such a product have not been given proper consideration prior to commercialization. Caulfield uses the marketing of pre-disposition testing as an example, articulating the

dependency of consumers on the results of pre-disposition test results for Alzheimer's and breast cancer. When these products were first introduced into the market, it was not with the consideration that the pre-disposition testing is a conclusive answer but is an aid used in diagnosis analysis with other variables.

Consideration should also be given to the potential increase in health care costs as a result of additional testing that is available in an inefficient market. The market is considered inefficient because of the knowledge discrepancy between providers and consumers. As such, many consumers will perceive a 'right' and 'need' for products such as pre-disposition diagnostic or prenatal testing that could cause a further financial hardship on an already financially challenged system. Regulation regarding the definition of such need versus right to such products and services would assist in this regard. Such regulation should give consideration to who should pay for such products in a largely socialized system of health provision.

CHAPTER FOUR

MYRIAD GENETICS

4.1 Introduction

The case of Myriad Genetics, headquartered in Utah, USA, and its patents on the BRCA1 and BRCA2 genes will be utilized to discuss patenting concerns, with specific consideration being given to the present patent system and the delivery of healthcare services. A comparison will then be made between the potential effects of the OECD Guidelines and the implementation options and the present Canadian intellectual property system, which must conform to the *Canada Health Act*.

4.2 Enforcing Patent Rights

In the spring of 2001, Myriad Genetics filed an exclusive patent application regarding testing for BRCA1 and BRCA2 breast cancer genes. At this time, four Canadian provinces used Myriad's genetic screening tests, Alberta, British Columbia (BC), Ontario and Quebec. Myriad sent letters to the Ministries of Health in each province informing the provinces that the firm now had patent rights to the genetic-sequencing tests: and that provincial testing programs would violate Myriad's patent. The provinces were informed that all samples should be sent to Utah and that the tests would be performed there for a per-test cost of C$3850 (Kent, 2001). This cost was more than triple what the provinces were spending at the time. Prior to the Myriad notice, the province of BC was spending C$1200 per test and Ontario was spending C$1150 (Eggertson, 2002). Due in part, to this cost increase and legal advice, the BC Ministry of Health decided to suspend its screening program in July 2001.

This decision by the BC Ministry of Health resulted in 300 patient samples that were awaiting analysis being left with minimal options. The British Columbia Cancer Agency (BCCA) was the government body that conducted the test analysis, but it was taking, on average, 18 months to get the test results due to staffing shortages (Kent, 2001). Myriad was offering to provide test results in 6 weeks and it is estimated that six of the patients paid these costs out of their own pockets (*Ibid*.). After about 18 months with no testing in BC, the BCCA reached an agreement with the province of Ontario to have the tests analyzed in that province. Results of the tests took about six months through this arrangement.

The Ontario government took a different approach to the letter received from Myriad. An assessment of the legal, ethical and financial implications was done and the government decided that the precedent that would be established was unsupportable and decided to continue screening programs. The then Minister of Health for the Province of Ontario, Tony Clement, said that Ontario would continue funding existing programs through their regional genetics centers and that payment to hospitals for these services "… does not constitute infringement of any valid claim of Myriad's patent" (Eggertson, 2002: 494). Myriad questioned whether Canada would uphold biotechnology patents.

The Alberta government also suspended its screening program to allow legal experts to assess the validity of the patent and its claims. After this assessment was done, the Alberta government resumed the screening programs that are funded through the Alberta Cancer Genetics Program. The Quebec government was the lone province that agreed to comply with Myriad's letter and sends all test samples to Utah for analysis.

The BC government's decision to comply with Myriad's request to suspend testing, ultimately supported the IP claims of Myriad. The government had the option of increasing the funding to cover the increased cost of the testing program but declined this option. William-Jones and Burgess (2004) suggest that this decision makes the BC provincial government complicit in discontinuing publicly funded health services. They argue that what this decision ultimately meant for women in BC was that the government "… engaged in *de facto* priority setting, placing IP protection ahead of equitable access and establishing two categories of patients, those who could and those who could not afford the test" (*Ibid*.:120).

The Canadian context of the Myriad patents rights assertion presents an interesting dichotomy. One province (Quebec) complied with the firm's request and sent test samples to Myriad for analysis and funded the extra cost through its health care system. A second province (BC) complied, but in the opposite manner and halted its screening program, thereby denying this service to its population. Finally, two provinces ignored Myriad's intention to enforce its IP and continued with the screening programs already in existence. All of this has taken place within a system of nationally funded health care that operates pursuant to the *Canada Health Act* and is supposed to provide equal access of healthcare services to all Canadians.

The decision of the provincial governments to stop offering BRCA gene testing through the publicly funded system has resulted in a decline in the number of genetic tests being performed on Canadian women. Preventative treatment opportunities were being lost as a result of the limitation on the performance of the number of predisposition tests for the BRCA genes.

Provision of healthcare services in Canada is primarily governed by the provinces however, the federal government regulates healthcare through its financial support by way of equalization payments and through the enforcement of the *Canada Health Act*. The *Canada Health Act* (CHA) requires that all Canadian citizens receive equal access to healthcare notwithstanding one's ability to pay for such services. A further cost to the government in the patenting of the BRCA genes resulted from the provincial governments being required to responded to Myriad's cease and desist demand in offering the tests and the cost of the tests thereafter more than tripling. The perception exists that this is tantamount to contravening the CHA based on accessibility subject to ability to pay. It could also be perceived that the patent granted to Myriad is within the realm of privatized services which is mostly restricted through both provincial and federal legislation.

Society and government pay the cost of restricted research and development into areas that could develop more economical testing methods. Monopoly rights granted to Myriad with its patents on the BRCA genes restricts any competitors from attempting to develop a 'spin-off' test as a result of the non-substitutable good available for a gene sequence. Any attempt to develop a spin-off would result in infringement and possible litigation related to the product based claim.

Clearly, Myriad's Canadian patent affected the delivery of healthcare services in Canada. While most of these effects were short term, until provincial governments were able to review and solicit expert legal opinions, at the extreme, the province of BC had no screening program operating for nearly two years. Additionally, it is impossible to discern how this patent

enforcement has affected any of the six provinces that do not presently offer screening programs but are considering developing such programs.

While it may be expected that Myriad would have turned to the courts to protect their IP in Canada, this did not happen. Myriad's BRCA1 and BRCA2 genetic tests are but one option for women to be tested for hereditary disposition of breast cancer. The province of Ontario's defiant response to Myriad's letter may have been more for political gamesmanship than anything as the province rapidly moved to adopting an alternative test. Beginning in 2003, the province began testing with denaturing high-performance liquid chromatography. The provinces of Alberta and BC also sought alternative tests and BC once again offers its own testing program.

Monopolistic behaviour was practiced by Myriad Genetics in the enforcement of their patent rights on genetic testing methods for the presence of the BRCA 1 and 2 used in identifying a patient's predisposition for breast and ovarian cancer. Myriad's patent enforcement resulted in higher prices for the tests and greater profits to Myriad – and less testing being done on women who met the testing criteria and an increase in diagnostic waiting lists. However, without doing a detailed calculation of the numbers but through a theoretical evaluation, it would appear that Myriad did not maximize its profitability as a lower price would have seen a higher number of tests being conducted and therefore more revenue being generated. The return on investment that could have been obtained by Myriad and the debate surrounding same can potentially be attributable to poor business decisions as opposed to patenting policies.

CHAPTER FIVE

OECD GUIDELINES

5.1 Introduction

The OECD determined that the IP system as it relates to biotechnology and genetic inventions largely serves its purpose. However, the OECD goes on to state that there are issues and concerns within the system that need to be addressed and have therefore produced their Guidelines for Licensing Genetic Inventions. The Guidelines contain principles and best practices for licensing generally, healthcare and genetic inventions, research freedom, commercial development and competition. Within the scope of these headings we see the OECD focusing on the concerns outlined above as relevant to the Canadian intellectual property system.

5.2 Article 1 – Licensing Generally

The OECD's general licensing principles and best practices are formulated to make available genetic inventions on a reasonable basis (free or at cost preferred), to stimulate research, to balance the interests of both the licensee and the licensor and to provide licensors with the licensing process to overcome freedom-to-operate issues. The OECD Principles and Best Practices state that licensing of genetic inventions should:

i) promote further genetics research by permitting licensees to improve existing genetic inventions;

ii) make readily available the products and/or services using genetic inventions by having patentees or licensors agree to terms that will maximize the use of the genetic invention;

iii) promote efficient and effective communication of information on genetic inventions by having clearly defined ownership, enforcement and collaborative rights and responsibilities; and

iv) provide return on investment opportunities by clearly defining the roles and responsibilities of the parties relative to the commercialization of the product or service arising from the genetic invention.

5.3 Article 2 – Healthcare and Genetic Inventions

Access to existing research and recognition of the need for a balance between return on investment and need for the innovation are applicable concerns. As well, timeliness, options for products and services and addressing unmet and urgent health needs were a focus of the OECD in creating the Principles and Best Practices for Healthcare and Genetic Inventions. This section of the Guidelines states that licensing practices should:

i) give a balance of consideration between delivery of innovations, healthcare needs and economic returns by utilizing strategic broad licensing practices;

ii) protect patient confidentiality to the highest possible standards by strict compliance with applicable laws and regulations;

iii) not restrict alternative product options to patients by permitting healthcare providers to offer alternative product or service options to their patients; and

iv) encourage the use of and provide access to genetic innovations to enhance healthcare services and the deliverance of same by utilizing broad licensing terms and exploring opportunities to license genetic inventions in other jurisdictions.

5.4 Article 3 – Research Freedom

Research freedom deals with the concern of stifled research, establishes licensing practices geared towards increasing access to inventions and not restricting educational training nor a researchers ability to publish in a timely fashion. Specifically, the Principles and Best Practices contained in the Research Freedom section of the Guidelines state that licensing practices should:

i) increase access to genetic inventions for research purposes;

ii) give consideration to commercialization requirements but should not obstruct research freedom nor restrict educational opportunities for students relative to genetic inventions; and

iii) give consideration to the requirement of non-disclosure pursuant to the *Patent Act* in defining patentability but should not unreasonably delay dissemination or publication of information obtained through research.

Each of these principles is suggested in the Guidelines to be practiced through education and clear communication of the responsibilities and requirements of confidentiality obligations for patentability together and with narrow licensing terms relative to confidentiality whenever possible and, specifically, should not restrict the disclosure of information in a timely fashion in public health situations.

5.5 Article 4 – Commercial Development

The Commercial Development section of the OECD Guidelines suggest that licensing principles should:

i) provide broad access to genetic inventions;

ii) be used to provide opportunities to develop new products and services from a genetic invention; and

iii) focus on coordination efforts for negotiating authorization of multiple genetic inventions required to further research.

The Guidelines suggest that the best practices for commercial development in licensing of genetic inventions include encompassing a single royalty payment with negotiating access to multiple genetic inventions and creating a realm of lower access barriers with no reach through rights for licensors.

5.6 Article 5 – Competition

The Guidelines suggest that licensing practices relevant to competition should:

i) encourage and promote economic growth through competition by not unreasonably restricted selling; and

ii) not be used to expand the exclusivity of intellectual property rights provided through the intellectual property system through avoidance of unduly restrictive non-compete clauses in a license agreement and utilizing non-exclusive agreements whenever feasible.

The following Section provides a comparison of the OECD Guidelines with the *Canada Health Act* and the *Patent Act.* This analytical component of the thesis connects the document and allows for an assessment of how the OECD Guidelines might have been used or interpreted during the Myriad issue.

CHAPTER SIX

ANALYSIS AND DISCUSSION

6.1 Introduction

Fundamentally, the *Canada Health Act* and the *Patent Act* deal with two differing aspects of Canadian society. The *Canada Health Act* has been created to "establish criteria and conditions in respect of insured health services" that are delivered in each of the Canadian provinces. The *Patent Act* was established to create the rules and regulations of patent rights within the Canadian intellectual property system to aid in the positive progress in research and commercialization of innovations. These two statutes converge when research and innovations are done in the areas of healthcare and biotechnology, which includes genetic innovations.

6.2 Methodological Assessment

Table 6.1 compares the five articles of the OECD Guidelines against the three fundamental components of the model in Chapter Three: legal; economic; and market. As above, the three important aspects of the *Canada Health Act* relevant to this research are assessed: competitiveness (C); universality (U); and accessibility (A).

Table 6.1: Guidelines and the Issues

Applicable Guideline	Legal Issues			Economic Issues			Market Issues		
	C	*U*	*A*	*C*	*U*	*A*	*C*	*U*	*A*
1	√		√		√		√		
2		√	√	√		√	√	√	
3		√							√
4	√		√	√		√	√		√
5	√			√	√	√		√	

≈ shaded cells are not applicable

6.2.1 Legal Issues

The requirements within the CHA are such that healthcare services be provided on a non-profit basis and that the provinces align the provision of those services according to the five criteria stated within the Act in order to receive federal financial support pursuant to the Act. Given this premise of the public healthcare system in Canada, the return on investment initiatives used to promote the intellectual property system and specifically patents creates a conflict. The political debate regarding private versus public healthcare is illustrated in these conflicting terms within these two Acts. It is arguable that the *Patent Act* by its very nature in attempting to garner returns and foster further research supports the advancement of a private healthcare system while the *Canada Health Act* impedes that development with its requirement that healthcare services be provided on a non-profit basis. The *Canada Health Act* does not allow for profitability in the delivery of healthcare services and the *Patent Act* attempts to provide the opportunity for exactly that return on patentable subject matter and does not restrict such subject matter from being within the definition of healthcare or healthcare services.

There does not appear to be any significant conflict between these two statutes in Canada. What is important to note, however, is that the Canadian healthcare system is in need of reform and is financially unsupportable as it is currently presented to the Canadian society (Romanow, 2002). It does appear that the terms of the *Patent Act* and the rights and privileges granted under same could be utilized to ease the burden on the healthcare system should it be seen that a return on investment is acceptable in the healthcare industry thereby encouraging private investment in the industry. While the *Patent Act* provides an avenue for government intervention to obtain use of a patent for what could be argued as healthcare purposes, utilization of such opportunity would be

contradictory to the benefits that are afforded under the *Patent Act* itself and may have a political/societal backlash.

6.2.2 Economic Issues

There have been numerous assertions that patents are essential to private R&D, yet this is increasingly being contested. A large share (some argue most) of the inventions that eventually enter the market come from non-commercial programs (e.g. drugs). Whether or not patents are necessary for invention, there is probably a stronger argument that private investment in commercialization may require patents (or some other way to control access to products). The SCC decision in Harvard v. Commissioner of Patents rejected patents on higher life forms. This puts Canada at odds with most other competing countries. Some have argued this would encourage some types of research in Canada, while others have argued it would chill R&D in Canada. So far the evidence supports neither hypothesis. It may be that because patents are only one form of protection, other forms have simply backfilled and protected the IP.

While there appears to be some evidence of blocking patents in some of the pharmaceutical research areas, there is little or no evidence of what impact those blocking patents have on R&D. There may be a case that Myriad's technology restricts and stops research in their field, but a research exemption does not necessarily help. The problem is that if the research exemption is used to develop a commercial technology or product, the inventor is actually putting themselves into a poor position. Research exemptions do not provide any means of negotiating a contract and leaves them open to stranding all of their sunk investments. A better model (which the public

could support) would be for researchers to request research licenses (which often have provisions for negotiating subsequent operational licenses.

Private-public partnerships have been shown to increase the efficiency of research and development as well as the rate of commercialization of innovations (Fuglie, 1996). Such partnerships are also utilized in an effort to address the economic issues associated with patenting and research and development.

6.2.3 Market Issues

There is no doubt that patents are a second best instrument. Through patents, trade secrets, trademarks, copyright and plant breeders' rights, we give inventors the right to exclude others from using their ideas without compensation. This allows them to act like monopolists, and reduce the amount of the product they supply to the market. This rationing of supply forces the price higher, allowing the inventors to recoup their investment. The underlying implication is that the inventor chooses to restrict supply, meaning that those demanding the product would pay more to purchase the product and as a result, the inventor now is able to earn a substantial profit.

It is uncertain whether Myriad is acting as a full economic actor. Myriad earned just over $US11 million in research revenues in 2004 (Myriad, 2004). Thus, they were only paid for about 4000 tests. If the public health officials are being honest about their efforts, they suggest they would apply the tests to maybe 20% of the adult female population, which creates a potential market in North America of 30 million. It would appear that Myriad is not optimizing its profits as its price

is not at the point where marginal cost equals marginal revenue. Hence, some patent problems are not due to the patents, but due to poor commercial practice.

Compulsory licensing, if it had been in effect during the time of Myriad, would have provided for mandatory licensing being provided to the provinces at a pre-determined price governed by legislation or a form of binding arbitration. Such price would then be based on market factors thereby potentially enhancing the commercial practice results obtained by Myriad.

6.3 Implementation Assessment – Guidelines and Options

Table 6.2 provides the framework to assess the key OECD articles against the several implementation options that are presented: hard law; soft law; educational; and institutional.

Table 6.2: Guidelines and the Implementation Options

Applicable Guideline	Hard Law	Soft Law	Educational	Institutional
1	√		√	√
2		√	√	√
3	√	√		√
4				
5	√	√	√	√

≈ shaded cells are not applicable

6.3.1 Hard Law

The hard law approach to implementation of the Guidelines will make the Guidelines legally binding on licensees and licensors and would require actual amendments to and/or interpretation of relevant legislations, specifically the *Competition Act* and the *Patent Act*. The Health Canada

Symposium on Human Genetics Licensing presented three opportunities for hard law implementation.

Section 5 of the Guidelines dealing with competition could be implemented through actual amendment of Section 65 of the *Patent Act* and through altering the judicial interpretation of Section 35 of the *Competition Act* which deals with anti-competitiveness. Section 35 of the *Competition Act* is broad in its terms thereby allowing for revision in interpretation merely requiring that judges consider the Guidelines when applying the section.

Access to genetic inventions is discussed and addressed in Section 2 of the Guidelines and can be dealt with through invoking use of the compulsory licensing provisions contained in Section 19 of the *Patent Act*. Alternatively, an amendment to the *Patent Act* enacting specific licensing provisions for genetic inventions would address this concern. The enactment of such an amendment could potentially create a realm of industry compliance to avoid use of the provision itself (Gold, 2006). The Canadian Biotechnology Advisory Committee also recommended this amendment to the *Patent Act*.

Finally, an amendment to the *Patent Act* through the enactment of a statutory research exemption would serve to implement Section 3 of the Guidelines dealing with Research Freedom. Dr. Arnold Naimark, Chair of the Canadian Biotechnology Advisory Committee, stated that the Canadian Intellectual Property Office (CIPO) provided little resistance to amending the *Patent Act* and the *Competition Act* as the amendments would provide clarity of sections of the Acts and not removal of sections or completely redrafting the Acts (Naimark, 2006).

6.3.2 Soft Law

Soft law or self-regulating options include adoption of the Guidelines as industry standards for both public and private institutions specifically requiring compliance with the Guidelines as a criterion for funding. From a public institution approach, research ethics boards could give consideration to the Guidelines as being a required part of a research proposal. As well, universities could either strongly encourage the use of the Guidelines or adopt them as compulsory for all of its researchers. From private industry, adoption of the Guidelines by industry groups as being compulsory for its members is an implementation option. A major group that could affect this type of implementation is BIOTECanada (Gold, 2006).

6.3.3 Educational

In his presentation to the Health Canada Symposium, Stuart Howe, Director, The Hospital for Sick Children, stated that the Guidelines, by way of principle, are already in effect in most technology transfer offices (Howe, 2006). Gold however states that this is not the case and opines that further education and training on intellectual property and its management would be appropriate in implementing the OECD Guidelines (Gold, 2006).

The educational approach to implementing the OECD Guidelines involves educating both licensees and licensors on the Guidelines and their ultimate purpose. For the full understanding to take place most licensees and licensors will require a more in depth knowledge of intellectual property and intellectual property management itself (Gold, 2006). Gold suggests that changing the measurement tool utilized in assessing patentability would be beneficial in this regard.

Specifically, Gold recommends placing more weight on the dissemination of information thereby netting in more non-exclusive licensing and broader access to patents. Implementation of intellectual property management as a section of management courses is a further option (Gold, 2006).

6.3.4 Institutional

Patent pools and clearinghouses are institutions that would implement the Best Practices contained in the Guidelines could be created in Canada and more specifically in the biotechnology industry as an implementation option. These institutions operate based on the concept of 'open source'. Open source is defined as a specialized licensing arrangement where the products or patents are contained in a commons and any improvements or advancements made thereto are returned to the commons and available for use to its members (Castle, 2006). Castle stated in his presentation to the Health Canada Symposium that open source is a solution that "does not require direct reform of patent legislation, but instead works on the basis of changed licensing practices." When applied to the biotechnology industry, Castle stated that open source will allow innovations to occur quicker with broader access to and greater dissemination of information. A reduction in licensing costs is a main motivator towards the use of open source. Reduction in licensing costs for researchers provides a greater avenue for accessing information. Any reduction in licensing revenues to firms is often considered to be offset by the benefits of faster, more economical technological advancements experienced in an open source regime. In addition, Shapiro (2001) states that firms may choose to participate in an open source system as the concerns surrounding freedom to operate are addressed and litigation issues are minimized resulting in increased efficiencies with an enhanced innovation process.

Castle (2006) suggests that government intervention may also be required to facilitate the implementation and initial success of an open source system. Such intervention may come in the form of funding and support for a business model to mitigate the effects of the time lag associated with changing the system.

A patent pool is an arrangement within which patent owners license their patents to others. Within a patent pool, licensees have access to the technology that is the subject matter of a patent and any enhancements made thereto. Of the differing types of open sourcing, Castle stated that patent pools are the most favored in the biotechnology industry however they are not without their challenges. Castle further articulates that patent pools are considered to enhance competition and to motivate future innovations by integrating complementary technologies, clearing blocking positions, reducing licensing costs, minimizing infringement litigation and increasing the dissemination of technologies.

Patent exclusivity and patent stacking are two of the main concerns associated with patent pools. Patent exclusivity is when a patent owner utilizes their exclusivity rights and restricts the use of the subject matter of their patent by others (Ebersole, 2005). Patent stacking is a situation that occurs when multiple licenses are required in order to conduct further research or commercialization (*Ibid*.). Castle outlines a few concerns with patent pools specific to biotechnology stating that patent pools constitute a method of price fixing and excludes competitors from the market, reduces opportunity for further research and development and unnecessarily inflates the price of competitively priced goods. In his presentation at Health Canada's Symposium on Human Genetics Licensing, James Simon, who works with ViroNative

BV & CoroNovative BV in the Netherlands, stated that patent pools are most effective if created in a cooperative manner and if the pool is organized by "type" citing examples such as the DVD and MPEG patent pools (Simon, 2006).

Clearinghouses for patent pools are contrived to be similar to that of clearinghouses in the financial market in that all of the processes associated with a patent transaction would be required to go through the clearinghouse. Dianne Nicol, Senior Lecturer with the Centre for Law and Genetics at the University of Tasmania in Australia, presented to the Symposium her thoughts on clearinghouses and defined three types of exchanges that would be facilitated through a patent clearinghouse: information exchange; technology exchange; and intellectual property exchange (Nicol, 2006). Nicol envisions a clearinghouse that provides a database of patents which patent offices would feed into and access information from and a venue from which royalties would be both collected and disseminated.

6.4 Implementation Assessment – Options and Issues

Potential areas of conflict have been illustrated between the *Canada Health Act* and the *Patent Act* of Canada. In an attempt to address and manage the areas of conflict and build a bridge over the gaps existing between the Acts while preserving the intent of both Acts, the OECD has provided its "Guidelines of Licensing of Genetic Inventions" and suggestions for their implementation.

The Myriad Genetics case assists in identifying the policy issues arising from the contrary provisions in the Acts and the potential gaps that exist between the Acts. From there a

comparison has been provided in Table 6.1 between the Guidelines presented by the OECD and the policy issues identified using the *Canada Health Act* as a basis for comparison. Table 6.2 summarizes the Guidelines and the implementation options presented by the OECD. The question then becomes whether or not there is an implementation option that would have an optimal impact on the policy issues. Table 6.3 contains a matrix comparing the implementation options as outlined in Section 6.3 and the policy issues identified in Chapter 3.

Table 6.3: Implementation Options and the Issues

Implementation Option	Legal	Economic	Market
Hard Law	1	2	1
Soft Law	1 or 2	2	1
Educational	3	1	2
Institutional	2	2	2

Table 6.3 Key: 1 – Optimal; 2 – Sub-optimal; 3 – Not Optimal

The analysis done to create Table 6.3 is based on whether or not and how much of a positive impact would be seen using each implementation option.

The hard law option or changes to the Acts is, overall, an optimal option to provide a positive change to addressing the policy issues. Legislation dictating the requirements and conformance around implementation and use of the guidelines will provide firm, concise direction for users and researchers. Repercussions associated with contravention to the legislation would be clearly articulated and therefore the system well regulated.

Soft law implementation of the guidelines would eliminate the bureaucracy and time required for implementation when compared to the governmental process required to be followed to amend legislation in Canada and would require that those wishing to research in this discipline do so within the auspice of the guidelines. This approach has potential to result in all actors accepting and utilizing the guidelines through a natural evolution.

Education about the patent system and working within it, as well as the guidelines and their purpose, is the third most optimal option for implementing the guidelines. This option requires that all researchers and users within the system work with the best interests and intents of the patent system in mind and keep the focus of future and furthered research and development paramount. It leaves use of the guidelines as optional and assumes that once a person is educated he or she will reach the same position as all others. Educating firms regarding market pricing strategies, the potential benefits to allowing use of innovations at reasonable costs and the use private-public partnerships would also be required. This would assist firms in maximizing their commercialization success and returns on investments,

The institutional approach is the least optimal overall as it requires that researchers, at least on some level, relinquish their opportunity to recover costs associated with research and development but also the ability to make a profit off of their efforts.

The positive impact analysis done in Table 6.3 does not take into consideration the feasibility of utilizing that implementation. External factors that affect feasibility of an option include bureaucracy and process associated with utilizing that option, the length of time it would take to

enact the option and the length of time it would take before seeing the impact on the issue. Table 6.4 revisits Table 6.3 with these considerations in mind.

Table 6.4: Implementation Options and the Issues Based on Feasibility

Implementation Option	Legal	Economic	Market
Hard Law	3	3	3
Soft Law	1 or 2	2	1
Educational	3	1	2
Institutional	2	2	2

Table 6.4 Key: 1 – Optimal; 2 – Sub-optimal; 3 – Not Optimal

The hard law option would take the longest period of time to implement. Changes to legislation require parliamentary participation which is often dependent upon external factors such as the political party in power at the time, the economy and special interest groups. These factors may change over the period of time from when a bill is introduced for such amendments to when it is enacted.

Initiating the soft law, education and institutional implementation options requires less "red tape" and bureaucracy when compared to the hard law option. The soft law approach encapsulates amendments to processes, procedures and regulations within institutions and boards. Once adopted, these guidelines are immediately available for use and to affect change. The uncertainty in the market for use of patent pool and clearinghouses reduces the optimization level of the institutional option.

Consideration of feasibility for implementation causes a change in the optimizing position of the options concluding with the soft law approach as the most optimal followed by educational and finally institutional.

A soft law approach to implementing the guidelines requires that standards be set for use by various institutions and funding agencies. Such standards would be best developed through a collaborative effort of the institutions and funding agencies that would be measuring if the standards have been met by approving funding, accepting applications and so forth. Some such entities are: BIOTECanada, Genome Canada and Health Canada.

The purpose of the guidelines is to bridge the gaps present with research, patenting and commercializing of genetic innovations and to assist in addressing some of the challenges of the health care system in Canada, including fiscal sustainability; specifically, to address the gaps between the *Patent Act* and the *Canada Health Act*. Implementation of the guidelines through soft law methods will allow for furtherance of research and development of genetic innovations for use in the Canadian health care system while providing a healthy derivative of the economic benefits of securing patent rights. This should provide for enhanced health care options to the average Canadian at more reasonable costs.

CHAPTER SEVEN

CONCLUSIONS

7.1 Summary of Results

The dilemma within Canada regarding the challenges between the objectives of the *Patent Act* and the *Canada Health Act* exist because the *Patent Act* provides for profit opportunities on genetic innovations while the *Canada Health Act* is a not-for-profit system. The Canadian healthcare system and the delivery of services are based on innovative technologies for which firms and investors expect a return on their investment.

It can be argued that the contrast between the Acts is reduced with the presence and use of Section 19 of the *Patent* Act which provides an avenue for either a federal or provincial government to obtain authorization to use a patent under certain criteria. This section would have allowed for provincial governments to make more of an effort through negotiations with Myriad Genetics to acquire the use of Myriad's patent on the BRCA1 and BRCA2 diagnostic testing processes. Failing such effort, the provinces could then have sought for authorization pursuant to Section 19 of the *Patent Act* thereafter supplying the domestic market with the product and compensating Myriad for its use on fair economic terms based on the market. Going one step further, however, the provinces could even have sought to seek use of the patents under the exception stated in Section 19 that the use is for public non-profit purposes. It would seem however that the precedent set by invoking such use of this Section would have a seriously negative effect on research and development initiatives and investments in the healthcare industry and genetics. Use of such right under the *Patent Act*, while fitting within the scope of

non-profit basis requirements of the *Canada Health Act*, would mitigate some of the rights afforded to a patentee under the *Patent Act*.

Outside of the scope of the return on investment in genetics research relative to the provision of healthcare in Canada and the debate on private versus public healthcare, there appears to be no real conflict between the *Canada Health Act* and the *Patent Act*. However, there are concerns that the intellectual property system is lacking as it pertains to biotechnology and genetics research. Such concerns discussed herein and addressed in the OECD's Guidelines for Licensing Genetic Innovations are freedom to operate, return on investment, timely access to information, monopolistic opportunities and nurturing future research. It is the choice of policy instrument for implementation of these Guidelines in Canada that will determine if these concerns are actually addressed and whether or not conflict is created between the intellectual property system and the healthcare system in Canada. Options for implementation include a hard law approach requiring amendments to the *Patent Act* or the *Competition Act*, a soft law approach making it compulsory for both public and private institutions and funding agencies to adhere to the terms and best practices set forth in the guidelines, an institutional approach seeing the creation of such entities as patent pools and clearinghouses and an education approach seeing the enhancement of knowledge and courses on intellectual property and intellectual property management for both researchers and institution management.

The question yet unanswered is: What is the best implementation approach for Canada giving appropriate consideration to the purpose of the Canadian healthcare system and the present intellectual property system?

Notwithstanding CIPO's response that amendments to the Act as would be required by the Guidelines are not considered revolutionary in nature, the hard law approach to implementing the Guidelines would in fact be an onerous approach requiring government intervention and may be too time consuming to serve the purposes of the Guidelines themselves. Clarity and application of both the *Patent* Act and the *Competition Act* can be obtained through knowledge and understanding of the Guidelines and their purpose and thereafter the adjudication of judges and patent officers. As such, the soft law approach appears to be the most viable option for implementation of the Guidelines in Canada with a hybrid approach giving consideration to the educational approach, as it is required to affect the soft law approach. It is the practices within the industry, by both licensors and licensees that are required to facilitate the change required to appropriately address the concerns of the intellectual property system relative to biotechnology and genetic inventions. The soft law approach takes the responsibility directly to the players in the industry itself providing a more time efficient method of implementing the practices and affecting change within the system itself. The educational approach is required to educate judges, patent officers, researchers and management of the Guidelines, their purpose, and the best practices for obtaining the desired goals. There may be a place in the Canadian intellectual property system for patent pools and clearinghouses – the institutional approach. However it would appear that these two entities would fare better with government intervention and perhaps additional or amending regulations. At this time, it would seem that the institutional approach would not have the buy-in that is required by the industry itself to be successful. The *Canada Health Act* and the *Patent Act* can remain unchanged and the concerns of the intellectual property system largely addressed by the implementation of the Guidelines utilizing the soft law and educational approaches.

7.2 Limitations

The lack of other examples that would provide additional insights or for comparative purposes can be seen as a limitation. The unavailability of additional data or information has resulted in the above being more of a case study than a research venture that could compare and contrast various scenarios and thus provide observations or recommendations with an enhanced level of value. As with any aspect of research regarding innovation, products or processes, one must expect a certain absence of information, data and/or knowledge, but that is the price that one must pay when engaging in research of this nature.

7.3 Extensions

As above, a natural extension of this research would be to examine similar cases in the health sector that could provide further, detailed insights and knowledge. As genomic research advances, so to, will challenging issues such as this. As was observed earlier, the number of patents on human genes has increased rapidly and as innovative research is undertaken involving the genomic makeup of human diseases and their potential treatments, a logical outcome of this is an increase in situations such as the one examined within the confines of this research. With the OECD Guidelines having been in place now for a few years, an assessment of their effectiveness would certainly be timely.

BIBLIOGRAPHY

Application of Abitibi Co. (Re) (1982), 62 C.P.R. (2d) 81 (Patent App. Bd. & Comm. of Patents).

Canada Health Act. Available on-line at: http://laws.justice.gc.ca/en/C-6/text.html. Accessed: April 10, 2006.

Canada *Patent Act*. Available on-line at: http://laws-lois.justice.gc.ca/eng/acts/P-4/index.html. Accessed: April 10, 2006.

Canadian Biotechnology Advisory Committee. 2004. *Biotechnology and the Health of Canadians*. Available on-line at: http://dsp-psd.pwgsc.gc.ca/Collection/Iu199-1-2004E.pdf. Accessed: April 2, 2011.

Castle, D. 2006. Open Source and Patent Pooling in Canadian Science and Biotechnology Policy. Presented at Health Canada Symposium on Human Genetics Licensing. March 20-21, 2006. Vancouver, BC, Canada.

Caulfield, T. et al. 2004. Informing Genomic Patent Policy. Saskatoon, Saskatchewan.

Cho, M., S. Illangasekare, M. Weaver, D. Leonard and J. Merz. 2003. Effects of patents and licenses on the provision of clinical genetic testing services. *Journal of Molecular Diagnostics* 5: 1: 3-8.

Dierker, D. and P. Phillips. 2003. The Search for the Holy Grail? Maximizing Social Welfare under Canadian Biotechnology Patent Policy. *IP Strategy Today* No. 6-2003. pp. 45-62.

Diamond, Commissioner of Patents and Trademarks v. Chakrabarty, 447 U.S. 303 (1980).

Ebersole, T. J., M. C. Guthrie and J. A. Gold-Stein. 2005. Patent pools and standard setting in diagnostic genetics. *Nature Biotechnology* 23: 937.

Eggertson, L. 2002. Ontario defies US firm's genetic patent, continues cancer screening. *Canadian Medical Association Journal* 166: 4: 494.

Fuglie, Keith, N. Ballenger, K. Day, C. Klotz, M. Ollinger, J. Reilly, U. Vasavada and J. Yee. 1996. Agricultural Research and Development: Public and Private Investments Under Alternative Markets and Institutions. *Agricultural Economics Report* AER735: 88.

Galushko, V., R. Gray and S. J. Smyth. 2010. Resolving FTO barriers in GM canola. *AgBioForum* 13: 4: 360-369.

Garland, S. B. and S. Smordin. 2003. The Harvard Mouse Decision and Its Future Implications. *Canadian Business Law Journal* 39: 163-180.

Gold, R. M. Herder and M. Trommetter. *The Role of Biotechnology Intellectual Property Rights in the Bioeconomy of 2030*. A report prepared for the OECD's International Futures Project. Available online at: http://www.oecd.org/dataoecd/11/58/40925999.pdf.

Gold, R. 2006. Uptake of OECD Guidelines for the Licensing of Genetic Inventions. Presented at Health Canada Symposium on Human Genetics Licensing. March 20-21, 2006. Vancouver, BC, Canada.

Harvard College v. Canada (Commissioner of Patents) (2000), 7 C.P.R. (4th) 1, 189 D.L.R. (4th) 385 (F.C.A.).

Howe, S. 2006. Presentation at Health Canada Symposium on Human Genetics Licensing. March 20-21, 2006. Vancouver, BC, Canada.

Jackson, B. 2003. Innovation and intellectual property: The case of genomic patenting. *Journal of Policy Analysis and Management* 22: 1: 5-25.

Jensen, K. and F. Murray. 2005. Intellectual property landscape of the human genome. *Science* 310: 239-240.

Kaminski, R., S. J. Smyth and P. W. B. Phillips. 2005. The evolution of patentability of life forms: A case analysis. Paper presented at the 9th ICABR Conference, Ravello, Italy, July 6-10.

Kent, H. 2001. Patenting move ends BC's gene-testing program. *Canadian Medical Association Journal* 165: 6: 812.

Merz, J., A. Kriss, D. Leonard and M. Cho. 2002. Diagnostic testing fails the test: The pitfalls of patents are illustrated by the case of haemochromatosis. *Nature* 415: 577 - 579.

Monsanto Canada Inc. v. Schmeiser, (2001) 12 C.P.R. (4th) 204 (F.C.T.D.), aff'd 2002 FCA 309.

Myriad. 2004. *Myriad Genetics, Inc. Annual Report 2004*. Available online at: http://terabook.net/myriad-annual-report-2004.html. Accessed: May 2, 2011.

Naimark, A. 2006. Presentation at Health Canada Symposium on Human Genetics Licensing. March 20-21, 2006. Vancouver, BC, Canada.

Nicol, D. 2006. Presentation at Health Canada Symposium on Human Genetics Licensing. March 20-21, 2006. Vancouver, BC, Canada.

Organisation for Economic Co-operation and Development. 2006. *Guidelines for the Licensing of Genetic Inventions*. Available on-line at: http://www.oecd.org/dataoecd/39/38/36198812.pdf. Accessed: May 12, 2006.

Ogilvey Renault, Life Sciences Practice Team, Intellectual Property Group. 2003. *The Mouse That Won't Roar - For Now*. Available online at: http://www.ogilvyrenault.com/en/ResourceCenter/ResourceCenterDetails.aspx?id=73&pId=27. Accessed: July 18, 2006.

Paradise, J., L. Andrews and T. Holbrook. 2005. Patents on human genes: An analysis of scope and claims. *Science* 307: 11: 1566-1567.

Phillips, P. W. B. 2007. *Governing Transformative Technological Innovation: Who's in charge?* Oxford: Edward Elgar.

Ramlall, V. R. 2003. 'Oncomouse' case shows need for Parliament to act. *The Lawyers Weekly* February 7, 2003: 14.

Romanow, R. J. 2002. *Building on Value: The Future of Health Care in Canada – Final Report*. Commission on the Future of Health Care in Canada. Available on-line at: http://www.hcsc.gc.ca/english/pdf/romanow/pdfs/HCC_Final_Report.pdf.

Scherer, F. M. The economics of human gene patents. *Academic Medicine* 77: 12: 1348-1367.

Shapiro, C. 2001. Navigating the patent thicket: cross licenses, patent pools, and standard setting. Paper at NBER Conference on Innovation Policy and the Economy, March 2001.

Siebrasse, N. Undated. The innocent bystander problem in the patenting of higher life forms. Available online at: http://law.unb.ca/Siebrasse/Download/Innocent%20Bystander.pdf.

Simon, J. 2006. Presentation at Health Canada Symposium on Human Genetics Licensing. March 20-21, 2006. Vancouver, BC, Canada.

William-Jones, B. and M. M. Burgess. 2004. Social contract theory and just decision making: Lessons learned from genetic testing for the BRCA mutations. *Kennedy Institute of Ethics Journal* 14: 2: 115-142.