

Health Care and Access to Patented Technologies

*Kathryn Garforth**

I Introduction

The past 25 years have witnessed a growing interaction between healthcare and intellectual property rights. This growth has been due to both new genetic technologies and the expanding scope of intellectual property protection. The interaction does not come without costs, however, and intellectual property rights are increasingly pointed to as a culprit in access to health care. Disputes over Myriad Genetics' patents over breast cancer genes have brought attention to this issue and it is instructive to examine how Canadian courts might react to a demand for funding for a patented genetic test in light of existing law.

Following this introduction, the article begins with a brief overview of the main provisions of patent law. Next, section III explores health care and access to patented technologies via a case study of Myriad Genetics and its patents on genes and genetic tests related to breast cancer. The role of how the cost for the test might affect access to existing and future treatments is explored in more detail through an analysis of relevant international and Canadian law. In particular, the section focuses on how Canadian courts, in light of the current case law, might consider the high cost of a patented genetic test when assessing medical necessity and justifications for discrimination under a section 1 *Charter* analysis. Finally, section V offers some concluding remarks.

II Introduction to Patent Law

A brief explanation of patent law helps to lay the framework for the discussion that follows. Patents are used to grant inventors exclusive rights to their inventions. Under the Canadian *Patent Act*¹, "'invention' means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement" thereof.² Section 28.3 of the *Act* also requires that an invention be non-obvious in order to receive a patent. Finally, mere discoveries and products of nature are not inventions as they lack the requisite novelty.³

* Kathryn Garforth, M.E.S.-LL.B. (York University, Osgoode Hall) is a law and policy researcher and consultant working in the areas of health, intellectual property rights, biodiversity and biotechnology. She can be reached at kathryn.garforth@mail.mcgill.ca. The discussions of Canadian statutory and case law build upon and update an earlier article, Kathryn Garforth, "Canadian 'Medical Necessity' and the Right to Health" (2003) 8 Canadian HIV/AIDS Policy & Law Review 63.

¹ *Patent Act*, R.S.C. 1985, c. P-4.

² *Ibid.* at s. 2.

³ *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623, at para.18 (QL).

A patent entitles an inventor to a twenty-year monopoly to prevent others from making, using or selling the invention.⁴ It is this monopoly period that frequently serves as a justification for patent law.

The difficulty comes because of the idea that information goods are not only non-rival (uses do not interfere with each other) they are also assumed to be non-excludable (it is impossible, or at least hard, to stop one unit of the good from satisfying an infinite number of users at zero marginal cost.) Pirates will copy the song, the mousetrap, the drug formula. The rest of the argument is well known. Lacking an ability to exclude, creators will be unable to charge for their creations; there will be inadequate incentives to create. Thus the law must step in and create a limited monopoly called an intellectual property right.⁵

The incentive provided by the monopoly is seen as particularly important in the medical field where large investments are needed to investigate new drugs and pay for the clinical trials necessary to bring a product to market.

These standards are not exclusive to Canada. The Uruguay Round of negotiations under the General Agreement on Tariffs and Trade created the *Agreement on Trade-Related Aspects of Intellectual Property Rights*⁶ (TRIPS) which sets certain international standards for patent law. In particular, Article 27(1) of the TRIPS Agreement embodies novelty, non-obviousness and utility as the standard for obtaining a patent.

III Case Study: Myriad Genetics

Myriad Genetics is a Utah-based company with patents on two of the genes linked to breast cancer as well as on tests and diagnostic kits for detecting mutations in these genes.⁷ Several Canadian provinces funded their own tests for detecting mutations in the breast cancer genes until Myriad sent them cease-and-desist orders in the spring of 2001 claiming that the provinces were infringing Myriad's patents.⁸ Myriad wants Canadians' DNA samples to be sent to its laboratory for testing but the price charged by Myriad is significantly higher than the price the provinces had been paying. How did this happen?

⁴ *Supra* note 1 at s. 42.

⁵ James Boyle, "The Second Enclosure Movement and the Construction of the Public Domain" (Paper presented at the Conference on the Public Domain, October 2001). Online: Duke University, <<http://www.law.duke.edu/pd/papers/boyle.pdf>>.

⁶ *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 15 April 1994, 33 I.L.M. 1197, being Annex 1C to the *Agreement Establishing the World Trade Organization*, 15 April 1994, 33 I.L.M. 1144 [TRIPS].

⁷ See e.g. Canadian patent 2196790, "17Q-linked Breast and Ovarian Cancer Susceptibility Gene", one of Myriad's Canadian patents on BRCA 1. For European patents, see *infra*, notes 30 & 31.

⁸ Laura Eggertson, "Ontario Defies US Firm's Genetic Patent, Continues Cancer Screening" (2002) 166 Canadian Medical Association Journal 494.

A. History of Myriad's Patents

1. *Myriad's Patents in Canada*

In the 1990s, Myriad succeeded in identifying, locating and isolating two genes, known as BRCA 1 and BRCA 2, that are linked to breast cancer.⁹ Mutations of these genes are factors in 5-10% of breast cancer cases.¹⁰ Myriad obtained patents in the U.S., Canada and Europe on both these genes as well as methods of their use, including screening for mutations.

Intuitively, genes would appear to be products of nature and thus not fall within the definition of invention described in section II, above. The courts and patent offices, however, have drawn a very fine line that allows genes in a certain form to constitute an invention. Genes as they exist in nature as part of the larger genome of an organism are not considered patentable but a gene isolated by human intervention is sufficient to constitute novelty.¹¹

After obtaining the patents, Myriad largely refused to issue licenses for other facilities to conduct the screening test.¹² Instead, the company required DNA samples be sent to its facilities in Salt Lake City where it would perform the test at a cost of approximately US\$2,500.¹³ Myriad argued that this was for quality control purposes – it wanted to ensure that the tests were performed accurately.¹⁴ It also, however, raises issues of access and affordability.

At the time of the cease-and-desist letters in May of 2001, eight Canadian provinces covered the costs of the tests for the breast cancer genetic mutations in their provincial health insurance plans and funded their own facilities to perform

⁹ Matthew Rimmer, "Myriad Genetics: Patent Law and Genetic Testing" (2003) 25 *European Intellectual Property Review* 20 at 20-2. It should be noted that Myriad was not working alone on the subject of genes linked to breast cancer. The company benefitted from the work of other researchers particularly Mary Claire-King in the U.S. and a group at the Institute of Cancer Research in England; *ibid*.

¹⁰ Canadian Cancer Society and National Cancer Institute of Canada, "Position on the Patenting of BRCA1 and 2 Genes" (8 March 2002) at 1, online: Canadian Cancer Society <http://www.cancer.ca/ccs/internet/standard/0,3182,3172_31282995__langId-en,00.html>.

¹¹ Nuffield Council on Bioethics, "The Ethics of Patenting DNA: A Discussion Paper" (2002) at 29, online: Nuffield Council on Bioethics <<http://www.nuffieldbioethics.org/fileLibrary/pdf/theethicsofpatentingdna.pdf>>.

¹² Myriad did license one company in Canada – MDS Laboratory Services – to conduct its diagnostic test but samples were still largely sent to Myriad's facilities in Utah, Myriad Genetics, News Release, "Myriad Genetics Launches Molecular Diagnostic Testing in Canada" (9 March 2000), online: Myriad Genetics Investor Relations <http://www.corporate-ir.net/ireye/ir_site.zhtml?ticker=mygn&script=411&layout=9&item_id=212154>

¹³ Donald J. Willison & Stuart M. MacLeod, "Patenting of Genetic Material: Are the Benefits to Society Being Realized?" (2002) 167 *Canadian Medical Association Journal* 259 at 260.

¹⁴ Seth Shulman, "Doctors Without Patents" *Technology Review* 104:10 (December 2001) 33 at 33.

the test.¹⁵ The screening test used by these facilities was different from the one claimed by Myriad in its patent. In Ontario and British Columbia, at least, the cost was also a lot cheaper.

The cease-and-desist orders sent by Myriad to the provincial health care authorities stated that the provincial screening tests infringed Myriad's patents by using the patented genes.¹⁶ The fact that the test used by the provinces was different from the one claimed by Myriad in its patents was not relevant because ultimately any screening test required use of the patented genes. The letters required all DNA samples be sent to Myriad's facilities for testing.¹⁷ If they did not comply, the provinces faced the risk of patent infringement litigation. Of the eight provinces, British Columbia initially suspended its funding for the test, then withdrew funding altogether, and has since resumed funding for a different test; Alberta and Manitoba quietly continued as they had been doing; Saskatchewan, Newfoundland and Nova Scotia sent their samples to Ontario so depended on the latter's decision; and Quebec complied with the order and began sending its samples to Utah.¹⁸ In September 2001, Ontario announced that it would not comply with the order, that it would continue to fund its own tests and that it did not believe it was infringing Myriad's patents. Subsequently, Ontario adopted a new test that is cheaper and more accurate than the one it had been using previously.¹⁹ There has been no response from Myriad to date.

¹⁵ *Supra* note 8; Bryn Williams-Jones, "History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing" (2002) 10 Health Law Journal 124 at 140 [Williams-Jones].

¹⁶ Tony Clement, "Myriad Gene Patent Issue" (Speech, 19 September 2001), online: Ontario Ministry of Health and Long Term Care <http://www.gov.on.ca/health/english/news/speech/sp_091901_tc.html> [on file with author].

¹⁷ *Ibid.*

¹⁸ *Supra* note 8; Edmond G. Lemire, Letter to the Editor, (2002) 166 Canadian Medical Association Journal, 1012 at 1012; "B.C. Government Yields to U.S. Company's Patent on Breast Cancer Gene" *The Vancouver Province* (20 October 2002), online: <<http://www.canada.com>> (date accessed: 21 October 2002) [on file with author]; B.C. Ministry of Health, News Release, "Federal Leadership Urged as Genetic Testing Resumes" (14 February 2003), online: Government of British Columbia <http://www2.news.gov.bc.ca/nrm_news_releases/2003HSER0009-000160.htm> (last modified: 7 January 2004); Williams-Jones, *supra* note 15 at 140.

¹⁹ "Ontario to Offer New Genetic Test for Breast, Ovarian Cancer" *CBC.CA News* (8 January 2003) online: CBC News <http://www.cbc.ca/stories/print/2003/01/06/test_genetic030106>; Charis Eng *et al.*, "Interpreting Epidemiological Research: Blinded Comparison of Methods used to Estimate the Prevalence of Inherited Mutations in *BRCA1*" (2001) 38 *Journal of Medical Genetics* 824, online: *Journal of Medical Genetics* <<http://jmg.bmjournals.com>> [Eng]. Whether the test now used in Ontario – known as denaturing high performance liquid chromatography or DHPLC – is also more accurate than Myriad's test is the subject of debate. Myriad uses full DNA sequencing of the two BRCA genes, which is expensive and time-consuming. Most public laboratories use faster and cheaper mutation screening methods such as protein truncation testing, single-stranded conformational polymorphism, or conformation-sensitive gel electrophoresis, which some argue are just as effective as Myriad's method – or at least can detect mutations that Myriad's method misses, see Williams-Jones, *supra* note 15. Numerous studies indicate that DHPLC is the most accurate of these other, mutation scanning methods and may be comparable to sequence analysis, see e.g. Eng, *supra*; E. Gross *et al.*, "A Comparison of BRCA1 Mutation Analysis by Direct Sequencing, SSCP and DHPLC" (1999) 105 *Human Genetics* 72; T. Wagner *et al.*, "Denaturing High-Performance Liquid Chromatography Detects Reliably BRCA1 and BRCA2 Mutations" (1999) 62 *Genomics* 369; N. Arnold *et al.*, "A Highly Sensitive, Fast, and Economical Technique for Mutation

Ontario is in a difficult position because it has already been ordered to fund the genetic test for breast cancer. In the late 1990s, the test was still considered experimental in Canada. Canadian women only had access to it if they participated in research studies, and these studies could take up to two years to return with the test results. Myriad's results, on the other hand, were available within a few weeks.²⁰ An Ontario woman named Fiona Webster had a family history of breast cancer and she wanted to know if she was at risk as well. At 39, she did not feel she could wait two years to know the test results. The Ontario Health Insurance Plan (OHIP) was willing to pay approximately \$20,000 for Webster to have a bilateral mastectomy and breast reconstruction surgery but was not willing to pay for Myriad's test.²¹ Webster appealed the OHIP decision to the Ontario Health Services Appeal Board. It ruled that the government must pay for the Myriad test if individuals can show a compelling case history.²² As it turned out, Webster did not have a mutation in her genes so the surgery would have been unnecessary.²³ As will be discussed below, any province that refuses to fund a genetic test could leave itself open to similar litigation.

2. Myriad's Patents in Europe

Before moving on to discuss the issues of access raised by Myriad's patents and gene patents in general, an examination of the situation in Europe is worthwhile. In Europe, unlike in North America, third parties have nine months to file an opposition to a patent once it has been issued.²⁴ While an opposition is ongoing, the patentee of the impugned patent cannot enforce its rights.²⁵ In Canada and the U.S., on the other hand, patents can be re-examined by the respective patent offices in light of new prior art.²⁶ This usually results in amendments to the patent claims

Analysis in Hereditary Breast and Ovarian Cancers" (1999) 14 Human Mutation 333; C. Seville *et al.*, "Testing for BRCA1 Mutations: A Cost-Effectiveness Analysis" (2002) 10 European Journal of Human Genetics 599.

²⁰ Carolyn Abraham, "Fiona's Choice: Lose Breasts or Risk Life" *The Globe and Mail* (17 July 1998) A1, CD-ROM: *Factiva* (Toronto: Dow Jones Reuters Business Interactive, 2002).

²¹ *Ibid.*

²² John Nicol, "Sleuthing for Medical Clues" *Maclean's* 112:38 (20 September 1999) 48 at 48.

²³ *Ibid.*

²⁴ *Supra* note 11 at 17. Opposition procedures are governed by provisions in the European Patent Convention. Oppositions must be on at least one of three grounds:

- the subject-matter of the patent is not patentable according to the terms of Articles 52 to 57 of the [European Patent Convention];
- the invention is not disclosed in the patent in a sufficiently clear and complete way for it to be reproduced by a person skilled in the art;
- the breadth of the patent's subject-matter exceeds the content of the application which was originally filed.

Ibid.

²⁵ Richard Gold, Timothy A. Caulfield, & Peter N. Ray, "Gene Patents and the Standard of Care" (2002) 167 Canadian Medical Association Journal 256 at 257.

²⁶ For Canada, see *supra* note 1 at s. 48.1(1).

rather than the patent being invalidated. Otherwise, the validity of patents must be challenged through litigation, a very costly and time-consuming process.²⁷

As mentioned, Myriad has patents on the BRCA 1 and 2 genes as well as on methods of using these genes in Europe as in North America. The Institut Curie, the Institut Gustave Roussy, and the Assistance Publique-Hopitaux de Paris, with the explicit backing of the French government, and along with numerous other European organizations have launched opposition proceedings against four of these patents.²⁸ Like the Canadian provinces, the French have also developed their own test for diagnosing mutations in BRCA 1 and 2. They claim their test is one-third the cost charged by Myriad and they do not want the company to be able to block them from using it.²⁹ As a result of the opposition, one patent was revoked in May 2004 after an opposition panel of the European Patent Office concluded that it did not meet the 'inventive step' requirement of the European Patent Convention.³⁰ The scope of the three other patents has been significantly narrowed, reducing the risk that they could block the activities of the European laboratories.³¹

²⁷ *Supra* note 11 at 18; John Barton, "Reforming the Patent System" (2002) 287 Science 1933 at 1933. Both the Ontario government and the Canadian Biotechnology Advisory Committee have recommended that Canada introduce an opposition procedure. See Government of Ontario, "Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare" (2002) at 51, online: Ministry of Health and Long Term Care <http://www.health.gov.on.ca/english/public/pub/ministry_reports/geneticsrep02/report_e.pdf>; Canada, Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues* (Ottawa: Canadian Biotechnology Advisory Committee, June 2002) at 23-24, online: Canadian Biotechnology Advisory Committee <[http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwapj/E980_IC_IntelProp_e.pdf/\\$FILE/E980_IC_IntelProp_e.pdf](http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwapj/E980_IC_IntelProp_e.pdf/$FILE/E980_IC_IntelProp_e.pdf)>.

The situation may also be about to change in the U.S. with legislation to amend the *Patent Act* tabled in Congress that includes provisions to create a post-grant opposition process, U.S., Bill H.R. 2795, *To Amend Title 35, United States Code, Relating to the Procurement, Enforcement, and Validity of Patents*, 109th Cong., 2005.

²⁸ *Supra* note 14.

²⁹ *Ibid.*

³⁰ EP 699754, 'Method for diagnosing a predisposition for breast and ovarian cancer'; Opposition Division, European Patent Office Ref. OPPO 06, Decision Revoking the European Patent (18 May 2004) at para. 13; EPO Press Release, "'Myriad/breast Cancer' Patent Revoked After Public Hearing" (18 May 2004), online: European Patent Office <http://www.european-patent-office.org/news/pressrel/2004_05_18_e.htm>. The University of Utah Research Foundation, which has been assigned Myriad's share of the patent rights, filed an appeal of this decision in January 2005. Institut Curie Press Release, "Another victory for opponents of patents held by Myriad Genetics: European Patent Office rejects the essential points of BRCA1 gene patents" (21 January 2005), online: Institut Curie <<http://www.curie.fr/upload/presse/myriadpatents310105.pdf>> [Institut Curie].

³¹ The other three patents are EP 705902, '17q-Linked breast and ovarian cancer susceptibility gene', EP 705903, 'Mutations in the 17q-linked breast and ovarian cancer susceptibility gene', and EP 785216, 'Chromosome 13-Linked Breast Cancer Susceptibility Gene'. Institut Curie, *ibid.*; EPO Press Release, "European Patent on Mutations in Breast and Ovarian Cancer Susceptibility Gene Amended After Public Hearing" (25 January 2005), online: European Patent Office <http://www.european-patent-office.org/news/pressrel/2005_01_25_e.htm>. To date, the University of Utah Research Foundation, which has also been assigned Myriad's shares of these patent rights, has filed appeals of the decisions on both the EP 705902 and EP 705903 patents. The three French research centres have also appealed the decision to maintain the narrowed EP 705903 – they are seeking its complete revocation. In addition, Myriad has filed a new patent application, EP 1260520, that claims the methods for diagnosing mutations in the BRCA 2 gene that were removed from EP 785216 during the opposition

B. Issues of Access

There are two broad issues of access in the Myriad example. These can be summarized as issues of cost, or access to existing treatments, and access to future treatments.

1. Access to Existing Treatments

The responses by the Canadian provinces to Myriad's threat of litigation illustrate three different approaches to the problem: fully fund the most expensive option, fully fund a cheaper alternative, or offer no public funding at all. It is questionable as to whether the health care system can afford the first option and whether individuals can afford the latter. Also, is it legal for a province to provide no funding for a test? This leads to questions about rights to health and health care and how resources should be allocated in the Canadian health care system. We will explore these questions at three levels: international law, Canadian statutory law and Canadian case law.

a. International Law

Four of six United Nations human rights treaties recognize a right to health. Most general is Article 12(1) of the International Covenant on Economic, Social and Cultural Rights³², which provides: "The State Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health". The Convention on the Elimination of All Forms of Discrimination Against Women³³, the Convention on the Rights of the Child³⁴, and the Convention on the Elimination of Racial Discrimination³⁵ also recognize the right to health and oblige State Parties to provide non-discriminatory access to health care.³⁶ Canada is a party to all these treaties and as such it must act in accordance with the obligations contained therein.³⁷ At the same time, however, "treaty obligations are not directly enforceable in Canadian domestic law; they must be implemented in legislation by the relevant level of government".³⁸ Nonetheless, courts have used Canada's international human rights obligations to interpret

proceeding, Institut Curie Press Release, "L'Office Européen maintient le brevet sur le gène BRCA1 réduit à une mutation particulière et sans effet bloquant sur l'activité des laboratoires européens" (6 July 2005), online: Institut Curie <<http://www.curie.fr/upload/presse/brca2-myriad-6-juil-05.pdf>>.

³² 16 December 1966, 993 U.N.T.S. 3 (entered into force 3 January 1976) [ICESCR].

³³ 1 March 1980, 19 I.L.M. 33 (entered into force 3 September 1981) [CEDAW].

³⁴ 20 November 1989, 28 I.L.M. 1456 (entered into force 20 November 1989) [CRC].

³⁵ 21 December 1965, 5 I.L.M. 350 (entered into force 4 January 1969) [CERD].

³⁶ CEDAW, *Supra* note 33 at Art. 12, 14.2(b); CRC, *supra* note 34 at Art. 23.2-23.4, 24.1, 24.2, 25 and 39; CERD, *supra* note 35 at Art. 5(e)(iv).

³⁷ Anne F. Bayefsky, ed., *The UN Human Rights Treaty System in the 21st Century* (The Hague: Kluwer Law International, 2000) at 452.

³⁸ Barbara von Tigerstrom, "Human Rights and Health Care Reform: A Canadian Perspective" in Timothy A. Caulfield & Barbara von Tigerstrom, eds., *Health Care Reform & the Law in Canada: Meeting the Challenge* (Edmonton: The University of Alberta Press, 2002) 157 at 160.

Canadian law, including in the context of access to health care, as will be discussed in more detail below.³⁹

b. Canadian Statutory Law

(i) Federal and Provincial Health Insurance Legislation

Federally, the *Canada Health Act*⁴⁰ governs the policy of the Medicare system but it does not explicitly grant Canadians a legal right to health care.⁴¹ Rather, the *Act* sets the criteria that the provincial health insurance programs must meet in order for them to receive full federal funding under the *Federal-Provincial Fiscal Arrangements Act*.^{42, 43} These criteria are the ‘famous five’ of the Canadian health care system: public administration, comprehensiveness, universality, portability, and accessibility.⁴⁴ Sections 8 through 12 of the *Canada Health Act* further define what a province must do to fulfill the five criteria. Section 9 addresses comprehensiveness and, when read in conjunction with the definitions in section 2, it requires provinces to insure hospital, physician and surgical-dental services that are “medically necessary for the purpose of maintaining health, preventing disease or diagnosing or treating an injury, illness or disability”.⁴⁵ The difficulty is that ‘medically necessary’ is nowhere defined in the *Canada Health Act*.

Quebec is the only province that provides individuals with a statutory right to health care but this right is circumscribed by fiscal considerations.⁴⁶ In addition, Quebec and all the other provinces, much like the *Canada Health Act*, state that they will insure ‘medically necessary’ or ‘medically required’ treatments and services but again, do not define what constitutes ‘medically necessary’.⁴⁷ While individual Canadians do not have standing to sue under the *Canada Health Act*, they can bring actions against provincial authorities and argue that certain aspects

³⁹ See e.g., *Slaight Communications v. Davidson*, [1989] 1 S.C.R. 1038, 59 D.L.R. (4th) 416; *Baker v. Canada (Minister of Citizenship and Immigration)*, [1999] 2 S.C.R. 817.

⁴⁰ *Canada Health Act*, R.S.C. 1985, c. C-6.

⁴¹ Rino A. Stradiotto and Jacinthe I. Boudreau, “Resource Allocation and Accountability in Health Care” (2000) 20 Health L. Can. 40, online: 2000 C.H.L. LEXIS 2 at 3 [cited to LEXIS].

⁴² *Federal-Provincial Fiscal Arrangements Act*, R.S.C. 1985, c. F-8.

⁴³ *Supra* note 40 at s. 2, definition of “cash contribution”; s. 4.

⁴⁴ *Ibid.* at s. 7.

⁴⁵ *Ibid.* at s. 2, definition of “hospital services”.

⁴⁶ *Health Services and Social Services Act*, R.S.Q., c. S-4.2 at s. 5 & s. 13.

⁴⁷ For example, under the *Quebec Health Insurance Act*, R.S.Q., c. A-29, the Régie de l'Assurance maladie du Québec assumes the costs of “all services rendered by physicians that are medically required” (s.3(a)). Section 1 of the *B.C. Medicare Protection Act*, R.S.B.C. 1996, c. 286 [*Medicare Protection*] defines benefits as “medically required services rendered by a medical practitioner ...”. The *Nova Scotian Hospital Insurance Regulations*, N.S. Reg. 11/58, states that “a resident is entitled to receive in-patient and out-patient services that are medically required by him, without charge as insured services ...” (s. 2(1)(a)).

of health care are medically necessary.⁴⁸ As will be discussed, this has occurred on a number of occasions with varying degrees of success.

(ii) Constitutional Law

The *Canadian Charter of Rights and Freedoms*⁴⁹ has also played an important role in Canadian medical law jurisprudence. We will focus on the right to equality in section 15(1) and, in particular, on attempts to justify infringement of this section in cases concerning access to medical services.⁵⁰ Section 15(1) provides:

Every individual is equal before and under the law and has the right to the equal protection and equal benefit of the law without discrimination and, in particular, without discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental or physical disability.

The right in section 15(1) is “subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society”, as provided by section 1 of the *Charter*.

c. *Canadian Case Law*

Moving on to the case law, we will concentrate on the role financial considerations have played in courts’ decisions on access to health care. In particular, we will assess whether the high cost of a patented genetic test would be considered by a court in reviewing a province’s decision not to insure the test. In this context, financial considerations arise in the interpretation of the two areas of the statutory law described above: the definition of ‘medically necessary’ in provincial health insurance legislation, and the determination of whether financial constraints can be used under section 1 of the *Charter* to justify a finding of discrimination in the provision of insured health care under section 15(1).

(i) Financial Resources and Medically Necessary

As described above, the provinces and the federal government agree to insure health services that are medically necessary but what does this mean? In *Stein v.*

⁴⁸Both Ontario and British Columbia have administrative tribunals to hear claims, Jocelyn Downie, Timothy Caulfield & Colleen M. Flood, eds., *Canadian Health Law and Policy*, 2d ed. (Markham: Butterworth, 2002) at 24. In other provinces, individuals have relied on constitutional arguments and other means, as will be discussed below.

⁴⁹*Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act*, 1982, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c. 11 [*Charter*].

⁵⁰The right to life and security of the person in section 7 has also been used by litigants trying to gain funding for particular medical treatments but with little success. See, for example, *Brown v. British Columbia (Minister of Health)* (1990), 66 D.L.R. (4th) 444; *Wynberg v. Ontario*, *infra* note 102; *supra* note 38 at 167-168. In a concurring decision in *Chaoulli v. Quebec (Attorney General)*, 2005 SCC 35 [*Chaoulli*], three members of the Supreme Court used section 7 to find the prohibition against the purchase of private insurance in Quebec for publicly insured health care unconstitutional.

Quebec (*Régie de l'Assurance-maladie*)⁵¹, the Régie de l'Assurance-maladie du Québec refused to pay for Barry Stein's out-of-country medical expenses.⁵² Among other things, Stein wanted the Régie to pay for a device known as an Infusaid pump that had been implanted in him by a physician in New York. The Régie refused to pay for the pump as it claimed the pump was an experimental treatment and not available in Canada.⁵³ Experimental treatments are not considered to be medically necessary.⁵⁴ In reviewing whether the pump was, in fact, experimental, the Quebec Superior Court considered evidence from Stein's American surgeon that the pump is standard procedure in cancer centres in the U.S.⁵⁵ It also referred to the Régie's own doctor who said that the pump is not available in Canada because of its cost.⁵⁶ The fact that the pump had been effective in treating Stein also seemed to play a role in the court's decision.⁵⁷ In ordering the Régie to pay for Stein's surgery, the court implied that the treatment was medically necessary regardless of its cost.⁵⁸

The next case on point is *Cameron v. Nova Scotia (Attorney General)*⁵⁹. Alexander Cameron and his wife Cheryl Smith turned to intra-cytoplasmic sperm injection (ICSI), a form of in-vitro fertilization (IVF), after their other attempts to have a baby were unsuccessful.⁶⁰ When the province refused to cover the procedures under the *Nova Scotia Health Services and Insurance Act*⁶¹, the couple brought an action claiming, among other things, that the treatment was medically necessary and the wording of the regulations⁶² under the *Act* thus required it to be insured.⁶³ The action was dismissed at trial.

On appeal, Justice Chipman writing for the court, reviewed the evidence of the medical experts who had testified during the trial that IVF is a standard treatment and ICSI is currently or is becoming the treatment of choice. The trial judge had felt that "neither 'medically indicated' nor 'standard medical procedure' equates to 'medically required'"⁶⁴ and Justice Chipman refused to find this to be

⁵¹ *Stein v. Quebec (Régie de l'Assurance-maladie)*, [1999] Q.J. No. 2724, (QL).

⁵² *Ibid.* at para. 1-3.

⁵³ *Ibid.* at para. 27.

⁵⁴ This creates an incentive for cash-strapped provincial health insurance plans to label expensive new treatments as experimental in order to avoid having to pay for them, Margaret Somerville, *The Ethical Canary: Science, Society and the Human Spirit* (Toronto: Penguin Books, 2001) at 228 [Somerville].

⁵⁵ *Supra* note 51 at para. 40.

⁵⁶ *Ibid.* at para. 40.

⁵⁷ *Ibid.* at para. 43.

⁵⁸ This decision did not actually turn on the question of medical necessity but on whether the Régie's refusal to cover the costs of the treatment was unreasonable, see *supra* note 51 at para. 23, which the court determined it was.

⁵⁹ *Cameron v. Nova Scotia (Attorney General)*, [1999] N.S.J. No. 297, (QL) leave to appeal to S.C.C. refused [1999] S.C.C.A. No. 531.

⁶⁰ *Ibid.* at para. 3.

⁶¹ *Health Services and Insurance Act*, R.S.N.S. 1989, c. 20.

⁶² *M.S.I. Regulations*, N.S. Reg. 41/69, see, in particular, s. 1(e).

⁶³ *Supra* note 59 at para. 28, 70.

⁶⁴ *Ibid.* at para. 41.

an error.⁶⁵ Justice Chipman also found cost to be a factor in why the province did not consider IVF and ICSI to be medically necessary:

I much prefer, however, the primary approach of Dr. Collins which simply was that in the scheme of things – in the order of priorities – these two procedures, having regard to costs, the limited success rate and the risks do not, at this time, rank sufficiently high to warrant payment for them from public funding. ... I am satisfied that this is the real explanation why these procedures were considered not medically necessary.⁶⁶

He went on to give his own interpretation of what must be considered in determining medical necessity:

Of necessity, what is or is not medically required must be judged by those placed in charge of the administration of the policy. The judgment call requires an appreciation not only of medical procedures, but the availability of funds to finance them.⁶⁷

In sharp contrast to *Stein* where the court rejected costs in determining whether a treatment was experimental, the court in *Cameron* explicitly incorporated financial considerations into the definition of medically necessary. By this interpretation, what is medically necessary treatment is no longer determined just by a patient's condition but also takes into account the ability of the province to pay for this treatment.⁶⁸

The final case in this section is *Auton (Guardian ad litem of) v. British Columbia (Minister of Health)*⁶⁹. In this case, a group of autistic children and their guardians brought an action against the B.C. government seeking, among other things, to “establish a tariff for the payment of Lovaas Autism Treatment by approved non-medical therapists. Alternatively, they seek orders compelling either the Minister of Education or the Minister of Children and Families to fund that treatment.”⁷⁰ The child petitioners had each received Lovaas Autism Treatment, a

⁶⁵ *Ibid.* at para. 90.

⁶⁶ *Ibid.* at para. 87.

⁶⁷ *Ibid.* at para. 101.

⁶⁸ Somerville, *supra* note 54 at 233-4.

⁶⁹ *Auton (Guardian ad litem of) v. British Columbia (Minister of Health)*, [2000] B.C.J. No. 1547, online: QL (CJ) [Auton #2 cited to QL], aff'd *Auton (Guardian ad litem of) v. British Columbia (Attorney General)*, [2002] B.C.J. No. 2258 [Auton #4], rev'd 2004 SCC 78 [Auton #5]. *Auton (Guardian ad litem of) v. British Columbia (Minister of Health)*, 1999 CanLII 5500 (B.C.S.C.) [Auton #1], was an attempt to have autistic children certified as a class. The certification was denied, the reasoning is not relevant here, and the case proceeded with the plaintiffs acting as individuals. *Auton #3* was the decision on remedies pursuant to *Auton #2*, see *infra* note 76.

⁷⁰ *Auton #2*, *ibid.* at para. 87.

form of applied behavioural analysis (ABA), which had cost their guardians between \$45,000 and \$60,000 a year per child.⁷¹

At trial, the petitioners argued “that Lovaas Autism Treatment is a medically necessary service insofar as it significantly improves the condition of these children. The Crown questions the proven efficacy of Lovaas Autism Treatment and rejects it as a ‘medically necessary service’.”⁷² In assessing medical necessity, the court weighed the scientific evidence for and against Lovaas Autism Treatment and concluded that the most effective therapies for autism are those based on ABA.⁷³ The court then examined the treatments provided by the B.C. government for autistic children, which it concluded were “positively discredited by one of the Crown’s own expert witnesses.”⁷⁴ Finally, the court examined government-supported treatment for autism in other jurisdictions – other Canadian provinces, the U.S. and Britain – and found that numerous other governments funded ABA therapies for autistic children.⁷⁵ As a result, the court found ABA treatment generally, although not Lovaas Autism Treatment specifically, to be a medically necessary service and the province was ordered to fund ABA treatment for autistic children.⁷⁶

Neither of the subsequent appeals of *Auton*, first to the B.C. Court of Appeal and finally to the Supreme Court of Canada, specifically discussed the medical necessity of ABA or Lovaas Autism treatments. At the Court of Appeal, the decision turned on the section 15(1) *Charter* analysis, discussed below, and the Court dismissed the appeal. At the Supreme Court, the Crown found a more receptive audience, which raised the medical necessity issue in a different manner.

Chief Justice McLachlin, writing for a unanimous court, discussed the medical necessity of ABA therapy in the context of the first step of the section 15(1) *Charter* analysis – whether the therapy was a benefit provided by law.⁷⁷ In analyzing the relevant statutory and regulatory scheme, she found that it does not fund all medically necessary treatments, nor was it intended to fund all such treatments.⁷⁸ Rather, the *B.C. Medicare Protection Act* guarantees full funding for “medically required services rendered by a medical practitioner”,⁷⁹ as required by the *Canada Health Act*.⁸⁰ In addition, the *Medicare Protection Act* also funds some

⁷¹ *Ibid.* at para. 24.

⁷² *Ibid.* at para. 29.

⁷³ *Ibid.* at para. 51-52.

⁷⁴ *Ibid.* at para. 66.

⁷⁵ *Ibid.* at para. 69-83.

⁷⁶ *Ibid.* at para. 102, *Auton (Guardian ad litem of) v. British Columbia (Attorney General)* (2001), 84 B.C.L.R. (3d) 259, 2001 BCSC 220 at para. 65 [*Auton* #3].

⁷⁷ *Auton* #5, *supra* note 69 at para. 30.

⁷⁸ *Ibid.* at para. 31-35.

⁷⁹ *Medicare Protection*, *supra* note 47 at s. 1, definition of ‘benefits’, para. (a).

⁸⁰ *Auton* #5, *supra* note 69 at para. 32.

services rendered by other types of ‘health care practitioners’.⁸¹ The providers of ABA therapy were not listed as health care practitioners under the Act. Justice McLachlin thus concluded that ABA therapy, while it may be medically required, was not a benefit provided by law.⁸²

The Supreme Court did not enter into an analysis of whether or not Lovaas Autism Treatment or ABA therapy are medically necessary treatments. The Court did discuss in obiter, however, the emergent nature of ABA therapy. The Court pointed out that:

in many jurisdictions ABA/IBI therapy remained unfunded at the time of trial. Indeed, it was only in the year preceding the trial that two Canadian provinces had authorized funding for ABA/IBI therapy to autistic children. ... People receiving well-established non-core therapies are not in the same position as people claiming relatively new non-core benefits. Funding may be legitimately denied or delayed because of uncertainty about a program and administrative difficulties related to its recognition and implementation.⁸³

These cases point to a three-pronged analysis in determining medical necessity: a review of the effectiveness of the treatment in question, a review of the services the government already insures for the malady in question, and a review of whether the treatment is standard in other jurisdictions. What is important here, however, is the fourth element added by the court in *Cameron*: cost. The precedent set by the Nova Scotia Court of Appeal is obviously not binding in other Canadian jurisdictions but it may be persuasive. Weighing against it would be *Stein* and the trial-level *Auton* decision, both of which ignore cost factors in determining what is medically necessary.

How does this relate to a patented genetic test? Applying this analysis to a situation where a province refuses to pay for the breast cancer genetic test leads to the conclusion that cost is the wild card. The genetic tests would appear to be effective in detecting mutations in the BRCA 1 and 2 genes. The other insured services for a genetic risk of breast cancer constitute a bilateral mastectomy combined with breast reconstruction surgery. Undergoing this surgery is a preventative measure, not one option to be pursued before turning to the genetic test. Given the invasiveness of these procedures and their probable uselessness if the genetic test is negative, a court would be unlikely to consider them a viable alternative. Other Canadian jurisdictions already fund either their own test or Myriad’s test as standard. Would a court consider the cost of Myriad’s test sufficient to preclude the test from the category of medically necessary? Furthermore, would a court consider Myriad’s threat of patent infringement litigation and the high costs that

⁸¹ *Medicare Protection*, *supra* note 47 at s. 1, definition of ‘benefits’, para. (b).

⁸² *Auton* #5, *supra* note 69 at paras. 32, 35-36, & 38.

⁸³ *Ibid.* at para. 55.

accompany such litigation as sufficient reason not to class a province's own genetic test as medically necessary? There is no way to answer these questions in advance but they are the sorts of difficulties courts are likely to face with increasing frequency as more patented genetic tests become available and more areas of medicine are subject to patent protection.

(ii) Financial Constraints and Justifying Discrimination

Determining whether the non-provision of funding for a medical service constitutes discrimination under section 15(1) of the *Charter* is beyond the bounds of this article except to say that the financial resources of the health care system have been explicitly held not to be relevant in the determination of discrimination.⁸⁴ What is relevant here is that once the court has found discrimination, it must turn to examine whether the discrimination can be justified under section 1 of the *Charter*. Courts will entertain financial considerations in the latter analysis and the Crown frequently invokes them.

The test for justification under section 1 was set out in *R. v. Oakes*⁸⁵ and restated in *Egan v. Canada*⁸⁶ by Justice Iacobucci:

First, the objective of the legislation must be pressing and substantial. Second, the means chosen to attain this legislative end must be reasonable and demonstrably justifiable in a free and democratic society. In order to satisfy the second requirement, three criteria must be satisfied: (1) the rights violated must be rationally connected to the aim of the legislation; (2) the impugned provision must minimally impair the *Charter* guarantee; and (3) there must be proportionality between the effect of the measure and its objective so that the attainment of the legislative goal is not outweighed by the abridgement of the right. In all s. 1 cases the burden is on the government to show on a balance of probabilities that the violation is justifiable.⁸⁷

As part of this analysis, the Supreme Court has stated that “[b]udgetary considerations in and of themselves cannot normally be invoked as a free-standing pressing and substantial objective for purposes of s. 1 of the *Charter*”.⁸⁸

⁸⁴ *Supra* note 59 at para. 165.

⁸⁵ *R. v. Oakes*, [1986] 1 S.C.R. 103.

⁸⁶ *Egan v. Canada*, [1995] 2 S.C.R. 513.

⁸⁷ *Ibid.* at para. 182.

⁸⁸ *Nova Scotia (Workers' Compensation Board) v. Martin*, [2003] 2 S.C.R. 504, 2003 SCC 54 at para. 109. The court recently reaffirmed this interpretation in *Newfoundland (Treasury Board) v. N.A.P.E.*, *infra* note 108, although ultimately in that case the court did find that budgetary considerations did justify discrimination.

In *Eldridge v. British Columbia (Attorney General)*⁸⁹, the plaintiffs challenged the province's refusal to insure sign language interpretation for the medical visits of deaf people.⁹⁰ In its attempts to justify the discrimination, the B.C. government argued that the denial of funding for sign language interpretation was based on budgetary constraints. The court estimated the cost of providing sign language interpretation to all of B.C. to be only \$150,000 or approximately 0.0025% of the provincial health budget: "In these circumstances, the refusal to expend such a relatively insignificant sum to continue and extend the service cannot possibly constitute a minimum impairment of the appellants' constitutional rights."⁹¹ This suggests that the cost of a health service must meet some level of significance before it will be sufficient to justify discrimination.

In *Cameron*, Justice Chipman found that the Nova Scotia government's decision not to insure IVF and ICSI constituted discrimination under section 15(1) of the *Charter*.⁹² He then proceeded to the section 1 analysis. Justice Chipman characterized the objective of the provincial government's policy "as being to provide the best possible health care coverage to Nova Scotians in the context of limited financial resources."⁹³ He then discussed the federal funding cutbacks to health care, the cost of IVF and ICSI and their variable success rates.⁹⁴ He estimated the cost of insuring IVF and ICSI procedures to be approximately \$1 million per year.⁹⁵ In light of these considerations, Justice Chipman concluded that the Crown had met the burden of the Oakes test.⁹⁶ In doing so, he distinguished the case from *Eldridge* as it denied funded access to only two procedures and not the whole system of medical services. Financial considerations at least partly justified the discrimination as evidenced by Justice Chipman granting policy makers some "latitude in balancing competing interests in the constrained financial environment."⁹⁷ In light of the role Justice Chipman gave to cost in determining what is medically necessary, it would have been surprising for him to find cost constraints to be anything but a justification for discrimination under the section 1 *Charter* analysis.

In the trial-level *Auton* decision, the court took a long-term view of the costs of the ABA therapy: "In a broad sense, it is apparent that the costs incurred in paying for effective treatment of autism may well be more than offset by the savings achieved in assisting autistic children to develop their educational and social potential rather than dooming them to a life of isolation and institutionalization."⁹⁸ The court thus found that the infringement of section 15(1) of the *Charter* could

⁸⁹ *Eldridge v. British Columbia (Attorney General)*, [1997] 3 S.C.R. 624.

⁹⁰ *Ibid.* at para. 1.

⁹¹ *Ibid.* at para. 87.

⁹² *Supra* note 59 at para. 208.

⁹³ *Ibid.* at para. 218.

⁹⁴ *Ibid.* at para. 219-232.

⁹⁵ *Ibid.* at para. 228.

⁹⁶ *Ibid.* at para. 243-245.

⁹⁷ *Ibid.* at para. 236.

⁹⁸ *Auton #2*, *supra* note 69 at para. 147.

not be justified under section 1. In upholding the trial court's decision on section 1, the B.C. Court of Appeal took a very unusual approach in assessing the second part of the Oakes test. It used the court's common law *parens patriae* jurisdiction to conclude "that the underlying thesis that the law works for the protection and advantage of children strongly argues against finding s.1 justification for the discriminatory administration of the health care scheme at issue in this case."⁹⁹ Besides the common law, the court also referred to international law and the Convention on the Rights of the Child as having "moral force" relevant to the interpretation of section 1.¹⁰⁰ The Court of Appeal also rejected the government's arguments that the court should defer to the legislature's decisions on the allocation of taxpayers' resources.¹⁰¹

The Supreme Court overturned the decisions of the lower courts in *Auton* on the grounds that the denial of funding for ABA therapy was not discriminatory under section 15(1) of the *Charter*. The Court did not, therefore, discuss possible justifications for discrimination under section 1. While this reduces the precedent value of the two lower courts' decisions in *Auton*, it does not eliminate their reasoning and interpretation of section 1. Accordingly, while cost may be relevant in justifying discrimination, it is by no means determinative.

In *Wynberg v. Ontario*¹⁰², another case of litigation over publicly funded access to therapy for autistic children, the Ontario Superior Court of Justice found that the cut off age of six in the province's Intensive Early Intervention Program (IEIP) constituted discrimination on the basis of age under section 15(1) of the *Charter*. In her application of the Oakes test, Justice Kiteley agreed that all the objectives of the IEIP were pressing and substantial during the design and development of the program except the goal of "allocat[ing] limited available resources in a manner that optimizes the program's benefits and maximizes the potential outcomes for children with autism".¹⁰³

In the rational connection portion of the test, the government relied, in part, on the reason of limited financial resources to rationally connect the age limit of the program to the objectives of the program. Justice Kiteley emphasized the role of balance in section 1. She questioned research relied upon by the government that only presented the economic costs of expanding the program and discussed other research that presented a cost-benefit analysis of expanding the IEIP.¹⁰⁴ In a similar

⁹⁹ *Auton* #4, *supra* note 69 at para. 61.

¹⁰⁰ *Ibid.* at para. 63. The Convention on the Rights of the Child was also raised in the appeal to the Supreme Court of Canada. In its arguments as an intervener, the Attorney General of Canada contested the use of the Convention in the Court of Appeal's section 1 analysis. The Attorney General claimed that the Convention does not require state parties to fund particular medical services. The issue was not discussed in the Supreme Court's judgment.

¹⁰¹ *Ibid.* at para. 57-59.

¹⁰² *Wynberg v. Ontario*, 2005 CanLII 8749.

¹⁰³ *Ibid.* at para. 644.

¹⁰⁴ *Ibid.* at para. 657-666.

vein to the B.C. Supreme Court, the latter analysis demonstrated significant long-term savings for the government. Justice Kiteley found that the government had accepted that there is a financial benefit from the program and, “[f]urthermore, it is difficult for the defendant to support the limited financial resources argument when the IEIP has been operating in a surplus.”¹⁰⁵ Accordingly, there was no rational connection between the financial argument and the age limit and, after proceeding with the rest of the Oakes test, Justice Kiteley found that the discrimination on the basis of age was not justified under section 1.¹⁰⁶

No clear-cut test for determining whether discrimination can be justified on financial grounds in health law cases emerges from this review. Different courts have used different reasoning including: a requirement for some level of significance to the additional cost that would be incurred by the government if the court orders funding for a health service; granting deference or latitude to policy-makers who must set priorities in a constrained fiscal environment; a requirement for some level of efficacy in the treatment for discrimination not to be justified; an invocation of the *parens patriae* power of the court and human rights obligations; and a balancing of costs and benefits. Interestingly, just as only the *Cameron* decision in the preceding section on ‘Financial Resources and Medically Necessary’ found cost to be relevant in determining medical necessity, only *Cameron* in this section found cost to justify discrimination. Unlike the preceding section, however, all the cases in this section considered cost much more explicitly. Given their consideration and rejection of cost in the section 1 analysis, these cases suggest that future courts would be less likely to use cost as a justification for infringing section 15 than they would for a medical necessity question. In other words, the role of cost in determining medical necessity is much less certain than its apparent limited role in justifying discrimination.

Applying these factors to a situation where a province refuses to pay for the breast cancer genetic test points to several areas a court may consider. First, a court would need to assess the likely level of demand for the test and whether meeting this demand would use a significant portion of the health care budget. Also, much like Fiona Webster’s situation and the findings in *Auton #2* and *Wynberg*, the cost of the test may be cheaper than the alternative, in which case it would be hard to justify denying the test as reasonable under the Oakes test. In weighing short- and long-term costs, the court may also consider the prospect of expensive patent infringement litigation. The *parens patriae* and human rights analysis in *Auton* was particular to the protection of children. Petitioners could certainly raise the right to health contained in international law but this may be difficult as the person seeking the genetic test is usually doing so for predictive reasons and is not usually considered ‘sick’.¹⁰⁷ Finally, courts will also need to consider whether to defer to

¹⁰⁵ *Ibid.* at para. 672.

¹⁰⁶ *Ibid.* at para. 692.

¹⁰⁷ This, of course, all depends on the definition of ‘health’, an analysis of which is far beyond this article. The Human Genetics Society of Australasia has voiced its concerns that gene patenting may result in

decisions made by policy makers in the context of limited financial resources and competing demands.

The Myriad situation is not likely to be the only instance of individuals seeking funded access to patented genetic tests. As research continues, new genetic tests for other illnesses will be developed. At times, the science of the tests is ahead of the science of the treatments and so, while it may be possible to determine if someone is genetically at risk of contracting a disease, it may not be possible to treat the disease in question. In this case, courts may find it both reasonable and ethical under section 1 not to fund the test.

Overall, the case law seems to indicate a trend to using section 15 to force governments to fund certain aspects of health care over claims that a specific treatment is 'medically necessary'. The case law points to an unwillingness on the part of courts to defer to the Crown and allow money matters to supersede medical treatment. On the other hand, when viewed from a broader perspective, the Supreme Court's decision in *Auton* can be interpreted as a refusal to interfere with the budgetary decision-making processes of the provincial health authorities.¹⁰⁸ Whether this unwillingness to defer to the Crown will continue in the appeal of *Wynberg*, the pending Ontario class action suit concerning the same IEIP, and as more aspects of health care come to be covered by patents remains to be seen.

In addition, the recent *Chaoulli*¹⁰⁹ decision may indicate a growing unwillingness on the part of the Supreme Court to use the *Charter* to engage in a re-distribution of economic resources in Canadian society. In *Chaoulli*, the Supreme Court ruled that the Quebec prohibition against the purchase of private insurance for services insured under the public health care system contravened the *Quebec Charter of Human Rights and Freedoms*. A minority of the court ruled that the prohibition also contravened the Canadian *Charter*.

At first glance, the *Auton* and *Chaoulli* decisions may seem somewhat contradictory in that the Supreme Court refused to intervene in the British Columbia healthcare system in *Auton* but decided to intervene in the healthcare system of

"[a]ttempts to narrow the definition of 'normal' and broaden the definition of 'disease' in order to create a market for a genetic test, prevention or treatment", Human Genetics Society of Australasia, "HGSA Position Paper on the Patenting of Genes" (May 2001) at 2.1, online: Human Genetic Society of Australia <<http://www.hgsa.com.au/policy/patgen.html>>. It should be noted that international law has taken a very broad definition of 'health': "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity", first recital of the preamble to the *Constitution of the World Health Organization*, 22 July 1946, Official Records of the World Health Organization No. 2 at 100 (entered into force 7 April 1948), online: World Health Organization <http://whqlibdoc.who.int/hist/official_records/2e.pdf>.

¹⁰⁸ Kirk Makin, "Top court steers clear of government priorities" *The Globe and Mail* (20 November 2004) A11, online: Canada Autism <<http://www.canadaautism.com/Default.aspx?tabid=55>>. This is all the more true in light of another recent Supreme Court case that did justify discrimination on budgetary grounds, see *Newfoundland (Treasury Board) v. N.A.P.E.*, [2004] 3 S.C.R. 381, 2004 SCC 66.

¹⁰⁹ *Chaoulli*, *supra* note 50.

Quebec in *Chaoulli*. Taking a step back, however, both decisions point to an acceptance of the logic of the market by the Court.

In both *Auton* and *Chaoulli*, the outcome is likely to be a move to the private sector to supply healthcare services – non-publicly funded autism treatment in the case of *Auton* and private health insurance in the case of *Chaoulli*. In effect, the Supreme Court is saying that it is not the role of the courts to provide or maintain the safety net of a publicly funded healthcare system where this is not being done by government. These decisions could lead to a shift in the payment for healthcare from the state to the individual. It may well become the individual's responsibility to ensure he or she has the funds to pay for private treatment or insurance where the government has a lack of funds to insure a service or maintain short waiting times.

This points to one of the ironies of the facts in *Chaoulli*. One of the appellants in the case, George Zeliotis, was angry that he had to wait almost a year for hip replacement surgery and was forbidden by law from buying health insurance that would cover him to have the surgery done privately. As a person with a pre-existing condition, however, Zeliotis would not have been able to buy private insurance even if it was legal. No health insurance company would cover him for a risk with a probability of one – i.e. a risk that is a certainty.¹¹⁰ Zeliotis is also subject to the logic of profit-driven health insurance: with a pre-existing condition, he will either have to pay for private treatment himself or wait in line for publicly-funded treatment like everyone else: "In other words, it was not the lack of private insurance that caused Mr. Zeliotis's pain and suffering, it was the lack of money to pay for private health-care services."¹¹¹

How does this relate to the Myriad Genetics case study and publicly-funded access for a patented genetic test? The market logic in *Auton* and *Chaoulli* may well support Justice Chipman's decision in *Cameron* where medical necessity was determined in part by the cost of the medical service in question. Where the cost of publicly insuring a patented genetic test is more than the public system can support then the test may well not be classed as medically necessary. Furthermore, where a province has refused to publicly insure a test, *Auton* and *Chaoulli* suggest that it is up to the individual to anticipate that Medicare will not pay for everything and be prepared with private health insurance or funds to pay for the test privately. Discrimination or other *Charter* arguments may not be sufficient to force payment from the province. If the individual cannot afford these costs, then they will experience the "pain and suffering" of Mr. Zeliotis while he waited for his hip

¹¹⁰ Mindelle Jacobs, "Private insurance won't help the sick" *Edmonton Sun* (14 June 2005), online: *Edmonton Sun* <http://www.edmontonsun.com/News/Columnists/Jacobs_Mindelle/2005/06/14/1087235.html>.

¹¹¹ Hugh O'Reilly and Fred Holmes, "Private health insurance" *The Globe and Mail* (21 June 2005) web exclusive, online: *The Globe and Mail* <<http://www.theglobeandmail.com/servlet/story/RTGAM.20050620.wcomment0621/BNStory/National>> [emphasis added].

replacement and Fiona Webster when she could not afford to pay for Myriad's patented genetic test.

2. Access to Future Treatments

Myriad would argue that without patents it would not have the funds to invest in the research and development necessary to create new treatments and bring them to market in the future. By this line of reasoning, if we try to improve access to existing medical treatments by reducing their patent protection, we risk undermining access to future treatments as well. This logic may be true to a point but also contains a hazard that if the patent protection is too strong, the patent system will no longer fulfill its purpose and will instead act as a disincentive to future research.

The Canadian provinces have been using a different test from the one developed by Myriad. Nonetheless, Myriad claims that any test infringes its patent because the test must use its patented genes. If Myriad can prevent anyone from using 'its' genes, this will actually act as a disincentive to innovation. No one will be interested in developing cheaper, more accurate tests if the use of these tests is contingent on approval from Myriad. The company would lose income if customers switched to other tests so its approval would only come at a high price.

The possibility of patents acting as a disincentive to research is not only a problem with Myriad. Merz *et al.* studied the effects that a patent on a genetic test for haemochromatosis had on genetic testing for the disease: "We have discovered that many US laboratories began genetic testing for haemochromatosis before the patents were awarded, but 30% of those in our survey reported discontinuing or not developing genetic testing in the light of the exclusive licence granted on the patents covering clinical-testing services".¹¹² Heller has termed this problem the "Tragedy of the Anticommons"¹¹³ and he and Eisenberg consider patents on small pieces of knowledge like genes to be a significant threat to bio-medical research.¹¹⁴

It would be difficult for courts to consider the issue of access to future treatments in litigation for funded access to patented medical technologies. In the cases discussed above, the courts have been called upon to determine whether there should be funded access to a particular medical treatment, service or technology, not how the funded access needs to be provided. In other words, if a court orders a province to fund access to a particular patented medical technology, it is still up to the province to decide whether to comply through means that support the incentives in patent law (i.e. use the patented technology) or to seek other options – a compulsory license, a generic alternative, or even challenging the validity of the

¹¹² Jon F. Merz, *et al.*, "Diagnostic Testing Fails the Test" (2002) 415 *Nature* 577 at 577.

¹¹³ Michael A. Heller, "The Tragedy of the Anticommons: Property in the Transition from Marx to Markets" (1998) 111 *Harv. L. Rev.* 621.

¹¹⁴ Michael A. Heller & Rebecca S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research" (1998) 280 *Science* 698.

patent. Whether these other options support or hinder access to future treatments depends, at least in part, on whether the original patented medical technology was itself supporting or hindering research – a difficult problem to assess. The need for the incentive of patents to create access to future treatments is more likely to arise in the decision over the validity of a patent, an analysis that is well beyond the scope of this article.

IV Conclusion

The review of the case law illustrates that it is possible for individual Canadians to force their provincial government to provide funded access to specific medical technologies through both ‘medical necessity’ and *Charter* arguments. If the Supreme Court’s decisions in *Auton* and *Chaoulli* are any indication, however, these successes may have come to an end. In a way, this may not be a negative development as the litigious approach to access to health care risks creating a sort of tragedy of the commons where the costs of meeting the health care demands of individuals gained through litigation depletes the total health care available to everyone. Indeed, this could lead to another form of two-tiered health care system with one class of health care for those who can afford to sue for funded access to what they need and another class for those who cannot.

In the coming years, as the field of genetics continues to develop, intellectual property protection is likely to follow. If past history is any guide, the growing interaction between health care and patents will not be limited to the field of genetics either, but will also include proteomics, genomics, and perhaps even areas like organ development. If Canada is going to maintain its publicly funded health care system, then federal, provincial and territorial governments need to prepare for demands for access to new patented medical treatments, technologies and services. Otherwise, the provincial and territorial governments in particular face the risk of funded access being forced upon them piecemeal by the courts. The broad range of issues at play – including international trade law and policy, science and technology development, human rights, and constitutional division of powers – means that the federal, provincial and territorial governments must cooperate in order for progress to be made in this area and to ensure that all Canadians can continue to enjoy affordable access to health care.

