PATENTS, THE CHARTER & A HEALTHY DOSE OF RIGHTS IN WRONGS: THE POISON IS THE ELIXIR FOR LIFE, LIBERTY & SECURITY OF THE PERSON

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What is it about our political process that enables legislatures and governments to ignore the most fundamental interests of significant segments of society with impunity?[1]

I. INTRODUCTION

There are some 3,000-4,000 hereditary diseases related to errors in our genetic code including cystic fibrosis, muscular dystrophy, diabetes and various forms of cancer (breast, stomach, colorectal etc).[2] The Canadian Breast Cancer Foundation estimates that 22,200 women will have been diagnosed with breast cancer in 2006 and 5,300 will die; of the 160 estimated new cases of breast cancer in men, 45 are expected to die.[3] Breast Cancer is a disease that disproportionately affects women, predominately those between the ages of 50-69.[4] Although breast cancer is the most frequently diagnosed cancer among Canadian women, it is also one of the most

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1 Martha Jackman, "Canadian Charter Equality at 20: Reflections of a Card-Carrying Member of the Court Party" *Policy Options* (December 2005 - January 2006) 72 at 77, online: <http://www.irpp.org/po/archive/dec05/jackman.pdf> [Jackman, "Charter Equality"].

2 Mark J. Fecenko, *Biotechnology Law: Corporate-Commercial Practice* (Markham,Ont.: Butterworths, 2002) at 13. See also Andrea D. Brashear, "Evolving Biotechnology Patent Laws in the United States and Europe: Are They Inhibiting Disease Research?" (2001) 12 Ind. Int'l & Comp. L. Rev. 183 at 186-87. For information on the genetic basis of breast cancer, see online: <http://www.breastdiseases.com/risksfac.htm>.

3 National Cancer Institute of Canada, "Canadian Cancer Statistics 2006," online: <http://www.ncic.cancer.ca>.

4 Over 50% of diagnoised breast cancer is in women between 50 - 69. Canadian Cancer Society "Media Backgrounder: Canadian Cancer Statistics 2006 - Screening: Breast, colorectal, and cervical" (11 April 2006), online: <http://www.cancer.ca>. Nevertheless, a gendered analysis of the issues and any potential equality-based constitutional claim under s. 15 of the *Charter* will not be pursued in this paper.

treatable; deaths could be reduced by one quarter if 70% of women in this age group receive routine clinical breast exams and biannual screening.[5]

Predictive genetic screening for cancer related genes is an effective and integral part of using new technology to battle cancer. Both the BRCA1 and BRCA2 genes have been linked with the propensity to develop breast and ovarian cancer while HMPPC has been associated with colorectal cancer. The American firm of Myriad Genetic Laboratories Inc. (Myriad), which holds the patents over both the above genes and their diagnostic testing, sought to enforce their exclusive rights in Canada by threatening litigation with cease and desist letters sent to the governments of British Columbia and Ontario in 2001.

For cancer patients and their political supporters, the exclusive right to control access and set the price for something which already *exists* as a product of nature makes gene patenting reprehensible and simply *wrong*. Ontario's then Premier, Mike Harris, refused to back down in response to Myriad's legal threats, saying in a speech to the Ontario Advisory Committee on Predictive Genetic Technology[6] that Canada needs to amend its laws to prevent privatization of human genes and that "[u]like new drugs, genes aren't invented – they are discovered. They have always existed." Additionally, Mike Harris urged that:

> [t]he benefits of a world-wide effort such as the human genome project should not be the property of a handful of people or of companies. Our genetic heritage belongs to everyone. We must share its benefits fairly. We must do what we can to make genetic tests and therapies affordable and accessible... [i]f we have the ability to save a life, we have a responsibility to do so.[7]

Tony Clement, Provincial Minister of Health at the time, consistently defended the position of the Ontario government for its continued diagnostic screening of BRCA1 and 2 despite criticism by industry that this constituted an uncompensated

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[5] Genevieve Beauchemin, "More screening could cut cancer deaths: report" *CTV News* (11 April 2006), online: <http://sympaticomsn.ctv.ca/servlet/ArticleNews/story/CTVNews/20060411/cancer_screening_060411>. See also Canadian Breast Cancer Foundation, online: <http://www.cbcf.org/news/events.html#erin>.

[6] This Committee undertook broad consultation and a review of the legal issues surrounding gene patenting. See generally, See Lisa Austin & Bita Amani, "Patents on Genes: Identifying Issues and Responses" (Discussion Paper prepared for and internally distributed to the Ontario Provincial Advisory Committee on New Genetic Technologies, Toronto, Ontario, October 2001) [unpublished, on file with the authors] also included as an annex to "Legal and Ethical Challenges of New Predictive Genetic Testing", Report of the Legal and Ethical Subcommittee of the Provincial Advisory Committee on New Predictive Genetic Technologies (2003) (Co-Chairs of the Committee: T. Lemmens & R. Mykitiuk and authors/contributors: Mireille Lacroix, Lisa Austin, Bita Amani).

[7] Robert Benzie, "Ontario to defy U.S. patents on cancer genes: Province will pay for $800 test, not $3,850 version by Myriad Genetic Laboratories Inc.: 'Share the Benefits'" *National Post* (20 September 2001) A15.

public taking.[8] Clement remained ever mindful of the limited resources and duty of his government to respond to the health needs of its constituents. Ontario continued its testing of Canadian patients in the public health system at approximately one-fifth of the cost without licence.[9] Since then, the Canadian Cancer Society (CCS) has taken the position that it opposes the exclusive rights of gene patent holders if they are used to interfere with an individual's health, impede the development of new knowledge, or restrict Canadian women's access to cancer-related genomic testing.[10]

While the governments in this case displayed an atypical preference for individual health rights by prioritizing the delivery of public health over private proprietary claims in the field of cancer genomics, nothing today bars the issuing of new gene patents nor is there any comprehensive policy for their regulation.[11] In fact, the Canadian Patent Office (CPO)[12] has long been granting patents on genes from a variety of species, proteins, and micro-organisms without public scrutiny, participatory debate, or attention to the need for cross-policy co-ordination. As the ensuing discussion will show, the validity of gene patents is increasingly at issue within patent law for failure to meet established legislative and doctrinal requirements. As DNA provides genetic *information,* it has been argued that granting patents for the discovery of genes based on their isolation or purification is actually an inappropriate *private* taking from the information commons.[13] The Commissioner of Patents nevertheless continues to grant these patents pursuant to his authority under the *Canadian Patent Act* (*CPA*).[14] This article addresses potential public authority liability for the granting of gene patents.

The BRCA1/2 controversy raises important considerations of distributive justice, legal ethics, economics, human rights, social costs related to the patenting of genes, the unintended consequences of legislative inertia, and the need for governmental accountability. Literature dealing with patents and human rights tends to reflect the hegemony of trade and proprietary values by disproportionately

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[8] See *e.g.* Tony Clement, Minister of Health and Long Term Care, "The Myriad Gene Patent Issue" (Speech delivered, 19 September 2001).

[9] See *e.g.* Bita Amani, "Patents and Public Health: International Trade Obligations and Domestic Policy Development" (2002) 22 Health L. Can. 76.

[10] Canadian Cancer Society, "The patenting of BRCA1 and 2 genes" (16 January 2006), online: <http://www.cancer.ca/ccs/internet/standard/0,3182,3172_31282995__langId-en,00.html>.

[11] See Austin & Amani, "Patents on Genes" *supra* note 6. See also Ontario, Provincial Advisory Committee on New Predictive Genetic Technologies, *Genetic Services in Ontario: Mapping the Future* (Ontario: Provincial Advisory Committee on New Predictive Genetic Technologies, 2001), online: <http://www.health.gov.on.ca/english/public/pub/ministry_reports/geneticsrep01/genetic_report.pdf>.

[12] For the Canadian Patent Database, see Canadian Intellectual Property Office, online: <http://patents1.ic.gc.ca/intro-e.html>.

[13] See Bita Amani, "What's Not *Right* About Intellectual Property? The Public Interest in Private Rights and the Human Right to Participate in Knowledge Production" [unpublished, on file with author].

[14] *Patent Act*, R.S.C. 1985, c. P-4 [*Patent Act*].

focusing on the economic costs of infringement under domestic patent laws and the larger cost of state non-compliance with trade-related patent rights under the World Trade Organization's (WTO) *Trade Related Aspects of Intellectual Property Agreement (TRIPS)*.[15]

Neither property nor health rights are expressly protected under the Canadian Constitution. Proposed public liability for the breach of an individual's right to health under the *Canadian Charter of Rights and Freedoms*[16] is, however, a much needed countervailing consideration against the threat of trade sanctions and would help ensure greater domestic accountability over the grant of gene patents which are presumptively valid[17] state granted monopolies that confer enforceable "exclusive" rights for the patent holder (patentee) for twenty years. Constitutional accountability, which has the potential to achieve positive health outcomes, should not be ignored.

This article fills the scholarly aperture by canvassing the *other* costs for non-compliance associated with the international human right obligation of health where gene patents are concerned. It does so by engaging in a *Charter* analysis informed by the Supreme Court of Canada (SCC) decision in *Jacques Chaoulli and George Zeliotis v. Quebec (Attorney General)*.[18] Doctor Jacques Chaoulli and Mr. George Zeliotis challenged Québec's legislation restricting the ability of Quebeckers to purchase private health care, in order to avoid the long waiting lists in the public system, Zeliotis had suffered a number of health problems which were exacerbated by delays in the public health care system. It has been reported that the waiting list for hip replacement surgery is two years and for radiation therapy after breast-conserving surgery, sixteen weeks.[19] Dr. Chaoulli was a practicing physician whose efforts to get a licence for private operations had met with consistent opposition. The Court of Appeal unanimously upheld the trial judge's finding championed, for the

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[15] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 15 April 1994, Annex 1C of the *Marrakesh Agreement Establishing the World Trade Organization*. Elsewhere I have argued that TRIPS impact on domestic policy choices may be mediated through a prescribed bifurcated approach for defending regulatory diversity to allow the trumping of human rights over industrial policy in order to avoid trade sanctions resulting from a successful WTO complaint. See Bita Amani, *Merchants and Missionaries: Patenting Life, Competing International Obligations and the Proselytization of a Realistic Utopia* (SJD Dissertation, University of Toronto, Faculty of Law, 2007) [unpublished, on file with author] [Amani, *Merchants and Missionaries*] wherein I dispel the mythology around the claim that international trade law mandates governments to give patent policy priority over health and human rights where biopatenting is concerned.

[16] *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*].

[17] S. 43(2) of the *Patent Act* provides the presumption of validity: "After a patent is issued, it shall, in the absence of any evidence to the contrary, be valid and avail the patentee and the legal representatives of the patentee for the term mentioned..."

[18] *Jacques Chaoulli and George Zeliotis v. Quebec (Attorney General)*, [2005] 1 S.C.R. 791 [*Chaoulli*].

[19] Colleen Flood & Terrence Sullivan, "Supreme disagreement: The highest court affirms an empty right" (2005) 173:2 CMAJ 142.

most part, by government experts tauting the propriety of Canadian wait times and the efficacy of the Canadian public health system. They concluded that the contested legislation did not violate either the Federal or Quebec *Charters*. The Supreme Court of Canada had a different perspective on the matter.

Only seven of nine members of the SCC sat for the appeal and, in a 4:3 split, the majority held that the contested legislation was impermissibly offensive to the individual rights and freedoms of Quebeckers and reversed the finding of the lower courts. Three of the majority justices, McLachlin C.J.C., and Major and Bastarache JJ., found that the prohibition violated s. 7 of the *Charter* and could not be justified as a reasonable limit under s. 1. The fourth justice, Deschamps J., found that as the prohibition violated the broader language of the Quebec Charter it did not require further consideration under the narrower provision of rights in the Canadian *Charter*.[20] The three judges forming the dissent, Binnie, LeBel, and Fish JJ., found that s. 7 was not violated and that the case pertained to the allocation of resources which is a policy issue more appropriately dealt with by the capable hands of democratically elected representatives than by judges. [21]

I argue that the recent judgment in *Chaoulli* can be analyzed broadly as the start of a constitutionalized right to health within an emerging public law action for regulatory negligence. Interpreted against a backdrop of "constitutional tort" jurisprudence, public sector liability may now be expanded to account for failure to protect individual health from unjustified state intrusion, whether that intrusion is from a faulty "operational" measure in applying the statutory standards for patentability set out in the *CPA* or a faulty "policy" decision by CPO in treating genetic sequences to be patentable subject matter *a priori*. Constitutional remedies could include a declaration (including invalidation of gene patents and a call for a moratorium), monetary damages, injunctive relief and other possibilities available under the *Charter* for failure to regulate public health in a manner consistent with Canada's obligations under international human rights instruments and now consitutionalized by *Chaoulli*.

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[20] This is because the language of the Quebec Charter includes the word personal "inviolability" as compared to the *Charter's* narrower "security of the person". See *Chaoulli*, *supra* note 18, paras. 26-33.

[21] "We are unable to agree with our four colleagues who would allow the appeal that such a debate should be resolved as a matter of law by judges. We find that, on the legal issues raised, the appeal should be dismissed." *Ibid.* at para. 161. Binnie and LeBel JJ., writing for the dissent, state in the same paragraph:

> The question in this appeal is whether the province of Quebec not only has the constitutional authority to establish a comprehensive single-tier health plan, but to discourage a second (private tier) health sector by prohibiting the purchase and sale of private health insurance. The appellants argue that timely access to needed medical service is not being provided in the publicly funded system and that the province cannot therefore deny those Quebeckers (who can qualify) the right to purchase private insurance to pay for medical services whenever and wherever such services can be obtained for a fee... This issue has been the subject of protracted debate across Canada through several provincial and federal elections.

II. OVERVIEW

The remainder of this article is divided into three parts. Part 1 provides a basic primer on patent law and considers traditional private law remedies for public sector liability in order to determine whether a private action in tort could be made against the government for the issue of gene patents. After identifying the limitations of a private law approach, Part 1 also considers the possibility of public law proceedings for regulatory negligence under the *Charter* and compares this with pursuing invalidity under patent law. Finally, Part 1 will also establish that the *Charter* applies to the impugned state action.

Having established that the *Charter* does apply to the grant of gene patents, Part 2 considers the second legal element for a successful constitutional challenge: Has there has been a violation of a *Charter* right? Canada's international human rights obligations clearly commit our government to protecting the individual right to health. Existing domestic implementation of these obligations are reviewed before considering *Chaoulli's* impact. The *Chaoulli* decision has been widely criticized as 'poisoning' Canada's public health care program by effectively sanctioning a two-tier system for health delivery that allows private insured services not offered in the public system. Its critics gripe that it has paved the way for an impoverished realization of the right to health[22] and definitively betrays the fantastical 'dream' of social justice that the *Charter* was to stand for.[23] However, it will be argued that perhaps the focus on how the *Chaoulli* decision constrains a positive right to health in the future is too narrow. A *progressive* defence of *Chaoulli* is offered, in the alternative, to unveil its potential for creating public authority accountability for the grant of gene patents by recognizing a nascent *negative* right to health. This recognition is necessary to ground a public law remedy given that, at present, neither tort nor patent law provide effective means to address the health-related harms arising from the CPO's actions.

Having established that the *Charter* applies and that s. 7 rights, as understood in *Chaoulli*, have been violated, Part 3 analyzes whether the resulting restriction of the right to health subsumed within the s. 7 rights to life and to security of the person is a reasonable limit prescribed by law and demonstrably justified in a free and democratic society under s. 1 of the *Charter*. Finally, a constitutional challenge of the CPO's grant of gene patents, informed by our new understanding of *Chaoulli's* potential, is presented.

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[22] See Martha Jackman, "The Last Line of Defence for [Which?] Citizens": Accountability, Equality and the Right to Health in *Chaoulli*" (2006) 44:2 Osgoode Hall L.J. 349, online: <www.healthcoalition.ca/Jackman-CHC.pdf > [Jackman, "Last Line of Defence"].

[23] Allan C. Hutchinson, "'Condition Critical': The Constitution and Health Care" in Colleen M. Flood, Lorne Sossin & Kent Roach, eds., *Access to Care, Access to Justice: The Legal Debate Over Private Health Insurance in Canada* (Toronto: University of Toronto Press, 2005), 101 at 103-05.

It is hoped that by working through a *Charter* challenge regarding cancer genomics, public law will be considered as an additional means for stymieing the proliferation of biopatents that fail to meet the requirements of "inventiveness" or otherwise extend to non-patentable subject-matter; and for achieving social justice by holding governments accountable for their failure to regulate with care where that failure impacts a *Charter* right. Addressing the constitutionality of gene patents has important applications in the field of predictive genomic screening, gene therapy, and cancer prevention; this issue must therefore be part of any intervention plan to improve health and cancer service access because access "is not just definitive final treatment, but begins with prevention and screening."[24]

PART 1 - PUBLIC SECTOR LIABILITY FOR "WRONGS"

Patent policy in Canada is incoherent and generally lacking in public consultation and democratic debate. A patent must be applied for at the CPO and is granted by a patent examiner on behalf of the Commissioner[25] for a period of twenty years if it meets the statutory requirements for "invention" defined as any "art, process, machine, manufacture or composition of matter" or a new and useful improvement to any of these.[26] An examiner may reject an application with reasons if positively unsatisfied that the statutory requirements have been met. Such a decision could then be appealed to the Patent Appeal Board comprised of senior examiners who make further recommendations to the Commissioner.[27] There is no discretion, however, in granting the patent if the CPO is otherwise satisfied that the statutory requirements have been met.[28] So long as the invention, which could cover product and process claims meets the statutory definition; falls into the scope of patentable subject matter *i.e.* is not expressly excluded by statute; and is new,[29] useful,[30] non-

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[24] T. Sullivan *et al.* "A Just Measure of Patience: Managing access to cancer services after *Chaoulli*" in Flood, Sossin & Roach, *ibid.* 454 at 457.

[25] *Patent Act*, *supra* note 14, s. 4, establishes the duties of the Commissioner and allows for the delegation of these duties pursuant to the legislation.

[26] *Ibid.* s. 2.

[27] David Vaver, *Intellectual Property Law: Copyright, Patents, Trade-Marks* (Concord, Ont.: Irwin Law, 1997) at 117 [Vaver, *Intellectual Property Law*].

[28] *Patent Act*, *supra* note 14, s. 40.

[29] *Ibid.* s. 28.2(1). Novelty refers to the fact that the invention has not yet been disclosed in public. Before a patent is granted there is a search of the prior art (that is any material already in the public domain) to ensure that the application is in fact a new invention and that as far as is known in good faith, it does not infringe any other patented inventions in that jurisdiction.

[30] Utility, in relation to inventions "means industrial value", sometimes it may mean industrial application and "must be apparent from the description to one of skill in the art." See Industry Canada, Canadian Intellectual Property Office, *Manual of Patent Office Practice* (March 1998), s. 16.02.01, online: <http://strategis.ic.gc.ca/sc_mrksv/cipo/patents/mopop/mopop_dnld-e.html>. The invention must have utility but our laws do not generally require a model prototype to be made or that its utility be *shown*.

obvious[31] and *fully disclosed,* then it is to be patented.[32] Where the patent examiners, the Patent Board and the Patent Commissioner do have discretion is in how strictly the patentability criteria are applied. This discretion makes these decisions "operational" and thereby subject to a negligence standard. The decisions of the CPO, Commissioner, examiners, or any other delegates, are made pursuant to statute and are therefore actions to which the *Charter* applies.[33] If, as in the field of biopatenting, judicial developments support patentability as likely, "the [C]PO may grant the application, leaving the courts to decide validity in contested litigation."[34] A patentee may appeal an adverse decision of the CPO directly to the Federal Court of Appeal and ultimately to the SCC. The *Charter*, of course, also applies to common law rules.[35]

1. Comparing Public Sector Liability in Private and Public Law

In this section I will compare and contrast the potential for public authority liability in tort and under the *Charter* for the issue of gene patents. Imagine I am a complainant who wants to challenge the issue of gene patents and is interested in pursuing the state for monetary damages. What are my avenues for redress? Tortious liability of the state has long raised complicated issues of immunity, justice, loss allocation, and limitations (including limitation periods) stemming from the various legislation regulating public sector liability. S. 5 of the *Proceedings Against the Crown Act* (*PACA*) allows for liability in tort against the Crown.[36] The *PACA* answers the procedural question of whether the Crown can be sued in tort but does not provide *when* the Crown owes a duty of care or how that duty may arise. Similarly, the *Public Authorities Protection Act* (*PAPA*)[37] establishes the requisite notice period and other formalities such as a six month limitation period which was substantially shorter than the six years applicable to other tortfeasors, both are now

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[31] S. 28.3 of the *Patent Act* was added in 1993 as a codification of this common law requirement of inventiveness. S. 28.3 of the *Patent Act* requires that the invention not be obvious and that it not be information publicly available "in Canada or elsewhere".

[32] *Patent Act, supra* note 14, s. 27.

[33] See *Charter, supra* note 16, s. 32; *Little Sisters Book and Art Emporium v. Canada (Minister of Justice)*, [2000] 2 S.C.R. 1120 applying the *Charter* to the confiscation of "obscene" material by Customs inspectors pursuant to authority granted by legislation [*Little Sisters*]; See generally, Peter Hogg, *Constitutional Law of Canada,* looseleaf, vol. 2, at p. 34-11 [Hogg, *Constitutional Law of Canada,* looseleaf].

[34] Vaver, *Intellectual Property Law, supra* note 27 at 117.

[35] Peter Hogg, *Constitutional Law of Canada,* 3rd ed., (Canada: Carswell, 1992) at 888 [Hogg, *Consitutional Law of Canada*, 3rd ed.].

[36] R.S.O. 1990, c. P.27, s. 5: "...the Crown is subject to all liabilities in tort to which, if it were a person of full age and capacity, it would be subject, (1) in respect of a tort committed by any of its servants or agents..."

[37] R.S.O. 1990, c. P.38.

replaced by a universal two year period without Crown favour.[38] The Crown may therefore enjoy immunity in tort either under statute or because of a lapsed limitation period. However the Crown can still be found liable under s. 24 of the *Charter*.[39] One of the benefits of actions under the *Charter* is that limitations arguably should not apply; the supremacy of the *Charter* would be undermined if Parliament could legislate out of its constitutional obligations. Also, since different provinces provide for different limitation periods, *Charter* rights would be incoherently variable.[40]

The Crown was historically immune from liability on the premise that "the king can do no wrong." Because there was no duty on the Crown at common law, these statutes were seen as generous in granting plaintiffs the right to sue and were initially narrowly interpreted. However, once it became established that the Crown could be sued, the statutes appeared to *restrict* individual rights by establishing formal and technical parameters for actions against the Crown and thus were often liberally interpretted.[41]

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[38] *Limitations Act, 202*, S.O. 2002, c. 24, Sch. B, s. 4 establishes the basic limitation period of 2 years while s. 3 binds the Crown to that period.

[39] See *e.g. Hawley v. Bapoo*, 76 O.R. (3d) 649 (Ont. S.C.J.) wherein it was found that two Crown Attorneys, although subject to suits for malicious prosecution, were immune from suits for negligence because of s. 5(6) of the *PACA*; other claims made were for abuse of public office, breach of a statutory duty and infringement of the plaintiff's ss. 7 and 11(b) *Charter* rights and vicarious liability of the Crown for its agents. Because the then 6 month limitation period had lapsed, all actions were dismissed by the Superior Court except for allegations claiming relief under s. 24 of the *Charter*.

[40] For a judicial precedent by the Ontario Court of Appeal that limitation periods do not apply to *Charter* violations and relief claimed under s. 24(2), see *Prete v. Ontario* (1993), 16. O.R. (3d) 161 (C.A.) at 68, Carthy J. writing for the Court, expounds:

> Put in this *Charter* context, I see no valid comparison between procedural rules of court and statutory limitation periods. I do see identity between statutes granting immunity and those imposing limitation periods after the time when the limitation arises. Having found that immunity is not available under the Proceedings Against the Crown Act from a claim for Charter remedy, it therefore follows that in my opinion s. 11 of the Public Authorities Protection Act should be read as not applying to relief claimed under s. 24(1) of the Charter.

But see the conflicting view in *St. Onge v. Canada*, [2001] F.C.J. No. 1569, aff'd [2001] F.C.J. No. 1523 (C.A.) (QL), at para. 2:

> [S]ection 45(1)(g) of the *Limitations Act*, R.S.O. 1990, c. L. 15 is an enactment of general application that applies to any civil liability action, irrespective of whether it is based on a violation of Charter rights. The six-year limitation period in the Act is immune to the controversy surrounding the constitutional validity of short limitation periods when they preclude the exercise of a Charter right.

[41] See *e.g. McNabb v. Ontario (Attorney General)* (2000), 50 O.R. (3d) 402 (Ont. S.C.J.). See also *Latta v. Ontario* (2002), 220 D.L.R. (4th) 157, where the plaintiff sued the Crown for serious injuries sustained during incarceration in a correctional facility when he tripped over a sand-filled pail that was being used as a door stopper. He notified the guards immediately, filled out an accident report but did not serve a notice of a claim for negligence on the Crown until after the 10 day limitation period required by statute under s. 5(1)(c) of the *PACA*. The Court of Appeal for Ontario generously found that the reporting of the accident was sufficient to satisfy "notice" within the 10 day limitation period.

Before liability may be found, a duty of care is needed and may arise under statute or common law. The *CPA* does not articulate any duty of care owed to the public generally or to individuals of the public privately by the Commissioner in granting or denying a patent application although the Act does provide the Commissioner and other Crown agents (such as examiners and the Board) immunity from personal liability. The SCC was instructive on public sector liability in *Cooper v. Hobart;*[42] a case about the Registrar of Mortgage Brokers, a statutory regulator, who suspended a registered mortgage broker's licence but was being sued in negligence for failing to act more promptly to avoid or diminish the losses suffered by investors who continued to advance money to the broker in the interim.[43] The Court found that if there is a duty of care to the public then a private duty of care to any individual is precluded.

Where legislation has failed to define the relationship between the public entity and the public, one looks to the common law to determine whether a duty of care is owed before tortious liability can be pursued against the public sector. *Cooper* articulates the appropriate test for finding a common law duty of care. McLachlin C.J.C. and Major J., writing for the Court, revisited the *Anns* test[44] for determining whether a statutory regulator owes a private law duty of care to members of the investing public for (alleged) negligence in failing to properly oversee the conduct of an investment company licensed by it. The SCC affirmed existing common law categories where a duty of care has been recognized – directing litigants to first determine whether their case falls into one of these categories or an analogous one. Where the duty does not fall within a recognized category of recovery, the Court must consider whether there is a relationship of proximity and reasonable foreseeability of harm which, if established, gives rise to a *prima facie* duty of care; and whether any overriding broader policy considerations might negate this duty.[45] Policy considerations are also important, the SCC found, for determining requisite proximity (that the defendant is in a close and direct relationship to the plaintiff such that it is just to impose a duty of care in the circumstance).

For example, a policy consideration that traditionally has negated a tortious duty of care is the belief that regulatory governance requires freedom to regulate without threat of liability for policy decisions. Thus, for example, there would be no liability for whether road maintenance is undertaken (a policy decision based on allocation of scarce resources) but where a policy for road maintenance is adopted,

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[42] *Cooper v. Hobart* [2001], 3 S.C.R. 537 [*Cooper*].

[43] *Ibid.* at para. 43, the Court provides that "[i]n this case, the statute does not impose a duty of care on the Registrar to investors with mortgage brokers regulated by the Act. The Registrar's duty is rather to the public as a whole. Indeed, a duty to individual investors would potentially conflict with the Registrar's overarching duty to the public."

[44] See *Anns v. Longon Borough Council*, [1978] A.C. 728 (H.L.). The decision "highlights and hones the role of policy concerns in determining the scope of liability for negligence." See *ibid.* at para. 1.

[45] *Cooper, ibid.* at para. 39.

there is an existing duty of care to ensure that it is not negligently performed.[46] Similarly, there would be no tortious liability for a policy decision finding genes to be patentable inventions based on the CPO's interpretation of patent legislation, so long as the patent is not negligently granted; that is, so long as the statutory requirements of patentability are met. This is the classic policy/operationalization dichotomy in tort law wherein the Crown has historically enjoyed immunity for the former on the basis that policy decisions necessarily entail financial, economic, social and political factors better left to the discretion of our elected representatives. In *Chaoulli*, the dissent emphasized this point, stating that "the resolution of such a complex fact-laden policy debate does not fit easily within the institutional competence or procedures of courts of law."[47]

If the patent office has assumed a *de facto* policy for granting gene patents, the first and most obvious basis for attacking gene patents is with respect to the statute's standards for patentability and their application by the CPO. An individual can claim that the statutory requirements for patents are being carelessly applied in relation to gene patent applications such that the artificial scarcity detrimentally affecting public health should never, by doctrinal standards, have been created. We know that in the private law of torts, "a government actor may be liable in negligence for the manner in which it executes or carries out the policy."[48] Such an attack against a decision by the Canadian Patent Office/Commissioner could be made on at least six different grounds under the *Act* and should ideally be coupled with a concurrent challenge to patent validity: 1) genes are not properly patentable subject matter; 2) they lack novelty – there is nothing "new" about the gene just because our ability to isolate them was newly found; 3) they lack an inventive step (they are not non-obvious) especially since the isolation of the gene is now routinely done by automated computing; 4) utility (more helpful if the issue is over patented Expressed Sequence Tags (ESTs) or DNA sequences of no known current utility); 5) sufficiency of the patent specification; and 6) incomplete disclosure of the existing prior art or alternatively a lax understanding of the person with ordinary skill in the art.[49] The *person having ordinary skill in the art* (PHOSITA) in patent law is very

[46] See *Just v. British Columbia*, [1989] 2 S.C.R. 1228 [*Just*]; *Swinamer v. Nova Scotia (Attorney General)*, [1994] 1 S.C.R. 445. See also *ibid.* at para. 36.

[47] *Chaoulli*, *supra* note 18 at para. 164.

[48] *Cooper*, *supra* note 42 at para. 38.

[49] See *e.g.* L. Burk & Mark A. Lemley, "Is Patent Law Technology-Specific?", 17 Berkley Tech. L.J. (2002) 1155 at 1191, online: <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=349761> at 2-3 where they state:

> The more skill those in the art have, the less information a patentee has to disclose to meet the enablement requirement--but the harder it is to meet the nonobviousness requirement. The level of skill in the art affects not just patent validity, but also patent scope. One reading of the biotechnology and computer software cases is that the Federal Circuit believes computer programmers are extremely skilled, while biotechnology experts know very little about their art.... We do not challenge the idea that the standards in each industry should vary with the level of the skill in that industry....[T]he use of the PHOSITA provides needed flexibility for patent law, permitting it to adapt to new technologies without losing its essential character."

much like *the reasonable person* in tort law – an ever-elusive fictional person creating a nebulous legal standard. Much of the legal variance in patent standards is attributable to the use of this legal construct to determine obviousness and enablement.

Even if one were able to locate a PHOSITA, as David Vaver notes, the meaning of the patent is ultimately a question of law to be "decided by a judge who usually is not skilled in any art or science, let alone the relevant one."[50] That patents have been extended to life by judicial fiat is an apt example of this.[51] Moreover, judges have complained, on more than one occasion, of the linguistic ambiguity in claim drafting[52] and that it compounds the existing difficulty in understanding the boundaries to technologically specific and often complex inventions. The claims draw a fence separating what is privatized under the patent from that which remains in the public domain. But there are other problems related to the desire to maximize this enclosure. What some call "kitchen sink" patents,[53] others refer to as "reach through claims" to describe the tendency of the patentee to claim overly broadly– to reach through the invention – to privately enclose more than that which is invented and disclosed.[54]

Reach through claims are anti-competitive and reflect the patentee's desire to demarcate as much of the market as possible in a particular field of technology as falling within his or her legal rights. The patentee's spot is 'reserved' for later and broader applications of the technology than actually disclosed. Suppose, for example, that I have invented X. Claim one in my patent would be abstracted to the broadest possible interpretation of what the invention is – the whole of an alphabet comprised of letters, which contains my X. If we consider genetic sequences as the alphabet coding for words (genes) in the "book of life", the danger with patenting the alphabet as a whole, or any of its letters, is more readily apparent. Unlike linguistic alphabets which are culturally constructed, genes are our common heritage; our endowment from nature; they are *not* "invented." Because genes are information and

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[50] Vaver, *Intellectual Property Law*, *supra* note 27 at 140.

[51] See Bita Amani & Rosemary Coombe, "The Human Genome Diversity Project: The Politics of Patents at the Intersection of Race, Religion, and Research Ethics" (2005) 27:1 *Law & Policy* 152.

[52] See *Xerox of Canada Ltd. v. I.B.M. Canada Ltd.* (1977), 33 C.P.R. 24 at 88, n. 14, where the judge complained that claims such as the one before the court passed from "riddle to enigma" – the claim to collect used toner from photocopiers was a sentence made of 178 words with little punctuation. See also the 281 word claim also held valid after a nine day trial despite some earlier proclaimed doubts by the judge during interlocutory proceedings. *Risi Stone Ltd. v. Groupe Permacon Inc.* (1990), 29 C.P.R. (3d) 243 at 247-48 (F.C.T.D.) rev'd (1995), 65 C.P.R. (3d) 2 at 9 (F.C.T.D.).

[53] See Kevin Rivette & David Kline, *Rembrandts in the Attic: Unlocking the Hidden Value of Patents* (Boston: HBS Press, 1999) at 21 which get their name "because they [the patents] sometimes appear to be asserting ownership of everything under the sun…"

[54] See Rebecca S. Eisenberg, "Reaching Through the Human Genome" (Keynote address presented to the Fifth Annual Technology and Intellectual Property Group Conference entitled, Dual Controversies of the Double Helix: Challenges of Regulating the Information and Property Aspects of Genetic Technology, at the University of Toronto, February 2004)

not true "inventions", there are no viable substitutes. Even if we concede that genetic information can be characterized as "invention" on the basis of labour alone, my claim to the alphabet subsuming my invention X if granted, worse yet, gives me a patent lottery because it reaches through to provide me with legal rights more expansive than for what I actually invented. That is what Myriad did with its BRCA1 and 2 diagnostic test patents.

Attacking patentability based on faulty application of statutory requirements was used against Myriad's BRCA 1 /2 gene patent and diagnostic testing patent in France and later Europe to challenge patent *validity*. What was first a dispute between the Institut Curie and Myriad eventually spilled over into all of Europe and involved the French government and European Parliament. The problem of gene patenting was further compounded by the over-broad nature of Myriad's claims which, by assuming a monopoly on *all* BRCA 1 and 2 related genetic tests and the genes against which such tests were developed, effectively limited alternative and possibly more accurate genetic testing. The Institut Curie, the Assistance Publique-Hopitaux de Paris and the Institut Gustave-Roussy filed an opposition notice with the European Patent Office (EPO) which, following public hearings on May 17 and 18 2004, resulted in revocation Myriad's patent on BRCAnalysis. The Canadian Cancer society reports in relation to Myriad's BRCA patents that since the EPO "has not yet issued a written discussion that describes the specific reasons it revoked this patent...it is difficult to know what impact this will have, if any, in Canada."[55]

However, using patent law to attack validity may prove cumbersome and not entirely satisfactory. First, the costs are too extensive to be borne routinely by private litigants. Consider some general statistics available from the American context. The United States Patent Office (USPTO) grants approximately 75% of all patent applications. Courts invalidate some 46% of litigated patent claims. Only a negligible 2% of patents, however, are litigated and "less than two-tenths of one percent of all issued patents actually go to court."[56] The costs of a full trial through to an appeal might approximate $1.5 million dollars for each party according to a study by Mark Lemley.[57] The high cost may be manageable as between private corporate firms who attack patent validity as a means of defending against a patent infringement suit, but is not a viable option for individual citizens seeking to correct a patent roster of all its "bad patents". Second, there are far too many gene patents to challenge on a case by case basis and such a remedial approach does little to contribute to public health in a participatory and anticipatory manner. Moreover, it is an inefficient use of judicial and private resources considering the total number of gene patents that have issued and continue to issue impacting on human health.

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[55] See Canadian Cancer Society, "Background on the patenting of BRCA1 and 2 genes", online: <http://www.cancer.ca/ccs/internet/standard/0,3182,3172_31282995_32749610_langId-en,00.html>.

[56] John R. Allison & Mark A.Lemley, "Empirical Evidence on the Validity of Litigated Patents" (1998) at 208, online: < http://papers.ssrn.com/sol3/papers.cfm?abstract_id=118149>.

[57] Mark Lemley, "Rational Ignorance at the Patent Office" (2001) 95:4 Nw. U. L. Rev. 1495 at 1501-02 [Lemley, "Rational Ignorance"].

According to the National Geographic, more than 4,000 of the approximately 24,000 human genes have been claimed in U.S. patents.[58] That is to say, 20% of the human genome has been patented; of these approximately 63% are assigned to private firms as compared to 28% to universities.[59] Yet, "the functions are unknown for over 50% of *discovered* genes."[60] Where the functions are unknown, there is a faulty "operational" decision because the patentee has failed to establish and disclose a clear "utility" as required by patent law – making the CPO's grant of those patents negligent. Attacking gene patents by seeking to impose public authority liability through tort law is also piecemeal and remedial at best targeting one gene patent grant at a time, much like invalidity proceedings do, with the additional scope for claiming monetary damages. The availability of tort actions does not impact what is now a *de facto* patent office policy for granting gene patents or eliminate the need for cross-policy coordination between the ministries of health and industry. If the patent is revoked under patent law, that gives a strong indication that there was a breach of the standard of care in an operational decision of a crown agent (in granting the patent in the first place) which may open up liability in tort depending on whether the plaintiff is able to discharge the burden of proof on the remaining elements for the tort of Negligence.

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[58] What is patented in the USA is routinely patented in other major industrialized countries and secures priority rights for doing so.

[59] Stefan Lovgren, "One-Fifth of Human Genes Have Been Patented, Study Reveals" *National Geographic News*, (15 October 2005) online: <http://news.nationalgeographic.com/news/2005/10/1013_051013_gene_patent .html>.

[60] Humae Genome Project, "The Science Behind the Human Genome Project", online: <http://www.ornl.gov/sci/techresources/Human_Genome/project/info.shtml> [emphasis added]. These statistics informed California Congressman Xavier Becerra's recent proposal of new legislation to ban human genetic patenting (U.S., Bill H.R. 977, *Genomic Research and Accountability Act*, 100th Cong. 2007 to Amend Title 35, United States Code), online: <http://thomas.loc.gov/home/gpoxmlc110/h977_ih.xml>. In his introductory speech before Congress in February 2007, Becerra implored:

> I rise today with the hope of fixing what I believe to be a regulatory mistake-a mistake that at first glance may seem minor in scope, but upon further examination has dramatic, costly and harmful implications for every American. I speak of the practice of gene patenting, where private corporations, universities and even the Federal Government are granted a monopoly by the United States Patent and Trademark Office on significant sections of the human genome... It is my belief that this practice is wrong, ill-conceived and stunts scientific advancement... My legislation, the Genomic Research and Accessibility Act, is straightforward: it ends the practice of gene patenting. It gives guidance to the United States Patent and Trademark Office (PTO) on what is not patentable-in this case, genetic material, naturally-occurring or modified. It is not retroactive-it does not rescind the patents already issued... We have overstepped our bounds. We have made a regulatory mistake. We have allowed the patenting of a product of nature. Fortunately, we have the power to end the practice expeditiously and for the benefit of all.

See Library of Congress, (U.S., *Cong. Rec.*, daily ed., at E315 (9 February 2007) (Rep. Becerra)), online: <http://thomas.loc.gov/cgi-bin/query/D?r110:60:./temp/ ~r110KYJQHb::>.

So far we have considered patent invalidity proceedings in addition to the private law duty of care: the first element for the tort of Negligence. If we could not proceed by way of an existing or analogous category of a duty of care consideration of a new duty would entail broader policy questions which, in *Cooper,* included considering the spectre of indeterminate liability and whether it would "loom large if a duty of care was recognized". Additionally, *Cooper* instructs us to consider the impact of the duty on taxpayers. Governments are self insurers. "To impose a duty of care in these circumstances would be to effectively create an insurance scheme...at great cost to the taxpaying public."[61]

To summarize, both a categorically recognized duty and a new prima facie duty of care would be problematic. A new duty would likely be negated by policy considerations. And, even if a categorical duty has been recognized, a terminally ill plaintiff would have difficulty proving on a balance of probabilities the remaining elements of the tort. She would have to establish that causation, remoteness, and damages relate to the *grant* of the patent in order to discharge her burden for imposing tort liability. Consequently, as applied to a faulty operational decision of a public authority the private law approach is uncertain and unlikely to succeed. Additionally, even if gene patents were expressly *allowed* by legislation, the Crown would not be liable in tort for resulting harms. Legislators have traditionally been immune from tort liability because legislative decisions are characterized as pure policy decisions and do not give rise to a private duty of care on the part of governments. Similarly, there would be no public sector liability for legislative omission for the *failure* to *ban* gene patents or to exclude them from patentability. Abstract theorem and scientific principles are expressly excluded under s. 27(8) of the CPA for rationales that would equally apply to genetic information: these are public goods necessary for basic science and research.

Gene patents could be excluded for public policy reasons. The *Manual of Patent Office Practice* (MOPOP) s. 16.02 protects public health interest by rearticulating a common law exception to patentability: "subject matter related to a process of surgery or therapy on living humans or animals is not considered to be within the scope of 'invention' as defined by s. 2 of the Patent Act."[62] Another option would be to establish a body similar to the Patented Medicines Prices Review Board which attempts to reach a compromise position between the interests of pharmacutical companies investing in drug research and development and individual need for access to medicine. These are effective means of achieving cross-policy coordination objectives even though consideration of health or other moral issues are irrelevant considerations for the CPO's determination of patentability under the CPA. Jurisprudence makes clear that there is no duty of care owed in the common law for policy decisions of the crown and its agents. In *Cooper,* the SCC expounds: "It is established that government actors are not liable in negligence for policy decisions, but only operational decisions. The basis of this immunity is that policy is

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[61] *Cooper, supra* note 42 at para. 56.

[62] *Manual of Patent Office Practice, supra* note 30.

the prerogative of the elected Legislature. It is inappropriate for courts to impose liability for the consequences of a particular policy decision."[63] This was the legal landscape until *Chaoulli* and it meant that faulty (negligent) policy decisions causing harm were immune from tortious liability. However, the CPO may also be considered to be acting unconstitutionally if they have overstepped the legitimate boundaries of the interpretation of patentable subject matter or misapplied the requirements for patentability and "invention".

In *Chaoulli,* the SCC found that "when the courts are given the tools they need to make a decision, they should not hesitate to assume their responsibilities. Deference cannot lead to the judicial branch to abdicate its role in favour of the legislative branch or the executive branch."[64] Therefore, the same set of facts that give rise to tort action may independently give rise to *Charter*-based damages claims.[65] The result is that social policies which are careless (negligent) and disregard the *Charter* impact on those foreseeably harmed, or are otherwise *wrongful* in breaching a constitutional right, can be the subject of public sector liability under the *Charter*; just as a standard of care based on custom or common practice can give rise to a negligence claim in tort if that custom or practice was itself negligent.[66] The two claims are not co-dependent however and it is not necessary to establish a basis of liability in tort in order to bring a *Charter* claim. To the contrary, the latter may be particularly helpful to address situations in which tort liability may seem untenable.

One might argue, then, that *Chaoulli* is not about the narrow issue of public or private delivery of health services but rather that *anytime* the *Charter* creates a regulatory scheme (whether for granting patents or delivering healthcare), it *must comply* with the *Charter* such that a failure to do so – a breach of the requisite standard of care in tort terms – is, in relation to s. 7 rights, unconstitutional. In other words, *Chaoulli* supports a parallel form of public sector liability based on a "constitutional tort" of *regulatory negligence*. The majority in *Chaoulli* confirmed this, finding that, "if the government chooses to act, it must do so properly."[67] This broad rule is consistent with s. 52 of the *Constitution Act, 1982* which requires that all of the laws of Canada conform with the Constitution.

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[63] *Cooper, supra* note 42 *at* para. 38.

[64] *Chaoulli, supra* note 18 at para. 87.

[65] *Nelles v. The Queen,* [1989] 2 S.C.R. 170; *Jane Doe v. Metropolitan Toronto (Municipality) Commissioners of Police* (1989) 58 D.L.R. (4th) 396 (Ont. H.C.), affirmed (1990) 74 O.R. (2d) 225 (Ont. Div. Ct). at 230, leave to appeal refused (1991), 1 O.R. (3d) 416 (note) (Ont. C.A.). The damages recovered may be limited to one or the other action.

[66] *ter Nuzen v. Korn,* [1995] 3 S.C.R. 674.

[67] *Chaoulli, supra* note 18 at para. 158. One obvious criticism of this premise is that the government then may simply chose not to act and thereby avoid liability entirely. I do not believe that the disincentive argument is compelling since there are political reasons governments may act and often those short term political reasons are not congruent with adverse economic outcomes but are imperative nonetheless.

An emerging constitutional tort for *regulatory negligence* may be found in the earlier SCC decision of *Vriend*[68] where the enactment of the *Individual Rights Protection Act* (*IRPA*) fell under *Charter* scrutiny for excluding sexual orientation as a prohibited ground of discrimination. This legislative "omission" offended the *Charter's* guarantee of equality rights and warranted review. As human rights legislation, to make it consistent with *Charter* principles, the *IPRA* required that the protection coverage be complete and inclusive of a specific group deliberately excluded from its protection but historically targeted by the discrimination the legislation was passed to address. *Vriend* highlights two key points. First, legislative omissions can draw *Charter* scrutiny even if they are precluded from similar scrutiny in the private law of tort due to their characterization as "policy". Second, if Parliament acts to create a regulatory scheme, that scheme must meet minimal standards of care. That is, it must not violate enumerated *Charter* rights.

In *Chaoulli,* McLachlin C.J.C. and Major J. posited that "[t]he courts have a duty to rise above political debate. They leave it to the legislatures to develop social policy. But when such social policies infringe rights that are protected by the charters, the courts cannot shy away from considering them."[69] Where policy decisions affect constitutional *Charter* rights, even if legislated, the Court can assert its jurisdiction to address the resulting harm and need not defer to governments. S. 52 of the Constitution states that the *Charter* is the supreme law of the land. Regulatory schemes, whether our regime for public health delivery (confirmed in *Chaoulli*) or for granting patent protection as argued here, must thereby comply with *Charter* principles as well as our international obligations under human rights instruments.[70] Having determined that the *Charter* applies, the next step in a constitutional challenge to the CPO's grant of gene patents is to determine whether any *Charter* rights have been violated. To make this determination, we must ask: Is there a constitutional right to health and if so, was it infringed?

PART 2: CONSTITUTIONALIZING HEALTH: THE PROGRESSIVE AND INDIVISIBLE CHARACTER OF HUMAN RIGHTS

Kirsten Hastrup suggests that:

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[68] *Vriend v. Alberta,* [1998] 1 S.C.R. 493.

[69] *Chaoulli, supra* note 18 at para. 89.

[70] See *Baker v. Canada (Minister of Citizenship and Immigration),* [1999] 2 S.C.R. 817. L'Heureux-Dubé J. wrote at paras. 69-70:

> International treaties and conventions are not part of Canadian law unless they have been implemented by statute... I agree with the respondent and the Court of Appeal that the Convention has not been implemented by Parliament. Its provisions therefore have no direct application within Canadian law. Nevertheless, the values reflected in international human rights law may help inform the contextual approach to statutory interpretation and judicial review.

> [r]ights are what unite us, as attributed to us by the global imagined community, glued together not by a sense of tradition and a shared past but by a hope for the future and a universal currency of rights...which now functions as the legitimate representation of a global moral economy.[71]

Under the 1945 *United Nations Charter* (UNC), the Economic and Social Council was born as the principal UN organ and was given a broad mandate pertaining to international economic, social, cultural, educational, health and related matters.[72] The 1948 *Universal Declaration of Human Rights* (UDHR) set out "a common standard of achievement for all peoples and all nations"[73] without drawing a distinction or establishing a priority between civil and political rights, and economic, cultural and social rights. The UDHR has served as the model for codifying human right protection in multilateral conventions, such as the *International Covenant on Civil and Political Rights* (ICCPR) [74] and the *International Covenant on Economic, Social and Cultural Rights* (ICESCR)[75] at least one of which most States are signatory to. The Vienna Declaration of 1993 reaffirms not only the universality of human right but their indivisibility, interdependence, and interrelation while acknowledging the need to consider diversity amidst universalizing ambitions.[76]

Human rights recognize the equal entitlements of individuals as their subject but do not assure equality amongst the rights recognized. The preamble to the UDHR provides "equal...rights of all members of the human family." Yet, some rights allow for *progressive realization,* limits, restrictions, and optional protocols or reservations, while others (such as political and civil rights proclaimed under the ICCPR) are more absolute and immediate. The fact that an internal hierarchy of

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[71] See Kirsten Hastrup, ed., *Legal Cultures and Human Rights: The Challenge of Diversity* (New York: Kluwer Law International, 2001) at 15.

[72] *Charter of the United Nations*, 26 June 1945, Can. T.S. 1945 No. 7. arts. 62-72,

[73] *Universal Declaration of Human Rights*, GA Res. 217(III), UN GAOR, 3d Sess., Supp. No. 13, UN Doc. A/810 (1948) [UDHR]. As a resolution of the UN General Assembly, it was not binding *per se*, but became the foundation for much of the later codified and customary international human rights law. See Hannum Hurst, "The UDHR in National and International Law" (1998) 3:2 *Health & Hum. Rts.* 145.

[74] *International Covenant on Civil and Political Rights*, 19 December 1966, 999 U.N.TS. 171, Can. T.S. 1976 No. 47, 6 I.L.M. 368 (entered into force 23 March 1976, accession by Canada 19 May 1976) [ICCPR].

[75] *International Covenant on Economic, Social and Cultural Rights*, GA Res. 2200A(XXI), UN GAOR, Supp. No. 16, UN Doc. A/6316 (1966), 993 U.N.T.S. 3 (entered into force 3 January 1976) [ICESCR].

[76] *Vienna Declaration*, World Conference on Human Rights, Vienna, 14-25 June 1993, UN Doc. A/CONF.157/24 (1993). Article 5 provides: "All human rights are universal, indivisible and interdependent and interrelated. The international community must treat human rights globally in a fair and equal manner, on the same footing, and with the same emphasis... [I]t is the duty of States...to promote and protect *all* human rights and fundamental freedoms." See also Article 6 of the *Declaration on the Right to Development*, GA Res. 41/128, annex, 41 UN GAOR, Supp. No. 53 at 186, UN Doc. A//41/53 (1986).

rights may exist does not in any way diminish their solidarity or indivisibility.[77] Economic, social, and cultural rights (ESCRs) tend to be qualified by the availability of government resources and therefore the ICESCR allows for their *progressive* implementation.[78] Eide and Rosas have argued, however, that "fundamental needs should not be at the mercy of changing governmental policies and programmes, but should be defined as entitlements."[79] The duty on the state cannot be invoked directly in domestic legal forums so the challenge with ESCRs is to encourage governments to give them content and thereby concrete legal relevance; some governments are simply ambivalent to do so[80] even though arguably, "human rights most urgently need asserting and defending, both theoretically and practically, where they are most denied."[81]

In 1950, the General Assembly adopted a resolution emphasizing the interdependence of all human rights and called on the UN Commission on Human Rights to adopt a single convention that would be legally binding on ratifying States.[82] However, under the influence of Western States in the following year, the Commission reversed its decision and created the twin covenants for civil and political rights (ICCPR) and for social, economic, and cultural rights (ICESR). The

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[77] Some advocate the full recognition of socio-economic rights but reject the view of a hierarchy. See discussion in *Gosselin v. Quebec (Attorney General)* [2002] 4 S.C.R. 429 [*Gosselin* (SCC)]. In *Gosselin* the court offers four main problems with social and economic rights. Since they are programmatic, they 1) do not provide for full benefits for those who participate in the program; 2) the design of the programs was not tailored in such a way as to ensure that there would always be programs available to those who want to participate; 3) the implementation of the programs present still more hurdles to overcome; 4) the government determines the availability of the program; at paras. 277-83.

[78] Article 2.1 of the ICESCR, *supra* note 75 provides:

> Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, *to the maximum of its available resources*, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures.

See also related General Comment 3 contained in 5th Sess., art. 2, para. 1, UN Doc. E/1991/23 (1990) [ICESCR, General Comment 3].

[79] See Asbjørn Eide, Catarina Krause & Allan Rosas, eds., *Economic, Social and Cultural Rights: A Textbook* (Canada: Kluwer Academic Publishers, 1995) at 18.

[80] The United States, for example, has not yet ratified the ICESCR and Canada, although having ratified the ICESCR, has not followed the government of South Africa in taking the additional step to expressly legislate the protection of these as positive rights within its Constitution.

[81] See David Beetham, "What Future for Economic and Social Rights" in Henry Steiner & Philip Alston, eds., *International Human Rights In Context: Law, Politics, Morals*, 2d ed. (New York: Oxford University Press, 2000) 249 at 255. The author suggest that human rights advocates and proponents of development economics can find common ground "...on a minimum core of rights such as...the right to food of an adequate nutritional value, to clothing, to shelter, to basic (or primary) health care, clean water and sanitation..." at 256.

[82] Draft International Covenant on Human Rights and Measures of Implementation: Future Work of the Commission on Human Rights, GA Res. 421(V), UN GAOR, 5th Sess. (1950).

development of two instruments is an artifact of the political economy at the time and does detract from the normative interrelation of *all* human rights. The Preamble to the ICESCR mirrors that of the ICCPR, and both provide that:

> the ideal of free human beings enjoying freedom from fear and want can only be achieved if conditions are created whereby everyone may enjoy his economic, social and cultural rights *as well as* his civil and political rights.[83]

Without a mechanism for individuals to hold their governments accountable for the protection of their human rights, the ICESCRs are no more than mere statements of aspiration[84] even though *all* human rights are fundamental to a life of *human dignity* and dependent on the state for their realization, "with the net effect that the breach of one will affect the realization of another."[85]

1. Justiciability: Manufacturing Rights From Ideals

Most major UN human rights treaties, or their related protocols, provide state undertakings to accept the oversight of specialized international supervisory committees (such as the Human Rights Committee which monitors compliance with the ICCPR) known as treaty bodies in order to ensure compliance with treaty obligations – with the exception of the Committee on ESCRs, established by ECOSOC under Resolution 1985/17 rather than by a treaty and monitors state compliance with the ICESCR.[86] Under the ICCPR, there is some provision for use of an inter-state complaint mechanism (under Art. 41, optional declaration but no state has filed one to date) and for individual complaint and petition mechanisms (under ICCPR-OP1). But, neither of these are available internationally under the ICESCR. Simply put, you cannot enforce your individual right to health in an international forum. Therefore justiciability, the ability to have an international human rights claim judicially determined, relies on domestic mechanisms. Unlike customary international law, which is automatically binding and like the common law needs no further domestic statutory incorporation, other international treaty norms require domestic implementation in order to be justiciable; it is domestic law that provides for a legal remedy. However, just as there is a presumption that all

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[83] ICESCR, *supra* note 75 [emphasis added].

[84] See ICESCR, General Comment 3, *supra* note 78 at para. 5: "Any suggestion that the provisions indicated are inherently non-self-executing would seem to be difficult to sustain."

[85] Rhona K.M. Smith & Christien van den Anker, eds., *The Essentials of Human Rights* (London: Hodder Arnold, 2006) at 37, see also Amyrta Sen, *Poverty and Famines: An Essay on Entitlement and Deprivation* (Oxford: Clarendon Press, 1981) observing that no substantial famine in the last fifty years has occurred in a state with a democratic form of government and free press.

[86] Article 16 of the ICESCR requires states to submit periodic reports to the UN Secretary General. Each body is comprised of state elected expert members and are responsible for four different procedures: 1) the review of periodic reports submitted by state parties; 2) investigation of systemic violations; 3) review of petitions filed by one state against another; and 4) and review of petition made by individuals against states parties. Smith & van den Anker, *ibid.*, at 385.

domestic law will conform with our Constitution,[87] there is a presumption that Canadian law conforms with international treaty obligations such that even in the absence of domestic implementing legislation, "while a litigant may not be able to place direct reliance on a right guaranteed by a Canadian treaty obligation, she is permitted to raise that right and rely on it for the purposes of interpreting a domestic provision."[88]

Civil and political rights are considered justiciable in that they are generally more easily applied by courts and require only restraint from intrusion on these negatively defined "freedoms" ('freedom from'). Conversely, social and economic rights have traditionally posed some problems for justiciability and have therefore been considered "programmatic" and subject to the politics of public policy ('freedom to'). One approach consistent with the Vienna Declaration is to incorporate ESCRs protection within domestic constitutional rights protecting civil and political liberties. The right to food and health, for example, may be subsumed within a right to life and security of the person.[89] Such an approach reaffirms the indivisibility and interdependence of all human rights. Ideally, constitutional protection for ECSRs would be as express as civil and political rights and require *positive* baselines to be delivered by public authorities along with the negative freedoms and liberties. South Africa's 1996 Constitution, however, remains virtually alone in this approach.[90]

In other contexts, domestic implementing legislation may open the door for interpreting government measures to be compatible with international human rights obligations. K.D. Ewing, writing about the *UK Human Rights Act* of 1998 [UK Act], argues that if domestic legislation is incompatible with Convention rights, a higher court is empowered under implementing legislation to declare incompatability. However, the *duty to construe* legislation to comply with Convention rights is imposed on all courts. In addition, Ewing argues the UK Act imposes an obligation on public authorities to comply with Convention rights and this obligation is directly enforceable in domestic courts. Summarizing the view of the Lord Chancellor, Ewing writes that the courts have a duty of acting compatibly with the convention not only in relation to cases involving public authorities but also in deciding cases between private citizens such that "Convention rights may be relied upon in

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[87] Hogg, *Consitutional Law of Canada*, 3rd ed., *supra* note 35 at 286.

[88] Mark Freeman & Gib van Ert, *International Human Rights Law* (Toronto: Irwin Law, 2004) at 350-51.

[89] The ICCPR, *supra* note 74, can be applied to protect economic, social and cultural rights reflecting an accepted interdependence between the twin instruments. In addition to the numerous text references supporting this position, the Human Rights Committee charged with monitoring state compliance with the ICCPR decided in *Lubicon Lake Band v. Canada* (1990), Comm. No. 167/1984, that ICCPR (Article 27) protects the right of persons to engage in economic and social activities that are part of the culture of the community to which they belong such that the expropriation of 10,000 square kilometers of land by the Alberta government for use by oil and gas interests violated an Aboriginal groups right to engage in protected economic and cultural activities. Query whether the granting of a gene patent is an analogous "taking".

[90] *Constitution of the Republic of South Africa 1996*, No. 108 of 1996.

litigation between private parties, but cannot themselves be the basis of a cause of action."[91] Rosemary Coombe echoes this position:

> The States' obligation to protect involve duties to prevent abuse of rights by third parties, including non-State actors, whereas obligations to fulfill involve active duties to take appropriate measures that create a framework for creating accountability.[92]

According to Ewing's and Coombe's analysis, these human rights, and their corresponding duties, could be raised as a defence to domestic actions for patent infringement or validity proceedings between private parties and even by the government to defend against patent infringement actions (if for example a government was sued by Myriad). However, the case by case, defensive nature of this approach makes it less than ideal for effecting patent policy changes, as well as protecting the underlying human right. According to CERA, [93] the Canadian government is increasingly criticized by the United Nations human rights bodies for its failure to ensure the realization of social and economic rights for all Canadians.[94] Of course, there are good reasons for governments to prioritize industrial and trade policy over health policy- to date, the risk of liability in domestic and international law and the simple cost of defending a patent infringement action was sufficient incentive especially since there are no similar costs associated for disregarding the individual's right to the *highest attainable standard of health.* If the "right to health" has acquired constitutional status an individual could possibly sue public authorities for granting patents in breach of her human rights and seek *Charter* damages, a declaration of invalidity and perhaps even a moratorium on gene patents being issued by the CPO until Parliament acts through legislation.[95] The provision of *Charter* remedies will act as an incentive, one would hope, for policy change.

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[91] See K.D. Ewing, "The Human Rights Act and Parliamentary Democracy" (1999) 62 Mod. L. Rev. 79 in Henry Steiner and Philip Alston, eds., *International Human Rights In Context: Law, Politics, Morals,* 2d ed. (New York: Oxford University Press, 2000) at 1010.

[92] Rosemary Coombe, "Intellectual Property, Human Rights and Sovereignty: New Dilemmas in International Law Posed by the Recognition of Indigenous Knowledge and the Conservation of Biodiversity" (1998) 6 Indiana Journal of Global Legal Studies 59 at 68.

[93] The Centre for Equality Rights in Accommodation, online: <http://www.equalityrights.org/cera/index.cfm?nav+prog&sub=escr>.

[94] In 1993 and 1998, the United Nations Committee on Economic, Social and Cultural Rights – which monitors Canada's compliance with its ESCRs obligations – criticized Canada for its poor record of upholding these rights. The Centre for Equality Rights in Accommodation, online: <http://www.equalityrights.org/cera/>. In May 2006, Canada underwent another review. An advance unedited version of the UNCESR Review (May 1-19, 2006), future E/C.12/CAN/CO/5 is available online: <http://www.ohchr.org/english/bodies/cescr/docs/E.C.12.CAN.CO.5.pdf>. It criticizes Canada for not doing enough to address social and economic rights such as food shortages, poverty, and homelessness as well as for the absence of an official poverty line.

[95] See discussion of a declaration as a possible remedy under s. 24 of the *Charter* in *Little Sisters, supra* note 33.

2. The Human Right to Health

The right to health is a fundamental human right recognized in international instruments administered under the auspices of the United Nations. The World Health Organization (WHO) – a specialized UN agency established in 1948 for the attainment of the *highest available standard* of health for all people[96] – recognizes human health as integral to the "happiness, harmonious relations and security of all peoples" and therefore defines health holistically in its *Constitution* as, "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."[97] WHO also stresses the importance of state responsibility for ensuring the protection of health, the need for state co-operation because health is a global public good which creates positive spillover effects for the rest of the world, and the essential right of each individual for the full realization of the *highest available standard* without discrimination based on the ability to pay ("economic or social condition"). Since health is part of one's overall wellbeing, it is integral to and subsumed within the right to life, liberty, and security of the person and their silent companion, *human dignity*. Article 25 of the 1948 UDHR reflects the confluence of human rights:

> Everyone has the right to a standard of living adequate for the health and well being of himself and of his family, including food, clothing, housing and medical care and necessary social services...[98]

The ICESCR imposes a positive obligation on States to ensure that these human rights are met. Article 11 recognizes the

> right of everyone to an adequate standard of living for himself and his family, including adequate food...and to the continuous improvement of living conditions...[99],[State Parties] *shall* take, individually and through international co-operation, the *measures...needed...by making full use of technical and scientific knowledge...*[100]

The right to health is internationally recognized as a fundamental human right regardless of its classification as part of our ESCRs or as civil and political rights.

3. Does Canada protect the human right to health?

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[96] This right set out in Article 12 of the ICESCR, *supra* note 75, and provides that state parties recognize "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."

[97] *Constitution of the World Health Organization*, online: About WHO in SEAR <http://www.searo.who.int/LinkFiles/About_SEARO_const.pdf>.

[98] UDHR, *supra* note 73.

[99] "[P]arties will take appropriate steps to ensure the realization of this right, recognizing to this effect the essential importance of international co-operation based on free consent." ICESCR, *supra* note 75.

[100] *Ibid.* [emphasis added].

Canadian constitutional law expressly protects key civil and political rights. Social and economic rights, unfortunately, have not garnered the same express protection. Historically, claims suggesting that they are implicitly subsumed within and indivisible from *Charter* freedoms have failed. Canada is signatory to these treaties and has ratified both the ICESCR and the ICCPR. In principle, Canada does recognize and is committed to the right to health as articulated in international human rights instruments. A patchwork of legislation strives to meet this obligation to protect health. The *Canada Health Act*[101] recognizes the need for public administration of a health care insurance plan that is comprehensive, universal, portable, and accessible. For a more effective system of public health, Colleen Flood and Sujit Choudry suggest *public administration* be expanded to include public *governance and accountability* as this will capture a needed element of "democratic accountability: how to ensure that the State, and decision makers empowered by it, take responsibility for the decisions they make, and are accountable in a fair and more direct and timely manner than is possible through elections every four or five years."[102] Constitutionalizing the right to health creates an additional platform for increasing democratic accountability for administrative decisions. The full protection of the right to health domestically very much relies on this right achieving constitutional status[103] and thereby rendering the international human right to health domestically *justiciable* through this new framework for governmental accountability.

Human health is not an expressly guaranteed right under the *Charter* even though public health issues are a priority within national, regional, cultural, political, and economic agendas. While the delivery of health typically falls within Provincial jurisdiction over property and civil rights,[104] the provinces are restrained by federal objectives conditioned on funding transfers (Canada Health and Social Transfer) as part of the shared-cost programmes within each province. This unique relationship makes inter-governmental co-operation and collaboration imperative for the viability

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[101] R.S.C. 1985, c. C-6 [*Health Act*].

[102] Commission on the Future of Health Care in Canada, *Strengthening the Foundations: Modernizing the Canada Health Act* (Discussion Paper No. 13) by Colleen M. Flood & Sujit Choudhry (August 2002) at 7.

[103] For persuasive arguments in favour of a constitutionalized right, see Martha Jackman, "Constitutional Jurisdiction Over Health in Canada" (2000) 8 Health L.J. 95 [Jackman, "Consitutional Jurisdiction"].

[104] *Constitution Act, 1867* (U.K.), 30 & 31 Vict., c. 3, reprinted in R.S.C. 1985, App. II, No. 5. [*Constituion Act, 1867*]. The grant of provincal authority over hospitals is established through s. 92(7). Under s. 92(13), power over health is included in the provincial property and civil rights, and under s. 92(16) as a matter of local and private nature. However, health can also fall under the federal power under s. 91(27) for criminal law aspects of health (criminal regulation of food and drugs) punishing conduct dangerous to health, within the general jurisdiction of the peace, order and good government federal power if the health problem has national dimension (such as the spread of epidemics like water pollution, pestilence, and SARS or the Anthrax scare) and in relation to labour relation standards under the federal jurisdiction. Essentially, the question of jurisdiction depends on "the purpose and effect of the particular health measure in issue." See Hogg, *Consitutional Law of Canada*, 3rd ed., *supra* note 35 at 476.

and internal coherence of the Canadian health care system.[105] Patent regulation is expressly granted to federal parliament under s. 91(22) of the *Constitution Act*,[106] making policy co-ordination between two jurisdictions and two separate ministries – provincial health regulation and federal industrial property regulation – all the more difficult. The situation continues despite the growing number of reports indicating the lack of co-ordination between health and industrial policy is a shameful worldwide phenomenon in need of immediate attention.[107]

It may be said that a strong patent system furthers the right to health by creating incentives for research and development and the early disclosure of inventions. However, there is no express evidence that the patent system is operating effectively to this end nor that alternative systems of reward could not be as effective.[108] Moreover, the negative impact on health and the economic costs of gene patents to society are not as apparent in the short term as the economic gains are further obscuring motivations for governments to (re)act. And, health lobbyists have hardly had a voice matching in tenor and volume with that of industry lobby, and therefore have failed to capture the ear of politicians in the same way; at least not in terms of priority in cross-policy co-ordination. According to Alison Brysk:

> private profit-making actors control citizens' lives and distort public decision-making in a variety of ways...In a more structural way, private economic interests may shape the rules and roles of governance – regardless of whether they influence a particular decision...[M]arket actors may dominate political life through shaping knowledge and consciousness of what is possible and desirable.[109]

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[105] See National Forum on Health, *Canada Health Action: Building on the Legacy – Final Report of the National Forum on Health* (Ottawa: Minister of Public Works and Government Services, 1997) at 20; Auditor General of Canada, *Report of the Auditor General of Canada to the House of Commons, 1999* (Ottawa; Minister of Public Works and Government Services Canada, 1999) c. 29 at 19. See Martha Jackman, "Constitutional Jurisdiction" *supra* note 103.

[106] *Constitution Act, 1867, supra* note 104.

[107] See William R. Cornish, M. Llewelyn & M. Adcock, *Intellectual Property Rights (IPRs) and Genetics:A Study into the Impact and Management of Intellectual Property Rights within the Healthcare Sector* (Cambridge: Public Health Genetics Unit, 2003), online: <www.phgu.org.uk/about_phgu/resources/word/s-ipr1.doc>; The Nuffield Council on Bioethics Discussion Paper, *The Ethics of Patenting DNA* (July 2002), online: http://www.nuffieldbioethics.org /publications/pp_0000000014.asp; The European Commission's Report on the *Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering* (Brussels: The Commission, 2002), online: <http://europa.eu.int/eurlex/en/com/rpt/2002/com2002_0545en01.pdf>.

[108] See *e.g.* Adam B. Jaffe & Josh Lerner, *Innovation and Its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and What to do About It* (Princeton: Princeton University Press, 2004); Peter Drahos & John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (United Kingdom: Earthscan Publication, 2002); Amani, *Merchants and Missionaries, supra* note 15,

[109] Alison Brysk, "Human Rights and Private Wrongs: Constructing Norms in Global Civil Society" online: < http://www.sscnet.ucla.edu/soc/groups/ccsa/Brysk.pdf> at 6.

And while public health in Canada has garnered much debate in relation to the *system* of public health delivery, the issue has been primarily increased funding and the prevention of private services rather than reducing the impediments to cost-effective care by re-examining policies in other sectors, such as patents. In the absence of express constitutional protection under the *Charter*, the protection of the right to health care remains fragile in Canada. There is apparently very little citizens can do to ensure their human right is not a *hollow* right when faced with harm resulting from a competing "policy" decision, such as the granting of gene patents, by government agencies.

A) *The Poison is the Elixir: How* Chaoulli *nurtures a "new" right*

The drafters of the *Charter* specifically excluded the right to property and freedom of contract from the enumerated constitutionally protected rights.[110] S. 7 of the *Charter* sets out that "[e]veryone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice." The substitution of "security of the person" for "property" in this section has, however, given rise to "new property" claims for welfare and other social benefits under the *Charter* inextricably tied to the welfare state's conception of the value of human life, liberty, security of the person, and integral to the concept of human *dignity*. The SCC left open the possibility of recognizing these "new" rights as subsumed within s. 7 constitutional rights in *Irwin Toy*.[111]

When faced with specific claims for benefits against the state, however, the Court has consistently rejected the recognition of "new property" claims imposing any *positive* obligation on the state for their delivery.[112] This reflects a general reluctance found in public sector liability *negligence* jurisprudence to impose liability in tort for policy based decisions of public authorities because of the financial, economic, political, and social factors involved – all considerations better suited for deliberation by our elected representatives.[113] In *Gosselin v. Quebec*,[114]

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[110] *Irwin Toy Ltd. v. Quebec (Attorney General)*, [1989] 1 S.C.R. 927 at 1003 [*Irwin Toy*].

[111] *Irwin Toy*, *ibid.* Dickson, C.J.C. speaking for the majority at para. 96, found:

> the rubric of 'economic rights' embraces a broad spectrum of interests, ranging from such rights, included in various international covenants, as rights to social security, equal pay for equal work, adequate food, clothing and shelter, to traditional property – contract rights. To exclude all of these at this early moment in the history of *Charter* interpretation seems to us to be precipitous.

[112] In addition to the cases discussed in text, see *Masse v. Ontario (Ministry of Community and Social Services* (1996), 134 D.L.R. (4th) 20 (Ont. Div. Ct.) trial decision where a challenge to the more than 20% cut in provincial social assistance rates was rejected as the Court found that the *Charter* did not guarantee a minimal level of public welfare assistance; *Fernandes v. Manitoba (Director of Social Services (Winnipeg Central))* (1992), 78 Man. R. (2d) 172, 93 D.L.R. (4th) 402 (C.A.) where it was held that the refusal by municipal welfare officials to cover the cost of part-time home care was not unconstitutional as, according to the Manitoba Court of Appeal at para. 13, "The personal choices of a particular individual are not generally to be considered when those choices affect the public purse."

[113] A public body would not be liable for the tort of negligence where reasonable care was not exercised in the making of that policy. For a discussion of this distinction, see *Just*, *supra* note 46; *Brown v.*

the argument in favour of a constitutional right to welfare proceeded from the Quebec courts to the SCC for determination on whether the government's reduction of welfare benefits to one third the base amount of that payable to those under the age of thirty who were not participating in training or work experience employment programs breached the recipient's s. 7 (and s. 15 equality) rights and was therefore a nullity. McLachlin C.J.C. found that nothing in the language or jurisprudence of s. 7 suggested a positive obligation on the state to guarantee adequate living standards and therefore the reduction of welfare rates did not violate the principles of fundamental justice.[115] This decision has been criticized by parties at both ends of the political spectrum. Conservatives argue that the major impact of *Gosselin* was to give judicial weight to principles not found in our domestic law. According to Neil Seeman, a lawyer and director of the CANSTATS project at the Fraser Institute of Toronto:

> Few in Canada are in favour of a legal right to a minimum annual income. A right to freeload? No way. Most Canadians reject the idea; and so, too, does a robust body of constitutional jurisprudence and legislation. ...Whatever the result, the real legacy of this case will be that litigants may turn to documentary evidence from international human rights instruments, nowhere legislated in domestic law, to push for ever greater economic benefits and state resources. Why work when you can sue?[116]

Poverty law advocates Martha Jackman and Lorne Sossin, on the other hand, have long advocated for the Charter's progressive advancement of positive rights. Jackman writes:

> Governments in all parts of the country have been elected and have thrived on poor- and welfare-bashing platforms. Poverty has been characterized by our political leaders not as a serious and systemic economic problem, but an individualized phenomenon blamed on the poor themselves, who are depicted as fraudulent, lazy and responsible for their own misfortune. In this political context Charter litigation has been taken up...not as a means of bypassing democratically elected governments, or undermining parliamentary democracy, but rather as a mechanism for calling the

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British Columbia (Minister of Transportation & Highways) [1994] 1 S.C.R. 420; *Cooper v. Hobart* (2000), 184 D.L.R. (4th) 287 (B.C.C.A.), aff'd [2001] 3 S.C.R. 537. See also *Dunmore v. Ontario (Attorney General)* (1997), 155 D.L.R. (4th) 193 at para. 50 (Ont. Gen. Div.) wherein the trial judge posited that "[t]here are many forms of injustice in our society, particularly those resulting from uneven distribution of wealth, that cannot be remedied by the courts through interpretation of the *Charter* and that must be remedied through the legislative process." [footnotes omitted]. A view also shared by the trial court in *Gosselin v. Quebec (Attorney General)*, [1992] R.J.Q. 1647 (C.S. Que.) trial decision. These and other decisions affecting social welfare are discussed in greater detail by Jackman "Charter Equality", *supra* note 1.

[114] *Gosselin* (SCC), *supra* note 77.

[115] *Ibid.* at paras. 81-84.

[116] Neil Seeman, "The UN's Right to Welfare" *Fraser Forum* (October 2002) 11 at 11. online: <http://www.fraserinstitute.ca>.

> legislative and executive branches to account for their failure to respect the basic rights and interests of a group...[117]

Professors Jackman and Sossin criticize the SCC's finding in *Gosselin* for intimating a false dichotomy between policy and operational measures and between positive and negative rights informing the evolution of *Charter* principles. Jackman asserts:

> The major difficulty facing low income litigants invoking the Charter in the social welfare context originates, I would argue, is a series of presumptions that are regularly applied by courts at all levels in welfare cases. These include the presumption that parliamentary sovereignty remains unfettered in the social policy context; that the state is neutral in its dealing with the poor; that social welfare policies and programs are benign in their intent and their effects in relation to low income people; and that welfare recipients themselves are primarily to blame for any disadvantage that they suffer. The presumption that social policy is beyond the legitimate purview of the courts is pervasive in the Charter cases.[118]

Sossin sums up the decision as one which found that the provision of the basic necessities for survival was a matter of governmental policy preference and not a matter of constitutional law even though this is incongruent with (a) Canada's commitment to the ICESCR and (b) the reality that participation in the rights that *are* constitutionally protected require a certain level of physical and mental integrity and security in place which can only be satisfied by the provision of basic housing and food. These basic necessities, in conjunction with access to health services, in turn affect one's health and together these rights affect one's ability to participate further in our social and judicial system.[119] All in all, both Jackman and Sossin view *Gosselin* as a blow against human rights protection.[120]

The SCC again visited the *Charter's* potential to accomodate ESCRs in *Auton v. British Columbia.*[121] In *Auton,* the British Columbia government refused to provide public funding (based on financial constraints) for services designed for autistic children which fell outside of the funded "core services" set out in provincial health service legislation. This policy was challenged under s. 15 (equality rights) of

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[117] Jackman, "Charter Equality", *supra* note 1 at 73.

[118] *Ibid.* at 75.

[119] Lorne Sossin, "Towards a Two-Tier Constitution? The Poverty of Health Rights" in Flood, Sossin & Roach *supra* note 23 at 171 [Sossin, "Two-Tier Constitution"]. See also Lynn A. Iding, "In a Poor State: The Long Road to Human Rights Protection on the Basis of Social Condition" (2003) 41 Alta. L. Rev. 513.

[120] Jackman, "Last Line of Defence", *supra* note 22 and Sossin, "Two-Tier Constitution", *ibid.* Sossin argues that "the better view is that the positive/negative rights distinction itself is pernicious. It assumes a world of rights-bearing autonomous individuals which is foreign to most low-income people." at 171.

[121] *Auton (Guardian ad litem of) v. British Columbia (Attorney General),* [2004] 3 S.C.R. 657, rev'g (2002) 220 D.L.R. (4th) 411 (B.C.C.A).

the *Charter*. The B.C. Court of Appeal ordered the government to provide these services to all autistic children finding that the policy violated *Charter* rights even though the legislation itself was constitutional. The SCC reversed that finding. Ultimately the claim in *Auton* failed because these services were not being delivered by hospitals or doctors, nor were they recommended by doctors but by therapists who were not designated as "health care practitioners". Moreover, the court was not satisfied that these services were medically necessary in light of possible alternative treatments; an important point since the *Canada Health Act* only reimburses provinces for medically *necessary* services.

Until recently then, it was clear that health was not a constitutionally protected right and that policy decisions could not attract "public authority liability" in tort. *Auton* signals the highpoint of judicial reluctance to protect a positive right to health under the *Charter*. Against this unfavourable judicial backdrop to ESCRs, it was widely anticipated that the SCC would not interfere with the legislative decision under Quebec's health and hospital insurance plans to prohibit private health services for services offered in the public system – despite the serious delays within that system negatively affecting individual health outcomes. Ironically, proponents for a constitutionalized health right, such as the CCPI/CHC who had intervener status in *Chaoulli,* opposed the striking down of the legislation on the basis of equity:

> [C]ontrary to the Appellants and their supporting interveners, and consistent with Canada's international commitments in relation to health and human rights...section 7 guarantees access to care *without barriers on ability to pay*... To the extent that the ...state's single-payer monopoly was necessary to safeguard that right, [the contested legislation] represented a positive measure required by the *Charter's* guarantees of equality and security of the person.[122]

The majority and dissent agreed on little except that delays in access to medical care in the public system impaired security of the person and, in extreme situations, endangered life. The majority's decision is criticized by the dissent and opponents for coming to three conclusions allegedly not supported by the evidence: that waiting lists in Canada are excessive, that the ability to purchase private insurance will mean

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[122] Jackman, "Last Line of Defence", *supra* note 22 at 3 [emphasis added]. With the greatest respect for Professor Jackman who acted as counsel for the Charter Committee on Poverty Issues (CCPI) and the Canadian Health Coalition (CHC) and by her own account has made a "scholarly career of claiming that Canadian *Charter*-based review of government decision-making in relation to health care and other social and economic rights is a legitimate and valuable accountability mechanism, that can also promote the fundamental *Charter goal of substantive equality*," I fail to see how insisting that everyone be treated alike is a good thing if they are all treated *equally poor*. The majority's decision is a better one for promoting progressive health protection in recognizing a right to have one's health not interfered with unlawfully by the state. It may well be that the short term impact of *Chaoulli* is inequality in so far as those who can afford treatment or medical services by parallel means will get it through private insurers and those without money are left in the public system with the state as their insurer. But this may, as some of the evidence suggested, in fact improve the public health care system by the exit of some users and in addition promotes substantive equality in that everyone enjoys equal treatment to have their health *free from* unjustified *interference* by other regulatory schemes.

that Canadians will not experience wait times for treatment, and that private insurance will not undermine the quality of publicly funded medicare.[123] However, the conclusion was based on the fact that the majority differed in its characterization of the issue and over whether deference was owed to the Quebec legislature and lower courts. McLachlin C.J.C. and Major J. wrote:

> The appellants do not seek an order that the government spend more money on health care, nor do they seek an order that waiting times for treatment under the public health care scheme be reduced. *They only seek a ruling that because delays in the public system place their health and security at risk*, they should be allowed to take out insurance to permit them to access private services.[124]

The existence of unmanageable waiting lists and the material contribution this made to increasing the *risk* of harm to individuals led the majority to find in favour of the appellants that a *Charter* violation had occurred. By doing so, the Court recognized a constitutional right to health as subsumed within the s. 7 negative rights. At first, we might narrowly conclude that the SCC is simply more eager to see a violation of s. 7 if a government plan prevents someone from obtaining a service in the private sector as in *Chaoulli*, rather than when government does not publicly cover a service, as in *Auton*.[125] These divergent claims, however, recognize that the right to health is, at a minimum, a "negative" right. For the reasons outlined, *Chaoulli* is about more than simply the private/public debate regarding provision of services and accountability for their neglect. The dichotomy of rights offered – though subject to significant criticism – is a positive step toward constitutionalizing the *progressive* realization of health rights as permitted by the ICESCR; and effectively protects health from positive intrusion through other state created regulatory regimes.

Roy Ramonov, head of the Commission on the Future of Health Care in Canada, disagrees. He was critical of the judiciary's finding. Commenting on the sanctity of medicare for Canadians and its importance as an integral part of the fabric of our society, our identity and our culture, he writes:

> In my view, there is no better window on the future of our nation than the manner [sic] which we collectively deal with medicare. How we handle the issues arising from the recurrent debates on the provision of health provides us with a glimpse of our future together – or not! ... Will a particular ideology prevail, despite the preponderance of evidence that its tenets are contrary to Canadians' core values? Will *this* decision end the great social experiment known around the world as Canada? [126]

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[123] For a discussion of these, see Flood & Sullivan, *supra* note 19 at 142.

[124] *Chaoulli*, *supra* note 18 at para. 103 [emphasis added].

[125] Thanks to Trudo Lemmens, University of Toronto Faculty of Law, for this comment.

[126] Roy Romanow, "Access to care, access to justice: The legal debate over private health insurance in Canada" *U of T Bulletin* (26 September 2005), online: <http://www.news.utoronto.ca

In fact, *Chaoulli* is a case criticized by many for a number of reasons, including the Court's ability to deal with expert technical evidence.[127] But, more vocally, it is an instance of judicial activism that has led, as Lorraine Weinrib notes, to social outrage – only this time from the political left instead of the political right. The split decision reveals "deep divisions on basic questions of Charter analysis, fact, and remedy."[128] Critics echo the dissent's concern that the health right recognized is impoverished, and fear that once the prohibition is removed in one province, other provinces will follow. Overall, this chain reaction will have a dire impact on Canada's most important social program – public health. But, the negative right to health recognized in *Chaoulli* corresponds with governments' duty of care and helps to explain how health can be rationally subsumed within s.7 *Charter* rights. A "negative right to health" imposes on the government an obligation to not directly harm or materially contribute to the risk of harm to the health of its citizens with regulatory measures adopted contrary to the realization of s. 7 rights. The anticipated impact on the *quality* of the right to health (as measured in terms of equal access for the rich and poor to health services) is the basis of opposition to *Chaoulli* by the political left since the poor may not be able to afford or qualify for insurance. Yet this other dimension to the decision shows how the precedent may come to protect (public) health from external threats of policy preferences that prioritize other regulatory schemes, administrative decisions, and proprietary interests; here the rich and the poor are equal beneficiaries.[129]

Chaoulli endorses the ability to seek privately insured services and so there may be merit in the perceived threats to the public health system. However, the decision may alternatively be seen as the first to mark the nascent origins of a constitutional right to health that will render poor policy, negligent operational measures, and administrative decisions subject to quasi-tortious constitutional liability as wrongs affecting *Charter* rights.[130] In short, *Chaoulli* has not simply led to a "two-tiered" health care system, a "two-tiered constitution" [131], the

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/bin6/thoughts/050926-1665.asp> [emphasis added]. He adds, "Whatever may be the eventual answers to these questions, we are at yet another serious crossroads in both health care and its contribution to nation building, Canadian identity and, not least, health outcomes."

[127] See *e.g.* Colleen M. Flood, Mark Stabile & Sasha Kontic, "Finding Health Policy 'Arbitrary': The Evidence on Waiting, Dying, and Two-Tier Systems" in Flood, Sossin & Roach, *supra* note 23 at 296.

[128] Lorraine E. Weinrib, "SCC's analysis fell short in its Chaoulli ruling" *Law Times* (14 November 2005) at 6, 15.

[129] Equal beneficiaries as subjects of the law that is and not in absolute terms since social stratifications, as Jackman and Sossin have noted, restrict equal access to the courts and the enforcement of the law.

[130] "Quasi-tortious" in the sense that there is a duty of care found and a foreseeability of harm but liability does not require fault and may not necessarily lead the same degree of damages. See Peter H. Russell, "Chaoulli: The Political versus the Legal Life of a Judicial Decision" in Flood, Sossin & Roach, *supra* note 23 at 6; and Bernard M. Dickens, "The Chaoulli Decision: Less than Meets the Eye – or More?" in Flood, Sossin & Roach, *supra* note 23 at 19 for the opinion that the decision is too narrow to stand for much of what it is perceived to establish and therefore is actually "less than meets the eye".

[131] Sossin, "Two-Tier Constitution", *supra* note 119.

"impoverishment of health rights"[132] or the affirmation of "an empty right".[133] Instead, the decision should be applauded for recognizing the indivisibility of human rights and that the civil rights and liberties contained in s. 7 guarantee a right to health consistent with Canada's international obligations and provide a mechanism for accountability for the state's harmful wrongs.[134] From this perspective, we may re-imagine that *Chaoulli* gives rise to possibilities that are in fact health promoting and that transcend traditional limitations of definitional dichotomies of "policy" versus "operational" decisions where the decision adversely imposes on the individual's constitutionally protected rights. As Peter Russell suggests, *Chaoulli* may be the kind of decision that can live a double-life, such that "[w]hat the decision comes to mean in the political life of the country may differ – indeed may differ wildly – from what the judges actually decided."[135]

Having established that the *Charter* applies and that there has been a violation of a *Charter* right, the burden shifts to the government to establish that the limit on the s. 7 guarentee of rights is justifiable under the law which we do next while working through a complaint.

PART 3: USING SECTION 7 RIGHTS TO PROTECT AGAINST PATENT WRONGS

Working through a *Charter* challenge helps conceptualize a challenge to the constitutionality of gene patents. I am a litigant BRCA1 carrier who, due to delay in testing by a state-created single source monopoly provider (as in *Chaoulli*), was unable to have my genetic hereditary screening done in time to have an elective mastectomy or take other preventative measures to avoid spread. As a result, my cancer has metasticized, I have suffered mental and physical harm, and death may be imminent. Where the issues are of public interest, the test from *Minister of Justice of Canada v. Borowski* applies; the issue must be serious, the claimants must be directly affected or have a genuine interest as citizens, and there must be no other effective means available to them.[136] I need not be a BRCA 1 or 2 gene carrier but can simply be an interested member of the public (i.e agents for a provincial or national cancer agency). I must be unable under the CPA to raise the issue of the legality of gene patent policy or the faulty operational measures extending patent law to dissonantly allow for the grant of gene patents. Genetic information and DNA sequences are,

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[132] Jackman, "Last Line of Defence" *supra* note 22.

[133] See Flood & Sullivan, supra note 19 at 142-43.

[134] Stanley H. Hartt, "Arbitrariness, Randomness, and the Principles of Fundamental Justice" in Flood, Sossin & Roach, *supra* note 23 at 505. Hartt writes, "Many see the landmark judgment as a courageous and brilliant blow struck by the judiciary, using the Charter as a sword, not a shield, for the right of human beings to insist that the State no longer be free to deprive them of life, or to cause them pain, suffering and deterioration of their health, by rationing scarce fiscal resources..."

[135] Russell, *supra* note 130 at 5.

[136] [1981] 2 S.C.R. 575. See also *Chaoulli, supra* note 18 at para. 35.

arguably, not patentable if the standards and statutory requirements for patentability are properly applied.[137] As a result, the only means of challenge under patent law is to seek revocation of the patent on a case by case basis through expensive invalidity litigation.[138] But are my health rights justiciable in light of the inconsistent historical treatment of health in *Auton* and *Chaoulli*?

In *Chaoulli*, McLachlin C.J.C. confirmed that, while health care is still not a free standing positive constitutional right "where the government puts in place a scheme to provide health care, that scheme must comply with the *Charter*."[139] This suggests an acceptance of a duty of care within s. 7 *Charter* language whereby a constitutional wrong may be found where the regulatory scheme breaches the *Charter* standards of care.

If we accept the broad interpretation of *Chaoulli* and agree that a negative right to health is subsumed within the language of s. 7, then we are acknowledging that the government owes a duty of care to individuals to ensure that s. 7 rights are not infringed by the patent regulatory scheme. This is easier than establishing a common law duty of care for negligence and, given that the SCC has said that "the mere fact that [a] question may have policy ramifications does not permit us to avoid answering it", constitutional litigation may be the preferred route to redress.

In establishing a public law (constitutional) duty of care, McLachlin C.J.C. finds that "[t]he jurisprudence of this Court holds that delays in obtaining medical treatment which affect patients physically and psychologically trigger the protection of s.7 of the *Charter*."[140] Once a constitutional duty exists, the next question is the

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[137] See Nuffield Council, "The Ethics of Patenting DNA: A Discussion Paper" (20 July 2002), online: <http://www.nuffieldbioethics.org/go/ourwork/patentingdna/publication_310.html>. The paper argues that "patents involving DNA sequences should be the exception rather than the rule. It makes recommendations for future policy in the area, including a number of significant changes to the way that patents are granted involving DNA sequences." See generally, Adam B. Jaffe & Josh Lerner, *Innovation and Its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and What to Do About It* (New Jersey: Princeton University Press, 2004). See also Congressman Xavier Becerra's opening remarks to his proposed Bill to ban gene patents, *supra* note 60.

[138] The costs as noted may be prohibitively high. See Lemley, "Rational Ignorance" *supra* note 57 at 1501-02. Several studies look at the paucity of institutional resources that result in the growing number of "bad patents" – these are patents of poor and questionable quality. See U.S. Federal Trade Commission, "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy", (2003) online: <http://www.ftc.gov/reports/index.htm>. See also William Blumenthal, "Aligning Competition Policy and Patent Policy: A Perspective From the Federal Trade Commission Staff", (30 June 2006) online: <http://www.ftc.gov/speeches/20060630FCBA BackgroundPaper.pdf>. Some authors recommend patent reform to allow for re-examination of the patent to challenge validity, see J.H. Barton, "Intellectual Property Rights: Reforming the Patent System" *Science* 287 (17 March 2000) 1933. For a discussion of the literature, see Bita Amani, "The Promise and Perfidy of Patents: Biotechnology, the Genetic Revolution, and the Invention of "invention"" forthcoming in Ikechi Mgbeoji, ed., *Intellectual Property and Biotechnology in the Age of Globalization: Challenges, Opportunities and Risk* (British Columbia: UBC Press).

[139] *Chaoulli, supra* note 18 at para. 104.

[140] *Ibid.* at para. 118.

basis for imposing liability for s. 24(1) damages or through other relief such as: an injunction on all existing gene patent rights and related licencing, a declaration of their invalidity as a species, or a moratorium on further grants by the CPO to allow for democratic debate and a parliamentary response.

Ken Cooper-Stevenson, in his seminal work *Charter Damage Claims*,[141] advocates that constitutional claims should be informed by the substantive principles of tort law.[142] While this has often been interpreted as requiring some degree of fault (whether negligence or intent), tort law does not require it. Historically, torts against the person captured in the Writs of Trespass were actionable *per se* and required the plaintiff to merely establish their occurrence at which point the onus would shift to the defendant to establish a legal defence or the absence of fault (intention or negligence).[143] I suggest that the protection of rights in s. 7 safeguard the same interest that tort law did against wrongs in the old Writs of Trespass and requires no degree of fault to be established for liability per se. Articulating the same principle, Lorne Sossin states that *Charter* violations should be determined on a no-fault (strict liability) basis for the duties the state owes to protect against wrongs against the rights recognized.[144] While a mere breach of a *Charter* right is enough to find prima facie liability strictly under the *Charter*, the presence of fault (whether intention or negligence) further entrenches the justness of such an outcome and is best determined when interpreting s. 7's internal limitation of rights through "the principles of fundamental justice". According to Lamer J., the principles of fundamental justice "are to be found in the basic tenets of our legal system."[145] Given the normative reliance on moral blameworthiness within the statutory and common law of our legal system in a range of fields – from private law subjects of contracts and torts to public law subjects including criminal law – we can conclude that one of the principles of fundamental justice in our society is accountability for fault.

Chaoulli encourages us to re-examine normative, substantive and procedural questions related to public sector liability for individual human health. Recognizing a positive right to health as part of the protected rights in s. 7 is fraught with

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[141] Ken Cooper-Stevenson, *Charter Damages Claims* (Toronto: Carswell, 1990). Cooper-Stevenson suggests this was the approach taken in *Just, supra* note 46, and other cases determining a public authority private tort duty of care.

[142] *Ibid.* at 18, 55, 83-90. See also Kent Roach, *Constitutional Remedies in Canada,* looseleaf (Aurora, Ont.: Canada Law Book, 1994).

[143] For law professor Kent Roach, negligence has an important role to play under the *Charter* with the familiar standard of objective reasonableness that finds support in the language of s. 1 imposing justified limits to *Charter* rights. Professor Lorne Sossin, on the other hand, rejects the policy/operation distinction quintessential to public sector liability in tort as infusing a *Charter* analysis. See Lorne Sossin, "Crown Prosecutors and Constitutional Torts: The Promise and Politics of Charter Damages" (1993) 19 Queen's L.J. 372.

[144] *Ibid.* at 404.

[145] *Reference re Motor Vehicle Act (British Columbia) S 94(2),* [1985] 2 S.C.R. 486.

definitional and operational difficulties, though not insurmountable, that human rights scholars and their critics often associate with social and economic rights more generally: what is the content and substance of a right to health (or welfare) and what obligations does that confer on the state for their provision? It also raises propriety issues of jurisdiction, judicial activism and restraint in determining economic resource allocation: how much health is the state obliged to provide and at what costs given that public resources are limited? Such questions are amenable to the description of "pure" policy issues within the purview of the legislature. However, if there is a constitutionally protected negative right to health, as *Chaoulli* articulates, then governments may be liable for express or even surreptitious intrusions on this right through legislation or other (administrative) state measures. Instead of requiring active state intervention, *Chaoulli* implicitly posits that the *constitutional* right to health only requires state forbearance. Governments may be complicit in failing to regulate non-interference with health or, worse, in positively sanctioning interference by legally elevating the rights of third party patentees over cancer patients. In so doing, health, an otherwise public good, is privatized and health policy is made subject to regulatory preferences for trade and industrial policy. The *Chaoulli* negative right to health is consistent with the existing negative *Charter* freedoms (such as life, liberty and security of the person); overcomes jurisdictional and definitional limitations; and is one progressive step closer to the full realization of health rights.

Whether the preference given to industrial policy demands deference is "based on two guiding principles of justification: the measure must be consistent with democratic values and it must be necessary in order to maintain public order and the general well-being of citizens."[146] Situations demanding deference are those:

> in which government is required to mediate competing interests and to choose between a number of legislative priorities... In short, a court must show deference where the evidence establishes that the government has assigned proper weight to each of the competing interests.[147]

The granting of gene patents has garnered much debate and public skepticism regarding the operation of the CPO and the interpretation of patent legislation. Failure to address this issue in recent amendments to the *Patent Act*[148] is an abdication of governmental responsibility and ignores the recommendations made for a legislative response by the Canadian Biotech Advisory Committee and the SCC.[149] The policy to grant such patents was *ad hoc* and bottom-up; derived from

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[146] *Chaoulli, supra* note 18 at para. 93.

[147] *Ibid.* at para. 94.

[148] *Patent Act, supra* note 14.

[149] See the *Jean Chrétien Pledge to Africa, Canada* Bill C-9, *An Act to amend the Patent Act and the Food and Drugs Act,* 3d Sess., 37th Parl., 2004, online: <http://www.parl.gc.ca/PDF/37/3/parlbus/chambus/house/bills/government/C-9_2.PDF>. In *Harvard College v. Canada (Commissioner of Patents)*, [2002] 4 S.C.R. 45 [*Harvard*, (SCC)], the Court accepted the Canadian Advisory Committee's final recommendation that the legislature act on this issue rather than the

Patent Office Practice rather than any real consideration or "weighing" of the competing interests involved. Clearly, no deference is owed to this measure. Deschamps J. found that:

> while the government has the power to decide what measures to adopt, it cannot choose to do nothing in the face of the violation of...[the] right to security. The government has not given reasons for its failure to act. Inertia cannot be used as an argument to justify deference.[150]

In addition, it is not clear whether there is a significant difference between state granted monopoly (to the state) in health coupled with wait lists and state granted monopoly (to a private proprietor) in patents coupled with wait lists and/or other analogous harmful conditions like exorbitant royalties and licencing fees.[151] Both are state created and materially increase the risk of harm for individual health. Patents contribute to delays and wait times in testing by giving the patent holder full control over the use and access to the invention. The BRCA1 and 2 patents, for example, created "scarcity" by imposing an artificial monopoly for the patentee – Myriad – whose exclusive rights empowered it to demand that *all* testing proceed through them or a licenced lab. This raised complicated issues of sovereignty. France complained, legitimately arguing that the requirement basically forces genetic samples to be sent out of country to Myriad labs in the United States over which there was no French regulatory oversight or control. In addition, researchers complained that they could not test or develop alternative improved methods for testing, undermining one of the main rationales for granting patents in the first place and making it difficult to scientifically validate the test. The B.C. Cancer Agency performed some 600 tests but Myriad's cease and desist letters effectively forced the B.C. government to discontinue its testing, favouring the rights of the patentee over individual rights to health. In response, over the next 2 years, the B.C. Cancer Agency referred 150 female cancer patients to Ontario's research study and were transferred there for testing free of charge (although Ontario's study was allegedly in continued patent violation). Approximately 30 additional women elected to have the testing done by Myriad Genetic Laboratories directly.[152] It may be argued that it is not the grant of a patent that is unconstitutional by violating s. 7 rights, but how

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courts. Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee*, (June 2002) online: <http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/ah00188e.html>.

[150] *Chaoulli, supra* note 18 at para. 97.

[151] Although B.C. resumed testing of cancer patients for the BRCA1 and 2 genes in 2003, the B.C. Cancer Agency reports that there is now a one year waiting list for counseling with 300 families waiting for testing. "Genetic Testing Resumes at B.C. Cancer Agency", (14 February 2003), online: <http://www.bccancer.bc.ca/ABCCA/NewsCentre/NewsArchive/2003/GeneticTestingResumesAtBCCancerAgency.htm>. See 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" (31 January 2005) online: <http://www.curie.fr /upload/presse/myriadpatents310105.pdf>. In November 2004, Myriad Diagnostics sold its BRCA patents to the University of Utah Research Foundation but continues to hold exclusive licences.

[152] *Ibid.*

that patent is exercised which is a private matter not attracting *Charter* application. However, how a patent holder exercises his monopoly is only secondary to the question of whether that monopoly right was *wrongly* conferred by a public authority acting outside of the statutory authority given, which is the basis of this constitutional challenge; successfully contesting gene patent harms will be easier within a constitutional "tort" framework than in the private law of torts.

Familiar principles of duty of care from tort law can reconcile divergent treatments of the right to health under the *Charter*. The majority in *Chaoulli* does not undertake a tort analysis for establishing a duty of care pursuant to the test articulated by the same court in *Cooper*. Nevertheless, implicit in the majority's finding of a public law duty of care within s. 7 rights are identifiable analogies to tort law where a private duty was found to be owed by a person who has undertaken a rescue, assumed care and control or has otherwise undertaken a duty of care (indicating a special relationship and proximity) as our government has to deliver health services publicly. In recognizing a s. 7 duty of care, the majority found that the government, having chosen to act, cannot do so *negligently* if the act adversely affects the life, liberty and security of the person – to do so is unconstitutional. Failure to provide timely health services in a public monopoly by managing waiting lists appropriately is exactly such a misfeasance; even if the "wrong", as in this case, is characterized by the majority as a "right" under s. 7. The law of tort is the law of *involuntary obligations* where "[r]ights and duties are the quintessential elements of the law..."[153] An offence against the public, such as long waiting times, is a public wrong but once consequences ensue for the individual, it becomes a private wrong actionable publicly. "All are wrongs," according to Fridman "in the sense that they involve behaviour that is not justified by the law, though they can occur without fault, i.e. either the intent to do wrong or negligence, on the part of the alleged wrongdoer."[154]

For the dissent in *Chaoulli*, the delays in the public system are a necessary and acceptable function of rationing high-quality care at a reasonable cost for as many people as possible. Gaining access to private insurance would undermine the interest of the less wealthy and uninsurable. Furthermore, the dissent was very concerned with how substantive content would be given to this new right: how long is *constitutionally too long* to be wait-listed for a medical service?

> What, then, are constitutionally required "reasonable health services"? What is treatment "within a reasonable time"? What are the benchmarks? How short a waiting list is short enough? How many MRIs does the Constitution require? The majority does not tell us. The majority lays down no manageable constitutional standard. The public cannot know, nor can judges or governments know, how much health care is

[153] G.H.L Fridman, *The Law of Torts in Canada*, 2d ed. (Toronto: Carswell, 2002) at 10.

[154] *Ibid.* at 14.

> "reasonable" enough to satisfy s. 7 of the *Canadian Charter of Rights and Freedoms*..."[155]

Binnie and LeBel JJ.'s dissent criticizes the majority's decision for their failure to provide direction for future adjudication on waiting periods and for assuming an adjudicative role for a policy matter outside of the Courts' jurisdiction. However, their criticism just as easily applies to judges in a court of law dealing with such nebulous concepts as the "reasonable person", "reasonably foreseeable risk", the "person of ordinary skill in the art" or difficult to determine elements of "causation". The divergent perspectives of the majority and dissent stem from two fundamentally different questions that each strives to answer – reconcilable through the familiar lens of tort law and in particular, negligence principles. While the dissent is influenced by the traditional doctrine which posits no duty of care owed for policy decisions, the majority examines whether the government owes a duty of care arising from s. 7 rights to protect the individual's health from unjustifiable intrusion whether or not the contested measure is a policy decision. The majority finds that "where a law adversely affects life, liberty or security of the person, it must conform to the principles of fundamental justice." Whether the intrusion meets the principles of "fundamental justice" is a matter raising the *standard of care* owed and, as with regular tort law, the standard of care is a question of law to be determined by the judge.

As in *Chaoulli*, the principle of fundamental justice here would be that laws that affect life, liberty and security of the person shall not be arbitrary. By analogy, the current state of the law in relation to gene patents and patenting life generally do appear to be arbitrary as the law in this area "bears no relation to, or is inconsistent with, the objective that lies behind [it]."[156] This, in turn, requires "consideration of the state interest and societal concerns that the provision is meant to reflect."[157] Moreover, "[i]n order not to be arbitrary, the limit on life, liberty and security requires not only a theoretical connection between the limit and the legislative goal, but a real connection on the facts"[158] the onus of which rests on the claimant. The court also finds precedents for the proposition that limits that are *unnecessary* to assure that those objectives are met may also be arbitrary.[159]

To determine the issue of arbitrariness, we must first determine the objective that underlies patent legislation and then proceed to assess whether the interference with the s. 7 rights of the person is impermissibly arbitrary in that it lacks a real connection to the purpose the interference is said to serve.

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[155] *Chaoulli*, *supra* note 18 at para. 163.

[156] *Ibid.* at para. 130, the hallmarks of "arbitrary" are set out.

[157] *Ibid.* at paras. 130-31.

[158] *Ibid.* at paras. 130-33.

[159] See discussion of *R. v. Morgentaler*, [1988] 1 S.C.R. 30 in *Chaoulli*, *ibid.* at para. 118-22.

The speed of biotechnological innovation has demanded that patent law quickly adapt but the adaptation has been *ad hoc*. By implication, the necessary public discourse for a thoughtful long term response to the challenges posed by, and to, biotech research and the incremental expansion of property rights to life has been compromised if not overlooked. The Canadian Federal Court of Appeal (FCA)[160] has identified two main reasons for granting a patent. First, patents are necessary to encourage innovation.[161] As economists point out, ideas, knowledge and information are not naturally scarce – that is, they can be shared infinitely without being diminished or depriving the original right holder.[162] Because knowledge is non-rivalrous and non-excludable,[163] property rights are required to protect against market failure and the *free rider* problem:

> Without patent protection, as soon as a product implementing a new idea is marketed, others could copy it and compete with the original inventor without having to have made the initial research and development investment. Competitors who did not have to cover such costs could drive prices down to such a level that the original inventor could not recoup the research and development investments made, let alone a return on that investment, thereby discouraging the creation of inventions.[164]

In the absence of patent rights granting exclusivity, a company, having invested significantly in innovation, would be disadvantaged by the free rider who comes along after the costs have already been borne to reap the commercial benefits of that which he has not sown.[165] The result would be a net welfare loss due to the disincentives to innovate. But, as Wendy Gordon aptly qualifies:

> [t]he issue of limits is vital... The law of intellectual property must be narrower than an entitlement to 'receive payment for all the benefits you generate'. After all, if we tried to give incentives to authors and inventors by eliminating all free riding, society would grind to a stop. Education, progress and community all depend on our sometimes being able to 'reap

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[160] *President and Fellows of Harvard College v. Canada (Comissioner of Patents)*, [2000] 4 F.C. 528 [*Harvard* (FCA)].

[161] *Ibid.* at para. 105. The majority of the court found that the purpose of a patent is "to permit the recovery of research and development investment necessary to produce the invention and a return on that investment to the inventor, commensurate with the value purchasers place on the invention."

[162] W.R. Cornish, Dr. M Llewelyn & Dr. M. Adcock, *Intellectual Property Rights (IPRs) and Genetics: A Study into the Impact and Management of Intellectual Property Rights within the Healthcare Sector*, (Cambridge: Public Health Genetic Unit, July 2003).

[163] IP is different from tangible property in that knowledge is non-rivalrous which means that it does not lose its utility as it is used and reused but remains intact and therefore can be imitated and transmitted at close to zero costs. Knowledge is also non-excludable which means that it can be consumed or possessed by more than one individual without depriving the right holder of any use. There are widespread public benefits from the sharing of knowledge but the costs are borne privately and so, the argument made is, government regulation is needed in this area due to market failure.

[164] *Harvard* (FCA), *supra* note 160 at para. 25.

[165] Vaver, *Intellectual Property Law*, *supra* note 27.

> without sowing', just as being members of a community requires us to tolerate some uncompensated mistakes and harms.[166]

In addition, the conceptual basis on which innovation is privatized under patent legislation perverts the nature of scientific discovery, particularly as it evolved in the field of genomics. In a seminal work by Thomas S. Kuhn, "The Structure of Scientific Revolutions,"[167] the author provides insight on what drives science; historically it has *not* been letters patent:

> To scientists, at least, the results gained in normal research are significant because they add to the scope and precision with which the paradigm can
>
> be applied.[168] That answer, however, cannot account for the enthusiasm and devotion that scientists display for the problems of normal research... Bringing a normal research problem to a conclusion is achieving the anticipated in a new way, and it requires the solution of all sorts of complex instrumental, conceptual, and mathematical puzzles. The man who succeeds proves himself an expert puzzle-solver, and the challenge of the puzzle is an important part of what usually drives him on.[169]

It was this truth-seeking, puzzle-solving, drive that led to the discovery of the double helix structure of DNA by James Watson and Francis Crick in 1953; DNA is "the fundamental hereditary material of all living organisms,"[170] comprised of amino acids arranged in sequences that code for genes, the basic functional and physical units of heredity that contain coded information necessary for understanding the functions of proteins (the study of proteomics). Genes affect everything from human intelligence and physical appearance to the propensity to develop specific diseases, differentially metabolize drugs, or respond to environmental or social changes such as diet and exercise. Genetic mapping was largely the result of an international public collaborative consortioum known as the Human Genome Project (HGP) even though its ultimate conclusion was expedited by resourceful abdicators in a rival

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[166] Wendy Gordon, *Intellectual Property Theory Intensive Course Reader 2000*, (University of Toronto, Fall 2000) at 7.

[167] Thomas S. Kuhn, "The Structure of Scientific Revolutions" in *International Encyclopedia of Unified Science*, vol. 2:2 (London: The University of Chicago Press Ltd., 1962).

[168] *Ibid.* at 38 where Kuhn adds:

> A man may be attracted to science for all sorts of reasons. Among them are the desire to be useful, the excitement of exploring new territory, the hope of finding order, and the drive to test established knowledge... What then challenges him is the conviction that, if only he is skilful enough, he will succeed in solving a puzzle that no one before has solved or solved so well... On most occasions any particular field of specialization offers nothing else to do, a fact that makes it no less fascinating to the proper sort of addict.

[169] *Ibid.* at 36.

[170] William K. Purves *et al.*, *Life: the Science of Biology*, 5th ed., vol. 1 (USA: Sinauer Associates Inc., 1998) at Glossary.

race.[171] Preventative medicine extends beyond genetic screening for specific disease related genes (like BRCA1 and preventative procedures such as elective mastectomies) to the potential uses of stem cell and gene therapy which can be controlled by those who hold patents on genes. Human embryonic stem (hES) cell research is attracting significant public funding because of its potential value. The National Institute for Health (NIH) spent $29 million in 2003 on such research, while California has committed to spending $300 million a year for the next ten years just in California. Despite the dedication of public funds to stem cell research, the patent over hES belongs to the University of Wisconsin's Alumni Research Foundation (WARF) and any California company or University wanting to take advantage of the California bond will have to first secure a licence from WARF. [172]

Furthermore, in the field of science, simultaneous independent invention is not uncommon due to the paradigmatic structure of the process to which Kuhn refers, such that rewarding one inventor over another may itself be arbitrary:

> To see how closely factual and theoretical novelty are intertwined in scientific discovery examine a particularly famous example, the discovery of oxygen. At least three different men have a legitimate claim to it, and several other chemists must, in the early 1770's, have had enriched air in a laboratory vessel without knowing it... [173] This pattern of discovery raises a question that can be asked about every novel phenomenon that has ever entered the consciousness of scientists. Was it Priestley or Lavoisier, if either, who first discovered oxygen? In any case, when was oxygen discovered? In that form the question could be asked even if only one claimant had existed. As a ruling about priority and date, an answer does not at all concern us. Nevertheless, an attempt to produce one will illuminate the nature of discovery, because there is no answer of the kind that is sought. Discovery is not the sort of process about which the question is appropriately asked. The fact that it is asked- the priority for oxygen has repeatedly been contested since the 1780's- is a symptom of something askew in the image of science that gives discovery so fundamental a role... Clearly we need a new vocabulary and concepts for analyzing events like the discovery of oxygen. Though undoubtedly correct, the sentence, 'Oxygen was discovered,' misleads by suggesting that discovering something is a single simple act assimilable to our usual (and also questionable) concept of seeing. That is why we so readily assume that discovering, like seeing or touching, should be unequivocally attributable to an individual and to a moment in time. But the latter attribution is always impossible, and the former often is as well.[174]

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[171] See Kevin Davies, *Cracking the Genome: Inside the Race to Unlock Human DNA* (New York: The Free Press, 2001).

[172] See Carl Gulbrandsen, "Stem-cell patent holder's view of the California challenge" (16 November 2004), online: <http://wistechnology.com/article.php?id=1352>.

[173] Kuhn, *supra* note 167 at 53. Footnote in the original refers to the classic discussion of oxygen's discovery, Andrew Norman Meldrum, *The Eighteenth-Century Revolution in Science—The First Phase* (Calcutta: Longmans, Green and Co.,1930) c. v.

[174] *Ibid.* Kuhn at 54-55.

There is tremendous inequity in granting any one individual (or entity) a right over a gene, ignoring the enormous public funds and co-operative international efforts expended in the mapping of the human genome.[175] Canada has a first to file requirement[176] for recognizing an inventor while the U.S. has a first to invent system; both systems create a "winner-take all effect"[177] and ignore the incremental and cumulative nature of science. Vaver articulates the paradox created by the rules of the patent system in light of our understanding of scientific knowledge and progress as a continuum:

> The decision on who gets the monopoly right where two or more persons invent something independently, without knowing of the other's work, is often more a matter of luck than anything else: the history of science and invention suggests that the phenomenon of simultaneous discovery is the rule, not the exception. The sower who first turns up at a patent office will reap; the other sower will rue.[178]

Juxtaposing the nature of scientific development with the legal atomistic view of the patent system is meant to comment obliquely on two points. First, the failings of our current regime warn against the administrative extension of patents on an *ad hoc* basis without democratic debate and Parliamentary overview to new subject matter; in particular where *Charter* rights are affected. Having a flawed regulatory system for an invented mouse trap is significantly different than having a flawed regulatory system for genes. The discovery of genes was not in need of an "incentive" since it was already significantly undertaken publicly and privately motivated by the potential for downstream applications. Instead of acting as *ex ante* incentives, patenting genes inefficiently creates *ex post* rewards while contributing to the violation of the state's duty to promote the human right to the *highest attainable standard of health*. The "mapping" of the human genome suggests by name a mere process of "discovery" rather than "invention" per se.[179]

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[175] For a discussion of the threat to the scientific commons, see Richard R. Nelson, "The Market Economy, and the Scientific Commons", (Paper presented at the International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime Conference, Dule Law School, April 2003), webcast online: <http://www.law.duke.edu/trips/webcast.html>.

[176] See *Patent Act*, *supra* note 14, s. 28.1.

[177] Edward Geller proposes an interim patent system as a means of addressing the "winner-take-all effect" of current national patent system. See Paul Edward Geller, "An International Patent Utopia?" (2003) 85 J. Pat. & Trademark Off. Soc'y 582. He suggests that the interim patent system use the Internet as the basis of posting new inventions. This would overlay national first-to-file and first-to-invent systems with an international first-to-post system. Additionally, he suggests that a globally distributed database with searchable connection to prior patent files laid open by the public and global novelty determination capacity of the new technology would also help remedy resulting inequities.

[178] Vaver, *Intellectual Property Law*, *supra* note 27 at 7 [footnotes omitted]. This same criticism can, of course, extend to prizes as well. In this manner, the contributions of Rosalind Franklin to the double helix structure of Watson and Crick were only later acknowledged.

[179] For a critical examination of law as a form of cultural appropriation, see Rosemeary Coombe, "Authorial Cartographies: Mapping Proprietary Borders in a Less-than-Brave New World" (1996) 48 Stan. L. Rev. 1357 at 1360:

Second, we should be wary of racing to provide more, stronger, and increasingly restrictive protection paradigmatically incongruent and cognitively dissonant with the scientific process. Richard Nelson expresses grave concern over the eroding scientific commons. He believes that keeping scientific findings in the public domain, tying the reward of the scientist to the acclaim of fellows, and providing public funding for research based on peer review of the scientific promise of both the proposal and the scientist are all important parts of an incentive and control system for fostering productive science.[180] Some evidence suggests that the incentive rationale the FCA offered is empirically unsupported:

> In both the United States and Europe, firms rate superior sales and service, lead time, and secrecy as far more important than patents in securing the returns to innovation. Patents are usually reported to be important primarily for blocking and defensive purposes.[181]

In light of the evidence, the incentive to invent theory for granting patents remains suspect. The only discernable relationship is that legal recognition of patentability of a subject matter, in this case life, corresponds with an increase in *patents* for that subject matter.

The second reason the FCA identifies for providing patent protection is to encourage public disclosure of new technology and the facilitation of its transfer. The theory is that without such legal protection knowledge embodied in new inventions would likely be kept a trade secret.[182] Again, there is no rational

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> The very tropes of discovery, invention, naming, and originality that animate modern intellectual property laws emerge from a historical era in which Europeans mapped the world in their own image – ignoring the human ecologies of others and denying any value to the pre-existing worlds of meaning in which such phenomena figured ontologically and spiritually... We can see the same processes at work in contemporary political debates – in the so-called 'New World Order' – as authorial tropes are deployed to legitimate new forms of social domination. Emergent elites naturalize their claims to represent the global 'we' – protecting 'our' biodiversity and preserving 'our' gene pool – while attaching their own signatures to the mappings they effect.

[180] See Nelson, *supra* note 175 at 2, 22-36.

[181] Bronywn H. Hall, "Business Method Patents, Innovation, and Policy" NBER Working Paper Series, working paper #9717 at 9, online: <http://www.nber.org/papers/w9717>. See also David Vaver, "Some Agnostic Observations on Intellectual Property" (1991) 6 I.P.J., at 125-53.

[182] Citing dictum from the Supreme Court of Canada's decision in *Cadbury-Schweppes Inc. v. FBI Foods Ltd.*, [1999] 1 S.C.R. 142 at para. 46: "[A]t least one of the policy objectives underlying the statutory remedies available to a patent owner is to make disclosure more attractive, and thus hasten the availability of useful knowledge in the public sphere in the public interest." This theoretical justification for a patent system is consistent with empirical findings presented in a dissertation written at the University of California at Berkeley using 19th century invention data from World's Fairs and Expositions. See Petra Moser, "How do Patent Laws Influence Innovation? Evidence from Nineteenth Century World Fairs" (2005) 95 Am.Econ.Rev. 1214, cited in Hall, *supra* note 181 at 8. Moser found that inventors in countries without a patent system do not innovate more than inventors in countries with a patent system but they do tend to innovate in areas that are more amenable to protection through trade secrecy.

connection between this rationale and the grant of gene patents. The international consortium of scientists involved in the various mapping projects, from the HGP to its successor the HAPMAP project (aimed at mapping genes clustered into haplotype communities) all publish their findings immediately as a means of disclosure and pre-emption of private proprietary claims (which are thereby defeated by the prior disclosure on the basis of novelty). According to Richard Gold, an eminent scholar in law, genetics, and ethics, we may conclude that the patent regime's current level of incentive for inducing sufficient biomedical research is questionable:

> The argument for greater patent protection should be understood for what it is: an attempt to maximize profit, not to maximize levels of innovation. Clearly, a company would prefer to have as large a monopoly as possible...But patent law is not about individual profit maximization; it is about maximizing the overall level of innovation in society. The two do not necessarily go together.[183]

In a recent article, Dr. Linda Wasserman, director of the molecular genetics lab in the department of medicine at the University of California in San Diego and director of clinical cancer genetics at the UCSD Cancer Center, commented on the harm:

> [G]ene patenting complicates testing...Every new gene getting patented means that whatever lab has the patent is the only one that can afford to do gene testing. It has a negative effect on developing quicker, more efficient ways to do a genetic test and it raises costs. The question is, should anyone have sole possession of a genetic test?[184]

Current patent law granting genes patents is arbitrary in that it neither is consistent nor necessary for the objectives of the Patent Act. Normatively, the rational measure of protection may need to be differentiated in relation to the degrees of protection necessary for creating incentives inter and intra industry, specific to our social and economic context. But, with limited exception, that is not permissible under *TRIPS*. Still, a rational national policy for IPRs would be one that provides neither over-compensation nor under-compensation, but a degree of protection that would ensure that the marginal benefits equal the marginal costs of such protection. The CPO's application of the statutory standards for patentability with greater care and stringency is a TRIPS-compliant means of achieving improved industrial policy. With gene patents, the so-called "inventors" are currently overcompensated because of lax application of patent standards. The SCC has recognized the importance of a careful balance in intellectual property policy:

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[183] E.Richard Gold, "Biomedical Patents and Ethics: A Canadian Solution" (2000) 45 McGill L.J. 413 at 423.

[184] Steve Benowitz, "French Challenge to BRCA1 Patent Underlies European Discontent" (2002) 94:2 Journal of the National Cancer Institute 80, online: <http://jncicancerspectrum.oxfordjournals.org /cgi/content/full/jnci;94/2/80>.

> The proper balance among these and other public policy objectives lies not only in recognizing the creator's rights but in giving due weight to their limited nature. In crassly economic terms it would be as inefficient to overcompensate artists and authors for the right of reproduction as it would be self-defeating to undercompensate them...Excessive control by holders of copyrights and other forms of intellectual property may unduly
>
> limit the ability of the public domain to incorporate and embellish creative innovation in the long-term interests of society as a whole, or create practical obstacles to proper utilization.[185]

An efficient IP policy striving for equilibrium will necessarily relate to the context and defining circumstances of a nation and "clearly involves a value judgment, a weighing of costs and benefits, striking a balance, and recognizing that the matter is one on which minds even within the same state – let alone among states – may reasonably differ."[186]

Chaoulli recognizes a negative right to health that is only engaged or activated as part of s. 7 freedoms where the government *creates* the situation of increased risk. In other words, the obligation to protect health in *Chaoulli* arises only if there is an increased risk of harm that is either state sanctioned or state created. Just as the Court was satisfied that a monopoly in health coupled with wait times would suffice, so too should a monopoly in medically related discoveries. S. 7 rights are distributive while the requirements of fundamental justice are substantive. The appropriate test case is not one in which the government would be sued for failure to provide the BRCA1 genetic test due to limited resources just as the failure to provide timely testing was not the basis of the constitutional challenge in *Chaoulli*. Such a suit would require the court to recognize a positive right to health and one that is set at a particular level. Rather, public authority liability under the *Charter* applies to a regulatory scheme that is operating negligently and is thereby an unjustifiable state intrusion on the right to health as subsumed in s. 7, regardless of whether the regime is the *public monopoly* legislated with exclusive rights to health delivery (with a ban on private providers) or the *private monopoly* created under the patent scheme with exclusive rights of use, manufacture, and control of genetic information, integral for

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[185] *Theberge v. Galerie d'Art du Petit Champlain*, [2002] 2 S.C.R. 336 at para. 6, Binnie recognizes the "globalization of the so-called 'cultural industries'" and the desirability "within the limits permitted by our own legislation, to harmonize our interpretation of copyright protection with other like-minded jurisdictions" but the harmonization and restrictions should be by *legislation*, not expansive administrative (and judicial) interpretion [*Theberge*]. See Amani & Coombe, *supra* note 51, regarding legislative inertia and judicial activism with respect to patenting life. The need for a balance IP framework was also discussed in *Harvard* (SCC), *supra* note 149 at para. 25, to support the conclusion that patent rights should be extended to a genetically modified oncomouse by Binnie J. in his dissent: "[i]t is necessary to feed the goose if it is to continue to lay the golden eggs. The *Patent Act* embodies the public policy that those who directly benefit from an invention should be asked, through the patent system, to pay for it, at least in part." He warns at para. 113 that the majority's conclusion "simply substitutes the Court's notion of good public policy for the judgment of Parliament, whose members are well aware of these and similar proposals."

[186] David Vaver, "Need Intellectual Property Be Everywhere? Against Ubiquity and Uniformity" (2002) 25 Dal. L.J. 1 at 4.

the future of preventative and therapeutic medicine (including neo-natal genetic screening programs and gene therapies). Having established that the measure in question is arbitrary, as a complainant I would next turn to s. 1 of the *Charter* to see if the state is able to prove that the derogation of my s. 7 rights are "reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society."[187]

Under the s. 1 analysis, the the reasonable limit on the *Charter* right must be "prescribed by law". According to constitutional expert Peter Hogg, "[t]he words 'prescribed by law' make clear that an act that is not legally authorized can never be justified under s. 1, no matter how reasonable or demonstrably justified it may appear to be."[188]

Significant discretion is granted to the CPO by the CPA to interpret and apply the requirements of patentability but as the SCC points out, "such discretion must be exercised in accordance with the *Charter*."[189] Hogg writes that "a law that confers a discretion on a board or official to act in derogation of a *Charter* right will satisfy the prescribed-by-law requirement if the disretion is constrained by legal standards."[190] The CPO is given clear legal statutory standards for patentability but if the CPO, in granting gene patents, interprets patent legislation in such a way that it is acting outside of its statutory authority then the actions of the CPO will not be "prescribed by law" for reasons set out by Hogg:

> Action taken under statutory authority is valid only if it is within the scope of that authority. Since neither Parliament nor a Legislature can itself pass a law in breach of the Charter, neither body can authorize action which would be in breach of the Charter. Thus, the limitations on statutory authority which are imposed by the Charter will flow down the chain of statutory authority and apply to regulations, by-laws, orders, decisions and all other action (whether legislative, administrative or judicial) which depends for its validity on statutory authority.[191]

It will be up to the presiding judges to determine this aspect of the s. 1 Charter justification analysis. I will proceed through the remaining burden the Crown must discharge in order to justify the infringement of s. 7 rights.

It has long been established that the contested measure must be assessed for constitutionality under s. 1 in accordance with the *Oakes* test.[192] Just as with

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[187] *Charter, supra* note 16.

[188] Hogg, *Consitutional Law of Canada*, 3rd ed., *supra* note 35 at 861.

[189] *Little Sisters, supra* note 33 at para. 133.

[190] Hogg, *Consitutional Law of Canada*, 3rd ed., *supra* note 35 at 863.

[191] Hogg, *Constitutional Law of Canada*, looseleaf, *supra* note 33 at 34-11; also cited in *Little Sisters, supra* note 33 at para 133.

[192] *R. v. Oakes*, [1986] 1 SCR 103.

Chaoulli and the desire to protect a public health system, no one questions the need to preserve a sound patent system as one which, theoretically and conceptually, exists to *promote* the innovation of health improving technologies with a short term trade-off of a limited monopoly to the inventor for commerciability. The government undeniably has an interest in protecting this system if we accept the fact the the twenty year patent period is a *fair trade-off* to create long term gains for the benefit of public and individual health. Thus, the objective of the patent system is pressing and substantial. However, it is not clear whether that objective translates in the same way to the granting of *gene* patents.

The next branch of the *Oakes* test is the proportionality requirement. Here we consider whether the granting of patents has a rational connection with the objectives of spurring innovation and its early disclosure as required for an effective patent system; and whether there is minimal impairment of constitutional rights. Is the granting of gene patents justified by the need for a patent system?[193] Unlike *Chaoulli*, a complainant does not have an internal safeguard that serves as an alternative – they cannot simply go outside of the province or country to receive services through an alternative provider since the patent grants a monopoly of exclusive rights to a single entity and these rights confer full control, often in multiple jurisdictions. In fact, an emerging service model of business operation is increasingly being used whereby instead of granting a licence over their patented invention, the patentee requires tissue samples and provides *all* of the genetic testing. This model is followed by Myriad Genetic Laboratories for their BRCA1 and 2 gene patents. Not only are there no alternative providers due to the patent monopoly, there may be limited regulatory or quality control mechanisms for the tests processed exclusively through Myriad because of its location outside of Canada. If the testing is performed through MDS Labs, Myriad's agent in Canada, it requires a sample which, from a research perspective, may create future impediments for researchers thwarting the very purpose of the CPA. The Europeans, for example, were not very accepting of the loss of sovereignty over BRCA testing in part because of the costs to have the test, the added cost of international shipment and delivery, the delays of having a single source assessor, and other impediments created for further cancer research. Had the efforts of Watson and Crick and the double helical structure of the DNA molecule been patented as genes are today, the HGP, a conglomerate of co-ordinated mapping efforts by international scientists and research into their coding for proteins (proteomics) would have been significantly slowed and encumbered. In fact, in 2006, a new project, the Genetic Association Information Network (GAIN) was launched as the latest collaboration. GAIN is based on a private-public partnership between the Foundation for the National Institutes for Health (FNIH), the National Institutes of Health (NIH), and Pfizer Global Research & Development. Its goal is "to unravel the genetic causes of common diseases over the next three years...The information derived from GAIN will be *publicly available* to researchers

[193] *Chaoulli, supra* note 18 at para. 14, refers to the preservation of a "sound public health system".

world-wide."[194] GAIN signals overdue recognition that genetic data is a public good that it should be *pre-competitive* and not subject to intellectual property claims.

Michael Heller and Rebecca Eisenberg brought concern over the growing transaction costs of doing research due to private enclosure into the fray. In a compelling and often cited 1998 article,[195] the authors observe a developing trend antithetical to the patents for the promotion of innovation rationale. The authors argue that patenting basic research such as the human genome imposes the need to bundle multiple licences, raises barriers to entry, and increases transaction costs, which all have long term deleterious effects on innovation and its dissemination:

> Under the commons model, the federal government sponsored premarket or "upstream" research and encouraged broad dissemination of results in the public domain. Unpatented biomedical discoveries were freely incorporated in "downstream" products for diagnosing and treating disease. In 1980, in an effort to promote commercial development of new technologies, Congress began encouraging universities and other institutions to patent discoveries arising from federally supported research and development and transfer their technology to the private sector...A resource is prone to underuse in a "tragedy of the anticommons" when multiple owners each have the right to exclude others from a scarce resource and no one has an effective privilege of use...Privatization can go astray when too many owners hold rights in pervious discoveries that constitute obstacles for future research...The result has been a spiral of overlapping patent claims in the hands of different owners, reaching ever further upstream in the course of biomedical research. [196]

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[194] National Human Genome Institute, News Release, "Novel Public-Private Partnership Created to Unravel the Genetics Of Common Disease Through Whole Genome Association Studies" (8 February 2006) online: <http://www.genome.gov/17516722>.

[195] Michael A. Heller & Rebecca S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research" *Science* 280:1364 (1 May 1998) 698, online: <http://www.sciencemag.org/cgi/reprint/280/5364/698.pdf>.

[196] *Ibid.* at 698. The tragedy of the anti-commons is where people underuse scarce resources because too many owners can block each other. "Privatization must be more carefully deployed if it is to serve the public goals of biomedical research. Policy-makers should seek to ensure coherent boundaries of upstream patents and minimize restritive licensing practies that interfere with downstream product development. Otherwise, more upstream rights may lead paradoxically to fewer useful products for improving human health." at 701. See also Hope Shand, "Gene Giants: Understanding the 'Life Industry'" in Brian Tokar, ed., *Redesigning Life? The Worldwide Challenge to Genetic Engineering* (Canada: McGill-Queen's University Press, 2001) at 226, commenting on patents as bars to entry for smaller less resourceful firms:

> The power of exclusive monopoly patents is giving these companies the legal right to determine who gets access to proprietary science and at what price. Participation in industry isn't possible unless a company holds patents or has the money to license them... Pioneer Hi-Bred, the world's largest seed company (now a wholly owned subsidiary of DuPont), claims that one of its new, genetically engineered, insect-resistant corn hybrids requires access to thirty-eight different patents controlled by sixteen separate patent holders... [S]maller enterprises will find it increasingly difficult to compete.

The excessive fragmentation of patent rights in the technological base for commercially oriented innovation may deter not only private competitors from investing in follow-up innovation, as Heller and Eisenberg suggest, but may produce greater and disproportionate transaction costs on the very institutions – universities – whose mandate hitherto has been to do property-less research. In such an environment, universities may find it too prohibitive to pursue large scale research endeavors and may have to redirect their focus to become teaching schools (sources for dissemination) of private labs under licence. These factors all reaffirm the arbitrariness of the measure. McLachlin C.J.C. and Major J. query "whether an arbitrary provision, which by reason of its arbitrariness cannot further its stated objective, will ever meet the rational connection test under *R v. Oakes*."[197] The absence of evidence that the granting of gene patents furthers the patent system's objectives, its inconsistencies with legislative objectives, and the fact that it is not *necessary* for the preservation or integrity of the patent system suggests that the government will fail in discharging their burden of a rational connection between the measure and the objective. However, if a court finds otherwise, crown counsel will still have to proceed through the remainder of the *Oakes* test.

On the issue of minimal impairment of the *Charter* rights, there are existing provisions within the CPA that protect against abuse of patents and provide for compulsory licencing of inventions for "government use". Again, these are piecemeal and any efforts to make use of these provisions would have to comply with statutory requirements. In addition, such an individualized analysis does not consider the propriety of the policy or operational discretion to grant gene patents in the first place. The resulting private enclosure of basic knowledge, which impacts on future research and development and the delivery of health in a timely and cost efficient manner, is not proportionate to the beneficial effects of granting gene patents to the patent system as a whole – particularly since genetic research would occur in the absence of this incentive. The measure goes further than necessary in granting exclusive rights for investment rather than "invention" without qualification or commitment to the legal requirements of patentability. There are a number of responses to the concerns raised by biopatenting that would help to ensure the necessary balance with the public's interest in patented inventions. The most obvious is to amend the CPA to exclude patentability of all life. Amendments could provide specific exemptions to infringement or public policy exclusions from patentability (i.e. genes or human/animal chimera are not patentable). Legislated special provisions, like those governing the Patented Medicines Prices Review Board,[198] could be drafted to respond to the concern over prohibitive prices that biotech patents create for the delivery of health by providing that patented genes, genetic tests and health products receive similar treatment as patented medicines and are subjected to price review mechanisms. These responses are TRIPS compliant and human rights consistent and were made in fact by Austin and Amani in relation

[197] *Chaoulli, supra* note 18 at para. 155.

[198] *Patent Act, supra* note 14, s. 83-85.

to gene patents to the Ontario Advisory Committee on New Genetic Technologies in 2001.[199]

The last requirement of the *Oakes* test is that the benefits of the measure, the granting of patents on genes must outweigh its deleterious effects. For the reasons discussed, they do not, especially given the paradoxical findings of the SCC in the two recent patenting life cases. In the *Harvard* mouse decision,[200] the SCC found that non-human genetically modified higher life (an oncomouse) was not a patentable invention under the CPA. As the case before the SCC in *Harvard* was only about animals, presumably that Court's consistent reference to plants and animals, and the specific finding in *obiter* that existing plant breeder legislation suggested that plants were not patentable, was an effort by the majority to prescribe a legal standard for treating the issue of patents on higher life forms as a class inclusive of plants *and* animals with the pending *Schmeiser* appeal in mind. However, *Harvard's* majority became *Schmeiser's* minority opinion and the deference to Parliament to legislate the patentability of higher life was quickly usurped by a reconstituted SCC in 2004. In *Schmeiser,*[201] Monsanto's patent covered claims to a chimeric plant gene that encoded for an enzyme which conferred resistance to glyphosate herbicide such as Roundup that Monsanto produces. The claims extended to plant cells that contained the chimeric gene. The SCC found that even though plants are not patentable, the collection, saving, and planting of seeds containing Monsanto's patented gene and cell constituted an infringing "use" of the invention, and contravened the patentee's guarantee of exclusive rights.[202] The implication of this decision was to provide back door protection for what has been found to be legally unpatentable by extending the definition of "use" under the CPA. This makes gene patents significantly more deleterious since a patented gene is now determinative of more expansive rights that will extend to anything that contains it even though these embodiments (plants and animals) are themselves not patentable by law. In addition, knowing that medical intervention exists but is unavailable due to the patent has significant mental and emotional harm as well as its associated physical harm. Just as it was in *Chaoulli*, "the physical and psychological suffering and risk of death that may result outweigh whatever benefit (and none has been demonstrated to us here) there may be to the system as a whole."[203] To conclude, *Chaoulli* is not necessarily the poison for public health but may prove to be the *elixir* for the rights to life, liberty and security of the person in finding that within these rights there exists a negative right to health when considering an existing quasi-

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[199] Lisa Austin & Bita Amani, "Patents on Genes: Identifying Issues and Responses." (October 2001) Discussion Paper prepared for and internally distributed to the Ontario Provincial Advisory Committee on New Genetic Technologies, Toronto, Ontario.

[200] *Harvard* (SCC), *supra* note 149.

[201] *Monsanto Canada Inc. v. Schmeiser*, [2004] 1 S.C.R. 902.

[202] *Ibid.* at para. 58, for a summary of the majority's proposition.

[203] *Chaoulli*, *supra* note 18 at para. 157.

tortious understanding of *Charter* obligations that posits "if the government chooses to act, it must do so properly."[204]

If the granting of gene patents is found to be unconstitutional, what are the remedies available under s. 24 of the Charter? Governmental accountability in Canada is enshrined under s. 24(1) and (2) of the *Charter*. One could seek Charter damages on the basis of the "constitutional tort" without the need to establish the remaining elements for Negligence within s. 7 since the mere violation of the *right* is itself *wrongful*. This helps the complainant with difficult burdens to discharge in terms of duty, causation, and remoteness, and arguably overcomes limitation periods and available common law defences. Second, a declaration of unconstitutionality coupled with an injunction on further grants of gene patents by the CPO, and a moratorium on enforcement are all helpful remedies that can be granted under the *Charter*. However, none of these address the economic and political costs necessary to deter governments from prioritizing industrial and trade policy over health policy. Nor do they compel Parliament in any way to remedy the current state of patent regulation and policy. Where an individual is bringing the case forward on the basis of actual harm in addition to the deprivation of his or her right, an individual award of monetary damages may be desirable as compensation and vindication of her rights and if pursued as a class action, may create the incentive necessary for reforming Canadian patent office practice and policy.

CONCLUSION

In response to the international crisis related to access to essential medicines, the Canadian government reviewed and amended our patent legislation in order to allow the manufacture and export of generic drugs (particularly those needed for the treatment of HIV/AIDS, malaria, and tuberculosis) to developing countries lacking manufacturing capacity, and thereby promoted the health of individuals abroad.[205] Yet, there was no corresponding effort to mediate the health impact of patenting life and biotech patents at home and so patents continue to issue on "inventions" such as the protein coding for the entry way to AIDS, the human stem cell and cancer related genes. Patent validity proceedings do not present a practical viable option for challenging all of the existing gene patents that have issued and will remain valid in Canada for years to come. Existing private action in tort law similarly does not offer a suitable means of ensuring public authority accountability in this context. What are the prospects for the vision of public law redress I have put forward in this analysis? Dr. Terrence Sullivan *et. al.* write that "the *Chaoulli* decision has the potential to affect how cancer services are organized and delivered in the future."[206]

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[204] *Ibid.* at para. 158.

[205] See Industry Canada, News Release "Government of Canada Reinstates Legislative Proposals to Enable Export of Low-Cost Pharmaceutical Products to Least Developed and Developing Countries" (12 February 2004), online: <http://www.ic.gc.ca/cmb/welcomeic.nsf/cdd9dc973c4bf6bc852564ca006418a0/85256a5d006b972085256e3800534dc9!OpenDocument>.

[206] Sullivan *et al.*, *supra* note 24 at 456.

The purpose of this article was to provide an opportunity to "rethink" public sector liability in relation to gene patents given the new treatment of the right to health under the *Charter*. I also mean to celebrate the decision, against a rally of criticism, for its potential progressive outcome. In the process, I wish to demonstrate the interdependence of domestic regulatory policies and the need for greater co-ordination to ensure a more efficient and effective system of governance between industry and health. That *Chaoulli* was marked by a 3:3 split on the *Charter* issue indicates that there is still quite a ways to go before any of my proposals become a reality. But the decision may start to influence lower courts to conceptualize health as a constitutionally protected right and to inform their decisions with this in mind such that eventually, there may be a body of law recognizing a right to health that parallels common law duties of government for wrongs in tort. In this way, the next time the SCC revisits the issue of health rights under the *Charter*, a more inclusive and human rights compliant framework may be adopted in favour of health protection. Additionally, I hope to have encouraged a rethinking of the granting of gene patents. The SCC's Decision of 2005 in *Chaoulli* has changed the prognosis on the utility of the *Charter* as a normative framework for prioritizing health over industrial policy by further developing government accountability for regulatory negligence.

To summarize, *Chaoulli* is an important decision of the SCC for several reasons. First, it recognized that appellants Dr. Chaoulli and Mr. Z, neither of whom was immediately affected by the infringement had standing to bring the constitutional challenge.[207] Second, the majority embraced social and economic rights as justiciable, rejecting the Attorney General of Canada and Quebec's submission that these are inherently political decisions. McLachlin C.J.C. writes: "There is nothing in our constitutional arrangement to exclude 'political questions' from judicial review where the Constitution itself is alleged to be violated."[208] Third, on the issue of deference, the majority asserted the Court's jurisdiction to judicially review government decisions, even if they are policy based, for conformity with *Charter* law. Fourth, not only was the Court's jurisdiction affirmed, the majority went further in finding a duty of the Court to act as steward of individual rights in order to ensure that the utilitarian goals of governance, and "social policy engineering" do not come at the cost of compromising individual rights. This is important since patents are normatively justified for their utility in encouraging research and development. The majority recognized harm within the language of s. 7 "life" and "security of the person" as extending to both serious psychological and physical suffering which arguably extends to situations where one knows that a genetic test exists but cannot access it for reasons associated with the state created patent monopoly. In determining whether any deprivation of the rights are in accordance with the principles of "fundamental justice" the Court draws some bright lines regarding arbitrariness. The decision recognizes the duty of care owed to citizens by their governments is one that requires our regulators not to interfere with

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[207] *Chaoulli*, *supra* note 18 at paras. 35, 186-89.

[208] *Ibid.* at para. 183. See also paras. 35-36, 183-85.

the realization of the right to health. This, I have argued, opens the door for constitutional tort damage claims for a breach of this duty of care in other regulatory contexts. For these reasons, *Chaoulli* fills me with excitement. I cannot help but share Professor Lorne Sossin's optimism and "believe the decision may yet have a surprisingly progressive influence on Charter jurisprudence [b]y establishing the connection between deprivations of the basic necessaries of life and fundamental rights".[209] When "rethinking public authority liability", this is a healthy place to start.

[209] Lorne Sossin, "Two-Tier Constitution", *supra* note 119 at 178.