A COMPLEMENTARY TENSION: THE INTERSECTORAL ISSUE OF GENE PATENTS IN HEALTH IN CANADA.

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Abstract

Who has no right to use your genes? It could be you. Human genetics and genomics research is costly and in it there is potential for commercial gain. In the decades of human gene-based research and development, much of the debate over the commercialization of genetic materials has occurred under the protective rubric of patent law and according to utilitarian rationales that justify the granting of exclusive rights that ostensibly will make the world a better place. However, questions arise regarding the effectiveness of patents in promoting health and well-being, given the lack of evidence supporting their exclusive rights exchange for disclosure. Patent policy may set out to combine the health improvement and economic growth objectives of innovation, but these two goals do not always align. The Canadian debate on human gene patents, illustrated by cases like Myriad Genetics' BRCA patents and the Children's Hospital of Eastern Ontario's struggles over Transgenomic's LQTS patents, highlights tensions between public and private interests. While exclusive patent rights have raised concerns about access to genetic tests, significant patent system reform in Canada may not be the solution. Instead, a comprehensive genetics policy approach is needed, alongside enhanced governmental expertise to ensure open and equitable access to gene-based technologies; it is again time for governments to reamass in-house expertise at the policy-evidence interface regarding genetics and genomics to mitigate a growing vulnerability in governance and oversight in these advancing areas of science, technology and biomedicine. Collaborative efforts among stakeholders in science, health, and industry are crucial for policy coherence, better inter-institutional cooperation, and better leadership. This study conducted in-depth interviews with 26 stakeholders from various sectors, complemented by case and doctrinal analysis of human gene patent-related litigation.

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1 INTRODUCTION

Patenting genes linked to human disease has been controversial from the outset. Technologies like genetic testing, crucial for clinical interpretation, are increasingly powerful in treating illness. After gene cloning and characterization, clinical testing often marks the first practical use of gene-based discoveries. This process, part of the research and development (R&D) pipeline, paves the way for broader genomics use, fueled by public-private investments. Various policies, including patent and health policies, influence the biomedical applications of genetic tests. Concerns about gene patents revolve around access to medical data stored in individuals' DNA. While the majority of public discourse focuses on this issue,[1] scholarly analysis explores potential solutions. Gene patents, particularly those for proteins with therapeutic value, have triggered legal dispute globally, with significant policy debates in Canada revolving around patents on disease-associated genes for genetic tests.

The biotechnology industry, known for its need for substantial capital investment, strongly advocates for robust intellectual property (IP) rights.[2] Patents play a crucial role in biotechnology and biomedical R&D by encouraging private investment. Despite many genetic discoveries originating from publicly-funded research, they are frequently patented. In biotechnology, patents are viewed as tools to advance innovation for commercial viability rather than mere incentives for

[1] A "gene patent" typically falls into two categories: product claims, covering genetic sequences like DNA or nucleotides, and process claims, focusing on methods involving genetic sequences. These claims can vary widely, including engineered complementary DNA (cDNA), drug screening techniques, and testing kits.
[2] Federal Trade Commission, *The Evolving IP Marketplace: Aligning Patent Notice and Remedies with Competition* (Washington, D.C.: FTC, March 2011), 43 [FTC 2011].

innovation.[3] The patent system, dominated by utilitarian economics,[4] is believed by some to be the best promoter and protector of innovation. Patents assure patentees of recouping their investments through technology commercialization[5] and protect initial inventions from appropriation. While patents grant a negative right to exclude others from making, using or selling an invention, they are essential for commercializing inventions, and uncertain patent rights can deter investor support for promising discoveries.[6]

According to a 2004 Organisation For Economic Co-Operation and Development (OECD) report, patenting growth reflects increased patent importance in the economy, shifting research reliance from individual firms to knowledge networks and markets. By 2004, OECD innovation processes became more competitive, cooperative, and globalized.[7] This research reorganization altered technology diffusion, leading businesses to seek more patents. Patents have supported biotechnology and R&D sectors' innovation waves, attracting private-sector funding and facilitating knowledge diffusion. Patent system changes, including broader eligibility criteria and stronger holder rights, promoted increased patenting. These changes, particularly in countries like Canada with health care costs concerns, raise new and old issues about balancing innovation and commercialization with health care equity.

My project focuses on the overlap of patents and health, exploring how genetics and biotechnology can improve diagnosis, prognosis, and treatment, including personalized medicine and gene

[3] Secretary's Advisory Committee on Genetics, Health, and Society, *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests* (April 2010) [SACGHS] at 20, online: <https://osp.od.nih.gov/wp-content/uploads/2013/11/SACGHS_patents_report_2010.pdf>.
[4] Williams F, "Theories of Intellectual Property" in Munzer S (ed.), *New Essays in the Legal and Political Theory of Property* (Cambridge: Cambridge University Press, 2001) at 169.
[5] FTC 2011, *supra note* 2 at 1.
[6] FTC 2011, *supra note* 2 at 43.
[7] Organisation for Economic Co-Operation and Development, *Patents and Innovation: Trends and Policy Challenges* (Policy Report) (Paris: OECD, 2004) [OECD 2004].

therapies. However, the introduction of patents into this area poses challenges. While patents are crucial for innovation and economic growth, concerns arise about gene patents hindering research access, health care innovation, and the availability of biomedical advances, as seen in cases like Myriad Genetics and long QT syndrome.

The prevailing literature and policy discussions regarding gene patents and genetic testing in Canada, including my own research, suggest that these patents pose obstacles to equitable access and cost-effective testing. Despite ongoing discussions over the past two decades on how to address these challenges, uncertainties remain about the extent of their impact. This issue remains situated at the intersection of public and private interests in patents and health. My specific aim is to take a closer look at this public-private divide, examining patents as a intersectoral issue affecting publicly-supported health research and care through the lens of the Canadian gene patent debate.

In this study, I explored policy conflicts surrounding Canadian human gene patents. I investigated tensions between promoting gene-based innovation and ensuring access, conflicts between public and proprietary science, and balancing exclusion rights with inclusive benefits. To do so, I interviewed 26 stakeholders involved in Canadian gene patent discussions and analyzed relevant case law and policy developments, especially in Ontario, regarding genetic testing provision. Throughout, I have argued that discussions on human gene patents are certainly relevant to patent law but extend beyond its domain, particularly concerning public interests. From my findings, I have drawn four main conclusions.

First, patents create uncertainty, requiring a purpose-driven regulatory approach to gene-based inventions in health research and care. Secondly, insufficient consideration has been given to

health policy in Canadian discussions on gene patents. We must take a constructive approach, utilizing health policy tools like research grants and open science initiatives, prioritizing non-economic factors. Thirdly, we need to enhance interdepartmental and interministerial coordination to govern gene patent use in health research and care. Collaboration, particularly with health authorities taking the lead, is key. Finally, the current "us vs. them" mentality regarding patents and health must shift towards a more cooperative approach. To develop genetics policy, we should build institutional capacity within government or regulatory agencies to foster trust, knowledge networks, and collaborations across institutions to strengthen governance, health care, and research.

1.1 Some Background

1.1.1 A Patent Is a Bargain

The Canadian patent system operates on a fundamental agreement: inventors gain protection and exclusive rights in exchange for sharing their inventions with society. This arrangement aims to foster innovation by encouraging inventors to invest in research and development. Patents grant monopolies over new, non-obvious, and useful inventions, preventing obvious variations or combinations of existing ideas.[8] Through these protections This system is believed to drive scientific and technological progress by providing incentives for inventors to pursue high-demand research and development projects.

[8] See, *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153, 2002 SCC 77 [*Wellcome*]; *Bristol-Myers Squibb Co. v. Canada (Attorney General),* [2005] 1 SCR 533; *Free World Trust v. Électro Santé Inc.,* [2000] 2 SCR 1024; Novelty: *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.,* [2008] 3 S.C.R. 265, 2008 SCC 61; Non-obviousness: Canada, Patent Office, Manual of Patent Office Practice (Ottawa-Hull: Industry Canada, Canadian Intellectual Property Office, 1998) c. 15.01.02; Utility: *Northern Electric Co. v. Brown's Theatres Ltd.,* [1940] Ex.C.R. 36 at 56 (Ex. Ct.), aff'd [1941] S.C.J. No. 5, [1941] S.C.R. 224 (S.C.C.).

The patent community view the 'patent bargain' as a key principle behind the Patent *Act*.[9] This concept involves patent holders sharing inventions with the public while retaining exclusive rights for a limited time.[10] Patent law aims to balance the interests of all parties involved,[11] however the power of patents, particularly in restricting access to goods and services, raises concerns about decision-making processes.[12] Striking the right balance of interests is not without its problems; after all, rights can and do conflict with one another[13] and can be especially challenging in critical areas like health care where conflicting interests often arise. This can highlight flaws in the patent bargain — regardless of natural or utilitarian justifications — depending on whose interests are prioritized[14] and why. [15]

From a natural law perspective, the law protects inventors' inherent rights,[16] while the utilitarian view suggests that inventors' rights exist because the law dictates so, serving the public interest.[17]

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[9] See, e.g., *Teva Canada Ltd. v. Pfizer Canada Inc.*, [2012] 3 S.C.R. 625 (CanLII) [*Teva*]. See also, Geist M, "Supreme Court serves stunning reminder of the patent bargain," The Toronto Star (17 November 2012), online: <https://www.thestar.com/business/2012/11/17/supreme_court_serves_stunning_reminder_of_the_patent_bargain_geist.html>.

[10] See, e.g., *Eldred v. Ashcroft,* 537 U.S. 186, 216 (2003).

[11] For an interesting discussion on the concept of balance, namely the "balanceable system" of IP, see Story A, "Burn Berne: Why the leading international copyright convention must be repealed" (2003) 40 Hous. L. Rev. 763, 785.

[12] See for e.g., Nedelsky J, "Reconceiving rights as relational" (1993) 1 Rev. Const. Stud. 1 (arguing that legal rights structure relationships of power, responsibility, obligation, and caretaking). See also, Sax J, "Takings, Private Property and Public Rights" (1971) 81 Yale L.J. 149; Singer JW, Beermann JM, "The social origins of property" (1993) 6 Can. J.L. & Jurisprudence 217.

[13] Joseph S, "Trade and the right to health," in A. Clapham and M. Robinson (eds*.), Realizing the right to health, Swiss human rights book series, vol. 3* (Zurich, Switzerland: Ruffer & Rub, 2009), 360.

[14] Appleton ME, *Whose Balance? Divergent Directions in Canadian Copyright Reform* (LL.M. Thesis, University of Toronto, 2009), 1.

[15] See, e.g., Joly Y et al., "The commercialization of the human genome in Canada" (2010) 6(2) Health Policy 24. Also, Caulfield TA, Gold ER, "Genetic testing, ethical concerns, and the role of patent law" (2000) 57 Clinical Genet. 370. And, Jamieson C., *The Next Frontier: Health Policy and the Human Genome*, Vol. 1(2), September 2001, 17.

[16] Kant I, *The Metaphysics of Morals* (Cambridge: Cambridge University Press, 1991), 106.

[17] No clear definition of "public interest" in the IP context exists, but legal scholarship has much to say on the topic. For a few examples, see: Fewer DA, *Defining the Public Interest in Canadian Intellectual Property Law* (LL.M. Thesis, University of Toronto, 1997); Boyle J, "Open Source Innovation, Patent Injunctions, and the Public Interest" (2012) 11 Duke Law & Tech. Rev. 30; Sitorus W, "Public interest in patent protection: The need of criteria" (2016) 45 J. L. Policy and Globalization 85.

Utilitarianism emphasizes the need for incentives to create new information,[18] but once disclosed, information should be freely shared.[19] Patent exclusivity addresses concerns about free riding, creating a scarcity and financial opportunities for patent holders. This economic rationale supports the idea that society accepts inventors' exclusive rights in exchange for new inventions and information. Balancing incentives and access becomes crucial, especially considering that many patent infringement cases do not involve allegations of copying.[20]

1.1.2 The Role of Patents

Patents provide incentives for producers to undertake endeavors like developing gene-based inventions,[21] and knowledge goods.[22] While some scholars criticize patents as ineffective,[23] they are seen as a means to achieve a balance between public and private interests in the patent system.[24] Particularly in the biotechnology sector, patents serve as the primary incentive for development and commercialization,[25] operating in a "patent-or-bust" landscape where success often hinges on patent protection due to the high risk involved in R&D. Despite the Canadian

[18] Landes WM and Posner RA, *The Economic Structure of Intellectual Property Law (Cambridge, Massachusetts: Harvard University Press, 2003).* Also, Posner R, *Economic Analysis of Law, 5th ed*. (New York: Aspen, 1998).
[19] Arrow KJ, "Economic welfare and the allocation of resources for invention" in Universities-National Bureau of Economic Research Conference. Series, in Nelson RR (ed.), *The Rate and Direction of Inventive Activity: Economic and Social Factors* (Princeton: Princeton University Press, 1962).
[20] Cotropia CA, Lemley MA, "Copying in patent law" (2009) 87 N.C.L. Rev. 1421..
[21] See, e.g., Scherer FM, "The economics of human gene patents" (2002) 77 Acad. Med. 1348, 1350.
[22] See, e.g., Gallini N, Scotchmer S, "Intellectual property: When is it the best incentive system?" (2002) 2 Innovation Policy & Econ 51, 53. Also, Hemel DJ, Ouellette LL "Beyond the patents-prize debate" (2013) 92 Tex. L. Rev. 303, 312, 371.
[23] *Id.*, Hemel and Ouellette at 314.
[24] See, Nordhaus W, *Invention, growth and welfare: A theoretical treatment of technological change* (Cambridge, MA: MIT Press, 1969). See also, Kitch EW, "The nature and function of the patent system" (1977) 20 J. L. & Econ. 265.
[25] Niosi J, "Alliances are not enough explaining rapid growth in biotech firms" (2003) 32 Research Policy 737. Also, Bernier LG, "Protection and innovation of biotechnology innovation in Canada and Quebec" (2019) 15(3) Industrial Biotech.162. See also, Vanderbyl S, Kobelak S, "Critical success factors for the biotechnology industry in Canada" (2007) 13 J. Commer. Biotechnol., 68.

biotechnology sector's strong performance, research in this field is still perceived as high-risk in, among other areas, health care.[26]

However, the reasons for patenting have evolved, moving away from traditional justifications. Arguments defending the centrality of inventiveness emphasize that truly innovative technologies, spurred by the incentive of patents, can overcome potential flaws in the patent system, such as lower patentability standards.[27] Yet, this perspective overlooks patents' primary goal of fostering innovation and expanding public knowledge. While patents should encourage innovation and facilitate follow-on developments, they must also apply legal rules neutrally across different technologies. Without contributing new knowledge to the public domain, patents solely offer private benefits, hindering the free flow of information[28] and undermining the social benefits of the patent system. To maintain its effectiveness, the patent system requires clear and predictable rules, ensuring long-term investment security and investor confidence in the protection of their investments.[29]

Ultimately, patent law aims to stimulate development, commercialization, and subsequent innovation,[30] fostering a responsive innovation marketplace by granting exclusivity to novel and useful inventions.[31] Governments regulate industries reliant on patents, such as biotechnology, post-patent, ensuring safety and quality, as does Health Canada in its review of goods and

[26] See, Vanderbyl S, Kobelak S, "Risk management for the biotechnology industry: A Canadian perspective" (2005) 14 J. Commercial Biotechnol 128.
[27] Cahoy DR, "Rethinking patents for optimal health care innovation," Huber Hurst Research Seminar, Pennsylvania State University, April 2005, 52.
[28] Boyle J, *The Public Domain: Enclosing the Commons of the Mind* (New Haven, Connecticut: Yale University Press, 2008), 7.
[29] Posner, *supra note* 18.
[30] OECD 2004, *supra note* 7.
[31] Boyle J, "The second enclosure movement and the construction of the public domain" (2003) 66 Law and Contemporary Problems, 33 at 7 (asking "why IP?").

processes before their authorization of sale. However, if the patent system fails to produce socially beneficial inventions, government regulation alone cannot rectify this without directed intervention.[32] Innovation reliant on patents thrives only when there is a market demand, without necessarily considering broader social consequences. Patent law need not concern itself with whether an invention helps achieve public good, decidedly leaving that up to the market.[33]

1.1.3 Law, Meet Genetics

The debate over patenting human genes[34] and life itself[35] in medical genetics reflects a tension in Canada between promoting innovation and ensuring affordable access to health care. Typically, policy conflicts have been addressed by focusing on improving the efficiency of the patent system and applying existing legal principles. Under this approach, courts often consider economic impacts and criteria like novelty, non-obviousness, and utility to balance public interests and prevent monopolization of public domain goods.[36] Conflicts over human gene patents in Canada's health research and care sectors have mainly been addressed as legal issues. Access to genetic materials and related technologies, like genetic tests, is a primary concern. Suggestions for dealing with access issues typically involve patent reform, such as restricting broad patents and tightening eligibility requirements.[37] Arguments against gene patents have centered on their lack of novelty,

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[32] Gold ER, "Making room: Reintegrating basic research, health policy, and ethics into patent law," in Caulfield TA, Williams-Jones B (eds.), *The Commercialization of Genetic Research: Ethical, Legal, and Policy Issues* (New York: Kluwer Academic/Plenum, 1999).
[33] Gold ER, *Body Parts: Property Rights and the Ownership of Human Biological Materials* (Washington, D.C.: Georgetown University Press, 1996).
[34] See, Eisenberg RS, "Genes, patents, and product development" (1992) 257 Science 903). Also Maher L, "The patent environment: Domestic and European community frameworks for biotechnology" (1992) 33 Jurimetrics 67.
[35] Some seminal North American e.gs. include the patenting of a canola plant and lower life form. See, *Monsanto Canada v. Schmeiser* [2004] 1 S.C.R. 902, SCC 34 [*Monsanto*]. See, the patenting of a transgenic mouse and higher life form in *Harvard College v. Commissioner of Patents (Canada)* [2002] 4 S.C.R. 45 [*Harvard*]. And the patenting of human tissue in *Moore v. Regents of the University of California*, 51 Cal. 3d 120 (1990) [*Moore*].
[36] For an e.g. of use in policy, see WIPO, *Patent Agenda: Options for the Development of the International Patent System*, WIPO document A/37/6.
[37] Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare*, Report to the Provinces and Territories, January 2002 [Charting New Territory].

non-obviousness, or utility, suggesting they are not patentable subject matter, regardless of meeting other criteria.[38]

An interesting yet complicated interplay exists between genetics and the law, where the interpretation of patentability criteria varies significantly, leading to diverse outcomes[39] and allowing for expansive definitions of inventiveness.[40] This complexity forms the backdrop of modern patent law in Canada, where human genes are deemed patentable subject matter, thereby placing their use under the purview of patent policy to regulate who can utilize them, how, and when. Consequently, issues pertaining to patented human genes have predominantly been addressed within the patent community.[41] Traditionally, the prevailing approach to resolving challenges associated with human gene patents in Canada has been to prioritize policy considerations within the patent system. Put simply, a patent-centric solutions approach to the human gene patent problem has been the typical approach in Canada.

1.1.4 Power and Paradox

In the biotechnology sector, patent rights are prized assets crucial for business success. While obtaining patents can be costly, the patent system is indispensable for modernizing and

[38] *LeRoy v. Tatum,* 55 U.S. 156 (1852). Regarding lack of utility, see Scanga V, *Human Gene Patenting and Canada: Science, Policy, and Law (*Masters in Law, Osgoode Hall Law School, York University, 2013).
[39] Brody B, "Intellectual property and biotechnology: The US internal experience — Part I" (2006) 17(2) Kennedy Inst. Ethics J. 69. And, Gold ER, Gallochat A, "The European Biotech Directive: Past as prologue" (2001) 7(3) Eur. J. Law 331 (explaining that the *Directive* was important to European patent law as it bound national governments to comply with it).
[40] Namely, with respect to "invention" including the idea of human intervention and an equivalence drawn between chemical compounds (patentable subject matter) and genetic sequences. See, for e.g., U.S. Federal Register (2001) vol 66, n 4, 5 January 2001, at 5. See also, *Directive 98/44/EC* of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions. Official J. of Eur Comm, 1998 [*EU Directive*].
[41] For some discussion on this, see generally: *Harvard, supra note 35*; *CLS Bank Intern v. Alice Corp. Pty. Ltd. 573 U.S. 208 (2014) [Alice]*; *Aronson v. Quick Point Pencil Co.,* 440 U.S. 257, 262 (1979).

streamlining national economies.[42] Protecting IP has become increasingly vital in the knowledge economy, granting control over the distribution of intellectual products. For example, discussions with one study informant, Lexchin, surrounding Canada's pharmaceutical patent system were central during negotiations of the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP). Though initially focused on the Trans-Pacific-Partnership, discussions regarding patent system changes were suspended after the U.S. withdrawal and the agreement's transition to the CPTPP.

According to economic theory, there is a discrepancy between patent law and patent theory, suggesting that aligning them could reduce costs and inefficiencies in patent practice, or that the traditional economic theory of patents may be flawed. However, society tacitly accepts the patent system despite its incomplete justification, viewing it as a contract with inventors institutionalized through the system. This acceptance hinges on the patent bargain, where the public supposedly benefits from the trade-off and trickle-down effect of patents. When this balance is disrupted, questions arise about whether patents serve their public purpose, leading to demands to limit patent monopoly power.

This tension is evident in the Canadian debate over human gene patents, highlighting the paradox of patents: they are policy tools that are meant at once promote goods for the public while also making them exclusive. The debate involves conflicting views, a 'right to health' perspective advocating universal access to medical care versus the stand of IP rights advocates emphasising

[42] For e.g., Collette et al., *IP Canada Report 2020* (Ministry Report) (Ottawa: Innovation, Science and Economic Development Canada and Canada IP Office, 2020). See also, European Patent Office and the EU Office for Harmonization in the Internal Markets, *IPR-intensive industries and economic performance in the European Union, Industry-Level Analysis Report* (Munich: European Patent Office and the EU Office for Harmonization in the Internal Markets, September 2019).

the necessity of granting private rights for commercial use of biotechnological knowledge. Discussions about access to gene-based technology expand into broader policy conversations addressing concerns about patents' impact on health research and care.

The Commission on the Future of Health Care in Canada emphasized the critical role of research and innovation in ensuring health care sustainability,[43] highlighting the substantial costs associated with innovation, particularly in the biotechnology sector, laying bare the reliance on patents.[44] This chapter delves into one of the brief references made regarding biotechnology innovation in the Romanow Report[45] but has since become an increasingly important area of innovation in health care: genetics.

1.1.5 Patents v. Health

Historically, biotechnology has emerged as a rapidly growing innovation sector in Canada, featuring prominently in both provincial and federal innovation strategies. However, its role within government agendas has not always been straightforward. Biotechnology often intersects with various policy areas, like trade or health, particularly those concerning health care and life technologies like genetic tests and reproductive technologies. [46] While it's recognized as a contributor to key domestic R&D priorities such as pharmaceuticals, its societal influence and policy significance have sometimes been overlooked by the state.[47] Recently, as personalized medicine gains traction in Canada, there has been a surge in demand for biotechnological

[43] Romanow RJ, *Building on Values: The Future of Health Care in Canada, Commission on the Future of Health Care in Canada,* (Final Report) (Ottawa: Commission on the Future of Health Care in Canada, November 2002) at xvi [Romanow Commission].
[44] *Id.* at 83.
[45] Id. at 209.
[46] Doern GB, Prince MJ, *Three Bio Realms: Biotechnology and the Governance of Food, Health and Life in Canada* (Toronto: University of Toronto Press, 2012), 56
[47] *Id.*

innovation more broadly.[48] Policy discussions on Canadian biotechnologies have primarily centered around patents and associated rights, especially regarding intellectual property and the commercialization of patented goods. Balancing private ownership with public access to these goods, particularly in the realms of health and life, remains a key point of debate.[49]

In Canada, debates surrounding patents in health care persisted for nearly two decades, primarily within policy circles. These discussions were sparked by a challenge from Myriad Genetics, Inc., particularly in Ontario, concerning patents on breast and ovarian cancer susceptibility genes (BRCA) and genetic tests (BRCAnalysis). The concern was that these patents granted supra-optimal control over access to these genes and tests, potentially compromising equitable health care delivery. Central to this concern was Myriad's licensing strategy, which was seen as potentially limiting patients' ability to make informed decisions about their treatment and well-being. These debates raised broader questions about whether Canada truly benefits from relying on patents to incentivize revolutionary innovations in health research and care.

Despite extensive literature in economics and law, there's no clear evidence on the overall benefits of the patent system, especially in healthcare innovation. This ambiguity has led to challenges in developing coherent policy frameworks for accessing patented genetic tests in Canada's healthcare system. The lack of clarity regarding the empirical benefits of patents in improving access to health research and care, despite the Supreme Court of Canada's emphasis of disclosure as the quid *pro*

[48] McCabe C, Husereau D, "Personalized Medicine and Health Care Policy: From Science to Value," Policy Brief No.9, Genome Canada, February 2014.
[49] De Beer J, Gold R, Guaranga M, "Intellectual Property Management: Policy Issues and Options" in *GE^{3}LS in Brief, A Primer on Genomics, Ethics, Environment, Economics, Law, and Society in the Biosciences*, Saskatoon: Centre for the Study of Science and Innovation Policy, 2017 [GE^{3}LS] at 27.

quo for valuable proprietary rights to exclusivity[50] and its role to fulfill the patent bargain,[51] undermines their perceived value in stimulating biotechnological innovation.

Modern patent law has distinct features that uphold the principle of disclosure in exchange for exclusive rights. Firstly, it prioritizes maximizing innovation by facilitating the introduction of new products and processes into society, regardless of their nature, including human genetic materials and living organisms.[52] Secondly, the patent system's focus is solely on incentivizing invention, without consideration of its social value.[53] Finally, as emphasized by Binnie J in *Wellcome*,[54] patents grant exclusive rights as a legal mechanism, creating knowledge and ownership-based relationships, facilitating access to new technologies, and enhancing market incentives.[55] While various sectors rely on the patent system, the biotechnology industry, with its heavy reliance on the private sector for capital, particularly tests the system's fitness. As discussed earlier, patents safeguard that investment and endurance. So long as the benefits of patents in enhancing access to health research and care remain unclear, they create uncertainties for both knowledge and technology producers and users in the field. This study acknowledges the absence of formal policy development concerning access to patented human genetic materials or tests in Canada.

[50] *Wellcome, supra note* 8 at para 37 (Binnie J).
[51] *Teva, supra note* 9 at para 80.
[52] Beier FK, Moufang R, "Patenting of human genes and living organisms: Principles of a possible international understanding," in Vogel F, Grunwald R (eds.), *Patenting of Human Genes and Living Organisms* (Heidelberg: Springer, 1995).
[53] Gold, *supra note* 32.
[54] *Wellcome, supra note* 8.
[55] See, e.g., *Polymer Technologies, Inc. v. Bridwell,* 103F. 3d 970 (Fed. Cir. 1996) citing *Hybritech Inc. v. Abbot Labs,* 849 F2d. 1446, 1456-57 (Fed.Cir. 1988).

1.1.6 The Patent-Centric Paradigm: Protecting Invention to Drive Innovation

Understanding the distinction between innovation and invention is increasingly vital for grasping patent policy's integration into federal economic plans and its implications from a public interest perspective. While often used interchangeably, "innovation" denotes technological change (Hawkins, p. 3), evolving within competitive, globalized markets driven by technology-based firms,[56] in part because of expanded markets generating larger networks of partnerships and knowledge.[57] Patents play a role in this landscape, offering opportunities for artificial profitability[58] and serving as markers of ownership rather than as direct drivers of economic growth. As a theory of economic growth, however, innovation is often poorly understood, and (much like in the field of genetics) even those who write frequently on the topic find themselves re-defining it. Patents may serve as evidence of inventions, but recognizing this distinction is crucial, as patents primarily document new developments through a legal process rather than solely fueling innovation.

Classical economic theory, influenced by scholars like Joseph Schumpeter (1939),[59] frame innovation as an entrepreneurial endeavor, where new enterprises create novel products, processes, or markets. Schumpeter's followers narrow innovation to technological change.[60] While innovation now encompasses commercialization, its focus has shifted toward commercializing science and

[56] OECD 2004, *supra note* 7.
[57] Doern and Prince, *supra note* 46 at 32.
[58] Nordhaus, *supra note* 24. Also, Kitch *supra note* 24 at 265.
[59] For, e.g., Schumpeter J, *Business Cycles:* A Theoretical, Historical, and Statistical Analysis of the Capitalist Process, Volume 1 (New York: McGraw-Hill Book Company, 1939).
[60] Freeman C, Soete L, *The Economics of Industrial Innovation* (London: Routledge, 1997).

technology inventions.[61] A key distinction emerging between invention and innovation lies in how society perceives value in adopting new discoveries:

> An innovation is different from an invention … the reason is if you're counting "inventions", then you're not counting anything with any *value* … what we're interested in is when some new factor (new technology, process, practice) actually creates an additional economic value that wasn't there before … that's a critical thing … so by the methodological definition, an innovation is not just producing more of the same stuff … it's producing something that you've never produced before … it's producing *value* where it's never been produced before. (Hawkins, p. 2, *emphasis added by informant*)

The informant highlighted that the definition of innovation has evolved largely within a policy framework. They emphasized the problem with broadening the concept of innovation, stating that inventions lacking utility aren't truly innovative, irrespective of their novelty:

> It's not something industry spends a lot of time thinking about … it really is an artefact of a policy deliberation … but I think in government these days, in Canada certainly, what innovation means is a new technology. (Hawkins, p. 3)

In this policy framework, innovation often stems from factors critical for a firm's management and organization,[62] driven by market decisions and institutional influences.[63] A seasoned observer of innovation trends in Canada expressed concern over society valuing innovation not based on its actual societal impact over time, but rather on the IP attached to it and its commercialization:

> This is the critical thing about the way innovation creates economic value … the value is not created by somebody coming up with an idea and patenting it and selling a company off … that creates almost no value … the value is created when that device, idea, invention gets adopted into some system over a period of time. (Hawkins, pp. 11–12)

While patents play a crucial role in documenting, protecting, and leveraging inventions, relying solely on the patent system to determine societal value may lead us astray from recognizing

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[61] Feller L, "Universities as Engines of R&D-based Economic Growth: They Think They Can" (1990) 19(4) Research Policy 335. Also, Mowery DR et al. (eds.), *The Ivory Tower and Industrial Innovation* (Stanford, CA: Stanford, 2004).

[62] Pavitt K, "What we know about the strategic management of technology" (1990) 32(3) California Management Rev. 17. See also, Christensen CM, *The Innovator's Dilemma: When New Technologies Cause Great Firms to Fails* (Cambridge, MA: Harvard Business School Press, 1997).

[63] Nelson R, Winter S, *An Evolutionary Theory of Economic Growth* (Cambridge, MA: Harvard University Press, 1982).

genuine societal benefits within a field of inquiry because "there's no necessary association between patenting and value creation through innovation" (Hawkins, p. 26).

1.1.7 Gene Patents Challenge Traditional Patent Features

1.1.7.1 Neutrality

In *Harvard*,[64] the Supreme Court of Canada ruled that a genetically engineered cancer-susceptible mouse's higher life form wasn't patentable. Both the majority and dissenting opinions deferred to Parliament for ruling on patentability of such life forms. The Court agreed that ethical concerns should be addressed through legislation outside the patent system, focusing instead on regulatory regimes during research and commercialization of the "oncomouse".[65] Despite the view taken by most policy makers that S&T development is value neutral,[66] some scholars argue that current regulatory regimes do not, however, align with the patent system's neutrality claim and that no technology is truly neutral. They advocate tailoring patent policies to specific technologies, to establish appropriate eligibility parameters.[67] For these scholars, technology shaped by human agency isn't inherently neutral,[68] an assertion often typified in the scholarship by the emergence of biotechnologies in particular like gene-based technologies.

Considering the role of patent offices and courts in applying the neutrality principle to grant exclusive patent rights in biotechnology might draw from precedents in other industries to reach

[64] *Harvard, supra note* 35.
[65] See, e.g., Dresser R, "Ethical and legal issues in patenting new life" (1988) 28 Jurimetrics J. 399. Also, Merges RP, "Intellectual property in higher life forms: The patent system and controversial technologies" (1998) 47 Maryland L. Rev. 1051.
[66] See, e.g., Jasanoff S, "New modernities: Reimagining science, technology, and development" (2002) 11(3) Environmental Values 253, 271.
[67] Burk DL, Lemley MA, "Is patent law technology-specific?" (2002) 17(4) Berkeley Tech. L. J. 1155.
[68] For e.g., see *Id.* at 264.

logical outcomes,[69] but it is not without challenges. Patent offices grant many patents annually without monitoring their use, hindering evaluation of patent policy's societal impact and addressing unintended consequences.[70] Concerns also arise about the courts' ability to shape patent policy effectively, given potential long-term effects like fragmented property rights[71] and access barriers.[72] Ultimately, patents' value determination lies with market forces, leaving societal welfare dependent on market existence.[73] This undermines the neutrality claim of the patent system, as the market itself is not free of bias, it is not neutral.

1.1.7.2 Market Reliance

The patent system gauges the social value of inventions through market demand and willingness to pay, prioritizing financially promising innovations accordingly. However, evidence from interviews with firms and venture capitalists suggests that patents also create significant barriers to market entry, for instance through prohibitive licensing fees.[74] Furthermore, even when sold in secondary markets, patents can harm surviving firms, as they are often acquired for strategic reasons rather than for actual use of the patented technologies.[75] Ineffective or inefficient use of the patent system across various markets can hinder knowledge dissemination and impede

[69] *Id*. at 1579. See also, Pleune SB, "Trouble with the guidelines: On urging the PTO to properly evolve with novel technologies" (2001) J.L. Tech. & Policy 365 (arguing for DNA-specific legislation).
[70] Moir HVJ, *Do Legal Rules Deliver on Effective Economic Outcomes?* (Cheltenham, UK: Edward Elgar, 2013), 1.
[71] See, Heller MA, Eisenberg RS, "Can patents deter innovation? The anticommons in biomedical research" (1998) 80 Science 698; Rai AK, "Fostering cumulative innovation in the biopharmaceutical industry: The role of patents and antitrust" (2001) 16 Berkeley Tech. L.J. 813; Rai AK, "The information revolution reaches pharmaceuticals: Balancing innovation incentives, cost, and access in the post-genomics era" (2001) U. Ill. L. Rev. 173.
[72] Burk DL, Lemley MA, "Policy levers in patent law" (2003) 89 VA. L. Rev. 1575.
[73] Gold, *supra note* 32.
[74] Some interesting discussions include: U.S. Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (Innovation Report) (Washington: Federal Trade Commission, 2003) [FTC 2003]; U.S. Department of Justice and Federal Trade Commission, *Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition (Discussion Report) (Washington: Federal Trade Commission, 2007;* Hall, BH, Helmers C, and von Graevenitz G, "Technology Entry in the Presence of Patent Thickets," NBER working paper 21455, revised 2017. See also, Ito J, "One venture capitalist's view on software patents," blog post, 8 July 2015, online: <https://joi.ito.com/weblog/2005/07/08/one-venture-cap.html>.
[75] Love BJ et al., "An Empirical Look at the 'Brokered' Market for Patents" (2018) 83 *Missouri Law Review* 359.

innovation.[76] Seen in this light, the patent system does not encourage the development of any or all invention. According to James Boyle (1996), this aspect of the patent system is part of a larger issue within IP law, favoring inventor interests over the public domain and public interest.[77] In sectors characterized by market failure, like Canada's health care sector,[78] relying solely on the market may not lead to the most useful inventions to fulfill the goal of promoting good health and well-being.

Policy reports[79] and experts from both patent and health care sectors acknowledge patents' importance in Canada's healthcare system. However, the market's focus on a "winner takes all" dynamic, controlled by a few major players, undermines prioritizing human health and improving quality of life. As one political economist said:

> Yeah, well the thing about technologies in the Canadian space … well, actually around the world … there are five or six countries [with] companies in these five or six major markets in the world that have 5 per cent of the market … Pharmaceuticals and medical devices … they control 90 per cent of the market … Canada is not one of them. (Hawkins, pp. 14, 16)

Against this backdrop, it would be unsurprising to find certain scientific endeavors sidelined. It is, after all, challenging to align evolving community values with health care needs in an all-or-nothing environment.[80]

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[76] Lemley MA, "The Regulatory Turn in IP" (2012) 36(1) *Harvard Journal of Law and Public Policy* 109.
[77] Boyle J, *Shamans, Software, and Spleens: Law and the Construction of the Information Society* (Cambridge: Harvard University Press, 1996).
[78] For e.g., see Roemer MI, "Market failure and health care policy" (1982) 3(4) J. Public Health Policy 419.
[79] Charting New Territory, *supra note* 37. See, Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues*, (Committee Report) (Ottawa: Government of Canada Biotechnology Ministerial Coordinating Committee, June 2002) [CBAC 2002]. Also, CBAC, *Human Genetic Materials, Intellectual Property and the Health Sector* (Advisory Report) (Ottawa: CBAC, 2006) [CBAC 2006].
[80] Phillips PWB and Schmeiser P, "Science and Innovation Policy for the 21st Century: Shaping the Dialogue" in GE^{3}LS *supra note* 49 at 9. And, Rogers E, *Diffusions of Innovation, 5th ed.* (New York: Simon &Schuster, Inc., 2003.

1.1.7.3 Right To Exclude

While the optimization of the patent system has been attributed to other defining features of the system, expressly, the conditionality of disclosure,[81] its power to exclude gives the system considerable dynamism as it works to maximize innovation in any and all fields without prejudice. This exclusion period aims to incentivize investment in innovation and allows the patent holder to recoup development costs.[82] Patents promote access to inventions, reducing secrecy and fostering technological advancement.

Critics of the patent system often argue that it prioritizes private monopolies over public interests, prompting calls to rebalance these interests. Discussions on recalibrating these interests when concerns arise concerning their misbalance typically revolve around adjusting the strength of patent rights. Economic studies often portray patents as essential for accessing competitive markets[83] and the Canadian government views patents as a measure of national economic well-being and innovation across sectors.[84] However, in industries like biotechnology where R&D are cumulative, the impact of patents becomes more complex.[85] Suzanne Scotchmer (1991) highlights

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[81] See, e.g., *Teva, supra note* 9 (focused on a Pfizer drug patent voided by the SCC due to lack of disclosure, violating the *Patent Act*'s bargain). Disclosure and dissemination are also crucial in policy. See, e.g., Gallini N, Hollis A, *To Sell or Scale Up: Canada's Patent Strategy in a Knowledge Economy,* Institute for Research on Public Policy Study No. 78, August 2019 at 8. But see also: The SCC in *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.* [1981] 1 SCR 504 at para 518 (acknowledging the *Act's* disclosure clause may insufficiently drafted for literal interpretation); Landes and Posner, *supra note* 18 at 299 (writing, "The requirement of public disclosure creates a situation of incomplete appropriability by the patent holder …").

[82] See, e.g., Lemley MA, "*Ex ante* versus *ex post* justifications for intellectual property" (2004) 71(1) U. Chicago L. Rev. 129. Applying neoclassical theory to technological change, see Nordhaus' seminal work in *supra note* 24.

[83] Owens RC, Robichaud M, "Defending our rights: An intellectual property strategy for Canada: Why intellectual property protection matters to Canada," *Defending Our Rights Series: An Intellectual Property Strategy for Canada*, Macdonald-Laurier Institute, May 2017 at 6.

[84] See, e.g., Papageorgiadis N, Wang C, Magkonis G, "Factors contributing to the strength of national patent protection and enforcement after *TRIPS*" (2019) 26(1) Transnational Corporations 87. This study updates patent law post-TRIPS with empirical data, expanding on previous research prior to *TRIPS* by Ginarte JC, Park WG, "Determinants of patent rights: A cross-national study" (1997) 26(3) Research Policy 282.

[85] Charting New Territory, *supra note* 37. See also, Eisenberg RS, "A technology perspective on the NIH gene patenting controversy" (1994) 55 U. Pitt. L. Rev. 633, 647 (writing "one firm's research tool may be another firm's end product.").

this oversight in economic analysis, which often neglects the spillover effects of early inventors on later developments.[86]

1.1.8 Patent Fault Lines

In the late 1990s, Myriad enforced their Canadian BRCA patents, sparking discussions with Ontario and other provinces, as well as federal departments. Ontario sought patent regulation changes to ensure access to BRCA genes and tests. In its response, Ontario had framed its concerns around access to Myriad's BRCA genes and genetic tests as a patent issue (Drouillard, p. 9). According to a former genetics unit manager at Health Canada, the department anticipated Industry Canada's reluctance to disrupt industry relations, saying:

> They [Ontario] wanted the [federal] government to say 'You can't patent these' or 'If you're going to patent these, you need to provide worldwide non-exclusive licenses' or whatever it is … The main thing is that Canada had, at the time, a fledgling biotech industry, and naturally, those were the key stakeholders for Industry Canada, and so, Industry Canada was like, 'We're not going to make any change to something that's going to kill off our fledgling biotech industry'. (Drouillard, p. 9)

Going on to clarify, Drouillard said:

> There was a lot of common cause between that small biotech industry and big name pharma … which has a huge voice …. Industry Canada was so strong … [and] their core stakeholders, both within the pharma industry and the biotech industry, were so fundamentally against any shift. (Drouillard, pp. 9, 13)

According to this informant, Industry Canada was approached by Ontario in those early days about Myriad's alleged patent rights abuse, seeking federal intervention in Canadian health research and care. As stewards of health care, the Ontario Ministry of Health was pursuing federal government intervention to deal with concerns around access to the patented tests. As stewards of the patent

[86] Scotchmer S, "Standing on the shoulders of giants: Cumulative research and patent law" (1991) 5 J of Economic Perspectives 29, 30.

system, despite concerns raised by Ontario's health policy unit, Industry Canada hesitated due to insufficient evidence of negative consequences from biotechnology firms' patent monopolies on genetic health products. (Informant 10, p. 11).

Industry Canada declined to amend the *Patent Act* regarding the Myriad controversy, fearing it could limit patent-holder rights without sufficient evidence. They noted that concerns about patented genetic tests were largely one-sided, as no other province, territory, or biotechnology industry members raised issues with them. As one former Industry Canada informant noted, "Absolutely no one came to us to complain about that" (Informant 10, p. 5). Industry Canada's concern was that changing patenting practices without a clear understanding of their impact on health research and care delivery might inadvertently hinder innovation. According to Informant 10, the current patent system balanced private and public interests adequately but acknowledged the need for mechanisms to address any imbalance:

> To cut to the chase, the *Patent Act* is a balance … We do try to strike a policy balance … That's why we have "the early working exemption" that allows generics to use brand name drug products so they can receive approval as soon as the patent expires … So, that's an example of a balanced approach … Another example is that we have the PMPRB [Patented Medicines Prices Review Board]. (Informant 10, p. 1)

The informant discussed Industry Canada and Ontario's health policy unit's talks on the Myriad BRCA patents, focusing on Ontario's worries about access to patented genetic materials and tests in public health research and care. They stressed the need for a deeper understanding of the patent system. While patent policy backs socially beneficial inventions, the informant emphasized its crucial support for private enterprise. They warned that without this support, Canadian industries, sectors, and society would all suffer:

> We produce useful innovations … overall useful to society … You're [non-industry actors] not investing in them so they otherwise wouldn't happen. You expect us [government] to pay for it. The only mechanism we have is through the sale of those technologies, and they

> can easily be copied once on the market … So, unless we have protection, we're not going to do it, and society is the overall loser. (Informant 10, p. 6)

It is clear that the right to exclude is critical to the perspective offered by Informant 10, with calls for ever-stronger patent rights having contributed to what some commentators consider a necessarily "pro-patent environment",[87] and with the role of the patent system increasingly shifting towards a broader expectation to incentivize innovation.[88]

In practice, a one-size-fits-all patent policy framework may not be Canada's primary challenge. Instead, policymakers grapple with determining which privately-held public goods, made possible only through patents, garner enough private interest to justify exclusivity while still producing socially valuable outcomes. In essence, the challenge lies in making exclusive offerings inclusive. The complexity of policy discussions, involvement of multiple government departments with differing views, and strained collaboration contribute to Canada's struggle to achieve coherent policy on human gene patents. Furthermore, pressure from gene patents and limited budgets perpetuate the prevalence of "wicked issues"[89] at the intersection of patents and health.

The ambiguity in U.S. gene patent law, stemming from key legal decisions and evolving patent office practices, poses a significant challenge. This uncertainty threatens to deter investment in bioscience,[90] impacting both U.S. and Canadian industries. However, Canada could potentially benefit from the situation by reducing health care costs through easier access to research tools and

[87] Mosoff A, "Exclusion and exclusive use in patent law" (2009) 22(2) Harvard J. of L. & Tech. 321.
[88] FTC 2003, *supra note* 74. Also, see generally, FTC 2011, *supra note* **2**.
[89] Petticrew M et al., "Better evidence of wicked issues in tracking health inequalities" (2009) 31(3) J. Public Health 453, 454 (author describes the intersection of IP and public health as a "wicked issue" and as "a problem that is complex, difficult to define, with no immediate solution, and one where every wicked problem can be considered to be a symptom of another problem").
[90] After recent USSC decisions, a commentator has called for Congress to amend patent laws to tackle usage uncertainties. See, Taylor D, "Confusing patent eligibility" (2016) 82 Tenn L. Rev. 157.

testing.[91] Yet, this advantage may not last, especially with proposed changes like the U.S. Senate bill aiming to reverse *Myriad*.[92] The important features of patents as offering incentives to innovate may lie in the fact that patent rights provide a degree of confidence in industry investment. Industry could exploit the implication from *Myriad* that the drafting of patent claims may influence their validity.[93] Instances of patents being granted for nucleic acids with slight variations from their natural forms indicate that companies may be achieving success through strategic claim construction for gene-based inventions.[94]

Over time, the patent system has shifted towards a regulatory approach rather than a mechanism for balancing social costs. This "regulatory turn in IP" has turned the patent system into a "Mother, may I?" regime, a bureaucratic obstacle, hindering innovation and market access.[95] The conflation of economic and health objectives in patent policy raises concerns about balancing private and public interests — "which right will prevail if the balance (or the illusion thereof) can no longer be convincingly maintained?".[96] This tension, particularly in health care,[97] calls for coordinated

[91] Mead K, "Gene patents in Australia: A game theory approach" (2013) 22 Pac Rim L & Policy J. 751 at 774. See also: Sichelman T, Graham S, "Patenting by entrepreneurs: An empirical study" (2010) 17 Mich Telecomm & Tech L Rev. 111 at 158; Hopkins M, Hogarth S, "Biomarker patents for diagnostics: Problem or solution?" (2012) 30 Nat. Biotechnol. 498, 499; Hall B, Harhoff D, "Recent research on the economics of patents" (2012) 4 Annual Rev. of Economics 541. And, Holman C, "The critical role of patents in the development, commercialization and utilization of innovative genetic diagnostic tests and personalized medicine" (2015) 21(2) Boston Univ J. of Science and Technology Law 297 at 307.
[92] The *Patent Eligibility Restoration Act of 2022* was introduced by Senator Thom Tillis (R_NC). If enacted into law, it would enable a reversal of the decision in *Myriad* and nearly a decade of subsequent legal developments.
[93] *Association for Molecular Pathology v. Myriad Genetics* (2013) 569 U.S. 576 [*Myriad* USSC] at 2118 (suggesting a different outcome if the claims focused on "chemical composition" instead of genetic information in isolated BRCA genes).
[94] Aboy M, Liddell K, Liddicoat J, et al., "After *Myriad*, what type of claim amendments change a patent ineligible isolated gene claim into an eligible patent claim that is 'markedly different' from nature?" (2018) 35 Nat. Biotechnol. 820.
[95] See, Lemley, *supra note* 76.
[96] Craig C, "The evolution of the originality in Canadian copyright law: Authorship, reward and the public interest" (2005) 2(2) University of Ottawa L. & Tech. 424 at 440.
[97] Charting New Territory, *supra note* 37. See also, CBAC 2006, *supra note* 79.

policies to support innovation and public health (Hawkins, p. 22).[98] This includes reflecting on how research is undertaken and how we facilitate the transfer of scientific knowledge to health care and translate its economic value. These questions must be central to how we conceptualize and develop public policies and governance concerning human gene patents.

1.2 Thesis Outline

This thesis is composed of four core sections. This introduction constitutes Chapter 1. Each of the core chapters – Chapters 2 to 5 – is both descriptive and analytical. Chapter 6 offers a conclusion and contemplates ways forward.

In Chapter 2, I consider what patent policy is at its most basic level and as it applies to human gene-based invention. The chapter begins with a commentary around how patents have been defined by their roles in shaping society (such as through innovation, industry, and human genetics) and that solving the policy conflicts associated with human gene patents has often amounted to a 'centricity' and 'one-size-fits-all' approach of the patent system to deal with those problems. In this chapter, I argue that while the 'one-size-fits-all' approach of the patent system may maximize innovation and the public good in many fields, it is unlikely to do the same for genetics health research and care in Canada. I conclude this chapter by asserting that where patent policy fails to meet its goal to conflate the economic and priority health objectives of society as a whole, greater consideration of non-economic reasons — reasons external to the patent system —

[98] See, e.g., concerns laid out in, Borden Ladner Gervais (BLG) "CIPO's examination guidelines for medical diagnostics turns three," online: <https://blg.com/en/News-And-Publications/Documents/CIPO-Examination-Guidelines_1033.pdf> (addressing concerns about CIPO's recent policymaking within Industry, Science, and Economic Development). See also, BLG "CIPO's examination guidelines for med diagnostics turns three," online: <https://blg.com/en/News-And-Publications/Documents/CIPO-Examination-Guidelines_1033.pdf>. And, CIHR, and its CDN$2.5 million funding "Antimicrobial Resistance: Point of Care Diagnostics in Human Health," online: <http://www.cihr-irsc.gc.ca/e/50815.html>.

must be given to flesh out the question of why, as a society, we use human genetic materials and want access to genetic tests in the first place. This assertion is maintained throughout Chapters 2-5, particularly in respect of how research is undertaken, how we facilitate the transfer of scientific knowledge to health care and translate its economic value.

Chapter 3 examines patents as an inter-sectoral issue in science and considers the issues that IP rights, in their current form, raise for the pursuit of scientific endeavour and a right to access the benefits of scientific research. This chapter argues that given the cumulative nature of scientific pursuit, the one-size-fits-all paradigm of the patent system generates uncertainty: uncertainty for various professionals (i.e., academic researchers, health care experts, those in biotechnology), uncertainty for government to enable fair and equitable access to what may be considered some of the most needed advances in the health research and care sectors, and uncertainty for the evolution of scientific endeavour to the benefit of knowledge production and for patients in need of genetic innovations. In this chapter I conclude that an institutional "alternative to intellectual property approach" to controlling access to scientific knowledge is worth considering (i.e., long-standing university modes of engagement like publications and reward-based systems) where knowledge does not rely solely on the economic reward system of the market. Here, I join other calls in the legal scholarship for a restructuring of academic-industry relations, particularly in early or upstream scientific research, around collaborations in R&D rather than IP. I argue that one way for governments to both support their innovation agenda and maximize the impact of research directly in fields of biological study (such as genetics) and further downstream in its use and application (such as in health care) is to consider using tools, other than patent law, already in their policy toolkit (such as direct R&D spending through grants and contracts) that can support cross-

sectoral collaborations (i.e. between academia, industry, government, patient groups) in the early stages of R&D in particular (such as with open science partnerships).

Chapter 4 describes the Ontario health policy landscape with respect to genetic tests and testing services and how this has interplayed with Canada's human gene patent debate. This chapter considers persistent health care sector concerns that patents create stumbling blocks for patients seeking to access high-demand tests and reflects on the limited consideration currently given to health-in-all-policies frameworks,[99] and a health care lens-informed perspective, in policymaking. This chapter urges that a perspective on appropriate human genetic research and gene-based health technology use external to the patent-centric, "patent-or-bust" paradigm, needs to be considered. I sought to do this by arguing that there needs to be a shift from the current 'patent paradigm' for finding solutions in the human gene patent debate. In this chapter, I conclude that this shift needs to include a re-imagination of what constitutes the public domain and a broadening of scientific and expert contribution at the public-private divide around appropriate use of human genetic materials and an exploration of how best, or sometimes when, to consider non-market values as they relate to patented genetic health invention. The chapter encourages more careful consideration of the question of why, as a society, we use human genetic materials to improve health and well-being.

Chapter 5 explores patents as representing an intersectoral issue in health that fully exposes the public-private divide in the IP debates — a divide traditionally characterized as an adversarial 'patents-versus-patients' opposition, presenting a binary choice between a stronger economy or a healthier society — and explores the argument that the right to good health is inherently at odds

[99] Rigby E, Hatch ME, "Economic policy as health policy," Public Health Post, 13 March 2017 <https://www.publichealthpost.org/research/economic-policy-health-policy/> (date accessed: 14 March 2019).

with rights attached to IP. The chapter reasons that, as an intersectoral issue, addressing the problems that gene patents raise for health research and care will require a multidisciplinary, coordinated approach, one that is not premised on what the patent system alone has to offer. In this chapter, I explore implications of the lack of empirical data and jurisdictional challenges on the normative tension between patents and health – between the right to health and the rights vested in IP - that suggests that market mechanisms, such as IP rights, are reaching their limits and how privileging private interests and IP rules over publicly-supported health has led to unintended consequences of limiting the responses of policymakers to concerns around access to patented invention. But I also consider this tension as a complementary one, such that the limits of patent law can be at least partially compensated by policy options that set out to satisfy the health improvement objectives of health and patent policy under, for instance, a health-policy-in-all-policies approach. I conclude that by including health policy alongside considerations in patenting policy, the underlying data gap problem could be addressed, knowledge and expertise around appropriate policy impacting access to health care in Canada could be developed, and real-world domestic evidence relating to the impact of patents on patient care could be collected and shared.

Each of the four core chapters deals with factors that set out and review the relevant common law jurisprudence to better understand the status of gene and test patents and competing policy challenges in the Canadian gene patent controversy. Factors were chosen based on a review of the selected documents (academic literature, non-academic reporting, government reports), legal analysis (legislation, case law), and data provided by key informant interviews. The particular focus of the information collected is on the narrative of the human gene patent controversy in Ontario as it unfolded between the years of 1999–2016. Each core chapter includes analysis divided into “the what” and the “the why” (see Appendix A) and data from semi-constructed

interviews with individuals who have at one time or another contributed to discussions and debates concerning human gene patents in respect of Canadian health research or care, the latter of these receiving greater focus in this study. The case studies of Myriad Genetics' BRCA patents (Myriad) and of the Transgenomic Inc. long QT Syndrome (LQTS) patents are the primary case examples used to unify elements throughout the thesis. This thesis has two pragmatic concerns — can anyone, but especially those who need it the most, access a patented genetic technology to better inform them of their health and what are those who are responsible to make that happen doing about it?

This thesis also attempts in part to answer the research question "What are the tensions being manifested in the Canadian human gene patent controversy?" and to identify possible solutions for improving equitable access to patented human gene-based inventions in public health research and in the health care sector where commercialization has presented challenges. These chapters together suggest that the gene patent debate should not be dominated by property discourse alone, that obsessions about stronger-versus-weaker patent rights and regurgitations about an unresolvable discord between the right to health and the rights vested in IP need to stop. Let us instead normalize the normative tension between health and patents and understand their relationship as a complementary one that merits less attention on their disparity and more on their shared agenda of benefitting or serving the well-being of the public.

Pulled together, this study, along with others discussed throughout this work, underscores a need for experts, cooperation, and state action. This thesis draws four main conclusions about the problem of gene patents in Canada. The first is that the patents create uncertainty around patient access to information and invention in Canada's publicly-provided genetics health research and

care. Here, I argue that the jurisprudence shows a divergence in the law governing the status of gene patents within the broader Canadian policy context, where patent policy is often pitted against health policy, and the lack of coherent policy for gene patent regulation contributes uncertainty around access. The second conclusion in this thesis identifies the need to construct a more comprehensive policy on gene patent regulation and calls for amassing expertise to permit better genetics health policy development. Thirdly, I conclude that the lack of an administrative body governing health policy deliberation is consistent with a watering down of government policy expertise around gene-based health invention and innovation, exposing a vulnerability in health care governance by federal and provincial health authorities. Finally, I conclude that an interventionist, cooperative government approach to gene patent policy is necessary. Canada should not view the differences of jurisdictional authority and inter-governmental responsibilities over patents and health between provincial and federal departments as acceptable vulnerabilities. Rather, governments should regroup efforts to make optimal use of the best patented developments in genetics health to apply a conjoined approach to patent and health policy coherence. This work supports a growing literature about Canada's response to innovation, access, and to some extent, preparedness in health care.

1.3 Case Studies: Myriad Genetics (BRCA) and Transgenomic, Inc. (LQTS)

This thesis investigates the case of access to patented gene-based invention with a primary focus on the health research and care sectors of Canada's public health system. This study considers how patent and health policy have each factored into the trajectory of the human gene patent debate in Canada, culminating each time in a practical tension between the right to health and the rights associated with patents. This work contributes to the literature that considers the impact of gene-

based patents on health research from an innovation perspective, and on health care with respect to limiting access to genetic materials and tests. This study draws on two of Canada's important biotechnology patent controversies: first, the policy storm that began in Ontario in the late 1990s with Myriad Genetics and its BRCA patents and second, the Federal Court challenge filed in 2014 by Ontario's Children's Hospital of Eastern Ontario (CHEO) against Transgenomic Inc. in relation to its LQTS patents.[100]

1.3.1 Myriad Genetics and the BRCA Patents

The 1980 United States case of *Diamond v. Chakrabarty*[101] made the patenting of biological materials and genes possible. The years that followed saw a surge in DNA-based patents[102] and start-up enterprises leading up to the Human Genome Project, with Myriad Genetics (Myriad) being one of those enterprises.[103] Myriad set out to make a genetic test for hereditary breast/ovarian cancer commercially available after joining the global race to identify the genes that would enable the development and marketing of such a test.[104] Successful in obtaining patents and government agreements around the world, including in Canada,[105] Myriad obtained exclusive rights in conducting tests to predict an individual's lifetime susceptibility to developing breast/ovarian cancer[106] and gained international attention in its exclusive offering of tests and the enforcement of its patents.

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[100] *Children's Hospital of Eastern Ontario v. University of Utah Research Foundation, Genzyme Genetics and Yale University,* 2014 T-2249 14 [*CHEO*].
[101] *Diamond v. Chakrabarty, 447 U.S. 303 (1980) at 303, 309 [Chakrabarty].*
[102] Caulfield and Gold, *supra note* 15. See also, Cook-Deegan RM, McCormack SJ, "Intellectual property: Patents, secrecy, and DNA" (2001) 293 Science 217.
[103] Gold ER, Carbone J, "Myriad Genetics: In the eye of the policy storm" (2010) 12(4) Genetics in Medicine S39.
[104] See, e.g., Bishop DT, Eaton DF, "Preface to the breast cancer linkage consortium papers" (1993) 52 Am J Hum Genet 677.
[105] Myriad Genetics, "Myriad Genetics launces molecular genetic testing in Canada — MDS Laboratory Services to provide BRCAnalysis throughout Canada," Press Release 9 March 2000.
[106] Gold and Carbone, *supra note* 103 at S43.

Myriad received wide criticism directed at its ownership over human-derived genetic material and at its enforcement of patent rights, the extent of which has been revealed in lawsuits concerning BRCA testing in the U.S.[107] and Australia.[108] At their core, the criticisms of Myriad ownership and patent practices were about the implications of patents for scientific knowledge and discovery, public health care, and access to medical services. For instance, common arguments advocated for adequate access to new knowledge for health research, care and patients. Arguments included challenges around patent-related issues of access to the BRCA tests because such gene-based inventions fell into one or more judicially-created exceptions,[109] were unfairly removed from the public domain and thus proved contrary to public interest,[110] and that using patents to promote innovation in the field of genetics was unnecessary[111] or inhibitory.[112] Altogether, Myriad's use of its patented genetic tests drove concerns that there would be a lack of access to academic research tools by researchers[113] and to primary testing by the clinical community and patients.[114] The controversy around Myriad served as a precursor to identifying situations in which patent policy could contribute to a failure in a public system of delivery of inventions intended to improve health, because gene patents grant monopolies over the development and commercialization of genetic tests that can dictate what access to those tests look like.

By 2000, Myriad had successfully enforced its BRCA patents in Canada through its agreement with the Canadian-based test provider MDS Laboratory Services, with MDS having been granted

[107] *Myriad* USSC, *supra note* 93.
[108] *D'Arcy v. Myriad Genetics 258 CLR 334 (2015) [D'Arcy].*
[109] *Association for Molecular Pathology v. USPTO, Case No. 9-CV-4515 (S.D.N.Y. 2010) [Myriad S.D.N.Y.]* at 23.
[110] *Id.,* at 20.
[111] *Id.,* at 17.
[112] *Id.,* at 19.
[113] McHugh A, "Invalidating gene patents: Association for Molecular Pathology vs US Patent and Trademark Office" (2010–2011) 62 Hastings L. J. 184. See also, Gold and Carbone, *supra note* 103 at S44.
[114] *Id.,* at 196 (author reports some low-cost tests discontinued once Myriad enforced its patent rights). See also, *Myriad* S.D.N.Y., *supra note* 109 at 9, 10. Also refer to, SACGHS, *supra note* 3, at 2, 33, 40, 43, 79, 90.

exclusive right to offer the BRCAnalysis test.[115] Then, as is now, private purchase of genetic testing was available, but with some commercial genetic tests, access depends upon a willingness to pay for it, and in cases where Canadians seek testing provided from abroad, a willingness to wait for results. In 2001, Myriad's efforts to enforce its patents in several provinces[116] ignited strong opposition in connection with issues of justice around universal and equitable access to the health care and its challenge to the overall governance of public health relating to new or emerging genetic health technologies.[117] Eventually, Myriad abandoned its efforts to enforce its BRCA patents in Canada, but the lack of a formal government policy response to human gene patents left an unmet opportunity to bring clarification to the test provision landscape with respect to certain high-demand genetic tests. The lack of a coherent policy response by federal and provincial governments also left the Myriad controversy as a vestige harbinger of the policy development and access issues that would resurface with respect to the use of gene patents in the Canadian public health care sector in particular.

Myriad thereby serves as a useful example through which to understand the challenges that human gene patents have created in the Canadian public health research and care space. The focus of the legal and policy issues associated with the commercialization of genetic tests afforded by the patenting of human genes will be confined to one provincial jurisdiction, but with an integral consideration of provincial and federal jurisdictional divisions around the authority over patents and health care. Consequently, while a trans-national comparison would be useful, it is beyond the

[115] Myriad Genetics, "Myriad Genetics launces molecular genetic testing in Canada — MDS Laboratory Services to provide BRCAnalysis throughout Canada," Press Release 9 March 2000.
[116] For an excellent review of events see generally, Gold and Carbone, *supra note* 103.
[117] Canada Press, "Ontario defies U.S. gene company over cancer test, arguing health care at risk" Excite News, 19 September 2001. Also, Eggerston L, "Ontario defies US firm's genetic patent, continues cancer screening" (2002) 166 Canadian Medical Association J 494.

scope of this dissertation, and the discussion will be localized to how the controversy unfolded in the province of Ontario.

1.3.2 Transgenomic Inc. and the LQTS Patents

The long QT Syndrome (LQTS), indicative of an inherited heart abnormality associated with palpitations, irregular heart beats, and sudden death in otherwise healthy individuals,[118] has a population incidence of 1:2000–1:2500.[119] Prior to local testing or repatriation efforts in 2010, Canadian hospitals seeking to test for LQTS outsourced to testing facilities in the U.S. at a cost of approximately USD$4,500 per test. The Children's Hospital of Eastern Ontario (CHEO) was one of the hospitals that received funding for medically necessary services not available domestically with respect to LQTS-related testing.[120] By 2009, in Ontario, the province's 19 licensed clinical genetic test laboratories together had a less than 15 per cent testing capacity for all "clinically actionable" genetic tests for Ontario patients.[121] The MOH sought to decrease the demand of test outsourcing expenses and proposed to "repatriate" tests that were unavailable domestically (i.e., to develop local testing capacity within public testing laboratories) and the LQTS genetic test was included in the list of tests for repatriation.[122] But by 2013, citing problems in having to deal with patents, the province's approach to gene testing changed. This launched another round of

[118] Kramer DB, Zimetbaum PJ, "Long-QT syndrome" (2011) 19 Cardiol. Rev. 217.
[119] Schwartz PJ, Stramba-Badiale M, Crotti L et al., "Prevalence of the congenital Long-QT syndrome" (2009) 120 Circulation 1761. See also, Genetics Education Canada, *Long QT syndrome*, online: <https://geneticseducation.ca/educational-resources/gec-ko-on-the-run/long-qt-syndrome/>.
[120] Krahn A. *Ottawa Heart Institute: Genes in long-QT syndrome*, 2006, online: <https://www.sads.ca/wp-content/uploads/2020/05/Genes-lqts.pdf>.
[121] Allingham-Hawkins D, Casey B, Chitayat D, et al., "A project to establish a quality management program for repatriated genetic testing laboratories in Ontario, Canada." 2010. American College of Medical Genetics (poster presentation).
[122] Ali Khan SE, Gold ER, "Gene patents still alive and kicking: Their impact on provision of genetic testing for long QT syndrome in the Canadian public health-care system" (2017) 19(11) Genetics in Medicine 1253 at 1255.

repatriation attempts for the LQTS test, except this time, requesting institutions wishing to provide the test were left to deal with the patents themselves.[123]

In 2014, CHEO filed a Statement of Claim with the Federal Court of Canada against the University of Utah, Genzyme Genetics, and Yale University over its ability to test for the genetic mutations associated with LQTS.[124] The Statement of Claim sought a challenge of any infringement relating to the five Canadian LQTS patent claims, including of the next-generation sequencing tests used to determine a predisposition to long QT, and of patent validity on claims to the nucleic acid sequences. CHEO also sought declaration of a public non-commercial use of the long QT gene and test patents under *section 19.1(2)* of the Canadian *Patent Act*, empowering the patent office with discretion over a patented invention's use through the federal or a provincial government.[125] The hospital settled out of court with the single defendant in the case, who had acquired the Canadian patents in 2015, U.S.-based Transgenomic Inc.[126] The "CHEO agreement"[127] established extended licensing to LQTS testing services conducted by CHEO and by any other Canadian public laboratory on a non-commercial, not-for-profit basis (i.e., use is at-cost or less). A notable feature of the agreement is its extension to third party use and its provision of a path to compulsory licensing measures.[128]

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[123] *Id.,* at 1256.
[124] *Children's Hospital of Eastern Ontario v. University of Utah Research Foundation, Genzyme Genetics and Yale University* (Federal Court), T-2249-19, 3 November 2014, online: <http://cdn.arstechnica.net/wp-content/uploads/2014/11/CHEO.complaint.pdf> [CHEO Statement of Claim].
[125] *Patent Act, RSC 1985, cP-4, s. 19(4) [Canada Patent Act]*.
[126] *Children's Hospital of Eastern Ontario v. University of Utah Research Foundation, Genzyme Genetics and Yale University* (Federal Court), T-2249-14, Notice of Assignment of Interest and Affidavit of Todd Schneider. 27 April 2015.
[127] Public Health Access Agreement in respect of Long QT Gene Patents. See, online: <https://www.cheo.on.ca/en/clinics-services-programs/resources/Documents/Genetics/Gene-Patent-Challenge/CHEO-Transgenomic-Settlement-Agreement-Signed-2016-03-08.pdf> (last accessed 22 January 2021).
[128] See, Melnitzer J, "Canadian patent settlement sets model for not-for-profit gene testing," Financial Post, 12 April 2012. See, online: <https://financialpost.com/legal-post/canadian-patent-settlement-sets-model-for-not-for-profit-gene-testing> (last accessed 22 January 2021).

Several implications of the settlement have been reflected upon in the literature, including a resulting reduction in health care system costs,[129] its opportunity of encouraging Canadian innovation in the fields of biomedical R&D,[130] or for eliciting a completely opposite effect in those fields.[131] Particularly notable is the CHEO settlement's purposeful address as a matter of public interest with respect to what equitable access to gene-based patented invention can look like in Canada. Meanwhile, patents continue to be granted in Canada on genetic inventions for diagnosis and treatment of heart disease (and of cancer), falling out of step with its sister jurisdictions of the U.S. and Australia following a series of courts decisions invalidating patents on the basis of claims over a law of nature,[132] natural product,[133] or abstract idea.[134] The CHEO agreement remains free to be taken up by the public health and clinical care communities to gain access to patented genetic tests for non-commercial, non-research purposes (i.e., patient testing).

1.4 Research Methodology

This dissertation employed three research methods: (1) document review of academic literature, non-academic reporting, and government reports; (2) legal analysis of Canadian patent legislation, case law; and (3) key informant interviews. These approaches were integrated to provide a comprehensive examination of the normative tension surrounding Canadian gene patents,

[129] Brown J, "CHEO reaches 'groundbreaking' settlement with gene patent owner," Canadian Lawyer Magazine, 21 March 2016, online: <https://www.canadianlawyermag.com/practice-areas/intellectual-property/cheo-reaches-groundbreaking-settlement-with-gene-patent-owner/270096>.
[130] Gold R, "New genetic testing deal could spur major research breakthroughs," Health Debate Opinions, 18 May 2016. See, online (last accessed 22 January 2021): <https://healthydebate.ca/opinions/cheo-genetic-testing-agreement>.
[131] Courage N, "Gene patents remain valid in Canada," Bereskin & Parr LLP, 10 March 2016, online: <https://www.bereskinparr.com/doc/gene-patents-remain-valid-in-canada>.
[132] *Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012) [Mayo]*; *Ariosa Diagnostics Inc. v. Sequenom* 788 F.3d 1371 (Fed. Cir. 2015).
[133] *Myriad* USSC, *supra note* 93; *D'Arcy*, *supra note* 108.
[134] *Alice, supra note* 41.

particularly in two Ontario controversies. This section outlines each method and its rationale for inclusion in this study.

In this work I avoid delving deeply into the economic debates surrounding human gene patenting and the varying strengths of patent rights. Instead, I propose a different approach for the Canadian context, suggesting a broader perspective beyond traditional narratives of the gene patent issue. Rather than viewing patents and health policies as conflicting, I propose considering how they can complement each other toward maximizing public benefit. This entails balancing the need to incentivize innovation through patents while ensuring open access to genetic health technology. This study maintains a focus on this delicate balance throughout (see Appendix B).

1.4.1 Document Review

For this research, I surveyed diverse academic and non-academic literature from Canada and abroad on gene patents, including articles from law, policy, and science fields, as well as recent press and business reports. Only publicly available documents were considered to construct a chronological framework, revealing two notable phases of activity in the gene patent debate in Canada. The first phase, from 1999 to 2004 (with a resurgence in 2007), was sparked by Myriad's BRCA patents, while the second phase began in 2014 following the CHEO Federal Court challenge. This study heavily relied on the insights from the Ontario Ministry of Health and Long-Term Care (MOH) 2001 report, *Charting New Territory in Healthcare*,[135] which illuminated key policy challenges in Canada's public health research and care. By contextualizing legal analysis

[135] Charting New Territory, *supra note* 37.

within this chronology and government reports, the study offers an informed, "law in context",[136] approach to a significant Canadian societal issue.

The document review also identified potential informants (see Appendix C) engaged in policy discussions on human gene patents in Ontario and at the federal level. This review occurred during the preliminary research phase. I undertook review of government documents during the exploratory stage of my research, thus its purpose was introductive and inductive.[137] For example, the *Charting New Territory* report and reports from the federally-appointed Canadian Biotechnology Advisory Committee (CBAC) highlight policy considerations on patented human gene-based inventions still relevant today across various government departments. To address these consideration, I examined published reports and key documents from federal standing committees, including evidence transcripts and reports outlining recommendations to the House of Commons. Additionally, I explored online publications from the Ontario government and legislative libraries covering the periods of 1995-2017 (federal) and 1999-2017 (Ontario). To be certain that I was searching reliable and relevant online sites in the province, I contacted the Metadata Services in the Ontario Information Services department. I primarily searched the Ontario Legislature debates and proceedings (House Hansard search), ministry reports, and their publications (GALLOP).

I reviewed documents for background information and to identify potential informants for my research. I also reviewed them to grasp recent discussions on gene patents following the 2016

[136] Emphasizing real-world occurrences over a strict adherence to legal doctrine, as opposed to a "black letter law" approach centered on statutes and court decisions. See, for e.g., Chui WH, McConville M, "Introduction and Overview" in MConville M, Chui WH (eds.), *Research Methods for Law, 2nd edition* (Edinburgh: Edinburgh University Press, 2017) 1.
[137] Bernard RH, *Social Research Methods: Qualitative and Quantitative Approaches, 2nd ed*. (Los Angeles: SAGE Publications, 2013) (author distinguishes inductive research as utilized during information and data recovery, differing from deductive methods typically employed in drawing conclusions).

CHEO case and to determine if comparable discussions were ongoing within government departments. Appendix D includes the list of federal and provincial documents I reviewed, along with the keywords I used to locate them.

Furthermore, I examined government documents for expert-advised policy directions on gene-based patents, especially concerning access to publicly-funded health research and care. Policy documents were used to identify tension or "wicked issues"[138] of policy pertaining to patents as an intersectoral issue in health.

1.4.2 Legal Analysis

This dissertation draws on insights external to legal scholarship (i.e., from the fields of S&T studies) to examine the conflict between patent and health policies in Canada's gene patent debate. While primarily grounded in legal analysis, it also explores broader concepts of law, particularly in the context of how governments implement policies affecting health innovation and care. In Canada, the regulation of patented human gene-based health technology lacks a dedicated statute, with existing laws like the *Assisted Human Reproduction Act*[139] indirectly addressing genetic materials for reproductive purposes. Furthermore, jurisdiction over health care and patents is split between federal and provincial governments, with authority dispersed across various departments. This division arises from the Canadian Constitution, granting provinces powers over hospitals and local matters.

[138] Petticrew et al., *supra note* 89.
[139] *AHRA*, S.C. 2004, c.2.

This study employed doctrinal research to examine legislation related to the patentability and access to human genetic sequences and tests in public health research and care.[140] Analysis involved studying statutes, court judgments, and academic literature, including key federal laws such as the Canada *Patent Act*,[141] and the *Canada Health Act*.[142] While Canadian jurisprudence lacks specific rulings on the accessibility of patented human gene-based technologies, the Supreme Court of Canada (SCC) has acknowledged *Charter* rights concerning timely access to health care. This study reflects on how common law and constitutional principles influence gene patent access within Canada's public health systems.

To pinpoint regulations affecting the accessibility of genetic tests for Canadians, I examined governmental web content at both federal and provincial levels. Federal regulations classify genetic tests as class III medical devices through its *Medical Devices Regulations*[143] under the *Food and Drugs Act*,[144] primarily focusing on safety and efficacy rather than access. Responsibility for test provision and accessibility lies with the provinces. I further explored academic literature and Ontario Ministry of Health materials to identify relevant statutes and regulations governing test accessibility. This aimed to determine decision-making responsibilities and ensure equitable delivery of genetic tests within the province, including any formal government frameworks or public bodies involved in facilitating access.

[140] Chui and McConville, *supra note* 136 at 3, 4. See also, Dobson I, John F, "Qualitative Legal Research" in in McConville M, Chui H (eds.), Research Methods for Law, 2nd ed. (Edinburgh: Edinburgh University Press Ltd., 2017) 18 at 21, 22.
[141] *Canada Patent Act*, *supra note* 125.
[142] *Canada Health Act*, R.S.C., 1985, c. C-6 [*Canada Health Act*].
[143] *Medical Devices Regulations*, SOR/98-282 (rule 4b) (Canada).
[144] *Food and Drugs Act,* R.S.C., 1985, c. F-27 (Canada).

1.4.2.1 Federal Authority and Legislation

Refer to the following appendices for a methodological framework used in this thesis relating to: patent policy (Appendix E), constitutional principles and granted authority of patents and health (Appendix F), and provincial authority as focused on Ontario (Appendix G).

1.4.2.2 Case Law

My research addresses the challenges of treating human genetic materials as patentable assets. While I provide an overview of the case law, my focus is not on disputing the patentability of genetic material itself. Instead, in Chapters 2 to 5, I question how patent system rules, like technology neutrality and exclusivity, can complicate access to patented gene-based invention in research and care, and explore policy responses to these challenges.

In addition to my two case studies, I examined judgement, documentation, and scholarly literature on prominent legal cases linking patents and health. These cases shed light on key legal and policy issues in the human gene patent debate, particularly those influencing Canadian discussions. For instance, analyzing *Mayo* offers judicial interpretations of the patent system's balance between granting exclusivity to holders and ensuring access to inventions. For another, the Harvard case before the Canadian Supreme Court examines patent eligibility for higher life forms, with various implications for the human gene patent debate, including the problem of industry's reliance on patents as incentives to innovate, patent eligibility in respect of life-derived material, and the role of government in these debates.[145]

[145] *Harvard, supra note* 35.

A close review of well-known cases from other jurisdictions, particularly of the case law surrounding Myriad's BRCA patents in the U.S.[146] and in Australia,[147] adds a comparative dimension to this study. I reviewed the jurisprudence on the justification of patents,[148] patent eligibility,[149] and the patent balance.[150]

1.4.3 Key Informant Interviews

In my research's final phase, I conducted key informant interviews in semi-constructed format, spanning Chapters 2-5.151 Key informants possessed unique insights inaccessible through printed sources,152 identified through purposive and snowball sampling methods. Although challenging to access, efforts were made to ensure diverse representation.153 Interviews targeted individuals with specialized knowledge relevant to the study's themes using non-probability techniques.154 The study was approved by York University's Human Participants Review Sub-Committee (STU 2015-043) from 11/09/208-11/09/2019.

Informants were selected through diverse methods. Using a chronology developed in the early research phase, I identified key periods in the Canadian gene patent narrative: pre- and pos-Myriad BRCA patents controversy (1999 to around 2007) and developments surrounding the

[146] *Myriad S.D.N.Y., supra note* 109. See also, *Association for Molecular Pathology v. USPTO*, 702 F. Suppl. 2d 181 (Fed. Cir. 2011) [*Myriad* FedCir].
[147] *D'Arcy, supra note* 108.
[148] For e.g., see *Wellcome, supra note* 8 ("The grant of a patent is in the nature of a bargain between the inventor on the one hand and the Crown, representing the public, on the other hand."). See also, *Teva, supra note* 9 ("The patent system is based on a 'bargain', or quid pro quo … This is the basic policy rationale underlying the *Act*.").
[149] For e.g.: *Chakrabarty*, *supra note* 101; *Harvard*, *supra note 35* ("I agree that the definition of 'invention' in the *Patent Act* is broad."); *Monsanto*, *supra note* 35 ("Our task, however, is to interpret and apply the *Patent Act* as it stands, in accordance with settled principles."); *Mayo, supra note* 132.
[150] For e.g.: *Moore*; *supra note* 35; *Bilski v. Kappos*, 130 S. Ct. 3218 (2010) at 3225 [*Bilski*]; *Harvard, supra note 35*; *Mayo, id.*
[151] Gilchrist VJ, Williams RL, "Key informant interviews" in Crabtree BF, Miller WL (eds.), *Doing Qualitative Research, 2nd edition* (Thousand Oaks, California: SAGE Publications, 1999) 71.
[152] *Id.,* at 72.
[153] *Id.,* at 75, 76.
[154] *Id.,* at 76, 77.

Transgenomic LQTS patents (2010-2017). Informants involved in discussions on gene patents during these periods were targeted. Their identification relied on contributions to publicly available documents, relevant legal and policy academic literature, and bibliographic content.

Some informants were referred by others with whom they had collaborated on gene-based technologies for the purposes of health research and/or care. Seeking to enhance data comprehensiveness and enrich thematic development, additional informants were approached to gain insight into patent and health contexts relevant to policy issues, particularly concerning patented genetic tests. For instance, individuals knowledgeable about innovation in Canada or health technology uptake were consulted for their expertise in equitable health care delivery. These informants have been actively engaged in roundtable discussions, consultations, government advisory groups, or ongoing efforts related to human gene patents in public health research or health care. This study consulted a diverse group of informants, including:

- research scientists,
- a genetic counsellor,
- genetic and health researchers,
- scholars in law, ethics, political economy, medicine,
- representatives from government, including the Ministry of Health (MOH), Ontario Ministry of Economic Development and Trade (MED, currently Ontario Ministry of Economic Development, Job Creation and Trade), Health Canada, Industry Canada (presented in the text as such, but currently known as Innovation, Science and Economic Development), the Organization for Economic Co-Operation and Development (OECD), and
- representatives from the genetic test and biotechnology sector (i.e., a trade association).

I invited 34 key informants to participate, 26 of whom were individually interviewed.

The informant pool is diverse, comprising policy researchers, senior government analysts and advisors, and professionals from public and private sectors in health, genetics, and biotechnology. Interviews were conducted across Ontario (19), Quebec (2), Manitoba (1), Alberta (2), British Columbia (1), and the United Kingdom (1). Detailed demographic data were not collected. Thirteen interviews were attributed, and 13 were anonymous. Despite efforts, a direct perspective from the Ontario Ministry of Health (MOH) was unavailable. However, interviews with representatives from Health Quality Ontario's committees on health technology and genetics advisory, along with document reviews, partly compensate for this. Below is a list of interviewed individuals and their positions, with "formerly" indicating their status at the time of their contribution to the gene patent narrative:

Informant	**Description**
1	Genetic counsellor (anonymous)
2	Health policy and strategy consultant (formerly) (anonymous)
3	Fiona Miller, Professor, Chair in Health Management Strategies, University of Toronto; Member, Ontario Genetic Testing Advisory Committee (OGAC), MOH
4	Bill Mantel, Director of the Life Sciences and Technology Branch, Ontario Ministry of Research and Innovation/MED (formerly)
5	Hasan Hutchinson, Senior Policy Advisor, Health Policy & Communications Branch, Health Canada (formerly)
6	Medical geneticist; Employee, Canadian private laboratory provider service (anonymous)
7	Iain Gillespie, Head, Science & Technology Policy Division, Organization for Economic Cooperation and Development (formerly)
8	Clinical geneticist, Ontario hospital (anonymous)
9	Biotechnology industry association representative (formerly) (anonymous)
10	Government of Canada employee (anonymous)
11	Arnold Naimark MD, Chair, Canadian Biotechnology Advisory Committee (formerly)
12	Science policy, Government of Canada (anonymous)
13	Policy Advisor for the Canadian Biotechnology Secretariat (anonymous)
14	Patent examiner, Canadian Intellectual Property Office (anonymous)
15	Clinical scientist, provincial health technology assessment (HTA) committee member (anonymous)

16	Genomics health sciences researcher (anonymous)
17	Joel Lexchin, Professor Emeritus, Health Policy and Management, Faculty of Health, York University.*
18	Health and law policy researcher (anonymous)
19	Wendy Ungar, Senior Scientist, Hospital for Sick Children Research Institute; Professor, University of Toronto; Member, Ontario Health Technology Assessment Committee (OHTAC), MOH; Chair, Ontario Genetics Advisory Committee, MOH; Canada Research Chair in Economic Evaluation and Technology Assessment in Child Health.**
20	Health and biotechnology law and policy researcher (anonymous)
21	Biotechnology industry association representative (formerly) (anonymous)
22	Richard Hawkins, Professor, Science, Technology & Society Program, University of Calgary
23	National and international advisor in the advancement of health and health care (anonymous
24	Richard Gold, James McGill Professor, Faculty of Law, McGill University.; Director, Centre for Intellectual Property Policy
25	Lisa Drouillard, Manager, Human Genetics and Innovation, Health Canada (formerly)
26	Christine Jamieson, Associate Professor, Social and Applied Ethics, Concordia University.

* Roundtable discussant with former Minister of Foreign Affairs Chrystia Freeland relating to IP and NAFTA negotiations.

** The views expressed are my own and do not represent the views of the MOH, the Hospital for Sick Children, the University of Toronto, or any organization or committee with which I am affiliated.

Informants underwent semi-constructed interviews tailored to their expertise, with some overlap to address similar topics. During code and theme development, I noted non-comparable content provided by informants, which I deemed relevant to the project and considered in data analysis for a comprehensive view. Most interview questions were crafted after reviewing documents, literature, and legislation. Prior to interviews, I also examined "grey literature" (i.e. position papers, technical reports) and media reports for background information and public perspective on the policy issues.

Interviews with informants took place between August 2017 and November 2018, and then again in November 2019, conducted in person, over the phone, or via video conference. Duration varied

from 30 minutes to under three hours, with most lasting around 1.5 hours. Prior to interviews, I provided consent letters outlining the purpose and questions, although interviews were conversational rather than scripted. All interviews were audio-recorded with permission, and transcripts were created for coding and analysis. Thematic categorization involved close readings of transcripts (i.e., highlighting, underlining, asterisking, numbering, making side notes), noting important data and connections to research or other informant input (i.e., repeated information or exampled used by informants),[155] aiding in analysis.[156]

The interview transcripts underwent thematic analysis, a method that categorizes, summarizes, and reconstructs qualitative data to capture key concepts.[157] Guided by theory, research literature, and informant input,[158] my analysis primarily relied on scholarly research and interview data. While some these were expected based on generated questions,[159] most emerged empirically,[160] often through repeated findings in literature and interviews.[161] For instance, the theme of "uncertainty" was identified, reflecting its prevalence in academic discussion on patent impact in biotech innovation and public health research. Close examination of interview transcripts supported this theme, particularly regarding the lack of evidence for developing health policy on accessing patented genetic tests. Progressive readings led to detailed memoing, facilitating ideal development, theme identification, and ultimately, drawing conclusions from the data.[162]

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[155] Ryan G, Bernard A, "Techniques to identify themes" (2003) 15(1) Field Methods 85, 89.
[156] Marshall C, Rossman GB, *Designing Qualitative Research* (Thousand Oaks, California: SAGE Publications, 2014) 158.
[157] Aryes L, "Thematic coding and analysis" in Given L (ed.), in Lewis-Beck M, Bryman A, Futing T (eds.), *The SAGE Encyclopedia of Qualitative Research Methods* (Thousand Oaks, California: SAGE Publications, 2008), 868.
[158] Lockyer S, "Coding Qualitative Data" in Lewis-Beck M, Bryman A, Liao TF (eds.), *The SAGE Encyclopedia of Social Science Research Methods* (Thousand Oaks, California: SAGE Publications, 2008), 138.
[159] Aryes, *supra note* 157 at 868.
[160] Ryan and Bernard, *supra note* 155 at 88.
[161] *Id.,* at 89.
[162] Bernard, *supra note* 137 at 530.

To ensure data reliability, I employed a triangulation approach, using multiple data collection methods where feasible.[163] For instance, to comprehend patent reform proposals, I consulted governmental documents, interviewed a political economist, and considered judicial perspectives on patent rights and access to care. Triangulation was facilitated by questioning multiple knowledgeable informants on specific research aspects, such as the context around CHEO's access to patented tests and the settlement impact. Additionally, I searched evidence notes from relevant committees and gathered informant insights to ascertain if discussions reached federal ministerial levels.

[163] Rothbauer PM, "Triangulation" in Given et al., *supra note* 157 at 893.

2 AT THE INTERSECTION OF PATENTS AND SCIENTIFIC PURSUITS

Where patent systems set out to encourage innovation and facilitate access to scientific knowledge, patents are expected to bring the benefits of shared knowledge and access to new goods to society. In return, society affirms the granting of ownership and protection of intellectual goods. Patents granted on human genetic invention are acceptable so long as via the patent system, "[d]isclosure is the *quid pro quo* for valuable proprietary rights to exclusivity which are entirely the statutory creature of the *Patent Act*."[164] In the absence of a clear objective for patent policy in legislation, the inclusion of the disclosure requirement has been broadly accepted within the legal community as the abiding condition set out by the patent system.[165] It is the main qualities of non-rivalry and non-excludability that exemplify a public good[166] that led the Human Genome Organization 2002 Ethics Committee to take the position on primary genomic sequences as global public goods that should be placed into the public domain.[167]

In this chapter, I explore how human genes can be seen as public goods within the context of modern scientific and patent law dynamics. Despite patents aiming to encourage investment into research and in the economic valorization of invention[168] while also share knowledge,[169] they pose challenges for genetic health research.[170] Here, I argue that the patent system's one-size-fits-all

[164] *Wellcome, supra note* 8.
[165] Amani B, *State Agency and the Patenting of Life in International Law: Merchants and Missionaries in a Global Society* (New York: Routledge, 2009).
[166] Kaul I, Grunberg KI, Sterm MA (eds.), *Global Public Goods* (New York: Oxford University Press, 1999).
[167] HUGO Ethics Committee, *Statement on Human Genomic Databases*, London, December 2002, online: <http://www.hugo-international.org/Resources/Documents/CELS_Statement-HumanGenomicDatabase_2002.pdf>.
[168] Nordhaus, *supra note* 24. Also, Kitch *supra note* 24.
[169] Encaoua D et al., "Patent systems for encouraging innovation: lessons from economic analysis" (2006) 35(9) Research Policy 1423.
[170] Patents being a solution to Arrow's so-called double problem. See, Arrow, *supra note* 19. Also, Nordhaus, *supra note* 24.

approach creates uncertainty and hinders scientific progress in health care. Regulatory policies supporting alternatives to patents, alongside market incentives and government efforts, can still promote innovation. With this conclusion, I join other IP scholars and advocate for restructuring academic-industry relations towards collaborative research rather than focusing solely on IP.

2.1 THE WHAT

2.1.1 Academia-Industry Co-Production

Most national innovation surveys since the 1960s suggest that patents play a minimal role in fostering innovation.[171] In Canada, patents are reported to have little to no incentive effects on innovation,[172] with limited evidence supporting the role of patents in economic models of growth (Hawkins, p. 31), challenging their effectiveness.[173] In fact, there is evidence indicating that patents can lead to anti-competitive behavior and hinder innovation.[174] While Canada, like other major patent-granting countries, views patents as crucial for innovation and economic growth, the extent of their impact remains questioned. Several reasons are discussed below, but an overarching justification is that, itself a regulatory framework, patent policy is purposely constructed to encourage private incentives for the production of public goods. In context of the long-established industry-academia collaborative norm, this justification is an important one, particularly in terms of biotechnology patents, but especially with respect to the human gene patent story.

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[171] Levin RC et al., "Appropriating the returns from industrial research and development" (1987) 3(0) Brookings Papers on Economic Activity 783.
[172] Gold ER, "On the Effectiveness of the Current Intellectual Property Regime in Canada" in GE^{3}LS, *supra note* 49 at 35.
[173] *Id*.
[174] Jaffe A and Lerner J, *Innovation and Its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and What to Do About It* (Princeton: Princeton University Press, 2006), 8. Also, Bessen J, Meurer M, *Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk* (Princeton: Princeton University Press, 2008).

Translating scientifically-relevant academic inventions into medically-relevant solutions that could transform public health has been difficult.[175] The reality is that, To bring academic discoveries to market, they typically must go through industry, making patent law a necessary exception to the workings of a modern market economy.[176] Industry's market-oriented structure determines which discoveries are developed, often favoring low-risk, high-return investments. This can be a tight filter for biotechnological development, particularly in the early research stages. Before 1980, firms profited from R&D through extensive patenting and proprietary know-how.[177] Since then, biotechnology companies have become significant players in the biomedical industry, bridging academic research and Big Pharma.[178] This 'wedging in' of biotechnology emphasizes the importance of public-private partnerships in advancing scientific progress and technological innovation.

In 1980, the U.S., *Chakrabarty* Supreme Court case expanded patent law's limbering of patent eligibility in molecular biology and the life sciences within the ambit of the patent system, fostering support of patent use within these areas[179] and risk tolerance in biotechnological ventures.[180] Similar trends in university-industry collaborations are emerging in Canada's life sciences and biotechnology sectors. Government R&D spending has declined since 2001, with increased

[175] Compare Gehr S, Garner CG, "Rescuing the lost in translation" (2016) 165(4) Cell 765 (discussion of academic culture with respect to R&D) and Ehrismann D, Patel DD, "University-industry collaborations: Models, drivers and cultures" (2015) 145 Swiss Medical Wkly w14086 (discussion of industry R&D culture).
[176] Liivak O, "Maturing Patent Theory from Industrial Policy to Intellectual Property" (2012) 86 Tul. L. Rev. 1163.
[177] Cockburn I, Chase CC, "The changing structure of the pharmaceutical industry" (2004) 23(1) Health Affairs 10, 12.
[178] *Id.* at 14.
[179] For e.g., *Bayh-Dole Act*, 35 U.S.C. § 200–212.
[180] Malinowski MJ and Littlefield N, "Transformation of a research platform into commercial products: The impact of U.S. federal policy on biotechnology" in Caulfield TA, Williams-Jones BA (eds.), *The Commercialization of Genetic Research: Ethical, Legal, and Policy Issues* (New York: Kluwer Academic/Plenum Publishers, 1999).

commitments to academic research and stronger links between academia and industry.[181] Rising R&D costs have led the biotechnology industry to rely more on academia for research and IP protection, [182] while academia benefits from industry support for commercialization and access to clinical data.[183]

The collaborative R&D model between academia and industry involves complex contractual agreements and knowledge about patent use. According to at least one informant, the co-production of knowledge and fit-for-market products and services produced by academia and industry collaborators is, in large part, built on shared goals in the improvement of diagnostic and treatment options to improve overall health care for individuals (Informant 21, p.34). Intellectual property (IP) acquisition facilitates knowledge sharing in scientific enterprise, traditionally seen as vital for producing public goods.[184] With most academic research that leads to new biomedical developments — such as seen in the field of human genetics — the deep cumulative knowledge and big data cohorts (i.e., from clinical trials out of academic hospitals) are crucial to the success of these developments. However, concerns arise regarding knowledge sharing, especially in biomedical R&D collaborations, where the focus is on individual and sectoral objectives. This tension is evident in debates over human gene patents, as discussed in subsequent chapters.

[181] Issues that were the focus of the Canadian Council of Academies, *Competing in a Global Innovation Economy: The Current State of R&D in Canada*, Expert Panel on the State of Science and Technology and Industrial Research and Development in Canada, 2018.
[182] *Id.* at xxi. See also: Bunnage ME, "Getting pharmaceutical R&D back on target" (2011) 7 Nature Chemical Biology 335; Hudson J, Khazragui HF, "Into the valley of death: Research to innovation" (2013) 18(13) Drug Discovery Today 610 (each group speaking about how the all-in-one-house development to combine biomedical research and clinical development capacities have not been effective in all disease areas).
[183] For, e.g., Science Metrix, *Scan of Canadian Strengths in Biotechnology*, Prepared for the National Research Council Canada Research Program Support Office, January 2005, sections 3.2 and 3.3.
[184] See, Nelson RR, "The simple economics of basic scientific research" (1959) 67 J. Political Econ. 297. Also, Arrow, *supra note* 19.

Information and knowledge, no matter the source, are public goods. The public good argument with respect to information and knowledge has been outlined by information economists Joseph Stiglitz[185] and Hal Varian.[186] In their definition, information and knowledge are non-rivalrous (no extra cost is incurred by others using it) and non-excludable (no one can be stopped from using it). Stiglitz and Varian also point out an interesting caveat, however. Namely, that information and knowledge can, in use, be excludable where private sector actors can determine gained value from controlling them, and can do so by way of regimes, such as in the form of taxes and patents. These important characterizations of information and knowledge are notably at odds with one another and open up questions like, "Which public?" and "Whose good?"

There is a growing push for raw information, whether qualitative or quantitative, to be treated as a public good, particularly in international development and humanitarian efforts involving human genomic data.[187] The drive behind this movement — similar to concerns expressed over the patenting of human genes — is the recognition of the value of new information and its responsible sharing for subsequent innovation, policy development, interventions (including during emergencies), and promoting social good. The role of patents as a source of scientific and technological information factors into the utilitarian claim that patents can do more good than harm and can offer a positive social impact. While discussions and debates relating to the impacts of patents on technology transfer is outside the scope of this research, I took the assertion that patents facilitate the diffusion of technological information into account, especially in publicly-funded

[185] Stiglitz JE, "Knowledge as a global public good" in Kaul et al., *supra note* 166 at 308.
[186] Varian HR, *Markets for information goods*, vol. 99 Discussion Paper Series, Institute for Monetary and Economic Studies, Bank of Japan, 1999.
[187] For, e.g., Wesolowski A et al., "Quantifying the impact of human mobility on malaria" (2012) 338 Science 267.

university research aimed at advancing knowledge and fostering collaboration supported by governments.

So, again, we return to the patent bargain. There is debate over whether patent policy effectively balances economic and social benefits, or if it primarily focuses on incentivizing new inventions and economic gains as the social benefit. If social benefits only arise from innovations incentivized by patents, we must question whether patents truly drive innovation and whether private monopolies justify societal costs such as barriers to accessing scientific advancements. These questions are crucial because while optimal patent policy may encourage innovation in human genetics and genomics, unintended consequences like limited access could hinder our ability to benefit from new knowledge.[188] These questions are important given that empirical evidence suggests that balancing public and private interests is essential for patent systems to yield economic benefits.[189] For example, patents can attract funding for the development of an invention towards a concept of "use" of an idea or method,[190] rather than solely incentivizing invention itself.[191] Patents could help make the leap from invention to helping society reap the benefits of innovation. As the saying goes, the stronger the patent right, the more efficient this "leap to reap."

Canadian health authorities' economic justification for IP has been a subject of criticism. Historically, they have struggled to balance public access with IP privatization, particularly when

[188] The right to benefit from science and its advances is a relatively dormant legal human right of all individuals "to share in scientific advancement and its benefits" as recognized by the United Nations Universal Declaration of Human Rights. Examples include: Universal Declaration of Human Rights (GA Res. 217A (III), UN GAOR, 3d Sess., Supp. No. 13, UN Doc. A/810 (1948) 71) (UDHR) at *art. 27*. This right also traces its origins to the 1966 International Covenant of Economic, Social and Cultural Rights, which has been signed and ratified by 165 countries and thus affects domestic national law. See, International Covenant on Economic, Social and Cultural Rights (993 U.N.T.S. 3, adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966, entered into force 3 January 1976 at *art. 15* (ICESCR).
[189] Moir, *supra note* 70 at 15.
[190] FTC 2011, *supra note* 2 at 1.
[191] SACGHS, *supra note* 3.

regulating gene-based inventions in health research. Analysts have turned to theoretical and scarce empirical evidence to address 'hot spot' issues around patent issues as they emerge. Identifying ways forward under these circumstances have led to public health providers putting together best laid plans for individual patients depending on test technology know-how, availability, and institutional or provincial funding. As testing technology evolves, however, the landscape for test provision is increasingly influenced by patent law. While patients may not be directly denied genetic tests, patents have introduced nuanced challenges to access, as noted by study informants. Consequently, some clinical geneticists and genetic health care researchers are calling into question the reliability and equitable delivery of testing services to patients.

In discussions with Health Canada and Industry Canada to advance health research and care in Ontario (and Canada more broadly, as other provinces expressed similar concerns), the Ontario health policy unit emphasized the overarching perspective of the right to health ("right to know")[192] as a fundamental and human right[193] recognized under international law.[194] They proposed patent reform and policies for commercial development in genetics, along with an expanded role for provincial Health Technology Assessment (HTA). HTA studies the impact of technologies on safety, efficacy, cost-effectiveness, and societal implications, informing decision-making.[195] Expanding HTA aimed to enhance provincial capacity to monitor scientific trends.[196] Additionally, they recommended creating a more predictable IP environment for Canadian biotech firms to bolster their role in life science R&D and innovation.[197] Pulled together, These

[192] Charting New Territory, *supra note* 37 at 22, 27.
[193] UDHR, *supra note* 188 at *art. 25(1)*.
[194] Access to health technologies is crucial for achieving optimal health standards, though it is not a standalone human right. See, ICESCR, *supra note* 188.
[195] Office of Technology Assessment, Development of Medical Technology: Opportunities for Assessment, 1976, online: < https://govinfo.library.unt.edu/ota/Ota_5/DATA/1976/7617.PDF> (accessed: 28 June 2021).
[196] *Id.*, at 84.
[197] *Id.,* at 91.

recommendations reframed the gene patent issue through a health policy lens, aiming to harmonize the right to health and patent rights beyond traditional approaches.

Given industries' dependence on academic research out of the life sciences and biomedical sectors' strong reliance on traditional forms of IP protection,[198] changes to privatizing genetic information have generated a degree of uncertainty for these industries.[199] For example, investors in Canadian biotechnology may hesitate due to fears of lost capital if investments fail to yield commercially viable products.[200] In the U.S., such uncertainties have prompted industry lobbying for legislative expansion to safeguard patent rights.[201] Uncertainty in biotechnology can mean missing out on "more innovative products more quickly" and products in health research and care (Informant 21, p. 31). Additionally, concerns arise about how patent users, like clinicians, can share information from patented test results with patients, potentially making public health institutions vulnerable to infringement suits (Informant 8, p. 6).[202] As one informant said:

> If you come out of the woodwork, you are potentially attracting the attention of a patent holder. So, if you're a hospital … Let's say I'm a government of Quebec, and I say "Okay, right now there are a bunch of labs at hospitals that are doing genetic tests" … At the hospital level, they just allocate a budget to a lab — they have no idea what they're spending it on—so the only people who actually know are the people doing it. And they're not accounting for it, and that means nobody's going to sue them. Now, let's say I decide to go to a single model. I'm suddenly saying "Sue me now" because I'm a central place … There's an inherent inertia to changing the system, but here's a legal liability that makes the system more transparent, opens the possibility of a lawsuit. (Gold, pp. 29–30)

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[198] See also, Zhang CH, Zhang P, "Maximizing the commercial value of personalized therapeutics and companion diagnostics" (2013) 31 Nat. Biotechnol. 803.
[199] Schwartz RM, Minssen T, "Life after *Myriad*: The uncertain future of patenting biomedical innovation and personalized medicine in an international context" (2015) 3 Intell. Prop. Q. 189 (offering scientific criticism of U.S. case law).
[200] Gold R, "US says no to gene patents now Canada must decide, and quickly," The Globe and Mail, Opinion, 14 June 2013.
[201] USPTO, *Patent eligible subject matter: report on views and recommendations from the public,* Rep. Dep. Commer., Washington, D.C., 2017, online: <https://www.uspto.gov/sites/default/files/documents/101-Report_FINAL.pdf> (lobbying for legislative expansion of patent protection).
[202] Melnitzer, *supra note* 128.

A key challenge for policymakers at this point is to establish principles for the use of patented genomic health technologies due to limited empirical evidence on how patents affect innovation in health research and care. Most econometric studies are criticized for statistical challenges, which cast doubt on widely accepted conclusions about the causal relationship between patents and innovation across sectors. While banning or weakening patents might seem like a solution to mitigate uncertainty and improve access to care, especially in the short term, it poses significant complexities.

However, uncertainty persists regarding whether measures to weaken or strengthen patent rights will enhance or hinder innovation in the transition from invention to applied technology.[203] Simply weakening patents overlooks their theoretical justification within longstanding innovation policy frameworks, crucial for biotechnology's development of genetic health technologies. Considering guiding principles for human gene patents in health research and care goes beyond the binary view of patents as solely beneficial or harmful to innovation.. Failure to do so has fostered a divisive, "us versus them", perspective between health care and industry in Canada (Gillespie, p. 14) and contributed to varying degrees of uncertainty in these sectors. Access to health research tools and genetic testing remains a key concern, with industry and government citing patents as crucial.

2.1.2 Patents Make Access to Genetics Health Research Uncertain

Innovation drives economic growth, and patents are believed to support this process. However, competitive markets may reduce research incentives due to the public good nature of ideas).[204] Under a research anti-commons narrative,[205] concerns have arisen over ambiguities in patentable

[203] FTC 2011, *supra note* 2 at 69.
[204] Nelson, *supra note* 184.
[205] Heller and Eisenberg, *supra note* 71.

subject matter and scope, as well as the unintended consequences on maintaining a robust public domain.[206] These concerns came early in the gene patent debate in Canada, where health policy units expressed worries about negotiating licenses[207] and potential barriers to multiplex test development.[208] In its 2002 Ontario's Ministry of Health recommended clarifying "experimental use" and "non-commercial clinical use" exceptions in the *Patent Act* and addressing cost barriers to genetic tests[209] while ensuring patents on technologies remain intact.[210]

With respect to gene patents, whatever the characterization of DNA — be it information or physical or chemical construct — as long as an invention has met the statutory thresholds of patentability, a patent can be granted. For instance, despite the different court rulings in the U.S. over Myriad's BRCA gene patents,[211] the final word came on the heels of *Mayo*[212] in which the Supreme Court drew distinction between patentable versus unpatentable subject matter. Departing from the traditional doctrine of excluding discoveries as patentable subject matter, some scholars highlight concerns over proprietary control of publicly-funded academic research and delineating between "invention" and "discovery" to ensure access for scientific advancement.[213] Policymakers may view these concerns as trivial, but they intersect with challenges in supporting commercial

[206] Andrews LB, "The gene patent dilemma: Balancing commercial incentives with health needs" (2002) 2 Hous. J. Health L. & Policy 65, 67.
[207] Eisenberg R, "Noncompliance, nonenforcement, nonproblem? Rethinking the anticommon in biomedical research" (2008) 45 Hou. L. Rev. 1059.
[208] SACGHS, *supra note* 3 at 3. See also, *Verizon Communications Inc. v. Law Offices Curtis V. Trinko*, L.L.P., 540 U.S. 398 (2004).
[209] Charting New Territory, *supra note* 37 at 58.
[210] *Id.,* at 49.
[211] On appeal on 29 July 2011 the U.S. Federal Circuit reversed the finding of unpatentability of the genes but affirmed the unpatentability of all method claims except for one. See, *See, Myriad FedCir, supra note* 146.
[212] *Mayo, supra note* 132 (having established that items or processes must be inventive or not naturally occurring to be patentable).
[213] See, for e.g., Eisenberg RS, Nelson R, "Public vs. proprietary science: A fruitful tension?" (2002) 131(2) Daedalus 89; Eisenberg RS, "How can you patent genes?" (2002). Also, Kane E, "Splitting the gene: DNA patents and the genetic code" (2004) 71 Tennessee L. Rev. 707.

development in genetics while ensuring access for non-commercial purposes in research and health care.

With a reward structure that values tangible outputs, including the number of patents and IP agreements acquired, academic research in Canada is encouraged to focus on innovations that carry the most commercial promise. As considered in an earlier chapter, this is problematic in the case of publicly-provided health research for several reasons. Challenges include, for instance, the capacity to adequately identify and respond to the needs of early-stage research, to support patients and the health care system in the effective spread and scale of technologies of value[214] and to develop metrics that evaluate the effectiveness of technologies and of the societal impact of health innovations out of human genetics and genomics research.[215] Patents on DNA technologies are a central feature of these challenges, in large part because of the way patent law has been used in the field of emerging technologies in general.

Patenting human DNA sequences relevant to clinical health research and genetic testing was destined and almost certainly revolutionary in several respects. Patenting human DNA led to patenting central methods in molecular biology research and its applications. It also shifted norms in licensing strategies that would alter the commercial landscape to include molecular biology applications for life sciences industries towards entirely new fields of biomedicine, such as personalized medicine or precision health. Research on the connection between academic research and industry R&D indicates that academia furnishes theoretical foundations, empirical findings, and new instrumentation for private firms to innovate and advance market segments

[214] Menon D, Stafinski T, "Role of patient and public participation in health technology assessment and coverage decisions" (2011) 11(1) Expert Rev. Pharmacoeconomics and Outcomes Res. 75.
[215] Bubela T, Caulfield T, "Role and reality: Technology transfer at Canadian universities" (2010) 28(9) Trends in Biotechnol. 447.

significantly.[216] Sometimes, patents are critical to this academic and industry co-production effort. Other times, other options should be explored, especially where patents can be an unnecessary nuisance.

In genetics research, unrestricted access to research findings and data is crucial due to the heterogeneity of genetic disorders. Exclusive licensing of common genes or variants can hinder research by requiring licenses for their use. Considering an institutional "alternative to intellectual property approach," such as open science, or the free sharing of scientific research, may be beneficial.[217] Open science relies on academic rewards like grants and promotions rather than market-based incentives. Despite concerns about free riding, collaboration is often how knowledge is realistically accessed. There is an implicit benefit to furthering research partnerships and, as the argument carried by the open science movement goes, it is likely that such partnerships stand to flourish better outside of patenting. This recognition has led to calls for restructuring academic-industry relations around collaborations rather than intellectual property.[218] Overuse of patents can lead to delayed or under-produced research, prompting cautionary tales in the field.[219]

[216] For e.g., see the works of: Jaffe A, "Real effects of academic research" (1989) 79 American Econ. Rev. 957; Mansfield E, "Academic research and industrial innovation" (1991a) 20 Research Policy 1; Mansfield E, "Academic research and industrial innovation: A further note" (1992) 21 Research Policy 295; Nelson R, "Institutions supporting technical advance in industry" (1988) American Econ. Rev. 186.
[217] David P, "The economic logic of 'open science' and the balance between private rights and the public domain in scientific data and information: A primer" in The Role of Scientific and Technical Data and Information in the Public Domain: Proceedings of a Symposium, Steering Committee on the Role of Scientific and Technical Data and Information in the Public Domain, Office of International Scientific and Technical Information Programs, National Research Council, 2003, online: <Bookshelf_NBK221855.pdf (nih.gov)> (accessed: 13 July 2021).
[218] Gold RE, "Should universities get out of the patent business?," Centre for International Governance Innovation, 23 April 2019, online: < https://www.cigionline.org/articles/should-universities-get-out-patent-business/ > (accessed: 13 July 2021).
[219] Bawa K, "After failing to commercialize, universities learn to set ideas free," Centre for International Governance Innovation, 25 April 2017, online: <After Failing to Commercialize, Universities Learn to Set Ideas Free — Centre for International Governance Innovation (cigionline.org)> (accessed: 13 July 2021).

While few scientists will check if they are infringing on patents in their research[220] and empirical evidence showing distress in genetics research due to patents has been hard to track down,[221] research certainly houses and generates a marketplace for gene-based technologies, so it is an area where patent holders can commercially benefit from researchers using their inventions. Academic research, however, may not be where the pooling of legal rights to enter commercial markets would face its biggest challenges. If an anti-commons effect were to take hold, it seems likely to happen further downstream, where patented inventions are used as input, rather than with upstream discoveries for economic reasons[222] and because researchers have other ways of ensuring research gets done, such as through efforts that involve inventing around pre-existing inventions or using technology without a license.[223]

Despite such tactics, the hunt for evidence of patent thickets and an anti-commons on innovation and access in research continues.[224] One reason for this may be because we still lack a fulsome understanding of the burden of patents on knowledge creation and to what extent research data sharing is stifled because of patents. Framing interventions through policy in terms of addressing a prospective anti-commons in research (usually as a "research exemption") is not particularly helpful if we do not have a clear understanding of where those problems are occurring, for what reasons, and when along the R&D process. Here, a gap in empirical evidence and an inability or unwillingness to join-up policy options that recognize opportunities to draw on the different

[220] Venter JC et al., "The sequence of the human genome" (2001) 291(5507) Science 1304.
[221] Brody, *supra note* 39.
[222] Kieff FS, "Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science — A Response to Rai & Eisenberg" (2001) 95 Northwestern University L. Rev. 691.
[223] *Id*.
[224] Campo-Engelstein L, Chang T "How gene patents may inhibit scientific research" (2015) 4 BiblioethiqueOnline 1.

interests and incentives of mutually beneficial academia-industry partnerships might also explain why there has been little forward-looking genetics policy development.

Following the 2013 USSC ruling in *Myriad*, concerns about an emerging research anti-commons resurfaced, particularly regarding the patentability of naturally occurring genomic DNA. Discussions highlighted the competitive advantage offered to private firms by protecting cDNA technology for test development.[225] In the wake of two of America's major biotechnology cases, *Mayo* followed by *Myriad*, the anti-commons warning has some practical significance, as they impact the use of patents in genetic test development, increasing pressure on researchers to commercialize their findings.. This uncertainty affects private investment decisions and influences which research studies are pursued and which technologies are developed in gene-based research.[226]

Beyond rulings on Myriad's BRCA patents, concerns arise regarding how firms negotiate patents in whole exome and genome sequencing. This affects resource allocation, research directions, and patient access in clinical care settings.[227] The *Mayo* case highlighted potential pre-emptive impacts on cumulative investigation in patented methods for drug dosage determination,[228] while Myriad's case also raised concerns about anti-commons effects.[229] A decade earlier in Canada, similar concerns emerged about an anti-commons effect spurred by Myriad's BRCA patents. However, discussions in scholarship and patent policy circles openly questioned the legitimacy of these

[225] See, for e.g., Omenn G, "Public health genetics: An emerging interdisciplinary field for the post-genomic era" (2001) Ann Rev Public Health 1.
[226] Williams H, "How do patents effect research investments?" (2017) 9 Annu. Rev. Econ. 441.
[227] Cook-Deegan R, Niehaus A, "After *Myriad*: Genetic testing in the wake of recent Supreme Court decisions about gene patents" (2014) 2 Curr. Genet. Med. Rep. 223.
[228] See, *Mayo, supra note* 132 at 1294.
[229] *Myriad* USSC, *supra note* 93 at 2116.

concerns,[230] particularly due to a lack of empirical proof and the nature of scientific discovery. As one informant put it:

> They found the BRCA1 gene, and I think there's this perception that there was going to be a whole bunch of these highly penetrant cancer genes or disease genes—not just cancer genes, disease genes — and they all were going to be valuable and worth a whole bunch of money. That just didn't play out …. I think that was part of the reason that you didn't see that much of an anti-commons phenomenon playing out. (Informant 18, p. 4)

The problem of a research anti-commons, exacerbated by patents, extends beyond traditional concerns of patent rights overreach. Pressures to patent findings challenge open science norms, particularly as pro-commercial incentives become more prevalent in policy and university environments..[231] In Canada, commercialization pressures affect all aspects of research funding[232] making each phase in the cumulative nature of S&T research a potential lightning rod for profitable development. The federal government increasingly supports researchers contributing to business and technology innovation.[233] In this environment, patent misuse or overreach could lead to widespread or deep impacts on access to inventions, depending on IP custody chains and licensing.[234] As one informant remarked:

> There's this real pressure on institutions to commercialize. I'm not saying that it is inherently a bad thing … we have to partner with industry in order to translate these technologies, that's required … We live in a market-driven economy and of course, you want to get these things into the clinic as fast as possible if they're beneficial. But, the problem is, this commercialization pressure is really the umbrella problem that needs to be addressed. (Informant 18, p. 4)

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[230] For e.g., Caulfield T, "Underwhelmed: Hyperbole, regulatory policy, and the genetic revolution" (2000) 45 McGill L. J. 437. Also, Caufield T et al., "Evidence and anecdotes: An analysis of human gene patenting controversies" (2006) 24 Nat. Biotechnol. 1091.

[231] Nelson RR, "The Market Economy and the Scientific Commons" (2004) 33 Research Policy 455.

[232] For e.g., see generally Doern and Prince, *supra note* 46. See also, Caulfield T, "Commercialization creep: Should scientists have to always show the commercial benefits of their research?," Policy Options, 1 December 2012, online: <https://policyoptions.irpp.org/magazines/talking-science/caulfield/>.

[233] Recent examples include the *Scientific Research and Experimental Development Tax Incentive* (to encourage academic R&D) and *Build in Canada Innovation* (government-enabled sharing of bench to bed side innovative products).

[234] Herder M, Gold R, *Intellectual Property Issues in Biotechnology: Health and Industry*, prepared for the OECD International Futures Project "The Bioeconomy to 2030: Designing a Policy Agenda," Third Meeting of the Steering Committee, 7–8 February 2008, Paris at 5. Also, Caulfield T, Ogbogu U, "The commercialization of university-based research: Balancing risks and benefits" (2015) 16 BMC Medical Ethics 70.

As shared previously, several influential surveys (Mansfield 1986, Yale study 1987, Carnegie Mellon study 2000) have documented empirical evidence of patents' role in attracting research investments. While these data remain valuable,[235] other analyses have explored the impact of changes in patent law on research investments.[236] However, stronger patent rights have not necessarily led to increased research investments, as noted by Lerner (2009).[237] Despite limitations in existing research confirming patents' impacts on scientific pursuits, Informant 18's assertion underscores the unintended, widespread effects of patents on academic research when unchecked.

Canadian drug policy scholars have similarly found a lack of reinvested funds into R&D for drug discovery following changes to the Canadian *Patent Act* in 1984. For instance, Lexchin notes a dearth of empirical evidence correlating decreased biopharma R&D and increased firm profits since the 1980s.[238] In cases where financial support stems from generous subsidies for public research, as has been the case in Canada,[239] IP can be lost to the highest bidder to overcome market failures to make it across the "valley of death" to advance development and regulatory approval (Informant 9, p. 6).[240] From this viewpoint, with their effectiveness in encouraging investment into

[235] E.g., Lerner J, "The empirical impact of intellectual property rights on innovation: Puzzles and clues" (2009) 99(2) American Econ. Rev. Papers & Proceedings 343. See also, Sakakibara M, Branstetter L, "Do stronger patents induce more innovation? Evidence from the 1998 Japanese patent law reforms" (2001) 32(1) RAND Journal of Economics 77.
[236] *Id*., Lerner. Also, *id.*, Sakakibara and Branstetter. See, Budish E, Roin B, Williams H, "Do firms underinvest in long-term research? Evidence from cancer clinical trials" (2015) 105(7) American Economics Review 2044.
[237] *Id*.
[238] He wrote about it in Lexchin J, *Private Profits and Public Policy: The Pharmaceutical Industry and The Canadian State* (Toronto: University of Toronto Press, 2016). See also, Ali Mohamed F, Chaufan C, "A Critical Discourse Analysis of Intellectual Property Rights Within NAFTA 1.0: Implications for NAFTA 2.0 and for Democratic (Health) Governance in Canada" (2020) 50(3) Intl. J. Health. Services 299.
[239] Doern and Prince, *supra note* 46. See also, Phillips and Schmeiser, *supra note* 80 at 9.
[240] See, for e.g., Coller BS, Califf RM, "Traversing the valley of death: A guide to assessing prospect for translational success" (2009) 1(10) Sci Transl Med 1.

new research developments still under scrutiny,[241] the role of patents may be more prospective than practical, according to some legal scholars such as Gold and colleagues.[242].

With the push for openness in science and innovation,[243] debates on anti-commons effects in research persist. While output metrics, like patent citations and filings, have been used often as a measure of sector-specific innovation, they are inadequate for measuring gene-based innovation due to unaccounted non-patented innovations.[244] Also, theoretical literature highlights negative impacts of patent rights on cumulative innovation,[245] the empirical data is wanting,[246] especially in genetics research.[247] For instance, by Murray et al. suggest a negative impact on patent rights[248] and more recent research indicates as much as a 30 to 40 per cent increased research diversity and academic paper citations after removing IP.[249] Court evidence suggests patents can hinder

[241] Abboy M, "After *Myriad*: What types of claim amendments change a patent ineligible isolated gene claim into an eligible patent claim that is 'markedly different' from nature?" (2018) 35 Nat. Biotechnol. 820 at 824. See also, Cook-Deegan R et al., "The next controversy in genetic testing: Clinical data as trade secrets?" (2013) 21 Eur J. Hum Genet. 585.
[242] See, generally Gold ER, Shadeed E, Morin J, "Does intellectual property lead to economic growth? Insights from a novel IP dataset" (2017) 13(1)) Regulation and Governance 107.
[243] See, Gold ER, "The fall of innovation and its possible rise through open science" (2021) 50 Research Policy 2.
[244] Williams H, "Intellectual property rights and innovation: Evidence from the human genome" (2010) 121(1) J. Polit. Econ. 1. Also, Murray F. et al, "Of mice and academics: Examining the effects of openness on innovation" (2016) 8(1) American Economic J.: Economic Policy 212.
[245] Scotchmer, *supra note* 86. Also, Green J, Scotchmer S, "On the division of profit in sequential innovation" (1995) 26(1) RAND J. Econ. 20. And see, Bessen J, "Holdup and licensing of cumulative innovation with private information" (2004) 82(3) Economics Letters 321.
[246] See Aled Edwards in see Weinman J, "The case for 'open science': Do we need intellectual property law?," Sixth Annual Patent Law Colloquium, University of Toronto, 16 November 2017, online: <https://www.law.utoronto.ca/news/case-open-science-or-do-we-need-ip-law-sixth-annual-patent-law-colloquim-features-aled-edwards>.
[247] Williams, *supra note* 244.
[248] Murray F, Stern S, "Do formal intellectual property rights hinder the free flow of scientific knowledge? An empirical test of the anti-commons hypothesis" (2007) 63(4) J. Econ. Behaviour and Organization 648. Also, Huang K, Murray F, "Does patent strategy shape the long-run supply of public knowledge: Evidence from human genetics" (2009) 52(6) Academy of Management J. 1198.
[249] See generally, *supra note* 244.

cumulative-driven innovation,[250] but reports differ on their quantitative impact on R&D.[251] Clearly, better monitoring of patents' effects on human genetic research is needed.

Despite conflicting reports on patents' overall impact on innovation, understanding their effects on access to technologies and follow-on innovation is crucial for policy design. From a policy perspective, this kind of information is socially valuable — it can help optimize policy goals to encourage innovation and access while minimizing unintended consequences.[252] Several study informants emphasized the importance of aligning patent law with societal norms to avoid noncompliance.[253] The pressure on researchers to commercialize publicly-funded findings may lead to a "patent-or-bust" approach, conflicting with the patent system's purpose to promote scientific progress. Although, some countries, including Canada, offer notable exemptions to patent infringement for non-commercial activities related to public health.[254]

In Canada, these exemptions are provided both by statute and common law. Section 55.2(1) of the *Patent Act* outlines statutory exemptions, primarily applicable to regulatory approval processes, for inventions in any technological area (i.e., not just biotechnology) and cases have mainly involved pharmaceuticals (i.e., drugs, not genetic tests). Common law exemptions, reaffirmed in the *Merck v. Apotex* case[255] and revisited in *Micro Chemicals*,[256] cover activities limited to

[250] Galasso A, Schankerman M, "Patents and cumulative innovation: Causal evidence from the courts" (2015) 130(1) The Quarterly J. of Econ. 317.
[251] Prior studies from the U.S. (Cohen), Australia (Nicol-Nielsen), and the OECD indicate biotech patents do not hinder research access *per se*. But also see, Sampat B, "Diagnostic method patents and harms to follow-on innovation" (2013) 126 Harvard L. Rev. 1370. Also, Sampat B, Williams W, "How do patents affect follow-on innovation? Evidence from the human genome" (2015) 109(1) American Econ. Rev. 203.
[252] See also, De Beer et al., *supra note* 49.
[253] Eisenberg, *supra note* 207 at 1097.
[254] See, Austin MA, Peyser P, Khoury M, "The interface of genetics and public health: research and educational challenges" (2000) 21 Annu Rev Public health 81. Also, Omenn G, "Public health genetics: An emerging interdisciplinary field for the post-genomic era" (2001) 21 Ann Rev Public Health 1.
[255] *Merck & Co. v. Apotex Inc.*, 2006 FCA 323.
[256] *Micro Chemical Ltd. v. Smith Kline & French Inter-American Corp.* (1971), 2 C.P.R. (2d) 193 (SCC).

experimentation or testing that do not serve commercial purposes. However, given the pressure for research to lead to commercialization and the lack of clarity in international legal precedents, Canadian researchers face uncertainty about using patented genetic materials or technologies. Recent international legal decisions challenge the market monopoly model in health research, particularly in exclusive licensing rights,[257] though the exact implications for Canada remain unclear. It is in this environment, according to one informant in this study, in which Canada is left in the "worst situation from a policy point of view" (Gold, p. 19) and in new unfamiliar territory regarding local development and access governing the use of patented gene-based technologies,[258] especially after the *Myriad* decision by the USSC (Gold, p. 17).

Within this framework, the effect of an anti-commons has been reported to have had a more perceptible impact with respect to access to clinical genetic testing than what is currently understood in the genetics research (academic and clinical) sector. The Canadian test provision landscape is changing rapidly and with it, the degree of uncertainty attributed to patents in relation to test access.

2.1.3 Patents Make Access to Genetic Tests in Health Care Uncertain

Unlike health policy, with its overarching primary goal of better health and well-being, patent law is an undirected means that sets out to maximize any and all innovation.[259] The development of inventions that are truly good or useful can happen when patents are involved, but it is not the concern of patent policy to ensure that this does happen, indeed, it has been argued that patents may not be exceptionally efficient at doing so anyway.[260] Consequently, some inventions valued

[257] Little J, Bradley L, Bray M et al, "Reporting, appraising, and integrating data on genotype prevalence and gene-disease associations" (2002) 156 Am J Epidemiol. 300.
[258] Gold, *supra note* 200.
[259] Gold, *supra note* 32 at 64.
[260] See generally, Moir, *supra note* 70 at Chapter 3. Also, *id.*

by society may be overlooked due to factors like availability or affordability. This limitation is unsurprising; patents as one-size-fits-all tools are somewhat relics from an industrial age now operating in a knowledge economy built on information from science- and tech-based industries.[261]

When patents complicate access to genetic tests, the typical response is to reassess the balance between private monopolies and the public interest that patents aim to achieve. If the focus on this problem rests (as it has traditionally) with the law having simply gone too far with stronger or longer protection rights governing when and who can access testing, a 'recalibration of rights' approach can make sense. However, the issue with patented genetic tests in health care extends beyond mere adjustments to patent law and, thus, far broader than knowing where to draw bright line rules around patent law alone. Take, for instance, predictive genetic tests (such as Myriad's BRCAnalysis), tools used to inform individuals of their genetic health status.[262] When patented human gene-based materials and technologies began to receive greater public attention following completion of the human genome map, some empirical studies drew attention specifically to the genetic testing sector (Miller, p. 6) and the demand for predictive genetic tests grew as pharmaceutical and biotech firms patented genetic markers correlated with diseases. [263] While health authorities recognized the benefits of industry interest in testing, concerns emerged about test quality, cost, and health care equity.[264] In Ontario, discussions focused on providing "good

[261] Bessen and Meurer, *supra note* 174.
[262] For e.g., Modell SM, Bradley DJ, Lehmann MH, "Genetic testing for long QT syndrome and the category of cardiac ion channelopathy," PLoS Currents Evidence on Genomic Tests, 03 May 2012, online: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3392134/>.
[263] For e.g., see Herper M., "Gene tests: Medicine's gold mine," Forbes, 14 December 2001, online: <https://www.forbes.com/2001/12/14/1214roche.html#35e327e134eb>. Also, Calnan M et al., "Medicine's next gold mine? The implications of new genetic health technologies for the health service" (2006) 9 Medicine, Health Care and Philosophy 33. Also in, Mathew C, "Science, medicine, and the future. Postgenomic technologies" (2001) 322 BMJ 1031.
[264] For e.g., see Baird PA, "Current challenges to appropriate use of new genetic knowledge in different countries" (2001) 4(1) Community Genet. 12. Also in, Charting New Territory, *supra note* 37.

value for money, where value is defined in terms of patient benefits" (Ungar, p. 6). The focus of these discussions centred on the cost of providing genetic tests through the public health care system (Miller, p. 6).[265]

Apart from a recent study by Ali Khan and Gold (2017), which highlights patents exacerbating access issues due to strained budgets, the extent to which patents contribute to these problems in health care test provision remains unclear. According to one informant, more empirical data is needed to understand the direct impact of gene-based patents on the chain of IP custody (Gold, p. 19). While most testing occurs locally, Canadian public health care providers heavily rely on out-of-country test provision high demand, often patent-protected (Informant 16, p. 9), predictive tests[266] like long QT testing. For instance, the exclusive licensing of tests by Transgenomic in the U.S. created barriers to repatriating tests for in-house laboratory use in Canada, ultimately resulting in the MOH leaving access efforts entirely to individual public health institutions (Informant 8, p. 12).[267] Rulings in the U.S. and Australia on Myriad's BRCA sequences have further fueled uncertainty in Canada, drawing on the assumption that the U.S. patents are still "somewhat valid" (Gold, p. 19), which carries several implications for Canadian health care depending on whether, from a policy perspective, the focus is on access efforts and cost considerations within the Canadian health care system (Gold, p. 19).

Hypothetically, in an uncertain policy climate and considering cost-efficiency, it might be more economical to send tests out-of-country to the U.S., where Canada can benefit from weakened monopolies and lower costs due to increased competition post the USSC ruling in *Myriad* (Gold,

[265] See also, Morgan S et al., "Predictive genetic tests and health system costs" (2003) 168(8) CMAJ 989.
[266] See, for e.g. at provincial level, Laboratory Services Expert Panel, *Laboratory Services Expert Panel Review: Final* (Toronto: Ministry of Health and Long-Term Care, 2015) [LSEP].
[267] See also, Ali Khan and Gold, *supra note* 122 at 1256.

pp. 17, 19). Whether these costs align with provincial austerity measures remains unclear, however; the overall cost of tests and associated patent expenses in Canadian health care is largely undisclosed, at least by public account (Gold, p. 27).[268] Moreover, Gold emphasizes that it's premature to gauge how U.S. firms are reacting to the Myriad ruling and its implications for Canada. Gold asserts that the impact of the ruling, for example with respect to test access or innovation, remains "unclear" and adjustments by industry in patenting strategies are still unfolding (Gold, p. 16). More specifically, according to Gold, this uncertainty poses a dual challenge for Canadian health care, with neither scenario offering a clear advantage.

If, for example, U.S. firms adapt to the decision by way of changing patenting practices to reflect appropriate returns, such as by way of changing claiming strategies[269] — which is already a longstanding practice in Canadian pharmaceuticals[270] — then the "incentives provided by patents are zero, but all the costs of a patent still exist" with respect to U.S. firms' hesitation to patent in Canada without access to the larger American market for better profits (Gold, p. 19). This could deter investment in Canada's gene-based technology market, impacting domestic innovation and health care (Gold, pp. 15, 18). Alternatively, if U.S. firms circumvent the ruling, then "we will see this come back in Canada … with the same patents" (Gold, p. 16). For now, Canada remains in a no-win policy "hiatus":

> Where we should be making policy proactively to avoid the problem, but of course we're not, we're going to wait until the problem happens … Because on the outside, that's what it looks like, so when anyone complains about it, it means they simply don't want to take responsibility—which they should, right? Our view is that the courts cannot fully answer

[268] Requests for an interview with Ontario's Laboratory and Genetics Branch were unmet.
[269] Aboy et al., *supra note* 94 at 824 (the e.g. of adding a fluorescent label to a previously ineligible nucleic acid).
[270] For e.g., the patentability of claims regarding use for "second medical" indications. See, *Shell Oil Co. v. Comm. of Patents* [1982] 2 S.C.R. 536. Or of keeping trade secrets within certain data sharing collaborations. See, for e.g., Cook-Deegan, *supra note* 241. See also, Conley J, *ACLU v. Myriad Genetics, Round 2: The Problem of Governance-by-Guidance*, Genomics Law Report, 9 June 2016, online: <https://theprivacyreport.com/2016/06/09/aclu-v-myriad-genetics-round-2-the-problem-of-governance-by-guidance/>.

> this. They can give some guidelines, but this is a policy decision. Policy decision means making policy. (Gold, p. 16)

During the Myriad period in Ontario, the province primarily depended on the clinical genetics community for testing mechanisms (Miller, p. 5). Establishing a comprehensive HTA management plan for genetic testing from the outset was a "shit show" in Ontario:

> [We will] get spikes in out-of-province service until we repatriate, but the difference in genetics is that those spikes just keep growing because we have a commercial lab sector in the U.S. that is not governed … [There is] no control on cost or prices, and we're [Canada] subject to that … Genetic testing is seen as important to clinical geneticists primarily. So no, genetics doesn't take up a lot of money, and that's the point … [We are] still waiting for the genetics revolution. [Although] now it's reframed as "personalized" [medicine]. (Miller, p. 6)

Funding challenges persist for Canadian hospitals and public laboratories, particularly regarding genetic testing.[271] While local testing for conditions like long QT syndrome may be cost-effective compared to outsourcing, the complexity of negotiating licensing agreements due to patents often leads to costly outsourcing to U.S. providers (Informant 8, p. 15). However, the exact contribution of patents to these costs remains publicly unknown. As discussed previously, unlike pharmaceutical price negotiations, it's uncertain if similar efforts are being made in the genetic testing sector. More specifically, questions linger about whether funding discussions are happening at the hospital level through 'special envelopes' (Ungar, p. 15), or within larger national coalitions like the pan-Canadian Pharmaceutical Alliance, led by provincial deputy health ministers, which negotiate with manufacturers using technology assessments from the Canadian Agency for Drugs and Technologies in Health (Informant 21, p. 22). According to one informant in Ontario's HTA community:

> I haven't heard about price negotiation over genetic tests … in HTA we would model the price that the manufacturer asks for, or rely on research that has micro-costed the test in an applicable jurisdiction … This sector of genetic testing technologies has not moved forward like the pharmaceutical sector with respect to price negotiating. (Ungar, p. 15)

[271] Ali Khan and Gold, *supra note* 122.

Nonetheless, Ontario hospitals, ill-equipped and resource-strapped, are expected to negotiate with test proprietors directly over the licensing terms to gain access.[272] With the eventuality of greater clinical reliance on next-generation sequencing technologies, some believe patents won't hinder access to next-generation sequencing technologies while others question this assumption.[273] Patent eligibility of cDNA is relevant to test development (Informant 8, p. 15) and may affect affordability, particularly as next-generation sequencing becomes more prevalent in clinical use. Cost has been a significant barrier for Canadian public health providers seeking access to high-demand patented genetic tests like the long QT test (Informant 8, p. 3).

However, one informant suggests that merely litigating patent cases involving genetic materials and tests may not lead to the desired access for patient testing. Instead, a more direct approach to addressing the broader policy context concerning patents and health innovation is needed, especially considering the differences in this context between Canada and its common law counterparts like the U.S. and Australia. As this informant put it:

> A Canadian provider would be worried about the patents here. So [currently], you probably get a better price going to the United States than staying in Canada. Also, no Canadian hospital will provide the service because if the patents exist, they will stay away. If all you cared about was cost, then the simple solution is to just ship as many as you can to the United States. The disadvantage is that you're moving money that could be spent in Canada outside, right? … But you're also depriving Canadian researchers of data. So that's the cost to it: by having a more restrictive environment in Canada, you're basically saying 'If you want to do next generation sequencing, don't do it in Canada'. That's why they [Health Canada] wanted us to answer this, but they wanted us to answer it in a particular way, and there's no guarantee they would've gotten the answer they wanted, right? So they were hoping, in Health Canada, that the Supreme Court or some court would come up with such a clear decision that nobody would ever litigate again … which is completely unrealistic. (Gold, p. 18)

[272] Ali Khan and Gold, *supra note* 122.
[273] For e.g., see Cook-Deegan and Niehaus, *supra note* 227 at 240.

In the Canadian context, recent developments underscore the critical issue of access to genetic tests amidst patent-related challenges.[274] Following the decisions around the BRCA patents out of the U.S. and Australia, and that of *Mayo* in the U.S., it seemed less likely that clinical providers could face infringement, but uncertainty persisted regarding the validity of Canadian method and product gene-based patents.[275] It wasn't until CHEO's Federal Court challenge in 2014 that action was taken to address this uncertainty. The resulting settlement produced a health policy-informed framework for more forward-thinking policy option supporting more equitable access to patented tests, benefiting both industry service providers and public health provision. The settlement was a win-win but more work needs to be done to determine how best to address issues of access moving forward:

> In the health field, how would we provide our researchers with the data they need without fear [of patent infringement]? It was reported to us anecdotally—hard to measure—that researchers would not contribute some of their research in a public way because they're afraid of attracting attention. We saw that Myriad pulled out of sharing its information around 2004, and so people are using big data as a way of protecting themselves. So, are we scaring people from sharing data? And then, you come to the decision of: do you deal with patents as a legal matter that you can't patent? Or do you deal with it as a licensing matter and have the government intervene? And that's where the choice comes up. (Gold, p. 31)

The CHEO agreement presents a solution to the dilemma faced by public users, eliminating the need to navigate between freedom to operate and infringement risks that can be associated with gene patents (Gold, p. 12). The agreement has been called as a "turn-key health policy" solution (Gold, p. 20), ready to provide a new transparency in licensing agreements between public health care providers and patent holders. It addresses concerns raised in previous policy reports; licensing transparency was a key concern reported in Ontario's 2002 *Charting New Territory* and by the

[274] Liddicoat J, Whitton T, Nicol D, "Are the gene patent storm clouds dissipating? A global snapshot" (2015) 33 Nat. Biotechnol 347.
[275] See, Nicol D et al., "International divergence on gene patenting" (2019) 20 Annu. Rev. Genom. Hum. Genet. 519 at 519.

OECD in its series on patents and access to genetic health technologies. But, as Gold and other informants in this study contend, government must be willing to take action. In Canada, addressing gene patents requires understanding their impact on access and innovation in health research and care, in light of landmark cases like *Myriad*, *Mayo* and *CHEO* amid ongoing advancements in science.

2.2 THE WHY

2.2.1 IP Faithful[276] (and Fleeting)

Patents are widely seen in legal circles as promoting economic growth through their requirement of disclosing new inventions.[277] However, the extent to which patents effectively balance private interests with public contributions through disclosure is debated.[278] This theory, while prevalent in law, lacks empirical support and faces scrutiny from economists due to the diverse roles of patents across industries[279] and their complex industry-dependent relationship with innovation.[280] For instance, in biotechnology and biomedical sectors, patents are deemed particularly valuable for start-up funding and business strategy, including in Canadian biotech firms..[281] This has been reported to be the case in Canadian biotech firms, too.[282] In 2000, Baldwin, Hanel, and Sabourin's

[276] The phrase "IP faithful" derives from work by Mark Lemley in his piece "Faith-based intellectual property" (2015) 62 UCLA Rev. 1328, 1338.
[277] Amani, *supra note* 165.
[278] See, e.g., Fromer JC, "Patent disclosure" (2008) 94 Iowa L. Rev. 539. See also, Devlin A, "The misunderstood function of disclosure in patent law" (2009–2010) 23 Harv. J. L. & Tech. 401.
[279] Mazzoleni R, Nelson RR, "Economic theories about the benefits and costs of patents" (1998b) 32(4) J. Econ. Issues 1031. See also, Moir, *supra note* 70 at 37.
[280] See, e.g., Scotchmer, *supra note* 86. Also, Merges RP, Nelson RR, "On the complex economics of patent scope" (1990) 90 Columbia L. Rev. 839. See also, Haber S, "Patents and the wealth of nations" (2016) 23(4) George Mason L. Rev. 811. See, Arnold Plant in Boldrin M, Levine DK, "The case against patents" (2013) 27(1) Journal of Economic Perspectives.
[281] See also, Hall BH, Ziedonis RH, "The patent paradox revisited: An empirical study of patenting in the U.S. semiconductor industry" (2001).
[282] Niosi, *supra note* 25.

study for Statistics Canada suggested that while large biotech companies are often seen as the most innovative, their reliance on patents as innovation incentives varies.[283] Instead, having patents can signal to investors that a firm is poised to develop exclusive products.[284] And, unlike U.S. counterparts, a follow-up survey to Baldwin et al. (2000) having focused on a sample of highly innovative Canadian firms, Hanel's (2003) study reported that patents are increasingly being used by the private sector, similar to other findings,[285] and they are employed strategically rather than solely for protecting new discoveries.[286] Like the U.S. surveys, the Hanel study found that patents are not the primary IP mechanism for Canadian firms, reporting that only two-thirds of the most innovative firms utilize patents to safeguard their innovations from imitation.

Thus, the idea that patents are to act as a means to an end[287] is no longer much in fashion[288] and concerns about being able to convince anyone to create something when there is a likelihood of copy-cat imitation and little to gain in return are legitimate.[289] Still, an empirical justification of the patent system's regulation of the free market to encourage innovation remains weak. Despite a surge in empirical studies[290] on "virtually every aspect of IP law and innovative and creative markets",[291] skepticism persists regarding their efficacy in promoting innovation. Critics argue

[283] Baldwin J, Hanel P, Sabourin D, *Determinants of Innovative Activity in Canadian Manufacturing Firms: The Role of Intellectual Property Rights*, Micro-Economic Analysis Division, Statistics Canada, 7 March 2000, online: <https://www150.statcan.gc.ca/n1/en/pub/11f0019m/11f0019m2000122-eng.pdf?st=BHlsWrhk>.
[284] Niosi, *supra note* 25 at 744.
[285] See generally, Aboy et al., *supra note* 94 at 824.
[286] See discussion, Hanel P, "Current intellectual property protection practices of manufacturing firms in Canada," in Putnum JD (ed.), *Intellectual Property and Innovation in the Knowledge-Based Economy* (Ottawa: Industry Canada, 2008).
[287] Gold, *supra note* 32 at 64.
[288] Epstein RA, "The disintegration of intellectual property? A classical liberal response to a premature obituary" (2010) 62 Stan. L. Rev. 455, 456. Also, Spulber DF, "How patents provide the foundation of the market for inventions" (2015) 11(2) J. Compet. L. & Econ. 271.
[289] See, e.g., Landes and Posner, *supra note* 18. See also, Lemley MA, "The economics of improvement in intellectual property law" (1997) 75 Texas L. Rev. 989.
[290] Significant portions of this work can be found in Lemley MA, "Property, intellectual property, and free riding" (2005) 83 Texas L. Rev. 1031.
[291] Lemley*, supra note* 276 at 1332.

that these studies fail to conclusively demonstrate patents' net positive impact on innovation,[292] leaving what empirical evidence there is modest at best and ideological at worst[293] and the logic of patent policy in Canada open to challenge."[294] Between scant evidence supporting patents even in questionable scenarios and the lack of a clear link between patents and innovation, ambiguity reigns. Despite this, patents remain heavily relied upon, raising concerns about government subsidies supporting Canadian biotech companies[295] without sufficient downstream development (Hawkins, p. 23). Consequently, the concern is while Canada may be in full compliance with international obligations,[296] the country potentially is falling out of sync with the U.S. and Europe regarding patent law changes, uncertainties loom over industry R&D.[297]

Moreover, where technological innovation in Canada continues to operate under pressures to commercialize (Hawkins, pp. 2, 3),[298] patents themselves are believed to be the primary drivers of this innovation. (Informant 18, p. 4).[299] The link between commercialization pressure and gene-based inventions is entangled with debates over patentable subject matter, including those involving gene-based invention. Courts have been hesitant to establish clear boundaries for patent rewards, leaving decisions in a vacuum without exploring alternative state-supported financial incentives for gene-based R&D, such as state-supported nonpatent incentives (i.e. direct grants

[292] *Id*., at 1334. See also, Ouellette LL, "Patent experimentalism" (2015) 101 Virginia L. Rev. 65.
[293] See generally, for e.g., *id.*, at Lemley. Also, Liivak O, "A crisis of faith and the scientific future of patent theory" (2016) 90 St. John's L. Rev. 639.
[294] Gold in GE[3]LS, *supra note* 49 at 36.
[295] *Id*.
[296] *Id.* (writing pharma and biotech urge for broader IP laws in Canada, sometimes friendlier to patent holders than the U.S., particularly regarding patent rights and data exclusivity).
[297] *Id.*, for a fuller summary on how the Canadian patent system is working.
[298] For discussion in the literature, see, for e.g., Caulfield T, "Policy conflicts: Gene patents and health care in Canada" (2005) 8 Comm. Genetics 223, 224; Kieff FS, "Property rights and property rules for commercializing inventions" (2001) 85 Minn. L.R 697; Ghosh S, "Patents and the regulatory state: Rethinking the patent bargain metaphor after *Eldred*" (2004) 19 Berkeley Tech. L.J. 1315, 1322–25 at 1322,1355; FTC 2011, *supra note* 2 at 1; Sichelman T, "Commercializing patents" (2009–2010) 62 Stan. L. Rev. at 366.
[299] See e.g., FTC 2003, *supra note* 74.

and contracts).[300] Despite ongoing debates, governments, including Canada, maintain a one-size-fits-all role for patents in incentivizing innovation.[301] Consequently, the uncertainty surrounding patentable subject matter exceptions and effective nonpatent incentives challenges confidence in the patent system.[302] As others before me have also claimed,[303] not everything about the debates relating to gene-based invention is about economics.

In this chapter and the ensuing ones, I look into the need for public science in the provision of health care innovation to better understand ways to cut through the tension between the right to health and rights vested in IP. What directly follows in this chapter is an examination of the framing of the gene patent debate, as with most debates about patentable products of nature, often framed as a binary choice between patents and no patents, thereby having us believe that the best way through the debate is to focus on the economic utilitarian question of patents being the best way to provide a net benefit to society.[304] However, I advocate for a broader approach, exploring supportive R&D frameworks like open science and policy alternatives such as non-patent incentives. By acknowledging this spectrum of solutions we may help resolve some conflicting interests and leverage government policy beyond patent policy alone, to foster consensus and innovation across the health research and care spectrum.

[300] See generally, Ouellette LL, "Patentable subject matter and nonpatent innovation incentives" (2015) 5 UC Irvine L. Rev. 1115 for a fulsome examination of non-patent government financial incentives to boost innovation. See also, Hemel and Ouellette, *supra note* 22.
[301] GE^{3}LS, *supra note* 49 at 36. See also, Niosi, *supra note* 25. And, FTC 2011, *supra note* 2 at 43.
[302] Ouellette, *supra note* 300.
[303] See, for e.g., *id.,* Ouellete suggests that state-sponsored financial incentives like grants, prizes, contract, and regulatory exclusivity could alleviate tensions.
[304] Rai, AK, "Diagnostic patents at the Supreme Court" (2014) 18 Marq. Intell. Prop. L. Rev. 1, 2.

2.2.2 Patent Policy: Numbers Game

According to economic theory, a greater number of patents would mean that there is more investment occurring, which means that more innovation could take place. The number of patents filed along with the number of patents granted are typical metrics used by the World Intellectual Property Organization (WIPO) and followed by patent offices in most major patent-granting countries, including Canada, to index innovation capabilities nationally and globally.[305] According to some study informants, measuring innovation by way of patent filing and granting is, or at least should be, seen by policymakers as being more complicated than a numbers game, falling short as evidence of innovation altogether. For example, filing a patent does not guarantee novelty or significant advancement within a field. Similarly, patent approval does not ensure groundbreaking innovation or meaningful impact on industry or people's lives. A pharmaceutical policy expert used the example of secondary patents on existing drugs and the little value these drugs bring to biomedical progress or clinical disease treatment.

Little evidence supports the notion that patents drive meaningful R&D investment, particularly in Canada's biopharmaceutical sector, which has witnessed a decline since the 1980s (Lexchin, pp. 2, 16). Lexchin argues that the current patent system's cost-benefit basis warrants re-evaluation, as strong patent rights fail to reverse declining R&D and ensure timely access to biomedical advances, especially amid discriminatory pricing linked to biotechnology patents regime (Lexchin, p. 6).[306] Moreover, patents can be utilized to withhold products from markets without any legal

[305] See, generally, any recent *IP Canada Report* by the CIPO.
[306] See, Ghosh, *supra note* 298 at 1322. Also, several works by Mark Lemley: Lemley MA, "Taking the regulatory nature of IP law seriously" (2014) 92 Tex. L. Rev. 107; Lemley, *supra* note 76; Lemley MA, "What's different about intellectual property?" (2005) 83 Tex. L. Rev. 1097, 1097.

obligation to license them.[307] As global patent applications, including gene-related ones,[308] continue to surge,[309] concerns grow that patents prioritize private gains over societal benefits, as emphasized by Lexchin and others.[310]

Patents play a crucial role in fostering innovation, but their effectiveness in defining inventiveness, as I have discussed elsewhere, warrants scrutiny as a matter of science.[311] In the context of human gene patentability, the 1980 *Chakrabarty* case in the U.S. has been said to provide some clarity by likening isolated DNA to chemicals..[312] Similarly, Canadian patent law allows genetic material like human DNA to be patented as compositions of matter under *section 2* of the *Patent Act*.[313] Patents undergo examination by agencies like CIPO in Canada, ensuring compliance with statutory requirements, including the Patent Rules,[314] and in Canadian jurisprudence, and granting protection only for the disclosed invention. Negotiations between inventors and examiners aim to strike a balance between broad protection and specific technological advancements disclosed in the invention:

> Usually, someone invented something the size of a nail head and their claim area of space in their initial patent application size is of a basketball — the *Act* and Rules don't allow for going to the nail head … the examiner's job is to try getting to the size of a golf ball to narrow the scope on whatever [else] is out there. (Informant 14, p. 8)

[307] Merz JF, "Disease gene patents: Overcoming unethical constraints on clinical laboratory medicine" (1999) 45(3) Clin. Chem. 324.
[308] Aboy et al., *supra note* 94.
[309] Owens and Robichaud, *supra note* 83 at 7, Chart 2: World Bank 1980–2017.
[310] For e.g., Dreyfuss RC, "Expressive genericity: Trademarks as language in the Pepsi generation" (1990) 65 Notre Dame L. Rev. 397, 405.
[311] Scanga, *supra note* 38.
[312] Calvert J, Joly P, "How did the gene become a chemical compound? The ontology of the gene and the patenting of DNA" (2011) 50(2) Social Sci. Info. 1.
[313] *Canada Patent Act, supra note* 125.
[314] SOR/96-423.

CIPO grants patents on gene-based inventions based on their novelty, non-obviousness, and utility, following global patent standards. Recombinant technology[315] and specific genetic sequence[316] may receive broad patent claims. Accessing broad patents, especially for fundamental inventions as to make inventing around them or developing follow-on improvements difficult, like recombinant proteins or DNA, often necessitates licensing, which can impede follow-on development.[317] In biotechnology, and given the breadth of gene patents,[318] obtaining licenses can be challenging due to the inventor's reliance on patents for market exclusivity. The disputes between Myriad and its competitors in the U.S. post-*Myriad* exemplify these challenges, with concerns arising about patient access to reliable genetic tests amid competing firms' reluctance to share proprietary data.[319]

Canada's biotechnology sector has thrived due to supportive legal and regulatory frameworks,[320] even as patent offices, including Canada's, adopt stricter granting practices;[321] Canadian patent examiners are known for issuing narrow claims, yet this has not hindered the growth of the biotechnology industry.[322] Despite stricter granting practices, demand for human gene patents remains evident from the number of applications filed with the CIPO, albeit not as high as in previous years:

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[315] See, e.g., *Amgen, Inc, v. Hoechst Marion Roussel, Inc*., 314 F 3d 1313 (CAFC 2003). See also, Bar-Shalom A, Cook-Deegan R. "Patents and innovation in cancer therapies: Lessons from CellPro" (2002) 80 *Milbank Q.* 637.
[316] Although less concerning since a competitor firm successfully challenged Myriad's broad claims on BRCA 1/2 in the U.S. See, *University of Utah Research Foundation et al., v. Ambry Genetics Corp.,* 774 F.3d 755 (Fed. Cir. 2014) 113 U.S.P.Q.2d 1241.
[317] Merges and Nelson, *supra note* 280.
[318] Three gene-based patent types exist: diagnostic (e.g. genetic test), compositions of matter (e.g. isolated DNA like cDNA), and functional gene use (e.g. disease-targeting drugs).
[319] For, e.g., Marcus AD, "Geneticists call on Myriad to share proprietary data to aid gene tests," The Wall Street Journal (12 January 2020), online: <https://www.wsj.com/articles/geneticists-call-on-myriad-to-share-proprietary-data-to-aid-gene-tests-11578851248>.
[320] Niosi, *supra note* 25.
[321] Science Metrix, *Study on the breadth of human gene patents granted by the CIPO, the EPO, and the USPTO,* Final Report Prepared for the Canadian Biotechnology Secretariat, July 2005.
[322] *Id*.

> [At] one point in time, they were higher, right? Now, because there has been so many genomes published, it's getting harder to find something new or very different from another one. They're [the patent claims] getting a little narrow … they're still coming in …. I was dealing with some previously …. There are still the mutation ones coming in: for example, someone finds a naturally-occurring mutation or mutates a protein and finds it has a new activity. (Informant 14, p. 8)

Despite Canada's more generous patent laws and regulatory framework, its R&D spending has seen a substantial decline, placing it at odds with global innovation trends.[323] Drawing on such metrics as the number of patents filed and granted, according to the WIPO and the OECD, Canada is not faring well in the innovation game.[324] The absence of empirical evidence to validate these measures is a concern, especially during free trade negotiations, such as with the Canadian European Trade Agreement which includes IP clauses.[325] Despite offering certain advantages for patent holders relative to the U.S. (i.e., relating to scope of patent rights, longer data exclusivity) Canada's industry spending on R&D remains below OECD levels, even after amendments to the *Patent Act* in the mid-1980s aimed at boosting innovation.[326]

Finally, Canada's patent policy, touted as among the strongest globally,[327] is a key tool for state regulators to drive knowledge dissemination, industry productivity, and public choice, alongside other mechanisms like research grants and competition law.[328] Industry Canada certainly has the biggest role in patent policy development, but despite calls dating back to 2002 to reconsider the boundaries of patent rights, particularly regarding gene-based technologies, Industry Canada has yet to fully engage in these discussions.[329] With no empirical evidence suggesting harm from

[323] Dutta S, Lavin B, Wunsch-Vincent (eds.), *The Global Innovation Index 2016: Winning with Global Innovation*, Cornell University, INSEAD, and WIPO.
[324] *Id*.
[325] GE^{3}LS, *supra note* 49 at 48.
[326] GE^{3}LS, *supra note* 49 at 36.
[327] Coalition for Action on Innovation in Canada, *An Action Plan for Prosperity*, 2010, online: <http://actiononinnovation.ca/en/media/ENG_Plan.pdf>.
[328] Owens and Robichaud, *supra note* 83 at 23.
[329] Gold, *supra note* 172 in GE^{3}LS, *supra note* 49 at 37 (re. the enhancement of institutional decision makers).

expanding patent rights in biotechnology, and lacking a permanent government body to gradually introduce policy changes, there is a prevailing view that Canada's patent policy requires attention and possibly strengthening.

Some suggest a shift in patent policy analysis from innovation to measurable IP outputs like patents, seen as a practical approach within the economic policy framework.[330] For instance, the Conference Board of Canada urges policymakers to encourage more patenting domestically and strategically.[331] his focus underscores the importance of maintaining incentives for innovation in Canada, crucial for domestic R&D investment and development in biotechnology. Certainty in this industry should also reassure health researchers and care providers about resource availability and cutting-edge products. Recognizing the collaboration between industry and health sectors underscores the need for diverse data in policymaking and a reminder for policymakers that most policy problems stemming from patents as an intersectoral issue are not simply matters of cause-and-effect, but rather of needing better and diverse quantitative and qualitative data at those intersections of policymaking. Again, much of creating that certainty at the intersection of patents and health boils down to how effective the patent system is at delivering on its bargain promise[332] and creating a safety net for both inventors and society when the balance of that bargain is pulled into question.

[330] Corbin R, *Intellectual property in the 21st century* (Ottawa: Conference Board of Canada, 2010).
[331] Conference Board of Canada, *How Canada Performs: A Report Card on Canada* (Ottawa: Conference Board of Canada, 2010).
[332] Standing Committee on Industry, Science and Technology, *Intellectual Property Regime In Canada, 41st Parliament*, First Session, (Committee Report) (Ottawa: ISED, March 2013) at 9 [INDU 2013].

2.2.3 More Is More

Occasionally, as in any formidable debate, somebody gets a slap on the wrist. The SCC, such as in *Teva,*[333] provided a stark reminder of the patent bargain as the basic policy rationale of the *Act*. Calls for stronger patent rights are often viewed as conflicting with the public interest, but proponents argue that strong protection can benefit both public and private interests by deterring unauthorized copying and promoting innovation.[334] Calls for ever-stronger patent protections focus on paradigms of patent law linking the use of patents to higher rates of national sectoral development, economic modernization and to an improved quality of life. Thus, strong patent protection upholds the patent bargain rather than running counter to it.[335] According to patent regime proponents, there are numbers to back this up.

For instance, studies trying to capture the relative strength of national IP regimes in general show that patents are crucial for market access, contradicting concerns about monopolies and their limitations on testing, test quality, price control, and patient decision-making.[336] Comparative indices, like domestic R&D productivity, support the idea that strong IP protection boosts economies, aligning with industry and government calls for enhanced patent rights and a pro-patenting environment.[337] Patents may be one factor of many that influence direct investment and

[333] *Teva, supra note* 9.
[334] Ghosh*, supra note* 298 at 1354.
[335] Arora A, Fosfuri A, Gambardella A, *Markets for Technology: The Economics of Innovation and Corporate Strategy* (Cambridge, MA: MIT Press, 2001). Also, Spulber DF, "Unlocking technology: Antitrust and innovation" (2008) 4(4) J. Comp. L& Eco. 915. And, De Rassenfosse G, Palangkarya A, Webster E, "Why do patents facilitate trade in technology? Testing the disclosure and appropriation effects" (2016) 45(7) Research Policy 1326.
[336] See, e.g., Owens and Robichaud, *supra note* 83.
[337] Gould D, Gruben W, "The role of intellectual property rights in economic growth" (1996) 48 J. Dev. Econ. 323. See also, for e.g., Hu A, Png I, "Patent rights and economic growth: Evidence from cross-country panels of manufacturing industries" (2013) 65(3) Oxford Econ. Papers 675. For a broader discussion relating to these studies, see Owens and Robichaud, *id*.

innovation systems,[338] and the biotechnology industries in Canada (Informant 21, pp. 13, 24–25) and abroad[339] strongly advocate for stronger patent rights. Some long-time observers of IP trends, including several informants in this study, suggest that bolstering Canada's patent framework is vital to address its innovation deficit and enhance global competitiveness.[340] By extension, Strengthening patents is argued to improve healthcare provision by promoting sectoral excellence.[341]

For some of these pro-patent stakeholders and observers, recent court decisions suggest movement in favour of more robust IP.[342] However, as a matter of how movement in the law will translate into appropriate policy, even those legal changes that set out to increase an incentive to patent cannot be expected to automatically or single-handedly lead to an increase in innovation. Despite the discussion above heralding the usefulness of measuring IP outputs such as patents, some commentators warn that the counting of such outputs are not especially helpful for gauging success because, once again, in the end, the production of more patents does not necessarily indicate innovation, and could instead lead to less of it.[343] Once more, the use of patents may be

[338] Maskus K, "The role of intellectual property rights in encouraging foreign direct investment and technology transfer" (1998) 109 Duke J. of Comparative & Intl. L. 161. Also, Phillips P, *Governing Transformative Technological Innovation: Who's In Charge?* (Oxford: Edward Elgar, 2007).
[339] See generally, FTC 2011, *supra note* 2.
[340] Owens R, "No wonder Canadians aren't more innovative: Look how poorly we protect innovator's rights," The Financial Post (28 June 2017), online: <https://financialpost.com/opinion/no-wonder-canadians-arent-more-innovative-look-how-poorly-we-protect-innovators-rights>.
[341] See, for e.g., Crowley BL, Lybecker K, "Improving Canada's drug patent protection: Good for Canada, good for trade," Policy Options, March 2012.
342 Owens R, "Canadian courts still think intellectual property laws matter," Financial Post, FP Comment, 27 February 2018, online: <https://financialpost.com/opinion/take-notice-copyright-infringers-canadian-courts-still-think-intellectual-property-laws-matter> (referring to decisions in *Access Copyright v. York University* and *Equustek v. Google*). See, *Access Copyright v. York University* 017 FC 669, [2018] 2 F.C.R. 43; *Equustek Solutions Inc. v. Jack*, 2018 BCSC 610. At the time of writing, the SCC ruled in favor of York University in its copyright tariff dispute with Access Copyright. See also the earlier e.g. of *Monsanto*, *supra note* 35 effectively reversing decision in *Harvard, supra note 35*.
[343] For, e.g., Bessen and Meuer, *supra note* 174.

worth the cost in the biotechnology and biomedical industries, but the unclear relationship between patents and innovation complicates determining by just how much.[344]

There are three general conclusions that arise out of the above discussion as to why, more broadly, the patent-innovation relationship remains somewhat ambiguous. Firstly, the patent system's inward focus may overlook opportunities for more socially optimal patent policies by neglecting broader policy considerations.[345] Secondly, debates shouldn't solely revolve around stronger versus weaker patent rights, especially in areas like publicly-funded healthcare where innovation differs. Lastly, expanding on the first point, optimizing patent use in areas like health care requires expertise from diverse fields. However, Canada often leans towards a rigid one-size-fits-all approach,[346] which I term as a patent-or-bust perspective, possibly impeding domestic innovation endeavors.[347] I will explore these points further in a Canadian context in the pages that follow.

2.3 Meanwhile, in Canada

In using S&T developments to solve some of the major challenges to economic growth and health, it is important to identify the right policy mix, although patents tend to dominate the IP debates about such developments and about S&T policy more generally. A good example to consider is Canada's S&T strategy within the broader federal innovation agenda. The Government of Canada, more than any other OECD country, is known for its ambitious contributions to subsidizing

[344] *Id*.
[345] For, e.g., De Beer et al., *supra note* 49.
[346] For example, see Government of Canada, "Government of Canada launches new intellectual property strategy," News Release, 26 April 2018, online: <https://www.canada.ca/en/innovation-science-economic-development/news/2018/04/government-of-canada-launches-intellectual-property-strategy.html>. See, Gallini and Hollis, *supra note* 81.
[347] See, Gold R, Abraham S, Gualtieri A, Gillespie IM, "Innovating a Canadian innovation system," Economy/Science & Tech, Policy Options, 6 July 2015, online: <https://policyoptions.irpp.org/magazines/clearing-the-air/gold-et-al/>.

research into S&T.[348] But most of these government subsidies remain unfocused, with funding channeled into the higher education sector where commercial application is typically unspecified, although tacitly expected to be directed into industry as *ex post* subsidies to cover research costs.[349] There is little empirical research examining the validity of using these metrics to assess the performance of the Canadian patent system[350] and assessments to determine the translation of scientifically relevant academic inventions that could transform public health have been notoriously difficult.[351]

A big challenge for policymakers is identifying solutions to these challenges on the public provision side of innovation, while also identifying policy that encourages direct investment, technology transfer, and innovation systems.[352] The OECD guidelines for licensing genetic inventions and its innovation strategy have encouraged the development of alliances and markets for collaborative efforts among the highest centres of innovative activity, namely universities, industry, and government.[353] However, collaboration in the intersectoral areas of patent and health policy in Canada, the two major areas that have a stake in the success of genetic health patents, has not always come easy. In the following chapter, I will discuss the policy context that hinders collaboration in the areas of publicly-funded health research and care. Finally, in Chapter 5, I will consider the governance context in which patents are an intersectoral issue, more specifically in regards to publicly-provided health care.

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[348] Doern and Prince, *supra note* 46 at Chapter 3. See also, Phillips and Schmeiser, *supra note* 80 at 9.
[349] Science, Technology and Innovation Council, *State of the Nation 2014: Canada's Innovation Challenges and Opportunities*, (Public Report) (Ottawa: STIC, 2015) [STIC 2015].
[350] *Id*.
[351] Gehr and Garner, *supra note* 175.
[352] See generally, Phillips, *supra note* 338.
[353] Etzkowitz H, *The Triple Helix: University-Industry-Government Innovation in Action* (London: Routledge, 2008).

2.3.1 Canadian Context

The SCC rulings in *Harvard* (2002) and *Monsanto* (2004) have been touchstones of the gene patent debates in Canada, the former having interpreted patent law to exclude higher life forms as patent eligible and the latter having reversed bearing of the *Harvard* exclusion by broadly interpreting the law to include genes and cells as patentable subject matter. Abroad, controversies about genetics or genomics and IP, most notably in the U.S. and Australia, have involved litigation around the validity of gene-based patents on cancer-susceptibility genes. Considering how sister countries have addressed concerns relating to human gene patents through the law is important for Canada given the growing uncertainty for domestic industry and public health use of patented human gene-based invention here.

Regulatory reform, as evidenced in cases like *Harvard*, *Monsanto*, and *Myriad*, is a complex and lengthy process, subject to interpretation by enforcing institutions. However, for Canadian S&T innovators and public users, direct policy solutions tailored to their context hold greater significance than legal changes. More important for Canadian S&T innovation would be to identify aspects of the patent system that can effectively mobilize new information in the economy and utilize patents for purposes beyond protection or incentivization.[354] A traditional approach to encouraging innovation in S&T would mobilize a 'patent-or-bust' logic, in which commercialization of IP is integral to innovation. The federal government expects Canadian biomedical sciences researchers to commercialize their findings[355] and expects research institutions to acquire IP rights to commercialize as well.[356] The picture of innovation painted here

[354] De Beer et al., *supra note* 49.
[355] See, Bubela and Caulfield, *supra note* 215.
[356] Smyth S, "Working at the intersection of ego and greed: A Canadian assessment of university technology transfer offices," VALGEN Working Paper, 2011.

is linear: prospective commercially valuable research protected by the academic institution is spun off into industry. However, innovation does not typically happen in this way; not in Canada, and not anywhere else in the world (Informant 18, p. 4; Hawkins, pp. 3–4). Again, the broad consensus is that innovation more often occurs 'outside the lines' rather than inside them.[357]

2.3.2 Context from Within

Regarding the goal of using human genetic materials to improve health and quality of life, the Canadian government traditionally views patent law as a primary tool for advancing biomedical innovation. I have discussed several features to illustrate how the patent system sets out to do that. Indeed, the patent system is one option among a variety of legislative or policy tools that can be used to influence technological invention, development, and commercialization.[358] However, an excessive reliance on the patent system to address issues with gene-based patents has caused Canadian policymakers to overlook opportunities and potentially unintended consequences.[359]

According to one informant, a belief in the merits of patents as the best incentive for innovation has provided a justification by Canada's biotechnology industry for the stronger enforcement of patent rights. Since the late 1980s, successive federal governments embraced the "free marketeer" orthodoxy, which entails less government oversight in markets generally, but in industries more specifically, especially the biotechnology industry (Hawkins, p. 20).[360] The result, according to this informant, has been an unfortunate demise in industrial policy in Canada, and broader still, a

[357] Lemley, *supra note* 276 at 1334.
[358] Gallini and Scotchmer, *supra note* 22.
[359] Gold in GE^{3}LS, *supra note* 49 at 35. Also, Corbin, *supra note* 330.
[360] Cianfarani C, "Why Canada is ripe for a new industrial policy," The Globe and Mail (17 May 2018), online: <https://www.theglobeandmail.com/report-on-business/rob-commentary/why-canada-is-ripe-for-a-new-industrial-policy/article34138869/#:~:text=Chief%20among%20them%20was%20that,talk%20that%20resembled%20industrial%20policy.>.

relinquishing of involvement in industrial policy with a greater reliance on the patent system.[361] According to Hawkins, strong industrial policy is fundamental to a strong economy and government working in the best interest of the public:

> Basically, it [industrial policy] means … well here's what it does not mean … People in Canada think it's about government ownership, but it's not about that … Or it's with government interference in what industry does … But we have to recognize that it's not government that produces things, it's industry that produces things. … Government has an oversight role … and … simple fact of the matter is that public sector and private sector *together* comprise an economy…This is not government being a lackey to industry … Industrial policy is about … joined-up policy … Industry policy is about active government … (pp. 21–23, *emphasis added by informant*) … So, we have a knowledge base here, and a national industry base that's likely worth ten times what the oil and gas industry is worth to Canada based here … Completely exportable … So, it's just there waiting to happen … Companies are sitting on their hands for government regulatory approval to do this, that and the other thing, so they look elsewhere. (Hawkins, p. 24)

Hawkins emphasized the significance of patents for specific firms, particularly during certain stages of the R&D life cycle, saying:

> If you're a company … small company … that *just* invented something … that patent could be the most important thing that you own … that's absolutely critical. (Hawkins, p. 26, *emphasis added by informant*)

But, reflecting on innovation and societal value, Hawkins highlighted that patents have created undesirable inconsistencies in the industrial innovation landscape, affecting both industry and society as a whole:

> But this is one of those strange anomalies … There's no necessary association between patenting and value … Patents have become an investment instrument … [and] … the problem is, when we're talking about investment, we're not talking about money that goes *into* a laboratory or *into* a company to do research and development … We're talking about speculative investment based on share price … We're talking about financialization … People are investing in the company, speculating that the company is going to become more valuable/less valuable depending on which position they're going to take. (Hawkins, p. 27, *emphasis added by informant*)

[361] See also, Liivak, *supra note* 176.

For those outside of industry but still affected by it, such as universities and end users in health research and care, patents serve as a means for industry to establish "pecking orders" and "priorities" with respect to "who is owed what" (Hawkins, p. 27). Patents are valuable in determining ownership and facilitating collaborations, yet they may disproportionately benefit larger industry players, potentially posing challenges for others:[362]

> Patents are really for net costs and industry rather than benefit … And basically, any wealthy entity can steal as much property as it wants with complete impunity … You don't even need to steal it … They simply go to the company who owns it and say: 'We're going to use it, and these are the terms we're going to go by, and you can take it or leave it … Take our terms or fight us in court, and we'll bankrupt you … So, this is hard ball … And most companies that own patents know this, are completely aware of this … and they build it into their business plans … part of their management portfolio, etc. (Hawkins, p. 28)

The role of patents can pose complexities for knowledge-driven sectors like biotechnology. According to Hawkins, patents hinder knowledge dissemination in two significant ways. The first is in the way that patents are being used as business tools, because essentially, "what patents do is that they tie down research streams and knowledge streams into patent streams … They're (about) not sharing data …" (Hawkins, p. 29). Secondly, "patents are not secrets" (Hawkins, p. 32). Therefore, patents may not only inadequately disseminate information but also inefficiently protect intellectual property. In fields like S&T research and sectors like biotechnology, which rely on existing information or technologies, "patents are really a problem" (Hawkins, p. 29):

> The knowledge function is multiplicative … It's a non-linear, complex function … Which means knowledge tends to advance the more people know more things … But when you patent something, what you're doing is you're establishing a kind of direction … Yes, it's open, because everyone knows what it is, you can license it, so you're establishing a way of going about doing things … So, for example, … medicines … One of the things we know about them is that they're not very efficacious … This is the problem … Once you establish something, even after the patent has run out … A good example is the epi pen … The technology and compound have been off-patent for ten years, and yet it's taken that long for a generic to appear on the market … *Patents slow access*. (Hawkins, p. 33, *emphasis added by informant*)

[362] Boyle, *supra note* **77**.

Seen in this light, patents often fall short in their role of facilitating access to new information and technology, sometimes even impeding it (Hawkins, p. 29). The tension arising from patents in areas like publicly-funded health research and care is not unexpected. According to some, this tension will persist as long as the federal government maintains the "naïve view" that innovation primarily involves obtaining and exploiting patents (Hawkins, p. 29). Consequently, valuable IP from sectors like biotechnology,[363] will continue to be sent "flying away from us out of the borders" (Hawkins, p. 16) because while Canada maintains its global edge as a powerhouse of ideas, research and innovation "we never figured out how to create *value* from that locally" (Hawkins, p. 17). Consequently:

> This very, very active ingenious sector has no Canadian market, so they go abroad … Typical fate for an entrepreneurial company in Canada is they start locally and immediately go global because there's no centre, the way there is in the U.S., Japan, Korea, China, all major European countries … is that they become extraordinarily vulnerable to just be simply bought up before they grow. (Hawkins, pp. 17–18)

In the end, "all the value gets shipped out with the sale of the IP in the company" (Hawkins, p. 5). Reflecting on the Canadian biomedical industry's development as an example, Hawkins said:

> So, like everywhere else in the world, Canada has pockets of expertise and niche markets, but trying to develop a major medical industry in Canada is kind of a fool's errand, which means we're probably investing all kinds of money into research that's essentially flying away from us out of the border, and then we buy it back … When a government in a place like Canada says 'We want to invest in technology', what they really mean is … they're talking about buying in technology … Meaning, the technology that doesn't originate here, they're importing it … So, what governments are thinking about when they're thinking about innovation in the medical sector is that they're thinking about increasing the size of that producer market in Canada. (Hawkins, pp. 16, 15)

Here, Hawkins raises a point that has been brought to Parliament's attention recently, a concern about Canada's vulnerable technology landscape, where domestic firms may be compelled to license or restrict access to foreign firms, potentially leading to the licensing back of taxpayer-

[363] See, Gallini and Hollis, *supra note* 81.

funded IP.[364] Consistent with a 2018 report from the Council of Canadian Academies, this reflects the Canadian innovation paradox: while Canada excels in *inventiveness* (with respect to scientific endeavour, venture capital access), it lags in *innovation* (with respect to R&D, commercialization).[365] The impact of this patent-innovation dynamic on the Canadian human gene patent debate is complex and will be explored further in subsequent chapters. First, a final reflection on the implications of international gene patent eligibility changes on technology access in Canadian industry and health care.

2.3.3 Context from Beyond: It's a Post-Mayo, Post-Myriad World and Canada Just Lives in It

For the biotechnology industry, already facing a challenging incentive and protective environment over various genetic inventions, the USSC ruling in *Myriad* was seen as another complication on the heels of *Mayo* from a year before.[366] Undeniably, the *Myriad* decision was unprecedented.[367]

Many legal scholars downplayed its broad impacts,[368] viewing the decision as specific to the facts of the case.[369] The USSC argued that naturally occurring genes should not be patentable due to their potential negative effects on innovation. Speaking on the 'laws of nature' provision, "As the Court has explained, without this exception, there would be considerable danger that the grant of patents would 'tie up' the use of such tools and thereby 'inhibit future innovation premised upon

[364] Standing Committee on Industry, Science and Technology, Evidence, No. 065, 1st Session, 42nd Parliament (6 June 2017) at 4.
[365] Issues that were the focus of the Canadian Council of Academies, *Competing in a Global Innovation Economy: The Current State of R&D in Canada*, Expert Panel on the State of Science and Technology and Industrial Research and Development in Canada, 2018. Emphasis added.
[366] Wales, Cartier, "The impact of *Myriad* on future development and commercialization of DNA-based therapies and diagnostic" (2015) 5(12) Cold Spring Harb. Perspect. Med. 1.
[367] Ratner M, "Myriad decision aftershocks ripple through biotech" (2013) 31(8) Nature Biotechnology 663.
[368] Holman C, "*Mayo*, *Myriad*, and the future of innovation in molecular diagnostics personalized medicine" (2014) 15(4) North Carolina J. L. & Technology 639, 652.
[369] Moore C, McBee S, Flasche W, "The USPTO Guidance in response to Myriad runs counter to Supreme Court precedent and the *TRIPS Agreement*" (2015) 10(2) JIPLP 115, 18.

them.'"[370] This stance aligns with the "laws of nature" provision in the U.S. *Patent Act*,[371] emphasizing that such laws should be freely accessible.[372] Exceptions such as these exist because they are said to represent "the basic tools of scientific and technological work"[373] or "the building blocks of human ingenuity."[374] But with regard to a naturally-derived product, to be patent-eligible subject matter, the guiding principle is that it must be "markedly different" from its natural counterparts, with some measure of "human intervention".[375] The same principle applies to process inventions as well, sometimes referred to as the "inventive concept," in which the claims must do "significantly more" than lay out a given law of nature, and was reaffirmed by the USSC in *Mayo*.[376] *Mayo* can be seen as instructive in the gene patent debate, being a significant turning point for biotechnology, and diagnostic methods, in particular.

The USSC's invalidation of Myriad's product claims has been praised for its pragmatic approach, seen as a political and legal compromise.[377] However, it has also faced criticism for its lack of doctrinal and scientific rigor, particularly in distinguishing between isolated DNA and cDNA.[378] The ruling didn't clearly define the scope of patentable subject matter for human genetic materials and derivative technologies, such as genetic tests, and their processes, like diagnostic methods.[379]

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[370] *Association for Molecular Pathology et al. v. Myriad Genetics, Inc. et al., No. 12 — 398 (Slip Opinion)* at 11 drawing on *Mayo, supra note* 132 at 17.
[371] 35 USC § 101.
[372] *Funk Bros Seed Co v. Kalo Inoculant Co* 333 US 127 (1948) at 130 [*Funk Bros.*] (a message also put forth years later in *Chakrabarty, supra note* 101 at 309).
[373] *Id.*, *Chakrabarty*. See also: *Diamond v. Diehr* 450 US 175 at 185 (1981), *Bilski, supra note* 150, *Mayo, supra note* 132, *Myriad* USSC, *supra note* 93.
[374] *Alice, supra note* 41 at 2354.
[375] *Chakrabarty, supra note* 101.
[376] *Mayo, supra note* 132 at 1294.
[377] Lee P, "The Supreme Court's Myriad effects on scientific research: Definitional fluidity and the legal construction of nature" (2015) 5(5) UC Irvine L. Rev. 1077.
[378] See, Palombi L, "*Association for Molecular Pathology v Myriad Genetics* (US) and *D'Arcy v Myriad Genetics* (AU): Are gene patents in Europe a threatened species?" (2016) 38 EIPR.
[379] Myriad's diagnostic method claims had earlier been invalidated by the Federal Circuit, though not addressed by the Supreme Court. See, *Myriad* FedCir, *supra note* 146.

Myriad's product patents granted it exclusive rights to all clinical genetic tests for BRCA-derived breast and ovarian cancer detection in the U.S., as "isolation is necessary to conduct genetic testing," leaving Myriad as the only firm to offer BRCA testing.[380] Despite limited empirical data backing an anti-commons effect before and after *Myriad*, much can be said about invalidating Myriad's product patents and eliminating broad monopolies in the field of genetic testing, like fostering competition in R&D, benefiting patients through reduced pricing and increased clinical options, as extensively discussed in literature.[381]

Post-*Mayo* and post-*Myriad*, U.S. lower courts are grappling with their implications,[382] particularly in health-related genetic research. While the extent of a "chilling effect" on academic research due to gene patents remains uncertain, earlier surveys suggest significant concerns among laboratories, with many foregoing new test development or clinical testing due to patent worries.[383] Although open research, unconstrained by patents, theoretically fosters more robust innovation,[384] empirical studies suggest academic researchers often overlook patent infringement, resulting in a de facto research exemption.[385] Myriad's lenient policy towards academic research on BRCA genes may

[380] *Myriad* USSC, *supra note* 93 at 2114.
[381] For, e.g., Saladino T, "Seeing the forest through the trees: Gene patents & the reality of the commons" (2011) 26 Berkeley Tech LJ 301. Anecdotal evidence suggests that other health care providers were offering BRCA testing at cheaper prices compared to Myriad's. For, e.g., see, Matloff ET et al., "Choosing a BRCA genetic testing laboratory: A patient-centric and ethical call to action for clinicians and payers," (2014) 20(SP7) AMJC, Commentary. See also e.gs. from the following: Andrews L, "Genes and patent policy: Rethinking intellectual property rights" (2002) 3 Nat. Reviews Genetics 803; Caufield, *supra note* 230; Cook-Deegan R et al., "The dangers of diagnostic monopolies" (2009) 458 Nature 405; Carbone J et al., "DNA patents and diagnostics: Not a pretty picture" (2010) 28 Nat. Biotechnol. 784; Hawkins N, "An exception to infringement for genetic testing — addressing patient access and divergence between law and practice" (2012) 43(6) IIC 641. See also, Robertson AS, "The role of DNA patents in genetic test innovation and access" (2011) 9(7) Northwestern J. L. & Tech. 377.
[382] See, e.g., *In re Roslin Institute (Edinburgh)* 750 F 3d 1333 (Fed Cir 2014), *University of Utah Research Foundation v. Ambry Genetics Corporation* 774 F 3d 755 (Fed Cir 2014), *Ariosa Diagnostics Inc v. Sequenom Inc* 788 F 3d 1371 (Fed Cir 2015).
[383] Cho M et al., "Effects of patents and licences on the provision of clinical genetic testing" (2003) 5(1) J. Molecular Diagnostics 3, 5. This in contrast to what has been reported in Australia. See, Australia Law Reform Commission, "Chapter 20: Gene patents and healthcare provision".
[384] Merges and Nelson, *supra note* 280 at 872.
[385] Holman C, "The critical role of patents in the development, commercialization and utilization of innovative genetic diagnostic tests and personalized medicine" (2015) 21(2) Boston Univ J. of Science and Technology Law

reflect a desire to maintain positive relations with the academic community.[386] Furthermore, as explained by the U.S. Federal Circuit, Myriad's cease and desist notifications were for the purpose of asserting its patent rights against laboratories engaged in potentially profitable commercial genetic testing.[387] Concerns about gene patents hindering scientific information and research are tempered by reports suggesting their impact on biomedical research may not be as severe as feared.[388] In Canada more specifically, there is a lack of clear empirical understanding regarding the extent to which genetic patents impede academic and clinical research (Gold, p. 22).

Finally, The similarity in arguments regarding medical diagnostic claims in both Myriad and Mayo underscores the limitations of a "patents-or-bust" innovation policy. This presents an opportunity for governments to reconsider non-patent mechanisms to support innovation and ensure access. The debate over interpreting the products of nature exception hinges on whether improving health outcomes necessitates patents. The Justices were not comforted by this "simple" choice in *Myriad* and, while likely aware of other publicly-provided innovation incentives, explored patent system options for companies like Myriad if gene patents were invalidated.[389] Frankly, what choice did the Court have but to seek an understanding of other patent claims that would still be available?

297 at 309. See also, Clark J, "Do patents and intellectual property protection hinder biomedical research? A practical perspective" (2011) 44(1) Australian Econ. Rev. 79 at 79 ("In the face of no empirical evidence, the myth that patents inhibit biomedical research, publication and dissemination of knowledge is promulgated"). And, Caufield, *supra note* 230 (echoing Clark's sentiment that in absence of empirical data demonstrating a negative impact of patents on R&D "the feared problems have not widely manifested.").

[386] Cohen W, Walsh J, "Real impediments to academic biomedical research" (2008) 8 Innovation Policy & Econ 1, 9–10.

[387] *Myriad* FedCir, *supra note* 146.

[388] Holman C, "Gene patents under fire: Weighing the costs and benefits," in Arezzo E, Ghidini G (eds.), *Biotechnology and Software Patent Law* (Oxford: Edward Elgar, 2011), 275.

[389] *Myriad* USSC, *supra note* 93, Transcript of Oral Argument at 11-16, online: < https://www.supremecourt.gov/oral_arguments/argument_transcripts/2012/12-398_h3dj.pdf>.

With little analysis relating to the full options of state-provided financial incentives for genetics research, patents indeed seem to be the "second best" option to support innovation.[390]

But most innovation is built on other ideas and there is no "fair use" for patents. As I have asserted above and continue to do so below, the open science movement pushes back on the encroachment of proprietary science in the development of fundamental biology in an effort to speed up innovation and to leave behind antiquated IP models in scientific research. One way for governments to both support their innovation agenda and maximize the impact of research directly in fields of biological study (such as genetics) and further downstream in its use and application (such as in health care) is to consider using tools, other than patent law, already in their policy toolkit (such as direct R&D spending through grants and contracts) that can support cross-sectoral collaborations (i.e. between academia, industry, government, patient groups) in early-stage research partnerships (such as open science partnerships).

2.4 Linking Statement

In Canada's health patents narrative, the ongoing challenges in the genetic testing landscape are noteworthy. Before Myriad, a U.S. study suggested gene-based patents impeded test development and access.[391] While Canada has seen less drastic effects than outright access stoppage, issues persist. For instance, accessing long QT testing in Ontario means longer waits and higher costs due to reliance on American labs (Informant 8, p. 12). This local implementation failure likely reflects broader policy issues, including overreliance on the patent system for technological

[390] Penin J, Neicu D, "Patents and open innovation: Bad fences do not make good neighbours" (2018) 25 J. Innovation and Economics & Management 57.
[391] For, e.g., Merz J et al., "Diagnostic testing fails the test: The pitfalls of patents are illustrated by the case of haemochromatosis" (2002) 415 Nature 577. Also see, Lee P, "The Supreme Court's Myriad effects on scientific research: Definitional fluidity and the legal construction of nature" (2015) 5(5) UC Irvine L. Review 1077.

progress. Ironically, the proposed solution often involves burdening the same system responsible for the problems, despite its lack of interest or accountability in certain areas.

Patents present challenges in the health provision landscape that the patent system alone cannot solve. While they may not completely hinder progress in genetics health research or restrict access to comprehensive clinical care, patents introduce uncertainty and can influence research direction and care provision in Canada, without backstop options to ensure that patents are generally doing Canadians more good than harm. Without safeguards to ensure patents benefit Canadians overall, there's a need for coherence between patent and health policies. The international community has long recognized the importance of addressing IP issues in health research and care, and it is time for Canada to make a domestic commitment. Coherence in the Canadian gene patent debate requires better consideration of health policy options, improved dialogue among stakeholders, and enhanced intra-governmental coordination, all of which are explored further in the following chapters.

3 HEALTH POLICY AND CANADA'S GENE PATENT DEBATE

In this chapter, I consider the persistent concerns out of Canada's health care sector that patents create stumbling blocks for patients seeking to access high-demand tests. I look to the long QT case mounted by CHEO to flush out some of these concerns and their relevance to the broader test provision landscape in Ontario and the gene patent debate more generally. This chapter urges the consideration of a perspective on appropriate human genetic research and gene-based health technology use external to the patent-centric, "patent-or-bust" paradigm, that includes a health-in-all-policies approach, one that is informed by the health and social implications of policies that influence health outcomes beyond the reach of the health sector and is driven by the desire for increased health and health equity. This chapter concludes that a re-imagination of what constitutes "public" at the public-private divide around appropriate use of human genetic materials involves an exploration of how best, or sometimes when, to consider non-market values as they relate to patented genetic health invention. This chapter encourages a more careful consideration of the current health care setting, the collection of information, and of government expertise relating to patents as institutional imperatives in answering the question about why, as a society, we use human genetic materials to improve health and well-being.

3.1 Health Policy and Law's Limits

Health policy has a singular goal — better health for everyone. The *Canada Health Act* states the primary objective for Canada's health policy is a need "to promote, protect, and restore the physical and mental well-being of its residents" and "to facilitate reasonable access to health

services without financial or other barriers."[392] Legislated within the *Act*, "reasonable access" to health care depends on the public administration of services by the provinces and territories.[393] As a federal state with a constitution that divides unexplicit legal authority between the federal government and its provinces and territories, Canada's division of powers in some areas of the law can result in complex and changing rules regulated by different rule makers. Health is one of those areas.

For instance, the federal government is responsible for the regulation of medical devices and drugs, while the provinces and territories are responsible for the delivery of these health care products and services. The majority of the federal government's constitutional authority over health care is under its spending power, whether under the *Canada Health Act* or through research funding, including authority over ensuring the provinces and territories have "peace, order, and good government."[394] With respect to the delivery of health care, provisions laid out in the *Constitution Act, 1987* (the *1987 Act*) provide Canada's provinces and territories with primary jurisdiction over the "establishment, maintenance, and management of hospitals, asylums, charities and eleemosynary institutions".[395] By contrast, jurisdiction over the financing of health care and authority over health more broadly is divided. With respect to the funding of health care, and in turn the impact of funding on delivery, the *1987 Act* offers little by way of direct instruction relating to the health sector and the *Canada Health Act* establishes conditions that provinces must meet to receive federal allocations, but it does not regulate these activities nor does the federal

[392] *Canada Health Act*, *supra note* 142 at *s. 1*.
[393] The remainder of the text will refer to "provinces" to distinguish from the whole of federal jurisdiction or authority with respect to "provinces" and "territories." Reference to "territories" will be made where their distinction from provinces is relevant.
[394] *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (UK), 1982, c 11, s 91(24) [*Charter*].
[395] Constitution Act, 1867 (UK), 30 & 31 Vict, c 3, s 92(7), reprinted in RSC 1985, Appendix II, No 5. s. 92(7) (Constitution Act); Originally enacted in the UK as the British North America Act 1867 (30 & 31 Vict c 3).

government have a direct say as to how allocations look like in the provinces or when they are made.[396] Consequently, interpretation of more general provisions relating to who governs delivery and funding of health care, when called into question, have often been left to the courts.[397]

The Canadian Constitution grants divisional authority such that the provinces and territories have specific powers over hospitals and law-making capacity regulating "property and civil rights" and "generally all matters of a merely local or private nature." In effect, provinces and territories regulate health care delivery and health insurance. Health Canada is responsible for harmonizing national health policy through its administration of the *Act*[398] and several public health agencies. Health law, in respect of the regulation of product and service access or availability, includes a variety of provincial and federal statutes based on constitutional and common law principles. For instance, the *Canadian Charter of Rights and Freedoms*[399] has been a means to accounting for equitable decision-making for those looking to access care and to improve accountability to patients and the public with regard to accessibility of care. Equitable access to care is a major objective of the Canadian health care system as reflected in several pieces of federal legislation of the Canadian health care system.

Given that the majority of human genetic materials are used for health-related purposes for an ever-increasing improvement of health and well-being, there is little reason to establish an

[396] *Canada Health Act*, *supra note* 142, *s. 35*.
[397] See Canada (Attorney General) v Ontario (Attorney General), [1934] ExCR 25, [1934] 3 DLR 483; Reference re Employment and Social Insurance Act, [1936] SCR 427, [1936] SCJ No 30 (S.C.C.); Reference re Employment and Social Insurance Act, [1937] AC 355 (J.C.P.C.) (affirming S.C.C.) (rulings having found that the provinces have broad authority to enact social insurance programs, including health insurance, under their jurisdiction over property and civil rights). In relation to federal "spending power", subsequent rulings recognized federal government role in funding and influencing social insurance programs through financial grants to the provinces. See YMHA Jewish Community Centre of Winnipeg Inc. v Brown [1989] 1 SCR 1532; Reference Re Canada Assistance Plan (B.C.), [1991] 2 S.C.R. 525.
[398] *Canada Health Act, supra note* 142, see generally c. C-6.
[399] *Charter, supra note* 394.

intermediate goal for health policy relating to the applications of genetics and genomics R&D; typically, human genetic materials are used for health research and care with the single goal of improving health. The question of whether the public interest of ensuring good human health lies in recognizing patent holder rights over gene-based inventions has led to questions about what might be the appropriate balance between protecting patent rights and having access to the inventions they protect. Here, the jurisdictional division in authority over health and patents is laid bare. The extent to which health care and health more broadly are interpreted to fall primarily under provincial and territorial jurisdiction, and the limits upon which federal action in health care impact decisions relating to the governance, regulation and funding choices made by the provinces and territories, have made it hard for federal policymakers to answer questions about an appropriate balance of public and private rights relating to human genetic invention.

Despite the general notion that individual creator rights in IP are constructed such that "any balancing must be done *within* the overall context of the public good,"[400] the patent system's implicit conflation of the economic and health-improvement objectives of innovation does not always work out as well as intended. That is, these two goals may not always align — the issue of access to patented gene-based technology in the human gene patent debate is illustrative — and we may also be expecting too much of the patent system should the degree of their alignment depend on the type and purpose of the gene-based technology in question.[401] The introduction of technologies into this system, gene-based technologies in particular, and what access to them looks like in Canada's public health research and care continues to present challenges for

[400] Waldron J, "From authors to copiers: Individual rights and social values in intellectual property" (1993) 68 Chicago-Kent Law Rev. 841, 848 (*emphasis added by informant*).
[401] Lauer A, "The disparate effects of gene patents on different categories of scientific research" (2011) 25(1) Har. J. Law & Tech. 179.

policymakers.[402] Missing from their efforts is a sharper health lens, such as a "health-policy-in-all-policies" framework[403] for example, that might adequately address intersectoral issues that present barriers to maintaining a sustainable and equitably accessible publicly-funded health research sector and care system in response to growing demands from the clinical and patient population.

Real world challenges of establishing clinical validity and utility can complicate the identification of effective implementation, and consequently, reliable, responsive policies with respect to reliable test access. Pressures external to, but having great impact on, the health care system have necessitated hypervigilance by health authorities around resource allocation and spending in health care. These pressures include a reliance on market forces to identify which tests are of value for adoption and a lack of formal regulatory frameworks to guide a changing health delivery landscape. The test provision landscape for genetic tests in Ontario is illustrative of these challenges.

3.2 An Eye on Ontario's Test Provision

The global clinical sequencing market is growing at an annual compound rate of roughly 28 per cent[404] and while the costs to produce gene sequencing tests have dropped to near USD$1, 000[405] and data interpretation of test results is improving, it is unclear whether such trends in growth are sustainable by health systems. For one, the cost of sequencing technology for users can still be a

[402] MacNeil M et al., "Enabling health technology innovation in Canada: Barriers and facilitators in policy and regulatory processes" (2019) 123(2) Health Policy 203. See also, Phillips KA et al., "Genetic test availability and spending: Where are we now? Where are we going?" (2018) 37(5) Health Aff (Millwood) 710.
[403] Rigby and Hatch, *supra note* 99.
[404] Bergin J, *DNA sequencing: Emerging technologies and applications*, BCC Research, May 2016.
[405] National Human Genome Research Institute, *DNA Sequencing Costs: Data*, Cost per Human Genome — 2021, online: <https://www.genome.gov/about-genomics/fact-sheets/DNA-Sequencing-Costs-Data> (last accessed 6 July 2022).

burden.[406] Even if providers cover the costs or offer reimbursements, such arrangements have limitations and are variable, in particular, for technologies like whole genome sequencing, given their unspecified target conditions[407] and unestablished or changing clinical usefulness.[408] In some cases, this means that access to a given test is left up to individuals who will pay for it, whatever the cost.[409] In areas of health care where market failure is high, achieving improvements of service is difficult in the absence of government intervention, and can leave patients facing high out-of-pocket spending to gain access.[410] Even with patients willing to pay out-of-pocket, innovation in the area of genetic health technology does not guarantee an improvement on existing genetic tests, and could do more harm than good by using up dedicated resources for potentially fruitless health-related research and care.[411] Making decisions around the (re)placement of test technologies in response to a changing test landscape has been challenging for Canadian policymakers,[412] but patents are making these challenges increasingly difficult as demand for the tests continues to rise.

A key concern in the test provision landscape, and a significant factor determining testing availability or access, lies with how policies and systems of health and governance will keep pace with the growth and expansion of genetic tests.[413] This is of particular concern where both testing

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[406] *Id*.
[407] Phillips KA, Deverka PA, Trosman JR et al., "Payer coverage polices for multigene tests" (2017) 35(7) Nat Biotechnol 614.
[408] Beuchaw S, Watcher Z, Rosenberg J, *Life Science Tools and Diagnostics: Insight Day Expert Feedback: Positioning in Diagnostics*, New York (NY), Morgan Stanley Research, 7 April 2017.
[409] Grant P et al., "Out-of-pocket and private pay in clinical genetic testing: A scoping review" (2021) 100(5) Clin Genet. 504 (authors suggest that despite decreasing out-of-pocket expenses, patients not eligible for full coverage still face significant costs, hindering their access to tests and follow-up care).
[410] Gold, *supra note* 32 at 69.
[411] One informant (Lexchin) observed the scenario where new pharmaceuticals offer no added value compared to existing products. Regarding biotech firm owned by big pharma, he suggested they may follow suit, prioritizing market advantage over health care needs.
[412] See, e.g., MacNeil, *supra note* 402. See also, Stafinski T et al., "Decision-making on new non-drug health technologies by hospitals and health authorities in Canada" (2019) 15(1) Healthcare Policy 82.
[413] Phillips KA, Trosman JR, Kelley RK, et al., "Genomic sequencing: Assessing the health care system, policy, and big-data implications" (2014) 33 Health Aff (Millwood) 1246.

options and spending are on the rise,[414] creating challenges of access for a variety or reasons. The days of regulating single-kit test use are being phased out as clinical reliance on whole genome sequencing rises, creating regulatory and funding or coverage policy challenges. Currently, the majority of genetic testing in Canada occurs within hospitals or public laboratories, with recent development plans around improving local implementation, and with the help of networked analyses of health technology assessment (HTA) under the provincial health ministry. However, most of these tests are still typically patent-protected, they are provided to these in-house sites from out-of-country, and they are highlighting challenges in terms of how best to identify not only the most efficient provisional landscape, but the most equitable one.

3.3 Making Room to Shift Paradigms

3.3.1 Consider Re-Imagining the Public Domain

Despite the often described patchwork construction of the Canadian health care system,[415] health policy can make room for greater considerations of a robust public domain.[416] If a genetic test or any part of it — for example, a genetic sequence included in the testing panel — is subject to a patent, then manufacturers and users wanting access to the test and the information contained within those sequences are required to purchase a license. It is possible that each holder will contend that their test or sequence is the best one available, and – if they agree to grant the license

[414] Unim B et al., "The provision of genetic testing and related services in Quebec, Canada" (2020) 11 Frontiers in Genetics 127.
[415] Bennett C, Archbold R, Kill or Cure? How Canadians Can Remake their Health Care System (Toronto: HarperCollins, 2001).
[416] The idea that health policy needs to be given greater consideration in discussions relating to patented genetic materials and tests in this work is built on the perspective by Richard Gold, *supra note* 32 at 70. In this piece, Gold contends that health policy concerns need to be addressed within or in supplement to the existing patent law framework with respect to human biological materials.

– may request a significant license fee in exchange for access and use.[417] Consequently, tests as private property can be expensive to access, and with costs subject to change, this can cause ongoing challenges for public health systems and implementation measures.[418]

Similarly, concerns around limiting competition are often raised within the health policy community based on the idea that S&T information that is open and accessible will build on existing knowledge and contribute to new findings within a field.[419] Boyle (1996) used the intersectoral issue of patents on gene-based inventions as proof of concept with respect to the overprotection of private interests at the expense of public ones, resulting in barriers to access by those who need access the most.[420]

Boyle (1996) argues that controlling access over something like a genetic test is not simply a matter of IP rights going too far, rather, that controlled access drains the public domain in biomedicine because human genetic materials form the basis of basic knowledge in the field. Here, the problem of overprotected private monopolies at the expense of the public domain can involve proposals of recalibrating their balance as sought explicitly through the patent system itself, such as a reformation of the system to better accommodate research exemptions, compulsory licensing, or the banning of patents on genes altogether.[421] For a fixed period of time, however, the current patent system does not achieve an open and accessible public domain, instead producing public

[417] Heller and Eisenberg, *supra note* 71.
[418] Ali Khan and Gold, *supra note* 122.
[419] "Data sharing and the future of science" (2018) 9 Nat Commun 9, 2817, online: <https://www.nature.com/articles/s41467-018-05227-z.pdf>.
[420] Boyle, *supra note* **77**.
[421] See several discussions about this: Mireles MS, "An examination of patents, licences, research tools, and the tragedy of the anticommons in biotechnology innovation" (2004–2005) 38 U. Mich. J. L. Reform at 206; Eisenberg RS, "Patents and the progress of science: Exclusive rights and experimental use" (1989) 56 U. Chi. L. Rev. 1017, 1023; Yoon M, "Gene patenting debate: The meaning of myriad" (2010) 9 J. Marshall Rev. Intell. Prop. L. 971; Nielsen CM, Samardzija MR, "Compulsory patent licensing: Is it viable in the United States?" (2007) 13 Mich. Telecomm. Tech. L. Rev. 511.

goods and protecting those goods under exclusivity rights that work to keep the goods under private control. Despite society's reliance on the patent regime to contribute to socially valuable biomedical advances, relying on a system that cares little whether a particular invention increases human health and improves quality of life seems ill-advised.

3.3.2 Consider Making Room for Non-Economic Reasons

Specific to the goal of good health and quality of life, the formulation of health policy draws on the distinction between human health from other categories that are important to well-being and advances in health. With respect to human genetic materials, there are, on one hand, ethical and social concerns around exclusive ownership of a part of nature itself and how it impacts access to information about ourselves. On the other hand, we risk not having that information available to advance that knowledge if investors worry they will be insufficiently rewarded for their risky venture into inventing. Insofar as we wish to take public health research and care seriously, we cannot continue to err on the side of making decisions driven by fiscal prowess or austerity for the primary purpose of economic growth, however. Nor can we ignore the many drivers for health outcomes that extend beyond the reach of the health sector.

While Canada has addressed regulation regarding access to and utilization of individual genetic information provided by genetic tests,[422] regulatory policy to ensure the equitable delivery or access to the tests themselves remains unclear, currently subject foremost to provincial criteria. This chapter sets out to examine the health policy landscape with respect to genetic tests and testing services, and how it has interplayed with Canada's human gene patent debate. The chapter furthers the argument of the dissertation in that room (or better consideration) must be made for non-

[422] *Genetic Non-Discrimination Act*, S.C. 2017, c.3 [*GNDA*].

economic reasons important to why, as a society, we use human genetic materials. The chapter focuses on genetic test access in the clinical setting and steadies itself on the example of Ontario.

3.4 THE WHAT

3.4.1 Genetic Tests: Trends and Tribulations

As testing technologies become cheaper, faster, and more readily available, genetic testing is providing an unprecedented production of genetic data. In the growing movements of personalized medicine and panel testing, each making whole genome sequencing increasingly relevant to clinical care,[423] the clinical research and care communities can analyze large amounts of genetic information to a greater extent than before. Despite acknowledgement in the literature of the potential benefits of genetic health technologies since the mapping of the human genome,[424] the Canadian health policy framework remains a cumbersome patchwork of regulatory coordination with respect to genetic tests and testing services.[425] A trend in publicly-provided health care has

[423] Mayer A, "Should genetic testing for cancer be available for all Canadians?" CBC News (Canada), 18 May 2013, online: <https://www.cbc.ca/news/canada/should-genetic-testing-for-cancer-be-available-to-all-canadians-1.1314320>.

[424] Cockburn I, Henderson R, "Public-private interaction in pharmaceutical research" (1996) 93(23) Proc. Natl. Acad. Sci. USA 12725; National Research Council, *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation and Public Health* (Policy Report) (Washington, D.C.: National Research Council, 2006). Also see, Lindor N et al., "Whole-exome sequencing of 10 scientists: Evaluation of process and outcomes" (2015) 90(10) Mayo Clin. Proc. 1327 (genetic testing should also empower individuals regarding decisions about their future health and well-being).

[425] Discussion about the policy concerns of gene patents in health care relating to a more robust regulatory regime for genetic tests began in the late 1990s in Canada with the Myriad controversy and has since waxed and waned. For an example of the breadth of conversations, see e.g., Caulfield T, "Genetic testing, liability, and regulatory policy: The Canadian situation" (2000) 41 Jurimetrics 7; Charting New Territory, *supra note* 37; Kaufert P, "Health policy and the new genetics" 51(6) Social Sci & Med 821; Ontario Ministry of Health and Long-Term Care, *Genetic Services in Ontario: Mapping the future* (Commissioned Reports and Studies) (Ottawa: Ministry of Health and Long-Term Care, 2001).

been to establish the use of genetic tests on the basis of clinical efficacy and utility in an effort to provide earlier and more accurate diagnoses.[426]

However, questions must be raised about what kinds of tests are available and how access to these tests is regulated. Such issues are further complicated by bioindustry's reliance on the traditional biomedical model of R&D, which includes a reliance on patents.[427] For instance, the increased public interest in genetic information is indicative of the power of induced demand (i.e. if people are aware the technologies exist, then they will want access to them) occurring, enabling increased access to new genetic health technology.[428] The arrival of BRCAnalysis may have ridden the wave of growing global anticipation of a genetics revolution in Canadian health care,[429] but the controversy it brought ushered in an era of uncertainty around how best to regulate genetic health invention, an uncertainty made more complicated by patents. Around the world, the American firm Myriad Genetics obtained exclusive rights in conducting tests (BRCAnalysis was one of its major ones) to predict an individual's lifetime susceptibility to developing breast/ovarian cancer. The firm received wide criticism directed at its ownership over human-derived genetic material and at its enforcement of patent rights. The majority of criticisms lashed out onto Myriad related to its ownership and patent practices and the implications of its gene patents on scientific knowledge and discovery, public health care, and access to medical services.

[426] Little et al, *supra note* 257. Also, Collins F, "Shattuck lecture - medical and societal consequences of the human genome project" (1999) 341 N Engl j Med 28.
[427] Caulfield TA, Knoppers BM, Gold ER, et al., "Genetic technologies, health care policy, and the patent bargain" (2003) Clin Genet. 15.
[428] Offit K, "Personalised medicine new genomics, old lessons" (2011) 130(1) Human Genet. 3; Phillips AM, "Only a click away - DTC genetics for ancestry, health, love … and more" (2016) 8 Appl Transl Genom. 16.
[429] See generally, e.g., Cook-Deegan R, Heaney C, "Patents in genomics and human genetics" (2010) 11 Annu. Rev. Genomics Hum. Genet. 383.

Despite concerns about legal, ethical and policy ambiguities regarding the use of gene-based testing technologies,[430] uncertainties about benefits or harms,[431] and varying concerns about assessing clinical efficiency and the utility of some tests, including direct-to-consumer tests,[432] the federal government generally characterizes genetic tests as another way of providing individuals with information about themselves.[433] With notable efforts resulting from funding recommendations for Oncotype DX tests (ODX)[434] by way of explicit consideration of equity and other elements under a classic HTA framework in Ontario, neither federal[435] nor most provincial[436]

[430] Hogarth S, Javitt G, Melzer D, "The current landscape for direct-to-consumer genetic testing: Legal, ethical, and policy issues" (2008) 9 Annu. Rev. of Genomics and Human Genetics 161; Allen L, Hamidi M, Argintaru N, "Direct-to-consumer genetic testing in Canada" (2011) 80(1) University Western Ontario Med. J. 15.
[431] Caulfield T, et al., "Harm, hype and evidence: ELSI research and policy guidance" (2013) 5(3) Genome Med. 21; Caulfield T, "Direct-to-consumer genetic testing in Canada: Should we be concerned?" Healthy Debate, 1 October 2014, online: <https://healthydebate.ca/2014/10/about-healthy-debate/opinions-about-healthy-debate/direct-consumer-genetic-testing/>; Covolo L, et al., "Internet-based direct-to-consumer genetic testing: A systematic review" (2015) 17(12) J Med Internet Res. E279.
[432] Matthews R et al., "Direct-to-consumer genetic testing for addiction susceptibility: A premature commercialization of doubtful validity and value" (2012) 107(12) Addiction 2069; Hogarth S, "Myths, misconceptions and myopia: Searching for clarity in the debate about the regulation of consumer genetics" (2010) 13(5) Public Health Genomics 322; Valles SA, "Should direct-to-consumer personalized genomic medicine remain unregulated?: A rebuttal of the defences" (2012) 55(2) Perspect Biol. Med. 250. However, more recently Cernat A, Bashir NS, Ungar WJ. Considerations for developing regulations for direct-to-consumer genetic testing: A scoping review using the 3-I Framework. In press, *Journal of Community Genetics*, 2022, online: <https://doi.org/10.1007/s12687-022-00582-3>.
[433] Picard A, "Controversial genetic self-testing kits coming to Canada," The Globe and Mail (4 October 2014), online: <https://www.theglobeandmail.com/life/health-and-fitness/health/genetic-self-testing-kits-to-come-to-canada/article20885678/>.
[434] A multigene predictive test, one of several tests available, to help determine therapy options for patients with early stage breast cancer based on risk of recurrence. The test has been used in Canada to assess the absolute benefit of chemotherapy or to avoid unnecessary chemotherapy. See, for e.g., Zhu X et al., "How Canadian oncologists use Oncotype DX for treatment for breast cancer patients" (2021) 28 Curr. Oncol. 800.
[435] For instance, direct-to-consumer tests lack strict regulation under Health Canada despite relative ease of access, limitations in medically useful information, and impact on quality of care with subsequent reliance on the health care system should users have additional inquiries relating to test results. Approval for the use of a genetic test happens through Health Canada, but approval addresses safety and efficacy and not clinical use or access. See, Webster PC, "Regulation of genetic tests unnecessary, government says" (2010) 182(16) CMAJ 1715 (with geneticists and clinicians warning of misleading or misinterpreted genomic information from genetic tests if test use and access are left unregulated).
[436] See, Unim *supra note* 414. At the provincial and territorial level, traditional genetic tests (e.g. medical diagnostic tests) by law are prescribed by a physician provided within a health care setting. These tests are primarily left to other means of regulation, such as marketing or privacy regulations or at the provincial and territorial level by way of health laws, consumer protection or other privacy regulations. For e.g., Authorized Acts. In: Professional Obligations. College of Medical Laboratory Technologists of Ontario; 2016; M-9 Medical Act. In: Legis Quebec. Gouvernement du Quebec, 1 November 2016.

governments see the need for formal policies governing the equitable access to traditional tests (e.g., medical diagnostics or predictive testing) beyond safety and efficacy approval. Canadian researchers have, however, reported that genetic testing services in terms of availability and access are not meeting the needs of patient populations.[437] Similar to remarks made by informants in this study (Ungar, p. 24; Informant 16, p. 4), a recent study by Unim et al. (2020) suggests there is a need to better understand the integration between genetics and the health care system and to better inform policymakers about this advancing area of genetics.[438] In Canada, conversations about how a province can ensure equitable access to genetic tests remain ministerial conversations, held tight in confidence within the context of the provincially-set risk-based formulary criteria for individuals wishing to gain access to a given test (Informant 16, p. 6). With growing clinical interest in genetic tests, some health science researchers and clinical geneticists interviewed for this work are worried that in Ontario, current provincial standards are overly restrictive and fail to facilitate reasonable access of health care in some cases. As Canadian demand for in-house tests remains strong, an informal or unregulated labyrinth of pathways to the provision of genetic tests could place unintended limitations on access to tests and on patients.[439]

Governing access to and use of genomic applications such as genetic tests requires considerable subject matter knowledge, appropriate and equitable public policies, and adequate funding. Some suggest that administration of genomic applications should occur through a centralized legislative

[437] Unim *supra note* 414.
[438] *Id.*, at 8.
[439] See, Canadian Agency for Drugs and Technologies in Health, "Focus On: Direct-to-Consumer Genetic Testing," Issue 18, Health Technology Update, June 2017 at 11. Health Canada*, Guidance for the risk-based classification system for in vitro diagnostic devices (IVDDs)*, (Ottawa: Public Works and Government Services, 2016); Ng PC et al., "An agenda for personalized medicine" (2009) 461(7265) Nature 724; "I had my DNA taken. With varying results," The New York Times (4 January 2014), online: <https://globalgenes.org/2014/01/04/i-had-my-dna-picture-taken-with-varying-results-new-york-times/>.

or governing framework.[440] Canada's approach has often consisted of a banding together of expert advisory committees, such as the CBAC, and various policy working groups within ministerial provincial and federal departments, to consider access to and the implications of deploying human gene-based technologies.[441] While policies and guidelines around testing service quality and accreditation are in place in Canada,[442] governing frameworks pertaining to accessibility and the appropriate use of genetic materials and tests (outside of provincial formularies regarding certain selected tests only) are lacking.[443]

Canada's proximity to the U.S. may indeed open up access to test availability even in the face of relatively limited power over negotiating better prices.[444] Contending with the fact that many of the patents on these tests are held by American entities and a growing demand for timely and reliable patient access to genomic sequencing[445] has presented Canadian health care with challenges sometimes due to the typically higher costs associated with patent-protected

[440] Ali Khan and Gold, *supra note* 122. See also, Lilley M, Christian S, Blumenschien P et al., "A centralized approach to out-of-province genetic testing leads to cost savings: The Alberta experience" (2013) 84 Clin. Genet. 373.
[441] At the federal level, see examples: Royal Commission on New Reproductive Technologies, Proceed With Care — final report of the Royal Commission on New Reproductive Technologies (Commission Report) (Ottawa: Minister of Government Services of Canada, 1993); Expert Working Party on Human Genetics, Intellectual Property and the Health Sector, *Human Genetic Materials: Making Canada's Intellectual Property Regime Work for the Health of Canadians* (Ottawa: CBAC, 2005) [CBAC 2005]. At a provincial level, see Charting New Territory, *supra note* 37.
[442] LSEP, *supra note* 266. See also, Canadian College of Medical Geneticists, *Establishing the professional and ethical standards of medical genetic services*, Homepage (accessed 28 December 2019). In addition, the *Tri-Council Policy Statement*, governing all federally funded research reliant on human subjects, contains specific provision for genetic research.
[443] Caulfield, *supra note* 425.
[444] International Trade Administration, *2016 Top markets report: Medical devices* (Executive Summary) (Washington: U.S. Department of Commerce, 2016), online: <https://legacy.trade.gov/topmarkets/pdf/Medical_Devices_Executive_Summary.pdf> (speaking of Canada's small medical device market and negative trade balance adjacent to the U.S., which represents the largest global medical device market share).
[445] *CHEO*, *supra note* 100. Transgenomic, Inc. became the American firm and party to the *CHEO* test case after it acquired the LQTS patents and GeneDx. See, Ali Khan and Gold, *supra note* 122 at 1254.

technologies.[446] In this respect, and with limited jurisprudence and no formal governing framework over genetic test accessibility and use,[447] Canadian policymakers have faced unique challenges in the development of appropriate frameworks for mediating clear access to non-drug health technologies.[448] Ontario's struggles with Myriad and various other test technology considerations that have followed since is emblematic of these challenges. As one of four Canadian provinces to have established formal provincial mechanisms (i.e., HTA committees sub-specialized in genetics) to inform decision-making pertaining to non-drug health technologies,[449] the province struggles to implement a responsive policy strategy governing genetic test access. Recent pilot projects like Genome-wide Sequencing Ontario (GSO) are expected to help inform these decisions if made permanent, but questions around how best to navigate substantial changes in technology and how to fund health systems in response to these changes are likely to linger unless more formally addressed. For this, a better understanding of the context in which gene-related tests are assessed for adoption by the health care system is needed.

[446] Caulfield R, Gold R, "Genetic testing, ethics policy and patent law" (2000) 57 Clinical Genetics 370. See also, McVeigh TA, "Clinical use of the Oncotype DX genomic test to guide treatment decisions for patients with invasive breast cancer" (authors contend that the cost-saving utility of the assay comes from patients spared chemotherapy. They go on to say that patents, however, can present a problem of access because "… while similar assays exist, the Oncotype DX assay is the only such tool that is validated for use in predicting response to chemotherapy" and that "such monopoly as well as patent protection means that the cost of the assay is unlikely to be reduced"). In addition, see Hall PS, McCabe C, Stein RC, Cameron D., "Economic evaluation of genomic test-directed chemotherapy for early-stage lymph node-positive breast cancer*"* (2012) 104(1) *J Natl Cancer Inst*. 56.
[447] Caulfield, *supra note* 425.
[448] For e.g., Canada was one of the first countries to institutionalize health technology assessment. See, e.g., Battista RN, "Health care technology assessment: Linking science and policy-making" (1992) 146(4) CMAJ 461; Menon D, Stafinski R, "Health technology assessment in Canada: 20 years strong" (2009) 12(Suppl.2) Value in health S14. But, Stafinski, *supra note* 412 at 84 (assessment processes for drugs and non-drug health technologies (i.e. medical devices, genetic tests) evolved along different paths, with a pan-Canadian process for assessment of the former but not the latter.
[449] Stafinski, *supra note* 412 at 84.

3.4.2 Myriad Comes to Ontario: Policy Cracks and Gaps

The rise of new technologies being introduced into health care systems complicates already complex policy challenges.[450] For the Canadian policymaker, ensuring that increasing innovation brings more benefit than harm to the public introduces unique challenges to Canada's publicly-supported health research and care. These challenges have been well-documented in instances where access to patented predictive genetic tests have been at issue. This chapter continues on this thesis' considerations about how patents may be impacting health research and care in the area of genetics. More broadly, this study advances a growing understanding of the Canadian health care context under the influence of macro-level factors, such as political structures (i.e., the division of jurisdictional authority over innovation and health between and within levels of government) and fiscal policies focused on frameworks to encourage innovation (i.e., the patent regime). I will also continue to examine these matters in the ensuing chapters. Given the pressing matter of appropriate and equitable health care delivery in relation to gene patents, the genetic test sector once again is a focal point.

3.4.2.1 Policy Cracks

The first big test Canadian health policymakers (in Ontario and British Columbia in particular) faced with respect to assessing the impact of patents on health care delivery occurred in 1999, when the American biotechnology firm, Myriad Genetics sought to enforce its patent on the BRCAnalysis test. The company was offering one of the first patented genetic tests to identify an individual's lifetime susceptibility to breast and ovarian cancer.[451] Ontario, which ultimately led

[450] OECD *New Health Technologies: Managing Access, Value and Sustainability* (Paris: OECD Publishing, 2017).
[451] Munro M, "Private lab offers screening for breast, ovarian cancer" National Post, 14 March 2000 at A1.

the charge in the Canadian gene patent debates particularly in the early 2000s,[452] was one of two provinces[453] who faced the legal threat of having to align their existing provision of the test with the exclusive licensing demands of Myriad. Although the province had become increasingly familiar with the Canadian realities in which new technologies are financed, developed and commercialized, it was becoming clearer still that such R&D activities were creating challenges around the provision of a sustainable and equitable health care system.[454] Questions about access to Myriad's BRCAnalysis laid bare the conceptual tension – that between the right to health and to the rights vested in IP – of patented gene-based technologies in Ontario's public health care sector. For Ontario, the concern was how to ensure an equitable delivery of the tests if clinical access was to be instructed by a private sector entity and market. Ontario's response to this threat led its health policy community to pioneering heights of interdisciplinary analysis on the topic.[455] In the Canadian context, the BRCA test was to gradually highlight a vulnerability in governance with respect to decisions around what access to genetic testing frameworks should look like in a publicly-provided health care system under the growing influence of private markets.

Around the time Myriad brought its patented technology to Ontario, the global "genohype" was taking hold, with genetics-related debates having intensified in Europe by the late 1990s over the enactment of the *Directive on the Legal Protection of Biotechnological Inventions* by the European

[452] Eggerston L, "Ontario defies US firm's genetic patents, continues cancer screening" (2002) 166(4) CMAJ 494.
[453] British Columbia was the other province. See, Gold and Carbone, *supra note* 103.
[454] See, Cohen J, "The genomics scramble" (1997) 275 Science 767; Parizeau MH, "Are the universities and sciences subservient to the economy? A summary and analysis" (2001) 2(4) ISUMA: Canadian J. Policy Res. 133. See also, Caulfield T, "The commercialization of human genetics: A discussion of the issues relevant to Canadian consumers" (1998) 21 J. Consumer Policy 483. And, Caulfield T, "The commercialization of human genetics: Profits and problems" (1998) 4(4) Trends in Molec Med 148. A global perspective on genomics in health was also important to the policy discussions between Ontario's health policy unit and Health Canada. For example of topic discussions, World Health Organization, *Genomics and World Health*, Report of the Advisory Committee on Health Research, Geneva, 2002, online: < https://apps.who.int/iris/bitstream/handle/10665/42453/a74580.pdf> [WHO].
[455] Charting New Territory, *supra note* 37.

Council and Parliament in 1998,[456] and with others, including Canadian commentators, weighing in on concerns over genetic exceptionalism.[457] In the U.S., alliances between academia and the biotechnology industry were being launched, largely due to biotech's support of a robust patent policy.[458] By 2000, when Myriad entered the Canadian genetic test market, Canadian efforts were focused on how best to integrate genetic tests into the health care system in terms of cost and effectiveness (Miller, p. 6). Efforts by the provinces, Ontario especially, also focused on how to address the forced adoption of a new health technology, not only because of the usual challenges associated with their uptake, but because patents were flagged as a potential policy issue (Informant 2, p. 2). Similar to other jurisdictions addressing the benefits and concerns of human gene-based technologies at that time, Ontario's focus was on how patents were being used and how to strategize formal policy schemes accordingly. From its beginnings, the problem of patents on genes in Canada was framed exclusively as a patent issue and the focus of Ontario policymakers was mostly targeted at patent system reform.

In 2001, the strategic health policy department in Ontario was galvanized into action upon receiving, along with all of the other provincial governments in Canada, a cease and desist from Myriad notifying them of the firm's patents on the BRCA genes and that their continued provincial program testing for BRCA-related breast/ovarian cancer constituted a patent violation. At the time, Ontario policymakers had growing concerns about Myriad's leverage to influence how access to

[456] *EU Directive*, *supra note* **Error! Bookmark not defined.**. The EU Directive sparked controversy for proposing patent rights on all biotechnological forms, including commercializing human and animal life. See, e.g., Crespi SR, "The Biotechnology Patent Directive is approved at last!" (1999) 17(4) Trends Biotechnol. 139. Also, see Gold and Gallochat, *supra note* 39.
[457] See, for e.g., Caulfield, *supra note* 230; Fleising U, "In search of genohype: A content analysis of biotechnology company documents" (2001) 20 New Genet Soc 239; Bubela T, Caulfield T, "Do the print media 'hype' genetic research? A comparison of newspaper stories and peer-reviewed research papers" (2004) 170(9) CMAJ 1399; Ransohoff DF, Ransohoff RM, "Sensationalism in the media: When scientists and journalists may be complicit collaborators" (2004) 4 Eff Clin Pract 185.
[458] Malinowski and Littlefield, *supra note* 180.

the BRCA test could change Ontario's delivery of health service structure through the firm's exercise of its patents (Mantel, p. 4). Consequently, much of the policy discussion with respect to genetic tests remained focused on their cost to the health care system — more specifically, at that time relating to costs per test[459] — and increasingly since, on how the patent regime stood to influence universal and cost-effective genetic testing.[460] The MOH health policy unit sought quick consultation to address what they saw as an aggressive business strategy underscored by the cease and desist from Myriad, which had acted swiftly upon entering the Canadian market (Informant 2, p. 2). From the outset, the health policy unit had a multidisciplinary vision to pursue a concerted course of action putting forth recommendations for how to mitigate barriers to Ontario's testing services.[461] The controversy around the BRCA patents quieted soon after it had started, however, with Myriad withdrawing its efforts to pursue exclusivity in the Canadian market[462] and leaving some analysts to question the merits of the MOH proposals.[463] The Myriad controversy nonetheless shone a light on the ability of an aggressively forward-looking health policy unit with a strong knowledge capacity to adequately consider a quickly evolving policy and health care landscape. It was a capacity that was lost when the unit was dismantled in the years following the Myriad controversy.

[459] Miller F et al., "Predictive Genetic Tests and Health Care Costs: A Policy Framework and Illustrative Estimates," Centre for Health Economics and Policy Analysis Working Paper Series, McMaster University, Hamilton, 2002 (authors developed an evaluation framework to guide an Ontario ministry advisory committee in 2001 on coverage decisions on predictive molecular tests), online: <http://www.health.gov.on.ca/en/common/ministry/publications/reports/geneticsrep02/chepa.aspx>.
[460] Liddicoat et al., *supra note* 274.
[461] Charting New Territory, *supra note* 37.
[462] See, Gold and Carbone, *supra note* 103.
[463] Caulfield T, "Reflections on the gene patent war: The Myriad battle, Sputnik, and beyond" (2011) 57(7) Clinical Chemistry 977. Also in, Caulfield, *supra note* 230.

3.4.2.2 Policy Gaps

Since Myriad, the test provision landscape in Ontario has undergone a major transformation regarding the genetic testing conducted in clinical laboratories. The shift involves a change from clinical reliance on using tests that screened for single-gene mutations to a process now where whole genomes are sequenced (Informant 8, p. 16). As a result, priority-setting regarding genetic tests in the province also faced major changes over determinations of how to allocate funding to testing as a health care service (Ungar, p. 16). This shift transformed both the test provision landscape and the delivery of and access to care because it is one that required major infrastructure investments in public testing labs with the adoption of multiplex testing techniques (i.e., whole genome and exome sequencing) being used increasingly in standard of care for patients (Ungar, p. 11). Prior to 2020, from a health policy perspective, the transformation to the landscape highlights a provincial policy gap with respect to what access to genetic tests should look like, including what room should be given to genetic health services under the existing priority-setting paradigm directing access to tests in the province. Following a positive funding recommendation in 2020 for whole exome sequencing (WES) and whole genome sequencing (WGS) for certain conditions,[464] a major implementation pilot project is underway in Ontario (the GSO), with similar pilots occurring across Canada, to facilitate better access province-wide.[465]

In Canadian provinces, the minimum threshold for justifying publicly-insured health care of a particular service or technology is its assessment within this framework as being a technology that is "medically necessary." Access to services or technologies that are not considered medically

[464] See, Health Quality Ontario, *Genome-Wide Sequencing For Unexplained Developmental Disabilities Or Multiple Congenital Anomalies*, Final Recommendation, March 2020, online: <https://www.hqontario.ca/evidence-to-improve-care/health-technology-assessment/reviews-and-recommendations/genome-wide-sequencing-for-unexplained-developmental-disabilities-or-multiple-congenital-anomalies)>.
[465] See, Genome-wide Sequencing Ontario online: <https://gsontario.ca/>.

necessary are determined by way of their availability for private purchase or through restricted though in some cases relatively more affordable access opportunities.[466] The *Canada Health Act* refers to providing "medically necessary" services, but despite the *Act*'s importance in defining the scope of provincial government responsibilities for public health care funding, 'medical necessity' is not defined, neither in federal policy nor in legislation.[467] The absence of a definition or clear criteria identifying medically necessary services relating to genetic health technologies constitutes a policy gap set to widen increasingly for provinces wishing to achieve equitable delivery of health care services. Wider policy gaps mean leaving access to some gene-based health services uncoordinated, uneven, or altogether uncertain.

Examples in Canadian case law show that this policy gap could be contributing to an unjust distribution of the benefits of health care, compounding existing issues of equity.[468] The lack of policy-based principles attached to the concept of medical necessity can leave provincial governments unsure as to how to apply the legislation for decision-making around any technology or service coverage.[469] Ultimately, decisions regarding what is considered 'medically necessary' rely on satisfying clinical utility[470] criteria and on "data on how this affects health care for patients or how this affects medical management" (Informant 16, p. 2). With no common ground on

[466] An example is patients seeking information on breast/ovarian cancer susceptibility through Toronto's Woman's College Hospital's research project, the Screen Project, must pay out-of-pocket for testing.
[467] Rachlis MM, "Defining basic services and de-insuring the rest: The wrong diagnosis and the wrong prescription" (1995) 152 CMAJ 1401. See also, Caulfield T, "Wishful thinking: Defining 'medically necessary' in Canada" (1996) 4 Health L. J. 63.
[468] See also, Jackman M, "The application of the Canadian *Charter* in the health care context" (2015) 9 Health L. Rev. 22.
[469] The *Canada Health Act* defines "medically necessary" as medical treatments and procedures, those provided by a physician or in a hospital setting, to be paid for by the publicly funded system. See also, Charles C, Lomas J, Giacomini M et al., "Medical necessity in Canadian health policy: Four meanings and … a funeral?" (1997) 75(3) The Milbank Quarterly 365.
[470] Waddell K, Wilson MG, *Rapid Synthesis: Examining the public provision and funding of clinical genetic testing*, McMaster Health Forum, 5 September 2017, at 6, online: <https://www.mcmasterforum.org/docs/default-source/product-documents/rapid-responses/examining-the-public-provision-and-funding-of-clinical-genetic-tests.pdf?sfvrsn=2>.

'medically necessary' criteria, decisions that can impact access to genetic tests can be influenced by a host of external factors, including marketing, interest groups, and a general range of actors and actions such as those around funding.[471] It is a framework that one informant says can leave access to tests to chance and inequities (Informant 16, p. 10).

In their report on *Genomics and World Health* (2002), the World Health Organization (WHO) claimed that research in the areas of genetics and genomics holds great promise for developing significant benefits in health and well-being.[472] According to informants in this study, the increased reliance on genetic testing by clinical geneticists corroborates the promise of benefits from developments out of the research sector, but implementing genetic technology into existing priority-setting health care systems is often disruptive[473] and has led to challenges in obtaining timely and affordable access to testing (Informant 8, p. 6). The exclusivity rights associated with Myriad's patents on their BRCA tests were just part of the genetic test landscape story; the other part involved the Canadian health care system's funding priority approach to the delivery of patient care. The benefits of such an approach are expected to include increased opportunities to inform patients of potential preventative medical treatments that can emerge through access to comprehensive testing (Informant 16, p. 7). In the case of Myriad enforcing their BRCA patents, its business model was threatening a broader disruption to the Ontario health care system that would force changes to test provision and delivery of tests already being offered in the province at a fraction of the cost.[474]

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[471] Baird P, "Getting it right: Industry sponsorship and medical research" (2003) 168(10) CMAJ 1267.
[472] WHO, *supra note* 454.
[473] See, Canadian Medical Association, *The Future of Technology in Health and Health Care: A Primer*, Discussion Paper, Health Summit, 2018, online: <https://www.cma.ca/sites/default/files/pdf/health-advocacy/activity/2018-08-15-future-technology-health-care-e.pdf>. See also, Schulman A, Vidal AV, Ackerly DC, "Personalised medicine and disruptive innovation: Implications for technology assessment" (2009) 11 Genet. Med. 577.
[474] See, e.g., Gold and Carbone, *supra note* 103.

The Myriad controversy led to a stark realization that nothing stopped gene patents of concern from being issued nor was there comprehensive policy for their regulation in Canada. Not much is different today.

3.4.3 Ontario Genetics Policy Landscape: Access and Health Technology Assessment

In the summer of 1999, just before the Myriad controversy unfolded in Ontario, a woman successfully challenged the Ontario government's decision not to fund her out-of-province BRCA test.[475] The choice to seek testing from Myriad through the private sector resulted in Fiona Webster, with a strong family history of breast cancer, paying for the service herself. Ms. Webster would later be reimbursed following a pursuit of public health coverage of the test cost, but not before a two-year waiting period for access to Ontario's research-based BRCA testing programs to make a fully informed decision against her physician's recommendation that she undergo prophylactic surgery. By winter of 2000, Ontario became the first province to pay for out-of-province genetic testing on a case-by-case basis, sending samples to the U.S. to screen for a genetic predisposition to breast or ovarian cancer. Ms. Webster's ordeal in 1999 highlighted the policy gaps and cracks around access to testing in the province and across the country, some of which more or less persist today. Chief among these issues is the *ad hoc* (i.e. case-by-case, patient-by-patient) nature of access to testing still determined for some conditions on an academic or clinical research basis.

[475] Abraham C, "Tenacious woman scores medical victory: Fiona Webster's fight." The Globe and Mail, 27 August 2019 at A1.

3.4.3.1 Ad Hoc Access

Currently, in Ontario, high-demand genetic tests include predictive tests, diagnostic tests, and tests for hereditary cancers.[476] Genetic testing is covered for Ontarians who meet certain established risk-based criteria, and for tests that have been classified as medically necessary.[477] When such eligibility criteria are met, genetic testing is covered in full,[478] and when such criteria are not satisfied, individuals can turn to other offerings for the test, including accessing private genetic testing services if they are willing to pay out-of-pocket. In the case of BRCA1 and BRCA2 in Ontario, as in several other provinces, testing has often been made available on a research basis, namely, through projects that select patients with a strong family history of the disease[479] or who have been previously diagnosed with the disease (Informant 15, p. 3). One genetics counsellor explained to me that compared to cheaper options available for testing that do not solely rely on formulary coverage,[480] screening through Ontario's universal health care typically happens at a cost to the system of about CDN$2,000–3,000 and entails wait times of up to one year (Informant 1, p. 3).[481] With respect to clinical assessment, patents add a layer of complication because they can interfere with an individual's timely access to test results[482] (Informant 8, p. 6). Whether patents are an existing issue with respect to access (i.e. contributing to a one-year wait time) or

[476] Trillium Health Partners. Genetics program. 2017, online: <https://trilliumhealthpartners.ca/patientservices/genetics/Pages/default.aspx> (Accessed 1 May 2019).
[477] See, Sunnybrook Health Sciences Centre, *BRCA1 and BRCA2*, 2017, online: <https://sunnybrook.ca/content/?page=brca1-brca2-gene-mutation> (Accessed 1 May 2019).
[478] Ministry of Health and Long-Term Care. Ontario Prenatal Screening: Multiple Marker Screening Program. 2003, online: <https://prenatalscreeningontario.ca/en/pso/about-prenatal-screening/multiple-marker-screening-mms.aspx>.
[479] Williams-Jones B, "Actor-Network Theory: A tool to support ethical analysis of commercial genetic testing" (2002) 22 New Genet. Soc. 271.
[480] See, for e.g., *The Screen Project*, Women's College Hospital, online: <http://thescreenproject.ca/> (date accessed: 10 October 2019). At the time of this interview, the Project offers BRCA testing at a cost of CDN$250.
[481] See also, Lam AA, "The Screen Project slashes wait time for break cancer screening," The Varsity, 21 October 2018, online: <https://thevarsity.ca/2018/10/21/the-screen-project-slashes-wait-times-for-breast-cancer-screening/> (date accessed: 10 October 2019).
[482] See also, Andrews, *supra note* 206 at 69.

compounding this issue (i.e. navigation of IP, extending wait times) is unknown at this time. In spite of this blind spot regarding test and test result accessibility, in consideration of the policy developments that have occurred in Ontario over the last two decades, one informant described the current genetic test provision landscape in Ontario as "backwards" (Informant 1, p. 1).

When talking more specifically about access to cancer susceptibility testing as a policy issue in the province, two genetics health science researchers reflected on the current model of access. These two informants shared concerns relating to the *ad hoc* access to genetic tests in the process (Informant 16, p. 6; Ungar, p. 10). For instance, access to testing through academia-industry partnerships is a growing trend in biotechnology R&D to capitalize on multi-stakeholder precompetitive collaboration research as industry in-house R&D continues to shrink.[483] One informant noted that under the current care provision model, of which includes reimbursement for out-of-country testing, some sought-after domestic testing options (such as those offered through research projects considered exploratory or experimental) are accessible in a case-by-case fashion, which can mean that access can happen "very much by chance" for some individuals (Participant 16, p. 10), saying:

> The funding structure for those tests are often offered only through people who manage to get [research] grants and make those tests eligible for [those] that are seen at academic and tertiary care centres. (Informant 16, p. 6)

Consequently, access to tests in the province is privileged under this model — privileging access only through those research trials that successfully secure funding and make testing publicly available. Access may also be privileged where some of these trials require out-of-pocket payment by individuals who fail to meet the provincial formulary risk-based criteria, but, like Fiona

[483] See, de Vrueh RLA, Crommelin DJA, "Reflections on the future of pharmaceutical public-private partnerships: From input to impact" (2017) 34 Pharm. Res. 1985.

Webster, who seek testing in order to be able to make informed decisions about their health sooner rather than later (Informant 16, p. 7). This kind of *ad hoc* test access can establish inequities of access and, in some cases, pushes new genetic technologies into the health care system without a fuller understanding of their usefulness or without receptiveness from the health care sector:[484]

> We're also privileging these research trials on technologies being offered through research because many of them, we don't know what the safety and efficacy is. We're privileging a positive outcome, but by the same nature, patients who have a leg up on this access might access something that doesn't work, which is obviously inherent in a trial. But, to be totally unbiased here, they put themselves at risk. So, by having access, you access something that you might not otherwise have had, but at a risk—with access to something that might not work or give any sort of actionable results. (Informant 16, p. 10)

There has been some groundwork by genetics health researchers and HTA bodies that could offer Ontario a promising trajectory for what access to a genetic test can feasibly look like. Informant 16 notes the case of ODX testing in Ontario in the late 1990s and introduced in the discussion above. Briefly, the ODX test is a prognostic which provides predictive information about the likelihood that a particular type of breast cancer will recur. Like most genetic tests, ODX provides a range of possible predictions upon testing that offers information to users who can consider options for further medical intervention based on ambiguous results (Informant 16, p. 8).

The ODX test was first made available to the public through a research pilot study, and the only way an individual would learn about it was if they learned about the test from their primary health care provider. Like most genetic tests funded in the province that are not considered medically necessary, and thus are not publicly funded, access to the test was *ad hoc*:

> Back to your question regarding access. It [ODX] was previously provided in Ontario to patients seen by oncologists in academic centres that were part of this [ODX] trial, and not to those oncologists who were not part of this trial. And that's the thing with research, when we're talking about new technology, is they're first inherently available as part of research. And who is part of research? Academic hospitals and those [clinical scientist] doctors, so

[484] Lehoux P et al., "How do values shape technology design? An exploration of what makes the pursuit of health and wealth legitimate in academic spin-offs" (2014) 36(5) Sociology of Health & Illness 738.

> that's a very basic but pervasive issue on how access to new technologies actually occurs now. (Informant 16, p. 10)

At that time, however, the test was not available locally, with little in-house development of genetic tests occurring in Canada, leaving the province to purchase the tests from a single American proprietor:

> One company out in California [that] set the price of the test, and that's what the government was paying for as part of their out-of-province budget, which is where many of the genetic testing that are funded in province that are not part of the public funding envelope get. (Informant 16, p. 9)

By the mid-2000s the ODX test had been used extensively in the U.S., and later in Canada, so when asked why tests were sought out-of-province and not developed in Ontario labs by the time it made its way for use in Ontario, the informant responded:

> Because a lot of these tests are patented and have proprietary protection. So, when that [availability] happened, that pushed OHTAC [Ontario Health and Technology Advisory Committee] to review the test — its cost-effectiveness — among other stuff. (Informant 16, p. 9)

However:

> Oncotype-DX testing was originally offered only as part of a trial when first identifying how predictive and prognostic the test really is among a patient group study, a pilot study. But in addition to this pilot study at the time, other women who wanted access to the test had to pay out-of-pocket. So, that made headlines and put pressure on the Ontario government to assess the test and ask if it should be provincially funded. (Informant 16, p. 8)

Informant 16 went on to say that the OHTAC, which provides recommendations to the health ministry regarding publicly-funded products and services, was involved because clinical access to the test was ambiguous and a comprehensive review of its efficacy and utility was needed to determine what access needed to look like for patients:

> I understand review of the test was already in the pipeline … [but] also because of patients wanting access … the Oncotype-DX test was an access issue. (Informant 16, p. 10)

According to this informant, the broader issue of access to genetic tests can be improved in several different ways. For example, academia-industry partnership studies can offer population screening for disease susceptibility or carrier status[485] while also raising awareness that formal policy around access to tests needs serious reconsideration. Access to testing through academia-industry partnerships is a growing trend in biotechnology R&D that capitalizes on multi-stakeholder precompetitive collaboration research as industry in-house R&D continues to shrink.[486] Such initiatives are said to operate within the *ad hoc* test access landscape, but because these initiatives are free from having to adhere to provincial test eligibility limitations, anyone willing to pay for it can get a genetic test to screen for their increased risk of developing breast cancer.[487]

But, while access to health care in Canada based on need rather than ability to pay is a founding national principle, equitable access to genetic tests within the public health system as part of that care remains elusive. The *ad hoc* manner of test access in the province reflects profound uncertainty in the test provision landscape and in patient care. Consequently, as new technologies become available, the work of provincial health policy advisory providing recommendations on how to achieve reliable and equitable access to genetic tests has in some ways become more challenging. As Informant 16 put it:

> We have been doing it forever, but maybe we've been doing it inappropriately. Just allowing these technologies into health care willy-nilly, without evaluating them and putting them through the same type of rigour of assessment and evaluation criteria we use for other technologies. It begs of genetic exceptionalism. (Informant 16, p. 5)

[485] The Toronto Screen Project is an example. See, online: <https://www.womensresearch.ca/research-areas/cancer/the-screen-project/>.
[486] See, de Vrueh and Crommelin 483.
[487] According to Informant 1, The Screen Project in Toronto offers testing to accepted participants for approximately CDN$250.

The concern for HTA is that policymakers are making decisions around the implementation of genetic tests in the Ontario health care system (or around the use of genetic health technologies and the interpretation of test results by clinicians more broadly) with an incomplete understanding of their clinical utility. In not appreciating the full utility of such tests, policymakers risk not taking full advantage of emerging innovation in the field. An additional worry is that this gap in knowledge also challenges the development of adequate genetics access policy to these technologies.[488] The implementation of new knowledge in practice requires a nimble and responsive policy and regulatory environment to support access to valuably co-created health care innovation that can also ensure better use of scarce resources in health care.[489] One way in which Ontario works towards this goal has been through its HTA community. Given that there is a significant reliance by the clinical care community on genetic tests and testing coming from out-of-country, I spoke with members of OHTAC and Ontario Genetic Advisory Committee (OGAC) to get a better sense of how technology assessment factors into test access in the province, and to better understand the potential impacts patents could have on the provincial austerity measures of priority-funding to facilitate this access.

3.4.3.2 Beyond Gold Standard Assessment

Various approaches to policy formulation, such as using data from evidence-based medicine (i.e., determining clinical efficacy), economics (i.e., determining cost-effectiveness), and ethics (i.e., determining fair distribution of resources, social implications, value of technology integration) help to optimize decisions about public health options and to predict what access to given technologies could look like. However, these methods are not always the most effective or most

[488] Unim *supra note* 414.
[489] International Trade Administration, *supra note* 444.

readily available for policy advisors and makers to assess which health technologies should be implemented and what equitable access should look like.[490] This is particularly true of genetic health technologies, ultimately making priority-setting around genetic technologies in Ontario's health systems a challenging area of analysis for HTA (Informant 16, p. 13).

Health technology is different from other forms of evidence-based research because it produces and provides information that can directly contribute to the decision- and policy-making process.[491] Health technology assessment bodies in Ontario, including the OHTAC and the OGAC, have been working to mitigate some of these challenges through a multidisciplinary approach to analyzing the implications of using genetic health technology as a from of medical intervention. Prior to OGAC, the HTA community in Ontario included the Genetic Testing Advisory Committee (GTAC), with a three-year legislated mandate to make evidence-based recommendations to the MOH on the clinical utility and validity of genetic tests in relation to the provision of tests in Ontario. The GTAC was created in accordance with the *Excellent Care for All Act* and the *Ontario Action Plan for Health Care*[492] to promote scientific and clinically-based delivery of care. With the disbanding of the GTAC in 2017, the OGAC continued in its place.

With innovation in health care technology booming and the cost pressures to the system that accompany their uptake, HTA provides important support to health authorities to inform decisions on technological implementation. Genetic tests in Canada remain characterized as new or emerging technologies (Informant 15, p. 4) and are particularly illustrative of the stewardship role

[490] See also Gibson JL, Martin DK, Singer PA, "Evidence, economics, and ethics: Resource allocation in health services organizations" (2005) 8(2) Healthcare Quarterly 50.
[491] OECD, *Biomedicine and Health Innovation* (Synthesis Report) (Paris: OECD, 2010).
[492] Government of Ontario, *Ontario Action Plan for Health Care*, Ministry of Health and Long-term Care, 2012, online: < https://www.health.gov.on.ca/en/ms/ecfa/healthy_change/docs/rep_healthychange.pdf>.

of the provincial HTA community. In the case of genetic tests, however, the need for HTA support is more acute in light of the limited existing policy frameworks and empirical data on provision, although this issue is pervasive to new technology assessment in Canada more broadly.[493] Recently, efforts to determine appropriate means of public access to genetic testing in Ontario are focused less on the use of orthodox assessment approaches (to determine whether a given test should be adopted) and relying more on developing stand-alone standards for gene-based health technologies to bridge into existing and future policy. The idea is that technology assessment relating to genetic health innovation should work to remain in line with the medical and economic assessment of technology based on patient need, rather than embracing "technology for technology's sake."[494]

Over the past several years, the clinical use of genetic tests in Ontario has been on the rise, with the majority of genetic testing occurring in hospitals domestically at costs of approximately CDN $55.1 million for the Ontario government in the 2013–2014 fiscal year, and a "large number" of testing services being conducted out-of-province at an approximate cost of CDN $24 million in that same time period.[495] A rise in the clinical use of genetic tests has been backed by the increasing demand for genomic and health-related data by clinicians and patients, but also likely due to an uptick in health technology innovation through the industry's personalized medicine movement and drug efficiency profiling by way of companion tests (Informant 15, p. 1). The demand for clinical testing has been driven by an increased demand for molecular diagnostics in particular, the fastest growing segment of diagnostics used in infectious diseases, oncology, and genetic disease

[493] Health Technology Assessment Task Group, *Health technology strategy: Final report* (Committee Report) (Ottawa: Canadian Agency for Drugs and Technologies in Health, 2004).
[494] Romanow Commission, *supra note* 43 at 83.
[495] LSEP, *supra note* 266 at 8.

screening.[496] Some Canadian health systems scholars have expressed concern with respect to whether greater access to testing will be adequately implemented by way of research and clinical genetics projects for the adoption of the most useful of valuable health care innovations and technologies by the health care system.[497] In response, the MOH banded together sub-specialized committees of OHTAC with expertise in genetics and genomic to form the OGAC (Ungar, p. 4). Further, the MOH has considered increasing access to testing through an increase in provincial testing capacity (i.e., the GSO pilot). Ultimately, Ontario's efforts towards this goal have included the banding together of expert-driven committees established to analyze evidence-based HTAs based on clinical and economic data[498] to achieve "best value for money" of technology integration (Ungar, pp. 6, 12, 22, 26; Informant 16, p. 7). These committees have also increased consideration of "a number of genetic testing topics" over the years (Ungar, p. 4) and considered various non-economic policy-relevant factors[499] with respect to clinical efficacy, clinical utility, safety, cost-effectiveness, ethical consequences, patient values and preferences, and budget impact of tests (Ungar, p. 20).[500]

[496] *Id.*, at 22.
[497] Begin M, Eggertson L, Macdonald N, "A country of perpetual pilot projects" (2009) 180(12) Canadian Med. Association 1185. See also, Snowdon A, Zur R, Shell J, Transforming Canada into a Global Centre for Medical Device Innovation and Adoption (White Paper) (Windsor: World Health Innovation Network, 2011), online: <https://innovatexchange.ca/wp-content/uploads/2015/07/ICHIL_Medical_Devices_White_Paper_FINAL2.pdf> (date accessed: 18 May 2020).
[498] Johnson AP, Sikich NJ, Evans G, et al. "Health technology assessment: A comprehensive framework for evidence-based recommendations in Ontario" (2009) 25(2) Int J Technol Assess Health Care 141. See also, Giacomini M, Winsor S, Abelson J, "Ethics in health technology assessment: Understanding health technologies as policies" (Summer 2013) Healthc. Management Forum 72.
[499] Giacomini et al., *id*.
[500] *Id*.

3.4.4 A Crisis in Data Collection

Clinical utility[501] in particular is an important criterion for determining whether a given genetic test is identified as medically necessary within the provincial priority-setting framework, according to a recent study from Hamilton's McMaster Health Forum (2017).[502] In Ontario, evaluations of clinical utility evidence assembled by the Ontario Health HTA team are conducted by the technology advisory committees. For genetic tests, it would be undertaken by the OGAC (Ungar, p. 4). However, as a methodological approach, collecting empirical data to understand a test's clinical utility is challenging (Informant 16, p. 3). For instance, most conventional clinical tests are used to detect evidence of an already-existing condition or disease. Predictive tests, on the other hand, "identify potential mutation of an underlying condition that will *eventually* make its way to impact clinical care, that will *eventually* impact morbidity, mortality" (Informant 16, p. 2, *emphasis added by informant*). In this way, genetic technologies are a particularly challenging class of technologies due to limitations associated with collecting the scientific and clinical data that might be necessary at a point in time to inform meaningful policy regulating test provision and thereby accessibility in the province. According to one informant:

> A lot of just the state of science of genetics and genomics is in its infancy. We don't have twenty years of data collected on cohorts like that. And unfortunately, it's a problem because the health science research and policy world hasn't really intersected much in the genetics and genomics community. (Informant 16, p. 3)

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[501] Holtzman NA, Watson MS. (eds.), *Promoting safe and effective genetic testing in the United States. Final report of the Task Force on Genetic Testing*, 1997, online: <https://biotech.law.lsu.edu/research/fed/tfgt/index.htm> (date accessed: 11 May 2021) (the task force proposed a commonly used framework to be used in establishing evidence-based guidelines to assess the use of genetic tests in clinical practice, referring to clinical utility as "the balance of benefits to risks"). Compare to, Khoury MJ, "Genetics and genomics in practice: The continuum from genetic disease to genetic information in health and disease" (2003) 5 Genet Med 261 (the author offers broader definitions of clinical utility to include, "… any use of test results to inform clinical decision-making" and "… any outcomes considered important to individuals and families (e.g. reproductive decisions and psychosocial support").

[502] Waddell and Wilson, *supra note* 470 at 12 (conducting study among comparator health system jurisdictions including each Canadian province and abroad). See also, Lin JS et al., "Evaluating genetic tests from bench to bedside: A practical framework" (2012) 12 BMC Medical Informatics and Decision Making 117. See also, Grosse SD, Khoury MJ, "What is the clinical utility of genetic testing?" (2006) 8(7) Genet in Med 448, 448.

Whether to "detect and manage" or to "diagnose and cure," health policy reflecting the best of what human genetics has to offer is a necessary first step towards this goal. Towards this goal, enabling health technology innovation can improve patient outcomes, address barriers of access, harness the potential of systematic evidence-based evaluations by technology assessment and consequently contribute to evidence-informed decision-making by policymakers.[503] One informant suggested that a formalization of genetics programs within the existing health care policy framework would need to be made operational for adequate HTA of genetic health technologies (Informant 16, p. 4). To serve the broader objectives of health improvement and the sustainability of the publicly-funded health care system, there have been several areas of emerging evidence-based policy work in Ontario addressing the need to improve assessment frameworks relating to genetic health technologies, and tests in particular.

For one, Canadian genetic health science researchers have been conducting new study designs to adapt randomized controlled trials to generate clinically relevant data on the utility of genetic tests.[504] The primary goal of this research has been to "generate high quality evidence so we're not constantly pointing fingers at a gap and not addressing it … to reach the same sort of evidentiary quality or grade" relating to the evidence standard of any other health technology (Informant 16, p. 5). Currently, the province is making decisions about access more or less under a "coverage with evidence development" model, by making "the tech funded for a given group for whom they

[503] MacNeil*, supra note* 402.
[504] See, e.g., Bogaerts J et al., "Clinical trials designs for rare diseases: Studies developed and discussed by the International Rare Cancers Initiative" (2015) 51 Eur J. Cancer 271. See also, Bombard Y, Bach PB, Offit K, "Translating genomics in cancer care" (2013b) 11(11) J Natl Compr Canc Netw 1343. And, Bombard Y, "Translating personalized genomic medicine into clinical practice: Evidence, values, and health policy" (2015) 58 Genome 491.

know or prior evidence shows it's more effective, and then provid[ing] access as part of a trial" (Informant 16, p. 11; Informant 15, p. 15). But, as Informant 16 emphasized:

> Most of the industrialized world is now trying to address … how can we decide our funding decisions based on real-world evidence — How do we have access to it [data] and collect it in a harmonized way to potentially de-fund or de-list access to tech/drug that does not seem to be doing what it was demonstrated to do. (Informant 16, p. 12)

Working to close the standards gap in this "real-world evidence" approach is particularly germane in the context of next generation genetic sequencing, but these efforts face unique challenges within the current HTA framework around gene-based technologies. For one, the collection of real-world clinical data from genetic testing is itself difficult. Efforts to distinguish between efficacy ("what happens in research") and controlled clinical trials data that are "not necessarily reflective of what happens in the real world" (Informant 16, p. 11), and effectiveness ("what happens in the real world") are not new challenges within the Ontario HTA landscape, but they are especially difficult challenges to address in relation to gene-based technologies (Informant 16, p. 12).

Currently, the challenge for assessment of gene-based health technologies lies in using the same HTA framework used to assess other technologies, but having to "reduce our thresholds because we don't have classic metrics, thresholds, or designs to address [HTA] criteria, specifically clinical utility" (Informant 16, p. 4). According to Informant 16, it is nonetheless a challenge worth addressing because closing the evidence gap based on real-world data on test technologies can provide an opportunity for better responsive policy,[505] one that could act as a "de-investment

[505] According to recent legal scholarship, "responsiveness" implies a nimble regulatory scheme, not static but rather "employing principled mechanisms to respond to emerging evidence of benefits, threats, and evolving societal values." See, Bubela T et al., "Canada's *Assisted Human Reproduction Act*: Pragmatic reforms in support of research" (2019) 6 Frontiers in Med., Article 157, 1.

approach" (i.e., to defund the least effective publicly-funded technologies) and thereby align with provincial austerity objectives in health care (Informant 16, p. 12).

Ontario Health has also been working to determine which tests in particular have been in demand from out-of-country as efforts around securing local test implementation have mounted over the past several years. These efforts operate within the "zero sum game" of the publicly-funded health system under financial constraints, a system unable to fund inefficient or ineffective genetic tests in demand even with evidence of clinical utility (Ungar, p. 26). The increase in demand for private genetic testing services in some jurisdictions, some still in the form of direct-to-consumer kit-based tests, may serve to satisfy some public demand. Although this can inflame concerns about diverting discussions about test access from one focused on publicly-provided care based on need, to gaining access to tests based on (private) ability to pay. While initially seen as a way to help alleviate rising demands on testing services, the worry is that if a private test is performed in addition to an already existing provincially-provided test, this introduces a greater cost burden to the system over the long term,[506] and that eventually, this bifurcation in testing services could lead to longer wait times for test results and more visits to specialists.[507]

With respect to genetic testing services, efficiencies of scale and poor or underdeveloped valuations of these services have become a challenge for policymakers.[508] As expressed by some informants in this study, this type of data collection is a slow process. Centralized processes established to facilitate clearer routes of access to tests have been suggested by a group of Canadian genetic counselors to improve cost savings and resource allocation by guiding better clinical data

[506] Miller, *supra note* 459.
[507] Charting New Territory, *supra note* 37.
[508] Ali Khan and Gold, *supra note* 122 at 1254.

collection, monitoring, and assessments of impacts on the health care system.[509] However, *CHEO* has made it clear that access to some high-demand testing services continues to be less than optimal for patients regardless of streamlined processes in Canada, and that patents continue to interfere with various routes to test access.[510]

3.4.5 Challenges for Implementation

Before understanding why establishing a coordinated and coherent policy to patented test access is an important step for the health care provision landscape in Ontario, a better understanding of the policy context around test implementation is warranted. According to one informant who serves on the OHTAC and OGAC, the role of these committees as "stewards" of the public health care system is widely understood as an extension of the stewardship and governance structure of the province over health care:

> My perception is that the MOHLTC wants to be good stewards, and that means supporting technologies that provide good value for money, where value is defined in terms of patient benefits. (Ungar, p. 6)

When asked to elaborate on the availability of genetic tests in the province under this stewardship, similar to Informant 16's illustration of Ontario's ODX testing above, Ungar explained that sometimes the reason an HTA of a test occurs is due to concerns around out-of-pocket payment and the impact on universal access:

> There are many genetic tests available in Ontario that patients pay out-of-pocket for, many. But sometimes, that's the impetus for bringing topics to our committee. For example, OGAC's recent review for non-invasive pre-natal testing (NIPT). The question arose as to whether it is *good value for money* in average-risk women … Just to say that when patients are paying out-of-pocket for things, that's a big part of the impetus for doing a formal health technology assessment and understanding whether it should be funded or not. (Ungar, pp. 6–7, *emphasis added by informant*)

[509] Lilley, *supra note* 440.
[510] Liddicoat et al., *supra note* 274.

In the case of long QT testing, a Canadian stakeholder study by Ali Khan and Gold (2017) involving hospital directors and clinicians reported that prior to *CHEO* in 2014, most of the testing was conducted out-of-country under LQTS gene patent licensees with costs to the province amounting to upwards of USD$3,000, potentially as much as USD$4,500.[511] long QT tests screen for long QT Syndrome (LQTS), an inherited abnormality of the heart associated with, at best, heart palpitations and, at worst, sudden death in otherwise healthy individuals. Prior to *CHEO*, Canadian hospitals seeking to test for LQTS typically have to outsource patient samples to testing facilities in the U.S. often at a significant cost to the hospital and/or province and to the patient in part due to the wait time for results. Test costs in general likely depended on bulk order negotiations between test provider and hospital users (Ungar, p. 11).[512] Although, Ali Khan and Gold (2017) report that budgets are expected barriers to universal test access because most public health providers are individual payers (hospitals, clinics) and therefore face challenges with respect to an ability or capacity to gain or negotiate test procurement.[513]

Similar to most genetic tests used in Canada, long QT testing is sought either through commercial providers[514] or through outsourcing tests out-of-country from the U.S, making procurement critical in some cases. According to Ali Khan and Gold (2017) and an informant from this study, most long QT testing applications prior to *CHEO* had been approved because the test has proven clinical

[511] Ali Khan and Gold, *supra note* 122 at 1254. See also, Familion genetic testing for cardiovascular disorders. The Familion LQTS — The First Comprehensive Genetic Test for LQTS, online: <http://www.transgenomic.com/labs/cardiology/familion/lqts.html> (date accessed: 21 May 2020).
[512] *Id.* at Ali Khan and Gold.
[513] Scott A et al., "Optimizing adoption and diffusion of medical devices at the system level" (Information Paper) (Edmonton: Alberta Health Services, 2015), online: <optimizing_adoption_and_diffusion_of_medical_devices_at_the_system_level.pdf>. The procurement process can also be a barrier to the adoption and spread of new technologies which may have long-term value to public health.
[514] Ali Khan and Gold, *supra note* 122 at 1255 (stating that as the "practice choice for most Canadian stakeholders" in their study).

utility (Informant 8, p. 6).[515] The cost of outsourcing tests was, however, a growing financial burden on already strained hospital budgets, despite efforts by provincial authorities to administer test outsourcing centrally in order to streamline costs to meet the demands for increased molecular testing in the clinical setting.[516] More broadly, the efficiency of health care systems has remained at odds with their ability to facilitate equitable access to testing.[517] Furthermore (and an added challenge for policymakers), the impact of patents on increased costs and lowered innovation is of concern the more centralized the testing is in a province.[518] With a CDN$24 million (and likely rising) outsourcing cost estimate in the 2013–2014 fiscal year,[519] Ontario's way forward to facilitate equitable access to several high-demand tests, including that for LQTS, [520] has often been through relying on procurement policies that favour the least expensive item.[521]

Following the Myriad controversy in the early 2000s, the idea of local test implementation (often referred to as repatriation) was well-received by public health officials in Ontario. In part, local testing was favoured for its potentially auspicious overall impacts on the health care system, including permitting better research, better patient care, and better testing business.[522] At that time, the Ontario health ministry realized that it was paying "a lot of money" (Informant 8, p. 7)[523] to send patient samples to the U.S. for long QT testing (Informant 8, p. 5). In the 2000s, the push to establish local testing for high-volume, high-cost tests with increasing referrals began circulating among the academic and tertiary-care centres and public lab communities (including hospital

[515] *Id* at 1254–55.
[516] *Id.* at 1254.
[517] *Id*.
[518] *Id*.
[519] See, LSEP, *supra note* 266.
[520] Ali Khan and Gold, *supra note* 122 at 1255.
[521] Scott, *supra note* 513.
[522] See also, Ali Khan and Gold, *supra note* 122 at 1255.
[523] According to this informant, at that time a patented LQTS testing conducted in a lab out-of-country was approximately CDN$4,500 whereas the same test could be done for less than half of that cost in the province.

directors and clinicians).[524] In the years that followed, the push led to rounds of calls by the Ontario health ministry for expressions of interest in the procurement of certain genetic tests. A successful expression of interest to establish a local test would secure additional provincial funds to the one public laboratory proposing to offer the test at its "most cost-effective level" (Informant 8, p. 11). Prior to the 2014 *CHEO* case, requests for expressions of interest in local implementation of testing was Ministry-driven because "the Ministry was so concerned about money going to the USA" (Informant 8, p. 14). The first round of calls for proposals in the late 2000s included long QT testing out of CHEO because the MOH saw an opportunity to save the health care system a significant amount of money:

> It [the health ministry] should be investing in this technology in Ontario, where it could do it cheaper …. And the ones they targeted in their first round of repatriation were cardiogenetic disorders, because the Ministry was spending the most money on those tests.[525] (Informant 8, p. 5)

Shortly following the province's call for proposals, however, the process for local implementation was mitigated by a host of factors that would threaten the delivery of equitable care in the province, similar to those reported to have raised concerns about access to the BRCA patents in the Ontario Myriad controversy. With the majority of molecular testing being conducted in Ontario hospitals, the implementation of sequencing technologies would mean significant investments into working up any new test for hospital-based laboratories and their departments of laboratory medicine (Ungar, p. 7). More often than not, the adoption of health technology innovation is successful for those that need the least amount of financial and infrastructure investments,[526] resulting in a

[524] Ali Khan and Gold, *supra note* 267 (writing of the findings by the Expert Panel of Quality Management in their presentation titled "Expert Panel on Quality Management: Project to establish a quality management program for repatriated genetic testing: Report of the expert panel" (2010)).
[525] According to Informant 8 (p. 3), genetic counsellors in the cardiac genetics unit at CHEO were seeing "many more people" with cardiac arrhythmia.
[526] Ross S, Robert M, Ducey A, "The short life cycle of a surgical device — literature analysis using McKinlay's 7-stage model" (2015) 4(2) Health Policy and Technology 168.

procurement process that is risk averse and said to be focused on cost-containment, but is somewhat disconnected from advances in knowledge and technological innovation.[527] The implementation and the use of new tests in the province happens within a broad understanding that the costs fall under the purview of the public institution wanting to provide the test, although hospital budgets are financed provincially, and some testing programs are subsidized with specific provincial funding envelopes. When tests are sent out of the country, these costs can fall to the province in some circumstances.[528]

According to Ungar, genetic tests are a challenging class of technology because the majority of testing in the province is still conducted in hospitals, and is thereby governed by the health ministry's Laboratories and Genetics branch (Ungar, p. 7). Also, data collection and evaluation of the clinical, social, ethical and economic implications of genetic tests can be difficult for several reasons. One reason for the difficulty is because procedurally, local implementation of the tests themselves could involve major work-up investments for hospitals. Where determinations of implementation and access "get really complicated," though, is around access to funding for public institutions, because funding models are not one-size-fits all, with some of it happening through institutional global budgets, other parts occurring through a fee-for-service community-based payment model, and still others through dedicated envelopes of funding (Ungar, p. 7). This kind of variable funding contributes to persistent barriers to testing in the province, but is a backdrop for test provision nonetheless.

[527] Prada G, "Exploring technological innovation in health systems: Is Canada measuring up?" (2008) 1(4) J. Management & Marketing in Healthc. 362.
[528] Ali Khan and Gold, *supra note* 122 at 1255.

Ungar also explained that the implementation of genetic tests in Ontario's health care system is further complicated by the way in which hospitals seek to access funding for technologies that require substantial investment for test provision (i.e., for local service delivery) and implementation (Ungar, p. 8). By 2010, Ontario hospitals had successfully negotiated with the provincial health ministry for additional supplemental funding, "special envelopes," to fund their access to "extremely valuable and useful tests …" (Ungar, p. 8). Ungar drew on the example of chromosomal microarray analysis. With the increase in demand for exome sequencing and the "lack of clarity or understanding of any alternative" (Ungar, p. 10), hospital-based laboratories who wished to offer sequencing could continue to seek provincial reimbursement through "special envelope" funding mechanisms. Deciding how to ensure equitable delivery of genetic tests in the province was creating a "whole new ballgame," with estimates of costing the system "large quantities of money," in some cases "millions of dollars," to fund tests as an entire health care service with the newer generation of genetic sequencing testing (Ungar, pp. 11–12). Such projected costs of securing access to funding for tests and their implementation have become disincentives for public health institutions to set tests up locally, including for long QT.[529]

3.4.5.1 Genetic Tests: "Whole New Ballgame"

According to several study informants, it is a matter of when, and not if, clinical genome-wide sequencing will become a routine part of health care in the province (Informant 8, p. 16; Informant 16, p. 15).[530] Efforts to offer genetic testing in Ontario are being ramped up, with Ungar saying the hope is for a more "transparent and formal process" to replace "special arrangements which seem *ad hoc* and not consistent" (Ungar, p. 10). Coordinated efforts on this front seem widely

[529] Ali Khan and Gold, *supra note* 122 at 1255.
[530] Since my discussions with informants in 2018, whole exome sequencing has become available in Ontario through initiatives like the GSO pilot projects by CHEO-Sick Kids.

encouraged. With a rise in gene discovery throughout the 2000s having led to a boon in test development in the U.S. already well on its way under biotech-supportive American federal policy,[531] according to one informant, the cost of outsourcing tests in Ontario also rose. The scale of such test development success has not been matched in Ontario (Informant 8, p. 6), and as more tests and testing services became available through the American market, more Ontario samples were sent to the U.S., such that by 2010, the Ontario government wanted to put a stop to it (Informant 8, p. 6). An offering of testing in Ontario, which meant at least fewer patient samples being shipped out to the U.S., seemed like a good alternative to hospitals negotiating for special funding, and preferable to the costly and resource-intensive process around out-of-country sourcing of tests for the province. That is, until the MOH had to deal with patents.

Soon after CHEO was awarded the contract to implement long QT testing locally, following the provincial expression of interest in 2010, the Ministry removed the test from its list of tests targeted for local implementation (or repatriation), and CHEO had to continue sending patient samples to the U.S., which meant it "was costing the Canadian health care system more … plus (testing) took longer because of the approval process by the Ministry for the payment" (Informant 8, p. 6). This time the reason was patents — various LQTS genes and the test were under patent protection, and efforts by the province to bring the test locally stopped as patents made the process more complicated. For public laboratories and provincial health authorities, the two options for access were, again, as with the Myriad BRCA patents, to negotiate a license or risk litigation for infringement. CHEO negotiated a license with the patent holder around licensing but found that

[531] See, also Malinowski M, O'Rourke M, "A false start? The impact of federal policy on the genotechnology industry" (1996) 13 Yale J. Reg. 163 (claiming that the focus on industry R&D and economic advantage in the life sciences could not have been realized at the extraordinary pace as characterized in the U.S. without supportive governance frameworks, including the approach to federal regulation of biotechnology and U.S. patent policy).

"in turn, it would've costed the province more … $4,500 [per test], and we figured we could do that for less than half in the province" (Informant 8, p. 7). The costs associated with the tests were still an issue, but CHEO stopped talks over licensing because "there was a much bigger principle" (Informant 8, p. 8), namely, patient access:

> There was the immediate problem of long QT, but really that was just tip of the iceberg. The bigger picture is why we went ahead with the legal challenge. The bigger picture was that there was this fantastic new technology — next generation sequencing — … because even back then we knew it was on the horizon … [The] bigger issue was how gene patents were preventing CHEO from introducing a powerful new technology that would greatly impact patient care. (Informant 8, pp. 7, 8)

Consequently, as a clinician, you had to go "fishing with holes in your net," that entire patented genes would be excluded from patient sample analysis because it was "impossible" for clinicians to stay on top of knowing which specific sequences within that gene risked IP infringement at any given time (Informant 8, p. 8). Regardless, Ontario's response was:

> 'Ok, we want your expression of interest to set up tests for other disorders, and if patents are an issue, it's your problem, and you'll tell us how you're going to deal with it.' (Informant 8, p. 12)

In the wake of this, local implementation for the long QT test had been stymied despite "strides" being made (Informant 8, p. 15) around concerns about the high costs associated with outsourced tests being compounded, because "patents make things more expensive" (Informant 20, p. 8) and with uncertainties around changes in patent ownership and use.[532]

Meanwhile, efforts to implement whole exome sequencing into Ontario's health care system continue (Informant 8, p. 15), but without significant changes (like the ones currently under consideration with the GSO pilot project), the process is said to likely be duplicative and impractical.[533] Cumbersome methods of access to funding, an absence of coherent, relevant policy

[532] *Id*.
[533] *Id*.

and guidance on test access by a clear authority, and a lack of unified provincial or national health policy about gene patents are short-circuiting short-term repatriation efforts and long-term improvement of genetic health services in Ontario. More broadly, the "dog's breakfast" policy landscape relating to genetic test access in Ontario has made it hard for public laboratories to know how to gain access to them in general (Informant 8, p. 14). In the case of patented tests more specifically, in the absence of formal ministerial or institutional policy or guidance, access is also happening under various scenarios. Ali Khan and Gold's (2017) data collected from hospital director informants across Canada revealed that generally, public sector laboratories take a "don't ask, don't tell" approach to accessing tests,[534] operating under conflicts-of-interest around revenues collected through licenses and royalty fees or under the risk of infringement.[535] Presumptions like these are creating uncertainties for the Canadian health care system and access to care.[536]

At the federal level, in the later half of the 2000s the health policy unit of Health Canada (specifically under its genetics unit) set about the task of working up a policy framework with respect to gene patents, seeking to take a forward-looking approach of their use in personalized medicine[537] and to consider issues of privacy and discrimination.[538] Mandates began to shift in the department, with an understanding that advocating for changes to the patent system was more of a long game as Industry Canada was dedicated to supporting a "fledging biotech industry" in

[534] Hawkins N, "The impact of human gene patents on genetic testing in the United Kingdom" (2013) 13 Genet Med 320.
[535] Ali Khan and Gold, *supra note* 122 at 1256.
[536] Nicol D et al., *supra note* 275.
[537] See, e.g., Klein RD, "Gene patents and personalized medicine" (2012) 32 Am Soc Clin Oncol Educ Book 81. And, Bonter KL, De Luca C, Guerrini CJ, "Gene patents in Canada: Is there a new legal landscape?" (2018) 22(2) Molecular Diagnosis & Therapy 149.
[538] See, e.g., Lemmens T, Pullman D, Rodal R, *Revisiting Genetic Discrimination Issues in 2010: Policy Options for Canada*, GPS Policy Brief No.2, 15 June 2010 (writing of policy issues relevant to the Canada context prior to enactment of *GNDA* in 2017).

Canada (Drouillard, pp. 9, 10). In response, by 2006, Health Canada sought alternative routes for dealing with gene patents in health care through work at the OECD. By 2010, the inward-looking national health policy framework around gene patents that was developing out of Health Canada had been "decimated" and the "expertise just evaporated" at the federal level (Gold, p. 10).

CHEO's pursuit of greater legal clarity regarding the impact of gene patents on access to health care provided a health policy solution that seeks to facilitate greater availability of publicly-provided testing options and to ensure an equitable access to tests while also respecting the incentive structures of the patent system. The resultant agreement from *CHEO* applies to health care use by public providers only (Informant 8, p. 14) without jeopardizing "commercial interests in areas that actually make you (the patent holder) money" (Gold, p. 13) and has been described as a "beautiful policy solution … that answered all of their [CHEO] concerns in a way that did not upset the industry side … we're not undermining their patents" (Gold, pp. 11–12). By this informant, the agreement is also described as a "turn-key health policy solution" set to create a "turn-key policy environment" (Gold, p. 20). Effectiveness of the agreement requires inter-departmental, inter-ministerial coordination from public health and patent law[539] and likely needs spearheading by ministers (Gold, p. 20). Currently, according to Gold, the agreement sits as a health policy instrument waiting for consideration.

3.5 THE WHY

The way in which society has offered legal and commercial protection to technological health inventions over the decades has transformed health research and care. Earlier inventions usually

[539] *Id.* at 1257.

had inventors turn to trade secrets to protect invention,[540] but with a trade secret, inventors would not want to publish or make public the results of their invention.[541] That all changed with the grant of patents and the protection they afford under proprietorship. In the 1970s, patent applications on biological molecules and genetically-engineered organisms led to the development of novel products and processes for research and medicine, particularly through early developments out of a fast-growing U.S. biotechnology industry with strong life lines to the academic public sector. These early movements of 1970s patent applications on biological molecules and genetically-engineered organisms led to novel research and medicine and to a rapid appreciation of the commercial prospects borne of the genome. The development of IP rights intensified in the life sciences, and the areas of genomics[542] and genetics[543] held little exception. To be sure, the patent system has a long and storied history in the life sciences and biomedical industry.[544]

Despite being a basis for "life," the patentability of biological molecules received little resistance by the courts in their classification as chemical compounds,[545] demonstrating that the patent system, through its key features of neutrality, market reliance and the right to exclude, can be worked to (over)protect private monopolies. When an overprotection occurs at the expense of the

[540] See, *Funk Bros., supra note* 372.
[541] Eisenberg RS, "Proprietary rights and the norms of science in biotechnology research" (1987) 97 Yale L.J. 177.
[542] The WHO defines "genomics" as the study of genes and their functions and related techniques, addressing all genes in relation to one another in their combined influence on growth and development. See, "WHA 57.13: Genomics and World Health, Fifty Seventh World Health Assembly Resolution" (22 May 2004) in Lewis R, *Human Genetics: Concepts & Applications 9th ed.* (New York: McGraw-Hill Primus, 2009) (genomics is the comparative study and analysis of genomes, defining a "genome" as "the complete set of genetic instructions characteristic of an organism, including protein-encoding genes and other DNA sequences" (p. 2 in Introduction)).
[543] The WHO defines "genetics" as the analysis of function and composition of single genes and the study of hereditary. See, "Genomics and World Health: Report of the Advisory Committee on Health Research" (Geneva: WHO, 2002) in Lewis R, *Human Genetics: Concepts& Applications 9th ed.* (New York: McGraw-Hill Primus, 2009) (genetics is the study of inherited traits and their variation (p. 2 in Introduction)).
[544] Dutfield G, Intellectual Property and the Life Science Industries: A Twentieth Century History. (Vermont: Ashgate, 2003). See also, Machlup F, Penrose E, "The patent controversy in the nineteenth century" (1950) 10(1) J. Econ. History 1.
[545] For a fuller discussion, see Calvert and Joly, *supra note* 312.

public domain, potentially jeopardizing the future of health technology innovation, the patent system fails to accommodate — and at times outright interferes with — the objectives and development of other major public policy areas. In the case of human gene patents, as illustrated by the Canadian examples of the BRCA and long QT patents, the patent system makes little room to consider non-economic values as they apply to the use of human genetic sequences for the betterment of health. The commanding 'patent-or-bust' narrative in the gene patent debate has interfered with an adequate and necessary consideration of non-economic values around access to patented human genes and tests.

How the law ought to regulate human genes and tests is not a discussion that can belong exclusively to the patent law domain. While a reconstruction of the historical discourse of property as applied to human genetics and the evaluation of this discourse with respect to its reliance on market values is beyond the scope of this work, I have drawn from these discourses as they pertain to the human gene patent debate in relation to the patenting of living organisms, of body parts (i.e., human genetic materials)[546] and with regard to the impact of patents on market access to various genetic health technologies (i.e. genetic tests).[547] The bulk of actionable legislative and policy-related response with respect to human genetics and genomics has focused on societal concerns with the regulation of genetic health technologies or related research regarding assisted reproductive technologies,[548] discrimination, and stigmatization.[549] Societal concerns raised in the

[546] The literature is extensive in some areas and the U.S. jurisprudence is relatively robust. For e.g., see: *Brenner v. Manson*, 383 U.S. 519, 534 (patent law represents a balance between two economic forces, namely those in the free trade of goods and the monopolistic forces associated in the R&D of new goods); *Bonito Boats, Inc. v. Thunder Craft Boats*, Inc. 489 U.S. 141, 146; *Funk Bros., supra note* 372 at 130 (in which decisions about whether to grant patent rights is determined upon whether a good is or is similar to a natural phenomenon); *Diamond v. Diehr*, 450 U.S. 175 (1981); *Chakrabarty, supra note* 101.; *California, supra note* 150. See, for e.g., Gibson J (ed.), *Patenting Life: Life Patents, Culture and Development 1st Edition* (Oxfordshire: Routledge, 2008).
[547] Robertson, *supra note* 381.
[548] *AHRA, supra note* 139.
[549] *GNDA*, *supra note* 422.

Canadian human gene patent debate however, have not secured the same legislative and policy attention, with the majority of the discussions around human genes and their applications being sequestered within property law discourse. This sequestering has pre-empted, in several ways, adequate consideration of gene patents outside of their economic value. Human genes remain patentable, and as such, continue to be discussed in market terms, in conversations often dominated by market actors.

Given that one important theme that emerged from the informant data in this study was the need for better consideration of the different and often conflicting interests of researchers, biotechnology, and patients in the gene patent debate, much of the work that follows borrows from areas of study that explore policy-relevant dimensions of the social and ethical, the right to health and to science. I believe that such consideration will offer me enough flexibility as a researcher to consider both the economic and the non-economic values attached to the use of human genes and derivative technologies. Previously, Richard Gold (1996) has noted the need for greater discussion and deliberation (a "making of more room") of health policy-related matters as they relate to human biological materials.[550] In his work, Gold explores "making room" for health policy within the patent system framework. Here, I borrow from Gold, but more than suggesting that we create room for health policy within the current patent regime framework, I push past that framework to suggest the need to give health policy something it has never quite been fully given in the discussions relating to gene patent policy in Canada — adequate consideration of its role, alongside patents, in advancing innovation in health care. As the biotechnology industry is unlikely to give up its various uses of patents in biomedical R&D (Informant 21, p. 13),[551] greater consideration

[550] Gold, *supra note* 32.
[551] See also, Niosi, *supra note* 25.

must be given to the needs of health research and care in order for these sectors to advance and to ensure the support of broader public interests in the human gene patent issue beyond — but not necessarily to the exclusion of — economic motives.

3.5.1 Re-Imagining "Public" in the Public Domain

Drawing on calls to "protect the public domain of science, nature, and ideas"[552] and building on the rationale that basic knowledge and biological materials in the area of human biochemistry form the basis of the public domain in that area,[553] human genes arguably are foundational discoveries in the fields of genetics and genomics such that they are "manifestations of … nature, free to all men and exclusive to no one."[554] It is together the main qualities of non-rivalry and non-excludability that exemplify a public good[555] and it is these defining characteristics that led the Human Genome Organization 2002 Ethics Committee to position primary genomic sequences as global public goods that should be placed into the public domain.[556] It appears, however, that the consistent challenge lies in formulating co-joined policy at the public-private divide between health and patents because discussions remain fixed within the patent law arena. Consequently, discussions tend to debate the relative strength and weakness of the patent regime, and often only in respect of considerations around domestic innovation capacity, global competitiveness, and trade. In the human gene patent debate, the problem of patents in public health research and care is not simply a matter of patent rights having 'gone too far'.

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[552] Kane, *supra note* 213 at 707 (stating a "public domain is explicitly recognized in patent law by judicial exclusion of laws of nature, natural phenomenon, and abstract ideas from patent protection").
[553] Gold, *supra note* 32 at 71.
[554] *Funk Bros., supra note* 372 at 130 (this case addressed the need for a robust public domain). Despite categorical exclusions of patent-eligibility, courts have created boundaries and threshold prohibitions that allow for patenting in some circumstances while ensuring a patent monopoly does not remove foundational discovery from a technological field. See also, *Chakrabarty, supra note* 101.at 309.
[555] For e.g., see Kaul et al., *supra note* 166.
[556] Human Genome Organization (HUGO), Ethics Committee, "Statement on Human Genomic Databases, December 2002" (2003) 14(3–4) J Int Bioethique 207.

Several informants in this study criticized the ways in which patent rights over genetic invention have been permitted to be exercised through the patent system in direct contradiction to the health improvement objectives of innovation, a phenomenon that has likely limited the contributions of human genetics and genomics to the public domain. In practical terms, the imbalance of public and private interests are creating barriers of access to the benefits of science. Fortunately, there are options to address these limitations of the patent system, and they need not involve significantly changing the patent system itself. I consider some options from outside of the patent system. First, however, some ground work must be laid down.

3.5.1.1 Re-Imagine the Imaginable

To re-imagine the public domain in genetic health would be to create a more open and accessible public domain of basic goods for human genetics research and care. Discussed at length in the literature and in some policy reports, traditional suggestions for achieving this have included implementing more or clearer research exemptions[557] and compulsory licensing schemes.[558] Here, I look to the other side of the debate somewhat juxtaposed to the patent-dominated narrative — the health policy regime — where the patent system in action in the health care sector in particular has raised so many objections in relation to gene-based patents. One way forward to do our best

[557] Some examples include work put forth in: Charting New Territory, *supra note* 37; OECD, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies*, OECD Publishing, Paris, 2002, online: <https://www.oecd.org/health/biotech/2491084.pdf> (date accessed: 2 August 2019); Mireles, *supra note* 421 at 206 (to exempt from liability "an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or … mere amusement"); Eisenberg, *supra note* 421 at 1023 (despite theoretical acceptance of the exemption in practice is has met limited success). In response to the limited applicability of the use exemption, there have been suggestions to evoke exception specifically to certain genetic tests to enable multiple test providers to increase patient access. See, for e.g., SACGHS, *supra note* 3 at 4 (noting however that the exemption to tests would apply only to regulated tests, such as test kits, and not those made in-house (i.e. on-site or hospital clinic) in laboratory setting).

[558] Nielson and Samardzija, *supra note* 421. But see also, Rai AK, Eisenberg RS, "Bayh-Dole reform and the progress of biomedicine" (2003) 66 Law and Contemp Probs. 289 (reminding us that a compulsory license must still leave intact an incentive to invent).

to make the best use of human genetics research and care would be to build a more robust public domain for gene-based foundational discoveries. A growing concern around access to the public domain of human genetics and genomics research has included the pressure to patent research findings, a worry that dates back to the tragedy of the anticommons[559] and about the uses of public goods if we are to consider human genes as the basis of the public domain in the field.[560] However, human genetic materials are rarely an end to a means, themselves often used as basic tools, or simply as the knowledge base for academic research, or, in advanced R&D, to create new and follow-on drugs, therapies and technologies.[561] The value of creating a more robust public domain in human genetics is that such a domain will support work on the most useful and needed inventions, contributing new knowledge to the field and in its application to health care, rather than being directed primarily by patenting practices and the patent system's reliance on market forces. The idea is not without its challenges though.

According to Boyle (1996), a real sticking point of patents as policy tools – even as a way to provide financing and socially valuable public goods – is that they grant holders the right to exclude access to their invention with very little backstop *ex post* to an overprotection of private interests, sectoral influences or regulatory capture, at the expense of the public domain. While license negotiation is a standard course of action by those wanting to gain access to gene-based invention, on a practical level, this can be an insufficient response,[562] and we have seen this approach lose public health user trust, most recently in Canada through the efforts of CHEO. Some informants have said that more often than not, government intervention is needed for certain

[559] Heller and Eisenberg, *supra note* 71.
[560] James Boyle has written extensively on the topic. See, for e.g., Boyle J, "Enclosing the genome: What squabbles over genetic patents could teach us" (2003) 50 Adv. Genet. 97; Boyle, *supra note* **77**.
[561] See, Charting New Territory, *supra note* 37.
[562] Boyle J, "The opposite of property" (2003) 66 L. & Contemp Probs 1, 27.

technology to develop from underneath the exclusivity of the patent right (Hawkins, pp. 21–22; Gold, p. 30)[563] and particularly so with significant portions of basic S&T research advanced under public funding (Lexchin, p. 5; Drouillard, p. 4). As academic researchers are under increasing pressure to stay informed of various Canadian government initiatives on the use of IP as a means for advancing research (Informant 14, p. 15) and subsequently for patenting findings,[564] the tension at the public-private divide steadily grows. The combined effect can comprise a riddling of the public domain with inefficiencies, uncertain access to research opportunities, and expensive access tolls to academic research.[565]

3.5.2 Making Room for Science

Informants in this study have more or less described the gene patent debate in Canada as an ecosystem populated with diverse stakeholders of a genomic commons — a collection of publicly-available repositories of human and non-human genomic data world-wide. With respect to drawing on this shared pool of information, Cook-Deegan and McGuire write that in order to be successful, this commons – as founded on the 1996 Bermuda Principles released by the Human Genome Organization wherein "the human genome is part of the common heritage of humanity,"[566] – requires stakeholder participation.[567] Such participation has often been characterized as involving

[563] Also, see, *id.* and Rai and Eisenberg, *supra note* 558.
[564] Bubela and Caulfield, *supra note* 215.
[565] The Royal Society, *Science as an Open Enterprise*, London, June 2012, online: <https://royalsociety.org/-/media/policy/projects/sape/2012-06-20-saoe.pdf> (date accessed: 9 August 2020) (arguing in favour of an open science approach to alleviate some of the pressure and tension by way of identifying greater overall R&D efficiency in early-stage research to support easier access to scientific inputs and outputs and greater economic benefits due to spill over effects and reduced costs through re-use of data); OECD, *Making Open Science a Reality*, OECD Publishing, Paris, 2015 (providing arguments in support of an open science approach to reducing delays in the re-use of scientific research and facilitate a faster transfer of knowledge from research in innovation).
[566] Human Genome Organization (HUGO), *Statement on the principled conduct of genetics research*, 1996, Rep., HUGO, Geneva, Switz.
[567] Cook-Deegan R, McGuire AL, "Moving beyond Bermuda: Sharing data to build a medical information commons" (2017) 27 Genome Res 897.

the negotiation of a tension between incentivizing research on one hand, and allowing for the valorization of invention to encourage future research on the other. Negotiating this tension, there are various paths that could be considered, but we are likely to reach the same solution: that there will be a need to protect the potential for downstream patentability of invention, while also reserving a robust domain open enough to allow for its future use. The success of such a solution in addressing the problem of patents in spaces of publicly-provided health research and care will depend on its ability to guide the promotion and regulation of access to patented goods for public benefit appropriately, and on its ability to ensure equitable and clear conditions of access to them.

In the case of the genomics commons, the supranational community has gone to great lengths to set forth declarations signifying both legal actionability and accountability. The bulk of the literature pertaining to common resource governance describes and assesses the roles of the communities that share common resources, and this approach can be applied to the genomics commons as an example of "polycentric multi-stakeholder governance".[568] For instance, in 1997, UNESCO adopted the *Universal Declaration on the Human Genome and Human Rights*, the first international declaration to frame genetic research prospectively, founding it on the principle of human dignity, asserting that the human genome is in "a symbolic sense … the heritage of humanity".[569] Additionally, one of the guiding principles of the declaration proclaims that the "[b]enefits from advances in biology, genetics and medicine, concerning the human genome" must be made "available to all."[570] More recently, in its revised recommendation in 2017 on "Science and Scientific Researchers",[571] UNESCO reiterated the largely dormant human right to share in

[568] Contreras JL, Knoppers BM, "The genomic commons" (2018) 19 Annu. Rev. Genom. Hum. Genet. 429.
[569] *125, art. 1*.
[570] *125, art. 12*.
[571] UN Educational, Scientific and Cultural Organisation (UNESCO), *Universal Declaration on the Human Genome and Human Rights*, 11 November 1997, *art. 21*.

scientific advancement and its benefits,[572] recognizing "the significant value of science as a common good", including "access to research results" as an ethical condition[573] in its preamble. In 2018, in further recognition that when accessible, the genomic commons offers a benefit to the scientists themselves and to the public at large, the ICESCR drafted their general comment[574] in interpretation of the right of everyone to benefit from science and its applications, such that research of the human genome stands to "open up vast prospects for progress in improving the health of individuals and of humankind as a whole."[575]

A significant portion of early-stage biomarker development relies on data derived from academic research, data that is heavily supported or funded by government.[576] By way of example, the publicly-available results from the publicly-funded international HapMap Project has been a rich source of data used to identify common genetic differences in individuals and how they relate to human health and disease.[577] Scientific efforts such as these can lead to downstream R&D and to new gene-based molecular diagnostics, efforts that align with modern Canadian science and innovation policy research agendas. The federal government's agenda of providing substantial support to early-stage research draws from Canada's resolve to address public policy problems by

[572] UDHR, *supra note* 188 at *art. 27*.
[573] *Id., art. 16(v)*.
[574] ICESCR, *supra note* 188, *General Discussion on a Draft General Comment on Article 15 on the International Covenant on Economic, Social and Cultural Rights: On the right to enjoy the benefits of scientific progress and is applications and other provisions of article 15 on the relationship between science and economic, social and cultural rights*, 64th session, Geneva, 9 October 2018, see online: <https://www.ohchr.org/EN/HRBodies/CESCR/Pages/Discussion2018.aspx> (accessed 20 September 2021).
[575] See, Permanent Mission of Italy to the United Nations, "The right to enjoy scientific progress and the freedom indispensable for scientific research," 22 February 2018, see online: <https://www.un.org/webcast/pdfs/180222-italy-concept.pdf> (accessed: 20 September 2021).
[576] Phillips KA et al., "Diagnostics and biomarker development: Priming the pipeline" (2006) 6 Nature Revs. Drug Discovery 463, 464 (data from genetic research studies can be directly used to test consenting patients and family members to develop testing technology based on scientific principles and progress testing technology driven by patient needs).
[577] Int'l HapMap Consortium, "A Second Generation Human Haplotype Map of Over 3.1 Million SNPs" (2007) 449 Nature 851. See also, Robertson AS, "Taking responsibility: Regulations and protections in direct-to-consumer genetic testing" (2009) 24 Berkeley Tech. L. J. 213, 221.

way of its embrace of science, an approach that has met considerable success in other research-intensive sectors.[578] More than most other countries, the OECD ranks Canada among the top countries in encouraging a strong push-model of scientifically-driven technological and economic development, with Canadian governmental contributions directed substantially towards the higher education sector or into industry as *ex post* subsidies for research expenditures.[579] Notably, biomarker development by way of early-stage genetics and genomics research can happen at a fraction of the cost compared to that needed to scale up downstream development and market availability in pharmaceuticals and biotechnology.[580]

The Canadian government will also provide robust support for market entry into clinical health care outside of patent grants. The case studies in this work have shown us that patient access to genetic testing in Ontario is occurring by way of patchwork, in sometimes mismatched modes of access facilitated in compliance with formulary criteria, *ad hoc* primary care and academic clinic know-how, and out-of-pocket payment by willing payers. Formulary compliant and *ad hoc* access are based on the predicted utility in a clinical setting despite, as asserted by informants in this study, clinical utility itself being difficult to measure. Here, the province has been known to adopt responsive approaches of covering the cost of genetic testing in order to recognize the potential clinical value of a particular test (Informant 16, p. 8). Arguably, benefiting from scientific discovery requires having access to it, such as through adequate health care. The ODX test

[578] Phillips and Schmeiser, *supra note* 80 at 9 (speaking of several broadly familiar Canadian examples of innovation in the areas of agriculture and telecommunications).
[579] STIC 2015, *supra note* 349.
[580] See, Schumacher A, Gassman O, Hinder M, "Changing of R&D models in research-based pharmaceutical companies" (2016) 14 J. Transl. Med. 105, 111 (reviewing publicly available information to suggest that the decrease of in-house R&D in research-based industry challenges the traditional innovation-driven model). In part, perhaps for reasons as provided by Robertson, *supra note* 381 at 390 (early-stage genetic tests research (i.e. identifying disease-linked genes) is comparably cheaper than the biological exploratory stages of pharmaceuticals development).

discussed above is an example of this. In the case of biomedical genetics, however, the patentability of genes has in large part found its success in the drug development analogy.[581] Thus, a combination of the early capital needed to finance exploratory biological and clinical trial research and the high failure rate of drugs may justify patenting to help carry product candidates through development to market.[582] This analogy between gene-based drugs and tests relates to the cost of commercializing patented products, although a comparison of R&D spanning early- to later-stage product development between drugs and genetic tests suggests specific and important points of departure.[583]

Regarding genetic tests more specifically, there is a departure from arguments about the need for patents as incentives to invent and to develop. Here, the cost of early-stage R&D in test development is illustrative.[584] It is widely known that given the costs associated with Health Canada approval, R&D-intensive industries will argue in favour of needing patents to offset losses from regulatory lag and to artificially de-escalate market risk by decreasing competition. Some commentators have pointed out that less regulatory oversight could mean fewer financial barriers to testing market entry.[585] In this connection, one informant reminds us that getting the balance between implementation in the health system to facilitate access to new technologies and developing a meaningful product in the first place is important, but really tricky in Canada:

> Without regulation though, you don't have reliable safety, proper adoption, or systems that can intake these devices. I know they're a big challenge because by the time they go through all the regulatory approval process provincially, to get into a hospital, to go in and get to the patient it [the device] is obsolete and the next thing has come in. (Informant 21, p. 35)

[581] Andrews, *supra note* 206 at 77.
[582] DiMasi JA et al., "The price of innovation: New estimates of drug development costs" (2003) 22 J Health Econ. 151, 151.
[583] See, Robertson, *supra note* 381 at 390–392.
[584] See generally, *id.*
[585] Again, it may be prudent to consider real-world differences in R&D between drug versus test market approval. See, *id*., at 392–395 from a U.S. perspective that seems comparable to Canada's landscape.

Challenges also remain in the creation, use and curation of scientific discoveries for researchers in individual disciplines[586] despite an encouragement of collaboration across disciplines[587] and despite the benefits of novel R&D public-private partnerships.[588] There are also persistent challenges for policymakers in their efforts to balance government's innovation and commercialization agendas with the equitable delivery of health care, including new products and services. Policymakers must make decisions about how best to achieve this balance in the face of public mistrust in authorities on science[589] and with diminishing resources, diminishing "expertise" in general[590] and loss of government "receptor capacity" in subject area expertise and policy development.[591] At the provincial and territorial level, one informant spoke of the need for greater expertise and practical know-how at the evidence-policy interface where applied research can inform policymakers about how to improve access to genetic tests by way of the public health care system:

> One big challenge with genetic testing is that for many new sequencing technologies they're only going to be made available in urban tertiary care centres … So, hard for many communities to access, not just with respect to geographically, but because of wait time to see a specialist who first has to recommend the test. A lot of issues there. We need people who understand policy to ensure we're cognizant of these challenges, so we can say when we make a test available: 'This is the way it should be done'. (Ungar, p. 24)

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[586] *Id.* at 10.
[587] *Id*.
[588] There are many examples of this from the pharmaceutical sector. See, for e.g., Yildirim O et al., "Opportunities and challenges for drug development: Public-private partnerships, adaptive designs, and big data" (2016) 7 Frontier in Pharmacology 1.
[589] CBC Radio, "A manifesto to fight scientific one hit wonders," 20 January 2017, online: <https://www.cbc.ca/radio/quirks/antarctic-evacuation-sloppy-science-laser-mice-and-more-1.3942939/a-manifesto-to-fight-scientific-one-hit-wonders-1.3945087> (date accessed: 29 November 2020).
[590] Kakutani M, "The death of expertise," The New York Times, 21 March 2017, online: <https://www.nytimes.com/2017/03/21/books/the-death-of-expertise-explores-how-ignorance-became-a-virtue.html> (date accessed: 29 November 2020). Also, Gibbs K et al., "The death of evidence in Canada: Scientists' own words," The Tyee, 16 July 2012, online: <https://thetyee.ca/Opinion/2012/07/16/Death-of-Evidence/> (date accessed: 29 November 2020).
[591] A phrase I borrowed from Castle D et al., *Receptor Capacity for Biotechnology Innovation in Canada* (Policy Brief) (Ottawa: Genome Canada, 2014). In this brief, Castle speaks to the lag in Canadian life science innovation because of the private sector's lack of "receptor capacity", or the sector's incapacity to "absorb and exploit the new knowledge arising from inventions and discoveries."

Evidence-based policymaking (as opposed to *status quo* or *ad hoc* policy development) is an approach that forces major areas of public policy to intersect, but it is important that intersectoral areas of policy be individually explored as important independent sources to resolve the policy issues of which they are a part. According to one informant, success stories about access and use of needed products in the biomedical space in Canada are increasingly few. Part of the reason is due to a growing need for research institutions, limited in resources or IP expertise, to negotiate access to patented gene-based products with more than one multinational enterprise holding multiple patents on, for example, multiple genetic sequences (Lexchin, p. 5). Another reason for a lack of success in access and use of biomedical products, associated with the *status quo* regulatory approach by way of the patent system more broadly, is the lack of multidisciplinary-informed policymaking. In this chapter, health research is seen upstream and in continuum with downstream developments available for uptake in the health care sector. Seen in this light, working towards cultivating a more robust public domain in human genetics and genomics research can help mitigate concerns of an overprotected private monopoly at the expense of the public interest in future research and towards its application in clinical genetic care.

To this end, we need to think of better options based on the best – the most accurate and where possible, the most independent – data collected. In the case of the human gene patent debate, one obvious source of empirical data is from those who generate and use basic S&T research data. Notably absent from the empirical data pool in the Canadian human gene patent narrative are the perspectives of basic science and clinical researchers and the quantitative data reflecting the impact of patents on their research, some of which has been noted by several informants in the previous chapter. Collecting this data is important in order to adequately inform the human gene debate to better inform government policy and action, particularly when issues around access to scientific

findings or to a patient's benefits arise. It is also worth remembering that the modern patent system sets out to incentivize any kind of invention, caring little whether or not it is an invention that is needed to address the needs of patients or the health care system. While it remains unclear how governments might access and assess S&T information most efficiently for policy development, the existence of a robust public domain in human genetics and genomics can offer a better chance of providing the best of what science can offer.

Open use of early-stage scientific work can have positive consequences for the right to benefit from science, which can include the right to health and the promotion of access in health, and it can enable downstream scientific and innovation opportunities that offer effective, coordinated, and real world solutions to pressing problems in biomedicine. These opportunities can also offer several social benefits towards which the forward-thinking utilitarian policymaker can work. However, they can also present some challenges. Society's agreement to relinquish subsequent stages of R&D to the private sector, who can use their IP to create a monopoly on an invention and attach a price tag of their choosing, compounds the challenges of policymakers seeking to conjoin the government's dual agendas to facilitate innovation/commercialization and equitable delivery of health care. A growing and robustly symbiotic relationship between academia and industry may align with the goals of these agendas,[592] but the role science plays in public policy decision-making, including health policy (such as the ways in which scientific discoveries for

[592] Chiose S, "Canadian universities want to increase private partnerships," Globe and Mail, 18 May 2018. Also, Caulfield, *supra note* 298 at 224 (drawing on the example that in 2002 the Federal Industry Minister Allen Rock said that academic institutions need to commit "to a link between public funding and economic outcomes"). See for example, Samuel T, McNally MB et al., "Technology transfer and innovation policy at Canadian universities: Opportunities and social costs" (2012) FIMS Publications 23, online: <https://ir.lib.uwo.ca/cgi/viewcontent.cgi?article=1025&context=fimspub>. The enabling legislation of the Canadian Institutes of Health Research, one of Canada's major funding bodies, around a formal commercialization mandate to promote economic development through health research is also demonstrative. See, Canadian Institutions of Health Research Act, RSC 2000, c6.

application in health care are made and the collaborative nature of scientific advancement) must be considered alongside innovation's commercial value.

3.5.2.1 The Empirical Evidence Gap Problem

The policy issues relating to the human patent debate as they are relevant to the Canadian publicly-provided research and care sectors reflect that while stakeholder engagement has been a priority for governments, maintaining the permanent institutional knowledge required to understand the complex fields of genetics and genomics has not been. This is troubling given that, assuming the permanency of health policy units in government, "the authoritativeness of policy analysis is significantly affected by the quality of data available to analysts in policy units."[593] The Federal Court challenge put forth by CHEO and data provided by informants in this study suggest that patents can impact test access in various ways, and not all pertaining to cost-containment efforts.

Using the example of genetic health technologies, over the years since the mapping of the human genome, both the federal and provincial governments have addressed the need to look at the translational benefits of genetics in health care through various commissions, advisory committees and working parties. However, despite initial moorings of "familiarity" with reproductive technology (Informant 13, p. 8), unlike the strides made to develop regulatory policy around access and use of human reproductive technologies, a review of the standing committee evidence reports of selected federal and provincial committees suggests that genetic health technologies have historically received little to no direct federal or provincial legislative attention.[594] As emphasized

[593] Lindquist E, "Policy capacity and recruiting expertise in public services: Acquiring talent in evolving governance environments," in Dobuzinskis L, Howlett M (eds.), *Policy Analysis in Canada* (Chicago: Policy Press, 2018), 170 [Dobuzinskis and Howlett].
[594] I conducted a review of Evidence reports of selected federal and provincial committees (listed in the Methodology section of the Introduction chapter). My findings suggested limited to no focus on matters relating to

by the highest courts in the U.S. and in Canada, science-based decisions for legislatures and the judiciary can be difficult[595] and so, science-based decisions have been said to require an understanding of the social and economic impacts of the decisions being made.[596] Most of these decisions have focused on a broader consideration of policy and regulation around the biotechnology industry and the bioeconomy, and thus a focus on economic impacts.[597] Similarly in Canada, movements in genetics research are increasingly linked to the knowledge-based economy in sectors such as biotechnology[598], and where the patent system is the dominant form of "invention-based governance."[599] Canada's innovation strategy has focused increasingly on building an innovation-based, economy supporting technological advancements by investing more into what the Canadian governments will say Canada is good at — ground-breaking research-based discoveries — in order to become an S&T innovation giant.[600] The place for science here is obvious, and it carries considerable promise for the development of areas that seek to improve health and health outcomes.

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human genes, and no focus relating to genetic tests and services or of the impact of patents on human genetic materials and tests.

[595] See, e.g., Honorable Stephen Breyer, "Science in the courtroom" (2000) 16(4) Issues in Sci and Tech 52.

[596] Drawing on an American e.g., Justice Breyer instructed that decisions need to be "grounded in realistic predictions of what science will do, and not [in] fanciful prediction of what science might do." See, The Honorable Stephen Breyer, "Genetic Advances and Legal Institutions," 12 May 2000, online: <https://www.c-span.org/video/?157058-1/genetic-advances-legal-institutions> (date accessed: 20 November 2020). The highest court in Canada has long-recognized the need for better understanding of the social and ethical context relating to gene-based invention in Canada *Harvard, supra note 35* at 199 is the seminal ruling in Canada (Bastarache J writing for the majority held that "the unique concerns and issues raised by the patentability of plants and animals necessitate a parliamentary response").

[597] OECD, *The Bioeconomy in 2030: Designing a Policy Agenda*, OECD Publishing, Paris, 2005.

[598] Phillips and Schmeiser, *supra note* 80 at 9.

[599] Gold in GE^{3}LS, *supra note* 49 at 35.

[600] Industry Canada, *Achieving Excellence: Investing in People, Knowledge, and Opportunity* in Industry Canada, (Performance Report) (Ottawa: Industry Canada, 2003) online: <https://www.ic.gc.ca/eic/site/017.nsf/vwapj/DPR2003E.pdf/$file/DPR2003E.pdf> (date accessed: 18 November 2020).

A 'right to science' approach to patents builds on the capacity of health policy to provide evidence-based frameworks that can better guide decisions about the medical, social, economic and ethical implications of human gene technologies. Such framework building was a focus of governments assembling expert committees to explore policy options concerning gene patents in health, but they too faced a problem gathering empirical evidence. Limitations around collecting reliable streams of empirical data pertaining to the impact of patents on Canadian research and patient care "became an issue of CBAC" when Ontario's health policy unit became "unhappy" with the step-wise address of the debate by way of exclusive licensing mechanisms (Naimark, p. 19). These limitations were accompanied by a loss of policy expertise aligned to assessing the tasks or issues through a greater health lens approach across government over time (Gold, p. 33; Drouillard, p. 26), an essential pre-condition, according to my informants, for any policy strategy to advance in the debate.[601] Coherent government policy development around the funding, implementation and use of genetic health technologies stands to leverage state-sponsored action in relation to who can draw on domestic S&T capacities or on the capacities of related public policy areas, such as health care and trade.[602] More recent literature has emphasized the importance of considering patent policy in the context of other major policy areas through which the state influences knowledge production.[603]

3.5.2.2 Shift the Paradigm

With respect to genetics research for the purposes of application in health care, the field of human genetics has been included in several significant forward-looking policy frameworks championing

[601] See also, Lindquist, *supra note* 593 at 178 (writing "[t]he authoritativeness of policy analysis is significantly affected by the quality of data available to analysts in policy units").
[602] Doern B, *Science and Politics in Canada* (Montreal: McGill-Queen's University Press, 1972).
[603] See, e.g., Hemel and Ouellette, *supra note* 22.

a fuller development of Canadian S&T to use "sound science" in decision-making. This, despite an initial government commitment to technological sovereignty and policy development around the growth and protection of a domestic S&T-based industry led in the 1960s[604] having dwindled by the 1980s, when Canada's once-strong industrial policy was replaced by a growing interest in the benefits of global trade (Hawkins, p. 24).[605] Internationally, patent policy advocates have debated the role of science in informing decision-making.[606] In Canada, these are choices that have not been taken lightly and examples of these efforts exist from both levels of government. At the provincial level, one informant on the OGAC said the province recognized its limitations in assessing genetics-based knowledge and its implications for health care when it established the provincial committee:

> I think OHTAC didn't have the capacity to review the genetic and genomic technologies. I also think, inherently, the kind of evidence that's generated around new genetic and genomic tests or technologies in general doesn't usually meet the same benchmarks or threshold levels usually used that OHTAC and other HTA agencies use for other types of technologies or drugs. (Informant 16, p. 1)

In the federal government, commitments have been made to establish institutions to build stronger connections between researchers undertaking policy-relevant work in genetics health S&T.[607] One example was the Science Council of Canada.[608] Other examples of Canada's efforts to boost access to the benefits of human genetics research have included the various initiatives spearheaded by the

[604] For example, the Science Council of Canada founded in 1966 to advise the Pearson Liberals on Canadian science policy. The Council was established as a crown corporation and became a fixture in Canadian politics in the 1970s.
[605] See also, Cianfarani, *supra note* 360.
[606] For example, the OECD has argued for the need to draw on biomarker studies underpinning pharmacogenetic research into policies set out to improve the use of existing medicines. See, OECD, *Pharmacogenetics: Opportunities and Challenges for Health Innovation*, OECD Innovation Strategy, OECD Publishing, Paris, 2009.
[607] In Canada, the issue of knowledge transfer has been among the top concerns for the three major federal granting agencies, CIHR, Social Sciences and Humanities Research Council (SSHRC), and Natural Sciences and Engineering Research Council (NSERC).
[608] The Council put out several reports to promote an interventionist industrial policy. Examples include: In Hard Times, Hard Choices (1981) and Science and Technology Policy in Canada (1990). See generally, Dobuzinskis and Howlett, *supra note* 593 at 322.

Canadian Institutes of Health Research (CIHR) dating back to the 2000s, including an increase in researcher and receptor capacity to provide opportunities to accelerate an understanding of the evolving science into policy.[609] Initiatives under the institute have included calls for a greater amount of genetics data to inform policymaking and to generate interest in the health policy community in exploring questions related to genetics research.[610] However, broader notions of what kinds of information can be used to effectively and germanely inform human gene patent policy could use some attention.[611] As also expressed recently in the scholarship,[612] several informants in this study note the need to re-establish a better use of knowledge at the evidence-policy interface, particularly where patents are tying "down research streams and knowledge streams into patent streams" (Hawkins, p.29). One suggestion was to enable a better collection and use of empirical data in user settings of gene-based technology (i.e., through hospital clinics) that could carry meaningful implications for policy development.[613]

Clearly, the empirical evidence gap problem needs fixing, but equally clear is the need for a rethink of the problem of patents on human genes — a paradigm shift to identify its solution. One reason for a rethink is to refocus on multidisciplinary approaches to identify solutions outside of the patent system, and it is likely that we will find several policy alternatives, depending on which disciplines weigh in. Not all alternatives are worth deeply exploring. In the case of what is happening at the

[609] CIHR, *Internal Assessment for 2011 International Review*, CHIR Institute of Genetics, online: <https://cihr-irsc.gc.ca/e/43733.html>.
[610] See, e.g., Miller FA et al., "The helix in the labyrinth: Do we need genetic health services and policy research?" (2008) 4(1) Healthc. Policy 30.
[611] For, e.g., informant data included above from a genetics health researcher and members of the Ontario HTA community that is informing the current development of health policy frameworks. Also, the idea that treating technologies as policies themselves — given their ability like policy to "get things done" and their influence over what gets done, by whom and when — to help inform policy in real time. See, Giacomini et al., *supra note* 498.
[612] For e.g., see earlier work in Dobuzinskis L, Howlett M, Laycock D, *Policy Analysis in Canada: The State of the Art* (Toronto: University of Toronto Press, 2007), 247 at 99 [DHL 2007]. In a more recent edited collection, the dispersion of expertise in policy sectors has been expanded upon. See, generally, Lindquist, *supra note* 593.
[613] See generally, Dobuzinskis and Howlett 2018, *supra note* 593.

public and private divide when we are talking about equitable access to patented human genes and genetic health technologies, those other disciplines will involve health research and care. A multidisciplinary refocus including these fields will help establish what matters when we talk about why we pursue genetics research, why we seek to apply its findings to the betterment of human health, and to identify the desirable societal outcomes related to human health. While the economic reasons for patenting in the area of human genetics are important, they are — and often remain — the sole focus of patent policy experts. We must also acknowledge that the significance of the human gene patent issue is not limited to economics alone and that non-economic values must be considered in establishing reasonable policies governing human genetics health research and care. Circling back to the same proposed solutions to the gene patent issue represents a failure to recognize the need for policy alternatives for the issues that remain in plain sight and are at risk of repeating:

> You'll have science-based policy units who work on one issue for twenty years, and then you remember what happened then, and you've got this whole body of evidence. I look at scans of snapshots of legal research that look at a question of gene patenting and I recall a paper … saying 'there's no empirical evidence of an anti-commons effect in gene patenting'. And it may be true. But it may be true for the narrow tranche of data that you have, which is not robust and it's not nuanced. If you have to go with the indicators you have — and so by not having a longer period of policy action and related collection of evidence then, you know, the claim that there's no empirical evidence … it's like you can open the door one day and say 'there's no empirical evidence of snow'. But you remember how cold you were last winter. We just need to keep looking out the door to see if it's snowing. And that's what didn't happen. (Drouillard, p. 24)

3.5.3 Making Room for Non-Economic Values

A 'right to health' narrative would say that the need for access to genetic materials and tests problem that patents create in health research and care is more fundamental than the IP protections afforded by a private holders right.[614] Scholars often toy with making a siren call of foregoing

[614] Gold, *supra note* 32 at 70.

patent protection on human gene-based invention to demand the outright placement into the public domain of human DNA and its information. Almost always, however, they reach the same conclusion: that this is not the answer. Given what we know of industry's need for protecting investments, the prospect of lowered incentives to innovate and questions around industry adaptability leave the problem of maintaining adequate delivery of health technology in doubt. For these advocates caught up in the property discourse of the gene patent debate generally, the obvious recourse has been to call on reforming the patent system to address issues of access in ways that can recalibrate the balance between public and private interests. However, reform of the patent system to at once encourage health care innovation in a rapidly changing S&T landscape, protect the proprietary rights of IP owners, and make innovation available to the people who need it is unlikely to take the unique cultural and societal dimensions of human genetics seriously.[615]

We can begin to explore the non-economic values of human genetics research by considering why we want to use human gene-based invention in biomedical research and clinical care relative to other patentable invention in the first place. Seen in this light, the 'right to genetic health' narrative warrants a non-economic consideration. Given the increasing sense of urgency around access to human gene-based invention in the health care space in response to patient needs, I consider why the gene patent problem could benefit from a broader consideration of existing health policy frameworks available (i.e., the CHEO agreement) and from ongoing developments in the Ontario test provisions landscape alongside the dominant traditional patent law discourse. In the case of access to patented gene-based invention, particularly in the case study of predictive genetic tests,

[615] Gold, *supra note* 33.

while health policies are fashioned to take into account fiscal or austerity measures in the delivery of health care services, they are not policies based solely upon economic considerations.

As shared values change with changes in technological advancement, health policy frameworks also seek to encompass broader ethical and social values that outline key guiding principles that can challenge existing frameworks that can guide policy development in the area of health.[616] That is, in addition to recognizing the importance of economic considerations, health policy can also incorporate considerations of the non-economic values that relate to human gene-based invention, those which cannot be adequately addressed by the current patent system. This perspective has been largely missing from the human gene patent debate in Canada, despite contributions by provincial and federally-based health policy communities and applied ethicists. It is also a perspective that has yet to be formally recognized, despite a public use framework provided in *CHEO*. Hence, here, I sought to better understand why looking at the Canadian human gene patent debate from a perspective of health policy is important[617] and how the social and ethical implications factor into this perspective.[618]

[616] Applied Research and Analysis Directorate, *The Next Frontier: Health Policy and the Human Genome: Strengthening the Policy-Research Connection* (Research Bulletin) (Ottawa: Health Canada, 2001).
[617] Jamieson C, *Genetic Testing for Late Onset Diseases: Current Research Practices and Analysis of Policy Development* (Policy Report) (Ottawa: Health Canada, 2001), 30 (writing "Perhaps, health is the basic factor shaping policy development in genetic testing for late onset disease. The importance of testing for late onset disease directly stems from the basic, vital value of human existence — health").
[618] Charting New Territory, *supra note* 37 at i (the Ontario health policy unit called on greater consideration of social and ethical implications of genetics in Canada's health care system, calling on Canadian governments to "match the determination and success of the efforts in science with an equal resolve to being to understand and address the ethical, legal, social and health-system implications of new developments in genetics").

3.5.3.1 Shared Public Values: All for One and One for All

As a matter of ethics, human genetic materials are considered unique as cultural and societal artifacts that register the distinctive features of what it means to be human.[619] The more that human genetic materials are associated with their human origins, the deeper the questions of how they are to be used and by whom because the more these materials are intended for use primarily in the areas of health research and care, areas imbued with non-economic values,[620] the more strongly they are attached to the broader cultural and societal meanings we assign to them.[621] As one informant said of human health generally and of health care more specifically, these associations between genetic materials and how they are used or for what purpose exist along a somewhat pre-existing scale of values within communities:[622]

> When you're dealing with health care, very often you're dealing with people living and dying. So, the values at that level are about life and death. But those aren't the only values

[619] UNESCO Universal Declaration on the Human Genome and Human Rights 1997. For scholarly reflections, see: Gold, *supra note* 33. See also, Koepsell D, Who Owns You?: The Corporate Gold Rush to Patent Your Genes (Hoboken, N.J.: Wiley-Blackwell, 2009.

[620] For example, health equity is a key focus in the delivery of health care and services in Ontario. Health Quality Ontario frames health equity as what allows fair, need-based, and individually appropriate quality care to reach their full health potential regardless of any other factors such as who they are and what they have. Health equity is about people getting the resources they need when they need it to improve health for all. See for example, Health Quality Ontario, *Health Equity Plan*, 2020, online: <http://www.hqontario.ca/Portals/0/documents/health-quality/Health_Equity_Plan_Report_En.pdf> [HEP]. See also See, Ontario Ministry of Health and Long-Term Care, *Improving the Odds: Championing Health Equity in Ontario*, Annual Report of the Chief Medical Officer of Health of Ontario to the Legislative Assembly of Ontario, 2016, online: <https://www.health.gov.on.ca/en/common/ministry/publications/reports/cmoh_18/default.aspx>; Ontario Ministry of Health and Long-Term Care, *Health Equity Guideline*, 2018 [HEG], online: <http://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/docs/protocols_guidelines/Health_Equity_Guideline_2018_en.pdf> (date accessed: 25 November 2020); Gold, *supra note* 32 at 75.

[621] For a comprehensive look at the ethical status of human DNA, there has been much discussion about it in the legal scholarship. See, for e.g.: Knopper BM, Luther L, "The Human Genome Organization (HUGO)." (March 1997) Politics and the Life Sciences 127; *Id*., at; Caulfield T, "From human genes to stem cells: New challenges for patent law" (2003) 21(3) Trends in Biotechnol. 101; Lemmens T, "Selective justice, genetic discrimination and insurance: Should we single out genes in our laws" (2000) 45 McGill L.J. 347; CIHR, NSERC, SSHRC (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada), Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2010; Nicholas GP et al., "Beyond the tangible: Repatriation of cultural heritage, bioarchaeological data, and intellectual property" (2009) 51(3) Anthropology News 10; Pullman D, Nicholas GP, "Intellectual property and the ethical/legal status of human DNA: The '(ir)relevance of context'" (2011) 35(1–2) Intellectual Prop. and Ethics 143.

[622] A point elaborated on by Jamieson's earlier work for Health Canada about policy development for genetic testing for late onset diseases, *supra note* 617.

> that direct human beings. We also have values that have to do with how we live together, the impact of our actions on others, cultural values about meaning and what makes sense in our life and what's important to us and what we care about. And sickness and illness often isn't about living and dying … when you're dealing with health … it's very often limited to … I would say autonomy and individual rights. But that is so narrow compared to how people actually live their lives (pp. 6–7) … it misses a whole communal aspect of what it means to be human. (Jamieson, p. 9)

Having participated in various roundtables discussing the impacts of genetic health technologies on Canadian society, Jamieson went on to suggest that health policy in particular offers a forum in which policymakers can draw on non-economic values in various combinations when developing policy and regulation over the use of human genetic technologies. For example, Jamieson explained that non-economic values can be shaped by the most fundamental or basic values of what is meant by human well-being, the instinctual value of protecting one's own life (Jamieson, p. 24), and staying healthy, or knowing what options are available when one is sick (Jamieson, p. 13). But deeper still is that whatever aspect of values at this level of basic survival shape the value judgements made by people about human genetic materials. These values come down to "the values where people talk about things like 'the value of my life', 'the meaning of my life', those [big] questions that we all ask" (Jamieson, p. 22).

In the eyes of patent law, the value of a human gene, and what makes it worthy of property protection is determined by how much someone is willing to pay to access it. But, this says little about the value chain for human genetic materials: it does not consider what is of value for the use of genes in research and why it matters who can access it, which gene-based inventions should be made available in health care and by whom and when, or what any of this means for the sustainability of a publicly-provided health care system. Understanding what society finds valuable about having access to information carried by genetic sequences also requires the kind of "social structures that facilitate human flourishing, of which part of that [flourishing] is [good]

health" (Jamieson, p. 15). Building a greater foundation of 'right to health' principles into discussions around the role of gene patents in health research and care, and establishing a clear focus on health equity in policymaking, is one way to encourage the kind of paradigm shift that would help resolve some of the tensions between patents and access to human gene technologies.. Benefits of policies built around such technologies could include timely access by individuals to their own genetic information and benefits to the whole of society because "paying attention to the good of the individual will also mean that good will spread out to the good of society" (Jamieson, p. 26).

Notably, Jamieson emphasized that what health policy has to offer the patent debate in particular is something broader than the traditional narratives on addressing issues of access as issues of individual rights. While Jamieson stopped short of comparing a maximization of public good to that of individual good — "it's not about bringing together a whole bunch of individual goods and then you have the common good" (Jamieson, p. 21) — they emphasized that systems such as Canada's public health care system can inherently facilitate the common good because it is a system that promotes working together "in a way that we achieve things that none of us could've achieved on our own" (Jamieson, p. 21). In this way, according to Jamieson, health policy makes room to consider what is "public" in Canada's public health care system. More specifically, while as a matter of ethics, issues of access to genetic health technologies have traditionally been considered as issues of human rights and individual autonomy, as a matter of social ethics, health policy allows for the consideration of non-economic values on a broader spectrum in satisfaction of a common good:[623]

[623] Ethical philosophy under utilitarianism provides that if any policy benefits the greatest number of people, then that policy serves the greatest social utility because it maximizes well-being to all affected individuals. This is also known as the democratic rule of decision-making based on majority opinion.

> I find the emphasis on the autonomous being problematic, and even the emphasis on human rights – and I think human rights are so important. I just think there is something broader and more inclusive than human rights, and it has to do with the common good … with social responsibility – not just individual rights or human rights, or not just about the economy. But recognizing that — human beings — we're more than that. (Jamieson, pp. 19–20)

With respect to how this might translate into facilitating equitable access to patented genetic tests, Jamieson claimed that at the core of the gene patenting issue is a need to better regulate the use and access of these technologies.

In 1996, Richard Gold recommended a useful framework for working through the concerns around the issue of patenting on access to gene-based invention in Canada's health care space. Gold argues that the requirement of biomedical test approval through the provincial government "provides Canada with a unique (at least as compared with the U.S.) opportunity to incorporate ethical considerations into debates over the use of biomedical materials."[624] The resultant public use agreement from *CHEO* recognizes a role for governments to act or develop policy with such considerations in mind. Further still, the agreement seeks to establish a conjoined, or cooperative, health *and* patents policy environment, rather than a divisive health *or* patents one. Gold has described the CHEO agreement as a health policy solution that operates from a standpoint in which the benefits of both patent use and access to health care can each in turn be recognized (Gold, p. 10).

3.5.3.2 The Charter: Right to Health Narrative

To the extent that human genetic materials and derivative technologies are valuable to end users (i.e., patients) for non-economic reasons, problems with patents in publicly-provided health can

[624] Gold ER, "Biomedical patents and ethics: A Canadian solution" (2000) 45 McGill L.J. 413.

also be seen more broadly as issues of social justice and about liberty or equity.[625] A reading of the *Canada Health Act* gives a sense that to Canadians, health is fundamentally about community — a collective — and shared values of health, life, and security.[626] The program conditions set out in the *Canada Health Act* underlie public expectations of the health care system, including the underlying principle that whoever needs health care is entitled to receive it, irrespective of ability to pay. The 2002 Romanow Commission wrote about access to health care as "equal and timely access to medically necessary health care services on the basis of need" and that access is a Canadian right, not a privilege of wealth.[627] The legislative measures taken by Canadian governments to ensure access to health services based on need are consistent with Canada's international human rights obligations[628] and with a domestic constitutional guarantee under the Canadian *Charter of Rights and Freedoms*.[629] Indeed, the Romanow Commission credited the few health care cases heard during the first twenty years of the *Charter* to "the relative universality, accessibility and comprehensiveness of Canada's existing Medicare system."[630] When the underlying principle of health care has been put to the test, the *Charter* has been a means to account for equitable decision-making for those looking to access the care they need.

As with other socio-economic rights in Canada, debates in health care over accessibility have included questions about improving accountability to patients and the general public.[631] Rights

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[625] A discussion of *Charter* cases regarding access to health care can be found in Jackman M, "*Charter* Review of Health Care Access," in Erdman J, Gruben V, Nelson E (eds.), *Canadian Health Law and Policy, 5th edition* (Markham: Lexis Nexus Canada Inc., 2017).
[626] Forster J, "A Communitarian Ethical Model for Public Health Interventions: An Alternative to Individual Behavior Change Strategies," Journal of Public Health Policy 3 (1982): 150.
[627] Romanow Commission, *supra note* 43 at xvi.
[628] ICESCR, *supra note* 188.
[629] *Charter, supra note* 394.
[630] Greschner D, "How will the Charter of Rights and Freedoms and evolving jurisprudence affect health care costs?" in McIntosh T, Forest P, Marchildon G (eds.), *The Romanow Papers, Volume 3: The Governance of Health Care in Canada* (Toronto: University of Toronto Press, 2004) 83, 93.
[631] Jackman M, "The future of health care accountability: A human rights approach" (2016) 47(2) Ottawa L. Rev. 437.

such as the right to give informed consent[632] and to have access to one's own medical information[633] are recognized as rights *in* health care in common law.[634] Some legal and S&T scholars have gone as far to argue that given that our understandings about what life is construct our social and political meanings of the biological (which would include human genetic materials), that should demand a rethink of derivative technologies, such as genetic tests, as being "bioconstitutional" in order to redefine state obligations to the care and well-being of its public.[635] However, in Canadian law, there is no freestanding right to receive health care[636] and this has led to questions about ensuring end-user rights of access in the public health care system.

The approach to resolving these contradictions in the Canadian public health care space has been political, or consensus-based, rather than the rights-based approach often drawn upon by international health and human rights law.[637] For instance, in *Eldridge* the SCC ruled that the *Charter* applies to institutional as well as individual health care providers, including governments, hospitals and private entities providing publicly-funded services.[638] However, as set out by Chief Justice McLachlin in *Chaoulli*, that is not to say that the *Charter* inscribes a right to health care *per se* in Canada.[639] Where accountability measures are lacking and explicit right to health legislation absent, the *Charter* has been invoked for its ability to seek accountability and respect

[632] A patient must consent to medical intervention. See, *Malette v. Shulman* (1990), 72 O.R. (2d) 417, 37 O.A.C. 281.
[633] A patient must be given the information needed to make their own informed choices about medical treatment. See, *Reibl v. Hughes*, [1980] 2 S.C.R. 880, 114 D.L.R. (3d) 1.
[634] Flood CM, Epps T, "Waiting for health care: What role for a Patients' Bill of Rights?" (2004) 49McGill L.J. 515 at 524 at 524.
[635] Jasanoff S, *Reframing Rights: Bioconstitutionalism in the Genetic Age* (Cambridge: The MIT Press, 2011) at 3.
[636] Narratives in the literature have included discussions around the judiciary's negative 'right to health care' approach rather than an interpretation of *s.7* of the Canadian *Charter* as including a positive right to care. See, for example, discussion in Flood et al., *supra note* 927. See also, Flood and Epps, *supra note* 634 at 530 (reflecting on leading *Charter* cases).
[637] Jackman, *supra note* 631.
[638] *Eldridge v. British Columbia* (A.G.) [1997] 3 S.C.R. 624, 38 B.C.L.R. (3d) [*Eldridge*] at para 71. See also, Jackman, *supra note* 468.
[639] *Chaoulli v. Quebec* (A.G.), 2005 SCC 35, [2005] 1 S.C.R. 791 [*Chaoulli*] at para 104.

for patient rights — for example, *section 15*, for its guarantee of equal protection and benefit of the law, *section 7*, for its requirement that a loss of life, liberty and security align with the principle of fundamental justice, and *section 1*, for its demand of reasonable and justified decision-making affecting access to care.[640] Examples out of the 'right to health' movement have suggested that while health policy narratives in Canada are often dominated by the voices of economists and government, there is room for the courts and for legal scholarship borne of this movement in policy analysis, given the capacity of the law to shape and challenge decision-making and resource allocation schemes.

Despite the potential of the *Charter* as a means of securing accountable and respectful decision-making within Canada's health care system, such arguments have nonetheless had limited success since the engagement of *Charter* rights by government action in *Eldridge*.[641] The failure to mount a constitutional challenge over the validity of patents on genes in the U.S. in *Myriad* also influenced the decision by *CHEO* not to pursue a *Charter* challenge in seeking access to the patented LQTS genes and tests.[642] Some commentators have attributed the limited success of *Charter* arguments to a combination of judicial deference to government funding choices around what is considered medically necessary in health care provision and a reliance by the courts on a negative rights approach to *Charter* guarantees overriding requests for positive government action

[640] Some examples include, *Carter v. Canada (Attorney General)*, 2015 SCC 5, [2015] 1 SCR 331 [*Carter*] (mounting *s.7* challenge to the Criminal Code prohibition on assisted suicide) ; *Cameron v. Nova Scotia (Attorney General)* [1999] N.S.J. No.33, 172 N.S.R. (2nd) (N.S.S.C.) [*Cameron*] (mounting *s.15* challenge to the lack of health insurance coverage for in vitro fertilization treatment). *Section 7* provides that: "Everyone 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." *Section 15* provides that: "Every individual is equal before and under the law and has the right to the equal protection and equal benefit of the law without discrimination and, in particular, without discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental or physical disability."
[641] See, Jackman, *supra note* 631.
[642] Personal communication with individual who assisted with the 2014 CHEO Federal Court challenge Statement of Claim.

on facilitating care.[643] Others say that leaving decisions of access to health to the courts can be particularly hard-won where patented health-related invention is involved because of the adversarial nature of patent disputes.[644] These disputes are often a matter of the private interests of the monopoly-holder being butted against the private interests of the potential infringer, and according to some strong defenders of the public domain this leaves limited room for other important public interests to enter the discussion.[645]

3.6 Linking Statement

While at both a provincial and federal level, the health policy communities were heavily invested in identifying solutions to address the immediate and looming impacts of patents on genes for health research and care, a dominant patent-centric approach stymied broader forward-looking health policy considerations and the formulation of conjoined, cooperative genetics policy. To better understand why this might be, this chapter considered the context within which these discussions occurred (namely focusing on the test provision landscape) in relation to patented human genetic materials and tests. This allowed for a better understanding of which aspects of health research and care and right-to-health principles did play a part in the human gene patent debate's trajectory and which aspects did not. Since considerations of the appropriate uses of human genetic materials are imbued with ethical and social concerns, and given that we are already committed to the development of health policy in Canada, in this chapter, I have advanced the main argument of the thesis: that a perspective on appropriate human genetic research and gene-based health technology use external to the patent-centric, "patent-or-bust" paradigm, needs to be

[643] Jackman, *supra note* 631.
[644] Gold, *supra note* **Error! Bookmark not defined.** at 71.
[645] Boyle, *supra note* **77**.

considered. I sought to do this by arguing that there needs to be a shift from the current 'patent paradigm' for finding solutions in the human gene patent debate. This shift needs to include a re-imagination of what constitutes the public domain and a broadening of scientific and expert contribution at the public-private divide around appropriate use of human genetic materials and an exploration of how best, or sometimes when, to consider non-market values as they relate to patented genetic health invention.

Discussions around how to address issues of access due to or exacerbated by gene patents in health research and care primarily by way of patent reform approaches have been dominated by central recommendations put forth by a heavily invested health policy community, in Ontario and at Health Canada, at the height of the debate. There may be no perfect solution to serving the goals of the patent system with regards to human genetics research and gene-based health innovation, and continuing to rely on the familiarity of the existing patent system to find a balanced solution to the gene patent problem is one way to carry on. But, it seems ill-advised to rely on patents to incentivize invention, development and commercialization knowing that not only can they set up inappropriate incentives to innovate in research and health care innovation but that, as noted in an earlier chapter, the patent system cares little of values external to what markets deem worthy of consideration. As such, given that we know better, we need to do better; we know that IP is an intersectoral issue in important public policy areas, and we know genetic health to be one of them.

In the chapter that follows, I zero in further on the intersection of patents with the publicly-provided spaces of health research and care in Canada. In context of the gene patent debate provided above, I expand on the debate as a "wicked issue" — "a problem that is complex, difficult to define, with no immediate solution, and one where every wicked problem can be considered to

be a symptom of another problem."[646] In Chapter 5, I build upon work from the previous chapters detailing the troubling impact of patents on access to new health care technologies by public users to gain a better understanding of the tension among key actors within the patent and health policy arenas that took part in the gene patent debate and in developments since. From there, I take a closer look at that actor network from the perspective of patents as an intersectoral issue in health in need of policy coherence in the Canadian context, joining others who have done so before me in relation to the issues of IP and public health.[647]

[646] Petticrew et al., *supra note* 89 at 454.
[647] See, for e.g., in Bubela TA, Gold ER, Morin J, "Wicked issues for Canada at the intersection of intellectual property and public health: Mechanism for policy coherence" (2011) 4(2) McGill J. Law and Health 3.

4 TENSION IN INTERSECTION

In this chapter, I focus on the intersection of patents and publicly-provided health research and care in Canada: a public-private divide characterized by the view that the right to good health is inherently at odds with rights attached to IP. More specifically, I explore the tension at that intersection as a complimentary one, such that the limits of patent law can be at least partially compensated by policy options that set out to satisfy the health improvement objectives of health and innovation policy. There is, however, work to be done. For quite some time, it has been said that the intersectoral issue of gene patents in health is a "wicked" one,[648] yet formulation of a comprehensive policy of their regulation in Canada, one that is not exclusively instructed by the patent regime, still remains. This chapter sets out to explore some of the persisting challenges that gene patents raise for Canadian health research and care that are impeding ways forward in policy deliberations, including the difficulties raised due to a lack of empirical data informing us how patents, to what extent, are creating barriers of access in those sectors and the complications arising from Canada's jurisdictional division of authority over patents and health. This chapter advances the notion, as others have done before,[649] that as in intersectoral issue linked to other important areas of public policy, such as health, a multidisciplinary approach to the formulation of a comprehensive framework for gene patent regulation is likely needed. The data presented in this chapter supports work put forth in the literature that not only will this approach benefit from interministerial cooperation and leadership — by both levels of Canadian government, but especially the provincial and territorial stewards of health care — but also concludes that a genetics policy agenda, whether it be a broad health-in-all-policies approach or a policy framework that

[648] Petticrew et al., *supra note* 89.
[649] See generally, Bubela et al., *supra note* 647.

guides cooperative efforts for synergistic benefits and supports minimal social and health-related harms, should be developed alongside considerations in patenting policy.

Finally, because what is happening beyond Canada matters in this debate, at the level of international policy discourse, the tension at the public-private divide in the human gene debate has been expressed as occurring between the provisions in TRIPS on one hand, and in international human rights law on the other.[650] It is also an intersectoral issue acknowledged by the United Nations Committee on Economic, Social, and Cultural Rights such that "[t]he allocation of rights over IP has significant economic, social and cultural consequences that can affect the enjoyment of human rights."[651] This work lays the groundwork for the following section, which identifies several key Canadian actor networks that have attempted to address the "wicked" gene patent problem at various times.

4A AT THE INTERSECTION OF PATENTS AND HEALTH IN CANADA

4.1 THE WHAT

4.1.1 Tension at the Public and Private Divide

Where patents meet health care, the relationship at its core is defined by what is seen as a contradictory, even forced, conformity of the utilitarian rights granted under a patent and the right to health. A right to health is acknowledged as a fundamental and universal human right,[652]

[650] United Nations, Sub-Commission Resolution 2000/7 at point 2 and Sub-Commission Resolution 2000/7 at point 7. According to the Committee, human rights trump economic rights and should be factored into economic rights policies.
[651] Statement by the Committee on Economic, Social, and Cultural Rights, Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social, and Cultural Rights. Follow-up to the day of general discussion on article 15.1(c), Monday 26 November 2001, *Human Rights and Intellectual Property*. See, United Nations Committee on Economic, Social, and Cultural Rights, E/C.12/2001/15, 14 December 2001, para.1.
[652] UDHR, *supra note* 188 at *art. 25(1)*.

established and elaborated in binding international law.[653] A challenge in implementing a right to health in practice is that it involves allocating scarce resources while, for the most part, society relies on the private sector to use its more abundant resources to develop new products. However, where private sector actors acquire IP, so too do they acquire control of market availability and access. This can create barriers to the availability of and access to new gene-based invention in Canada's public health research and care and, as such, patents remain at the heart of the policy predicament. Relying on the private sector to deliver new health products and technologies means understanding that private firms will allocate their resources in favour of their own commercial interests, interests often protected as IP. If Canadian public health authorities need to cooperate with industry to acquire private sector resources for public health-related gains in a "patent-or-bust" R&D ecosystem, then it is likely that the exercising of patent rights on genetic health technologies will continue to be characterized as a wicked problem. Here, from within the logic of the patent system, a right to health can be viewed as being at odds with the potential positive welfare gains for public health.

With respect to the provincial discussions concerning the BRCA patents, nearly twenty years after advocating for a more balanced approach to the debate on behalf of Ontario's MED, one informant expressed exasperation over the actions of an American biotechnology company having then almost inadvertently — although some say erroneously (Gold, p. 11) — set in motion a chain of events that would negatively impact how health care delivery was to happen in the province. The informant explained it like this:

> Anything to do to restrict access meant cabinet ministers' grandmothers weren't going to get drugs or genetic tests they needed. Therefore, there was no way ministers would pass legislation that would impinge on drug access …. Bottom line — Myriad Genetics … of

[653] ICESCR, *supra note* 188. Stating that access to health technologies is not itself a stand-alone human right can clearly be important in attaining the highest possible standard of health.

> the U.S. isn't going to tell us that we can't treat our patients properly because you were the first ones to patent the BRCA gene … Like Harris' response … 'We've been using this for a long time' …. They never came after us for it. Why? I believe because if they did, Ontario would have challenged gene patentability as patentable subject matter. (Mantel, p. 3)

The high profile of breast cancer historically has made the commercialization of a breast cancer test a particularly tense issue (Gold, p. 3).[654] One thing became clear to the Ontario health policy unit in those early days of the gene patent debate — patents were going to be a problem. As one informant said, provincial funding for tests was always a challenge, such that "through the 2000s … it [Ontario] was paying a lot of money sending patient samples to the USA labs to have genes looked at" (Informant 8, p. 5) and patents were an additional barrier.[655]

Patents on genetic tests, such as the BRCAnalysis, were a concern because of the difficulty of inventing an alternate test by using a different method[656] or because using patented DNA sequences for non-commercial purposes, such as academic research, exposed users to patent infringement. The overriding concern was about access to the genes and tests because once patented, a patent holder is granted veto power over the invention and its functional uses. In the case of the patented BRCA DNA sequences, that would mean full control over the coding sequences and of testing procedures using them. The availability of only one predictability test seeded worries about stalled developments in genetic health R&D,[657] about the quality of

[654] See, Rabino I, "How human geneticists in US view commercialization of the Human Genome Project" (2001) 29 Nat. Genet. 15. Also, Cho et al., *supra note* 383. See also, Merz et al., *supra note* 307; Benowitz S, "European groups oppose Myriad's latest patent on BRCA 1" (2003) 95 J. Natl. Cancer. Inst. 8. And, Nicol D, Nielsen J, *Patents and medical biotechnology: An empirical analysis of the issues facing Australian industry*, Centre for Law and Genetics, Occasional Paper no. 6., University of Tasmania, 2003.
[655] See also, Ali Khan and Gold, *supra note* 122.
[656] *LeRoy, supra note* **38** ("the avowed policy of patent laws" is the alternativeness of patentable inventions).
[657] Carbone et al., *supra note* 381.

testing,[658] and about treatment or therapy options in the clinical setting.[659] Ontario's health policy unit was focused on keeping its existing testing service in place and not being left vulnerable to Myriad's incoming exclusive licensing model (Informant 2, p. 2). The threat of these licensing practices in the public health care system was seen as a patent issue, and further, a failure of patent policy to effectively distribute the benefits of genetic technological innovation to publicly-provided health spaces generally (Informant 2, p. 1). In its 2002 *Charting New Territory* report, Ontario shared several concerns with other countries and international bodies about the patentability afforded to gene-based health-related inventions.[660]

Notably in the U.K., the human gene patent debate struck a completely different tone from what was happening elsewhere that resulted in a more direct and pragmatic, collaborative management of issues relating to genetic testing access. The U.K. established a prime ministerial-led task force, the Prime Minister's Pharmaceutical Industry Competitiveness Dispatch Force, that was, in theory, chaired by the Prime Minister, in practice, chaired by the Health Minister and included ministers from five government departments, and chief executive officers from three of the top global multi-national pharmaceutical and biotechnology firms. In other words, "it was *very* high level" (Gillespie, p. 14, *emphasis added by informant*).[661] The task force generated an action plan that

[658] Ibarreta D, Bock A-K, Klein C, Rodriguez Cerezo E, *Towards quality assurance and harmonisation of genetic testing services in the EU, IPTS — Institute of Prospective Technological Studies*, Publ. EUR 20977 2003; Cho et al., *supra note* 383.
[659] Cook-Deegan and Heaney, *supra note* 429.
[660] For instance, The Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (Discussion Paper) (London: Nuffield Council on Bioethics, 2002). Also, the European Commission regarding the *EU Directive, supra note* **Error! Bookmark not defined.**. Also, "Genetic Technologies To Enforce BRCA test rights in Australia, New Zealand," Press Release, 2008, online: <https://www.genomeweb.com/archive/genetic-technologies-enforce-brca-test-rights-australia-new-zealand#.YL-t6PlKg2w> (date accessed: 25 November 2020). In the U.S. regarding a focus on stronger academia-industry ties and strong patent rights, see explanation in Malinowski and Littlefield, *supra note* 180.
[661] See, for e.g., The Pharma Letter, *UK Pharma Industry Competitiveness: One year on*, 26 May 2002, online: <https://www.thepharmaletter.com/article/uk-pharma-industry-competitiveness-task-force-one-year-on>. In 2011, the U.K. government continued support of U.K.'s global leadership in life sciences and SME enterprise long-term in their 10 year Strategy for UK Life Sciences. See, HM Government, *Industrial Strategy: government and industry*

established "a more friendly participating system" with a "standing dialogue" between the competitive profit-driven supply side (i.e., biopharma industry) and the publicly-provided and efficiency-driven demand side (i.e., the National Health Service) in the U.K. (Gillespie, p. 15). The government had stewarded what resulted in a "collegial relationship" between the life sciences industries and the publicly-funded health care system of the U.K., establishing various research institutes and increasing capacity to — and access for — primary clinical testing (Gillespie, p. 15). The institutional cooperative response led by government was similar in some ways to the approach taken in response to concerns over access to the JAK2 test in 2007 in Ontario.[662]

Existing genetic health technologies and the introduction of new ones into the health care system raises the issue of testing access and regulation. At the core of access to and regulation of patented genetic health technologies is the issue of gene patenting by the companies that create such technologies. Following Myriad but before JAK2, federal advisory group the CBAC and the MOH closely followed the developments in *Harvard* and *Monsanto* (Informant 13, p. 18), with the CBAC advising on the patent-eligibility of higher life prior to the start of *Harvard*, and Ontario serving as an intervener in *Monsanto*. The MOH had held expectations of clarity on the matter of patentable art and subject matter and the measurable harm of patents on gene-based inventions in following the cases,[663] but that did not happen with the ruling in *Harvard* having been at odds with that in *Monsanto* with respect to the patenting of higher life forms. By the late 2000s, public discussions of patents on genes in Canada fell silent within the majority of government policy

partnership, Strategy for UK Life Sciences: One Year On, 2012, online: <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/36684/12-1346-strategy-for-uk-life-sciences-one-year-on.pdf>.

[662] For a detailed explanation of this event, see Gold and Carbone, *supra note* 103.

[663] See, for e.g., The House Judiciary Subcommittee on Courts and Intellectual Property, One Hundred Sixth Congress, 2nd session (13 July 2000) (Statement of Dr. Harold Varmus), online: <http://commdocs.house.gov/committees/judiciary/hju66043.000/hju66043_0f.htm>.

circles, both patent- or health-related, as public laboratories in Ontario were told that it was "okay" to ignore the BRCA patents (Informant 8, p. 11). The opportunity to develop a formal institutional or government policy addressing the oversight of access to patented genetic tests was lost (Gold, p. 33), and with it, a chance to develop a coherent government policy response to gene patents. A patent-centric approach to the gene patent problem by Ontario stymied adequate consideration of solutions through a "health-policy-in-all-policies" analysis,[664] but the lack of empirical data pertaining to the impact of patents on health care delivery — good or bad — had become a real problem for Canadian health policymakers.

4.1.2 Empirical Data and Other Call to Arms

If licensing agreements are involved in patents' introduction into the test provision landscape, then the implementation of a test can be more challenging to consider because "patents mean higher costs" (Informant 20, p. 8) which, as some of my informants pointed out, can be associated with changing market prices and upkeep costs once adopted. The province was providing BRCA testing by the late 1990s at approximately half the cost compared to Myriad's exclusive Canadian provider.[665] The province had no choice but to "resist the legal action and be ready to support that" because it lacked policy to leverage an actionable solution to the threat of gene patents to their health care (Drouillard, p. 23). Consequently, this exposed a vulnerability of governance over genetics health care in the province (Drouillard, p. 23).

The provincial vulnerability revealed a gap in federal oversight; through the administration of the *Canada Health Act*, Health Canada and other public health agencies (e.g., the Public Health

[664] Rigby and Hatch, *supra note* 99.
[665] CBAC 2006, *supra note* 79.

Agency of Canada, or the PHAC) are mandated to harmonize national health policy. However, federal health agencies have fallen short of putting forth any responsive policy on the matter. Over a decade following Myriad, *CHEO* would show that little had changed at either level of government in Canada. The case also exposed a gap in empirical data to support the use of patents while ensuring patent use was not interfering with access to health care. My study informants asserted the need for this gap to be filled, but with some claiming that without statistical data to clearly demonstrate that these patents are creating barriers of access in upstream to downstream research, that concerns about technologies not reaching the clinical setting are warranted, that "patents are killing people," or that gene-based patents are creating a health research and care system in "crisis," any sort of responsive policy based on a case of one is seen as anecdotal at best (Informant 18, pp. 6–7).[666]

Questions about short-term costs associated with patents remain unanswered today. Aside from limited public access to genetic technologies due to the inflated cost of genetic tests,[667] little is known about certain costs in relation to patents in this space (Gold, p. 28), and even less is known specifically about how biotechnology patents directly impact costs in health care.[668] In part, due to with the challenges of having to navigate patent licenses held by U.S. firms, Ontario has tried to better understand the indirect costs of establishing genetic test services to respond to challenges of local test implementation (Informant 8, p. 6), more recently through its GSO pilot. Nonetheless, the likelihood of fully understanding these costs, at least any time soon, in terms of contributory costs of patents on genetic tests,[669] is slim because according to Gold, there is a big incentive for

[666] See also, Caulfield, *supra note* 466.
[667] Caulfield et al., *supra note* 427.
[668] Gold ER et al, "Are patents impeding medical care and innovation?" (2009) 7(1) PLOS Medicine 1.
[669] Scholarship and policy focus more on patent costs for drug access and their impact on health care costs. See, for e.g., The Canadian Health Coalition comment on the 2016 PMPRB Guidelines Modernization Discussion Paper,

users not to reveal this information out of fear of facing allegations of patent infringement. The policy context around the long QT tests on the broader test provision landscape is illustrative:

> One of the things that worried us about this is that it encourages that type of thing, right? The less we know, the less likely something bad is going to happen, right? If no one knows who's doing a test and how many tests, then trying to find someone to sue becomes difficult … The reason that the long QT came out is that the province was going to issue a competition for long QT, so then there was a target … So, this leads to not making information transparent because making information transparent is more likely to attract that attention. (Gold, pp. 28–29)

The added concern about not having information about how many patented tests are being used in public laboratories and how much they impact access to in-house testing is that it is difficult to conduct a true HTA and, thereby, difficult to make decisions relating to real-world needs upon which to base formulary inclusion or resource allocation accordingly (Gold, p. 29). Although existing patents likely continue to make R&D more expensive as researchers and companies seek to clear patent rights to do their work,[670] the impact of patents on the total cost of medical care in Canada remains unknown. It also remains unclear to what extent or how patents increase the cost of medical services involving the use of genetic tests and so, despite concerns around their pervasiveness, just how patents are taxing the sustainability of the health care system remains largely unknown.[671] Interview attempts with the MOH (including the Negotiations and Accountability Division) were unsuccessful. However, the provincial public health laboratory sector is exploring out-of-country genetic test provision. One informant claimed that a better understanding of this situation would require better intra-provincial data relating to outcomes in health, such as determining costs to funding for test services, determining proportions of

online: <http://www.pmprb-cepmb.gc.ca/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Cdn_Health_Coalition_Oct_2016.pdf>.

[670] Gold, *supra note* 669.

[671] See, LSEP, *supra note* 266.

individuals experiencing problems accessing tests, and assessing the impact on the provincial health scheme by determining the number of people requesting coverage for out-of-province testing (Naimark, p. 16). Another informant asserted that it is imperative for provincial and federal and federal agencies to make a joint effort to determine empirically how to go about collecting this data (Drouillard, p. 24). These questions persist despite previous efforts for clarity sought in *CHEO*, in which the cost of out-of-province testing, lack of local test implementation, and greater joint efforts to face gene patent problems in the clinic were reported as significant barriers of access to the long QT test (Informant 8, p. 6).

Theoretically, purchasing prices that lie somewhere between monopoly and competitive prices suggest a bilateral monopoly scenario in which a single seller and buyer can negotiate price.[672] In a public health system such as Canada's, where the state is the largest buyer of some products, a bilateral monopoly can allow health authorities to take aggressive action such as through reference-based pricing to reduce prices from the monopoly level. However, the combination of provinces having to provide medically-necessary health care while honouring the patent right of private entities exposes the potential to exploit provincial purchasing under practices that favour the latter, such as the use of formularies as *de facto* patent term restoration extending market exclusivity for manufacturers (Mantel, p. 10). Consequently, provinces may struggle to facilitate equitable and timely access to patented genetic health technologies while also keeping to budgets. Seen in this light, a fundamental failure of not formulating a genetics health policy here is the application of medical necessity — which forces the purchase of products and services by governments irrespective of the price — combined with patent rights — which grant holders the power to set a

[672] Machlup F, Taber M, "Bilateral monopoly, successive monopoly, and vertical integration" (1960) 27(106) Economica 101.

price. In terms of research and regulatory approval trajectories, the costs associated with accessing and developing genetic materials and genetic tests may currently be less of a problem for private entities compared to the cost incurred from R&D in pharmaceuticals, but this can change as demands for tests increase as personalized medicine regimes build.[673] On their own, each of medical necessity and patent rights are reasonable expectations. Taken together, however, they risk resulting in unlimited private profits with limited social benefits and potentially, a greater public burden in relation to costs.

Studies relating to the impact of patents on other sectors may be instructive, but where quantitative, such studies remain focused on economic outcomes as a measure of commercial or marketable innovation.[674] According to some study informants, from a legal or policy perspective, mounting a challenge to policy developments around the regulation of patented genetic health technologies in general has been difficult for health authorities. From a legal perspective, it has been difficult to challenge the misuse of legal rights of proprietors over genetic tests in Canada such as, for instance, to mount arguments that human genes are discoveries and not invention[675] or that business practices were in violation of Canadian competition laws by stopping others from offering breast cancer predictive tests.[676] As it stands, human genes are patentable subject matter in Canada, and the use of patents to exclude competitors is an acceptable use of patents and aligns with the very purpose of a patent.

[673] McCabe and Husereau, *supra note* 48.
[674] See, for e.g., Owens and Robichaud, *supra note* 83 at 29–33 for discussion of the empirical economic research relating to the economic effects of IP rights in economies with knowledge-intensive sectors.
[675] Matthijs G, Halley D, "European-wide opposition to breast cancer gene patents" (2002) 10 Eur J. Cancer Care 783.
[676] Kaufert, *supra note* 425.

From a policy standpoint, Ontario did not contest Myriad's commercial strategy directly by way of producing an analysis of the economic impact on health care delivery upon which changes to policy could be justified by both Industry Canada and Health Canada (Informant 10, p. 11). From a broader public interest perspective, when used too far "upstream" (i.e., in laboratory work) in research or early invention development phases, patents stand to confine access instructed by private interests alone (Hawkins, p. 29). When used too far "downstream" (i.e., during the intermediate and final stages of product development), public user access can fall prey — as reported with respect to patented genetic health technology in Canada — to "don't ask don't tell" practices.[677] Important to this perspective are discussions about public and private goods and IP schemes at the public-private divide. The formalistic approach to distinguishing between such 'goods' by assigning privately-supported goods to the market and publicly-funded goods to the state is often compelling. Except, as discussed previously, health care goods often combine public and private contributions given the public-private nature of innovation in the sector and the nature of the building blocks for that innovation — scientific knowledge and genetic materials, among the closest pure examples of 'public goods' known. A better understanding of innovation (as discussed in an earlier chapter) is thereby critical — how it happens, for what purpose, and to what end.[678]

4.1.3 Jurisdictional Challenges

With its concerns with the BRCA patents, Ontario had sought federal leadership to clarify patent laws as they applied to gene-based health-related invention (Informant 2, p. 1). The Ontario MOH

[677] Ali Khan and Gold, *supra note* 122.
[678] Some argue that cDNA, not gDNA, is the most valuable patent for incentivizing innovation from basic research. See Rai A, Cook-Deegan R, "Moving beyond 'isolated' gene patents" (2013) 341(6142) Science 137. However, patented gDNA may gain in value for private entities as genomic sequencing technology continues to advance and grow in clinical demand.

approached Health Canada in good faith around shared concerns over a lack of regulatory policy relating to gene patents in Canada's health care. Health Canada's response to Ontario's 2002 *Charting New Territory* report was the assembly of a three-person genetics policy group (Hutchinson, p. 1) to speak with Industry Canada's Life Sciences and Patent Policy branches. The Life Sciences branch had aligned with the province's expressed concerns (Hutchinson, p. 3). The Patent Policy Directorate, on the other hand, held that changes to the law were empirically unsubstantiated and a "very emotional thing for some people" (Informant 10, p. 6).

A Government of Canada policy advisor recalled Ontario being really "up in arms at Myriad Genetics" over the firm's enforcement of its patents (Informant 10, p. 1), noting that there was "a lot of heat but not a lot of fire" and as "true believers" talks with the MOHLTC health policy group included discussions around the ethical patenting of higher life forms (Informant 10, p. 10) and human genes as "morally wrong" (Informant 10, p. 6). Conversations with Ontario were "charged" (Informant 10, p. 5) and again, "very emotional" (Informant 10, p. 6) and never produced the kind of information that Industry Canada could use to justify changes to the patent system (Informant 10, p. 11). For Industry Canada, that a genetic invention "existed at all" was critical to justifying the right of industry to protect their inventions (Informant 10, p. 6). Ontario's *Charting New Territory* report asserted a right to equitable access to patented genetic health inventions, but according to Informant 10, the question for Industry Canada was 'at what cost to the sustainability of the Canadian public sector?':

> They never heard a really good counter-argument like "Well, the public sector maybe should be conducting this R&D, or we should push for universities to do this R&D." There was never that to my recollection. We didn't see eye-to-eye on this stuff. The narrative was "big bad pharma exploiting." (Informant 10, p. 6)

Ontario was the only province that had approached Industry Canada with its concerns about gene patents. No other province or territory approached the federal department with concerns or data suggesting a harmful impact of patents on health research and care, so the idea of changing patent policy based on the one test case of Myriad in one province was bad policymaking (Informant 10, p. 3). As for the biotechnology industry, "absolutely" no members requested a meeting with Industry Canada over concerns that gene patents were impeding biomedical R&D (Informant 10, p. 5). Even when Industry Canada sought direct consultation with industry members, no clear concerns were expressed on the matter of gene patents getting in the way of R&D (Informant 10, p. 5).

One of the biggest problems Industry Canada had with Ontario's requests to change policy over the BRCA patents was the lack of measurable harm attributed to the patents on health care delivery. The lack of evidence-led discussions from Ontario left elected officials at Industry Canada saying "this is a loser" (Informant 10, p. 5). In the end, Industry Canada saw Ontario's call to action to change or develop specific policy or to advance legislative initiatives on the matter of patent use as baseless:

> There was no economic study that clearly demonstrates 'this is the amount of money they [industry] invested to produce the drug', 'here's the amount of money they recouped from it, windfall profits', even if they made a lot less than that — It wasn't based on that, it was a different set of arguments being made [by Ontario and Health Canada]. No one ever put numbers in front of me, I never had to pull my calculator out, I never gave things to my economist and said "develop an economic model that tells me what's going on here." (Informant 10, p. 11)

A large part of ensuring for the design of meaningful and well-performing policy to address a particular issue or to support particular practices is contingent on the quality of data available to analysts that can be provided to the decision-makers.[679] Because "no one could do an economic

[679] Lindquist E, Desveaux J, "Policy analysis and bureaucratic capacity," in DHL 2007, *supra note* 612 at 123.

impact analysis for us", discussions with the genetics policy unit about genetics policy development in relation to patents were severely limited; there was no overall understanding of the "positive or negative" impacts of gene-based patents on access to genetic tests and no traction to discuss policy changes (Drouillard, p. 13).

A senior official from the then MED claimed that no economic modelling had been developed, in part, because too many assumptions would have to be made on key variables in the sector, such as on economic growth (Mantel, p. 13). Industry Canada felt that the *Patent Act* was doing a good enough job of balancing public and private interests (Informant 10, p. 6) and thus, in managing any inherent tension in that balance where gene patents were concerned (Informant 10, p. 10). Nearly two decades following these discussions around Myriad, one informant summarized them by saying:

> We had other ways to talk about access — compulsory licensing! But they [Ontario health policy unit] didn't want to talk about that — "It's my gene, you can't patent my gene" they would say. But you're not patenting your gene. People don't fundamentally understand the *Patent Act*. No one is patenting *your* gene. They thought that with BRCA, if patents were associated with their use, then that would somehow prevent them as a human being from doing something with something as a part of their body … It [the gene patent] prevents you as a company from using and selling or using it for that test, commercializing it. But that was a fundamental disagreement, and they were very passionate about that. (Informant 10, p. 7 *emphasis added by informant*)

A post-Myriad Canada was quiet on the subject of gene patents for years. Having lost interest in Canada's comparatively small market size on the global stage and having lost patience with Ontario's unwillingness to negotiate licensing, the American firm eventually gave up.[680] When Ontario's health policy unit was forced to redirect attention to the severe acute respiratory syndrome (SARS) outbreak by 2004, the new direction led to the collapse of the provincial group

[680] Gold and Carbone, *supra note* 103. Also, Crowe K, "Breast cancer gene patents: The Canadian story," CBC News Health, online: <https://www.cbc.ca/news/health/breast-cancer-gene-patents-the-canadian-story-1.1338883>.

on gene patenting[681] and of joint Ontario and Health Canada-led priorities on the genetics policy file. Instead, Health Canada brought their efforts to the biotechnology division at the OECD to contribute to the OECD *Guidelines for the Licensing of Genetic Inventions* (Drouillard, p. 6).[682] Aside from the JAK2 "second coming" by 2007 (Drouillard, p. 20; Gold, p. 5), Canada's policy considerations relating to human gene patents had dried up, until 2014 when an Ontario hospital chose to mount a legal challenge over its ongoing struggles to gain reliable clinical and research access to the high-demand patented genetic test and genetic sequences associated with LQTS.

4.2 THE WHY

Gene patents have long been generating uncertainty for downstream developments relating to genetic tests, their availability in the test landscape, and in the delivery of testing services.[683] The patent paradox may explain the normative tension that traditionally characterizes the public-private divide in Canada's gene patent debate. But the tension at that divide extends beyond an economic justification of protected private rights and "rights as trump"[684] prevalent in property talk around questions about how to resolve rights problems more constructively as collective, even if contested, choices.[685] Below, I explore implications of the lack of empirical data and jurisdictional challenges as discussed above as a normative tension between patents and health that suggests that market mechanisms, such as IP rights, are reaching their limits. But I also consider this tension as a complementary one, such that the limits of patent law can be at least partially compensated by

[681] *Id.*, Gold and Carbone at S53.
[682] OECD, *Guidelines for the Licensing of Genetic Inventions*, OECD Publishing, Paris, 2002, online: <https://www.oecd.org/sti/emerging-tech/36198812.pdf>.
[683] SACGHS, *supra note* 3 at 90.
[684] A phrase coined by Dworkin R, *Taking Rights Seriously* (Cambridge: Harvard University Press, 1978.
[685] See, *Article 15* of the International Covenant on Economic, Social and Cultural Rights, "to enjoy the benefits of scientific progress and its applications" and in consideration of Nedelsky, *supra note* 12 at 2–6. Similarly, in my exploration, I question this notion, considering the dynamic between patents and health, and whether they must be viewed as mutually exclusive.

policy options that set out to satisfy the health improvement objectives of health and innovation policy under, for instance, a health-policy-in-all-policy framework.

4.2.1 Public Health Care Is Different

Pharmaceutical and biotechnology firms invest billions into many slow returns over many years.[686] Public goods theory captures the nature of invention and a justification for patents in the life and biomedical sciences industries.[687] Innovation is encouraged by patent-created rights excluding free-ridership and alleviating the public goods issue, particularly where the use of new information is vulnerable to appropriation, such as with the copying of technology. A justification of patents includes its defining feature of exclusion, unique to IP and considered essential to incentivizing innovation. Patent law's broad exclusionary rule is often justified for being economically necessary and administratively easy to manage. In fact, a diminished exercise or unmitigated infringement of these rights would be contrary to the patent holder's liberty to make use of their IP afforded under law,[688] international conventions,[689] and to the detriment of effective innovation policy and of the wider innovation process.[690] Consequently, justifications of a right to exclude often revolve around discussions around the relative strength versus weakness of a patent right.[691] The idea being that a stronger and broader right to exclude under the patent system is expected to

686 Capital for R&D in smaller markets, like Canada, is often limited in biotechnology. See, Hon. Ohlhausen MK, "Climate rights in a climate of intellectual property rights skepticism" (2016) 30(1) Harvard J. L. & Tech. 1. See also, PHRMA, 2015 Profile Biopharmaceutical Research Industry 36, April 2015, online: <http://phrma-docs.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf> (reporting between 2000-2010, drug development costs averaged $2.6 billion, including failure expenses).
687 Burke and Lemley*, supra note* 72 at 1585, 1615–19.
688 *Canada Patent Act, supra note* 125. Also, Drahos P, "Biotechnology patents, markets and morality" (1999) 21(9) EIPR 441 at 315.
689 *General Agreement on Trade-Related Aspects of Intellectual Property, 1869 U.N.T.S. 299, 33 I.L.M. 1197 [TRIPS].*
690 Merges RP, "What kind of rights are IP rights?" in Dreyfuss RC, Pila J (eds.), *The Oxford Handbook of IP Law* (Oxford: Oxford University Press, 2018).
691 Gold in GE^{3}LS, *supra note* 49.

incentivize innovation to increase the expected social value of innovating.[692] Seen in this light, for the purposes of clinical care, the right to exclude is not harmful to upstream innovation nor to downstream development.[693] It remains broadly perceived that in the absence of alternative sought-after reward structures, such as regulatory exclusivity or prizes as examples, progress in the fields of life science, biomedicine and biotechnology towards broad social welfare together would suffer without patent protection.[694]

Consequently and traditionally, members of Canada's biotechnology industry have asserted that patents are necessary to stimulate R&D, to produce needed new health products and services, and to help satisfy health improvement objectives (Informant 21, p. 13). When asked "At what cost to health care has this assertion by the biotechnology industry factored into tensions at the public and private divide?", one informant said that the public interest mandate of the biotechnology industry may be "very politicized," but it is not coincidental (Informant 21, p. 12). For this informant, describing the relationship between health care and industry, for instance, as one fraught with tension is a mischaracterization:

> I don't think there has to be a tension (p. 33) … Without industry, you have very limited health options and health improvement options (p. 34) … Without regulation though, you don't have reliable safety, proper adoption systems that can take these devices. (Informant 21, pp. 34–35)

According to this informant, patents are instrumental to biotechnology's satisfaction of its public interest component of innovation in health care delivery:

> We clearly live in a society where capitalism exists and private sector industry with profit goals. Those products provide societal good, but there needs to be a return because of the way our economic system works. People forget that if you really break it down to its

[692] Owens and Robichaud, *supra note* 83.
[693] The concept of a monopoly that could be more conducive to innovation rather than competition is often referred to as "Schumpterian theory." See, Eisenberg R, "Patents and the progress of science: Exclusive rights and experimental use" (1989) 56 U. Chi. L. Rev. 1017, 1038.
[694] Burke and Lemley, *supra note* 72 at 1615.

> fundamentals, biotechnology is trying to find solutions to today's problems [and] then, how do you get those to people. (Informant 21, p. 12)

From this perspective, this informant went on to explain that health policy itself has an important role in making space for patents in health care, and is in a good position to consider both the needs of industry and of the health care sector:

> Health policy is how biotechnology interacts with the rest of the system and the rest of society. Because health policy asks 'How do you introduce new innovations into our current system?', 'How do you ensure that there's uptake, how do you ensure that the Canadian economy, landscape, ecosystem can accommodate and cultivate those technologies, how do you ensure we see this process to the end?' (p. 11) … Patents are important because you leverage that to secure investments to move forward. Biotechnology is a very competitive sector … Why would any international company want to come here if they knew their ideas are at risk? (p. 25) … Health policy is all these things (p. 35) … I see it as all of these decisions coming together in these discussions are health policy (p. 36) … and we really need to go back to fundamentals of just wanting good public policy. (Informant 21, p. 36)

The concern remains, however, that if we rely on market forces to tell us which new innovations should be adopted into health care, then we are setting the system up to fail[695] and we also risk consumers having either to pay the monopoly price or to do without products or services that could have potentially been affordable under greater market competition (Lexchin, p. 6).[696]

Diagnosis and prognosis in clinical care are the leading and most lucrative early-stage applications of genetic technologies. Consequently, the demand for genetic tests in Canadian hospitals, where the majority of testing funded by the provinces is happening, is growing.[697] Federal and provincial legislation directs guaranteed public provision of all needed health care services, and these requirements, genetic testing included, apply only to the set "list" of provincially-provided

[695] Gold, *supra note* 32.
[696] See also, Olson LM, Wendling BW, *The Effect of Generic Drug Competition on Generic Drug Prices During the Hatch-Waxman 180-Day Exclusivity Period*, Fed. Trade Comm'n. Bureau of Econ., Working Paper No. 317, 2013.
[697] LSEP, *supra note* 266 at 8.

physician and hospital services.[698] In the case of Canada's public health care system, the provinces are each the single-payer public authority, and often the largest buyer, of health care products and services. The intrinsic challenge of implementing the delivery of equitable care by health authorities in practice is it involves allocating scare and rivalrous resources or resource-intensive services. Decisions about what to list onto formularies are often impacted by decisions around resource allocation and priority-setting for each province alone[699] and can influence provision of and access to a particular health care product or service across the country.[700]

4.2.2 Policy Incoherence: Hollowed Expertise, Hollowed Opportunities

Several informants who took part in the Ontario and federal consultations about genetic health patents agree that health policy considerations failed to maintain priority in policymaking circles (Gold, p. 26; Drouillard, p. 6). This failing became clear by the time of *CHEO*. The lack of policy traction exposed another big threat to the development of forward-looking genetics policy, namely, a complacency of provincial and federal governance.

There are few examples of a hollowing of expertise and of vulnerabilities in governance capabilities out of the Canadian human gene debate post-Myriad from which the intricacies of the tensions that arose can be best captured. But as limited as they are, for informants in this study these examples are important. Assertion of the JAK2 gene patent against Ontario public health providers by 2007 was an early sign that Ontario's past call to policy action with Myriad had not

[698] Williams-Jones B, Burgess MM, "Social contract theory and just decision-making: Lessons from genetic testing for the BRCA mutations" (2004) 14(2) Kennedy Institute of Ethics J. 115. See also Flood CM, "The Structure and Function of Canada's Health Care System," in Downie JG, Caulfield TA (eds.), *Canadian Health Law and Policy* (Toronto: Butterworths, 1999).
[699] Williams-Jones B, *Genetic testing for Sale: Implications of Commercial BRCA Testing in Canada* (Ph.D. Thesis, McGill University, 2002) at 113–17.
[700] Williams-Jones and Burgess, *supra note* 698.

been fully considered.[701] By 2010, health authorities would again be given a chance to address policies and practices related to the licensing of the long QT patented genes and tests. At CHEO, clinical geneticists were struggling to access timely out-of-province testing and test results, while also trying to navigate the province's efforts to implement high-demand testing locally in cost-effective ways (Informant 8, p. 12). By Federal Court Statement of Claim filed in 2014, CHEO sought to declare the invalidity and non-infringement of five Canadian patents that were related to the long QT genetic and protein sequences implicated in long QT syndrome, an inherited deadly cardiac disorder.[702] In its Federal Court challenge, CHEO raised similar issues that were brought up throughout Myriad's court troubles in the U.S. over its BRCA patents. For example, one key issue related to an invalidation of the isolated long QT sequences under *section 2* of the *Patent Act* on the basis of an insufficient departure from their naturally-occurring counterparts and for a lack of novelty, obviousness, and utility. Notably, CHEO was "not anti-patent," rather "it was anti-gene patent"; an important distinction made because "patents are important, but these particular patents" on the long QT genes were impeding adequate patient care for the hospital "in terms of time for results and cost to the province" (Informant 8, p. 3).

CHEO settled, securing a public health access agreement for Canadian non-commercial public health providers to access patented LQTS genetic sequences and testing at cost. However, this agreement excludes the research community from negotiating access to patented genes or gene-based technology. Following the settlement,[703] CHEO approached the federal and provincial governments to implement the CHEO agreement, which was presented as a health policy blueprint

[701] Gold and Carbone, *supra note* 103 at S54.
[702] CHEO Statement of Claim, *supra note* 124.
[703] See, CHEO's Terms of Settlement with Transgenomic, available online: <https://www.cheo.on.ca/en/clinics-services-programs/resources/Documents/Genetics/Gene-Patent-Challenge/Standard-Long-QT-Patent-License-Agreement.pdf>.

that could be used to address patent-related issues of access with respect to other genetic tests (Gold, p. 31). To date, neither order of government has formally responded, except for the sound of "crickets" (Gold, p. 11). For one informant, what is left now for Canadians is an uncertainty and an unclarity for domestic industry innovation and health care delivery, particularly in the wake of *Myriad* in the U.S. (Gold, p. 10), all of which Health Canada has chosen to accept:

> If you look at the United States, the uncertainty that the Myriad decision has, uh, a whole bunch of people patenting, figuring out how to patent anyway. The number of gene patents has gone up, so, in fact, our solution was superior. But instead of taking that silver platter, they just didn't want to touch it …. Industry Canada at least took a meeting with us, Health Canada wasn't interested. (Gold, pp. 8–9)

According to Gold, the CHEO agreement is a solution that says "It doesn't matter if something is patented or not, we are providing you with a freedom to provide this test for free" (Gold, p. 10). Institutionally, governments did not have a policy in place and "were not prepared to take a clear side," possibly because "they saw a conflict between advancing health and reducing health costs and on other side, helping the industry" (Gold, p. 5). Even with a health lens-focused framework in hand, there was no clear entity in government where the agreement could have been formally considered; governmental health policy units had been systematically dismantled (Gold, p. 26), with "inward looking policy decimated" across government since the Myriad controversy (Gold, p. 10) and with it, any expertise capable of assessing new information on the file:

> Whatever passion had been there was not in the key decision makers … and all the people who had been educated about it were gone. The Health Canada unit dealing with it was gone … Had a few people at Health Canada, but the policy unit during the Harper years — the policy units were all gutted … so all that knowledge was no longer concentrated. (Gold, p. 5)

4.2.3 Vulnerability in Governance

By the time *CHEO* went to court, the motivation for Canadian governments to make forward-looking policy with respect to human gene patents in the Canadian public health care system was

low. Without responsive policy to the problems gene patents are creating for public health care, Canada will remain in a state of "hiatus" to wait "until the problem happens" again (Gold, p. 16), and not for terribly ideological reasons (Gold, pp. 6, 34) but for what became political ones:

> There are no smoking guns. There are no major problems … It would be interesting to look at how much governments are spending on genetic tests … For all I know, we're spending lots of money but nobody cares … We're likely not promoting research, but what's the constituency for that? It's a bunch of things that will not likely motivate the average voter to do anything, and therefore, likely the average government … So, right now they can get away with doing nothing. (Gold, p. 27)

At the federal level, the institutional lead on the gene patent file has always been Industry Canada (Informant 12, p. 3), because the file is "definitely seen as a patenting issue" and the "final decision on who has the stewardship, ownership of the policy from the federal government rests with Industry Canada" (Informant 12, p. 5). For Health Canada, problems around gene patents in public health research and care require looking at different aspects of the patent system for answers (Drouillard, p. 3), which is why its focus remained fixed on changing the *Patent Act* (Drouillard, p. 5). However, along with the lack of empirical data showing measurable harm of patents to health care delivery and patient care, some of my informants suggest that complacency by health authorities also factored into stalled policy considerations on the file, as did inter-ministerial discord (Drouillard, p. 6; Informant 12, pp. 3, 5; Gold, pp. 11, 26). With Myriad, the division of ministerial control created a hostile policy environment in talks about gene patents, where "the control over the *Patent Act* came under one Minister but the impact was felt by another" (Drouillard, p. 6). Given the lack of authority of the federal health minister to direct the delivery of health care or instruct Canadian research enterprise, Health Canada is ultimately left without jurisdiction over how to direct health research, how the patent system is used, or how health care systems decide to deliver their services (Drouillard, p. 6).

On the matter of jurisdictional authority over patents and health, several informants spoke of the overall constitutionally challenging work on gene patenting in Canada. Health Canada in particular found the jurisdictional division of power over genetics health care particularly challenging because of its instructional limitations in policy development as regulators (Drouillard, p. 6). Another informant said that the "postal code health care system" in Canada leaves provinces open to abuses of the patent regime because of price differences in products and services that impinge decisions about formulary coverage (Hawkins, p. 43). Another informant said given its "jealously protected provincial model" for health care (Gillespie, p. 13) Canada struggles with a "size effect problem," with a strongly driven federal approach to developing business and innovation and a "very strong provincial approach" to the demand side by health care (Gillespie, p. 15). With respect to policy development and governance around gene patents in public health research and care, some worry that federal government ministers continue to point fingers and "no one wants to take responsibility" (Gold, p. 26).

When the Myriad controversy reached a "stalemate" following the threat of Myriad's legal action (Informant 12, p. 6), "a decision was made" by 2010 (Informant 12, p. 6) that there was to be a "big shift in position and of our resources" with respect to the gene patenting file (Informant 12, p. 6). Health Canada narrowed its focus from one less concerned about the general issues with patents on genes and to one more concerned about the potential issues of gene patenting in pharmacogenomics (Informant 12, p. 7):

> We'd reached a dead end in terms of gene patenting in Canada, anyways. We had done all that work, kind of lay of the land, people knew the different positions from Industry Canada, Health Canada and others, like stakeholders and OECD. (Informant 12, p. 6)

The conversation with Industry Canada to "ban gene patents" was raised as *CHEO* went to court, as it had been raised before by Ontario regarding the BRCA patents (Informant 12, p. 17). CHEO,

however, had not sought a ban on gene patents and instead, had requested that Health Canada adopt the CHEO agreement under federal health policy to facilitate access to patented genetic materials and tests by public institutions for non-commercial purposes (Gold, p. 26). CHEO also took this same request to the MOH (Gold, p. 11). The CHEO agreement, characterized as a "turn-key health policy" (Gold, p. 20), and "a policy solution that fit with both Health Canada's needs and Industry Canada's needs" (Gold, p. 8), was denied formal consideration at both levels of government (Gold, p. 11).

When Myriad gave up enforcing its BRCA patents in Canada, the average spectator seemed satisfied; the majority of public scrutiny surrounding the patents became generalized to all gene patents throughout the course of the controversy[704] and a disappearance of Myriad meant the removal of an overriding threat to patient care. Some commentators, however, continue to say that clearer empirical data is needed, but add that government policymakers need to want to develop meaningful policy strategies to deal with the gene patent problem in health (Gold, p. 16; Drouillard, p. 6). By the time CHEO reported its struggles with patient access to long QT testing, there was nowhere — and no one — either at the level of provincial or federal government to continue discussions of genetics policy development in relation to gene patents:

> It's disappointing that the government even — it wasn't just Harper, it was other governments — have really walked away from policy development. I don't even know who to go to, to make policy. (Gold, p. 33)

With the uncertainty for Canada following the U.S. ruling in *Myriad* (Gold, p. 10),[705] the loss of government policy expertise remains the norm in Canada (Hawkins, p. 25), and it has contributed

[704] Caulfield, *supra note* 230. And, Caulfield T, Bubela T, Murdoch CJ, "Myriad and the mass media: The covering of a gene patent controversy" (2007) 9 Genet. Med. 850.
[705] See also, "U.S. gene patents: Patient care stymied in Canada, hospital claims," Health, CBC News online, 3 November 2014, online: <https://www.cbc.ca/news/health/u-s-gene-patents-patient-care-stymied-in-canada-hospital-claims-1.2820211> (accessed 6 July 2019).

to a loss of some key central locations for policymaking (Gold, p. 33). The question, — "Who's making policy for the future?" (Gold, p. 33) implies a vulnerability in governance as a result of the disappearance of any inter-ministerial coordination that was once present on the file and leadership that failed to make optimal use of the benefits of patents in genetic health-related research and care.

4B WHO'S WHO: GOVERNANCE IN CANADA'S GENE PATENT DEBATE

4.3 THE WHAT

With increased pressures to commercialize findings in S&T genetics and genomics research (Informant 18, p. 4; Drouillard, p. 31),[706] several policy reports since the 1990s document that patent protection granted to genetic health invention in Canada has raised numerous related issues about the patentability of human genetic materials and tests, life forms, licensing and pricing of patented biotechnologies.[707] Canadian policymakers in these areas have for years faced the challenges of better aligning policies that shape economic incentives for innovative labour with those that facilitate access to the fruits of that labour.[708] More often than not, policymakers looking to align policy around issues of IP and health must contend with the customary support by federal policy of strong patent protection as itself fundamental to Canada's overall innovation strategy.[709]

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[706] Joly, *supra note* 15.
[707] Several considered throughout this work include: Charting New Territory, *supra note* 37; CBAC 2005, *supra note* 441; CBAC, *supra note* 135; Science Metrix, *supra note* 321. See also, Decima Research, *Public Engagement on the Future Government of Canada role in Biotechnology* (Report) (Ottawa: Canadian Biotechnology Secretariat, Industry Canada, 2006).
[708] See, e.g., De Beer et al., *supra note* 49.
[709] See: Assistant Commission of Patents, Patents Branch, CIPO public commentary on guiding principles of patent law, 2016, online: <https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/vwapj/ken-bousfield.pdf/$file/ken-bousfield.pdf>. See generally, Industry Canada, *IP Canada Report 2019*, online: <https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/vwapj/IP_Canada_Report_2019_eng.pdf/$file/IP_Canada_Report_2019_eng.pdf> (date accessed: 3 May 2020); Doern D, Sharaput M, *Canadian Intellectual Property: The Politics of Innovating Institutions and*

The federal government has convened various committees (e.g., Task Force on Biotechnology, Royal Commission on New Reproductive Technologies, National Biotechnology Advisory Committee, CBAC). to explore the complexities at the crossroads of patents and health, especially concerning health-related biotechnologies. However, making matters more complicated, IP is deeply integrated within the broader regulatory schemes of health care and biotechnology development, generating unique regulatory challenges for policymakers.[710] In *CHEO*, the plaintiffs sought to address some of the uncertainties about the legal status of claims on human genetic sequences[711] and to protect patient and clinical access. *CHEO* was the surgical strike in which Canada had an opportunity to decide what access to patented genetic tests should look like for Canadians.[712] According to informants in this study however, this is not an intersectoral issue that can be resolved entirely by settling the legal uncertainties. Around the world, governments have taken higher political or legislative action with respect to the proprietary science that emerges from biomedical research and biotechnology. Earlier in this work I cited the U.K example of Tony Blair advocating increased collaboration between research and industry to enhance health care, but other notable examples exist.[713] More recently, first in 2019 and again in 2022,[714] the U.S. Senate

Interests (Toronto: Toronto University Press, 2000) at 153; Doern B, Global Change and Intellectual Property Agencies. (London: Pinter, 1999) (discussing the Uruguay Round leading to WTO and TRIPS).

[710] For e.g., see Flood C, Hardcastle L, "The private sale of cancer drugs in Ontario's public hospitals: Tough issues at the public/private interface in health care" (2007) 1 McGill JL & Health 5. Also, Doern and Prince, *supra note* 46 at 58, 151.

[711] CHEO Statement of Claim, *supra note* 124.

[712] "U.S. gene patents: Patient care stymied in Canada, hospital claims," Health, CBC News online, 3 November 2014, online: <https://www.cbc.ca/news/health/u-s-gene-patents-patient-care-stymied-in-canada-hospital-claims-1.2820211> (accessed 6 July 2019).

[713] In the U.S., *Bayh-Dole Act*, *supra note* 179 and its establishing the Court of Appeals for the Federal Circuit (28 U.S.C. § 1295). In the European Union, see, for e.g., *EU Directive, supra note* **Error! Bookmark not defined.**. In Australia, consider, *Intellectual Property Laws Amendment (Raising the Bar) Act* No. 35, 2012.

[714] In 2019, the U.S. Senate Judiciary Committee reviewed a bipartisan bill to expand patent subject matter beyond the 2013 USSC *Myriad* ruling. See, Servick K, "Controversial U.S. bill would lift Supreme Court ban on patenting human genes," Science, 4 June 2019, online: <https://www.sciencemag.org/news/2019/06/controversial-us-bill-would-lift-supreme-court-ban-patenting-human-genes> (date accessed: 10 October 2019). On August 2022, Senator Thom Tillis (R-NC) introduced the Patent Eligibility Restoration Act of 2022. If enacted, the bill would reverse the USSC Myriad decision and the subsequent decade of legal developments. See: online: < https://www.ipwatchdog.com/wp-content/uploads/2022/08/Patent-Eligibility-Restoration-Act-One-Pager-

is poised to reconsider the USSC decision in *Myriad*, potentially impacting access to health care and, in reflection of the 2020 COVID pandemic, an ability to quickly respond to dangerous viral outbreaks.

In Canada, discussions about human gene patents have notably taken place among expert or independent policy working groups, sometimes commissioned by federal departments (namely Industry Canada and Health Canada) and other times within provincial strategic policy units such as by Ontario's Minister of Health, but have rarely occurred in the upper echelons of the political executive. At least since 1996, with the bulk of activity and reporting in the early- to mid-2000s, gene patents were raised within the agendas of several relevant federal government standing committees.[715] By law, new and inventive biological materials are patentable in Canada, with the CIPO practice manual confirming that "claims to nucleic acids, polypeptides, proteins and peptides are … directed to statutory matter."[716] The early contributions by intergovernmental deliberations failed to produce any formal or coherent policy development, nor were they enough to maintain the momentum by policymakers to adequately consider advances in the field of genetics and the health care sector by the time CHEO had challenged CIPO and industry practices. Beyond *CHEO*, other challenges do persist, including the coordination of adequate technology assessments of novel and repatriated tests[717] and the lack of expertise needed at the evidence-policy interface to interpret the clinical impact of patents on the tests. But as genetic testing becomes increasingly standardized in clinical practice and applied to various areas of R&D in the life sciences industry,

Final.pdf>, < https://www.ipwatchdog.com/wp-content/uploads/2022/08/Patent-Eligibility-Restoration-Act-One-Pager-Final.pdf>.

[715] Evidence reports from Health Canada and Industry Canada standing committees include discussions on or related to gene patents. Appendix D has a list of this.

[716] CIPO, Manual of Patent Office Practice, December 2015 update (Ottawa-Gatineau: Industry Canada, 1998) at chapter 17.02.04.

[717] See also, Ali Khan and Gold, *supra note* 122 at 1258.

failing to address the effect patents are having directly in these areas is unlikely to pave the best way forward.

One informant asserted that for ways forward, like the CHEO agreement, to be taken seriously, dedicated policies that help both orders of government to leverage their existing approaches to innovation — allocating funding into S&T research and patent policies that value private sector interests and freedoms — while also "making the call" to the federal government to help lead on ways forward are required (Drouillard, p. 37). When asked what it will take for this to happen, some informants said short of "interventionist government" (Hawkins, p. 44; Gold, p. 17), it will take a crisis (Gold, p. 14; Drouillard, p. 37). The COVID-19 pandemic is our most recent example of such a crisis; it has jeopardized social and economic systems, exposed public policy inequities, and has shown that even presumably unbiased, evidence-based, and technocratic areas of policy that we assume are structured to improve health and the economy, such as the patent system, can cause unintended issues of access to life-saving diagnostics and medicines where governments fail to be adequately proactive. A fuller consideration of the impact of patents in the early years of the pandemic is discussed in a subsequent chapter.

Tied up in broader economic and social issues and Canadian constitutional law, the human gene patent debate illustrates that decentralization in policymaking is difficult, despite attempts to navigate federal and provincial divisions in their authority over patents and health. Here, I identify several important "who's who" institutional policymaking actors from both levels of Canadian government who were at one time or another involved in the discussions and debates concerning human gene patents (see Appendix H). Actor network interests have been explored to better understand the purpose, goals and relations among several key actors or institutions in their

contributions at several key moments to policy discussions involving human gene patents. The idea of examining the Canadian gene patent dialogue in this way is to expose the extent to which access to gene-based patents for the purposes of health research and care is shaped by specific people and by specific institutions. See Appendix C for an outline of the stakeholder assemblages drawn upon in this study relating to the issue of access in the Canadian human gene patent debate.

Integral to my research question is "What is the tension?" that characterizes human gene patents as an intersectoral issue at the public-private divide of public health research and care. The work presented in this section sets out to advance the central argument of the thesis, namely that the tension at the public-private divide in the debate is in part due to a lack of leadership in looking beyond the patent system to identify forward-looking multidisciplinary solution options that may rely on aspects of the system, but should not solely be developed in response to satisfying its objectives alone. This section identifies key actor networks (institutions, individuals) who have contributed to the dialogue and debates regarding human gene-based patents in Canada's health research and care between the years of 1999–2019. In this section, greater focus has been given to the events around the provision and access to patented genetic tests that unfolded and the policy deliberations that occurred in response to those events.

4.3.1 Tension at the Patent and Health Policy Divide

In Canada, jurisdiction over patents and health is divided between the federal and provincial governments, as well as split among different departments within. At the federal level, two ministries divide stewardship of patents and health; Industry Canada is in charge of patent laws through its administration of the *Patent Act* and oversees industrial policy respecting biotechnology, Health Canada, on the other hand, is responsible for harmonizing national health

policy through its administration of the *Canada Health Act* and oversight of several public health agencies. The provinces independent from one another manage and pay for the public health care system through their health ministries, making Canada relatively less centralized than other federal-state programs;[718] Canada's health care has been described as a series of health insurance systems operating within broad federal parameters.[719]

Despite periods of intergovernmental cooperation having led to important policy decisions,[720] intergovernmental structures remain weak compared to the intensity of the divisions between government departments within and between various orders of government.[721] The gene patent debate in Canada is illustrative. Intergovernmental negotiations in the Canadian debate have often relied on a banding together of committees at the level of policy analysts and advisors, government officials and sometimes ministers. The provinces have a clear oversight role in ensuring equitable access to patented tests, much like what would be supported under the CHEO agreement. However, where patents factor into those threats, federal departments must recognize the need for coherence between IP and health policies to bring the agendas that facilitate health innovation and access to genetic health technologies into better alignment. The lack of leadership at either level of government on the genetics file has constrained a harmonization of IP and health agendas.

An effective patent system should be able to operate within the policy plans and regulations of other important areas of public policy. The *Patent Act* sets out to encourage the innovation of *any* and *all* technologies, including health care technologies, and through its disclosure conditionality,

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[718] Banting K, Corbett C, "Introduction" in, Banting K, Corbett C (eds.), *Health policy and federalism: A comparative perspective on multi-level governance* (Montreal: McGill-Queen's University Press, 2002) at 14.
[719] Maioni A, "Federalism and Health Care in Canada" in *id*.
[720] For e.g., the Social Union Framework Agreement was in response to tensions between provinces and the federal government following the 1995 budget cuts.
[721] For e.g., Banting and Corbett, *supra note* 718 at 16.

the patent system is believed to do just that. In Canada, however, the intersection of patents and health manifests as a combative relationship. When we look at patents as an intersectoral issue in health, the tension at the public-private divide has been characterized as normative, but I believe this characterization has been a disservice to the policy efforts Canada has made to address the problems with human gene-based health patents. As the number of gene-related patents continues to rise in the U.S.,[722] Canada has some hard decisions to make: hard because government must be more cooperative or maybe even interventionist to be more proactive. Even if disclosure in the life sciences and biotechnology sectors were enough to enable follow-on inventing and even if the lure of market exclusivity and augmented business strategy capacities were enough to incentivize private firms to innovate in those sectors, even if we can all agree we are okay with human genes being patentable inventions, the law can only take us so far.

The division of jurisdictional authority pertaining to IP and health agendas is a challenge for policymakers to navigate, but it is clear that short of national implementation of a coherent policy to govern Canadian human gene patents in health specifically, coordination across multiple government departments is key. Canadian law and policy scholars have long discussed the need for policy coherence to ensure informed and just decision-making when addressing issues that arise from the use of patents in the health sector. In the past, scholars have called for greater inter-ministerial coordination and permanency[723] and a transdisciplinary approach to analysis of the issues for a proactive role in public policy.[724] This study joins others that call for an open but deeper discussion and collaboration between key actors and institutions as an essential early step

[722] Abboy M, Liddell K, Liddicoat J et al., "*Myriad's* impact on gene patents" (2016) 34 Nat. Biotechnol. 1119.
[723] Bubela et al., *supra note* 647.
[724] For, e.g., Gold ER et al., "Needed: Models of biotechnology intellectual property" (2002) 20(8) Trends in Biotechnol. 327.

towards realizing the benefits of genetics medicine,[725] but also towards accommodating moments of extraordinary need to access medicine and care. While drafting this thesis, COVID-19 deepened global concerns over vaccine access and IP rights. Study informants echoed these worries, stressing the need for policymakers to address patent-related threats to medicine and health tech access, driven by the crisis's urgency. This study joins other Canadian studies that have called for optimizing the equity and efficiency of gene-based medicine and care through coordinated intra-provincial and intra-ministerial efforts.[726] This study joins their call for a coherent, collaborative national conversation.

4.3.2 A Wicked Issue

Followers of the gene patent debate over the decades in Canada have said that if the goal is to find an appropriate balance between the economic and health care objectives of gene-based innovation, then discussions of gene patents need to reach higher levels within and across governments.[727] Growing demands for health products and services spurred by S&T development are often joined by notions of a positive right to health in public health care systems, where expectations of government involvement in health care have strong connections to international instruments.[728] Similar calls for implementing various levers for existing policy structures have been made in Canada, such as a call from the genetics branch of Health Canada to adopt the 2006 OECD

[725] But see also, Adair A, Hyde-Lay R, Einsiedel E, et al., "Technology assessment and resource allocation for predictive genetic testing: A study of the perspectives of Canadian genetic health care providers" (2009) 10 BMC Med Ethics 6. And, Christian S, Blumenschein P, Lilley M, "An assessment of Canadian systems for triaging referred out genetic testing." (2015) 88 Clin Genet 90.
[726] Bubela et al., *supra note* 647. But see also, Adair A, Hyde-Lay R, Einsiedel E, et al., "Technology assessment and resource allocation for predictive genetic testing: A study of the perspectives of Canadian genetic health care providers" (2009) 10 BMC Med Ethics 6. And, Christian et al., *supra note* 725.
[727] Id., Bubela et al.
[728] *Id.* Also, see examples: UDHR, *supra note* 188. See also, ICESCR, *supra note* 188. And, Constitution of the WHO, stating "The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being …" (Off. Rec. WHO Org., 2, 100). For general discussion see, Kinney E, "The international human right to health: What does this mean for our nation and world?" (2001) 34 Ind. L. Rev. 1457, 1459.

licensing guidelines of genetic inventions by way of Canadian funding agencies (i.e., CIHR, NSERC) as part of their best practices mandates for research grant applications (Drouillard, p. 15). As a matter of law, SCC jurisprudence explains that timely access to health care is important for equitable access.[729]

Discussions between various governmental provincial and federal departments around gene patents have been contentious. As an intersectoral issue within the debate, IP in health has presented Canadian policymakers with a "wicked issue",[730] particularly in the public health care sector (Drouillard, p. 6). An informant who served on the CBAC noted that, deeper still, the clash of political will has been an issue. As put forth by the SCC in *Harvard* and supported by several informants in this study, questions regarding the patentability of human genes are not to be answered by the law alone, and political will is required. According to Naimark, what is required at this point in the debate is a matter of "political exigency" (p. 13) at the level of the Cabinet, but especially through "the big recognizer in government" of policy issues, namely the Prime Minister (Naimark, p. 17). Several informants insisted, as also discussed in the literature,[731] that policy traction of this kind around an issue like gene patents in health care, again, requires "interventionist government" (Hawkins, pp. 21, 44) but also "big political players" (Drouillard, p. 27) in order for governments to actively coordinate disparate needs and interests among the different stakeholders in the debate.

[729] See, *Chaoulli, supra note* 639. For general discussion of *Charter* cases on health care access, see Jackman, *supra note* 625.
[730] Petticrew et al., *supra note* 89.
[731] Bubela et al., *supra note* 647.

Inter-ministerial coordination may be difficult, but it is not impossible.[732] Internationally, some policy coherence efforts on patents have been considered successful, such as at the European level of policymaking[733] and in Switzerland in particular.[734] Canada has a federalist system to contend with, but the JAK2 case demonstrates the potential to achieve intergovernmental coordination to facilitate access to patented genetic tests in Canada. In this study, examining what tensions have defined the gene patent debate in Canada and why they persist has revealed fractured efforts and a gradual reluctance to commit to formal and forward-looking genetics policy development. The lack of a formal policy framework has contributed to an inability to systematically address problematic gene-based patents in health, and in a failure to progress in coherent policy development as needed during times of public health crises, as seen during the 2020 COVID-19 pandemic response to domestic vaccine availability. According to some informants, these problems in part stem from when or how patents are being used, but they have also raised questions about who is — and who is not — taking a leadership role in the development of human gene patent regulatory policy.

One informant has suggested that an underlying reason for these impasses is the continued "us versus them" perspective of the health care and industry relationship seen in Canada and more evident here than in any other OECD country (Gillespie, p. 14). Not only are problems concerning patents *per se* or evidence of aggressive licensing schemes visible, some claim that broader system failings are at work, such as a lack of provincial priority-setting agendas in response to growing

[732] For e.g., see *id* at 11 generally.
[733] Wiechoczek O, *The EU's Contribution to Global Governance: The Case of Global Infectious Diseases* (Bruges: College of Europe, 2006), 44.
[734] Gerhardsen T, "Swiss initiative seeks to dispel 'black-and-white' view of patents" Intellectual Property Watch (19 December 2006). Also, Kickbusch I et al., "Global health diplomacy: Training across disciplines" (2007) 85(12) Bulletin of the World Health Organization 971.

demands for tests (Informant 6, p. 17) or "careful" regulatory frameworks to leverage Canada's one-buyer model.[735] Reflecting on the lessons from Myriad for other firms looking to enforce their gene patents in Canada, one informant surmised:

> Chewing on them doesn't usually get you friends when you've got one buyer, and that's what Myriad learned, right? So Myriad, what it's doing now is trying to get contracts because it has facilities, and it may be able to provide these services at a lower cost and higher quality … That's where they should be competing, and Myriad is doing that … What they care about (now) are private companies that would sue the gene patent for drug development, for 23andMe type testing. (Gold, p. 12)

Patents are exacerbating these failings and can take advantage of vulnerabilities laid bare by inadequate priority-setting criteria, for instance, particularly if the province is unable or unwilling to fill in the gaps in testing service and technology left by public-provider cost constraints:

> Hospitals are stretching for every last dollar, so where patents, licensing and exclusivity really hurts is where it threatens something people are already doing [testing for a given condition] … If you don't have an opportunity to evolve into that something new because of a patent, or because someone got an exclusive contract, that's what threatens [provision]. (Informant 6, p. 14)

According to this informant, the impacts extend into a lower standard of care for patients due to restricted choices in test providers (Informant 6, p. 13), negative impacts on equitable access to care (Informant 6, p. 14), and a failure of the province to carry out its objectives to innovate in the sector as it plays it "safe", falling into complacency while "everyone passes you on innovating" (Informant 6, p. 12). Part of the challenge here emerges from what one informant describes as Canada's "jealously protected provincial model" of health care (Gillespie, p. 13) that operates in "silos" (Gillespie, p. 16). Once head of the OECD Science and Technology Policy Division, Gillespie went on to say that as a part of Canadian "identity", the operation of Canada's health care system within "silos" need not necessarily be a "fundamental problem of issue" (Gillespie, p. 13), particularly where options are available. Such options can include a greater role for

[735] Jamieson, *supra note* 617.

stakeholders, such as scientists, clinicians and innovators invested in genetics research, to determine ways in which they could communicate with one another through collaborative networks. Other solutions could include using institutional mechanisms, including licensing guidelines or patent pools, to alleviate some problems associated with gene patents if and when they arise. Another possible solution, as discussed at greater length elsewhere in this work, looks to engage state action.

Discussions around formulating joined-up or intersectoral regulatory governance for patented genetic health technologies in government have waned with each new controversy in Canada. Although the broader implications of the USCC decision over the BRCA patents remain uncertain,[736] notably for Canadian biotech but particularly for the U.S. following the *Prometheus* decision, some commentators suggest that the fallout expected in the wake of the U.S. biotech patent cases could be insignificant with respect to R&D in the sector more broadly (Informant 18, p. 19).[737] This is in part because, at least with respect to the BRCA patents, it was the legal arguments relating to the patentable scope of human genetic sequences as patentable subject matter that made the biggest impact on these areas, and that it is time to focus on the social policies around the patent system rather than the patents themselves:

> If you're talking about policy energy and where we should be focusing our attention … the attention should be around the patenting process. It should be on the social policies that surround that. Because if, let's say, we're going to fix this problem by saying that you can't patent genes, but if the problem really is the commercialization pressure, you end up with all the same bad outcomes you're trying to avoid. You end up with secrecy, you end up with inappropriate competition … so, from a policy perspective, your focus needs to be somewhere else. (Informant 18, pp. 9–10)

[736] See, for e.g., Cartwright-Smith L, "Patenting genes: What does Association for Molec. Pathology v. Myriad Genetics mean for genetic testing and research?" (2014) 129(3) Public Health Rep. 289. See also, Graff GD et al., "Not quite a myriad of gene patents" (2013) 31 Nat. Biotechnol. 404. And, Schwartz and Minssen, *supra note* 199.
[737] Wales M, Cartier E, "The impact of *Myriad* on the future development and commercialization of DNA-based therapies and diagnostics" (2015) 5(12) Cold Spring Harbour Perspective Med. 1.

4.4 THE WHY

4.4.1 "Us versus Them" at the Public and Private Divide

During the Myriad controversy, the Ontario health ministry together with then MED understood patents on genes and genetic tests as a threat to the provincial delivery of health care (Mantel, p. 3). At the federal level, not only was the approach to this threat distinct from provincial counterparts (i.e., federal authorities adopted a 'wait-and-see' approach), but there were motivations behind this approach, too. According to some informants, notably from Health Canada, issues that surfaced in the debate were indeed a product of political will whereby policy analysts seemed to have been grappling with determining the appropriate ideological balance provided by the *Patent Act* in the case of human gene-based invention used in health care (Drouillard, p. 5). As explained by one informant:

> Drafters of the *Patent Act* had a principles-based approach … As a government, as a policymaker, if you're writing legislation that is very specific to current technology, then you're quickly out of date. And that's not what the *Patent Act* is about (p. 3) … The whole idea about the *Patent Act* is a question of balance, it contains … checks and balances to protect IP of innovators while guaranteeing access. (Informant 10, p. 9)

To elaborate further on getting this balance right, this informant drew on conversations Industry Canada had with the MOH about the province's concerns around access to genetic tests at the time of Myriad, saying:

> People will work to sway things to their side. A public hospital with limited funds on one hand, wants private to do research to find new applications, drugs, therapies, but if they don't have to pay full price for it, why not? It's really about managing that tension between you want to provide just enough incentive for private sector to develop the therapy, but not a penny more, and that's a tough thing to get right for every product. (Informant 10, p. 10)

Industry Canada's approach to the gene patent debate was that health care needs the patent system for innovation in that space to happen at all (Informant 10, p. 6). However, should a patent holder withhold a patent or license on unreasonable terms, public providers or the Ontario health ministry

could rely on the compulsory licensing provisions through the *Patent Act* (Informant 10, p. 4). According to this informant, Ontario was not interested in leveraging mechanisms available under existing patent law:

> There's a compulsory licensing regime that exists, all you have to do is file an application to the Commissioner of Patents … But if there's a mechanism in place that exists to redress the very issue you're trying to address but you've refused to use it, on grounds that it's never been used before? I had very little patience for that, and nor did anyone else here. (Informant 10, p. 4)

The "mechanism" this informant is referring to is compulsory licensing. Decisions made with respect to compulsory licensing provisions under the *Patent Act* regarding biomedical products or services concern Industry Canada (responsible for the *Act*), Health Canada (likely to request compulsory licensing) and CIPO (who grants the license). Under normal circumstances, the federal or provincial government must first attempt to secure authorization from the patent holder for access to their invention before the Commissioner of Patents will consider an application. Under usual circumstances, Canadian law permits the federal government to issue a compulsory license, but the government must negotiate terms of compensation with the individual patent owner (usually a private manufacturer). Notably, a Canadian bill was passed by lawmakers to speed up the process to issue a compulsory license for medical products during the 2020 COVID-19 pandemic.[738] However, no Canadian government has exercised this right under usual circumstances, nor in circumstances that may be considered a public health crisis as enshrined in international trade agreements. There are also no sustained deliberations maintained between

[738] Bill C-13, *An Act respecting certain measures in response to COVID-19*, House of Commons of Canada, First Sess., Forty-third Parliament, 68–69 Elizabeth II, 2019–2020, online <https://www.parl.ca/DocumentViewer/en/43-1/bill/C-13/third-reading>.

government departments about when or how to use compulsory licensing, regardless of normal or crisis times.[739]

Speaking of the tensions carried throughout the gene patent discussion, one federal government informant characterized discussions with Ontario as emerging from "acrimonious reasons" for the talks (Informant 10, p. 6) and that the discussions were the "most acrimonious" they had ever participated in on a file (Informant 10, p. 7):

> I never heard a really good counter-argument like "Well, public sector, maybe should be conducting this R&D" or "We should push for universities to do this R&D." There was never that, to my recollection. We didn't see eye to eye on this stuff … People don't fundamentally understand the *Patent Act*. (Informant 10, pp. 6, 7)

The tension during these consultations was also felt by Industry Canada's cohorts in Health Canada's genetics unit. Part of the consultations focused on questions proposed by the CBAC regarding how to ensure access to patented genes and genetic tests for Canadians. One of the key consultations was about patent system reform. One informant described the tensions that defined the talks as consisting of one side being taken by Ontario and Health Canada and the other side being occupied by Industry Canada (Hutchinson, p. 3). Another informant at Health Canada said:

> I can attest to the fact that while the environment was always collegial, it was fairly clear that there were two sides. There were definitely two sides. No questions. (Drouillard, p. 5)

Saying further:

> Funny direct quote. We were talking about what did the (kind of) different sides of (sort of) Health Canada versus Industry Canada, what did that look like? I remember walking out of one of the CBAC consultations with my colleague from Industry Canada, and you know, we were hearing all sorts of testimony from different people around the subject. And as we were walking to coffee, she said to me "I don't care what they say about any of this stuff, so long as they don't touch *my Act*." So, the issue is 'We might want, there might be a problem here, and there might be fixes, but stay away from the *Patent Act*'. That was essentially the directive. (Drouillard, p. 5, *emphasis added by informant*)

[739] Bubela et al., *supra note* 647 at 22.

The decentralization of policy development capacity in both federal departments likely contributed to the loss of policy coherence on the gene patent file, but here, it also created limitations for inter-ministerial and intergovernmental collaboration, flaring tensions between the policy units involved (Drouillard, pp. 6, 7). The loss of policy development capacity on the file is a real issue, Drouillard notes:

> If the same teams of people continued to work on this stuff within Health Canada and Industry Canada in the same collaborative way—if even sometimes adversarial, we still had very close — we all knew each other, we knew all of each other's positions on everything, right? If that simple policy capacity in both departments had continued on, there would've been a greater chance that on a federal level we would've continued to do some oversight of the application of those [OECD] guidelines. (Drouillard, p. 14)

Informants involved in these consultations said that tensions between patent and health policy units could be largely attributed to the divergent mandate-driven positions expressed by discussants, which left them feeling that their hands were tied on finding a shared solution. As one informant put it:

> It was a huge game of inter-departmental cooperation, and that was very hard won … It's just that working across departments and agencies, you always need a champion, right? It doesn't happen naturally … On the gene patenting file, in light of all the jurisdictional issues on the human genetic file, generally for anything to have any runway, you need champions across all of the different agencies. (Drouillard, p. 19)

Put differently by another informant:

> I think there was a lot of heat, but not a lot of fire. Yes, people did talk about it a lot, but at the end of the day, it was just a charged issue to get into that. So, people in the patent law community, it was being said that you need to follow 'Harvard Mouse',[740] explicitly provide for patenting of higher life forms. But then, you're an elected official looking at it, and you say, "This is a loser." There are no winners on this file. (Informant 10, p. 5)

[740] *Harvard, supra note* 35.

There was clearly a need for greater coordinated efforts between the province and the federal government (Drouillard, p. 14), and the failure of these efforts has been a lasting legacy of the human gene patent debate in Canada.

4.4.2 A Health Lens Focus: Efforts of Health-Policy-In-All-Policies Approach

The use of patents to flag commercially viable pursuits in S&T research was identified as a concern by several informants because used in this way, patents are ultimately problematic for progress in any given field:

> If multiple companies hold multiple patents on different genes that are necessary to do a research project, being able to do that research becomes difficult because you have to negotiate patent rights with a number of companies, and they may not all agree, so you can have research which can't move forward. (Lexchin, p. 5)

Public-private partnerships do not correct this unintended consequence, with at least one informant claiming that upwards of at least 50 per cent of what industry has claimed as its R&D partnership investments is actually targeted to marketing (Hawkins, p. 45). Also, despite initial increases in R&D spending following changes to Canadian patent law in 1984, investments have been steadily declining since (Lexchin, p. 16), and the concern is that patents are wasting public-dollar investment as they interfere with the development of some of the most publicly-needed health care products (Lexchin, p. 6).

The received wisdom is that patents are used to make a new technology public, and in this process of going public, inventions can have a long way to go before becoming socially useful, since innovation is a "process of everyone having to adapt to it, having to adopt it, having to figure out how it works, how it fits into existing ecosystems of technology and practice" (Hawkins, p. 12). However, according to some informants and as discussed in Chapter 2, patents are increasingly being used for private-driven purposes, and this is happening in two distinct ways. The first is that

patents are used to define ownership (i.e., who owns what and how much over whom), although not necessarily inventiveness (Hawkins, p. 27).[741] The other dominant role of patents is their use, as with other IP rights, as business strategy tools (Hawkins, p. 32). As such, patents have defined new ways in which information is shared, and through these ways, they are re-shaping the knowledge-based economy; "now just being used as poker chips in a giant financial game" by private firms (Hawkins, p. 40) and being used by regulators and research institutes to structure economic and commercial agendas for new technologies.[742] How patents are being used and by whom for what purpose has made the art of innovating anything but easy because "patents used intelligently and effectively can actually stimulate the [innovation] process and not retard it, but it's just getting so complicated" (Hawkins, p. 41).

Just how complicated was something some provinces were forced to contend with from the earliest days of the gene patent debate in Canada. Ontario's MED had quickly recognized Myriad's BRCA patents as an intersectoral issue, with linkages to health care as well as economic development for the province, where the "biotech wave became the innovation wave became the start-up wave" advancement through academic and industry partnerships and organization developments in S&T (Mantel, p. 11). The MED was consulted in the policy discussions surrounding Myriad's BRCA patents and in relation to the provincial response to the 'cease and desist' order on their use. During that time, the Ontario health ministry together with MED understood patents on genes and genetic tests as a threat to the provincial delivery of health care (Mantel, p. 3). Also at that time, the MED was already being "heavily hammered" by "big pharma" with respect to patent policy and patent restoration in response to industry's dissatisfaction with Health Canada's regulatory process and

[741] Also see, Phillips, *supra note* 338 at 205.
[742] *Id.*

the time it took for manufacturers to get their products and services onto the provincial formulary (Mantel, p. 1). In addition to their concerns regarding health care delivery, the MED also worried about the economic impacts on the province of Myriad enforcing their patents (Mantel, p. 1) and had "always advocated balance" between the province's economic and health agendas (Mantel, p. 6). Reflecting on the controversy at that time over the patents, Mantel recalled the tensions that flared from what seemed to be a hostile takeover effort by an American firm of the test provision landscape in the province:

> There were a lot of issues around genetic technologies and their benefits. The problem was as much on the side [of] access as it was on the side of economic development. Bottom line — Myriad Genetics … going to tell us that we can't treat our patients properly because you figured out, first ones to patent … We've been using this (test) for a long time …. They never came after us for it. Why? Because if they did, it's quite likely that Ontario would have challenged gene patentability as patentable subject matter. (Mantel, p. 5)

From this vantage point, MED set out to look at a related but somewhat separate response to address concerns about patents in health care, through an economic policy lens, but one in which the MED had been "trying to get economic policy to have an impact on health and on access policy in health" (Mantel, p. 3). Recognizing the inevitable impacts of economic policy on health care and how such impacts stand to shape the trajectory of biomedical innovation in the province and Canada-wide, in part, the idea behind the MED response was to bridge persistent gaps around data and political will between the ostensibly separate policy frameworks enabling innovation and better health care (Mantel, p. 3). This "health-policy-in-all-policies" approach is in accordance with a focus on health and equity, whereby policymakers across different sectors work to improve the overall well-being of individuals and communities.[743] With this focus, policymakers pay greater attention to health impacts as they consider options and form policies in other important

[743] Tonelli M, Tang KC, Forest PG, "Canada needs a 'Health in All Policies' action plan now" (2020) 192(3) CMAJ E61.

intersecting areas of public policy.[744] The challenges MED faced in its effort to consider economic policies through a health lens — how economic policies would effect upstream drivers of health and social conditions — can be better understood through the recent work by public health and policy scholars looking into government interventions to boost social equity and health in Canada. Notably, challenges of data inadequacies and political will that have plagued regulatory policy development relating to human gene patents are similar to those faced by advocates seeking to drive systemic changes supported by a health-policy-in-all-policies approach to minimize health-related and social harms.[745]

By the time Myriad became a concern in Ontario, MED had set into motion a proposal about how to better align the objectives of economic and health policy for a positive outcome on access policy in health (Mantel, p. 3). According to Mantel, the purpose was to open up discussions about how economic policy (i.e., as a supply-side policy to increase production by R&D intensive industry) could be put to better use for the purposes of fulfilling health policy objectives related to improving access to new emerging health care-related products or services while keeping investor returns in biomedicine and biotechnology a priority. In the early 2000s, MED had successfully got "industry in the room … to have negotiation discussions" with respect to details of the proposal, but the controversy with Myriad put an end to talks (Mantel, p. 3). Discussions about how to adopt new genetic health technologies did nothing to shrink the gap between health and economic policy. The province could not get an "honest view of tech value" on genetic tests, and unlike drugs, seen in some ways as an easy, cost-effective part of health care delivery, in part, because drugs could work at keeping the number of people entering the provincial health care system for additional and often

[744] Rigby and Hatch, *supra note* 99.
[745] See, e.g., Tonelli et al., *supra note* 743 at 4.

costly treatments. Thus, genetic health technologies were beginning to be understood as cost drivers, given their need for broad systemic implementation (Mantel, p. 8). The alliance between health care and industry for the purposes of biomedical innovation was seen as adversarial, an 'us-versus-them' relationship because "economic policy will never trump health policy" (Mantel, p. 3) and "that was always it: access versus spurring innovation" (Mantel, p. 7).

4.4.3 Complacency at the Public and Private Divide

Throughout its discussions relating to gene patents, federal response from Industry Canada has been consistent, as has — to the dismay of some long-time contributors to these discussions — the response from Health Canada. The role of Health Canada was made clear from its 'early days' involvement, and it led to its work with the OECD to develop a user guide on how to license access to genetic inventions (Drouillard, p. 20). Having taken over the genetic patents agenda by 2003, it was Health Canada that took the lead on Canada's main effort at the OECD, and this was the only reason why the international body became part of the Canadian narrative on gene patents (Gold, p. 7). This was a different role for Health Canada from its role in discussions with Industry Canada regarding gene patents, where the department had an understanding that it would not be free to take the lead on the development of regulatory policy concerning human gene-based patents. The resultant licensing agreement from *CHEO* was an opportunity — at least in part — to change this situation by offering Health Canada a chance to augment its governing capacity on genetic-related health care. According to one informant, however, not much has changed, and Health Canada made a choice to not seize these opportunities:

> Industry Canada has been somewhat consistent. They believe in the patent system. Their job is … to help those firms who rely on patents to get patents and to do it. So, they're not going to come out and say: "Let's put limitations on patents." If it doesn't come from Health Canada, it ain't going to be there. And that's consistent, right? If you go back to 2000/2001, [Industry Canada] were not that willing to push against Myriad, and so they've

> been consistent. But, Health Canada deciding to take a back seat is a decision Health Canada took. (Gold, p. 8)

There was also some expression of disappointment in the *CHEO* settlement by Health Canada (Informant 12, p. 8). Another informant reflected on this with mirrored disappointment:

> We gave them a silver platter with a policy solution that fit with both Health Canada's needs and Industry Canada's needs, and they [Health Canada] were mad at us for not doing their job is essentially what they're complaining about, right? They wanted this answer without getting their hands dirty. What we gave them was a policy solution that was much more subtle than they ever would've gotten from a court, much better for them. (Gold, p. 8)

According to Gold, when CHEO launched its lawsuit in 2014, institutionally, governments did not have a policy in place with respect to how to address access to high-demand, patented genetic tests, nor were they yet prepared to take a clear side on the issue because governments still harboured views that 'helping health' conflicted with 'helping industry' (Gold, p. 5). The response by Health Canada and Industry Canada was to do nothing, despite provisions by *CHEO* of a step-by-step guide on how to proceed with the CHEO agreement as a health policy solution (Gold, p. 31) and how to evoke compulsory licensing measures only if necessary through *section 19* of the *Patent Act* (Gold, p. 7). When CHEO sought support from Health Canada directly, the department was "silent," "completely unhelpful," despite "even getting the benefits of the settlement, they've been useless" (Gold, p. 6). CHEO had maintained "constant contact" with the minister's office at Health Canada, but:

> You know, Health Canada just wasn't interested. So, they can complain all they want, but it's because someone else didn't want to solve their problem for them … What more do you need? I mean, if Industry Canada can worry about the industrial consequences on Canadian biotech … But if what you care about is the delivery of health services, the agreement CHEO came up with didn't depend on changes in patent law. That's what was beautiful about it. It didn't require litigation. It was a clear pathway forward. That they didn't do anything about it was, frankly, their own fault. (Gold, pp. 10–11)

Other federal departments, which were "completely in power" (Gold, p. 8) to develop policy to govern Canadian human gene patents, also chose not to take up implementation of the agreement into a formal regulatory framework:

> It wasn't like we hadn't talked to people [at Health Canada]. They had advised the minister's office before it was launched. I mean, Health Canada could've come out at the launch and said something. They could've found other ways to support it. Industry Canada could've done the same. The patent office could've done something. But none of them were interested … because it's easier to do nothing. (Gold, p. 7)

With the delivery of health care under the stewardship of the provinces, Gold said they had also approached Ontario with the agreement. The request to the Commissioner of Patents for a compulsory license under the CHEO agreement can only be made by a minister, at either level of government, so any viable prospect of access would require explicit government intervention (Gold, p. 20). Except complacency also settled in at the provincial level:

> At the province level, too, they didn't do anything … We gave the provincial governments a way to say "Okay, if there's a gene patent that causes trouble, we have a solution." So, the access that a federal minister or provincial minister can seek a compulsory license …And what we went to was the federal government and the provincial government, and said "We think you should develop a policy about how you're going to this" … and nobody did anything, crickets. (Gold, p. 11)

No order of Canadian government has expressed a desire to engage in policy development and both provincial and federal divisions have, on the whole, "walked away" from doing so (Gold, p. 33). According to Gold, the failure of policymakers to develop policy on the lessons from previous gene patent challenges in Canada forced CHEO to turn to the courts, though "we all recognize that the courts are the least best option other than doing nothing" (Gold, p. 25).

When asked what has been the most shocking moment throughout his entire experience in the patent debate, which has spanned about two decades, Gold responded, "I thought that having facts would matter" (Gold, p. 33). Gold said that it is hard to determine where policy is currently being

made in government, and this may be symptomatic of how Canadian governments now operate, saying:

> If you blow away your policy units, you're not in a position to be pro-active … Then there was nobody left, and everyone is pointing that it should be them. Health Canada is pointing to Industry Canada and Industry Canada says "Its health issues and access, that's Health Canada, not ours". Patent office says "We just issue patents." So, it's pointing fingers, and no one wants to take responsibility. (Gold, p. 26)

Both federal and provincial governments were also provided with a regulatory framework accompanying the CHEO agreement to offer guidance on its utility. With respect to these efforts with the provinces, Gold said:

> We even wrote this out, 'what you need to do is to develop a policy that says 'if the hospital is threatened with a suit, we will then ask the company to sign this agreement. If they refuse we would then go to *section 19* of the *Patent Act* and ask the Commissioner of Patents to issue it' … So we told them how to do it. That's what you have to do as a province. (Gold, p. 14)

With respect to federal government policy development, Gold continued:

> You need, as Health Canada, you need to backstop that, and help the provinces develop these policies. And as Industry Canada, you need to come up with a process within the patent office about how you make this request. You don't even have to make any policy decision other than 'here is a clear process' … All we were saying is 'lay out a process'. We said 'Here's a starting point.' Crickets … If nobody wants to do it, I would imagine it will come up again when there's another crisis … Will it be in a different domain? Because this [CHEO agreement] is not restricted to gene patents, that's the beauty of this, right? It's anything similar. This is a policy instrument waiting to go. (Gold, pp. 14–15)

For Gold, the impact of government inaction on the gene patent issue will likely have broader implications in Canada beyond the expressed challenges of gene patents as they relate to S&T development and public health. Gold believes unresolved issues with patented gene-based patents in health will also mean unfavourable outcomes for national innovation and the economy because it means that "we're wasting money and potentially not encouraging firms who could've developed here" (Gold, p. 30):

> We [Canada] want an innovation economy. We talk about that, but are we actually willing to bring in the policy that makes it happen? No. (Gold, p. 30)

For now, the Canadian debate on patented human genes has settled well into complacency which has, for better or worse, exposed vulnerabilities in governance capabilities at the intersection of patents and health.

4.4.4 Hands Tied at the Public-Private Divide

The Canadian example of the gene patent controversy illustrates, from one perspective, how privileging private interests and IP rules over publicly-supported health has led to unintended consequences of limiting the responses of policymakers to concerns around access to patented invention. According to an informant who served as a policy advisor on the now disbanded Canadian Biotechnology Secretariat (CBS), a support team for various federal-level committees, including the CBAC and the Biotechnology Ministerial Coordinating Committee (BMCC), policymakers being bound to the political mandates of their departments meant that "things that don't fit into a single political mandate don't tend to happen" (Informant 13, p. 13). Here, the informant reflected on the BMCC in particular, and the lack of policy alignment among contributors on the topic of gene patents as it pertained to patented gene-based materials and technologies specifically, but also more broadly, to the patenting of higher life forms. The BMCC comprised a group of deputy ministers with significant biotechnology-related mandates from seven departments, including Health Canada and Industry Canada, meaning any recommendation adopted by the committee would make its way to the ministerial level of those departments.

According to this informant, none of the recommendations from the gene patent file put forth by the CBS went far up the ministerial chain because to have been adopted by the BMCC, all of its sitting members had to agree to them, and that failed to happen. The likelihood of unanimous

ministerial support on the file was tenuous at best, according to the informant, because "you have Industry and Health Canada on the same committee — don't hold your breathe" (Informant 13, p. 17). Also at that time, CBS was helping the CBAC put together its 2002 report on patenting higher life forms. In that report, the CBAC recommended that higher life forms that meet the statutory requirements of patentable subject matter be recognized as patentable.[746] According to this informant, the "CBAC recommended that higher life forms be patentable because we were told that's what had to be recommended" — namely, it was a directive that came from the Deputy Minister of Industry (Informant 13, p. 18). In *Harvard*, the SCC ruled that higher life forms fail to meet the statutory requirements of patentability, although, notably, CBAC's 2002 report was cited extensively by both the majority and the minority.

When the gene patent issue resurfaced in *CHEO* and despite communication by the clinical genetics community that patents were interfering with access to genetic tests, Health Canada approached the issue as it had over a decade earlier with respect to the BRCA patents. According to a Canadian government informant, the gene patent file was handed to Health Canada primarily as a bioethics issue, with a continued "real emphasis" on the patentability status of a human gene (Informant 12, p. 19). Because the focus was on the status of patents themselves, Health Canada presumed that any consideration beyond the moral issue of human gene patenting rested with Industry Canada (Informant 12, p. 3), further entrenching the patent-centric paradigm of the gene patent discussions in Canada, as it was "definitely seen as a patenting issue" (Informant 12, pp. 5, 29). Explaining how Health Canada saw its role in the gene patent narrative at the time of *CHEO*:

> The actual government policy on the patenting of human genes is the responsibility of Industry Canada and the patent office. Health Canada's role in that policy was to provide information or critique of actual policy … So, Health Canada was never lead on the file, let's put it that way. It was always led by Industry Canada. We didn't have a way at Health

[746] CBAC 2002, *supra note*, 79 at x.

> Canada to say yea or nay on the policy per se. That still exists today (p. 5) … but its impact is on health, so that's why we were involved. (Informant 12, p. 29)

This informant expressed disappointment in the *CHEO* settlement insofar as the opportunity for the case to go before the courts to rule on the status of the patents on genes themselves was lost (Informant 12, p. 8). Health Canada expressed its support to CHEO and for what the department could do as far as its discussions with Industry Canada were concerned (Informant 12, pp. 16–17), however, Health Canada was "only involved in persuading them because the Minister of Health does not have authority over the [*Patent*] *Act*" (Informant 12, p. 29). In relation to the policy concerns raised and the result in *CHEO*, Health Canada had primarily pursued talks with the Patent Policy Directorate about changing patent law, maintaining a line of communication with the Minister of Industry consistent with requests for a ban on gene patents was a reasonable way to deal with the gene patent problem in health (Informant 12, p. 17). Industry Canada took a "wait it out" approach that became a "We have a settlement [in *CHEO*], so we don't need to worry about the issue" final response (Informant 12, p. 17):

> People at Industry Canada, that's what they said — "Let's see this go to courts. They tell us to change our rules, then we will." It didn't happen. Then the outcome is a health care agreement, but it's basically an agreement on patents. (Informant 12, p. 30)

During the *CHEO* proceedings, Health Canada did not re-establish communication with the MOH as the department had previously done during Myriad, although CHEO did put in a request for that to happen:

> Their requests of Health Canada was asking if Health Canada could take some leadership and bring the provinces together on implementing this particular agreement, and maybe using it as a model for other agreements … More or less [Health Canada] … did not see this as a top priority for the department … [it] felt it to be more of a provincial jurisdiction … [Health Canada spoke] with individuals from the academic health care organization HealthCareCAN.[747] (Informant 12, p. 32)

[747] I reached out to HealthCareCAN about patient access to patented genetic testing and their response to Health Canda's information post-*CHEO*, but I did not get an interview.

Health Canada's "hands are going to be tied" beyond fulfilling its regulator role in declaring a patented gene-based product or service safe and efficacious, concluding:

> It's up to the provinces and territories if they have the capacity to legislate on these products … We're not going to have mechanisms in place to deal with concerns about genetic health technologies. (Informant 12, p. 13)

Brought to light in this study, particularly by way of the *CHEO* settlement, this is not entirely true (Gold, p. 7). Even over a decade earlier with Myriad's BRCA patents, in its authority to oversee national health policy development, Health Canada understood that it had an opportunity to develop forward-looking policy on the intersectoral issue of patents in health. There was, however, little reason for Health Canada to believe that its discussions with Industry Canada would result in coherent policy given the sustained contrary views expressed and the fact that there was "no real voice for the health implications of the *Patent Act*" relating to patents (Drouillard, p. 21). Discussions with Industry Canada informed Health Canada that the attitude in the debate was one of "Yeah, that's the *Patent Act*, deal with it" (Drouillard, p. 21). Following silence from Parliament in response to *Harvard*, Health Canada believed that it had reached an impasse with Industry Canada, both departments agreeing that the gene patent problem was not something that could be solved domestically (Drouillard, pp. 6, 7). Health Canada sought to work with the OECD because it "levelled the playing field and gave a voice to health policymakers in this debate" while back in Canada, it was being told "We [at Health Canada] don't have anything to do with the *Patent Act*, go deal with your own problems" (Drouillard, p. 20). By that time:

> There was a decision made that we'd reached a dead end in terms of gene patenting in Canada anyways … a stalemate … And at the same time, we had this decision to put gene patenting into a larger context — personalized medicine … to get into the issue of pharmacogenomics. (Informant 12, pp. 23–24)

Moreover, because Health Canada has no responsibility for "the patent system or the health system or health research" to create policy directives on matters over which it has no legal mandate to

satisfy, as a federal department, it has a "little tiny window of opportunity" to drive policy development on something such as gene patenting (Drouillard, p. 6). With the OECD, Health Canada's efforts led to a prescriptive policy framework with respect to how to address issues of access to patented genetic health inventions. Notably, the bulk of this framework was formulated to seek solutions through the patent system, with policy options and recommendations put forth to Industry Canada for exceptions to existing IP rules or reform of the system (Drouillard, p. 12). Despite this clear attentiveness to the patent narrative, in order to move efforts forward on the file, Health Canada held low expectations for the formal uptake of their recommendations:

> Industry Canada was so very strong that their core stakeholders both within the pharma industry, the biotech industry were so fundamentally against any shift. (Drouillard, p. 13)

Moreover, unlike investments into research in the natural sciences, viewed by the federal government as investments into innovation and job creation, research in the area of health has limited to no inclusion in federal innovation mandates (Drouillard, pp. 17, 18). This has meant lost opportunities for leveraging the significant government funding available upstream to support innovation and commercialization processes in biomedical research, as federal government devotes little attention to how that research can inform downstream development of health and innovation policies (Drouillard, p. 17). The impasse between Health Canada and Industry Canada was understood by Health Canada as an indication that, at least at the federal level, with respect to human gene-based patents, "there was not going to be a legislative regulatory response to this question" (Drouillard, p. 26). The lack of uptake of the resultant public use agreement from *CHEO* by any one federal department was, therefore, not at all surprising (Drouillard, p. 28).

According to Drouillard, if Ontario lacks the "tools" or policy "levers" to navigate the gene patent issue through health policy frameworks as it did during Myriad, then the province remains limited

in its oversight response (Drouillard, pp. 21–22). For Drouillard, the response by Health Canada to *CHEO* suggests that the provinces still lack these tools; in speaking with Gold in the wake of *CHEO*, we have a better understanding of some of the reasons why. Expecting changes to take shape by reframing the debate through a health lens analytical approach was certainly a "Hail Mary" approach (Drouillard, p. 22). According to Drouillard (p. 37) and Gold (p. 14), in a post-*CHEO* Canada, the initial push on formal policy development around patented genetic materials and technologies—particularly for the purposes of health care—has to come from provincial leadership, with a backstop provided by the federal government. According to Drouillard:

> I would say that the provincial government does have a bigger role to play than they've been able to manifest in the past. Provincial government has a bigger role to play because they're responsible for both health care and research … So, there's always an intent in doing it, but the feds in the Canadian constitutional context really couldn't do it … But on the provincial level, we have a single-payer system for health care, and we're making all this investment in research. Let's make sure one of these is feeding the other … and then, with regard to health policy, feds have to lead as they did in this instance where there is a genuine provincial interest in their being federal policy action. They have to respond to the call. (Drouillard, p. 37)

Presently, Health Canada is joining the open science movement under its science policy agenda as a way through which the federal government can encourage a more harmonized approach to access in health research for the benefit of patient care across Canada (Informant 12, p. 10). Although with little having changed post-Myriad and post-*CHEO*, at least one informant expressed little hope for Health Canada's contribution (Drouillard, p. 30). Like other informants, Drouillard believes that short of active government intervention, especially from the provinces, an outside influence is needed, and it might just need to be a crisis (Drouillard, p. 37).

5 CONCLUSIONS AND WAYS FORWARD

The 2013 USSC decision in *Myriad* declared isolated genetic sequences to be "products of nature" and thereby ineligible as patentable subject matter. In 2015, the Australian High Court essentially followed suit in *D'Arcy* by invalidating the Australian BRCA sequence claims as those that were invalidated by the USSC in *Myriad*. In contrast, the European Union provides relatively broad patent protection over naturally-occurring genetic sequences, whether of human origin or otherwise, so long as the utility of the sequence is disclosed in close review of the other patent eligibility requirements. At present, since 1998, the controlling legislation for biotechnological invention in Europe is under the European Biotechnology *Directive*. This is, in part, a result of the arguments that came before the USSC in *Myriad*. In Canada, 2016 saw a Federal Court challenge mounted by an Ontario hospital against the validity of patents on human genetic sequences and tests that legally bar access to life-saving technology unless permitted by the patent holder. The results in these cases carry significant implications for new genetic health technologies that rely on natural phenomena that use known, broadly understood techniques. These decisions have also raised various degrees of legal uncertainty about what types of gene-based subject matter are patent eligible, and more broadly, so too have they opened the door to an unclarity over how the law and policymakers are to treat genes and related subject matter across countries, including in Canada.

Myriad and *D'Arcy* have also created practical uncertainties in the research and health care sectors. The rulings have generated uncertainty around the generation of new ideas and around access to and availability of products and services. For the biotechnology industry, the result can be lost opportunities to de-risk innovation through secured investments or cost-sharing, to obtain optimal leverage of their IP, and to establish meaningful collaborative partnerships. This way of doing

business in biotechnology brought dramatic changes to the ways in which scientific innovation, government activity, and patient care were conducted where biotechnology products would be concerned. Much of that change was based on a central principle of Canadian innovation policy that patents drive innovation. Those recognizing the problem with that tenet identify the barriers to change as a patent-centric, patent-or-bust *status quo* approach to innovation and a collective lack of leadership. The 2020 COVID-19 crisis is the most recent example of this.

Genetic information brings legal, social and ethical issues around its use and around the appropriate conduct of research and health care, issues that must be addressed as they arise. These issues open up legal and policy dilemmas that require consideration and decisions that must be made based on shared social values in the broader context of the human gene patent debate. The use of genetic information also raises issues that extend beyond provincial/territorial purview, to areas of federal commitment. This study does not address the particular ways in which genetic information can impact communities in terms of potential discrimination and stigmatization. Instead, this study considers the importance of having access to and availability of genetic information and health technologies and investigates how such access has or has not occurred in a specific and fast-changing research and commercial context.

It may be legally difficult to distinguish patents on isolated genetic sequences from existing patents on chemical compounds, but gene patents – human gene patents especially - raise more fundamental questions about our patent system and the progression of science and the provision of health care. When scientists discovered the correlation between a mutated gene and an increased likelihood of onset of cancer, the discovery led to the creation of a diagnostic test available to patients to identify their individual risk. The way in which the patent holder of the BRCA genes

decided to use these patents led to a series of challenges, with most of the controversy surrounding what is commonly referred to as a "gene patent" involving claims on compositions of matter, rather than their use in therapeutics or genomic sequencing. Proponents support patents on human genes for the rehearsed reasoning that patents are necessary for innovation, and without them, society would be the poorer in health and economic stability. Critics looking at the effects of patents on availability of and access to that innovation claim that gene patents harm more than help, noting that a monopoly on a genetic sequence places limits on scientific advancement and effective commercialization because of IP and siloed knowledge sharing. An under-protection of genetic health technologies carries the risk of fewer new developments and less socially valuable information available to the public, however, as seen in the battles with Myriad and Transgenomic, overprotection means that these technologies can be hostage to monopolistic pricing and restrictive licensing or business practices.

To be sure, most stakeholders will make compelling arguments about the pros and cons of gene patents. However, it is well past time for us to recognize that asking the question of whether we should continue to grant gene patents or ban them altogether has limited value. Gene patents are important for the development of a variety of S&T developments, including research tools and genetic tests. Each of these gene-based technologies tend to be governed differently, depending on R&D costs, incentives to innovate under pressures of commercialization or markets, and licensing practices which can in turn impact costs and incentives for better or for worse. Discussions regarding ways through on these economic issues have often been focused on patent system reform or, where patent rights have been thought to go too far, on finding a better balance between public and private interests relating to a particular invention. This is fine and well: best to leave talk of

property to the experts. But what about considerations of benefitting from new invention and innovation, or when patents are contributing or creating "wicked" problems?

Abandoning the "should we/should we not" line of questioning about patenting genes can help do away with patent-centric dilemmas and allow us to ask better questions — to go beyond the realm of patents — to think more closely about when and under what circumstances or stage in development patents on genes are beneficial and not harmful, and then set up incentives (patents or otherwise) accordingly. Chapter 2 examined the theoretical and empirical literature to better understand the goals of the patent system to incentivize invention and encourage further innovation. In Chapters 3 and 4, this work questioned the extent to which these goals are advanced by gene patents in the context of satisfying health improvement objectives in genetics research and health care. The chapters in turn reflected on the impact of gene patents in the research setting and in relation to genetic testing in Ontario's health care setting. Many of the issues related to gene patents are not entirely new or unique, except the specific factors around genetic information and the provision of tests do raise particular social and ethical concerns that no single policy intervention or existing regulatory framework on its own will adequately address. In Chapter 5, focused on identifying the "who", the relationships and responsibilities between actor networks (sometimes individuals, but mostly institutions) that shaped the trajectory and outcome to date of the Canadian human gene patent debate.

Some may say that one way to move forward from a problem is to work around it. There is a growing body of literature, "IP without IP" (intellectual production without intellectual property), that argues that innovation in research-intensive economies does not need patents in order to occur and that at certain times or in some circumstances, non-patent innovation incentives can better

address problems of resource allocation and barriers to access that originate from treating knowledge as an economic good.[748] Each of the chapters in this work has explored the disparate effects of gene patents on different types of gene-based scientific research and how the impact of these patents on access to care creates a "silo effect" problem for Canadian policymakers, who are generally isolated from the pursuits of exploratory discovery and the practical aspects of health care delivery.[749] This makes the policymaker's task of satisfying both the innovation and the betterment of health agendas of government a formidable one. Clearly, there is no perfect solution that serves both the goals of the patent system and the health-improvement objective of genetic health research and care, nor to reconciling the different normative goals of a right to health and the rights attached to IP, and no panacea to extinguish tensions at the public and private divide of health and patents. However, we do know that a one-size-fits-all approach — whether it be that all patents on genes are permitted or none are at all — is unlikely to advance and maximize innovation for a maximization of public good. Fortunately, we do not need perfection to achieve good policy.

When the linkage between the intermediate and ultimate goals of the patent system starts to fray, a terse and unconstructive opposition between the policy arenas traditionally tasked to consider economic and non-economic factors becomes visible. In the Canadian gene patent debate, several informants shared the challenges that arose when a trumping of economic considerations over non-economic ones left little room in discussion and debate to revisit or develop policy frameworks that support non-IP related benefits. Early in my doctrinal research, I came across an astonishing statement; astonishing because in its simplicity, it had sounded so authoritative and final. It

[748] For e.g., see Dreyfuss RC, "Does IP need IP? Accommodating intellectual production outside the intellectual property paradigm" (2010) 31 Cardozo L. Rev. 1437. An open science approach is also an example of innovation happening where IP is not a primary innovation incentive or whereby innovation can happen without IP.
[749] Lehoux P et al., "Health technology assessment in the Canadian health policy arena: Examining relationships between evaluators and stakeholders" (2008) 14(3) Evaluation 295.

appeared in a report by the U.S. Congressional Office of Technology Assessment, now over thirty years ago, but no less startling then than now, and it was about federal policy options for supporting a scaling up of genomic research. The sentence reads: "genome projects raise no new questions about patent or copyright law."[750] My hope is that the work presented here shows, if even in some small measure, how misleading this sentence really was.

It is hard to know what the appropriate relief to the tension between the right to health and the right to IP should be — should it be in favour of fundamental rights or utilitarian ones? Do we need further government intervention? Reflecting on Robert Merges' justification of IP, in which Merges claims that IP rights are things to which people have some intrinsic entitlement, but that "social utility alone is not reason enough to override,"[751] Mark Lemley aptly puts this notion into perspective. For Lemley, if "IP is some kind of pre-political right to which inventors and creators are entitled," whereby IP is "an end in itself,"[752] then all the evidence in the world would not dissuade proponents that patents are "doing the world more good than harm."[753] Several informants in this study have asserted that empirical evidence to better understand to what extent patents are positively or negatively impacting innovation and access in relation to genetic health technologies would be helpful. However, as examined herein, there are several key reasons why empirical data at the intersection of patents and health research and care in Canada remains elusive or absent, and policy decisions must be made despite these limitations. Consequently, I agree with Lemley, particularly in consideration of the incentive-versus-access compromise that rests at the core of IP debates. Even without definitive proof supporting the inducement imperative of the

[750] U.S. Congress, Office of Technology Assessment, *Mapping Our Genes-Genome Projects: How Big, How Fast?*, OTA-BA-373 (Washington, DC: U.S. Government Printing Office, April 1988a).
[751] Merges RP, *Justifying Intellectual Property* (Mass.: Harvard University Press, 2011), 3
[752] Lemley*, supra note* 276 at 1338.
[753] *Id* at 1335.

patent system, the negative impacts of this system on availability of gene-based patented invention and on access to applications in health care have become increasingly clear. We need better interministerial coordination and cooperation to produce better patent and health policy coherence and to normalize greater policy diversity in decision-making.

5.1 In This Thesis

At its essence, my project lies at the crossroads of patents and health. We acknowledge the vast potential of genetics and biotechnology to revolutionize diagnosis, prognosis, and treatment, ushering in groundbreaking advancements like personalized medicine and gene therapies. Yet, introducing patents into this equation raises critical questions about access, innovation, and ethical considerations. Indeed, we are discussing patents concerning biological materials – ranging from cells to genes, even down to the DNA level. We may argue that patents play a crucial role in fostering innovation in these domains, encouraging the sharing of research findings, and contributing to Canada's economic vitality – an outcome we all aspire to. However, the crux of the matter, as we have come to understand, lies in the concerns surrounding patents on naturally occurring biological materials, such as gene sequences or gene patents. These concerns manifest in various ways: they may hinder access to inventions in research and health care, create barriers or uncertainties in innovation within these sectors, and pose challenges to the availability of and affordability of biomedical breakthroughs.

In Canada, these concerns have crystallized around gene patents and commercial genetic testing, sparking debates in policy circles and legal battles. For instance, attention has been drawn to Myriad Genetics' BRCA patents for hereditary breast and ovarian cancer. More recently, the Children's Hospital of Eastern Ontario has challenged the validity of patents related to long QT

syndrome, a heart rhythm disorder critical for timely diagnosis and management, which can be life-saving for both adults and children. The prevailing literature and policy discourse on gene patents and genetic testing in Canada, including my own research, indicate that such patents may hinder equitable access and cost-effective testing. However, the extent of these challenges remains uncertain. Despite discussions spanning over two decades on how to address these issues, they persist, rooted in the complex dynamics between the public and private sectors in patents and health care. In this work, I set out to explore this public-private divide, specifically focusing on the Canadian gene patent debate.

My goal was to reveal the tensions existing between the rights to health and the rights endowed in IP, along with access challenges in gene-based innovations, within the overarching governance framework where the discourse has evolved since the 1999 Myriad Genetics controversy. To accomplish this, I conducted in-depth interviews with 26 stakeholders involved in gene patents discussions. I also analyzed case law and major policy movements, particularly in Ontario, concerning the provision of genetic testing. In my research, I identified four tension areas, presented in chapters 2-5 of my thesis. I highlighted the complexity of balancing the government's goals of promoting gene-based technology innovation while ensuring access. Ultimately, I argued that debates on human gene patenting go beyond patent law, emphasizing the need to consider broader public interests. Fundamentally, however, we need to carefully consider the regulatory policies surrounding gene patents and genetic testing in Canada. It is time we view the tension within the gene patent controversy as complementary, albeit sometimes confrontational and almost always complicated. But in those thorny contested areas of wicked problems where patents and health meet, the problem with gene patents is a symptom of bigger challenges for Canada's innovation ecosystem, and we find ourselves at a critical juncture.

Unlike two decades ago, we now have viable options to significantly better align IP and health policies, some of which have been discussed in this work, some of which will benefit from the systematic application of science to drive technological progress. An intentional application of science into Canada's broader innovation ecosystem underscores the crucial role of governments in supporting innovation in both public and private sectors, as well as fostering institutional partnerships to translate scientific discoveries into technological progress. We should also keep in mind that while esteemed academic research is important and should be encouraged, so too should the creation of IP and promotion of technological output. This vital role by governments can only be fulfilled with supportive, intentional, more joined-up policies in place.

The challenge is that Canadian governments continue to prioritize the connection between S&T and the nation's economic growth potential, but they refrain from broader government intervention, opting instead for more generalized, one-size-fits-all frameworks. As such, the concern arises from the possibility of settling for an inadequate integration of foundational research and scientific knowledge into Canada's innovation ecosystem. Such an effect could impede the utilization of modern science to advance health care and lead to misaligned patent and health policy decisions. Such misalignment could counterintuitively hinder efforts to improve patient outcomes and respond effectively to emerging health issues and threats. Study informants voiced concerns about misaligned patent and health policies contributing to the uncertainty surrounding gene patents in Canada's health research and care settings.

Meanwhile, Canadian governments have long recognized the importance of technological innovation but have grappled with how best to pursue and sustain it. Canada's perpetual low ranking on innovation is a familiar narrative within its innovation landscape. The ongoing debate

over human gene patents, coupled with advancements in genetics and biomedicine, serves as a stark example of the country's limited investment in scientific infrastructure and its struggle to translate research into practical applications. Figuring out how to integrate early research into sectors like biotechnology and pharmaceuticals is crucial for Canada's productivity and economic growth cannot be understated. However, research often ends up exported abroad as intellectual property or ideas, hindering Canada's global market competitiveness. The reasons behind Canada's lag in technological innovation are well-documented: heavy investment in slow-growing sectors like natural resources, preference for low-risk ventures, reluctance or limited expertise to adopt cost-saving technologies, and a fragmented economy of small and medium enterprises where intellectual property poses both challenges and opportunities. These factors impede the modernization of science and technology applications, limit the potential of public-private partnerships, and defer access to the latest innovations across various industry sectors and the broader innovation ecosystem.

Fortunately, governments are taking action. As of 2022, the federal budget has integrated updates to S&T policy into federal budgets, now including innovation policy elements and increased business investment in R&D. The introduction of a federal supercluster program promotes cross-sector collaboration, while Ontario is exploring patent pools to retain Canadian IP. In formulating these policies the specifics require careful consideration. For instance, it remains unclear how the government plans to shift focus from upstream and early-phase R&D. Moreover, this shift prompts inquiries into the dependence on private sector and proprietary models for innovation. It brings to light the complexities surrounding patents and their specific implications for innovation, particularly within the realm of genetic health. As discussed throughout this study, the emergence

of gene-based technology in biomedical research and health care underscores the prevalence of "wicked" issues at the intersection of health and IP in Canada.

As such, and to avoid unending debate, it is imperative for countries like Canada to establish coherent policy around the use and access to patented genetic health technologies, like those in health research and care, that effectively balances feasibility, costs, and benefits. While nothing prevents a country from engaging in active policymaking to rethink IP and health and to establish regulatory policy or supporting institutions for these frameworks, in Canada's context, bold, even ambitious, proactive policy experimentation is needed. This level of political commitment requires broader government intervention beyond R&D to support the progression of technology from "spark of genius" to commercialization, especially in sectors like biotechnology, including gene-based biotechnology. The COVID-19 pandemic served as a stark reminder to Canada of the crucial role its governments play in these areas, as government intervention not only influenced but visibly altered the trajectory and nature of gene-based innovation in health care and biomedicine.

Beyond the need to reassess policy and institutional governance networks, the human gene patent debate in Canada underscores the potential for extensive collaboration both domestically and internationally. The COVID-19 pandemic has reshaped our understanding of biotechnological and drug development processes, revealing the benefits of low barriers to open science collaboration for pioneering new research and business models in Canada. While genetic researchers have historically embraced open science collaboration, the mapping of the human genome has highlighted the need for improved translation of research efforts into clinical practice, informed health policy decisions, and stimulated economic growth and innovation. In this thesis, harmonizing with other voices in legal scholarship, I have argued for restructuring academic-

industry relations, especially in early-stage scientific research, to prioritize collaborations in R&D over IP, recognizing the limitations of relying solely on the patent system.

Certainly, governments wield considerable influence in bolstering innovation agendas and amplifying research impact through the strategic utilization of tools beyond patent law. Direct investment in R&D via grants, contracts, and public use agreements holds the potential to foster cross-sectoral collaborations and multidisciplinary approaches, particularly in the early stages of R&D with respect to open science partnerships. While these aspects have been deeply examined in this thesis, there remains a pressing need for further exploration into the organizational dynamics of S&T, particularly concerning their alignment with our industrial strengths. This exploration should scrutinize how these intersections converge at the juncture of the public-private divide, particularly regarding IP. Thus, ministerial leadership is crucial for navigating the tension between health and IP constructively, aiming to enhance existing frameworks rather than simply critiquing or dismantling them. But proactive engagement is key to achieving coherence in patent and health policies. In this conclusion, several ways forward have been proposed.

5.2 Patents Create Uncertainty

Human gene-based technologies, like all technologies, can be governed by the general parameters of IP law. Patent law applies to new technologies in distinctive ways and, with very few exceptions, the legal standards or rules by which the statute is used or interpreted can vary among fields. However, uncertainties arise over the extent in which the law can adequately govern the validity of patents in a varieties of technologies. Where uncertainties arise, so too does controversy and concern. Patents in the fields of human genetics and genomics have generated their fair share of uncertainties. To date, Canada has chosen to navigate the problems of gene patents by focusing on

the positive public welfare gains that can emerge from using human genes, primarily by seeking out that perfect balance between the public domain and private enterprise almost exclusively by way of the patent system. However, this is a status quo approach that should concern Canadian policymakers. While patents broadly set out to advance the goals of incentivizing invention, development, and commercialization of knowledge, the broader social implications of human gene patents in some public user spaces remain unknown, problematic, or even damaging. Here, there is room to act on an awareness that gene patents are not the only way — or even the best way — to innovate in those spaces, and to consider additional pathways external to the patent system for possible solutions. To offer an American example, the Patient Protection and Affordable Care Act was passed by U.S. Congress to give a public health authority the institutional agency to grant market exclusivity over a particular therapeutic protein.754

While much remains unknown about the effects of different incentives, it is important to consider different incentive mechanisms to strive for the best outcomes for public and private interests together. Patents need not be completely excluded from these options, but how reassuring for Canadians to know that as we wait for another opportunity to achieve greater clarifications in the law, we need not idle in uncertainty due to decisions made elsewhere or those lacking domestically. The stakes for Canadian patients remain high as we idle because domestic regulatory policy remains incoherent in relation to human gene patents. If the results in Myriad, D'Arcy and more recently, in CHEO are of any indication, the disagreements around the role of patent policy in reducing uncertainties in publicly-provided genetic testing in Canada are far from over.

[754] Pub. L. No. 111–148, § 7002, 124 Stat. 119, 807 (2010) (codified at 42 U.S.C.A. § 262(k)(7)(A) (West Supp. 2010).

5.2.1 Patents and Uncertainty Due to International Divergence in Law

The ontological relationship between science and law755 is a contentious one, and policymakers, courts, and patent offices have struggled, with little shared satisfaction, to determine the eligibility parameters of patent claims on isolated DNA sequences. Drawing on the scientific underpinnings of allowable patenting on isolated genes as eligible subject matter (such as a genes' classification as "chemical") has itself been key in the patenting of DNA-derived or gene-based materials.756 These foundations have been discussed elsewhere757 and have not been included in this work. Rather here, the legal analysis and differences in policy approach among different jurisdictions on human gene patents has provided a useful starting point for the study of the Canadian gene patent debate. Further, this study also considers the question relating to the extent to which these differences impact the Canadian gene patent debate beyond matters of patent eligibility. Reflection on two of the leading biotechnology patent cases outside of Canada, Myriad in the U.S. and D'Arcy in Australia, was useful for these purposes.

Where Europe758 since 1998 and the U.K.759 have taken the view that isolated genes are patentable subject matter, more recently other leading jurisdictions such as the U.S. and Australia have decided that the 'nature argument' required a more nuanced approach through cases involving Myriad's BRCA patents. A survey of American jurisprudence tells the story of a more active use of its section 101 patent eligibility doctrine as a "policy lever" to outline the scope of patent

[755] Cook-Deegan R. "Law and science collide over human gene patents" (2012) 338(6108) Science 745. See also Koepsell, *supra note* 619.
[756] Calvert and Joly, *supra note* 312.
[757] Scanga, *supra note* 38. Also, Rinehard A, "Myriad lessons learned" (2015) 5 UC Irvine Law Rev. 1147 at 1150. The Australian High Court in *D'Arcy* also offers an explanation of the relevant science. And *D'Arcy, supra note* 108, at 39–61, 100–113, 194–216.
[758] *EU Directive, supra note* **Error! Bookmark not defined.** at Articles 3(2) and 5(2).
[759] *Human Genome Sciences Inc v. Eli Lilly & Co* [2012] RPC 6 (HGS).

rights760 relating to products of nature. Australian jurisprudence also shows greater reliance on the concept of a manner of manufacture and of patent-eligible invention to influence the policy objective of granting patents to meritorious subject matter. Decisions of the apex courts in the U.S. and Australia on patent claims regarding the BRCA gene sequences both denied the patentability of what they referred to as isolated naturally-occurring gene sequences, but diverged in regards to cDNA patent eligibility, with the U.S. affirming and Australia denying eligibility. Given the ability for research and genetic tests to be shared globally and with relative ease, patent holders have this additional reason to ensure patent right exclusivity,761 the consequences of which can impact other major areas of public policy, such as trade and negotiations relating to IP protection.

Various transdisciplinary perspectives on the changing legal landscape also offered a helpful premise from which I gained a better understanding of the various policy solution options put forward in the Canadian debate, particularly in response to the USSC *Myriad* decision. According to Dan Burk, Director of the AI Global Public Policy Institute at the University of California, the shift in philosophical thinking by the Court mid-decision suggests an effort by the justices to curb gene patenting practice without undermining existing and future patents used in the biotechnology and pharmaceutical industries.[762] Fellow at Stanford University's Center for Law and the BioSciences, Jacob Sherkow, has claimed that the Court's decision frees up development of clinical genetic testing, and in effect, access to tests, given the use of isolated genes in this process.[763] Bioethicist David Resnik of the National Institute of Environmental Health Sciences

[760] Burke and Lemley*, supra note* 72.
[761] *Bayer AG v. Housey Pharm Inc., 340 F.3d 1367 (Fed. Cir. 2003)*.
[762] Burk L, "Curious incident of the Supreme Court in Myriad Genetics" (2014) 90(2) Notre Dame L. Rev. 505.
[763] Levy S, "Our shared code: The Myriad decision and the future of genetic research" (2013) 121(8) Environmental Health Perspectives A250.

has discussed his support of the balance struck by the Court over the longstanding question of how much human ingenuity is required to change a natural object into a patentable invention.[764]

On the Canadian front, some informants in this study and others from the patent law and research communities[765] contend that the *CHEO* settlement provided an opportunity to bring into better balance the public and private interests pertaining to human gene-based patents in Canada's public health care sector. In a press release dated 9 March 2016, CHEO announced the settlement, stating that these patents "will no longer stand in the way of diagnosing a life-threatening disease."[766] The *CHEO* case opened up the space to rethink the conflation of economic and health improvement objectives of patent policy in the human gene patent problem on Canadian soil. The settlement in *CHEO* also seems to align with an equitable and patient-driven delivery of care. It is worth noting, however, that while human gene-related subject matter is not excluded from patent eligibility, in 2015, the CIPO released guidelines for changes to its examination of diagnostic methods. In practical terms, this change in patent office policy means that gene-related subject matter presented in diagnostic method claims can be blocked from patent eligibility at the examination level, unless the guidelines are challenged in court. The patentability of diagnostic method claims may have been affirmed, whether in regards to human genes or not, had the Court challenge to the long QT patents pushed forward.

The gene patent debate also drew inspiration from considerations around the patenting of life forms, namely plants and animals, and resolving where the bright line lies on the patenting of these

[764] *Id.*
[765] Stobo Sniderman A, "DNA match," University of Toronto Nexus, Fall/Winter 2014, <https://www.law.utoronto.ca/news/nexus/nexus-archives/nexus-fallwinter-2014/dna-match>.
[766] Ground-breaking settlement changes landscape for genetic medicine in Canada, <https://www.newswire.ca/news-releases/groundbreaking-gene-patent-announcement-in-canada-571458001.html>.

higher life forms has involved navigating strong moral objections against the patenting of human DNA.[767] Following a long history of the phenomenon of the nature argument in the courts, the USSC in *Myriad* was reluctant to draw that line,[768] nor did the High Court in *D'Arcy* bring greater clarity on the matter for Australians. In Canada, the issues of patenting higher life forms reached the Supreme Court in *Harvard* and in *Monsanto* — the latter decision being important in Canada because it made claims to modified genes and cells (of plants and animals) allowable without the post-*Harvard* limitations imposed by the CIPO, such that these materials must be isolated. In other words, plant or animal gDNA is patentable *in vivo* — isolation is not a requirement. In *Harvard*, the Court said that because the *Act* does not clearly say that higher life forms are patentable, and "since the patentability of such life forms is a highly contentious matter that raises a number of extremely complex issues",[769] it falls to Parliament "to engage in public debate, a balancing of competing social interests, and intricate legislative drafting."[770] Despite years of health providers navigating gene patent issues as they arose, and despite a growing divergence in the law now, reawakening threats of a chilling effect to follow-on research and on the advances possible by personalized medicines, Parliament remains silent on the matter following *CHEO*.

In absence of Parliament answering this call put out by the *Harvard* Court, it does make some good sense that traditionally, the goal of policymakers has been to focus on solutions through an existing regulatory framework, with the patent system being the obvious choice. Solutions through the patent system alone conceivably have a chance of finding an agreeable balance between its

[767] Schrecker T, Wellington A, *Patenting of Higher Life Forms and Human Biological Materials: An Introduction to the Issues*, Prepared for the Project Steering Committee on Intellectual Property and the Patenting of Higher Life Forms, CBAC, January 2000 (this research was funded by Industry Canada to develop a policy on the patenting of biotechnology, including higher life forms).
[768] See, Gold, *supra note* 33, Chapter 4 at 78.
[769] *Harvard, supra note* 35 at Pt. B(1).
[770] *Id.,* Pt. B(2).

two important goals of encouraging follow-on research and incentivizing innovation, but it is a great white hope to expect the modern patent system to do so beyond the economic interests of its users. This is likely not a big revelation to members of the patent law community; in most major patent-granting countries, the biggest challenge is that IP is not built for social policy considerations.[771]

All of this suggests strongly that the gene patent debate should not be dominated by property considerations and obsessions about stronger-versus-weaker patent rights any longer. This is significant insofar as patent rights continue on a "status quo" trend of exception and expansion, despite limited evidence of patent law's accomplishment of its dual goals of maximizing innovation while serving a useful social end.[772] Some legal scholars go as far as to say that a reconsideration of this kind of *status quo* is necessary given the "IP-faithful" among us.[773] Questions of the subject matter patentability of human genes have given the gene patent debate different dimensions in relation to other statutory requirements of patent law, that have identified distinct policy consequences for areas of industry and of science. But an all-or-nothing approach as vested in solutions through a tinkering of the patent system in this way might not be the best way forward in Canada's gene patent debate. The bigger picture in Canada is that it has introduced concerns about access to S&T knowledge, research and patient care.

[771] Caulfield T et al., "Patenting human genetic material: Refocusing the debate" (2000) 1 Nat. Rev. Genetics 221 at 229.
[772] Lemley, *supra note* 752 at 1335.
[773] See generally, *id.*

5.2.2 Patents Create Uncertainty in Health Research

With respect to publicly-provided research, the Canadian gene patent story is not particularly robust, although it has garnered some attention,[774] more notably in respect of pharmaceuticals.[775] Not currently at the forefront of policy concerns, it was nonetheless important to understand the Canadian narratives about the impact of patents on publicly-supported academic research within the broader context unfolding in the gene patent debate. This understanding proceeded from two important starting premises. The first premise was to keep in mind that in Canada, there is limited to no empirical data about the impact of patents on knowledge access within the academic research setting similar to the oft-cited work conducted by Cho et al. (2003) in the U.S or by the 2004 Australian Law Reform Commission in Australia.[776] Whatever this gap in the data means in terms of how urgently it is needed to ensure the pursuit and excellence of academic research in Canada is beyond the scope of this study. The second premise was that, ultimately, no one is interested in suing a researcher, academic or clinical, and that whatever working solutions have been adopted within Canadian research settings, the general consensus is that these solutions suffice for both researcher and patent holder.

Reports out of economics scholarship have suggested that concerns around patents interfering directly with research pursuits may be limited,[777] but still, patents may not be necessary to incentivize private involvement in the development and commercialization of new test methods given better test affordability in some cases (compared to exome sequencing, genome sequencing remains pricey in Canada), compared to pharmaceuticals.[778] These reports indicate that where

[774] Bubela and Caulfield, *supra note* 215. See also, Caulfield, *supra note* 232.
[775] Lexchin, *supra note* 238.
[776] See Cho et al. and ALRC, *supra note* 383.
[777] More recently, Sampat, *supra note* 251. Also, Ali Khan and Gold, *supra note* 122.
[778] Robertson, *supra note* 381.

there is cause for concern, it is primarily connected with the scope and use of patents in the given sector or field more specifically.[779] One case in particular is notable for having situated discussions about the rights of researchers over human-derived materials.[780] In the Moore case, these materials were cells and tissues, but by extension, the consideration of genetic sequences is also implicated. The U.S. federal court decision in Moore — that Moore did not have a proprietary interest in the tissue and cells removed from his body — showed that there was a conflict of property claims but, and of particular import to the human gene patent debate, the case revealed the different interpretations of patent law when applied to human-derived materials.[781] Moore staking claim to his own spleen and derived tissue and cells caught considerable attention within legal and ethics scholarship.[782] The rights discourse that emerged from the case has, however, revealed broad and important legal considerations that require further exploration when talking about human-derived materials and the rapid growth of proprietary science.

Research, innovation and progress in the biomedical and life sciences are reliant on access to a large amount of knowledge and data. The free sharing of knowledge and data is a lifeline of modern science. With the expansion of patent law to cover the biological foundations of human genetics, its tools and methods, universities are encouraged to adopt proprietary measures which can scale-up development of important products and further an understanding of the fundamentals of the science and the new data. A problem arises in environments where free sharing and proprietary

[779] Sampat, *supra note* 251.
[780] *Moore*; *supra note* 35.
[781] Gold, *supra note* 33 at 25 (author claims that the four separate opinions in the case speak to the nature of property discourse and the impact of this discourse on the human body).
[782] See, Boyle, *supra note* 77. See also, Danforth MT, "Cells, sales and royalties: The patient's right to a portion of the profits" (1988) 6 Yale L. and Policy Rev. 179; Hardiman R, "Toward the right of commerciality: Recognizing property rights in the commercial value of human tissues" (1986) 34 UCLA Law Rev. 207; Parker PM, "Recognizing property interests in bodily tissues: A need for legislative guidance" (1989) 10 J. of Legal Medicine 357.

approaches fall out of line with one another, such that the latter over-extends into the former. The problem, or the extent of the problem, could also be more nuanced than learning to navigate the advancement of genetics research around IP and growing concerns about proprietary science.

For instance, property and property rights considerations themselves are attached to economic goods in the enhancement of other major public policy areas, like trade or innovation in health care. Other considerations include property as a "plurality of values"[783] or when seeking to resolve rights disputes, developing a better understanding of that plurality.[784] From a policy perspective, the overarching concern of all this talk about 'rights' in health research rests on talk of an anti-commons effect. Again, little empirical evidence of this chilling effect of patents on the commons has been reported, where researchers are forced to divert their pursuits away from patented fields.[785] To be sure, proving that research has been limited or restricted entirely, whether because of patents or not, is difficult. Moreover, in the absence of patents on genes, the assumption is that genes would decidedly be placed into the public domain.[786] The cautionary tale of Celera suggests it may be prudent to be aware of unintended consequences occurring in the absence of patents. The assumption that the absence of patents is a better alternative to their availability, in spite having an established regulatory system dedicated to their proper use regardless of technology presupposes the potential for unintended consequences in particular circumstances.

The *Moore* case is also salient with respect to considerations over whether the cost of using gene patents to bring new discovery to light is more beneficial than not, given the way in which patents

[783] Gold, *supra note* 135 at 27.
[784] See, generally Nedelsky, *supra note* 12.
[785] See, Sampat, Williams, *supra note* 251 at 207. Also, Caulfield, *supra note* 431.
[786] *Id.*, Sampat and Williams.

work in gene-based research.[787] All R&D genetic technology is not created equal, however; the cost of developing therapeutic proteins is often comparatively cheaper relative to that of developing genetic tests.[788] Consequently, patents on genetic sequences can operate to satisfy the goals of the patent system in different ways depending on the costs and incentives of the technology involved. For instance, gene patents associated with a test may confer limited market exclusivity[789] while research in academic settings is often incentivized for reasons not related to what patent protection has to offer it.[790]

An anticommons interference with S&T innovation has been one of the most serious concerns around the potential impacts of gene patents in research sectors that lead to the development of new treatments and technologies. The concern has been for researchers who want access to pre-existing technology. In some areas of research more than others, researchers face a world that deals with uncertainties in R&D, such as those associated with the commercial value of DNA sequences, by raising costs for example.[791] Where researchers rely on upstream discoveries for downstream innovation opportunities, academic research would suffer were there a lack of funding to support end-product development in the sciences.[792] This could easily be the case where gene-based patent protection becomes limited enough to disincentivize the private biotechnology firm willing to invest in the development and commercialization of improved testing technology.[793] The extent to which the development of genetic tests relies on patents to satisfy the primary goals of the patent

[787] Scherer, *supra note* 21.
[788] SACGHS, *supra note* 3.
[789] Dreyfuss RC, "The patentability of genetic diagnostics in U.S. law and policy" 14 N.Y.U. Scho. Of Law, Pub. Law Research Paper No. 1–68, 2010, online: <http://papers.ssrn.com/sol3/papers.cfm?abstract_id-1678123>.
[790] *Id*.
[791] Mireles, *supra note* 421.
[792] Kesselheim and Avorn, *supra note* 248.
[793] *Id*.

system in these distinct ways is of particular interest when we consider the impact of patents on basic and early-stage research.

Arguably, the majority of concerns relating to early-stage gene-based research discussed in this study could be addressed by adopting some form of experimental use exemption, whereby researchers, including scientists and genetic test developers, could use subject matter of an invention for experimental purposes.[794] Europe holds such a research exemption,[795] as does Australia.[796] In North America, the U.S. Federal Circuit narrowly interpreted an experimental use defence[797] and in Canada, recent legislation was introduced[798] that brought changes to the *Patent Act* regarding the scope of patent protection by providing exemption from infringement for the experimental use of patented technologies.[799] Where no formal experimental use exemption previously existed in the *Patent Act*, Canadian jurisprudence held that making or using a patented invention as part of an experimentation phase, and not for commercial purposes, was not an infringement.[800] The greatest gain of such an exemption could be greater scientific discovery and development. The biggest drawback, in addition to potentially curtailing the incentives offered by patents, is having to determine what research exemptions look like in Canada's pressure cooker environment where researchers are expected to fall in line with the patent-or-bust approach to exploring and innovating.[801] This jurisprudence coupled with the *Bayh-Dole Act* codifying U.S. policy permitting scientists to seek patent rights in government-supported findings has fostered a

[794] Bor F, "Exemptions to Patent Infringement Applied to Biotechnology Research Tools" (2006) 28 EIPR 510.
[795] See, for e.g., *Patents Act* 1977 (U.K.) s. 60(5)(b).
[796] *Patents Act* 1990 (Cth) s. 119C.
[797] *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002) [*Madey*].
[798] *The Budget Implementation Act*, 2018, No.2.
[799] *Canada Patent Act, supra note* 125 at s.53.3(1).
[800] *Micro Chemicals Ltd. v. Smith Kline & French Inter-American Corp.* (1971), 1971 CarswellNat 388, 2 C.P.R. (2d) 193 (S.C.C.); *Merck & Co. v. Apotex Inc.*, 2006 FCA 323; *Teva Canada Limited v. Novartis AG*, 2013 FC 141.
[801] Although in the U.S., the Federal Circuit eliminated patent law's experimental use defence in *Madey, supra note* 797.

research sector that supports the expectation that patented academic research discoveries would prove to be commercially valuable.

Limited data exist to support a negative effect of gene patents on follow-on innovation in basic or early-stage research settings,[802] and there remains little evidence around whether or not researchers are at risk when using patented gene-based tools without seeking a license[803] or whether researchers will seek legal recourse in response to working around patents.[804] It may be worthwhile to learn if and to what extent Canadian genetics researchers are experiencing patent-related barriers or an encroachment of patent use in early-stage pursuits. In this work, several informants spoke of the emerging discourse around open science and open innovation to limit or work around the negative or unknown affects of this data gap. The open science approach has been said to be in need of serious consideration given its ability to remove the roadblocks of proprietary science, de-risk innovation and support risk-sharing, and to leverage new or alternative forms of partnership that may be necessary to generate new ideas, new products and new services to satisfy patient needs.

With respect to genetics and genomics research, academic institutions should be encouraged to explore alternative routes in partnership development, particularly in early-stage research by going open science for example, that support collaborations with industry partners that can help address challenges relating to optimal leveraging of research output and IP in both sectors. In response to the COVID-19 pandemic, researchers and governments turned to open science partnerships as a way of addressing the need to improve drug discovery quickly. The abandonment of proprietary

[802] Caufield, *supra note* 230.
[803] See, Holman CM, "The impact of human gene patents on innovation and access: A survey of human gene patent litigation" (2007) 76 UMKC L. Rev. 324, 359.
[804] Caufield, *supra note* 230.

science early in the pandemic led to repurposing drugs and the development of diagnostics.[805] But these efforts remain the exception, not the rule.

5.2.3 Patents Create Uncertainty for Equitable Access to Genetic Tests

Looking downstream of genetics research to the provision of genetic health care and delivery, there are notable distinctions to be made relating to patents in this sector. For instance, as explained in Chapter 4, the test provision landscape in Ontario is *ad hoc* with respect to access to some genetic tests, the majority of which are patented. Many that are in high-demand are requested out-of-province. While the *ad hoc* access can act to fill gaps left open by the lack of data supporting a greater uptake of tests into the health care system, it can also mean uncertain access and availability in the test provision landscape. The long QT test is an obvious exception. BRCA mutation detection's clinical actionability remains uncertain, despite the cost-benefit analysis of treating positive cases, due to the lifetime percentage risk factor of susceptibility. As described to me by one informant, access to genetic tests in this way is left to chance, creating inequities in the delivery of care. While studies to develop more robust standards for genetic test assessment continue in the province of Ontario, most notably, those like the GSO, the lack of empirical evidence that the benefits offered by some genetic tests warrant their use or changes to long-term health care delivery may be exacerbating other barriers to test access, such as the availability of funding and patents.

Significant costs are associated with establishing local testing, and it often falls to the public institution providing the test to cover these costs,[806] except testing options located out-of-province,

[805] Rogers A, "Blood from COVID-19 survivors may point a way to a cure," Wired, 24 March 2020, online: <Blood From Covid-19 Survivors May Point the Way to a Cure | WIRED> (accessed: 26 June 2020).
[806] Ali Khan and Gold, *supra note* 122 at 1255.

as these tests are paid for directly by the appropriate provincial government.[807] Therefore, from a public health provider's cost and provision perspective, establishing a local implementation framework for tests can be favourable. This is where the Canadian problem with gene patents is also notable — patents can hinder test implementation efforts. In the Canadian context, public health institutions are expected to deal with patents on their own, with limited knowledge and resources to navigate the IP. For some time, patents have been generating uncertainties for test repatriation efforts[808] and for the general delivery of genetic tests.[809] Ali Khan and Gold's recent study of the Canadian test provision landscape (2017) reports that public laboratories across the country have attempted to repatriate tests, but that patents continue to be a persistent barrier.[810]

Moreover, the legal uncertainty due to a divergence in patent law as a result of *Myriad* together with *Mayo* adds to uncertainties regarding access to patented tests. Since the U.S. *Myriad* decision in 2013, the market price of genetic tests has been on the decline.[811] In several ways, the legal uncertainty in the U.S. has presented an opportunity to lower health care expenditures on genetic tests in Canada.[812] But, this is an opportunity for Canada only for as long as the legal landscape stays relatively the same in the U.S., and the pressure for change in the U.S is growing.[813] Understanding the ways in which patents are being used in the Canadian test provision landscape, ways that have prevented equitable access to tests and which have often proven to be costly when patented technology is be a factor, is important to the outcomes of health research and care.

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[807] *Id.*
[808] Lerner-Ellis J, Wang M, White S, et al. "Canadian Open Genetics Repository (COGR): A unified clinical genomics database as a community resource for standardising and sharing genetic interpretations" (2015) 52 J Med Genet 438.
[809] Richer J, Nelson TN, Evans J, et al., *CCMG statement on gene patents* (2012) 82 ClinGenet 405.
[810] Ali Khan and Gold, *supra note* 122 at 1255.
[811] Cook-Deegan and Niehaus, *supra note* 227.
[812] See, Mead, *supra note* 91 at 774.
[813] Duan C, "Gene patents, drug prices and scientific research: Unexpected effects of recently proposed patent eligibility legislation" (2020) 24(2) Marquette IP L. Rev. 139.

Informants in this study expressed concerns around the higher costs associated with patented tests and technology, although these costs are not fully understood with respect to Canada's test provision landscape. As discussed in Chapter 4 and suggested elsewhere,[814] no one fully knows what these costs are to Canada's health care system.

If no one knows the costs of patented tests to the public health care system, then it is difficult to know to what extent patents are contributing to the higher overall costs of tests or to outsourced testing services, or to what extent their impact factors into decisions about the uptake of test technologies. Not knowing to what extent patented tests are imposing greater costs on the public health care system challenges adequate health technology assessment, resource allocation, and cost-savings.[815] To be sure, Canada can take advantage of the legal uncertainty in a post-*Mayo*, post-*Myriad* world. However, while a broadening of the "nature" exception to patentability (by way of these cases) could potentially affect the range and trajectory of health research remains to be seen, challenges over biomedical applications are steadily making their way through the courts. For instance, after the USSC's decision in Myriad, another district court raised "substantial questions" about the patentability of Myriad's remaining BRCA-related claims.[816] Canadian public health authorities and policymakers would do well to note that the advantages introduced by the legal uncertainty over the boundaries of patentable subject matter could be fleeting, and that backstops to the encroachment of proprietary approaches into the publicly-supported health care sector could be beneficial to health care as well as industry.

[814] Waddell and Wilson, *supra note* 470.
[815] Lilley, *supra note* 440.
[816] See, In re BRCA1 — and BRCA2 — Based Hereditary Cancer Test Patent Litig., 3 F. Supp. 3d 1213, 1219 (d. Utah 2014).

Here, the CHEO agreement comes to mind. The agreement can act as a backstop where governments institute a compulsory licensing scheme that offers patented genetic tests under reasonable licenses offered by gene patent holders.][817] A compulsory licensing framework, for example, will leave rewards (through licensing fees) intact for a holder who shares their discovery of gene-based technology with the rest of the world. The CHEO agreement for non-commercial use of patented genetic tests in Canada could serve as a model for wider public use, including health research. The option to use compulsory licensing is one of the major flexibilities under the TRIPS to WTO member countries.[818] However, challenges akin to those posed by patents on research tools remain, hindering the utilization of upstream genetic technologies supporting downstream commercial products. Also, much like an experimental use exemption, such a framework raises questions about sufficiently incentivizing firms to develop and commercialize technologies. If these avenues are called upon, we run the risk that firms with patented gene-based technology we wish to access can nonetheless refuse to sell in markets where they find controls to be too restrictive or intrusive.

The CHEO agreement, however, can act as a policy lever to complement potentially cooperative policy instruments that already exist. In practice and under given circumstances, the agreement could leverage patent owners of a patented genetic test to license the use of their rights against a price agreed upon by both owner and user. For example, the agreement could put into practice the theoretical complementary relationship between compulsory licensing and price controls to ensure access to a patented test. In the Canadian scenario, where test provision is reliant on a publicly-

[817] See, Holman, *supra note* 803. But, genetic technologies such as research tools have "no immediate therapeutic or diagnostic value." Also, Gold RE et al., "Genetic research tools, the research exception, and open science" (2005) 3(2) GenEdit 1.
[818] See, for e.g., Maskus KE, "Parallel imports" (2000) 23 World Economy 1269.

funded and a one-buyer system, the agreement leaves intact the rights attached to any IP without an outright challenge of patent eligibility over product claims or of a patent owner's gain of market exclusivity. Critics of *CHEO* claim that the agreement fails to establish a legal precedent because the settlement stopped short of determining subject matter eligibility by the court,[819] and as such, the opportunity was lost to settle the legal uncertainty surrounding the patenting of human genes in Canada.[820] However, regardless of the side on which the critic sits, the agreement offers room for consideration of a potential win-win-win for equitable health care delivery, public and private interests.

The paradoxical logic of the patent right creates confusion over how to appropriately wield a policy tool set out to promote a maximization of innovation and of public good in new technologies precisely by excluding access to those technologies. Canada's strategy in finding appropriate solutions to this paradox has been to seek solutions to gene patent problems in health almost exclusively through the patent system. It is a strategy that suggests that the best policy action is the one that gets us the newest technologies,[821] and that this best course of action is mostly about correcting the market failures caused by the 'public good' nature of knowledge-based innovation. However, we know that patents are being used for more than awarding limited monopolies to genius inventors. Furthermore, it is an approach that sees the treatment of disease as requiring an individual approach rather than a cooperative one or one that considers a collective society.[822]

[819] Courage, *supra note* 131.
[820] Bonter et al., *supra note* 537.
[821] See, Ouellette LL, "How many patents does it take to make a drug?: Follow-on pharmaceutical patents and university licensing" (2010) 17 Michigan Telecomm. and Tech. L. Rev. 299.
[822] See, Gold, *supra note* 33 at Chapter 2.

5.2.4 A Way Forward: Celebrate the "Social" in Social Contract

Work from the economic literature on cumulative innovation considered in this thesis has suggested that depending on where patent protection is exercised, a patent can either solve a public good problem or inhibit technological progress. Patents are one key way to influence investment, but they, too, continue to have a direct role in directing which technologies become developed because it is up to the private entity to determine availability and who has access when. That is because patents may not be the best way in which human gene-based invention, intended to improve the health of individuals, can be made available for public consumption. Patent policy may set out to conflate the economic and health improvement objectives of innovation to keep public and private interests aligned throughout the art of inventing, but innovation, in contrast to invention and often conceptualized as commercialization, is driven by market forces and is reliant on exclusivity, and a patent can become weaponized under these circumstances. The result is that patent policy can fail to get the alignment of its objectives right, leaving questions sensibly focused on how to improve its efficacy through the rules that govern the validity and infringement of patents on technologies, on patent scope, and on the terminology of the law. Answers to these questions certainly matter, but they should — and can — extend beyond the binary choices of "patent-or-bust" and "all-or-nothing" answers when corrections of the law fail to account for patents acting as a social contract between inventor and society.

To move beyond the double bind of (social) good and (commercial) goods at the heart of the patent paradox, we must do the following. First, and in a similar vein as to what has been proposed by Gold,[823] we must identify what is important in our use of human genes in research for the purposes

[823] See Gold, *supra note* 32.

of better health and health care by determining which policies secure this purpose, and then, we must develop the incentive system accordingly. If we consider patents as the appropriate incentive, then we apply a purpose-bound approach, with deliberate attention to protecting human genetic sequences and their applications to both space (i.e., bound to function or purpose for use of an invention throughout its development and improvements) and time (i.e., mid-to-late stages in the R&D process). A central conflict in the human gene patent debate has been the extent in which an inventor will lay claim to a gene's potential use despite a limited knowledge of the gene's function and informational value at the time of discovery.[824] Several European jurisdictions have adopted a more purpose-bound approach to the protection of human genetic sequences, in which a specific use of a patented genetic sequence is stated in the claim.[825] Enhancing the patent system "patent-or-bust" expectation by way of this two-step approach offers more opportunities to better align economic and health-improvement policy objectives along the length or duration of a technology's R&D trajectory. Augmenting the *status quo* under this two-step approach would also make room for considerations of broader non-economic interests that several informants in this thesis assert is lacking in relation to patented human gene-based invention. Such an approach would also support exploration of the complementary aspects of an open science and proprietary science framework.[826]

[824] Eisenberg R, "Re-examining the role of patents in appropriating the value of DNA sequences" (2000) 49 Emory L. J. 788. See also, Scanga, *supra note* 38.
[825] See *§1a (4)* of the German *Patent Act* and *Art. L. 613-2-1* (Act No. 2004-800 of 06 August 2004, *art. 17*) (English translation).
[826] Caulfield T, Harmon S, Joly Y, "Open science versus commercialization: A modern research conflict?" (2012) 4 Genome Med. 17.

5.3 "Make Room" for Health Policy: Institutional Permanency

The second conclusion in this thesis — the need for permanent institution and active construction of forward-looking genetic health policy — calls for re-amassing government expertise to allow for greater genetics health policy development. This would achieve two things. One, in practice, such an approach could adequately consider the diverse, sometimes disparate and changing but nevertheless important, non-economic considerations typically associated with human genetics discovery (i.e., their cultural and social meanings, considerations of a right to health) and how science could adequately inform these decisions. Two, in principle, health policy can keep such non-economic considerations in sight — considerations that inherently imbue the use of human genetic materials towards goals of better health and well-being — while also allow the patent system to independently keep intact the best of what patents have to offer in supporting gene-based biotechnological innovation.

The idea to "make room" for health policy was put forth by Richard Gold in 1998 in his addressing some ways forward from the policy issues already then visible on the Canadian landscape relating to gene patents in the delivery of health care. [827] In that work Gold suggests the need to "make room" for health policy, where health policies that facilitate the kind of health and well-being we seek from the use of human genetic materials warrant greater consideration within the patent system framework such that incentives for getting us what we want in this respect are subsequently devised accordingly. Here, I borrow from Gold but more than suggesting that we make room for health policy within the current patent regime framework I push past that framework, and beyond economic motives, to suggest we give health policy considerations something they have never

[827] Gold, *supra note* 695.

quite been fully given in the policy discussions of Canada's gene patent debate: adequate consideration of the non-economic reasons, such as access to care and health equity, as to why we use human genes for the purposes of health research and patient care in the first place. This is something health policy already sets out to do, so we should leverage it.

As the legal and policy effects of *Myriad* and *D'Arcy* decisions continue to be fully understood, the number of gene patents continue to grow.[828] In Canada, as several informants in this study and others have pointed out,[829] gene patents obstruct equitable and affordable genetic testing. As it is widely understood, the availability of better and newer tests is of high provincial priority.[830] Where an individual meets the eligibility criteria under the formulary, the cost of genetic testing can be fully covered. When such criteria are not satisfied individuals can turn to other offerings of the test, including private genetic services. As learned in Chapter 4, access to tests can also happen on a research project basis where patients can be tested, often in an *ad hoc* manner reliant on physician suggestion or referral. In some of these cases individuals are also paying out-of-pocket.

My analysis in this work took shape initially in response to the key policy recommendations put forth by the authors of Ontario's 2002 *Charting New Territory* report. These recommendations were particularly striking because they set out to address a very specific concern, namely obstructions to access to commercialized gene-based biomedical and biotechnological innovations, shared by two of the most important sectors in Canada — health research and care. The biggest concern for Ontario was about Myriad's restrictive licensing practices under its gene patents. In time, part of Ontario's response included preliminary technological assessment of

[828] Aboy et al., *supra note* 94.
[829] Liddicoat et al., *supra note* 274.
[830] For e.g., see Bombard Y, Rozmovits L, Trudeau M, et al. "Access to personalized medicine: Factors influencing the use and value of gene expression profiling in breast cancer treatment" (2014) 21 Curr. Oncol. e426.

selected genetic tests, by 2010, the long QT test being one of them. But, as this study and others[831] suggest, patents deterred the local uptake of the test, making informed assessments and decision-making by patients considering using these tests impossible. For this reason, in the current health care setting, the collection of information and government expertise relating to patents is an institutional imperative. The Ontario test provision landscape laid out in Chapter 4 has illuminated this necessity in Canada.

5.3.1 Filing the Data Gap: Adequate Data for Better Policy

In Canada's post-Myriad and post-*CHEO* world, there remains a need to better understand the downstream impacts of patents on public health research and care. With recent events taking place in Ontario's test provision landscape involving CHEO's efforts to gain access to patented genetic tests, I sought to better understand the impact of patent use on the equitable delivery of health care. In this study, I have documented stakeholder concerns about gene patents impeding access to research and tests and potentially leading to a decline in innovation, challenging more widespread understandings of the availability and affordability of genetic tests. These concerns persist today, despite the policy work of Ontario and federal government advisory and expert committees struck in response to Myriad in the early 2000s. They are concerns that persist despite direct requests by federal government departments for quantitative data and economic modeling to inform whether and how gene patents might impede access to genetic tests. These concerns continue despite a rise in reports suggesting that patents impact different areas of gene-based research, development and commercialization as well as the provision of health care differently. Aside from the study by Ali Khan and Gold (2017), little empirical data is available with respect to how gene patents are

[831] Ali Khan and Gold, *supra note* 122.

creating barriers of access to genetic testing in Canada. Speaking with informants who have helped shape or inform the Canadian gene patent debate, this study suggests that an important feeder problem of the debate is the lack of quantitative data indicating what is helpful versus harmful about patent use in public health care.

A lack of quantitative, clinically-informed data is not a new problem in the Canadian test provision landscape. As one informant noted of the genetic test landscape in Ontario, *ad hoc* access to genetic tests by patients operates under several limitations in the HTA of these technologies. Most challenging of these is the difficulty of evaluating the tests' clinical utility under the same robust standards used to assess new drugs and other non-genetic health technologies. So, a critical mass of data regarding the utility of a given test is not always available. From a policy perspective, with little to no data about the patent system's role in health care, there is little to spur governments into action to review or advocate for changes to the law. In accepting how patent rights in human gene-based invention are being deployed by biotechnology firms, policymakers have, in effect, been accepting a health policy that says Canadian health care improvement needs the patent system — itself a system reliant on a market that is indifferent to its failures in health care[832] — to instruct what test access needs to look like.

From a legal perspective, it has been difficult to challenge the violation of the proprietary rights of patent holders of genetic tests in Canada with so few private disputes erupting over human gene patentability[833] or to challenge business practices relating to predictive cancer tests.[834] There are aspects of the *Patent Act* that make patent law an attractive form of regulation of gene patents,

[832] Roemer, *supra note* 78.
[833] Matthijs and Halley, *supra note* 675.
[834] Kaufert, *supra note* 425.

including its creation of private rights that can support the public interest by encouraging widespread invention and sharing of innovation.[835] Limits on patent rights (i.e., bright lines delineating patent scope and subject matter patentability) are, however, important, not only to ensure that the patent system is given the best chance to achieve its goals, but to ensure that in satisfying its objective to maximize innovation, the patent system does not unintentionally interfere with the goals of other important areas of public policy. Also, if these limits on patent rights produce unintended consequences, then it is important to have the appropriate backstops in place to counteract what may include an overextension of proprietary rights or a disregard of broader public interest or need.

Addressing the gene patent problem exclusively through making changes to patent law would constitute a purely economic regulation approach to the problem. Instead, I contend that a more deliberate integration of health policy considerations into the human gene patent debate is essential to establish guidelines for the provision of genetic materials, including when and by whom. By including health policy considerations alongside patenting policy, the underlying data gap problem could be addressed, knowledge and expertise around appropriate policy impacting access to health care in Canada could be developed, and real-world domestic evidence relating to the impact of patents on patient care could be collected and shared. The 'siloing' of knowledge and of clinically-derived data from research projects is part of what prevents the collection of relevant data on the impact of patents on genetic research and care in Canada. Further, this siloing likely contributes to challenges around developing a broad understanding of the direct impact of patents in the test provision landscape. The problem may not be that we are unable to get the right kind of data or

[835] For instance, to use the *Act* as a piece of legislation that has as a focus "the intentional activity of attempting to control, order or influence the behaviour of others." See, Parker C et al. (eds.), Regulating Law (Oxford: Oxford University Press, 2004) at 1.

even enough of it from the evolving test provision landscape. For the most part and at this point, it is clear what kind of data we need to collect. Projects like the Genome-wide Sequencing Ontario pilot are currently working towards this effort.

Another barrier of access to genetic tests, a barrier which is increasingly considered in policy movement scholarship,[836] relates to state agency in securing adequate and permanent subject-matter and policy development expertise in policy advisory within government departments. Informant data collected for this study suggests that in the case of CHEO, by the time patents on the genetic sequences and test became an issue for the hospital, the province was not in the position institutionally (i.e., as a matter of having inter-departmental coordination, multi-sectoral, multi-stakeholder dialogue) to guide the hospital in its desire to deliver the long QT test. My informants noted that a lack of clear empirical understanding within government policy units of the effects of patents, helpful or harmful, on test delivery in the clinical care setting contributed to the barriers experienced by CHEO's researchers and clinicians. These challenges are not unique to Canada, although they are symptomatic of broader networked challenges specific to Canada's handling of them within its borders. The division of authority over patents and health, as well as inter-governmental discord, had been exposed by the policy controversy surrounding Myriad Genetics' BRCA patents in the late 1990s. The cumulative effect to date has been a policy deficit concerning the regulation of human gene patents. Study informants advised me that inadequate consideration of policy options in the gene patent debate can be attributed to a combination of some unfortunate changes in government departments and an imbalance of decision-making power between departments. The most striking of the changes identified by informants was a shrinking of health policy units across both provincial and federal governments. Shrunken independent health policy

[836] See generally, Dobuzinskis and Howlett, *supra note* 593.

units at the provincial and federal levels of government reduced the capacity and capability of these units to manage health policy considerations as the gene patent debate continued to take shape over the years.

5.3.2 A Way Forward: Be Constructive

The gene patent problem is about a clashing of rights, namely between a right to health — the entitlement to receive a given standard of medical care — and the rights attached to IP — private rights granted for the ownership and commercialization of biotechnological ingenuity. To move beyond biotechnology patents and the barriers they create to genetic test access, for instance, requires a policy framework that facilitates access in all health-related areas of development and commercialization. Such a framework might be established by identifying the shared goals or values of the biotechnology industry and of the biomedical community or patients.

Under a human rights framework, biotechnology patents affect a right to life, liberty, and security (*section 7* of the *Charter*) and to equality (*section 15* of the *Charter*). One could contend that the *Charter* is conducive to adopting a more constructive stance towards both the right to health and the rights IP. This perspective suggests that the *Charter* may offer a framework capable of fostering the coexistence or harmonization of these two rights, thereby potentially resolving any tensions or conflicts that may emerge between them. Based on what we have learned from the gene patent debate in Canada to date, a constructive approach to the patent problem may involve options that work to reconcile the interests of patent holders, public health researchers and providers, and patients, that are not served entirely by the patent system. Such options could include schemes that draw on compulsory licensing to reward patent holders for discovering and patenting important gene-based technologies as well as broader institutional mechanisms or guidelines suggested by

CHEO that could regulate public health in a manner consistent with Canada's obligations under the *Canada Health Act* and as constitutionalized by *Chaoulli,* as well as under international human rights instruments.

In major patent-granting countries, including Canada, the grant of a patent gives its holder the responsibility to decide what knowledge will benefit society. In the gene patent debate, Canada's patent-centric assumption is that the best way to innovate in the public interest is by protecting the rights of inventive scientists and the private sector. Consequently, for inventors and for industry, the prospect of doing away with patents generates a fear of losing out on the latest biomedical breakthrough. In a case like the long QT test, the absence of patents could mean society being at risk of losing out on a life-saving assessment tool. Considering the trends of court decisions over patentable subject matter in Canada's patent law sister jurisdictions of the U.S. and Australia, the USSC has repeatedly stated[837] (and this is corroborated by popular scholarly opinion)[838] that the overriding justification for viewing patents in this way is utilitarian (i.e., empirically, based on economic efficiency).[839] It is a justification that holds, despite particularly strong objection in fields of discovery such as human genetics and genomics, where patents are strongly contested because of a lack of empirical data supporting their effectiveness or efficiency to incentivize development or to spur follow-on innovation. According to some legal scholars, the court has little recourse but to act on "the starkness of the choice it has been offered: either there are patents, or innovators must rely solely on private incentives" to mitigate any fallout from eliminating state-supported financial incentives for innovation.[840] As I have argued here and as have others before me, patents

[837] *Alice, supra note* 41 at 2354 (in which the Court places an explicit focus on the economic cost-benefit analysis of patenting).
[838] See, e.g., Rai, *supra note* 304.
[839] See, e.g., *id*. But see, Merges, *supra note* 751. Also, Lemley, *supra note* 752.
[840] Ouellette, *supra note* 300 at 1117.

are not the only tools through which innovation can be incentivized,[841] and in some cases where patent policy can lead to unintended consequences or do more harm than good for the public at large, backstops to patents exist and should be considered.[842]

I have argued that the choice of how to incentivize the development of genetic health technology, for the most part, has taken shape within an all-or-nothing "patents-or-bust" paradigm.[843] The idea being that biotechnology patents are the best way to innovate in the fields of S&T. Patents set out to disclose technical know-how to encourage follow-on innovation but, in the case of biotechnology patents, the sufficiency of sharing information in this way remains unclear. For example, some argue that disclosure promotes innovation by sharing upstream advancements with downstream producers.[844] In Chapters 3 and 4, I asserted that even if patents were helpful in disseminating new genetics knowledge, they do not account for the non-economic, human and social value of that knowledge. In health research and care, the primary value of biotechnology is its ability to enhance human welfare and the general well-being of individuals. To this end, I have argued that health care is a fundamental right that warrants permanency in institutions (i.e., established expert groups within existing policy units) and mechanisms (i.e., cooperative agreements) capable of protecting that right both at the level of the system of care and at the level of individual access to that care. Health policy allows for the consideration of this right, whereas patent law does not.

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[841] For e.g., see generally, *id*. Hemel DJ, Ouellette LL, "Knowledge goods and nation states" (2016) 101 Minnesota L. Rev. 166.
[842] Ali Khan and Gold, *supra note* 122.
[843] Others have described the paradigm similarly as "patent or nothing." For e.g., Ouellette, *supra note* 300 at 1125.
[844] Ouellette LL, "Access to bio-knowledge: From gene patents to biomedical materials" (2010) Note, Stan. Tech. L. Rev. N1, para. 106–13 (author discusses Mandel GN, "The generic biologics debate: Industry's unintended admission that biotech patents fail enablement" (2006) 11(4) Va. J.L. & Tech. 8). For, e.g., see Arora A et al., *Markets for Technology: The Economics of Innovation and Corporate Strategy* (Cambridge, Mass.: The MIT Press, 2001) at 138–41).

Searching for incentives to innovate outside of the patent system is not a new undertaking of patent law nor of economic scholarship,[845] particularly where lifting the burden on courts to define the bright lines of patentable subject matter can also serve the utilitarian policymaker to factor in more comprehensive cost-benefit considerations.[846] *Ex ante* and *ex post* rewards for new biomedical innovations from outside the patent system, such as regulatory exclusivity and direct R&D spending and tax incentives, are suggestions that are often made in response to the problems with patents. Such approaches, similar to the granting of patents, require decisive action by the state with respect to their development and deployment. The Canadian gene patent debate has been a litmus test of the patent system and its affect on public health care provision. Regulatory exclusivity can be a helpful measure for ensuring that specific public objectives for specific members of society are achievable. For example, research exemptions can help clinical researchers gain access to knowledge and scientific innovation without fear of being sued under patent infringement. But, even with such measures in place, researchers can face pressures to commercialize their findings or may be inadvertently influenced by market forces to pursue research exclusively deemed to be commercially valuable for health and well-being rather than pursuing research that may best contribute to the public good. Hence, even research exemptions can succumb to the powerful influences of economic regulation rather than make financial gain secondary to broader socially desirable outcomes. Again, here, the CHEO agreement can be instructive.

As a health policy measure, there are several things that the CHEO agreement can do. According to the agreement's drafters, while not necessary policy for the enjoyment of its intended benefits

[845] See, e.g., Wright BD, "The economics of invention incentives: Patents, prizes, and research contracts" (1983) 7 American Economic Rev. 691.
[846] See, Ouellette, *supra note* 300 at 1130–1137.

by public non-profiting entities, the agreement can (although not must) be required through the *Patent Act* without having to change Canadian law or practice.[847] Rather, the agreement remains contractual between litigating parties unless patentholders challenge public entities wishing to offer testing using a patented gene or method. If a challenge were advanced, the agreement sets out that public providers seek *section 19* of the *Act* to compel state action in support of obtaining a mandatory license. In this way, the agreement makes room for variations of cooperative policy based on the changing needs of stakeholders. Conceivably, the agreement can directly seek to leverage the use of the *Act's* compulsory licensing mechanism and, beyond its formal implementation, it can leverage its regulatory purpose in cooperation with other interventions mitigating barriers to access, such as price controls or market entry restrictions. The agreement can consider the distinct and shared public and private interests at stake in the dissemination of knowledge and use the law where the agreement's regulatory policy guidance falls short of achieving agreement between stakeholders. It can also mobilize best practices to improve communication between stakeholders who are already interested in conducting, using and applying human genetics research in industry and health care while honouring the different interests of stakeholders that would encourage and maintain continued buy-in and collaboration.

What the agreement cannot do, however, is compel governments to act on it. It can, nonetheless, introduce something of a new policy framework that is different from standard compulsory licensing laws alone as well as a governance tool for governments to standardize avenues of equitable access and oversight relating to genetic testing. Now that the agreement sits in wait for governments and institutions to develop the policies and procedures for its uptake, the lingering question is that of the epistemic basis of decision-making, questions to be answered by the "who's

[847] As outlined in Ali Khan and Gold, *supra note* 122.

who" in the gene patent debate. Discussions like these require inter-ministerial, interdepartmental conversations. In Canada, that means coordinating discussions trans-nationally across provinces and territories and between provincial and federal governments. This study, along with others in Canada,[848] underscores a need for state action to take up this call.

5.4 Shrunken Independent Health Policy Units Have Exposed A Vulnerability In Governing Responsibly And Equitable Access To Gene-Based Technologies

The third conclusion of the thesis is that the loss of health policy expertise on the genetics file at both levels of government in the years that followed the *Myriad* controversy has meant a reduced capacity to collect and analyze salient empirical data from the biomedical research and clinical care communities to inform any kind of regulatory policy relating to gene patents in publicly-supported health research and care. This loss of critical mass in government health policy units has dramatically reduced government receptor capacity.[849] In the case of human gene patents in health research and care, the loss of subject-matter and science policy expertise has resulted in an incapacity for government to incorporate new knowledge borne from invention and discovery in the life sciences and biomedicine. At the same time, innovators with commercially viable gene technologies are left uncertain about how best to pursue their scientific endeavours free of worry about patent infringement, while public health providers also face significant challenges within the genetic test provision landscape. Where access to patented genetic health technologies is typically the immediate concern, it may be more difficult to encourage policymakers to focus on the more fundamental imperative of appropriate governance. Nonetheless, the Canadian gene patent debate

[848] See, Ali Khan and Gold, *supra note* 122. Also, Adair et al., *supra note* 726. And, Christian et al., *supra note* 726.
[849] For a reminder of what is meant by "receptor capacity", see Castle, *supra note* 591.

has shown us that the unintended consequences of policy inertia and fragmented government responsibilities around patented subject matter and health care produce both economic and social costs too important to ignore.

To promote innovation and facilitate access to innovation both orders of government will need to adopt a range of tools and approaches, including soft law, regulations, stakeholder and public engagement, and the use of incentives. My discussion on incentives has primarily focused on patents, but other forms exist, like grants and prizes, which incentivize research in the public sector. Grants push researchers and investors to pursue early-stage research, while prizes reward successful outcomes. Both methods aim to stimulate research and separate R&D costs from market access costs. However, success isn't guaranteed, and questions remain about product viability and protection from unintended effects like free riding. The provincial and federal roles as decision-making authorities and the importance of knowledge capacity in relation to policy issues in genetics and genomics have been brought into sharp focus in the human gene patent debate. Jurisdictional overlap and division of authority between and among government departments and different levels of government over patents and health have been widely reported in the literature to stymie policy making. This study also maintains that overlaps in responsibilities among and divisions between orders of government and different government departments have created key stumbling blocks in the decision-making capacity of the health sector in particular. These governance challenges can be understood as particularly wicked problems demanding intersectoral collaboration to address policy issues about gene-based invention.

As an existing policy framework, the patent system, to some degree, already regulates biotechnology, but other mechanisms exist. In 1998, the European Parliament and Council

harmonized the European Union's approach to patents in biotechnology by passing a directive on the legal protection of biotechnological invention. The *EU Directive* also addresses moral and socio-economic concerns about obtaining patents on gene-based invention. As a major patent-granting country, Canada does have several international instruments at its disposal to determine how its social contract with society can be arranged. One such instrument, the *Convention on Biological Diversity*, came into force in Canada in 1993 and provides states with domestic control over their genetic resources and thus, jurisdiction over how these resources are accessed and used. National legislation instructs whether and which types of human genetic materials are patentable. Among the most technologically advanced powerhouses in human genetics and genomics, Europe, the U.S., and Australia have shared different positions on the patent eligibility of human genetic materials. It is the task of the state to determine the texture of the social contract between a society and the biotechnology industry. As discussed in Chapter 2, another international mechanism, the *TRIPS*, states that patents shall be made available for all inventions of any technological type. For the purposes of this thesis, this doctrine of non-discrimination codified in *article 27(1)* says that the *TRIPS Agreement* encourages a technology-neutral approach to patenting.

However, this approach must be balanced against established member state doctrines such that the patent system can act as a social contract that lends itself to reflecting broader contracts between governments and society that can align with domestic jurisprudence. As we have come to understand, patent law is not the sole approach available to regulate gene patents. The patent paradigm itself has been criticized increasingly for misdirecting policy development into the

production of outdated[850] or inadequate,[851] even harmful frameworks.[852] It remains a challenging task for Canadian policymakers to find appropriate and nimble approaches to regulating the uptake of emergent gene-based biotechnologies, as typified with the latest developments in gene-based invention.[853] As presented in Chapter 5, the division of government authority over patents and health in Canada has forced provincial health care authorities, institutions, and public laboratories to respond to most issues of access to patented genetic tests as they arise. The delivery of health care services has often been said to occur in provincial silos, but patents may be converting those silos into fortresses. For the Canadian policymaker, making decisions at the intersection of patents and health care is both a familiar and a formidable challenge, in large part due to a lack of cross-policy coordination and leadership at that intersection of economy and health.

The gene patent controversy put a spotlight on the absence of coordinated intra- and inter-governmental mechanisms and leadership that can adequately address concerns of access to health care. The siloing effect and its roots in the division of constitutional powers in addressing issues with gene patents was identified as problematic by some informants in this study, but a more fundamental problem, according to these informants, is an unwillingness for governments to cooperate. In Chapter 4, I described how the federal government has constructed the Canadian health care system as set out by the provisions of the *Canada Health Act*. The provinces and territories are responsible for the development, management, and delivery of health services under

[850] Kelly SE, "Public bioethics and publics: Consensus, boundaries, and participation in biomedical science policy" (2003) 28 Sci. Technol. Hum. Val. 339.
[851] Jasanoff, S. *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton University Press, 2005).
[852] Gold in GE^{3}LS, *supra note* 49 at 35.
[853] Maclure J, Hughes D, "How should Canadian policy react to CRISPR babies?" Policy Options, 25 April 2019, online: <https://policyoptions.irpp.org/magazines/april-2019/how-should-canadian-policy-react-to-crispr-babies/>. See also, National Academies of Sciences, Engineering, and Medicine. Human Genome Editing: Science, Ethics, and Governance (National Academies Press, 2017).

section 92 of the *Act*. With respect to genetic tests and their delivery, provincial jurisdiction over hospitals, property and civil rights gives the provinces regulatory authority over health and hospital services. However, from a right-to-health perspective, as we have come to understand, the *Charter* can serve as a means for ensuring equitable decision-making about how such services can be provided.

The uptake of human-derived genetic materials has brought significant changes to the biotechnology industry and it has contributed to the growth of individually-based approaches to the treatment of disease as entailing a problem of unique genetic make-up[854] under the personalized medicine movement.[855] Others have said that addressing an individual treatment of health to maximize individual well-being leads to an ineffective and expensive health care system.[856] As with other socio-economic rights, concerns about these changes have included questions about how to improve access to care and accountability to patients as a matter of public interest. The potential of the *Charter* as a means of securing accountable decision-making within Canada's health care system has, nonetheless, been met with limited success. Canadian constitutional scholars who have written about this, with respect to public funding of services and the lack of clarity regarding the term "medically necessary," also call for greater government cooperation with

[854] Abby Lippman referred to policy supporting such approaches as the "geneticization" of health care. See also, Lippman A, "Prenatal genetic testing and screening: Constructing needs and reinforcing inequities" (1991) 12 American J. of L. and Medicine 12.
[855] Traditional drug development, targeting entire populations, has shifted to personalized treatments tailored to individual responses. See, Agyeman AA, Ofori-Asenso R, "Perspective: Does personalized medicine hold the future for medicine?" (2015) 7(3) J. Pharm. Bioallied. Sci. 239.
[856] See, e.g, Evans RG, *Strained Mercy: The Economics of Canadian Health Care* (Toronto: Butterworth, 1984) at 256; White JB, *Justice as Translation: An Essay in Cultural and Legal Criticism* (Chicago: University of Chicago, 1990) at 57

respect to the development of access policy in health.[857] In short, in Canada, a constitutional right to health care does not exist.[858]

However, if as a starting point, we were to say that decisions concerning health care must respect the *Charter* and international human rights guarantees, then accountability for health care takes on a broad multidisciplinary approach. Namely, issues of patents in Canadian public health spaces can be treated as much as a matter of cooperative patent and health policy as of constitutional and human rights, as well as a collective approach in treating human disease.[859] The benefits of commercial availability[860] and theoretical underpinnings in law say a broader and stronger right to exclude increases the expected value of innovation leading to valuable inventions for societal benefit.[861] Changes in the law internationally are changing the rules around what is patentable about genetic sequences and to what extent. A cooperative approach to regulating the use of biotechnological knowledge expands the property discourse of human gene patents beyond economic concerns and beyond policy choices provided by allocating property rights to human genetic materials.

Informants from this study have suggested that in order to appropriately address the deficits in human gene policy governance, the provinces — especially the largest of them, namely Ontario, British Columbia, and Quebec — must demand that the federal government work with the provinces to develop a collaborative approach to addressing the problems with genetic health

[857] Ries N, "The uncertain state of the law regarding health care and *section 15* of the *Charter*" (2003) 11 Health L.J. 217. Also, Leeson H, "Constitutional jurisdiction over health and health care in Canada," Submitted to the Commission on the Future of Health Care in Canada, Discussion Paper No. 12, 2002.
[858] See a discussion paper that discusses this by Hogg PW, "Is there a constitutional right to health care in Canada?," 23 October 2003, online: <https://www.brianday.ca/news/is-there-a-constitutional-right-to-health-care/>.
[859] Jackman, *supra note* 631.
[860] Kieff, *supra note* 298 at 707.
[861] Owens and Robichaud, *supra note* 83.

patents. The call by the provinces can itself serve as a harbinger of re-establishing permanency in health policy expertise in the area of gene-based patents at both the provincial and the federal levels of government, in the ministries of health and Health Canada. Within adequately and appropriately staffed provincial and federal health policy units, room can and must again be made to discuss, debate and formulate the kinds of policy options Canada needs to develop to move forward, some of which have been discussed in the sections above. In Chapter 5, we learned that the provinces must produce and supply the federal government with empirical data regarding patient access to patented genetic tests and the economic impact of service delivery of these tests to patients. We also learned in Chapter 5, that in the case of Ontario, at least, currently, there is no place within the health policy unit at the MOH for such data to be collected or interpreted. With this data missing, it will be nearly impossible for Canadian policymakers to mount a challenge to existing policy on access to patented human gene technology from either a policy or a legal perspective.

From a policy perspective, with little to no data about the patent system's impact on health care delivery, there would be little justification to spur government into action to review existing policy or to advocate for changes to the law. From a legal perspective, it can be difficult to challenge the misuse of patent holders' legal rights over genetic tests in Canada with so few disputes over human gene patentability[862] or over business practices governing access to breast/cancer susceptibility test technology.[863] Certainly, these capabilities may be within the mandate of the OHTAC or OGAC, although at the time of this study, such capabilities were not clearly articulated in the public documentation or in the informant data. At the research and clinical level, academic institutions

[862] Matthijs and Halley, *supra note* 675.
[863] Kaufert, *supra note* 425.

can play a role in better aligning technology licensing and laboratory services to mitigate barriers of access to testing. Although ultimately, governments have a responsibility to oversee and take action when harm to human health is foreseeable, particularly through technologies born from public funding. The Canadian government has powers that have yet to be put to use: to ensure that patent rights promote health under existing regulations,[864] and to regulate accordingly when that fails to happen.

Ensuring equitable access to patented genetic health technologies will require a different approach than most other technologies and drugs require. Genetic health technologies are not merely another option for treatment in some cases. They can offer patients options ranging from various forms of medical intervention to life-saving diagnostic information. In some cases, they may be the only treatment option because of their reliance on specific genetic sequences. Cooperative work and efficient data sharing among government departments should be encouraged at every level to improve the odds of establishing a range of successful treatment options, and to conduct the best possible assessment of the safety and efficacy of human gene based treatment and testing. Canadian biotech researchers should be encouraged to share and pool their knowledge at different stages of R&D, but especially in the early stages, where new ideas flourish and lead to follow-on pursuits. Patents can get in the way of this. Canadian governments could re-establish their policy analysis capacity to better pool their resources and investments in R&D and biomanufacturing, in addition to bolstering their bargaining power to negotiate access to research innovation and testing together when necessary. A way forward for governments is to ensure that their departments are staffed with experts in genetics and genomics, but also with those who have an understanding

[864] Examples in Ontario include the *Excellent Care for All Act* (see Chapter 3 text surrounding discussion about the GTAC) and the *Health Promotion and Protection Act* R.S.O. 1990, c. H.7.

about how policy is made (by policy analysts, policymakers) in relation to new knowledge provided by genetics and genomics expertise.

5.4.1 A Way Forward: Be Experts

This study identifies the need for facilitators (or leaders) and strategies (or formal frameworks) to create a coherent, effective and cooperative genetics and access to genetics science and health-related policy without patents getting in the way. While the delivery of public health care is the responsibility of provincial and territorial governments, informant data collected in this study suggests that Health Canada also has a role to play in its delivery. Given this division in public health responsibilities, federal and provincial governments must be held accountable for their role in improving access to research and technologies currently protected by genetic health patents. This can be addressed by developing better cooperative cross-policy coordination within and among government departments and ministries. Despite efforts undertaken by the MED at the time of Ontario's Myriad controversy, innovation functions tend to lie outside of the scope of health authorities. For example, at the federal level, innovation and health departments are often siloed with different mandates and conflicting goals.[865] Within the provincial and territorial governments, innovation and health departments tend to act at different times of a technology's development or in relation to assessments regarding their uptake or access once adopted in the health care system, such as with respect to funding their research and regulation.[866] The result can be investing into technologies that do not improve health care or delivery to Canadians and ignoring other innovations that could enhance each of these.

[865] Lehoux, *supra note* 749.
[866] *Id*.

Further, provincial and federal governments must mitigate a growing vulnerability in the governance of the intersectoral areas of Canadian science, health care and biotechnology. They can do so, in part, by re-staffing public health policy units with appropriate subject matter and policy development experts. Efforts by governments to reamass expertise within their units could create further opportunities to knock down knowledge silos, improve access and sharing through establishing strong collaborative team networks comprised of public and private researchers and stakeholders, particularly where patents reportedly threaten these partnerships.[867] Such actions could help all stakeholders in the development of human gene technologies to reimagine together the interdependent relationship between public health and private enterprise and draw on their strengths. Governments can encourage these relationships by creating opportunities, like open science modeling, and support these approaches through research grants and shared benefit agreements in the use of big data.[868]

In short, provincial and federal governments can create the conditions for developing a strong human genetics policy framework for Canada by: (a) establishing permanent in-house expertise within existing provincial health policy units by securing staff who have cross-policy knowledge about health innovation, the science, and the assessment of genetic health technologies in order to mount realistic policy recommendations based on the impact by patented technologies in the

[867] See, for e.g., the discussion put forth by invited speaker Aled Edwards in Weinman J, *supra note* 246. Edwards, co-founder of the non-profit Structural Genomics Consortium, uses the open science model (not patents) to publicly share research, including research from the start-up Meds For Kids. When a colloquium participant put forth, "The patents themselves aren't holding you hostage. The fact that some people behave badly —," Edwards interrupted, "*Some* people? … "Come to my world." During the talk, Edwards also argued that patents create a "cloud of IP" and that the act of patenting a discovery itself creates issues of trust that dissuades others from using it and researchers to share what they know.

[868] Scanga V, "Federated Data Systems Filling Canada's Health 'Data Gap': Going Big with Big Data," Blog, Social Pharmaceutical Innovation, 5 February 2022, online: <https://www.socialpharmaceuticalinnovation.org/post/federated-data-systems-filling-canada-s-health-data-gap-going-big-with-big-data>.

Canadian publicly-provided health care landscape, and (b) implementing a comprehensive data-sharing system of information to include a rapid-cycle response government task force, including members of these expert groups as needed to deliberate and to respond to unmet public health care needs or to scale-up technologies.[869]

5.5 The Tension in the Canadian Gene Patent Debate Boils Down to an "Us versus Them" Opposition between Patents and Publicly-Provided Health Research and Care

As patentable subject matter, genes and genetic technologies are appealing to both public and private interests. Genes are themselves structurally informative and act as information templates for healthy cellular function,[870] for indicating problems in gene function[871] and as potential indicators of disease.[872] Genes that are isolated, purified and modified can be used to develop therapeutic drugs.[873] Genetic testing can provide information about likely individual responsiveness to specific drug therapies to optimize patient treatment and about the propensity for an asymptomatic individual to develop a particular disease in their lifetime.[874] There are few examples of effective and clinically-proven products derived from public sector R&D alone, with society bestowing much of the burden of the downstream development required to make products publicly available to the private sector. Patents may be one way to incentivize innovation to identify and treat disease and, in such cases, patents covering human genes associated with

[869] See, Challinor A, *Adopting our advantage: Supporting a thriving health science sector in Ontario*, 2016. Online: <http://occ.ca/wp-content/uploads/OCC-HTI-Adopting-Our-Advantage-Report.pdf>.
[870] Albert B et al., *Molecular Biology of the Cell, 6th ed.* (New York: Garland Science; 2014).
[871] Mutations include a variety of changes to DNA, including deletions, substitutions, translocations and translation errors. See, Albert B et al., *Molecular Biology of the Cell, 6th ed.* (New York: Garland Science; 2014) at 216.
[872] For e.g., see Hanahan D, Weinberg RA, "The hallmarks of cancer" (2000) 57 Cell 57.
[873] See generally, Herzog RA, Cao O, Srivastava A, "Two decades of clinical gene therapy — success is finally mounting" (2010) 9 Discovery Med 105; Wurm FM, Production of recombinant protein therapeutics in cultivated mammalian cells. (2004) 22 Nature Biotechnol. 1393.
[874] See, e.g., Kane EM, "Patent-mediated standards in genetic testing" (2008) 835 Utah L. Rev. 837.

diseases and derivative testing technology can be undeniably valuable scientific solutions in health care. Much practical technological development depends upon linking public interest and private resources.

The right afforded under patent law for the protection of human inventiveness is recognized under the law of human rights, most prominently in the *Universal Declaration of Human Rights*[875] and in the *United Nations Declaration of the Rights of Indigenous People*.[876] Although IP rights have found their way into human rights, the two cannot be conflated. Interpretations of the *TRIPS Agreement*[877] and arguments that support a right to health as, for instance, flowing through the Doha Declaration[878] subject IP rights to limitations in the public interest. Where the exercise of exclusive proprietary rights runs counter to expectations of openness of research and accessibility of health care is where equitable access to important medicines or health technologies becomes a concern. For health care, these limitations matter. For public institutions and private firms concerned with health research and care, a framework that captures a richer inter-penetration of both public and private interests relating to the use and application of human genes and tests would offer practical options for each sector without advocating for any one dominant approach.

This study reveals that the intersectoral issue of patents in health in Canada, as typified by the human gene patent debate, continues to be appropriately characterized as an "us versus them" relationship — a patents-versus-patients conflict, a stronger economy or healthier society. Patents

[875] *Art. 27(2)*, the "right to protection of the moral and material interests resulting from any scientific, literary or artistic production of which one is the author."
[876] UN General Assembly, *United Nations Declaration on the Rights of Indigenous Peoples: Resolution/adopted by the General Assembly*, 2 October 2007, A/RES/61/295 .
[877] *TRIPS*, *supra note* 689.
[878] The WTO Doha Declaration on the *TRIPS Agreement* and Public Health helped frame the health policy context of intellectual property emphasizing the need for TRIPS to be a part of the broader international dialogue of with respect to public health.

governing access to technology or testing in health care contribute to this narrative as they continue to be seen as suspicious and invasive. From the perspective of long-time participants in the human gene patent policy development story, some of whom were interviewed for this work, uncertainty around what is deemed patentable subject matter by Canadian law and a lack of transparency over how patent rights afforded by that law are being exercised persists. Other common law jurisdictions may have heaved a collective sigh of relief over the harmonized rulings of their apex courts on the patentability of isolated genetic sequences, however short-lived this may be.[879] In Canada, however, these issues remain legally undecided. There has been limited opportunity in Canada for clarity in the law around gene patents, but the lack of any formal policy to mitigate the effect of the legal uncertainty and support what we want to accomplish with gene-based invention has been problematic. According to some of the informants in this study, the lack of coherent genetic policy governing the use of patented materials and technologies is the product of a choice by Canadian policymakers in favour of deliberate inaction. For them, the willful acceptance by key government actors of the patent-centric *status quo* or narratives that currently typify the gene patent debate — and complacency — has brought the debate to an impasse, where it currently sits.

The interdependency between patent law and health research and care suggests a natural link to address human health objectives collaboratively. The notion that the patent system and health policy share the same ultimate goal of maximizing public good can provide a promising starting place for a co-informed, shared policy framework. A right to health views the patent system as inherently at odds with the goal of achieving universal and equitable access to health care. This normative tension between the (public) right to health and the (private) rights associated with a

[879] For e.g., see Servik K, "Controversial U.S. bill would life Supreme Court ban on patenting human genes," Sciencemag.org, 4 June 2019. <https://www.sciencemag.org/news/2019/06/controversial-us-bill-would-lift-supreme-court-ban-patenting-human-genes>.

patent is important. Should the appropriate relief come through government intervention to reconcile normative goals or through a prioritizing of broad fundamental human rights over narrow utilitarian ones is a question that remains. This study took a public interest approach to patent and health policy coherence as one way to resolve the conflict of interests. Working through the conflict will necessitate aligning an agenda of innovation and commercialization with one that facilitates equitable access to public health needs, careful not to compromise either agenda and to create opportunity to use the best of what each can offer.

One way to do that is to not set our sights on forcing what may be an unnatural balance of their objectives: let us leave patent law to concern itself with incentivizing maximum innovation through its means, and for health policy to matters of health and well-being in its fashion. But, let us take care to not accept their goals of maximizing innovation on one hand and better health on the other as ends in themselves, as if severed from one another, through their shared ultimate goal of maximizing public good. If patents are said to be granted because they maximize innovation but, instead of doing that, they are being used to maximize an inventor's right to exclude, then patent policy cannot be expected to successfully conflate its economic and health improvement objectives of innovation; in this way, we have set it up to fail. In this scenario, we can expect greater economic benefit at the expense of health improvement because of having locked down a sharing of new information to spur follow-on innovation or of having locked away access to new technology. Similarly, if a particular health policy were to potentially impinge upon a biotechnology manufacturer's right to exercise that right to exclude, then we threaten an inventor's legal right to invention and we run the risk of not getting timely or necessary treatment or technology options in our health care delivery. The normative tension between the right-to-health view and the rights attached to IP as manifested by the human gene patent debate is important as

a matter of instructing the development of policy that by its "wicked" nature is as complicated as it is necessary.

Despite more recent developments concerning a framework for access, policy offered by way of the CHEO agreement for example, policy talks seem to have fully stopped. However, a deeper consideration of the debate external to its traditional moorings in the problem, being framed as a problem with patents solved only by reform of the patent system, offers a fresh perspective. The challenge with addressing the 'us versus them' tension between patents and health at the public and private divide is not that their respective objectives or purposes *per se* must align in order to find relief from this tension. And, it is not that a conflation of economic growth and health improvement objectives is a purpose to be altogether abandoned. Rather than considering innovation and health as unconditionally separate from one another, I have taken the view that the two are inherently linked in their goals to maximize the greater social good. I believe that being mindful of this shared goal can help to reframe discussions and debate, when necessary, about the most critical outcomes of genetics research and the goals of better genetic health. Rather than solely characterizing the tension between patents and health as being one of discord, I have maintained that theirs is a complementary relationship that merits less attention on their disparity and more on their shared agenda of benefitting or serving the well-being of the public.

Under the orthodox approach of patent acquisition and IP commercialization, if the solution is to clear paths to mitigate patent thickets and barriers to sharing of knowledge and products, then the question is, "how?". Some research suggests that this is in part what strong patent rights have to offer.[880] Because we are talking about knowledge and invention, Boyle (2008) would argue that

[880] Kieff F, "Removing property from intellectual property and (intended?) pernicious impact on innovation and competition" (2011) 19(1) Supreme Court Economic Review 25.

the approach needed is "the opposite of property": to have "a lot of material" in the public domain "that can spread without property rights."[881] Rai and Boyle (2007) apply this principle to synthetic biology.[882] Knowledge flow solutions such as that proposed by the 2010 OECD "Innovation Strategy"[883] build on this principle and force the question of how best to ensure access. One solution gaining popularity in the IP management and social innovation literature is to exploit expertise networks and partnerships in R&D.[884] Examples have included policy options that bypass the use of IP (free-revealing) and those that use IP to "require rather than restrict access" to patented technologies (i.e., open source).[885]

Both options offer non-legislative and open scientific approaches that policymakers can consider in order to improve upon the existing paradigm rather than replace it outright, leaving the use and enforcement of patent rights intact to protect from copying and profit-stealing,[886] Such options also address the social and economic problems as a "partial solution"[887] to human gene patents in health to allow a broader public use of human genes and take into account the changing public and private sector collaborative landscape in biotechnology R&D.[888] It remains to be seen whether

[881] Boyle, *supra note* 562.
[882] Rai A, Boyle J, "Synthetic biology: Caught between property rights, the public domain, and the commons" (2007) 5(3) PLoS e58.
[883] For key findings, see OECD, *The OECD Innovation Strategy: Getting a Head Start on Tomorrow* (Ministerial Report: Working Party on Biotechnology, 2010), online: <https://www.oecd.org/sti/45326349.pdf>.
[884] Phillips P, "The challenge of creating, protecting and exploiting networked knowledge," in Einsiedel E, Timmermans F (eds.), *Crossing Over: Genomics in the Public Arena* (Calgary: University of Calgary Press, 2005), 7. See also the evolving structure of tech industries, including non-profit and for-profit sectors, Cockburn IM, Chase C, "The changing structure of the pharmaceutical industry" (January/February 2004) 23(1) Health Affairs 10.
[885] De Beer et al., *supra note* 49.
[886] Described as leveraging IP rights through collaborative or 'open' licensing models". See, De Beer et al., *supra note* 49 at 31, 47.
[887] Joly Y, "Open source approaches in biotechnology: Utopia revisited" (2007) 59(2) Maine L. Rev. 385.
[888] For e.gs, see: Johnson S, *Where good ideas come from: The natural history of innovation.* (New York: Putnam, 2010); von Hippel E, Democratizing Innovation. (Cambridge: The MIT Press, 2004); Benkler Y, The Wealth of Networks: How Social Production Transforms Markets and Freedom. (New Haven: Yale University Press, 2006); Phillips P, "Technology, ownership and governance: An alternative view of IPRs," in *Foresight on Emerging Technologies*, E. Einsiedel (ed.) (Calgary: University Calgary Press, 2008) at 307; Doern and Prince, *supra note* 46; De Beer et al., *supra note* 49; OECD, *supra note* 682; Etzkowitz*, supra note* 353.

such models would be championed as a viable policy approach compared to those used to address other health-related crises for humanitarian purposes,[889] or if it would meet a similar fate of failed efforts to changing policy, as seen with the use of patent pools in the field of genetic diagnostic tests.[890] As articulated by one Health Canada informant in this study, to what extent these kinds of licensing collaboratives have been exercised in Canada, with the exception of at the University of British Columbia, remains unclear.[891]

In a time when access to patented genetic materials and tests is still of concern to researchers and health care providers, it may be difficult to refocus the attention of the public and of policymakers towards the larger imperative of governance, if at all, good governance around human gene policy.[892] However, aspiring to good governance is necessary to respond to issues of patents and health, both to what may be initial hurdles in the short term and to guide preventative measures in the long term. It is clear that in Canada, governance at the intersection of patents and health is complicated by jurisdictional divisions, especially when good governance requires a clear understanding of who is responsible for what to respond to and when. Since the SARS outbreak in 2003, changes were made to provincial and federal public health governance, including the creation of the Ontario Public Health Agency and the PHAC, public health bodies whose mandates concern a variety of aspects of public health, such as developing public health policy, enabling innovation in public health, and oversight of health care delivery that includes a defence of users'

[889] Biotech patent pools have cleared patent rights for HIV treatment and fortified genetically modified rice. See, Gold et al., *Preliminary legal review of proposed medicines patent pool. The Innovation Partnership*, 2007, online: <https://www.chaire-epi.ulaval.ca/sites/chaire-epi.ulaval.ca/files/publications/tip.pdf>; OECD, *supra note* 883.
[890] Simon et al., "Managing severe acute respiratory syndrome (SARS) intellectual property rights: The possible role of patent pooling" (2005) 83(9) Bulletin of the World Health Organization 707.
[891] See comments and surrounding text by Drouillard in Chapter 3, p. 144.
[892]The concept of good governance places responsibility on governments and governing bodies over the needs of the society as a whole rather than select sectors. See, "What is Good Governance." UNESCAP, 2009, online: <https://www.unescap.org/resources/what-good-governance> (accessed 24 November 2020).

rights to health care treatment and technology. In their role of developing solutions that can fulfill the goals of the patent system with respect to health research and care, such institutional bodies can offer best practices or guidelines for facilitating collaboration among stakeholders, for example by increasing communication and reconciling divergent interests between patent holders and the scientific communities both interested in genetics health research and care.

Institutional mechanisms for increasing communication between stakeholders can also increase opportunities for licensing opportunities and consequently expand into new avenues for collecting revenue. Such mechanisms can also motivate the development of medically necessary technologies that potentially carry fewer negative impacts on private incentive structures compared to experimental use exemptions or compulsory licensing in some cases. The development of new gene-based technologies could subsequently lead to earlier diagnoses of conditions or diseases and result in cost-savings for the health care system due to decreased reliance on the system by individuals. However, through an institutional public health approach alone, the biggest challenge is that guidelines or best practices — such as those proposed under the CHEO agreement and open science model — can be treated as optional or as mere suggestions. Through such a model, achieving the cooperation of industry stakeholders in licensing to others their patented genes may be a challenge, and getting gene patent holders to participate voluntarily could be a struggle.[893] What is needed is sufficient recognition of the right to genetic health in the provincial political system, preferably through adoption of a comprehensive provincial health policy or regulatory structure with a detailed plan for realizing the right to genetic health that is aligned with IP rights and is backed by the federal government.

[893] See, for e.g., Mireles, *supra note* 421 at 177.

If we continue to believe that patents are necessary for advancements in biomedicine, then we need to get serious about easing the tension of patents and health access that has challenged policymakers' efforts to identify and develop opportunities to make forward-thinking policy. These challenges have been laid bare by the issues of gene patenting in Canada's public health research and care. To move forward, policymakers need to focus on being cooperative rather than be satisfied with being complacent or vulnerable. This can only happen if governments are willing to act.

5.5.1 A Way Forward: Be Cooperative

Challenges to engaging in cooperative policy discussions and debate around the human gene patent controversy resulting from Canada's thirteen distinct provincial and territorial jurisdictions create a constrained Canadian policy context. Each jurisdiction has its own priorities, legislation, research funding, and provider and procurement models.[894] The siloed effect of policy differences across multiple jurisdictions is challenged further by a lack of national oversight and strategic priorities in the health innovation sector.[895] Forging stronger relationships between the government departments formulating health and innovation policy can lead to better monitoring and assessment of the impacts of patents on the health system, adequate resource allocation, and cost savings.[896] Removing silos between the departments that are responsible for health and innovation policy and strengthen their linkages will encourage more robust and contiguous policy efforts between the policy analysts within those departments on matters concerning patented genetic health

[894] Snowdon, *supra note* 497.
[895] For e.g., see Naylor D et al., *Unleashing Innovation: Excellent Healthcare for Canada*, Advisory Panel on Healthcare Innovation (Report) (Ottawa: Advisory Panel on Healthcare Innovation, 2015), online: <https://www.canada.ca/en/health-canada/services/health-care-system/advisory-panel-healthcare-innovation.html>. See also Lehoux, *supra note* 749.
[896] Lilley, *supra note* 440.

technologies. Bridging innovation policy with health sector expertise could better identify overlapping or shared interests between innovators or investors and health policy experts and ensure that publicly-supported investments and delivery of care are responsibly allocated to genetic health technologies even when effectiveness in the health sector is not yet fully assessed.

Also, developing a policy ecosystem that facilitates collaboration among public and private stakeholders in research, health care and industry in identifying and understanding each other's different goals will improve outcomes. Two strategies I champion to enhance cooperative cross-policy coordination include: (a) A single framework — an example considered in this study was the CHEO agreement — for policymaking to get governments to agree on a single principled approach to policy development, driven by a shared understanding of what we mean by good genetics health and quality of life, and (b) permanent policymaking capacity to improve coordination of knowledge sharing and collaboration involving joint actions by the state and its key stakeholders (including business interests, NGOs and civil society) to encourage consistent decision-making around priority-setting and access to technologies to adapt to changes in demand.

5.6 A Thought on COVID-19

To the extent that this work is about putting public health policy into dialogue with patent policy while also not losing sight of the social goals and values of each, the interplay of public health access and private interests in patents has never been clearer than it has been in this time of the global severe acute respiratory syndrome-related coronavirus (SARS-CoV-2, or COVID-19) pandemic. A patent-centric approach to genetic health innovation — which has included a significant contribution of government to funding S&T research and patent policies that value private sector interests — has threatened the "public" in public health policy. For instance, the

concern for public health care providers and researchers in Canada and abroad has been that public interest and the public domain have not been protected in the patenting of technologies and medicines, such as diagnostics and vaccines used in the fight against COVID-19. Patent-centric logic has limited our understanding of what and who the "public" is and has limited access to essential technologies due to prohibitive costs and a lack of dedicated policy coherence. As with the human gene patent debate, the COVID-19 pandemic has cast patent policies, which are designed (ostensibly) to encourage new treatment and technology developments for public good, into an unfavourable light.

Moreover, the pandemic has reminded us that government inaction and public policies that result in limiting equitable access to health care jeopardize our economic and social systems, similar to what we have seen in the human gene patent debate. As we have learned with respect to the pressures on researchers to commercialize their findings, the Canadian government continues to rely on the modern-day patent system and the shaping of patent policy that allows the private sector to capitalize on innovation cycles shaped by scientists to develop socially valuable technologies. With a decentralized and market-driven innovation system and limited scale-up capacity and coordination of publicly-funded infectious disease surveillance,[897] the limitations on Canadian R&D for supporting the development of domestic testing and vaccine technologies for SARS-CoV2 have been laid bare. While inequitable access to tests and vaccines has been a significant

[897] Robertson G, "'Without early warning you can't have early response': How Canada's world-class pandemic alert system failed," The Globe and Mail, 25 July 2020, online: <https://www.theglobeandmail.com/canada/article-without-early-warning-you-cant-have-early-response-how-canadas/>. But, Brewster M, "Public Health Agency launches intelligence team to prepare for future pandemics," CBC News, 24 June 2021, online: <https://www.cbc.ca/news/politics/phac-intelligence-pandemic-covid-1.6077639>.

issue throughout the pandemic,[898] the Canadian federal government has had to procure tests and vaccines from multinationals.[899]

Notably, it remains clear that the federal government continues to view patents as necessary in the fight against COVID-19 given that part of Canada's plans to increase its response to COVID-19 and to future potential pandemics involves remaining globally competitive by way of boosting domestic development of patentable pandemic-fighting technologies.[900] However, the concern is that the domestic procurement process will mean that COVID-fighting solutions, including tests and vaccines, are (or soon will be) patent-protected and the Canadian government will need to navigate the IP protecting these technologies owned by foreign entities to maintain access to these solutions.[901] However, other countries have been able to set into motion widespread access to and provision of testing that, even when contending with patents, had other institutional mechanisms in place that at times minimized the deadly impact of COVID-19 throughout waves of the pandemic.

For example, South Korea seems to have in some ways benefited from its federated coordination of health care and from past lessons learned from coronavirus outbreaks. South Korea also has a different approach to innovation policy compared to Canada that appears to include special

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[898] See, for e.g., Inveniuk J, Leon S, An uneven recovery: Measuring Covid-19 vaccine equity in Ontario, Wellesley Institute, April 2021, online: < https://www.wellesleyinstitute.com/wp-content/uploads/2021/04/An-uneven-recovery-Measuring-COVID-19-vaccine-equity-in-Ontario.pdf>.

[899] Public Services and Procurement Canada, Canada's vaccine agreements: A strategy to cover all bases, Government of Canada, 08 December 2021, online: < https://www.tpsgc-pwgsc.gc.ca/comm/aic-scr/ententes-agreements-strat-eng.html >. See also, Tasker JP, "Canada has ordered more than 400 million COVID-19 vaccine shots: Here's the progress report", Politics, CBC News, 21 May 2021, online: < https://www.cbc.ca/news/politics/canada-vaccine-deliveries-progress-report-1.6034624>.

[900] Government of Canada, *Patenting to Fight Pandemics: The Canadian Story*, Report from the Canadian Intellectual Property Office, November 2020, online: https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr04853.html.

[901] Clavette C, de Beer J, "Patents Cannot Impede Canada's Response to Covid-19 Crisis", Centre for International Governance Innovation, 06 April 2020, online: < https://www.cigionline.org/articles/patents-cannot-impede-canadas-response-covid-19-crisis/>.

attention to its industrial sector and the development of a robust industrial policy. Similar to what was reported in this study in Chapter 4, with respect to government task force efforts in the U.K. in response to the growing concerns in that country over potential impacts of Myriad's BRCA patents on health research and care delivery, prior to the pandemic, South Korea already had in place a system of close communication[902] and shared capacity building[903] between its government and R&D-intensive industry (diagnostics sector in particular). Having proactive and cooperative ties already in place meant quick turn-arounds in testing developments and thus, greater opportunities for fewer inequities in access.

Patents may incentivize innovation, but the right to exclude commercially viable products can cause even the most socially beneficial of technologies to be the most expensive. With several notable examples,[904] there have been concerns in Canada that COVID-19 vaccines and treatments will come with high price tags that threaten access to them and public health benefit while also stalling economic recovery. As discussed in Chapter 2, in Canada, decisions about patented drug pricing are in the hands of patent holders through the Patented Medicines Prices Review Board (PMPRB), a body tasked with establishing price controls to combat the disproportionate pricing of patented drugs. However, as I learned from one Canadian drug policy expert interviewed in this study, there has been long-held concern among long-time observers of Canada's patented drug

[902] Yim DS, Wang DK, "The evolutionary responses of Korean government research institutes in a changing national innovation system" (2005) 10(1) Science, Technology, and Society 31.
[903] The Government of the Republic of Korea, "How Korea responded to a pandemic using ICT: Flattening the curve on COVID-19," 15 April 2020, online: <https://www.ioe-emp.org/fileadmin/ioe_documents/publications/COVID-19/20200422_KEF_SK_and_Covid.pdf>.
[904] Examples such as access to drugs for the treatment of HIV (Truvada), diabetes (insulin), and COVID-19 (Remdesivir) in that order, see: Morgan R, "HIV prevention drugs illustrate just how bad pharmaceutical patents are for our health," NBC News, 1 December 2020, online: <https://www.nbcnews.com/think/opinion/hiv-prevention-drugs-illustrate-just-how-bad-pharmaceutical-patents-are-ncna1249428>; Ardizzone K, "Role of the US federal government in the development of GS-5734/Remdesivir," KEI Briefing Note, 25 March 2020, online: <https://www.keionline.org/wp-content/uploads/KEI-Briefing-Note-2020_1GS-5734-Remdesivir.pdf>; Belluz J, "The absurdly high cost of insulin, explained," Vox, 7 November 2019, online: <https://www.vox.com/2019/4/3/18293950/why-is-insulin-so-expensive>.

regime over the PMPRB's effectiveness in bargaining in the pricing of drug and of associative health technology.

In Canada, as in several other patent-granting jurisdictions including Europe, there is the option for governments to step in under standard compulsory licensing laws to compel patent holders to license their inventions to others to make or sell them in order to serve the public interest.[905] Moreover, under Canadian patent law, *part 12* of *Bill C-13* amends the *Patent Act* to allow the Government of Canada to respond to a public health emergency to make, use, or sell a patented invention to the extent necessary in a matter of national concern.[906] As expressed in the Myriad controversy of the gene patent debate and through the conversations held between the MOH and the Patent Policy Directorate of Industry Canada, to date, in Canada, there have been no reported cases of compulsory licensing in the jurisprudence. However, in the case of COVID-19, Canada joins a few other countries, including Germany and Chile, in having amended patent laws to facilitate the compulsory licensing of tests, vaccines and treatments.[907] Thus, there is hope that with policies like these, greater market competition is spurred, bringing with it more affordable pricing and greater access to tests, vaccines and treatments within Canada's public health care system.

The Canadian government appears to believe that serving the public's interest in health care and well-being entails ensuring the development of new treatments and technologies and protecting these developments to an extent that permits the granting of exclusive rights of commercialization to some of even the most socially valuable technologies. However, similar to the Canadian gene

[905] 't Hoen E, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines* (Amsterdam: Health Action International, 2016).
[906] *Bill C-13*, *An Act respecting certain measures in response to COVID-19*, 1st Session, 43rd Parliament, 2020.
[907] 't Hoen E, "Protect against market exclusivity in the fight against Covid-19" (2020) 26 Nat. Med. 813.

patent debate, the COVID-19 pandemic has shown us how a patent-centric approach to human gene-based technologies loses sight of the benefits of improving cross-communication and cross-policies between health researchers and care providers, the patent policy community, industry, and policymakers in order to better identify and address the needs of all Canadians, including for the most vulnerable among us.

5.7 Contributions to Knowledge

1) This study (a) provides a brief history of patent policy internationally and domestically (Chapter 2) and the issues of patents in health research (Chapter 3) and care (Chapter 4) tracking the context of the human gene patent debate through Canada's first controversial encounter over access to Myriad Genetics' BRCA patents to its most recent with the LQTS patents under Transgenomic Inc. and, (b) lays the groundwork for a better understanding of why each of these policy arenas have been important contributors to attempts to develop a broader policy context consistent with Ontario's goal to better align its innovation and commercialization agendas with its desire to deliver equitable health care through genetic research and tests.

2) Against the backdrop of a conceptual tension between the right to health and the rights attached to IP, this study (Chapter 4) represents an attempt to better understand the intersectoral issue of biotechnology patents in the genetic test provision landscape in Canada's public health care system (focused in Ontario) through consciously reconciling the shared patent and health policy normative goal of maximizing public good.

3) In exploring the normative tension at the intersection of patent policy and health policy through case studies of patented genetic tests in Ontario, this study (Chapter 5) exposed several

vulnerabilities in the governance of publicly-provided health spaces of genetics health research and care in Canada. This study also proposed opportunities, or recourse, for relieving the normative tension between the two major areas of policy in the human gene debate through recent case developments, thereby contributing to a growing literature about Canada's response to innovation, access and preparedness in health.

4) Finally, this study is unique in its use of data drawn from informants from diverse and multi- or cross-disciplinary fields, each having at one time participated in shaping the Canadian gene patent debate or having contributed to addressing the legal and/or policy challenges of its time. Informants included those who have participated in some of Canada's major gene patent cases and/or policy controversies, those who have reflected on the broader associated issues of Canada's innovation and industrial policy landscapes, those at the forefront of developing evidence-informed health care-priority setting and policy, and those who have considered problems of access to genetic health technologies through an international or social ethics lens. The data from this diverse group of informants offers the literature a distinct legal and policy profile unique to Canada's gene patent problems in its public health research and care spaces that allows for an integrated perspective in making practical recommendations to improve policy development with respect to patented genetic tests in particular.

APPENDICES

Appendix A The "What" and the "Why" Explained

Before outlining each chapter in turn, it is worth explaining how and why each became structured in the format presented. The core chapters were divided into larger sections entitled "what" and "why." The "what" set out to encompass my research of what it is (i.e., what features, frameworks, practices of law and policy) about patents and/or scientific pursuit and/or health and the normative tension between these two areas with respect to human genes that contributed to the Canadian controversy. The "why" set out to better understand and examine the key ways in which the "what" has impacted the policy discussions and debates about human gene patents. For instance, with respect to patent policy, a study of the relevant law and data from documents and informants led to my focusing on issues around domestic innovation and the role of the patent system in maximizing new invention and the public good. In the case of health policy, my methods led to focusing on issues of access to genetic tests at the point of delivery on the provisional landscape, as made more challenging by patents.

In studying the tension characterizing the intersection of patents and health, the focus was on uncertainty, evidence-informed policy, and a clash of norms. Notably, it was the focus areas pertaining to the tension between patent and health policy that led to creating a final core chapter addressing the role of an important actor network in the Canadian gene patent controversy. The final core chapter (Chapter 5) was dedicated to identifying the "who," likely familiar to long time watchers of the controversy, focused on the relationships and responsibilities between actor networks (sometimes individuals, but mostly institutions) that shaped the trajectory and outcome of the debate.

Appendix B Study Premise

The starting premise of this study focus was that patent policies should not unduly impinge on access to gene-based technology in the public health space. For example, access to patented genetic materials and test technology should not privilege those who can afford to pay for them over those who cannot, nor those who can best navigate licensing strategies. The universal right to health has been acknowledged in various manifestations of the law; at the international level in various human rights frameworks[908] and in Canada through jurisprudential recognition by the Supreme Court of *Charter* rights to timely access to care.[909]

However, and as the second starting premise, it was recognized that a flourishing of the overall health status and economic development of a country is largely determined by what becomes available through private sector initiative to research and develop new technologies and therapies, in which case patents play a significant role. While it is easy to say that the answer to facilitating access to patented gene-based materials and tests likely rests somewhere between these two premises, there are limited practical examples of how best to manage policy or the balance of interests at the intersection of patents and health.[910] In the Canadian context, an additional challenge has been the difficulty of determining Canada's national interest for aligning patent rights and public health using data that could inform appropriate alignments.[911]

[908] UDHR, *supra note* 188. Also, ICESCR, *supra note* 188 at *art.27*. The right to health is also held by the World Health Organization in its Constitution, stating "The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being …" *The Right to the Highest Attainable Standard of Health*, UNCESCROR, 22nd Sess., UN Doc E/C/12/2000/4 (2000), entered into effect 7 April 1948.

[909] For e.g., in *Chaoulli, supra note* 639. See also, Jackman, *supra note* 625.

[910] This in part is due to ambiguous evidence to date that patents are needed for the development of new technologies and the best ways forward to develop policy relating to patents. For several examples, see: Lemley, *supra note* 752 at 1334 (discussing the complicated industry-dependent relationship between patents and innovation relating to the notion that IP rights serve a social utility by encouraging innovation); Ghosh *supra note* 298 at 1315, 1322–25. And, see several works put forth by Lemley, *supra note* 306 at 107. See also, Herder, Gold, *supra note* 234. For e.g., in Bubela et al., *supra note* 647.

[911] See, *id*., at Bubela et al. The authors discuss a misalignment in part due to limited categorization data of the core activities of firms in given industries and if even the industry is itself included as a category. The authors use the example of Canada's statistical reliance on the North American Industrial Classification System (NAICS), lacking specific data about products and fields. The authors use the examples of medical devices and biotechnology in their discussion of the challenges in using such widely accepted non-specific information in making decisions about policy.

Appendix C Stakeholder Assemblages

Semi-structured interviews with individuals from several institutions and groups was used in this work to collect a better understanding of the complex technical and social relations that underpin the human gene patent debate in Canada. Stakeholder interests are explored in this chapter to better understand the purpose and goals of each in their contributions during either one event or during several key moments involving human gene patents in public health care. The mapping of stakeholder interests allows for a tracing of relations among key actors and/or groups (sometimes individuals, but mostly institutions) in the debate and offers a greater understanding of these multifaceted, multidisciplinary interactions. In particular, examining the Canadian gene patent dialogue in this way exposes the extent to which access to gene-based patents for the purposes of health research and care is shaped by people, institutions, and the technology itself. Information such as this can better inform academic analysis and public debate about the social, ethical and policy implications of patented gene-based technologies.

This work set out to identify key stakeholder assemblages who have contributed to the dialogue and debates around gene-based patents in Canada's health research and care sectors, primarily between the years of 2000–2016. In doing so, this work consults with individuals comprising the "who's who" within the discussions (further discussed in Appendix I), drawing on data from the core chapters (Chapters 2–5) to identify and associate the roles of specific actors within patent and health policy groups at the levels of both federal and provincial government. The Canadian human gene patent debate relating to access to patented gene and test technologies, including the cumulative scientific findings from which they are derived and the data they produce, is the result of complex interactions between actors as diverse as research (academic and clinical) scientists, universities and their scholars, health care professionals, the pharma and biotech industry, the patent system, patients, and consumers. The debate in Canada, and around the world, can be said to be comprised of different and often changing stakeholder networks based on the changing nature of actors (e.g., with the introduction of new approaches in the development of testing techniques) or the changing nature of society's use and demand of the technology itself. For purposes of this work, the human gene patent debate relating to access to patented gene-based technology is comprised of stakeholder groups that include academic researchers (in science, health research, patent law, innovation), life science industries (biotech and pharma), public health care services (i.e. clinicians), government (such as agencies, departments, working groups, advisories), and intergovernmental actors.

This work was also constructed keeping in mind the notion that the Canadian human gene patent debate has a history – and thereby a larger context - both national and globally, when it comes to access with respect to genetic inventions and the rise of patents with their increased use in human health care. The larger context, including the impact of patents on access to products and services, on information sharing for researchers, clinicians and patients in the broader health care setting, was kept in mind when considering the various interactions between individuals, groups and technology relating to the research, development and commercialization of the genetic health technologies discussed.

Appendix D Federal and Provincial Standing Committees Searched and Key Words Used

Key word
* variations and abbreviations were also used

Genetics	CHEO	Science and technology	(Health) policy	Genetic materials
Genome	Diagnostics	Gene patents	Genetic technology	Higher life
Breast cancer	(Medical) devices	Genes	Cancer	Intellectual property
BRCA	Patent	Patent rights	Biotechnology	Emerging technology
long QT	Cancer screening	(Patent) policy	Reproduction	Genetic tests

Federal (Committees)
Standing Committee on Health (HESA)
Standing Committee on Industry/Industry, Science & Technology (post-2000) (INDU)
Standing Committee on Justice & Human Rights (JUST)
Standing Committee on Human Rights & the Status of Disabled Persons
Standing Committee on the Status of Women (FEWO)
Standing Committee on Access to Information, Privacy & Ethics (ETHI)
Sub-Committee on *Bill C-49*, *The Human Reproductive & Genetic Technologies Act*

Ontario (Online sites)
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Key Word(s)	Session, Date, Topic
Gene patents	None
Patents on genes	None
Cancer Screening, breast	37.4, 19 June 2003, Cancer Screening
BRCA, breast cancer, genetic testing	41.2, 3 November 2016, *Human Rights Code Amendment Act* (Genetic Characteristics)
Patented technology	None
Patented rights	37.2, 19 November 2001, Pharmaceutical Industry

Appendix E Federal Authority and Legislation — Patent Policy

The Canadian *Patent Act* prescribes certain requirements that must be met for an "invention" to be considered patentable. An "invention" under *section 2* of the Canadian *Patent Act* is defined as "… any new and useful art, process, machine, manufacture or composition of matter or any new and useful improvement in any art, process, machine, manufacture or composition of matter."[912] Patentability of an "invention" is decided upon through several well-defined statutory criteria in Canada's *Patent Act* — novelty,[913] inventiveness or non-obviousness,[914] industrial applicability or utility,[915] and the invention must fall within the judicially-recognized categories of patentable subject matter (in regard to the definition of "invention" in *section 2*). While the *Act* should be read broadly, natural phenomena, laws of nature and scientific principles are excluded from patent eligibility.[916] In Canada, a human genetic sequence as a "composition of matter" or "manufacture" satisfies subject matter eligibility within the statute, and is thereby considered an "invention" valid for patentability.[917] There are three general categories of patents that include genetic materials: product patents covering genes and genetic material, process patents covering manufacturing processes, and use patents covering the use of particular products for given purposes. The current practice of the CIPO is to grant patents in satisfaction of the *Patent Act*, Patent Rules,[918] and jurisprudence for both isolated genomic (gDNA) and complementary DNA (cDNA) and derivative technologies, assuming that the other statutory requirements of patentability are fulfilled.

[912] *Canada Patent Act, supra note* 125 at s. 2.
[913] *Id.*, *s. 28.2* (the subject matter of the claim in question must not have been disclosed "in such a manner that the subject-matter became available to the public in Canada or elsewhere.")
[914] *Id.*, s. 28.3 (the subject matter of the claim in question must be subject matter that "would not have been obvious on the claim date to a person skilled in the art or science to which it pertains …").
[915] *Canada Patent Act, supra note* 125 at s. 2 (the requirement for utility — some useful function — of a product derives from the definition of "invention" in the Act as a "new and useful art").
[916] *Bilski*, *supra note* 150.
[917] *Chakrabarty, supra note* 101.
[918] SOR/96-423.

Appendix F Federal Authority and Legislation — Constitutional Principles and Granted Authority over Patents and Health.

● Constitutional Principles

Since one aspect of my research question ("what is the tension") encompasses the role of health policy in the gene patent debate, discussions about health policy will include consideration of some of the non-economic values — here, of constitutional rights and right to health — ascribed to human genetic materials. As a matter of a philosophical human right to health, the Romanow Report provided that "equal and timely access to medically necessary health care services on the basis of need" is a Canadian right, not a privilege of wealth.[919] The legislative measures undertaken by Canadian governments to ensure access to health care based on need and as enshrined in principles of equity are consistent with Canada's international human rights obligation[920] and with domestic constitutional guarantee under the Canadian *Charter of Rights and Freedoms*.[921] When an underlying principle of public health care has been put to the test, as with issues of access to care, the *Charter* has been a means to account for equitable decision-making.

As with other socio-economic rights in Canada, issues of access to care have included questions around improving accountability to patients and the public.[922] Rights such as the right to given informed consent[923] and the right to have access to one's own medical information[924] are recognized as rights *in* health care in common law.[925] Some commentators have claimed that our understandings about what life is deeply construct our social and political meanings of the biomedical and that should import a rethink of things, like genetic health technologies, as "bioconstitutional" to redefine state obligations over the care and well-being of its public.[926] There is, however, no freestanding right in Canadian law to receive health care,[927] and this led to questions about how best to ensure equitable health care user rights to those needing access the most.

Where accountability measures are lacking and explicit right-to-health legislation absent, the *Charter* has been invoked for its ability to seek accountability and respect for patient rights — *section 15* for its guarantee of equal protection and benefit of the law, *section 7* for its requirement that a loss of life, liberty and security align with the principle of fundamental justice, and *section*

[919] Romanow Commission, *supra note* 43.
[920] ICESCR, *supra note* 188 at *art. 12(1).* Also, Committee of Economic, Social and Cultural Rights, General Comment No. 14, The Right to the Highest Attainable Standard of Health, UNCESCROR, 22nd Sess., UN Doc E/C/12/2000/4 (2000).
[921] *Charter*, *supra note* 394.
[922] Jackman, *supra note* 631.
[923] A patient must consent to medical intervention. See, for e.g., *Malette v. Shulman* (1990), 72 O.R. (2d) 417, 37 O.A.C. 281.
[924] A patient must be given the information needed to make their own informed choices about medical treatment. For e.g., *Reibl v. Hughes*, [1980] 2 S.C.R. 880, 114 D.L.R. (3d) 1.
[925] Flood CM, Epps T, "Waiting for health care: What role for a Patients' Bill of Rights?" (2004) 49McGill L.J. 515 at 524.
[926] Jasanoff, *supra note* 635 at 3.
[927] See footnote text generally, *supra note* 636.

1 for its demand of demonstrable, reasonable and justified decision-making affecting access to care.[928] Examples out of the right-to-health movement have suggested that while health policy narratives in Canada are often dominated by economists and government, there is room for legal scholarship in policy analysis, given the capacity of the law to shape and challenge decision-making and resource allocation schemes. As such, my legal analysis included a reflection on the case law that may be seen as relevant to my topic surrounding leading *Charter* cases within the Canadian public health care system, such as *Eldridge*[929] and *Chaoulli*.[930]

● Constitutional-granted Authority over Canadian Patents and Health

For instance, the provinces regulate health care delivery and health insurance. The provision of funding by the federal government through the *Canada Health Act*,[931] however, ensures that provincial health insurance programs meet certain criteria. At the federal level, two ministries divide stewardship of patents and health care. Industry Canada is in charge of patent laws through its administration of the *Patent Act*[932] and of industrial policy respecting, for example, biotechnology. Health Canada is responsible for harmonizing national health policy through its administration of the *Health Canada Act*[933] and several public health agencies. Within this divisive landscape, patents on human genes and genetic tests confound an already complex regulatory landscape. Health law, where the regulation of genetic test access or availability belongs, includes a variety of provincial and federal statutes backdropped by constitutional and common law principles. Here, I chose what I considered to be the most relevant law regarding the gene patent controversy.

[928] See, *Carter, supra note* 640; *Cameron, supra note* 640.
[929] *Eldridge, supra note* 638.
[930] *Chaoulli, supra note* 639.
[931] *Canada Health Act*, *supra note* 142, c. C-6.
[932] R.S.C., 1985, c. P-4.
[933] R.S.C., 1985, c. C-6.

Appendix G Provincial Authority and Legislation — Health

Provided by the *Canada Health Act*, the overriding objective of Canadian health policy is "to protect, promote and restore the physical and mental well-being of its residents and to facilitate access to health services" without financial burden and in a "reasonable" manner.[934] As a federal state with a constitution that divides unexplicit legal authority between the federal government and its provinces, in Canada this division of power in some areas of the law can mean complex and changing rules regulated by different rule-makers. Health care is one of those areas. Drawing on an example raised above, the federal government is responsible for the regulation of medical devices and drugs, while the provinces are responsible for the delivery of such health care products and services. The federal government's constitutional authority over health care includes those relating to spending and the power "to make Law for the Peace, Order, and Good Government of Canada."[935] With respect to the funding of health care, the *Canada Health Act* establishes conditions that must be met by the provinces for federal allocations towards the provincial provision of health care. The *Canada Health Act* may be considered to be the cornerstone of health care in Canada in the sense that it is an applicable federal statute that establishes the law in accordance with financial provisions by the federal government to the provinces and territories to support the delivery of goods and services. But the *Act* does not directly regulate the delivery or operations of health care; the federal government sets limits around, for example, which medical devices are deemed to be safe and effective enough to be provided in Canada, however, how theses devices are made available to the public is under the authority of the provinces and territories.

Regulatory statutes intended to protect public health are set out by both federal and provincial governments under their constitutional duties. Key federal statutes such as the *Food and Drugs Act* govern the making and selling of medical devices (i.e., genetic tests) in Canada by setting standards and approval processes, with the help of the Canadian Agency for Drugs and Technologies in Health (CADTH). With the enumeration of patents in the Canadian Constitution,[936] the dominant assumption among both levels of government continues to be that decisions concerning the use of patents in the spaces of health research and care need to be made from within the patent law arena. As such, the expectation is that any legislation and movement on gene-based patents should be made by Parliament and the federal government. It is, however, the responsibility of the provinces to govern accessibility directly within their health care systems. There has been study into a possible dual authority of federal and provincial governments over the regulation of patented health technologies.[937] However, this work explored regulation over patented health biotechnologies from an IP perspective and not with respect to the access of these technologies under health policy objectives by end users. Nonetheless, a starting premise of this study included this perspective of IP and federalism in biomedicine more broadly. Specifically, I used this work to inform and interpret my findings in consideration of documented and informant-reported issues of access pertaining to patented genetic materials and technologies from a public health user perspective, with a particular focus on health care.

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[934] *Canada Health Act*, *supra note* 142, c.6, s.3.
[935] *Constitution Act*, *supra note* 394.
[936] *Id.*
[937] De Beer J, Brusnyk C, "Intellectual property and biomedical innovation in the context of Canadian federalism" (2011) 19 Health L.J. 45.

● Provincial Authority and Legislation (Ontario)

Through acts and regulations, the Government of Ontario has the policy authority to determine who can make what types of decisions within the government (e.g., the MOH) and among the organizations and professionals in the health system. These acts and regulations apply across the entire health system or to specific programs (e.g., the formulary or Ontario Public Drug Program), to places (e.g., public health laboratories), and to people (e.g., health care professionals). In some cases, the provincial government has retained its policy authority to make decisions (i.e., what and who gets covered under the formulary) with advisory help from particular agencies, for example, Health Quality Ontario. It has also decentralized some of its authority to government agencies, such as Health Quality Ontario. In Canada, provinces share national constraints on health care in a constitutional and macroeconomic context. For instance, as medical devices, genetic test approval happens at the federal level with the help of CADTH, which provides formulary recommendations to the provinces. It is then left to the provinces to decide independently on their uptake for use in their respective health systems.[938]

Additionally, despite the stated objective of Canadian health policy set out in the *Canada Health Act,* its purpose is directed to the funding of insured health services that are provided under provincial law.[939] Concerns that result from federal-provincial power sharing often revolve around the impact on health care delivery under provinces under pressure to reduce costs. Ontario carries the largest health care budget and is therefore an important driver of health care policy direction in the country. For example, Ontario passed the *Ministry of Health and Long-Term Care Act*[940] to establish the overall administrative structure of health systems with ministerial oversight over the entire ministry and its function, and the *Health Protection and Promotion Act*[941] intended to ensure the delivery of services to promote health and to prevent disease. Another measure, in 2010, involved the Ontario legislature's passing of the *Excellent Care for All Act,*[942] a measure through which the health ministry influences the delivery of health care by way of its agency over the quality of the health care system (i.e., the Ontario Health Technology Assessment Committee and the Ontario Genetics Advisory Committee are both under Health Quality Ontario). The *Excellent Care for All Act* sets out to link evidence-based care by consolidating policy research from provincial advisory bodies, such as those conducting health technology assessment.

Also taken into consideration in this work is the argument that society should be guaranteed medically necessary health care and that such an argument supports greater health policy-informed decisions regarding what may be thought of as "medically necessary." But formulating policy based on what is considered medically necessary in the context of scarce resources is difficult, especially in the absence of criteria for determining "medical necessity" under federal policy or legislation.[943] Still, one crucial question is whether access to certain social services, such as genetic

[938] Provinces independently retain individual requirements of which technologies become publicly funded under individual fiscal sustainability.
[939] *Canada Health Act*, *supra note* 142 at s. 4; 1995, c. 17, s. 35.
[940] RSO 1990, c M.26
[941] R.S.O. 1990, c. H.7.
[942] SO 2010, c 14.
[943] Under the *Canada Health Act*, comprehensiveness is broadly defined to include medically necessary services "for the purpose of maintaining health, preventing disease, or diagnosing or treating an injury, illness or disability." See, *Canada Health Act*, *supra note* 142, c. C-6, s.2 in description of "hospital services."

testing, should be considered medically necessary on a basis of scarce resources. For instance, a society must determine how best, if at all, to distribute a scarce resource such as health care according to an individual's differences in need, ability to pay, or social worth. Answers to this question are beyond the scope of this thesis, but in my examination of current health policy practices, I situate my analysis in consideration of an important underlying principle in Canada's public health care, namely equity.

Equitable access to care is a major objective of the Canadian health care system, as reflected in several pieces of federal legislation of the Canadian health care system. It is also an objective echoed by the provinces with the enactment of policy at the provincial level (e.g., Championing Health Equity in Ontario, Health Equity Guideline).[944] This research avenue sought to increase transparency and clarify accountability of relationships and responsibilities[945] when it comes to where decisions can be made and by whom in respect of ensuring equitable delivery and access to patented genetic materials and tests in public health settings. This dissertation does not explicitly discuss these statutes, but my exploratory research included identifying legislation that was relevant to my topic and helpful in my analyses.[946]

The pharmaceutical industry is likely the most well-established regime impacting commercial authority in the health system, and such authority is particularly important for its jurisdiction over gene-based technologies as well, such as genetic therapies and tests. The federal government has a significant role here in regulating which therapies and tests make it from laboratory to market, however, provinces have a role in developing social policy regarding the circumstances under which new technologies can be implemented or accessed and what information can be produced through their use in the health care system. Nonetheless, the commercialization of human gene-based goods and services, in part, has produced the tension that characterizes the intersection of patent and health policy, of patents in health, at the public and private interest divide. This characterization is in part due to society's assignation of non-economic values to human genes.[947] One perspective is that the field of biomedical genetics is different — society associates non-economic value to human genes that places human health in a different category from other non-health care innovation. To further an understanding of that tension at the divide, I reflected on two areas worth considering, areas that, from a public interest perspective, act to protect the well-being of society and facilitate access to health services. The first included a consideration of what communal values mean for well-being and access with respect to the human gene patent debate; the second considered the role of science and the right to benefit from its advances, which includes the right to health and promoting equitable access in health.

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[944] See, HEG, *supra note* 620.

[945] Scott C, "From welfare state to regulatory state: Meta-regulation and beyond" (2014) 11 University of Tokyo J. of Law and Politics 159.

[946] For instance, of particular note was in the *preamble* of the *Excellent Care for All Act* 2010, stating that "[t]he people of Ontario and their Government … [r]ecognize the importance of providing Ontario's health care providers with support to help them plan for and improve the quality of the care that they deliver based on the best available scientific evidence" and "[r]ecognize the value of transparency in the health care system." Also, of particular note was to *The Protection and Promotion Act* 1990, R.S.O. 1990, c. H.7, s. 2, in its intention to "to provide for the organization and delivery of public health programs and services, the prevention of the spread of disease and the promotion and protection of the health of the people of Ontario" in its Part II, 5(4) v "screening programs to reduce the morbidity and mortality of disease."

[947] Gold, *supra note* 32.

As a matter of communal values, human genetic materials carry distinct cultural and societal meanings[948] both as vehicles of information and of identity.[949] Some communal values are reflected in law, but the law can be vague and thus, can leave room for interpretations broader than what might best serve the public interest at a given time and in a given situation. Almost all genetic materials are expected to be used for health-related research, and in this way, society has linked this purpose to the goal for genetics, namely, to protect the health and well-being of human life. The more strongly human genes are attached to the cultural and social meanings we attribute to them,[950] the stronger are the principles of equity they evoke.[951] The more that human genetic materials are associated with their human origin, the more they are seen as distinct features of what it means to be human.[952] A right-to-health narrative would say that access to commercialized human gene-based materials and tests should not come at the expense of protecting the exclusive rights attached to specific legal instruments, such as patents, which can run counter to expectations of accessibility to technology and other necessary resources for health-based research and care. Recognizing that equity of access to health care is a vitally significant concept to Canadians,[953] I looked at the role of health policy in the human gene patent debate by situating the concept of medical necessity within narratives of reasonable access to health care services.[954]

As a matter of policy authority, the capacity for government to determine what data and research is required in order to make decisions about public health system adoption of health technologies, and thus, access within that system is an important factor in facilitating equitable delivery of care. Access to genetic tests can be facilitated through legislative enactment, judicial decisions, or through other measures, such as the self-regulatory environments. However, science-based decisions for legislatures and the judiciary can be difficult. For instance, the Supreme Courts in the U.S. and in Canada have emphasized that science-based decisions require an understanding of the social and economic impacts of the decisions made.[955] Committees such as those under Health Quality Ontario, including the Ontario Health Technology Advisory (HTA) Committee and the Ontario Genetics Advisory Committee, provide the MOH with empirically-driven recommendations informed by an understanding of the potential impacts relating to the medical, economic, social, and economic implications of development and use of health technology.[956] The 2004 Federal-Provincial-Territorial Advisory Subcommittee of the Deputy Ministers of Health

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[948] Gold, *supra note* 33.
[949] Koepsell, *supra note* 619.
[950] See list of contributors, *supra note* 621.
[951] For example, health equity is a key focus in the delivery of health care and services in Ontario. Health Quality Ontario frames health equity as what allows fair, need-based, and individually appropriate quality care to reach their full health potential regardless of any other factors such as who they are and what they have. Health equity is about people getting the resources they need when they need it to improve health for all. See, HEP, *supra note* 620. See also, HEG, *supra note* 620.
[952] See generally, Koepsell, *supra note* 619
[953] Romanow Commission, *supra note* 43.
[954] *Canada Health Act*, *supra note* 142 at s.3 "to facilitate reasonable access to health services without financial or other barriers."
[955] In the U.S., Justice Breyer instructed that decisions need to be "grounded in realistic predictions of what science will do, and not [in] fanciful prediction of what science might do." See, The Honorable Stephen Breyer, "Genetic Advances and Legal Institutions" in *Harvard, supra note* 35 at 199, Bastarache J writing for the majority held that "the unique concerns and issues raised by the patentability of plants and animals necessitate a parliamentary response."
[956] Giacomini et al., *supra note* 498.

called for Canadian HTA agencies to expand their scope of analysis[957] to increase policy relevancy,[958] but HTA still conventionally holds an advisory rather than a policy deliberation or decision-making capacity in the provinces. As a form of policy inquiry relating to the overall genetic test provision landscape in Ontario, I looked at the role of Ontario's genetics advisory HTA to learn about the current policy outlook on the uptake of high-demand publicly-provided testing services, such as the long QT test, in the province.

The capacity for government to deliberate on and debate human genetics and genomics data and research elicited by policy inquiries, such as those provided by the HTA community, is also an important factor in securing the delivery of equitable health care. As a matter of policy authority, expert opinion has traditionally provided a backbone to policy decision-making[959] and is one way in which governments strengthen their capacity to manage and assimilate data and research put forth for policy development considerations at an evidence-policy interface.[960] Scholarship in Canadian policy analysis, however, contends that the growing consensus by federal and provincial governments towards a more centralization of policymaking has contributed to a "hollowing-out of the policy development capacity in departments"[961] and an overall weaker policy analytical capacity.[962] I kept this policymaking context in mind for the purposes of my analyses in relation to the ability of Canadian governments to manage health policy considerations in the human gene patent debate.

In the fields of genetics and genomics, there have been efforts to buttress the impact of this gradual diminishing of departmental subject matter and policy expertise,[963] expertise that is integral to providing coherent and effective policy responses.[964] Internationally, policy advocates have debated the general role of science in informing decision-making.[965] In Canada, the 2012/2013

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[957] Henshall C, Mardhani-Bayne L, Fronsdal KB, Klemp M, "Interactions between health technology assessment, coverage, and regulatory processes: Emerging issues, goals, and opportunities" (2011) 27(3) Int J Technol Assess Health Care 253; Gibis BR, Juzwishin D, "Devolving healthcare delivery to regional health authorities: Is health technology assessment prepared to follow?" (2003) 16(1) Healthcare Management Forum 24.

[958] Health Technology Assessment Task Group, *Health Technology Strategy 1.0: Final Report* 2004 Federal/Provincial/Territorial Advisory Committee on Information and Emerging Technologies Report. See also, Levin L, Goeree R, Sikich N et al., "Establishing a comprehensive continuum from an evidentiary base to policy development for health technologies: The Ontario experience" (2007) 23(3) Int J Technol Assess Health Care 299.

[959] Haga SB, Willard HF, "Defining the spectrum of genome policy" (2006) 7 Nature Rev. Genet. 966.

[960] See generally, Lindquist EA, "Policy capacity and recruiting expertise in public services: Acquiring talent in evolving governance environments," in Dobuzinskis L, Howlett M, Policy Analysis in Canada (Chicago: Policy Press, 2018).

[961] McArthur D, "Policy analysis in provincial governments in Canada" in DHL 2007, *supra note* 612 at 247. The author contends that while empirical data to establish the extent of this is lacking, most senior deputy ministers would confirm this downward trend of diminished expertise beyond provincial premiers' offices and cabinet secretariats since the 1980s.

[962] *Id.*, at 246 (author writes this to be the case more at the provincial rather than federal level although my research (Chapter 4, 5) suggests that the watering down of expertise has also systematically happened within federal departments relating to the handling of gene patents in health).

[963] CHIR Institute of Genetics, *Initiative 4: Health services for genetic diseases — building a knowledge translation community for our genetic and biochemical discoveries*, Internal Assessment for 2011 International Review, 2011, online: <https://cihr-irsc.gc.ca/e/43733.html?pedisable=true#c4>.

[964] *Id.*, at 247.

[965] For example, the Organization of Economic and Cooperative Development argued for the need to draw on biomarker studies underpinning pharmacogenetic research into policies set out to improve the use of existing

federal budgets generated debates around government science-funding decisions and about their in-house and institutional capacity to accurately and objectively assess the information needed to inform policymaking.[966] Results from my empirical data relating to the actor network in which gene patent and health policy issues were discussed and debated prompted a brief look at the scholarship investigating the role of science in creating more robust evidence-informed policy in the area of genetics.[967]

medicines. See, Organization of Economic and Cooperative Development, Pharmacogenetics: Opportunities and Challenges for Health Innovation, OECD Innovation Strategy (Paris: OECD Publishing, 2009).

[966] GE^{3}LS, *supra note* 49 at 74.

[967] For instance, scholarship in S&T studies has devoted considerable attention to the role of science in advisory and policymaking. E.g., Jasanoff S, *The Fifth Branch: Science Advisors as Policymakers* (Cambridge, Mass.; Harvard University Press, 1990).

Appendix H Who's Who re: Policy Deliberations in Canada's Gene Patent Debate

The Canadian health care system is a mixed public-private system, pluralistic in governance and multi-stakeholder networked in structure. The *Constitution Act* establishes joint jurisdictional responsibility over health care between the provincial and federal governments.[968] The responsibility shared between the different levels of government in Canada is fractured further into a more direct role by the provinces for the delivery of health care[969] and an indirect, though powerful, role of the federal government over the use of its spending power. Coupled with a jurisdictional authority over "property and civil rights," the governance model for health care in Canada is structured under provincial laws.[970] The delivery of health care and access to care relies on the stewardship capacity of the provinces,[971] but delivery and access can be impacted by federal jurisdiction over patented innovations, by way of its authority to regulate drug safety and approval and in price control mechanisms over patented drugs and related technologies through constitutional and patent legislation. Once passed for safety and efficacy under Health Canada, the uptake of gene-based products and services is left to the provinces.[972] The SCC has, however, acknowledged that the division of power over health and health care does not rest within one level of government exclusively.[973]

At the national level, the range of heads within *section 91* of the *Constitution Act* suggests federal health-related authority, the most prominent of federal powers being the spending power of Parliament provided in *sections 91(1)(a)*, *91(3)*, and *106* of the *Constitution Act* and set out in practice under the *Canada Health Act*.[974] The *Canada Health Act* requires that "medically necessary" hospital, diagnostic, and physician services be insured under provincial and territorial plans and sets out conditions which provinces must satisfy in order to receive federal contributions for their stewardship of health care.[975] To be eligible for full federal cash contributions towards health care, the provinces must comply with five program principles, one of which is accessibility. The principle of accessibility calls for reasonable access to health care services and the prohibition of user fees (e.g., out-of-pocket payments at point of service) in an effort to mitigate barriers to access that could lead to inequalities of health care delivery. Federal health funding is especially important during a crisis; by Fall 2020, provincial and territorial level spending alone amounted to more than CDN $29 billion in response to COVID-19-related costs.[976]

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[968] *Constitution Act*, *supra note* 394.
[969] *Id*., at *s. 92(7)* (giving the provinces exclusive jurisdiction over the "establishment, maintenance, and management of hospitals, asylums, charities, and eleemosynary institutions"). See also*, Eldridge, supra note* 927 at para 24 (holding that the *Charter* applies to hospitals, extending the application of the *Charter* under *s.32*).
[970] *Id.*, at *s. 92(13)*, affirmed in *Eldridge, supra note* 638.
[971] *Canada Health Act*, *supra note* 142.
[972] See generally, Klein A, "Jurisdiction in Canadian Health Law," in Erdman et al., *supra note* 625.
[973] See generally, *supra note* 927. Also, *Canada (Attorney General) v. PHS Community Services Society*, [2011] S.C.J. No. 44, 2011 SCC 44 at para. 68 (S.C.C.).
[974] The *Canada Health Act* is an example of the use of the federal spending power in respect of the Canada Health Transfer that may be provided the *Federal-Provincial Fiscal Arrangements Act sections 24.2* and *24.21*.
[975] *Canada Health Act*, *supra note* 142 at *s.2*. See discussion, Jackman, *supra note* 625 at 98.
[976] *Id.* at 14.