



At the intersection of health and intellectual property: Issues, tools and directions for Health Canada

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EXECUTIVE SUMMARY

As part of its mandate to maintain and improve the health of Canadians, Health Canada's responsibilities include developing policy at the intersection of health innovation, health impact, and access to health care. This Report examines some of the policy challenges that lie ahead at the intersection of health and intellectual property and makes recommendations about how Health Canada can, within its mandate, positively affect policy development in these areas.

The Canadian health innovation environment is complex both in terms of regulatory framework but in terms of actors and interests. Health Canada exercises regulatory authority under a number of federal laws including the *Food and Drugs Act*, the *Canadian Environmental Protection Act* and the *Pest Control Products Act*, and the Patented Medicines (Notice of Compliance) Regulations (the "NOC Regulations"), each of which affects which health products are developed, which are placed on the market and by whom. Other agencies reporting to the Minister of Health, such as the Canadian Institutes for Health Research, the Patented Medicine Prices Review Board (PMPRB), the Public Health Agency of Canada (PHAC), and Assisted Human Reproduction Canada (AHRC), develop policies that have – to a greater or lesser degree – an impact on Canada's health innovation environment. Finally, other government departments and agencies, notably Industry Canada and the Canadian Intellectual Property Office, have mandates that include innovation policy (including health innovation) and the delivery of innovation through the private sector.

By way of background, the report describes Canada's R&D and manufacturing capacity in pharmaceuticals, biologics and medical devices. Unfortunately, the data is inconsistent and sparse. Nevertheless, it can readily be observed that the primary funder for Canada's R&D activities is the public sector. Industry investment is still significant although much is invested in

clinical trials that result in few patents and low levels of training. Canada has a large trade deficit in both biopharmaceuticals and medical devices. This is likely related to the historically low levels of industrial investment in Canadian R&D and to the poor (from an innovation perspective) quality of that investment that leads to less product development in Canada.

Canada faces a number of challenges with respect to health innovation. These include the following:

1. Ensuring that university research – funded in the greatest part by the public sector contributes to further research and innovation. Universities can better contribute to the innovation environment by ensuring that their inventions and their materials are made widely available to other researchers and industry.
2. Part of the problem in helping universities meet this goal is the lack of empirical data to measure IP and health impact. Given that new innovation models focusing on collaboration and partnerships are emerging in the life sciences, new metrics are required. Further, there is a need to assess licensing practices of TTOs and their equivalents, as well as Canadian patenting data.
3. The NOC system is producing inefficiencies given that both patent holders and generic producers litigate every conceivable aspect of the *NOC Regulations* and the underlying *Patent Act*, creating significant delays and costs.
4. The problem of sub-standard and counterfeit medicines is relatively small in Canada. Nevertheless, Canada, along with other countries, is negotiating the Anti-Counterfeiting Trade Agreement (ACTA), in which Canada has taken the position that the key ACTA obligations dealing with counterfeit medicines would be limited to trademark counterfeiting enforcement.

5. Traditional knowledge (TK) is a critical aspect of the Canadian health innovation system – it can be both a source of new innovation and can play a role as a complementary health intervention for First Nations, Inuit and Métis. Overall, Canada has made little practical progress toward the national implementation of access and benefit sharing provisions or any formal recognition of property or other rights specifically in TK despite being a signatory to the *Convention on Biological Diversity*.

While Health Canada must operate within its mandate, by coordinating activity with agencies that report to the Minister of Health and with other governmental departments, Health Canada can play an important facilitating role in ensuring that Canadians benefit from new health technologies and services. In short, Health Canada can facilitate better policy coherence between Health Canada and Industry Canada with respect to health and intellectual property; provide a coordinated response against problematic business models such as those pursued by genetic diagnostic companies; promote new open models of innovation to support research and biomedical product development such as public-private partnerships; assist Industry Canada in making changes to the NOC Regulations that will limit litigation and achieve its stated policy objective; encourage the Department of Foreign Affairs and International Trade to ensure that the scope of ACTA in dealing with the issue of substandard drugs is limited to trade-mark infringement; provide the media with clear information and data that build up Canadian capacity in policy development; facilitate data collection on health and IP; engage First Nations and Inuit Peoples in Access and Benefit Sharing; and develop internal Health Canada IP policies on whether and when to patent its inventions, whether, when and with whom to license those inventions and whether, when and with whom to openly share data.

RECOMMENDATIONS

Recommendation 1: Health Canada should, jointly with Industry Canada, create an inter-departmental working group on intellectual property and health. The mandate of this working group should be to pro-actively identify and address issues that cross their mandates, such as issues relating to the *NOC Regulations* and issues of biomedical innovation and access to health products.

Recommendation 2: Through the inter-governmental working group proposed in Recommendation 1, Health Canada and Industry Canada should examine the recommendations put forward by the Secretary's Advisory Committee on Genetics, Health and Society to determine their applicability and implementation in Canada.

Recommendation 3: Health Canada should encourage the Minister of Health to adopt a coordinated approach to gene testing and commercialization that involves not only Health Canada but the Canadian Institutes for Health Research.

Recommendation 4: Health Canada should ensure that its own licensing policies and practices correspond to the OECD *Guidelines on the Licensing of Genetic Inventions* and to *In the Public Interest: Nine Points to Consider in Licensing University Technology* and the *Rome Agenda*.

Recommendation 5: Health Canada should facilitate discussions among the research and industrial communities on how best to structure and support public-private partnerships in pre-competitive research. These discussions should address issues of intellectual property, licensing and access.

Recommendation 6: Through the inter-departmental working group proposed in Recommendation 1, Health Canada and Industry Canada should share information on the functioning of the NOC regime to identify problems and concerns.

Recommendation 7: Health Canada should support the Department of Foreign Affairs and International Trade in limiting the scope of ACTA to trade-mark infringement so as not to interfere with the functioning of the Canadian health innovation system and access to generics.

Recommendation 8: Health Canada should prepare policy documents that are accessible to the public over matters of health innovation. This could include, for example, information about patents and generic pharmaceuticals and research that it conducts.

Recommendation 9: Health Canada should provide all of its research data, data collected in the course of carrying out its regulatory duties (subject to confidentiality and data protection laws) in an open, accessible manner to researchers. It should encourage the Canadian Institutes for Health Research and the Canadian Intellectual Property Office to make their data similarly accessible and to work together to link health-related patents, research and data in an accessible manner.

Recommendation 10: Health Canada should develop policies, in conjunction with the Canadian Institutes for Health Research, the Department of Indian and Northern Affairs, and Environment Canada with respect to access to and the use of traditional knowledge and genetic resources in health research and delivery.

Recommendation 11: Health Canada should develop an internal intellectual property policy that stresses the sharing of research materials, results and data. At this time, the costs of opening a technology transfer office within Health Canada do not seem to justify the benefits of doing so.

INTRODUCTION

As part of its mandate to maintain and improve the health of Canadians, Health Canada is responsible for developing policies and regulations to ensure the safety and efficacy of new drugs and devices and is committed to improving health care systems across the country. For the purposes of this report, the mandate covers a range of tools from establishing regulatory policy, to funding health research and assessing technology. In coordination with Industry Canada – which has responsibility over industrial policy, including intellectual property – Health Canada has an important role in ensuring that Canadians benefit from the best health products and services in a safe and effective manner.

Given the breadth of its mandate over new health technologies, it is natural that Health Canada should be concerned about (1) the impact of its policies over intellectual property and (2) the impact of intellectual property over its policies. For example, regulation may unintentionally disturb innovation environments in which intellectual property acts. Conversely, intellectual property policy may inadvertently encourage market conduct that undermines, rather than enhances, the ability of Canadians to benefit from leading edge health technology. By examining these issues, Health Canada can proactively develop policies, together with Industry Canada, provincial health departments and appropriate federal agencies, that diminish the chances of adverse or conflicting effects.

In previous work for Health Canada, we have examined issues related to the licensing of genetic inventions and university technology transfer,¹ particularly in light of international instruments such the OECD's *Guidelines on the Licensing of Genetic Inventions*,² in which

¹ Tina Piper and E. Richard Gold, *Practices, Policies and Possibilities in Licensing of Human Genetics*, a study for Health Canada, April 18, 2008, available online at: <http://www.theinnovationpartnership.org/data/documents/00000015-1.pdf> (accessed March 15, 2010)

² OECD, *Guidelines for the Licensing of Genetic Inventions*, (Paris: OECD, 2006) available online at:

Health Canada played a prominent role. With the increasing pace of change in both innovation and in the environment in which innovation occurs, Health Canada confronts these as well as many other issues. In addition to examining the implications of intellectual property on genomics and recent scientific advances, these include changing business models, particularly in the pharmaceutical sector, the significance of pharmaceutical product costs for the sustainability of health systems and the role of traditional knowledge in promoting health, especially for First Nations, Inuit and Métis communities.

This report describes the above issues and examines the policy tools that Health Canada has to address them. In Part I, we set out the legislative, institutional and policy context in which these issues arise. This sets the stage for the discussion in Part II in which we describe some of the more pressing issues facing innovation in health products and services today. Part III begins a discussion of the policy tools at the disposal of Health Canada to address, within its jurisdiction, these issues. This part also points to where useful coordination with other departments, agencies and institutions may best address policy concerns. The report ends with a conclusion that sets out steps that Health Canada may wish to consider to address the issues discussed in this report.

PART I: THE CANADIAN CONTEXT

Issues related to health product innovation cross through many aspects of federal jurisdiction that comprise and extend beyond Health Canada's mandate. In this Part, as background, we sketch out the legal and regulatory environment in which health product innovation exists. This will establish the context for the discussion of challenging issues in Part II and the policy tools available to Health Canada to address those issues in Part III.

<http://www.oecd.org/dataoecd/39/38/36198812.pdf> (accessed March 15, 2010).

a. The Regulatory Framework at the Intersection of IP and Health

Health Canada's regulatory mandate under the *Food and Drugs Act*, the *Canadian Environmental Protection Act*³ and the *Pest Control Products Act*⁴ have a significant impact on health innovation in Canada and constitute non-patent barriers to entry into the Canadian market that complements the patent regime. According to its mandate, Health Canada ensures the safety and efficacy of biologics and gene therapies (e.g., blood and blood products, viral and bacterial vaccines, gene therapy products, tissues, organs and xenografts), health products and biotechnology products.⁵ Regulation over safety and efficacy of products takes place not only prior to obtaining approval to sell the product in Canada but also through post-sale monitoring. One of the largest costs in drug development involves clinical trials.

There are three implications to Health Canada's regulatory mandate. First, the cost of complying with regulatory requirements – including clinical trials – is used to justify existing patent rights. The argument is that with high and increasing costs of clinical trials, companies need secure and exclusive market access in order to recoup their investments in research and development. Second, the cost of meeting regulatory requirements presents a significant barrier to market access in addition to that provided by patents. Only firms with substantial financial resources that can carry the costs of investment for a long period of time can afford to enter the market. Data protection rules maintain this barrier by preventing Health Canada from sharing clinical data with later entrants for a period of eight years (eight and a half years for pediatric medicines).⁶ Third, linkages between market approval and patents lead to attempts to balance the

³ Canadian Environmental Protection Act, S.C. 1999, c. 33.

⁴ Pest Control Products Act, S.C. 2002, c. 28.

⁵ See <http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/index-eng.php>.

⁶ Regulations Respecting Food and Drugs, C.R.C., c. 870, s. C.08.004.1.

interests of innovator companies in recouping their investments against those of the general public and generic companies in particular.

There are other policies at both the federal and provincial levels that also have an impact on health innovation and access such as reimbursement policies, technology assessment and the sharing of best practices. While relevant, these policies are not directly within the scope of this report.

The Patent Act

Canada's *Patent Act* sets out the terms for patent protection over inventions that are new, useful and non-obvious. The goal of this law is to stimulate the creation of new technologies with practical applications through the grant of exclusive rights to make, use, sell and import inventions for a period of 20 years. Without patent protection, anybody could copy them and compete with the originator without incurring the full costs of the inventive process and of building market demand and a distribution process.⁷

Patents have, throughout their history, been a controversial means of encouraging innovation and are certainly not the only means of doing so. A patent abolition movement in the 19th century and an investigation by Congress in the late 1940s and early 1950s provide two historical examples of this.⁸ Contemporary debates over patents, biomedical innovation and access to affordable and appropriate health technologies are but the modern exemplars of this debate.⁹ The crux of these controversies is that, despite increasing study, we understand relatively little about how patents function in practice and their interrelationship with increasingly complex innovation systems. While economic theories abound – some heralding the

⁷ D. Vaver, *Intellectual Property Law* (Toronto: Irwin Law, 1997) at 113 [Vaver].

⁸ Fritz Machlup and Edith Penrose, "The Patent Controversy in the Nineteenth Century" (1950) 10 J. of Econ. Hist. 1.

reward for investments into innovation, others the coordinating function of patents as property rights – these debates will continue at least until and unless we have empirical evidence pointing clearly in one direction or another. We do know that the business models of pharmaceutical, (and, to a lesser degree, biotechnology and medical equipment industries) rely on patents as a means of maintaining vertical integration over the innovation and commercialization processes, attracting investment, and trading knowledge.¹⁰ In any event, and despite the absence of clear empirical evidence, policy-making continues.¹¹

The Patented Medicines (Notice of Compliance) Regulations

As part of Health Canada’s mandate under the *Food and Drugs Act*¹² to regulate the safety and efficacy of pharmaceuticals, Health Canada is also responsible for portions of the Patented Medicines (Notice of Compliance) Regulations¹³ (the “NOC Regulations”), enacted pursuant to subsection 55.2(4) of the *Patent Act*.¹⁴ (Industry Canada is, however, ultimately responsible for the NOC Regulations themselves). The *NOC Regulations* establish patent-related rules that innovators and generic manufacturers must follow in seeking marketing approval for drugs subject to patent rights. These regulations have a clear innovation policy objective: to facilitate R&D and distribution of new therapeutics to Canadians by balancing the interests of innovators in maintaining the exclusivity accorded by virtue of their patents with the interests of generic manufacturers and their timed ability to enter the market upon expiry of the innovator’s

⁹ See, generally, E. Richard Gold, Warren Kaplan, James Orbinski, Sarah Harland Logan and Sevil N-Marandi, “Are Patents Impeding Medical Care and Innovation?” (2010) 7 PLoS Medicine: e1000208. doi:10.1371/journal.pmed.1000208. See also F.M. Scherer “The Economics of Human Gene Patents” (2005) 77 Academic Medicine at 1350.

¹⁰ Scherer, *supra*, note 9.

¹¹ E. Richard Gold, Tania Bubela, Fiona Miller, Dianne Nicol and Tina Piper, “Gene patents – more evidence needed, but policymakers must act” (2007) 25 Nature Biotechnology 388. But see, Timothy Caulfield, Robert Cook-Deegan, Scott Kieff and John Walsh, “Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies” (2006) 24 Nature Biotechnology 1091.

¹² *Food and Drugs Act*, R.S., 1985, c. F-27

¹³ Patent Medicines (Notice of Compliance) Regulations SOR/93-133, as enacted by S.C. 1993, c. 2, s. 4; 2001, c. 10, s. 2.

¹⁴ Patent Act R.S.C., 1985, c. P-4, 55.2(4) (as enacted by S.C. 1993, c. 2, s. 4; 2001, c. 10, s. 2).

patents.¹⁵ Thus, the *NOC Regulations* are a central component of the pharmaceutical innovation system.

In order to achieve the policy objective, the *NOC Regulations*, along with the *Food and Drug Regulations*,¹⁶ establish the following scheme.¹⁷ When an innovator seeks approval to market a drug – that is, a notice of compliance that the drug meets safety and drug efficacy standards – it must file a new drug submission (NDS) and list¹⁸ all the patents that it holds relevant to the drug on the Patent Register, which Health Canada maintains. Once it is established that the innovator meets the regulatory standards, the Minister issues an NOC.¹⁹

When a subsequent manufacturer – usually a generic, called a “second person” by the Regulations – seeks approval to market a generic version of the drug, the normal rule that Health Canada approves the drug following a demonstration of bioequivalence with a drug that has an issued NOC is suspended when a listed patent continues to exist in respect of that drug. In such a case, the Minister may only issue an NOC once the generic has proven not only bioequivalence, but also that either it is not infringing any valid patents listed on the Patent Register with respect to the innovator’s NOC, or that the patent in question was invalidly listed on register, has expired

¹⁵ Regulatory Impact Analysis Statement, *Canada Gazette*, Part II on October 18, 2006; *AstraZeneca Canada Inc. v. Canada (Minister of Health)* [2006] 2 S.C.R. 560 at paragraphs 15, 16 and 38

¹⁶ Food and Drug Regulations, C.R.C., c. 870

¹⁷ See *Ferring inc. v. Canada (Health)* [2007] FC 300 for a detailed description of the scheme. The Supreme Court of Canada also deal with the Regulations in *AstraZeneca Canada Inc. v. Canada (Minister of Health)* (2004), 36 C.P.R. (4th) 519, *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, [2005] 1 S.C.R. 533 and *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)*, [1998] 2 S.C.R. 193 (*Merck Frosst*)

¹⁸ Section 4(2) of the Regulations set out the criteria used to whether a patent is to be listed or not. To be listed, the patent must contain: (a) a claim for the medicinal ingredient and the medicinal ingredient has been approved through the issuance of a notice of compliance in respect of the submission; (b) a claim for the formulation that contains the medicinal ingredient and the formulation has been approved through the issuance of a notice of compliance in respect of the submission; (c) a claim for the dosage form and the dosage form has been approved through the issuance of a notice of compliance in respect of the submission; or (d) a claim for the use of the medicinal ingredient, and the use has been approved through the issuance of a notice of compliance in respect of the submission

¹⁹ Note that there may be many NOC related to the same drug depending on the use of the drug and patents are only listed for a particular NOC. Note also that once an NOC has been obtained, the innovator can make supplemental fillings (administrative and technical issues such as name changes, merger of corporations to changes to the drug itself) by way of a supplemental new drug submission (S/NDS).

or that the manufacturer does not qualify as a “second person”²⁰ as described in the NOC Regulations and so, does not need to address the patents.

Since its enactment in 1993, this scheme has led to substantial litigation. If the Minister decides to issue the NOC to the generic manufacturer, the innovator may challenge this decision by way of judicial review to the Federal Court, with appeal potentially going all the way to the Supreme Court of Canada. Alternatively, should the generic manufacturer choose to challenge either the listing of the innovator’s patent on the register or the validity of the patent, this will set in motion a series of court procedures. The generic manufacturer has to issue a Notice of Allegation setting out the grounds for the challenge (section 5 of the NOC Regulations). The innovator then has 45 days within which to commence an application for an order prohibiting the Minister from issuing a notice of compliance until after the expiration of a patent that is the subject of the notice of allegation (usually in the Federal Court). If the innovator fails to respond within 45 days, the Minister may issue the NOC. Note, however, that failing to respond does not prevent the innovator from pursuing the generic manufacturer for patent infringement under the *Patent Act*. Unless the innovator does respond within 45 days or proceedings have concluded in favor of the generic, the Minister must wait 24 months before issuing an NOC.

Given the complexity of the NOC scheme, the litigious nature of the parties, and frequent modifications to the NOC Regulations, it is unclear whether the NOC Regulations achieve the stated policy objective of appropriately balancing the interests of innovators and generic companies. That is, the *NOC Regulations*, as implemented, may not appropriately serve either Canada’s interests in promoting biomedical innovation or its desire to ensure access to technologies.

²⁰ The definition of a “second person” has been the subject of much litigation (see *Ferring inc. v. Canada (Health)* [2007] FC 300). The Regulations define a “second person” as the person referred to in subsection 5(1) or (2) who files a submission or

Price Controls

Prior to 1987, Canada relied on compulsory licences as the means through which to ensure that pharmaceutical prices remained affordable. Because of the vertically integrated²¹ structure of the pharmaceutical industry adopted from the late 1930s to meet increasing regulatory demands, the fact that physicians – not patients – made decisions about which medicines to purchase but did not have to pay the cost of those medicines, and the increased importance of marketing, the market did not, itself, provide adequate mechanisms to ensure adequate downward pressure on prices.²² The adoption of compulsory licensing in 1969 for all medicines led to Canada having the lowest costs of medicines in the 1970s.²³

Due to increasing emphasis on trade and to complaints about Canada's system from trading partners, Canada amended the *Patent Act* in 1987 to phase-out compulsory licences as the preferred means of controlling pharmaceutical prices in favour of regulatory review by an independent, quasi-judicial agency: the Patented Medicine Prices Review Board (PMPRB). The PMPRB's mandate is to ensure that the prices of patented drugs are reasonable compared to those in other developed countries. Data supplied by pharmaceutical companies indicate²⁴ indicates that the PMPRB reports annually to Parliament on its activities, on R&D spending by pharmaceutical companies and on drug pricing trends.²⁵

In respect of most medicines that represent either a change in dosage or a small improvement, the PMPRB compares the price of medicines sold on the Canadian market to

supplement referred to in those subsections.

²¹ Vertical integration in this context applies to a firm that controls all aspects of the pharmaceutical development pipeline from R&D to marketing and sales.

²² Peter Temin, "Technology, Regulation, and Market Structure in the Modern Pharmaceutical Industry" (1979) 10 *Bell J. of Econ.* 429.

²³ Danyl Stotland. *Biotechnology Law Report*. February 1987, 6(1): 13-15. doi:10.1089/blr.1987.6.13.

²⁴ *Patent Act*, R.S.C. 1980 c. P-4, s. 88; *Patented Medicines Regulations*, S.O.R./94-688, ss. 5 and 6

²⁵ *Patent Act*, R.S.C. 1980 c. P-4, s. 89.

existing Canadian medicines.²⁶ For breakthrough medicines, the PMPRB will compare the Canadian price to the median price in seven reference countries: France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States.²⁷ When prices exceed these amounts the PMPRB will commence an investigation.

Should the PMPRB find a price to be excessive, the company has the choice of either agreeing to cut its price and pay excess revenues to the federal government or, alternatively, having a public hearing held by the PMPRB. If the hearing supports the conclusion of an excessive price, the PMPRB will impose a penalty of up to twice the amount of excess revenues earned by the drug in question.²⁸

b. Agencies Reporting to Minister of Health

In addition to Health Canada, several agencies with a role (often peripheral) over health innovation report directly to the Minister of Health. We outline these here.

Public Health Agency of Canada

Created pursuant to federal legislation, the Public Health Agency of Canada (PHAC) is the principal federal agency responsible for public health.²⁹ PHAC's primary goal is to strengthen Canada's capacity to protect and improve the health of Canadians and to help reduce pressures on the health-care system.³⁰ To do this, PHAC seeks to promote good health, help prevent and control chronic diseases and injury, and protect Canadians from infectious diseases and other threats to their health.³¹

²⁶ *Patent Act*, R.S.C. 1980 c. P-4, s. 85. See also PMPRB, Frequently Asked Questions, <http://www.pmprb-cepmb.gc.ca/english/View.asp?x=272#16> (accessed March 15, 2010).

²⁷ Patented Medicines Regulations, S.O.R./94-6888, Schedule.

²⁸ *Patent Act*, R.S.C. 1980 c. P-4, s. 83.

²⁹ Public Health Agency of Canada Act, R.S. 2006, c-5.

³⁰ Public Health Agency of Canada, *Who We Are* online: Public Health Agency of Canada <http://www.phac-aspc.gc.ca/about_a_propos/who-eng.php>.

³¹ *Ibid.*

PHAC's mandate neither touches directly on innovation policy or intellectual property. Nevertheless, in addressing infectious diseases and preparing for and responding to public health emergencies, it may be faced with questions of intellectual property over, for example, vaccines or medicines. In an emergency, should PHAC determine that a medication or vaccine cannot or will not be produced by a patent holder in sufficient quantities and of sufficient quality, it may suggest to the Minister of Health, for example, that the Minister seek a compulsory licence over that medication or vaccine under sections 19 and 19.1 of the *Patent Act*. Under ordinary circumstances, the Commissioner would only consider granting an application for a compulsory licence after the government has attempted to obtain authorization from the patentee under reasonable commercial terms. However, s. 19.1(2) of the Act provides that the government is exempt from this obligation in cases of “national emergency or extreme urgency or where the use for which the authorization is sought is a public non-commercial use.”³²

While PHAC has never made such a recommendation, the question of a compulsory licence in emergency circumstances was debated in Canada during the 2001 anthrax scare. The then Minister of Health, Allan Rock, never made a formal request for ciprofloxacin at that time.

Assisted Human Reproduction Canada

Created in 2006 by an Order in Council pursuant to the Assisted Human Reproduction Act,³³ Assisted Human Reproduction Canada (AHRC) is responsible for protecting the health, safety, dignity and rights of Canadian donors, patients and offspring of assisted human reproduction technologies.³⁴ AHRC has no direct role over the patent system. Nevertheless, as a regulatory body contemplated by the Act to eventually (when regulations are promulgated) regulate certain

³² *Patent Act*, R.S.C. 1985, c P-4, s. 19.1.

³³ Assisted Human Reproduction Act, R.S. 2004, c. 2.

forms of biomedical research – namely human reproductive material – AHRC will likely have an impact on the type of regenerative medicines and reproductive technologies being researched, and thus patented, in Canada. As the interaction between AHRC rules, biomedical research funding and patent law is complex, it is important to examine the spill-over effects of AHRC decision-making on the innovation environment. For example, the AHRC strictly controls research involving human embryos, including human embryonic stem cells. At the same time, fertilized eggs and totipotent stem cells are not patentable subject matter in Canada.³⁵

Canadian Institutes for Health Research

The Canadian Institutes for Health Research³⁶ (CIHR) is responsible for the funding of health research in Canada.³⁷ While the CIHR has no direct responsibility over the patent system, its rules and regulations have a significant impact on how university researchers and universities patent health innovations and manage those patents. For example, the CIHR collects information on the number of patents held by researchers who apply for funding and makes this information available to peer-review committees. Under some funding programmes, researchers must work with an industry partner that is likely to patent.

Unlike the National Institutes of Health (NIH), CIHR's equivalent in the United States, the CIHR has not issued any guidelines for its funded researchers with respect to the patenting of certain biomedical inventions. For example, the NIH has issued guidelines on the sharing of biomedical resources³⁸ and the licensing of human genes.³⁹ Further, CIHR has so far taken no

³⁴ Assisted Human Reproduction Canada, *About Us*, online: Assisted Human Reproduction Canada <<http://www.ahrc-pac.gc.ca/doc.php?sid=7&lang=eng>>.

³⁵ Canadian Intellectual Property Office, *Manual of Patent Office Practice* Chapter 17. [http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/vwapj/2009-01-01chapitre17-chapter17-eng.pdf/\\$file/2009-01-01chapitre17-chapter17-eng.pdf](http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/vwapj/2009-01-01chapitre17-chapter17-eng.pdf/$file/2009-01-01chapitre17-chapter17-eng.pdf). A totipotent stem cell is one with the potential to proceed through all stages of development and form a whole organism.

³⁶ Created by the Canadian Institutes for Health Research Act, R.S. 2000, c. 6.

³⁷ Canadian Institutes of Health Research, *Our Mission* online: Canadian Institutes of Health Research <<http://www.cihr-irsc.gc.ca/e/7263.html>>.

³⁸ Department of Health and Human Services, *Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts*, (1999) 64 Federal Register 72090-72096

action to implement the OECD's *Guidelines on the Licensing of Genetic Inventions*⁴⁰ despite the prominent role played in their creation by Health Canada.

Patented Medicines Price Review Board

The role of the PMPRB is discussed above in the section dealing with price controls.

c. Canada's R&D and Manufacturing Capacity in Pharmaceuticals, Biologics and Medical Devices

Surprisingly, there is little consistent or coherent data available on Canada's research and development environment, manufacturing capacity, domestic markets and trade and investment flows for pharmaceuticals, biotechnology and medical devices. The reason for this is due to the fact that official statistics in Canada are based on the North American Industrial Classification System (NAICS) that categorizes each company according to its core activity. For example, the NAICS does not have a category for biotechnology. Medical devices are not just confined to Medical Equipment and supplies manufacturing (NAICS 33911) but overlap with other categories such as Electromedical and Electrotherapeutic Apparatus Manufacturing (NAICS 334510), Irradiation Apparatus Manufacturing (NAICS 334517) and Other Electronic and Precision Equipment Repair and Maintenance (NAICS 811219). In the case of pharmaceuticals, NAICS does not list pharmaceutical companies as a category but, instead, pharmaceutical and medicine manufacturing (NAICS 32541). In this category, only companies with pharmaceutical manufacturing as their core activity are listed. A pharmaceutical company more focused on R&D, as with many contract research organizations or human health biotech companies, is often listed in a different category, such as Research and Development in the Physical, Engineering and Life Sciences (NAICS 541710), Other Specialized Design Services (NAICS 541490), Other

³⁹ Department of Health and Human Services, *Best Practices for the Licensing of Genomic Inventions: Final Notice*, (2005) 70 Federal Register 18413-18415.

Scientific and Technical Consulting Services (NAICS 541690) or Medical and Diagnostic Laboratories (NAICS 621510). Each of these categories includes not only pharmaceutical firms but other types of firms, which makes it very difficult to provide accurate information specific to pharmaceuticals. The problem is even more acute for biotechnology due to the lack of a specific category. Nevertheless, drawing on a variety of sources, we attempt, in this section, to provide an overview of the current situation.

The Pharmaceutical Industry (Name Brand and Generic)

According to IMS Health, Canada has the seventh largest pharmaceutical market in the world, accounting for about 2.5% of the world market by sales, with an annual growth of 8% (fourth fastest growing market). According to Statistics Canada, the Canadian pharmaceutical industry employed 27,376 employees in 2007, obtained revenues of \$8.3 billion, and produced \$4.8 billion in added-value. In 2007, the Canadian pharmaceutical industry exported \$6.8 billion worth of medicines while Canada imported \$12.2 billion, leaving a trade deficit of \$5.4 billion. All but one of the top 10 pharmaceutical companies in Canada are located in either Montreal or Toronto.⁴¹

Canada's Research and Development Based Companies (R&D) estimated that their members (brand name companies) spent \$1.21 billion in research and development expenditures in 2006. According to the Patented Medicines Prices Review Board's (PMBRB) 2008 Annual Report⁴², the distribution of R&D expenditures for patented medicines is as follows:

⁴⁰ OECD, *Guidelines for the Licensing of Genetic Inventions* (Paris: OECD, 2006) available online: <http://www.oecd.org/dataoecd/39/38/36198812.pdf> (accessed March 15, 2010).

⁴¹ *Ibid.*

⁴² Online at: <http://www.pmprb-cepmb.gc.ca/English/View.asp?x=1211&mp=91>

Table 1: Current R&D Expenditures by R&D Performer, 2008 and 2007

R&D Performer	2008		2007		Annual Increase in Expenditures (%)
	\$Millions	%	\$Millions	%	
Intramural	620.5	49.2	679.5	53.3	-8.9
Patentees	620.5	49.2	679.5	53.3	-8.9
Extramural	640.8	50.8	594.5	46.6	7.7
Universities and Hospitals	162.1	12.9	177.1	14.0	-8.5
Other Companies	282.6	22.4	251.4	19.7	11.9
Others	196.1	15.5	166.0	13.1	18.1
Total	1261.3	100.0*	1274.0	100.0*	-1.0

Source: PMPRB

* Values in this column may not add to 100.0 due to rounding

Table 2: Current R&D Expenditures by Source of Funds, 2008 and 2007

Source of Funds	2008		2007		Annual Increase in Expenditures (%)
	\$Millions	%	\$Millions	%	
Company Funds	1182.7	90.2	1207.3	91.1	-2.1
Federal/Provincial Governments	36.3	2.8	32.8	2.5	10.7
Others	91.7	7.0	84.9	6.5	8.0
Total	1310.7	100.0*	1325.0	100.0*	-1.1

Source: PMPRB

* Values in this column may not add to 100.0 due to rounding

As Table 3 demonstrates, only a small proportion (15.9%) of funding is provided to basic research that is critical to the sustainability of Canada's research environment, as opposed to the more expensive but less significant for Canada's scientific infrastructure, spending on clinical research. Note, further, that in general, a tax subsidy of more than 50% is available for R&D

expenditures.⁴³ By taking into account a conservative 50% tax subsidy for R&D, net business expenditures for R&D account for less than 20% of total R&D funding in the health field in Canada.

Table 3: Current R&D Expenditures by Type of Research, 2008 and 2007

Type of Research	2008		2007		Annual Change in Expenditures (%)
	\$Millions	%	\$Millions	%	
Basic	200.2	15.9	259.0	20.3	-22.7
Chemical	126.4	10.0	122.6	9.6	3.1
Biological	73.8	5.9	136.4	10.7	-45.9
Applied	723.2	57.3	688.2	54.4	4.9
Manufacturing Process	90.5	7.2	92.1	7.3	-1.7
Pre Clinical Trial I	30.7	2.4	12.4	1.0	147.6
Pre Clinical Trial II	62.1	4.9	46.3	3.7	34.1
Clinical Trial Phase I	53.1	4.2	62.0	4.9	-14.3
Clinical Trial Phase II	125.0	9.9	121.6	9.6	2.7
Clinical Trial Phase III	361.8	28.7	353.8	27.9	2.3
Other Qualifying R&D	337.9	26.9	326.8	25.6	3.4
Total	1,261.3	100.0*	1,274.0	100.0*	-1.0

Source: PMPRB

* Values in this column may not add to 100.0 due to rounding

The two biggest players in the Canadian generic sector are Apotex (Canadian-owned) and Novopharm (Israeli-owned).⁴⁴ They account for approximately 6 percent and 2 percent of the Canadian drugs market, respectively. The Canadian Generic Pharmaceutical Association claims that, while most brand name drugs are imported into Canada, almost all generics are manufactured domestically. It further contends that most of Canada's pharmaceutical

⁴³ McKenzie, Kenneth. "Measuring Tax Incentives for R&D." *International Tax and Public Finance*. 15, 2008: 563-581

⁴⁴ See http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn00021.html, the Canadian Generic Pharmaceutical Industry (http://www.canadiangenerics.ca/en/resources/economic_benefits.asp)

manufacturing capacity is generic.⁴⁵ Canada's generic drug industry generates 40% of its sales volume from exports, most of which go to the United States.⁴⁶ Estimates are that generic manufacturers spent \$615 M on R&D, as compared to \$1,325 M for name brand firms. Note that according to PMPRB numbers, brand name firms spent only \$1,207.3 M.

Intramural expenditures are defined by the OECD as "all expenditures for research and development (R&D) performed within a statistical unit or sector of the economy during a specific period, whatever the source of funds."⁴⁷ In 2007, for Pharmaceutical and Medicine manufacturing companies (including both generics and most brand names) intramural expenditures were \$1,046 million.⁴⁸ Of those firms performing pharmaceutical R&D in Canada, only 34% of expenditures were made by Canadian-controlled companies.

Of the total \$1,046 million in intramural funding for research and development, \$466 million was spent by Canadian R&D performing companies, \$119 million was invested by the federal government and other Canadian sources, while \$461 million originated in foreign sources.⁴⁹

Based on 2005 data, it is estimated that patented drugs account for 71 percent of total sales in the pharmaceutical industry. The PMPRB estimates that sales of patented drugs were \$11.5 billion in 2005. Sales of non-patented drugs, from generic and brand-name companies were near \$5 billion in 2005. Further, Canadian drug export revenues have more than doubled since 1998, with 72 percent of exports going to the United States. Internet pharmacies (IP), a

⁴⁵ The Canadian Generic Pharmaceutical Association, *The Role of the Generic Pharmaceutical Industry in Canada's Economy*, online: http://www.canadiangenerics.ca/en/advocacy/docs/The_Role_of_the_Generic_Pharmaceutical_Industry_in_Canada%27s_Economy.pdf.

⁴⁶ *Ibid.*

⁴⁷ (<http://stats.oecd.org/glossary/detail.asp?ID=1441>)

⁴⁸ Industrial Research and Development: Intentions, 2009; Catalogue # 88-202-X

⁴⁹ Industrial Research and Development: Intentions, 2009; Catalogue # 88-202-X

relatively new phenomenon, contribute to this increase in exports by exploiting the drug price differential.⁵⁰

Table 4: Total Canadian Pharmaceutical Trade 2000–2006

Year	Exports (\$ Billions)	Imports (\$ Billions)
2000	1.6	5.3
2001	2.1	6.4
2002	2.3	7.3
2003	3.0	8.2
2004	3.6	8.6
2005	3.9	9.1
2006	5.1	10.2

Source: Statistics Canada (Industry Canada, Sector Profile, <http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/hn01656.html>)

According to Industry Canada’s sector profile on the pharmaceutical industry,⁵¹ within Canada, drug stores and hospitals are the primary purchasers of pharmaceutical industry products. The leading therapeutic class in terms of purchases, in 2008, was cardiovasculars (15.3 % of the market), followed by the psychotherapeutics class (12.6% of the market), gastrointestinal and genitourinary medicines (6.7%), cholesterol agents (4.5%), hormones (5.5%), anti-infectives systemic (5.4%), analgesics (4.9%), diabetes therapies (4.3%), neurological disorders (4%) and diuretics (3.8%).⁵² Lipitor, an antihyperlipidemic agent from Pfizer, was the leading product in terms of sales in Canada. Sales of Lipitor represented approximately 3.3 percent of total patented drug purchases in Canada for the year ending

⁵⁰ IMS Health database accessed March 1, 2010.

⁵¹ http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn00021.html

⁵² IMS, “Top 10 dispensed therapeutical classes in Canada, 2008” available online: http://www.imshealth.com/deployedfiles/imshealth/Global/Americas/North%20America/Canada/StaticFile/Trends02_En_09.pdf (accessed April 9, 2010).

December 2008.⁵³ Abbott's Synthroid, used to treat hypothyroidism was the second most proscribed drug in Canada (2.5 percent).⁵⁴

The Biotechnology Industry

Data regarding biotechnology research and development is the most difficult to assess since data sources seldom differentiate between health and agricultural biotechnology companies. Most innovation in this area is clustered around Toronto, Montreal and Vancouver.

According to BIOTECCanada, the Canadian biotechnology industry has a value of \$78.3 billion, 63% of which is due to health biotechnology.⁵⁵ BIOTECCanada, however, provides no methods on how they obtained these numbers and appears to use multiplying factors out of proportion with the custom runs of Statistics Canada's input-output tables, which provide relevant information on interactions between inputs and outputs of sectors of the economy.

CANSIM provides data on biotechnology up to 2005. According to the CANSIM series, human health biotechnologies accounted for 58% of all biotech companies in Canada, 71% of revenues, 87% of R&D expenditures and 81% of employment. The problem with the CANSIM series, however, is that there is an important overlap between biotechnology companies and brand-name pharmaceutical companies that do research in biotechnology, allowing the possibility for double-counting when comparing biotechnology with pharmaceutical companies. Nevertheless, according to another series by Statistics Canada that distinguishes between biotechnology companies and brand-name or generic pharmaceutical companies, biotechnology or biopharmaceutical companies spent \$395 million in 2007 on R&D on therapeutic health

⁵³ IMS, "Top 50 dispensed medications in Canada, 2008" available online: http://www.imshealth.com/deployedfiles/imshealth/Global/Americas/North%20America/Canada/StaticFile/Trends03_En09.pdf (accessed April 9, 2010).

⁵⁴ *Ibid.*

⁵⁵ <http://www.biotech.ca/en/what-biotech-is/bio-based-economy.aspx>.

products (as compared to \$174 million in 2005).⁵⁶ The federal government spent \$ 921 million on R&D in all biotechnology fields in 2007 according to Statistics Canada.

Overall, Canada has shown strong growth in R&D capacity in biopharmaceuticals. According to Industry Canada, “Canada’s biotechnology firms continue to diversify their products and processes and to work in more than one biotechnology sub-sector. As well, Canadian universities and research hospitals are conducting research with significant commercial potential. Currently there are almost 500 products in the biopharmaceutical product pipeline from research through to market.”⁵⁷

Medical Devices

According to MEDEC⁵⁸ (representing Canada’s Medical Technology Companies), the medical device industry in Canada,⁵⁹ not including medical imaging and assistive devices, employs over 35,000 people in close to 1,500 corporate facilities. The industry is comprised of small, medium and large sized facilities with the bulk of the industry represented by small and mid-sized companies. Large companies however, represent 43% of industry’s employment (100+ employees). The medical device industry has key clusters in Vancouver, Winnipeg, Calgary, Edmonton, Ottawa, Toronto, Montreal and Halifax.⁶⁰ However, like the pharmaceutical industry, the medical device industry is heavily concentrated in Ontario and Quebec, where 42% and 32%, respectively, of all facilities are located. Twenty two percent of medical device facilities are located in the West and only 4% in Atlantic Canada.

⁵⁶ (Industrial Research and Development: Intentions, 2008; Catalogue # 88-202-X)

⁵⁷ http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn00079.html

⁵⁸ <http://www.medec.org/>

⁵⁹ This includes medical, surgical and dental equipment (including electromedical equipment and related software), furniture, supplies and consumables, orthopaedic appliances, prosthetics and assistive devices and diagnostic kits, reagents and equipment (http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn00002.html)

⁶⁰ http://investincanada.gc.ca/eng/publications/medical_device.aspx

A 2005 Industry Canada report found that, in 2000, sales by the industry amounted to \$3.8 billion and R&D expenditures were \$126 million (90% of which were financed by business enterprises). The ratio R&D/sales was thus 3.3%. Assuming that the same ratio applied in 2006 and using MEDEC numbers on sales, we can estimate that R&D expenditures in this sector were \$198 million that year. Considering that 10% of funding came through the public sector, and 50% of business R&D was paid through tax subsidies, we can conclude that net R&D expenditure of the business sector in medical equipment was around \$89.1 million in 2006.

According to data from Canadian Industry Statistics,⁶¹ manufacturing revenues for this industry increased from \$1.4 billion in 1998 to \$2.6 billion in 2007, or at an average compound annual rate of 6.3% per year. The end of the period shows a decline in sales, however: between 2006 and 2007, manufacturing revenues decreased by 6.9%. Manufacturing value-added for the industry increased from \$826.8 million in 1998 to \$1.5 billion in 2007, or at an average annual rate of 6.3%. Between 2006 and 2007, however, value-added decreased by 5.7%. In 2008, the Canadian medical device industry had exports worth \$930 million while Canada imported \$4,275 million in products, leaving a trade deficit of \$3.3 billion.

Summary of Canada's R&D and Manufacturing Capacity

The primary funder for Canada's R&D activities is the public sector. When tax credits are taken into account, the public purse funds most research in the pharmaceutical and biotechnology sectors. Public policy, rather than patent policy, thus shapes to a great degree the nature and direction of biomedical research in Canada. Nevertheless, industry investment is significant, although much is invested in clinical trials that result in few patents, low levels of training and low long-term benefit to the Canadian innovation environment.

⁶¹ Available through Industry Canada website on Manufacturing Production Medical Equipment and Supplies Manufacturing (NAICS 33911) <http://www.ic.gc.ca/cis-sic/cis-sic.nsf/IDE/cis-sic33911defe.html> (accessed March 24, 2010).

Canada has a significant trade deficit in both biopharmaceuticals and medical devices. This is likely related to the historically low levels of industrial investment in Canadian R&D and to the poor (from an innovation perspective) quality of that investment that leads to less product development in Canada. Patents do not appear to be a major factor in investments as, even with patent laws at world standards since at least the mid-1990s, Canada's share of pharmaceutical R&D remains significantly below our competitors.⁶² Even France, with much more significant price controls than Canada, has a much higher level of investment in pharmaceutical innovation than do we.⁶³

Given the important role of public funding and policy in Canada's biomedical innovation environment, Health Canada can play a significant role in helping to develop a more vibrant R&D environment.

d. The Significance of IP Protection for Different Biomedical Products

The *Patent Act* applies to most health-related technologies, including pharmaceuticals, vaccines, and genetic tests. We discuss each of these technologies and the exception made for methods of medical treatment here.

Pharmaceuticals and biopharmaceuticals

Patents have been a major factor within the pharmaceutical industry's business model since the 1940s. As Temin explains, the combination of high regulatory barriers, increased reliance on prescription decisions by physicians rather than direct purchases by patients, the effectiveness of marketing in distinguishing even similar products from one another, and the availability of patents of medicines led pharmaceutical companies to move from a pattern of non-exclusive

⁶² Patent Medicines Price Review Board, *Annual Report 2008*, available online at: <http://www.pmprb-cepmb.gc.ca/english/View.asp?x=1211&mp=91> (accessed March 24, 2010).

⁶³ *Ibid.*

licensing of molecules to multiple parties to vertically integrated companies each with its own product domain.⁶⁴ Patents provide the means through which the industry maintains its vertical integration and is able to link its marketing to physicians to its research and production of medicines. In the golden age of drug discovery in the 1950s and 1960s, during which many of today's antibiotics were discovered, the industry relied on their internal ability to screen a large number of compounds for effectiveness in killing pathogens without necessarily understanding the biochemistry involved. With patents over such compounds, integrated pharmaceutical companies were able to delineate their own products and dominate the market with little downward pressure on prices.⁶⁵

As the easy-to-find compounds have now been discovered, drug discovery has become much more complex and expensive.⁶⁶ In this new reality, pharmaceutical companies find that they cannot identify new compounds themselves: they need to rely on a combination of publicly-funded research, the work of specialized companies and networks of knowledge to both develop the new tools of drug discovery and to quickly identify new compounds and move them through the discovery process. Given this changing context, leaders in the pharmaceutical industry have realized that their business models based on using patents to keep all activity within the firm are no longer useful and are searching for new models that enhance R&D collaboration, which do not rely as heavily on patents.⁶⁷

The biotechnology industry that followed the drug discovery boom tried to emulate the pharmaceutical business model but with little success. In the thirty or so years since the industry

⁶⁴ Temin, *supra*, note 22.

⁶⁵ *Ibid.*

⁶⁶ Bernard Munos, "Lessons from 60 years of pharmaceutical innovation" *Nature Reviews Drug Discovery* 8, 959-968 (December 2009) | doi:10.1038/nrd2961.

⁶⁷ International Expert Group on Biotechnology, Innovation and Intellectual Property, *Toward a New Era of Intellectual Property: From Confrontation to Negotiation* (Montreal: The Innovation Partnership, 2008) available online: http://www.theinnovationpartnership.org/data/ieg/documents/report/TIP_Report_E.pdf (accessed March 15, 2010).

commenced, it has not, overall, ever broken even.⁶⁸ Unlike the pharmaceutical industry, which has been questioning its business model for the last half decade, the biotechnology industry persists in hoping that it can succeed by taking a strong patent position and not sharing its knowledge. Except in the rare case, this has been a failure.

The Canadian Generic Pharmaceutical Association has taken issue with many aspects of the *Patent Act*. For example, it demands the right to manufacture and export pharmaceutical products to the United States and other countries if there is no patent in effect in that country, regardless of whether the Canadian patent has expired.⁶⁹ It has also demanded faster approval for generics.⁷⁰ Finally, it also contests the policy of the Quebec government of artificially extending the patent monopoly granted to novel drugs via its list of refunded medicines.⁷¹

Vaccines

The impact of patents on vaccine development is still largely unknown. The Bill and Melinda Gates Foundation attempted a patent landscape for HIV/AIDS vaccine research and development. However, the Foundation concluded that compiling such a patent map would require the dedication of substantial financial and personnel resources.⁷² There are thousands of potentially relevant patents, each of which would require expert interpretation of their relevance to HIV/AIDS vaccine development. In addition to HIV/AIDS related vaccines, there may other

⁶⁸ *Ibid.*

⁶⁹ The Canadian Generic Pharmaceutical Association, *Export Restrictions in Canada's Patent Act*, online: The Canadian Generic Pharmaceutical Association <http://www.canadiangenerics.ca/en/advocacy/export_restrictions_f.asp>.

⁷⁰ The Canadian Generic Pharmaceutical Association, *Federal Generic Drug Approval Times*, online: The Canadian Generic Pharmaceutical Association <http://www.canadiangenerics.ca/en/advocacy/approval_times.asp>; For other examples of the Canadian Generic Pharmaceutical Association's causes, please see: The Canadian Generic Pharmaceutical Association, *Advocacy*, online: <<http://www.canadiangenerics.ca/en/advocacy/index.asp>>.

⁷¹ Réginald Harvey, *Le Devoir*, Médicaments génériques - Le Québec fait bande à part pour le choix des médicaments, 7 novembre 2009.

⁷² See: Lori Knowles and Tania Bubela T "Challenges for Intellectual Property Management of HIV Vaccine-Related Research and Development: Part 1, The Global Context" (2008) 16 Health Law Journal 55-96, and for the Canadian context see San Patten, Tania Bubela and Lori Knowles "Challenges for Intellectual Property Management of HIV Vaccine-Related Research and Development: Part 2, The Canadian Context" (2008) 16 Health Law Journal 97-142. A simple Canadian patent landscape, primarily illustrating its complexity is available in The Health Sciences Policy Division of Health Canada (2007) Tania Bubela

relevant patents on research tools and methods including patents on assays, adjuvants, vectors and methods that may impact HIV vaccine research but are not HIV-vaccine specific. In addition, in this area, patents are complemented by proprietary trade secrets. This is particularly true with respect to more downstream production and innovation.

Canadian researchers do not identify patents as one of the main non-science barriers to achieving an HIV vaccine.⁷³ Very few researchers interviewed in a study of them viewed patents as an obstacle,⁷⁴ and this is consistent with the CIHR's statement that it has yet to receive a report from the research community identifying patents as an obstacle.⁷⁵ However, this may be due to the early-stage of much of the research and the fact that the primary application for an HIV/AIDS vaccine is in the developing world.

Even if patents played a role in disrupting research or making vaccines prohibitively expensive, the policy tools to address the concern are limited. Except in cases of pandemics or annual influenza vaccines, the vaccine market is small and there are generally few financial incentives for the private sector to develop new ones.⁷⁶ Further, except in cases of large-scale pandemics or severe health crises, governments are unlikely to request compulsory licences.⁷⁷ While Health Canada can certainly work with vaccine producers and patent holders to find ways to facilitate the production and distribution of vaccines, it may have to consider providing funding to overcome the high costs and risks involved in vaccine production.

for San Patten and Associates, Inc. for the project titled: "Overview of the Canadian Patent Landscape of HIV Vaccine-Related Technologies." Contract Reference Number: 4500160376

⁷³ San Patten, Tania Bubela and Lori Knowles, "Challenges for Intellectual Property Management of HIV Vaccine-Related Research: Part 2, The Canadian Context" (2008) 16 Health Law Journal at 99.

⁷⁴ *Ibid.* at 113.

⁷⁵ *Ibid.* at 113.

⁷⁶ Paul Offit, "Why are Pharmaceutical Companies Gradually Abandoning Vaccines?" (2005) 24 Health Affairs at 623.

⁷⁷ *Patent Act*, R.S.C. 1985, c P-4, s. 19.

Diagnostic Genetic Tests

In Canada, genes, mutations and diagnostic tests for those mutations have been widely patented. Human genes, purified and isolated, or put in a non-natural state (for example, isolated in a test-tube or inserted into a species different from its natural host) as well as artificial genes can, it would seem, be patented. Despite a recent US district court decision, patent law generally considers an ‘invention’ to be anything that is in an altered form (from its natural state) due to human intervention.⁷⁸ Likewise, despite that same decision, patents over diagnostic tests qualify as “method patents”, that is, they are methods for detecting mutations in these genes.⁷⁹ Myriad Genetics’ patents over genes related to hereditary breast and ovarian cancer and associated diagnostic tests,⁸⁰ patents covering genes and methods of testing for Alzheimer’s disease (of which Athena Diagnostics is the exclusive licensee) and patents covering testing for Canavan’s disease, hemochromatosis and other single-gene conditions are all examples of such patents.

While patent offices have been granting thousands of these patents for over twenty years, these patents continue to raise concerns regarding whether they impede research by preventing researchers and clinicians from conducting research on genes and improving tests and whether they increase costs and decrease accessibility to diagnostic testing.⁸¹ While in most fields, the evidence is largely that industry does not pursue researchers conducting basic research,⁸² this is not true of the clinical genetics field. Laboratories view their provision of tests to other researchers under a research protocol as research, whereas patent holders view this as a

⁷⁸ A recent decision of the District Court of the Southern District of New York ruled otherwise in the United States. See, *Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al.* (March 29, 2010) 09 Civ. 4515, available online: <http://www.aclu.org/files/assets/2010-3-29-AMPvUSPTO-Opinion.pdf> (accessed March 30, 2010).

⁷⁹ *Ibid.*

⁸⁰ E. Richard Gold and Julia Carbone, “Myriad Genetics: In the Eye of the Policy Storm” (forthcoming 2010) *Genetics in Medicine*.

⁸¹ This was certainly a concern expressed by the court in *Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al.*, *supra* note 78.

⁸² Walsh JP, Ashish A, Cohen W. Patents in the Knowledge-Based Economy. In: Cohen W, Merrill S, eds. *Effects Of Research Tool Patents And Licensing On Biomedical Innovation*. Washington, DC: National Academies Press; 2003.

commercial service.⁸³ As a result, clinicians, in contrast to other researchers, do not ignore patents and respond to threats of patent enforcement.⁸⁴

Medical and Surgical Treatments

Methods of medical treatment are unpatentable in Canada even if they involve the use of patented medicines.⁸⁵ The rationale behind this exclusion is two-fold. First, it is thought that it would be wrong to allow the patent system to hinder the saving of lives and alleviation of suffering achieved by modern medicine. Secondly, medicine is considered to be a profession whose members should share their skills for the good of the patient and society.⁸⁶

PART II: CONTEMPORARY PROBLEMS AT THE CROSSROADS OF HEALTH AND INTELLECTUAL PROPERTY

While responsibility for the *Patent Act* and the drafting of the *NOC Regulations* rests with Industry Canada, the discussion above illustrates the important role that Health Canada and health-related agencies play over the interplay of health and intellectual property. Not only does Health Canada administer the *NOC Regulations*, it is responsible for regulating biomedical products, it conducts research, it participates in discussions with Industry Canada and the Department of Foreign Affairs and International Trade over domestic and international issues relating to trade, access and innovation and its Minister is responsible for the Canadian Institutes of Health Research, PHAC and the AHRC, all of which have a greater or lesser role in determining Canada's health innovation environment.

With changes in the pharmaceutical and biotechnology landscape due to both technological changes and economic circumstances, a growing international awareness of the

⁸³ Gold and Carbone, *supra* note 80.

⁸⁴ Cho MK, Illangasekare S, Weaver MA, Leonard DG, Merz JF. Effects of patents and licenses on the provision of clinical genetic testing services. *J. Mol. Diagn.* 2003; 5(1): 3–8.

⁸⁵ *Vaver supra* note 2 at 130.

links between innovation and health and known problems in some of the domestic linkages between health and intellectual property, such as the *NOC Regulations*, this Part provides an overview of the challenges that Health Canada and its partners will face over the next few years. While not exhaustive, these issues were identified by the authors in conjunction with Health Canada as constituting challenges to the health innovation system over the coming five to ten years.

a. Genetic Testing

As a result of the controversy of Myriad Genetics' patents over breast and ovarian cancer genes and diagnostic tests, various bodies such as the Nuffield Council on Bioethics,⁸⁷ the National Academy of Sciences,⁸⁸ the Ontario Ministry of Health⁸⁹ and the Australian Law Reform Commission⁹⁰ (to name but a few), issued reports and recommendations. Academic articles examined the concerns and the role of industry, universities and legislative reform in addressing these concerns.⁹¹ France expanded compulsory licensing laws⁹² and Belgium carved out a diagnostic use exemption from patent infringement liability.⁹³ The United States Patent and Trademark Office developed guidelines specifically directed towards assessing gene patent

⁸⁶ *Vaver supra* note 2 at 131.

⁸⁷ Nuffield Council on Bioethics. *The Ethics of Patenting DNA* (2002), online at: <http://www.nuffieldbioethics.org/fileLibrary/pdf/theethicsofpatentingdna.pdf>.

⁸⁸ Merrill SA, Levin RC, Myers MB., editors. *National Research Council. Committee on Intellectual Property Rights in the Knowledge-Based Economy. A Patent System for the 21st Century*. Washington, D.C: The National Academies Press; 2004.

⁸⁹ Ontario Report to the Provinces and Territories. *Genetics, Testing and Gene Patenting: Charting New Territory in Healthcare* (Toronto, January 2002). Available at: http://www.health.gov.on.ca/french/publicf/pubf/ministry_reportsf/geneticsrep02f/report_e.pdf (accessed February 20, 2010)

⁹⁰ Australian Law Reform Commission, *ALRC 96 Essentially Yours: The Protection of Human Genetic Information in Australia* (Sydney, Australia, 2003) Available at: <http://www.austlii.edu.au/au/other/alrc/publications/reports/96/> (last accessed February 20, 2010).

⁹¹ See for example, Nicol D, Nielsen J. *Patents and medical biotechnology: An empirical analysis of issues facing the Australian industry – Occasional Paper No. 6* Sandy Bay, Australia: Centre for Law & Genetics; 2003; Gold ER. *Biomedical Patents and Ethics: A Canadian Solution*. *McGill Law Journal*. 2000;45:413.

⁹² LOI n° 613-16 as amended in 2004.

⁹³ Overwalle GV. *The Implementation of the Biotechnology Directive in Belgium and its After-Effects. The Introduction of a New Research Exemption and a Compulsory Licence for Public Health*. *International Review of Intellectual Property and Competition Law*. 2006;889:908-918.

applications.⁹⁴ Recognizing that many of the concerns could be addressed through better licensing practices, institutions also developed licensing guidelines, some of which were aimed at universities and others at industry. These include the National Institutes of Health's (NIH) *Best Practices for the Licensing of Genomic Inventions*,⁹⁵ the Organisation for Economic Cooperation and Development's *Guidelines for Licensing of Genetic Inventions*,⁹⁶ and *In the Public Interest: Nine Points to Consider in Licensing University Technology*,⁹⁷ drafted by 12 universities and endorsed by the Board of Trustees of the Association for University Technology Managers (AUTM). Since then, approximately 50 other institutions and organizations have also endorsed the 9 Points guidelines (although they have not been well enforced). All of these guidelines focus on establishing broad dissemination through non-exclusive licensing of gene-based inventions as the norm, particularly for publicly funded research. In February 2010, in the United States, the Secretary's Advisory Committee on Health Genetics and Society (SACGHS) released a report⁹⁸ on gene patents, licensing practices and patient access to genetic tests. Most recently, the District Court for the Southern District of New York held that neither an isolated gene nor genetic tests based on a comparison of a patient's gene to a reference gene constitute patentable subject-matter in the United States.⁹⁹ This ruling is unlikely to stand on appeal and does not represent Canadian law, but demonstrates continued concern over the effect of patenting human genes.

One of the central problems with gene patents appears to be the behaviour of university

⁹⁴ Utility Examination Guidelines and Written Description Examination Guidelines. Vol 66: Federal Register, Friday, January 5, 2001.

⁹⁵ Best Practices for the Licensing of Genomic Invention. Vol 70:18413: Federal Register; 2005.

⁹⁶ Organisation for Economic and Co-operation and Development, Guidelines for the Licensing of Genetic Inventions" http://www.oecd.org/document/26/0,3343,en_2649_34797_34317658_1_1_1_1,00.html.

⁹⁷ In the Public Interest: Nine Points to Consider in Licensing University Technology 2007; http://www.autm.net/aboutTT/Points_to_Consider.pdf.

⁹⁸ Secretary's Advisory Committee on Genetics H, and Society; National Institutes of Health. Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests 2010.

⁹⁹ *Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al.*, *supra* note 78.

technology transfer offices – which continue to license genes exclusively – and the biotechnology industry which demands exclusive licences in order to shut down other laboratories providing genetic testing.¹⁰⁰ In fact, SACGHS concluded, after a careful study of data and case studies it had commissioned, that there is no credible evidence that patenting and exclusive licensing are necessary in the diagnostic field. In most cases, it is public funding – and not investment attracted by the prospect of a patent – that has allowed researchers to sequence a gene and discover mutations in the gene that allow for the test. Once the sequence is known, developing a test to identify the mutation is inexpensive and quick. In fact, by the time a patented test comes to market, many laboratories are providing testing and are constantly improving it. Patents may actually get in the way of such delivery and improvement.

While the 9 Points and other guidelines were designed to prevent such exclusivity, exclusivity remains the norm. As a result of the failure to follow these guidelines, the Secretary's Advisory Committee on Health, Genetics and Society (SACGHS) found itself without a choice but to recommend changes in patent law to ensure continued research on and access to genetic tests through the creation of limited exceptions covering genetic testing. SACGHS further

¹⁰⁰ Nelson R. Observations on the Post-Bayh-Dole Rise of Patenting at American Universities *Journal of Technology Transfer* 2001;26(1-2):16; Mowery DC, al. e. The growth of patenting and licensing by U.S. universities: an assessment of the effects of the Bayh-Dole Act of 1980 *Research Policy* 2001;30:99-119; Pressman L, al. e. The licensing of DNA patents by US academic institutions: an empirical survey. *Nature Biotechnology*. 2006;24:31-39; Pressman L. *AUTM Licensing Survey: FY1999* Northbrook, IL2000. See also Julia Carbone, E. Richard Gold, Bhaven Sampat, Subhashini Chandrasekharan, Lori Knowles, Misha Angrist, Robert Cook-Deegan. “DNA patents and Diagnostics: Not a Pretty Picture”(Manuscript); Gold&Carbone, “Myriad Genetics”, *supra*, Duke University case studies; Angrist M, Chandrasekharan S, Heaney C, and Cook-Deegan R: “Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Long QT Syndrome.” *Genetics in Medicine*, forthcoming 2010; Chandrasekharan S, Fiffer M: “Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Hearing Loss.” *Genetics in Medicine*, forthcoming 2010; Chandrasekharan S, Heaney C, James T, Conover C, and Cook-Deegan R: “Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Cystic Fibrosis.” *Genetics in Medicine*, forthcoming 2010; Chandrasekharan S, Pitlick E, Heaney C, and Cook-Deegan R: “Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Hereditary Hemochromatosis.” *Genetics in Medicine*, forthcoming 2010; Cook-Deegan R, DeRienzo C, Carbone J, Chandrasekharan S, Heaney C, and Conover, C: “Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Inherited Susceptibility to Cancer: Comparing Breast and Ovarian Cancers to Colon Cancers.” *Genetics in Medicine*, forthcoming 2010; Colaianni A, Chandrasekharan S, and Cook-Deegan R: “Impact of Gene Patents and Licensing Practices on Access to Genetic Testing and Carrier Screening for Tay-Sachs and Canavan Disease.” *Genetics in Medicine*, forthcoming 2010; Powell A, Chandrasekharan S, and Cook-Deegan R: “Spinocerebellar Ataxia: Patient and Health Professional Perspectives on Whether and How Patents Affect Access to Clinical Genetic Testing.” *Genetics in Medicine*, forthcoming 2010; Skeehan K, Heaney C, and Cook-Deegan R: “Impact of Gene Patents and Licensing Practices on

recommended that universities carefully consider the need to patent genetic inventions and, when they do, ensure that the inventions will be widely available. Further, SACGHS recommended that universities release details over their licensing arrangements so that the government can assess whether universities are complying with these guidelines.

b. Research Funding

It is no secret that Canadian universities are under serious financial pressure. They are therefore cutting back on administration and salaries and are postponing maintenance and other upgrades (although there has been some funding for new infrastructure from funding agencies such as the Canadian Foundation for Innovation¹⁰¹). Nevertheless, according to data from Statistics Canada set out in Table 5 below,¹⁰² the great bulk of health-related research and development in Canada is conducted at universities and colleges. In comparison, the business sector – which comprises both domestic and foreign firms – accounts for less than 20% of R&D spending once tax subsidies are accounted for.

Because of financial pressures, universities and colleges are seeking ways to diversify their funding. One method that many such institutions have considered is the patenting and commercialization of their innovations, particularly those related to health. Unfortunately, the data suggests that far from generating revenue, university efforts to patent and license their technology are a cost centre rather than a revenue source. Worse, the use of exclusive licensing and other methods of commercialization may construct blockages within the innovation system. We discussed this problem in the previous subsection and return to it in the next subsection.

Access to Genetic Testing for Alzheimer’s Disease.” *Genetics in Medicine*, forthcoming 2010.

¹⁰¹ <http://www.innovation.ca/en>.

Table 5: Gross Domestic Expenditures on Research and Development (GERD) in the Health Field – Performing Sector Funding Sector

	Federal Government¹	Provincial Government²	Business Enterprise	Higher Education³	Private Non-Profit	Foreign	Total
Millions of dollars							
Performing Sector							
2004	203	31	2,248	3,585	60		6,127
2005	210	26	2,235	3,767	60		6,298
2006	217	21	1,937	3,784	63		6,022
2007	217	28	1,999	3,801	64		6,109
2008	224	26	2,008	3,839	65		6,162
Funding Sector							
2004	1,093	353	1,667	1,606	458	952	6,127
2005	1,230	330	1,639	1,626	481	991	6,298
2006	1,180	333	1,579	1,670	507	755	6,022
2007	1,185	341	1,619	1,677	509	777	6,109
2008	1,201	342	1,628	1,694	515	781	6,162

Source: PMPRB

1. Non-program costs (indirect costs) are excluded.
2. The provincial totals represent the following surveyed provinces: Alberta, British Columbia, Manitoba, Ontario, Quebec (a survey of only research and development statistics is conducted by the Institut de la Statistique du Quebec and shared with Statistics Canada) and Newfoundland and Labrador. As of 2000, The Centre for Addiction and Mental Health is reported under the higher education sector.
3. Includes teaching hospitals.

Note: Due to rounding, components may not add to the totals.

¹⁰² Statistics Canada, Estimates of Total Spending on Research and Development in the Health Field in Canada, 1997-2008 (March 2009, Stat Can #88-001-X).

Statistics from the US support the conclusion that university licensing is a cost centre. In 2006, US universities, hospitals, and research institutions received US \$1.85 billion in revenues from licensing, less than 5% of total academic research funding, compared to US \$43.58 billion from government and industry. Moreover, revenues were highly concentrated at a few universities that had patented “blockbuster inventions.”¹⁰³ According to Macdonald, 60% of US universities and half of UK universities do not earn enough from their licensing activities to cover the costs of their technology transfer offices.¹⁰⁴

c. Technology Transfer

One of the primary concerns related to technology transfer is the patenting of early-stage or pre-clinical research and research tools by universities. The patenting of research tools may impose such significant costs in terms of time and money in identifying and negotiating licences with licensees that research could be abandoned or, at least, delayed. This is known as a patent thicket which occurs when many overlapping patent claims cause uncertainty about freedom to operate, increase transaction costs because of the multiple license negotiations required, and stack royalty payments beyond the value of a single innovation. A patent thicket has also been referred to as an ‘anti-commons’.¹⁰⁵ There is, however, considerable controversy in the literature over the magnitude of the effect of patent thickets with some stating that there is no empirical evidence to demonstrate its existence¹⁰⁶ and others finding, through various forms of statistical analyses, that there has been a reduction in research publications following a patent grant in the

¹⁰³ A.D. So *et. al.*, “Is Bayh-Doyle Good for Developing Countries? Lessons from the American Experience” (2008) 6 PLoS Biology at 2079.

¹⁰⁴ S. MacDonald, “When Means Become Ends: Considering the Impact of Patent Strategy on Innovation” (2004) 16 Information Economics and Politics 149.

¹⁰⁵ Michael A. Heller, and Rebecca S. Eisenberg, “Can Patents Deter Innovation? The Anticommons in Biomedical Research” (1998) 280 Science 698.

¹⁰⁶ Timothy Caulfield, Robert Cook-Deegan, Scott Kieff and John Walsh, “Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies” (2006) 24 Nature Biotechnology 1091; but see E. Richard Gold, Tania Bubela, Fiona Miller,

same research area¹⁰⁷ or over a specific human gene.¹⁰⁸ While the evidence remains, at this point, inconclusive, it should also be noted that patent offices and courts in developed countries have recently been more cautious in granting patents over genetic research tools and have invalidated several DNA patents.¹⁰⁹

It is not only the patenting of research tools that gives rise to concerns, but also their dissemination through the use of Material Transfer Agreements (MTAs). MTAs are contracts that govern the transfer of tangible research materials (patented or not) from one researcher to another for testing purposes.¹¹⁰ Recent interviews of health researchers in various sectors have revealed that MTAs are a cause for concern for many researchers.¹¹¹ Chief among these concerns is that the need to negotiate MTAs significantly delays research and that MTAs may impose conditions on that research that may hamper downstream use.

The NIH developed a simplified, standard form MTA, which is also used by the NIH for intramural research.¹¹² This was one of the recommendations in the context of functional genomics using the mouse as an experimental model that came out a meeting in Rome in 2009.¹¹³ However these principles have far broader applicability for biomedical research. The Rome Agenda concluded that “within the academic community, processing of MTAs has become a major impediment to the open and timely dissemination of mouse resources and

Dianne Nicol and Tina Piper, “Gene patents – more evidence needed, but policymakers must act” (2007) 25 *Nature Biotechnology* 388.

¹⁰⁷ F. Murray & S. Stern “Do formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? (2007) 63 *Journal of Economic Behavior and Organization*, 648.

¹⁰⁸ K. Huang & F. Murray, “Does Patent Strategy Shape the Long-Run Supply of Public Knowledge: Evidence from Human Genetics” (forthcoming) *Academy of Management Journal*.

¹⁰⁹ Yann Joly, *Wind of Change: In re Fisher and the Evolution of the American Biotechnology Patent Law*, *Law in Context* (2006) 24:1, 67-84.

¹¹⁰ Patten, Bubela & Knowles, *supra* note 73 at 111.

¹¹¹ Zhen Lei, Rakhi Juneja, Brian D Wright, “[Patents versus patenting: implications of intellectual property protection for biological research](#)” (2009) 7 *Nature Biotechnology* 36.

¹¹² *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources* Federal Register 64, 72090–72096 (1999); available at http://grants.nih.gov/grants/intel-property_64FR72090.pdf

¹¹³ Schofield, PN, Bubela T, et al. (2009) Post-publication sharing of data and tools. 461 *Nature* 171-173.

associated data. Onerous terms and conditions in many MTAs have increased transactional costs for institutions and have become a major cause of delay in negotiations and the sharing of resources.” The Rome Agenda recommended “materials and data be shared under the least restrictive terms possible. If documentation is necessary for any reason, then the minimum NIH sharing policy should be applied. This 1999 policy states that materials developed using NIH Federal funding should be freely transferred between researchers using “... either no formal agreement, a cover letter, the Simple Letter Agreement of the Uniform Biological Materials Transfer Agreement (UBMTA), or the UBMTA itself .”

d. Need for More Empirical Data to Measure IP and Health Impacts

One of primary functions of technology transfer offices (TTOs) is to facilitate the relationships between publicly funded research institutions and industry and to mobilize publicly funded research for the benefit of society as a whole as well as for local and national industry. The tools used to assess whether TTOs have succeeded in achieving this goal are, however, inadequate. These tools treat TTOs as if they were profit centres for universities rather than as innovation and knowledge mobilisers. As described below, the use of these tools has perverse effects on not only on TTOs themselves, but on government policy-making.

Currently, a set of metrics developed by AUTM drives technology transfer policy for publicly funded research in university and government sectors. In its most recent survey on the state of technology transfer in the United States, well over a hundred universities and colleges reported statistics to AUTM.¹¹⁴ AUTM provides reported data to its members and compiles aggregate reports for public dissemination.

¹¹⁴ AUTM U.S., “Licensing Activity Survey, 2007: A Survey Summary of Technology Licensing (and Related) Activity for U.S. Academic and Nonprofit Institutions and Technology Investment Firms (FY2007)” (2007), online: AUTM <http://www.autm.net/AM/Template.cfm?Section=FY_2007_Licensing_Activity_Survey>.

The AUTM metrics and their equivalents around the world have been criticized as being overly focused on input/output measures such as number of disclosures of inventions from researchers in an institution to the TTO, number of patents filed, number of patents granted, license revenue generated for the institution, and number of spin-off companies created (regardless of profitability and longevity).¹¹⁵ Unfortunately, such metrics have come to dominate science policy at a broader level, since these are easily synthesized and understood by institutional and governmental policy-makers, even if they inadequately capture the broader societal benefits of publicly funded research institutions.

At present, new innovation models are emerging in the life sciences in which the emphasis is placed on collaboration and partnerships.¹¹⁶ There is a recognition that no one entity can itself do most of the research and development given increasing technological complexities and enhanced understanding of the complexity of living systems. Indeed, as noted above, even pharmaceutical companies that traditionally have relied on a vertical integration of research through product development and marketing activities now recognise that new drugs will only be developed through innovative partnerships with public research institutions and biotechnology companies.¹¹⁷ This opens a new world of opportunities and relationship management for research institutions and their TTOs. With enhanced understanding of the complexities of a new generation of therapeutics and diagnostics (e.g., monoclonal antibodies, microarray genetic testing, whole genome sequencing, cell therapies and biologics), TTOs will need better to define and manage pre-competitive research (also known as upstream research) which most enhances research and public benefit by remaining in the public domain. Facilitating the creation and

¹¹⁵ C.H. Langford *et al.*, “Indicators and outcomes of Canadian university research: Proxies becoming goals?” (2006) 35 Research Policy 1586.

¹¹⁶ The International Expert Group on Biotechnology, Innovation and Intellectual Property, *supra*, note 67.

¹¹⁷ Munos, *supra*, note 66.

maintenance of pre-competitive research raises the bar of knowledge for all actors engaged in research and development without limiting their ability to appropriate knowledge and innovation that is closer to practical application.¹¹⁸

If we are to measure TTO contribution in this more complex collaborative system, key metrics are missing for understanding how knowledge migrates across institutional and other boundaries.¹¹⁹ These missing metrics include tacit knowledge flows; the training and movement of researchers, students and post-doctoral fellows; technology diffusion; social networks; and institutional culture. Advances in the fields of bibliometrics, scientometrics, and Geographic Information Systems, which allow for new objective analyses of, for example, the tracking of tacit and formal knowledge flows, technology diffusion, and some aspects of science culture such as collaboration networks allows for the quantification of some of these metrics. Additionally, if we accept the importance of networks in enhancing innovative research, technological development and the diffusion of innovative products, processes and trained personnel, then we may wish to measure a number of factors that affect this research, including the following: knowledge and technology creation and flows, especially to developing countries; movement of trained individuals; patterns of collaboration between researchers and other network members.

All of these network based metrics, however, are time consuming, labour intensive and computationally expensive. While creating a more accurate model of the circular, iterative and relational nature of innovation, they also miss important data. Probably the most important variable missing is data on licensing practices of TTOs and their equivalents. Cook-Deegan and

¹¹⁸ Aled M. Edwards *et al.*, “Open access chemical and clinical probes to support drug discovery” (2009) 5 *Nature Chemical Biology* 436; Johan Weigelt, “The Case of open-access chemical biology” (2009) 10 *EMBO reports* 941.

¹¹⁹ C.H. Langford *et al.*, “Indicators and outcomes of Canadian university research: Proxies becoming goals?” (2006) 35 *Research Policy* 1586.

colleagues have commented at length on the paucity of licensing data even in aggregate and anonymised form for publicly funded innovation, especially health innovation.¹²⁰ In addition, Canadian patenting data is still relatively difficult to search, access and analyse because it is not included in value-added search engines and patent analysis tools such as Delphion.¹²¹

e. Failures in the NOC System

As previously discussed, the patent policy objective underlying the NOC Regulations is to balance the innovator's right to protect its exclusivity during the term of its patents with the generic company's right to promptly enter the market upon expiry of the innovator's patents. This is argued to be the best way to promote the development and distribution of useful therapeutics to Canadians. Given the intense competition between these actors, however, such a balance is difficult to obtain and maintain. The *NOC Regulations* remain unstable as both patent holders and generic producers litigate every conceivable aspect of the *Regulations* and the underlying *Patent Act*, creating significant delays and costs to the drug innovation and commercialization processes.

Under section 7 of the *Food and Drug Regulations*,¹²² the Minister of Health is under a duty to issue an NOC promptly. However, the *NOC Regulations* override this duty by requiring the Minister to wait for up to 24 months before issuing such an NOC unless the innovator has not taken any action for 45 days or that the proceedings instituted by the innovator have already been concluded in favour of the generic. In *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)*, the Supreme Court of Canada, described this stay as “draconian”:

¹²⁰ Robert Cook-Deegan, Subhashini Chandrasekharan, Misha Angrist, “[The dangers of diagnostic monopolies](#)” (2009) 458 *Nature* 405 doi:10.1038/458405a, at p. 406 .

¹²¹ www.delphion.com

¹²² SOR/98-166, s. 6; 2006-242, s. 4

There may be good policy reasons for the operation of the regulatory scheme in this fashion. However, it would be manifestly unjust to subject generic drug producers to such a draconian regime without at least permitting them to protect themselves and reduce the length of the presumptive injunction by initiating the NOC process as early as possible.¹²³

Excessive time delays not only result from the 24 month stay but are exacerbated by excessive litigation that takes place under the *Regulations*. A simple search of court proceedings from May 1, 2005 to May 1, 2008, turns up well over 250 proceedings relating to the *NOC Regulations*. The Canadian public and the Canadian judicial system is paying a high price in terms of costs and burden for these proceedings, which bring no benefit, in themselves, to the Canadian public.

f. Substandard/ “Counterfeit” Drugs

In industrialized countries the incidence of sub-standard and counterfeit medicines is estimated to be less than 1% of the market value.¹²⁴ In Canada, Criminal Intelligence Service Canada (CISC) reports that the problem of counterfeit pharmaceuticals remains relatively small.¹²⁵ However, there are reports of increasing numbers of incidents of counterfeit medication globally and the WHO estimates that 10% of medication globally is counterfeit.¹²⁶ The problem is most prevalent in African countries, in parts of Asia, Latin America, and countries in transition.¹²⁷

Discussions over counterfeit and substandard medicines are closely related to intellectual property. The Canadian Chamber of Commerce has, for example, suggested that one way to

¹²³ Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare), [1998] 2 S.C.R. 193 at paragraph 33.

¹²⁴ <http://www.who.int/mediacentre/factsheets/fs275/en/>

¹²⁵ http://www.cisc.gc.ca/pharmaceuticals/pharmaceuticals_e.html

¹²⁶ http://www.cisc.gc.ca/pharmaceuticals/pharmaceuticals_e.html

prevent the spread of counterfeit medicines is through greater enforcement of intellectual property.¹²⁸ Attempts are being made to bring the issue of intellectual property and counterfeit medicines to the World Health Organization.¹²⁹ While counterfeits may not be a significant problem in Canada, the impact of an international response to them may have an impact on Canada's patent enforcement mechanisms including access to generic products.

CISC reports that only a small number of Canadian criminal groups have experience in the illicit synthetic drug market and have established smuggling routes both domestically and internationally.¹³⁰ CISC reports two main criminal cases in Canada – in 2003 and 2005 – related to the smuggling of Viagra or other medicines used to treat erectile dysfunction. The 2003 investigation involved an estimated \$1.1 million worth of counterfeit Viagra pills (approximately 74,000 doses), and the 2005 case involved an estimated \$366,000 to \$2,440,000 – depending on whether the pills were intended to be trafficked in bulk amounts or in individual doses (approximately 120,000 doses) – worth of the same pills.¹³¹

While counterfeit drugs within licensed pharmacies in Canada are a rare occurrence, law enforcement officials and health agencies are concerned about illegal Internet pharmacies.¹³² These websites are difficult to track as they open and close easily, change their names, and operate from servers based in other countries. Moreover, there is concern that consumers may find it difficult to discern which sites are legitimate. Canadian law enforcement officials indicate that some illegal Internet pharmacies mimic the appearance of licensed sites or disguise

¹²⁷ <http://www.who.int/mediacentre/factsheets/fs275/en/>

¹²⁸ See, generally, <http://www.chamber.ca/> (accessed March 24, 2010).

¹²⁹ Kaitlin Mara, "Counterfeit Medicines At WHO: Off Board's Agenda, Still On Secretariat's", Intellectual Property Watch, 11 December 2009, available online: <http://www.ip-watch.org/weblog/2009/12/11/counterfeit-medicines-at-who-off-board-s-agenda-still-on-secretariats/> (accessed March 24, 2010).

¹³⁰ http://www.cisc.gc.ca/pharmaceuticals/pharmaceuticals_e.html

¹³¹ http://www.cisc.gc.ca/pharmaceuticals/pharmaceuticals_e.html

¹³² http://www.cisc.gc.ca/pharmaceuticals/pharmaceuticals_e.html

themselves as originating from Canada to take advantage of U.S. consumers seeking Canadian pharmaceuticals.¹³³

At the international level, Canada along with others, for the most part high-income, countries¹³⁴ are negotiating the Anti-Counterfeiting Trade Agreement (ACTA). While negotiations are secret, Foreign Affairs and International Trade Canada describe ACTA as follows:

The objective of an eventual ACTA is to put in place international standards for enforcing intellectual property rights in order to fight more efficiently the growing problems of counterfeiting and piracy. The proposed agreement will cover three areas: improving international cooperation, establishing best practices for enforcement, and providing a more effective legal framework.¹³⁵

Canada's position has been that the key ACTA obligations dealing with counterfeit medicines would be limited to trademark counterfeiting enforcement and that pharmaceuticals would not be the focus of the agreement.¹³⁶ However, Canada has recognized that counterfeit and substandard medicines are a global problem and that ACTA would be open to further accessions which would enhance its ability to combat the trade of counterfeit medicines.

An alternative to dealing with this problem under ACTA would be to enter into a multilateral agreement that would be more comprehensive compared to an intellectual property rights enforcement treaty.¹³⁷ Such a treaty would address not only the enforcement of counterfeit drugs, but would also deal with issues such as quality control. This would set counterfeit

¹³³ http://www.cisc.gc.ca/pharmaceuticals/pharmaceuticals_e.html

¹³⁴ The negotiating countries are as follows: Canada, Australia, the European Union and its member countries, Japan, Korea, Mexico, Morocco, New Zealand, Singapore, Switzerland, and the United States.

¹³⁵ http://www.international.gc.ca/trade-agreements-accords-commerciaux/fo/intellect_property.aspx

¹³⁶ <http://www.international.gc.ca/trade-agreements-accords-commerciaux/fo/summary-resume.aspx>

¹³⁷ <http://www.international.gc.ca/trade-agreements-accords-commerciaux/fo/summary-resume.aspx>

medicines apart from other counterfeit goods dealt with in ACTA and would allow for this issue to be categorized, more appropriately, as a public health issue.

g. Traditional Knowledge

Delivering health to Canada's aboriginal peoples and involving aboriginal peoples in health research both involve addressing the issue of recognizing, protecting and utilizing traditional knowledge (TK). TK can be both a source of new innovation – for example, through the identification of genetic resources useful in the treatment of certain health conditions – and can play a role as a complementary health intervention for First Nations, Inuit and Métis. In both ways, TK is a critical aspect of the Canadian health innovation system.

In Canada, protection of TK including traditional medicines is tied up in broader socio-cultural issues, Canadian constitutional law, and self determination for Aboriginal peoples. Since 1982, aboriginal rights have been constitutionally recognized in Canada. The Canadian doctrine of aboriginal rights affords protection to activities, practices, and customs that are integral to the distinctive cultural continuity of aboriginal communities, as well as protecting aboriginal land rights and treaty rights. The multiple dimensions of TK suggest it may be itself protected within the doctrine of indigenous rights, or may be protected as an element of broader indigenous rights.¹³⁸ The Supreme Court of Canada has further recognized legal entitlements for aboriginal rights holders to participate in decision-making which may impact their rights.¹³⁹ This duty of governments to consult with Aboriginal peoples is apparent in a wide variety of legislation related to education, health, criminal justice, social services, and environmental management.

¹³⁸ Bubela, T.E. et al., “Respecting, Promoting and Protecting Traditional Knowledge : A Comparative Case Study of Brazil, Kenya and Northern Canada” prepared for the International Expert Group on Biotechnology, Innovation and Intellectual Property (2008), working draft online at: <http://www.theinnovationpartnership.org/en/ieg/cases/> (accessed March 1, 2009).

¹³⁹ *Haida Nation v. British Columbia*, [2004] 3 S.C.R. 511, *Taku River Tlingit First Nation v. British Columbia*, 2004 SCC 74; *Mikisew Cree First Nation v. Canada (Minister of Canadian Heritage)* [2005] 3 S.C.R. 388

Canada has made little practical progress toward the national implementation of access and benefit sharing (ABS) provisions¹⁴⁰ or any formal recognition of property or other rights specifically in TK despite being a signatory to the *Convention on Biological Diversity* (CBD). Starting in 2004, a series of Federal/Provincial/Territorial (F/P/T) meetings, working groups and task groups have been formed to address ABS arrangements. A consultation document on ABS policies for Canada was released in 2005,¹⁴¹ and in 2008 a Federal/Provincial/Territorial Task Group¹⁴² was established to develop a policy to address access to genetic resources and a related ABS framework.¹⁴³ This policy will also consider TK and associated TK held by Aboriginal and local communities. Key Aboriginal organizations that have participated in the process on health issues include the National Aboriginal Health Organisation (NAHO) and the Inuit Tapiriit Kanatami. It remains to be seen how widely the views of First Nations and Inuit diverge from those of the Canadian government and other stakeholders and whether the consultation process will result in concrete action on recognizing and respecting TK in Canada and instituting an ABS regime.

However, in Northern Canada, and other regions covered by modern land claims treaties and self government agreements, indigenous communities may have a greater ability to maintain and protect their TK because it is closely aligned with the inherent right to self-government recognized under the Constitution and implemented across much of Canada's three territories.

¹⁴⁰ ABS schemes set up a mechanism whereby in return for access to genetic resources and associated traditional knowledge on the use of those resources, there is a return of benefit to individuals, communities and/or the country of origin. The benefit need not be monetary, but may include capacity building and technology.

¹⁴¹ Federal/Provincial/Territorial Working Group on Access and Benefit Sharing of Genetic Resources (2005) *ABS Policies in Canada: Scoping the Questions and Issues*. Available at Environment Canada Internet Portal on Access and Benefit-Sharing: http://www.ec.gc.ca/apa-abs/documents/ABS_policies_e.pdf

¹⁴² The Task Group is being led by Environment Canada, with guidance from the Canadian Council of Resource Ministers. The Task Group identified a series of options on an ABS policy framework for Canada. <http://www.ec.gc.ca/apa-abs/utilisant-using2/default.cfm?lang=eng>

¹⁴³ <http://www.ec.gc.ca/apa-abs/developpement-developpement/default.cfm?lang=eng>

Self-government enables indigenous communities broad scope to design their own legal structures for the protection and management of TK in both environmental and health contexts.

Similarly, Territorial scientific research permitting laws refer to First Nations and Inuit communities when research is to be conducted within their territory. Most systems do not require the sharing of benefits; however, the way is open for the imposition of contractual obligations on researchers when accessing genetic resources and TK in First Nations and Inuit territories. There are a number of examples of community-driven, collaborative research where TK is considered as an equally valuable knowledge system alongside western science, including in health research. These include the Northern Contaminants Program¹⁴⁴, some research projects associated with recently completed International Polar Year¹⁴⁵ and with the large Networks of Centers of Excellence devoted to Arctic research, ArcticNet¹⁴⁶.

PART III: TOOLS AVAILABLE TO HEALTH CANADA TO HELP ADDRESS THESE ISSUES

This Part sets out some of the instruments and roles that Health Canada can play, either alone or in conjunction with partner agencies, to address the problems discussed in Part II. While Health Canada must operate within its mandate, by coordinating activity with agencies that report to the Minister of Health and with other governmental departments, Health Canada can play an important facilitating role in ensuring that Canadians benefit from new health technologies and services.

¹⁴⁴ Indian and Northern Affairs Canada (INAC), Northern Contaminants Program, Available at: http://www.ainc-inac.gc.ca/ncp/index_e.html

¹⁴⁵ Government of Canada (INAC), IPY-API 2007-2008: http://www.api-ipy.gc.ca/index_e.html

¹⁴⁶ ArcticNet (<http://www.arcticnet-ulaval.ca/index.php?fa=ArcticNet.aboutUs>)

a. Better Policy Coherence Between Health Canada and Industry Canada

Setting coherent policies with respect to health and intellectual property in Canada can be difficult given that jurisdiction over patents and health care is split not only between the federal and provincial governments, but between different federal departments. At the federal level, Industry Canada – whose jurisdiction is further split between the Patent Policy Directorate and the Canadian Intellectual Property Office – is in charge of the *Patent Act* and the *NOC Regulations* as well as industrial policy regarding biotechnology. Meanwhile, Health Canada is mandated with national harmonization and health policy, through its administration of the *Canada Health Act*,¹⁴⁷ drug safety and efficacy under the *Food and Drugs Act* as well as the administration of the *NOC Regulations*. Given the overlap in jurisdiction and the impact of intellectual property policy on health, it is critical for the departments to establish mechanisms to ensure proper communication and trust to allow for coherent policy development.¹⁴⁸

The dispute in Canada involving Myriad Genetics and its diagnostic testing for hereditary breast and ovarian cancer is a case in point.¹⁴⁹ Myriad entered the Canadian market with its patented diagnostic test for certain hereditary forms of breast and ovarian cancer expecting that the provinces would cease providing existing diagnostic testing and send all blood samples to be analyzed at Myriad’s Salt Lake City laboratories. Provinces were left grappling with how to address Myriad’s patents and business model – with the belief that Myriad was the first of many companies that would soon come forward with genetic testing for other diseases – that presented cost concerns and a threat to the ability of the provincial health authorities to independently

¹⁴⁷ *Canada Health Act*, R.S.C., 1985, c. C-6

¹⁴⁸ E. Richard Gold and Julia Carbone) “Myriad Genetics: In the Eye of the Policy Storm” (forthcoming 2010) *Genetics in Medicine*.

¹⁴⁹ See *ibid*, for a detailed account of the controversy and the role that each of Health Canada and Industry Canada played.

decide on which basis to organize and reimburse health interventions (the cornerstone of the public health care system).¹⁵⁰

By establishing the Federal/Provincial/Territorial Coordinating Committee on Genetics and Health, Health Canada and provincial governments agreed that a coordinated policy was needed in order to ensure that Canadians had efficient and equitable access to those genetic testing services with clinical value. One of the potential mechanisms they identified for ensuring that this would be the case was through patent reform and through the administration of the patent system, both falling within the jurisdiction of Industry Canada. Industry Canada and, in particular, its Patent Policy Directorate, did not agree to investigate whether changes in patent administration or in patent policy could help resolve this health care concern. This decision was based on the premise that before taking any step, there had to be clear and unequivocal evidence that patents were the primary cause of the problem and that no other avenue existed to address the problem. It therefore resisted any attempt to assist in addressing the Myriad controversy.¹⁵¹

The result of this incident was that, instead of working cooperatively to bring together the perspectives of health and industrial policy, the two departments worked at counter-purposes, with Health Canada working with the provinces to investigate whether patent practice or law could help solve the policy problem and Industry Canada refusing to consider patent law as a vehicle through which to solve the problem. The failure to join forces and come up with practical solutions prolonged the controversy with Myriad. As a result, Myriad lost the Canadian market, Myriad's Canadian licensee lost its licence and Canadians do not benefit from Myriad's high quality test. That is, both health and industrial policy suffered. Ultimately, no solution regarding

¹⁵⁰ Ontario, *supra*, note 89; P. Willcocks, "Canadian Premiers Wade into Gene Patenting Debate" Reuters News (August 3, 2001).

¹⁵¹ Gold and Carbone, *supra*, note 80.

gene patents was found, leaving open the likelihood of controversies to come. In fact, as noted in the next subsection, two such controversies have already arisen.

Recommendation 1: Health Canada should, jointly with Industry Canada, create an inter-departmental working group on intellectual property and health. The mandate of this working group should be to pro-actively identify and address issues that cross their mandates, such as issues relating to the *NOC Regulations* and issues of biomedical innovation and access to health products.

b. Provide Coordinated Response Against Problematic Business Models

As previously discussed, genetic diagnostic companies have pursued business models that threaten further research and development as well as access to genetic testing services. Whether a private company/exclusive licensee or university spin-off company, these companies develop genetic testing services based on a business model that relies not only on patenting sequences and mutations – not objectionable in itself – but on restrictive licensing and enforcement practices that prevent other institutions, including universities, from combining, improving or deploying these tests.

Once again, the case of Myriad Genetics and its patents over BRCA1, BRCA2 and methods for diagnostic testing of breast and ovarian cancer is illustrative of these practices and business models.¹⁵² Armed with its patents, Myriad Genetics sent cease-and-desist letters to laboratories that it viewed as providing commercial genetic testing services. There is no evidence that Myriad Genetics ever blocked research¹⁵³ – in fact, it maintains that it only sent letters to those providing commercial services (whether to the public or to researchers). Nevertheless,

¹⁵² *Ibid.*

¹⁵³ Myriad has contributed data to public databases (for example, the President–Greg Critchfield–identifies 7,000 papers published that mention BRCA1 or BRCA2) (Declaration of Dr. Gregory C. Critchfield in Association for Molecular Pathology,

clinicians feared being pursued for patent infringement and so either ceased conducting research in the area, ceased to contribute mutations that they found to public databases or ceased published academic articles out of fear of being pursued. In countries with public health-care systems, health administrators objected to Myriad's business model of requiring all testing to be conducted by them at their Salt-Lake City facility on the basis that it removed their ability to deploy genetic tests to their citizens in the manner that they viewed as most efficient. While the biotechnology industry tried to portray Myriad as an outlier, a series of detailed case studies¹⁵⁴ conducted by Duke University's Center for Genome Ethics Law and Policy indicate that Myriad's business model is far from unique: it is the industry standard. Diagnostic companies such as Athena Diagnostics and PGxHealth have adopted a similar business model, and shut out university laboratories from offering genetic testing for diseases such as Long QT Syndrome and Alzheimer's disease. As these companies and their business models move into Canada, one can only expect new controversies to arise here. Because, as noted above, no solution was found to the Myriad controversy from the last decade, Canadian provinces and the federal government have no existing tools to deal effectively with these controversies.

A recent case in Canada involving Ipsogen and Warnex Medical Laboratories has raised

et al., v. United States Patent and Trademark Office, et al. Civil Action No. 09-4515 (RWS) (S.D.N.Y., filed December 18, 2009), <http://docs.justia.com/cases/federal/district-courts/new-york/nysdce/1:2009cv04515/345544/158/0.pdf>

¹⁵⁴ Chandrasekharan S, Fiffer M. Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Hearing Loss. *Genetics in Medicine*. Forthcoming April 2010; Chandrasekharan S, Heaney C, James T, Conover C, Cook-Deegan R. Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Cystic Fibrosis. *Genetics in Medicine*. Forthcoming April 2010; Colaianni A, Chandrasekharan S, Cook-Deegan R. Impact of Gene Patents and Licensing Practices on Access to Genetic Testing and Carrier Screening for Tay-Sachs and Canavan Disease. *Genetics in Medicine*. Forthcoming, April 2010; Cook-Deegan R, DeRienzo C, Carbone J, Chandrasekharan S, Heaney C, Conover C. Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Inherited Susceptibility to Cancer: Comparing Breast and Ovarian Cancers to Colon Cancers. *Genetics in Medicine*. Forthcoming, April 2010; Powell A, Chandrasekharan S, Cook-Deegan R. Spinocerebellar Ataxia: Patient and Health Professional Perspectives on Whether and How Patents Affect Access to Clinical Genetic Testing. *Genetics in Medicine*. Forthcoming, April 2010; Chandrasekharan S, Pitlick E, Heaney C, Cook-Deegan R. *Genetics in Medicine*. Forthcoming, April 2010; Angrist M, Chandrasekharan S, Heaney C, Cook-Deegan R. Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Long QT Syndrome. *Genetics in Medicine*. Forthcoming April 2010; Skeehan K, Heaney C, Cook-Deegan R. Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Alzheimer's Disease. *Genetics in Medicine*. Forthcoming, April 2010.

alarms.¹⁵⁵ A French public laboratory, the Institut Gustave Roussy (together with other French public institutions) applied for patents (including a Canadian patent)¹⁵⁶ over the JAK2 gene and related diagnostic methods for myeloproliferative disorders (affecting blood cells).¹⁵⁷ The Institut Gustave Roussy then exclusively licensed the JAK2 gene and associated test to Ipsogen, a French company, which granted Warnex Medical Laboratories the exclusive Canadian operation rights for the intellectual property related to the V617F mutation of the JAK2 gene and testing. Warnex then sent out notices to Canadian laboratories that it had the Canadian rights over this mutation and invited laboratories to contact it. Given the experience with Myriad, Canadian laboratory directors were afraid that Warnex was following the route that Myriad had laid out. As the Canadian patents over the JAK2 gene will likely soon be issued – they have in the US – this dispute is likely to intensify in the near future. We are also aware of clinical laboratories feeling threatened over another genetic test, that for Long QT Syndrome patented by PGxHealth, a division of Clinical Data.

As noted earlier, SACGHS found that the evidence strongly suggested that patents are not a driver of innovation in the field of genetic testing¹⁵⁸ since third party laboratories develop and make available testing services soon after publication of the gene sequence and long before a patent issues. This was the case for both Myriad and Warnex in Canada in which the patents issued long after the tests were put on the market for laboratories. Based on this finding, SACGHS suggested that the US expand an existing exception that insulates health practitioners from patent infringement – a provision that seeks to accomplish the same policy goal as Canada’s rule that methods of medical treatment are not patentable subject-matter – to cover the

¹⁵⁵ See Piper and Gold, *supra* note 1.

¹⁵⁶ Patent Application number CA 2585062

¹⁵⁷ Patents have issued in the United States (US 7,429,456) and in Europe (EP1692281).

¹⁵⁸ Secretary’s Advisory Committee on Genetics, Health and Society, *supra* note 98.

provision of diagnostic testing by a health practitioner or laboratory.

Health Canada and other agencies reporting to the Minister of Health have several tools available to address the above concerns. While, as noted in the last section, coordination with Industry Canada is most likely to provide a long-term solution, through appropriate use of existing tools, Health Canada can reduce the risk that Canadian taxpayer money is used to cause similar problems in the future.

Recommendation 2: Through the inter-governmental working group proposed in Recommendation 1, Health Canada and Industry Canada should examine the recommendations put forward by the Secretary’s Advisory Committee on Genetics, Health and Society to determine their applicability and implementation in Canada.

As most research leading to the identification and characterization of human genes takes place or at least commences in university laboratories funding through public research grants, there is an opportunity to follow the lead of the NIH and the suggestion of SACGHS to strongly encourage university TTOs either not to patent genetic tests or, if they do so, to license them in a manner that ensures access to those tests.¹⁵⁹ There is little institutional or policy reason for CIHR – the primary funder of health research in Canada – not to adopt guidelines that require Canadian universities to ensure access. While the NIH cannot enforce its guidelines because of its limited jurisdiction,¹⁶⁰ CIHR is not so bound. Further, following the recommendation of SACGHS, CIHR can require disclosure of licence agreements entered into with respect to its funded research results. Similarly, Health Canada can require such disclosure with respect to any research it directly funds.

Recommendation 3: Health Canada should encourage the Minister of Health to

¹⁵⁹ *Ibid.*; Cook-Deegan, Chandrasekharan and Angrist *supra* note 120.

adopt a coordinated approach to gene testing and commercialization that involves not only Health Canada but the Canadian Institutes for Health Research.

Recommendation 4: Health Canada should ensure that its own licensing policies and practices correspond to the *OECD Guidelines on the Licensing of Genetic Inventions* and to *In the Public Interest: Nine Points to Consider in Licensing University Technology and the Rome Agenda*.

c. Promote Public-Private Partnerships

One mechanism that addresses the points above is the development of new open models of innovation to support research and biomedical product development. It seems unlikely that a direct translation of the open source movement to biomedical innovation will work except in respect of data collection and databases. In other ways, the cost of patenting and the lack of common standards will get in the way of effective open source mechanisms. Rather, the most likely option is the development of patent-free zones surrounded by smaller spheres of patented products. The key here is to use a combination of contract and norm development to ensure the integrity of the patent free zones and to clearly demarcate where patenting can take place. Efforts such as the Structural Genomics Consortium and the developing iBOL consortium are leading the way. Both are managed through Canadian institutions, thus demonstrating an existing lead that Canada can harness for its own advantage.

Both Health Canada and its sister institution, CIHR, can promote partnerships either through direct funding of such initiatives or establishing competitions to create pre-competitive research consortia with open innovation policies.

Recommendation 5: Health Canada should facilitate discussions among the research

¹⁶⁰ The NIH is restricted by the Bayh-Dole Act 35 U.S.C. § 200-212 from enforcing any rules about the licensing of funded

and industrial communities on how best to structure and support public-private partnerships in pre-competitive research. These discussions should address issues of intellectual property, licensing and access.

d. Changes to NOC Regulations

The first option in addressing these endemic problems would be to drastically simplify or replace the *NOC Regulations*. Justice Hughes in *Ferring inc. v. Canada (Health)*¹⁶¹ called the Regulations “arcane” while Justice Sharlow in *Ratiopharm Inc. v. Wyeth*¹⁶² stated that “the *NOC Regulations* spawn a great deal of litigation because the financial stakes are high, even in relation to what may amount to only a delay in the entry of a generic drug product into the market.” Given the adversarial relationship between patent holders and generic producers, litigation will inevitably continue notwithstanding regular efforts to refine and optimize the NOC regulations.

Short of replacing the *NOC Regulations*, the best approach to limiting litigation and achieving stated policy objective is to allow the courts to interpret the regulations and reduce uncertainty rather than regularly making piecemeal amendments that may have far reaching, unforeseen impacts. The courts are institutionally better positioned than either Industry Canada or Health Canada to control litigation. Amending the *NOC Regulations* in bits and pieces undermines their ability to do so, thus increasing and not reducing litigation.

The current situation is a case in point. In implementing the NOC Regulations, an issue arose regarding which patents a generic manufacturer had to address in order to obtain an NOC. Increasingly, innovators were listing patents related to an NOC obtained after the issuance of their NOC – amounting to “evergreening”. The Supreme Court of Canada in *AstraZeneca*¹⁶³ did

inventions.

¹⁶¹ [2007] FC 300.

¹⁶² [2007] FCA 264

¹⁶³ *AstraZeneca Canada Inc. v. Canada (Minister of Health)* [2006] 2 S.C.R. 560.

its job of answering the open question of which patents could be listed on the Patent Register. In November of 2006, the Supreme Court of Canada held that the generic manufacturer only had to address patents that were listed at the time the generic filed its ANDS. At the same time, the Government came out with its 2006 amendments, which had essentially the same effect as the Supreme Court decision, with respect to which patents the generic manufacturer had to take into account. Then in 2008, the Government once again amended the *NOC Regulations*, this time to limit the application of the 2006 amendments to only patents listed after the 2006 amendments to address the following concern:

If the Supreme Court of Canada’s reasoning opens the door to a broader unsettling of the jurisprudence on the listing requirements as they were prior to the 2006 amendments, this could give rise to a proliferation in litigation, contrary to one of the stated objectives of the 2006 amendments.¹⁶⁴

However, the effect of the 2008 amendments was to retrospectively change the authoritative interpretation of the pre-2006 NOC Regulations and undermines the certainty of the law and the calculations that all parties made on reading those regulations. Retrospectively changing the NOC Regulations will risk greater uncertainty than allowing the courts to supervise the natural elucidation of the regulations. We suggest that this progressive and consistent judicial approach to elucidating the law is preferable to the disruptive and ad hoc modifications.

We further note that addressing problems with the *NOC Regulations* is complicated by the split in jurisdiction between Health Canada and Industry Canada. While Health Canada maintains the Patent Register,¹⁶⁵ decides when to issue an NOC and is named as a party in NOC proceedings, it is Industry Canada that is responsible for amendments to the Regulations. It is

¹⁶⁴ Regulatory Impact Statement, P.C. 2008-1090 June 12, 2008.

¹⁶⁵ See <http://www.patentregister.ca/>.

therefore important to have mechanisms in place through which to facilitate the sharing of information between Health Canada and Industry Canada, particularly as this information reveals problems and challenges in the implementation of the NOC Regulations.

Recommendation 6: Through the inter-departmental working group proposed in Recommendation 1, Health Canada and Industry Canada should share information on the functioning of the NOC regime to identify problems and concerns.

e. Substandard Drugs

Health Canada has two import tools at its disposal with respect to counterfeit or substandard drugs. First, it can continue its efforts in regulating medicines put on the Canadian market and increase its attention to Internet pharmacies in conjunction with law enforcement officials. Second, it can work with the Department of Foreign Affairs and International Trade in respect of the latter's negotiation of ACTA to buttress the Canadian position that ACTA should only deal with pharmaceutical products to the extent of trade-mark protection. This will ensure that Health Canada maintains primary responsibility for the quality of medicines in Canada – rather than leaving such decisions to border guards – and that Canada has the policy flexibility to enable the transport of medicines from a country to a country in which no patents cover the medicine.

Recommendation 7: Health Canada should support the Department of Foreign Affairs and International Trade in limiting the scope of ACTA to trade-mark infringement so as not to interfere with the functioning of the Canadian health innovation system and access to generics.

f. Making use of the Media to Promote New Models of Innovation that Encourage Access to Health Innovation

The public receives much of its health information from television, radio, magazines, newspapers, and increasingly from the Internet.¹⁶⁶ This last has transformed the nature of the media and has enabled highly motivated individuals to learn about health issues and participate in policy discussions and collective decision-making. New media or Web 2.0 allows for significant interaction between stakeholders, with input and commentary from, for example readers, to news and other information present on the web. In addition, issues may be addressed in web fora and social networking sites.

The media do two things: they influence, to some degree, public perceptions¹⁶⁷ and reflect policy debates. Indeed few decisions are made by policy makers without the media in mind. One example of an issue at the intersection of health and IP policy that received significant coverage in the media was the controversy surrounding Myriad Genetic's BRCA patents. An empirical study concluded as follows:

Myriad's patents were largely portrayed as a negative story, except in Utah where Myriad Genetics is located, and as an example of the problems associated with gene patents. The story was primarily framed as a social dilemma that needed to be addressed. In Canada there was a disproportionate level of coverage of the political response to the threat of patent infringement action against government testing laboratories and potential impacts

¹⁶⁶ For reviews on these issues see: Bubela T, Nisbet, M, et al. (2009) Science Communication Reconsidered: Challenges, Prospects, and Recommendations. 27 Nature Biotechnology 514-518: 14; 8. Bubela T, Caulfield T. Media Representations of Genetic Research. Einsiedel EF, Timmermans F (eds) Crossing Over. Genomics in the Public Arena. (Calgary, AB, Canada: University of Calgary Press, 2005).

¹⁶⁷ For a number of caveats on this assumption see: Bubela T, Nisbet, M, et al. (2009) Science Communication Reconsidered: Challenges, Prospects, and Recommendations. 27 Nature Biotechnology 514-518: 14

on public health care. In Europe and elsewhere in the United States, the opposition to gene patenting at the European Patent Office predominated.¹⁶⁸

The study provided some support that the “media coverage helped to drive the policy agenda, although the resultant policy response received almost no media attention.”¹⁶⁹

Another issue relating to IP and health that received significant media traction was the debate around access to medicines and the enactment of the Canadian Access to Medicines Regime (CAMR).¹⁷⁰ Stakeholders involved in all sides of the debate from government actors to the brand-name pharmaceutical, generic industry and NGOs all engaged the media through press releases. Rx&D, the main brand-name pharmaceutical industry lobby group in Canada, even placed a full page advertisement in *The Globe and Mail* stating its position on CAMR. From 31 August 2003 to 25 November 2006 there were 87 newspaper articles on the issue of access to medicines in Canadian newspapers despite the highly technical content about amending the *Patent Act* and the *Food and Drugs Act*.

These examples indicate public interest in health, health innovation, and even seemingly esoteric issues such as innovation and intellectual property models for health innovation. If framed in the appropriate way, to capture public interest which is significant on health related issues including reforms to health systems, the media could certainly be engaged in promoting new models of innovation that enhance access to health innovation in Canada. Structures such as the new Science Media Centre of Canada¹⁷¹ in Ottawa, designed to facilitate access by the media to experts in science and science policy, could significantly enhance communications efforts.

¹⁶⁸ Timothy Caulfield, Tania Bubela and CJ Murdoch, "Myriad and the Mass Media: The Covering of a Gene Patent Controversy" (2007) 9 *Genetics in Medicine* 850 at 850.

¹⁶⁹ *Ibid.* at 853.

¹⁷⁰ Tania Bubela and Jean-Frederic Morin, "Lost in Translation: The Canadian Access to Medicines Regime from Transnational Activism to Domestic Implementation" Submitted August 2009 *Health Law Journal* (under review)

¹⁷¹ <http://www.sciencemediacentre.ca/smc/>

Health Canada can facilitate media coverage of health and intellectual property issues by issuing its policy documents in an accessible manner and making them accessible to the media through the Science Media Centre of Canada or otherwise. The CIHR has moved to help ensure that publications that result from its funding will be available in publicly accessible databases. While most of this information is highly technical, it does support public debate and can be used by the media as background. Further, Health Canada can support those engaged in public debates by facilitating access to its data and studies. We turn to this next.

Recommendation 8: Health Canada should prepare policy documents that are accessible to the public over matters of health innovation. This could include, for example, information about patents and generic pharmaceuticals and research that it conducts.

g. Facilitating Data Collection on Health and IP

New bibliometric and scientometric analytical tools have great potential for providing more nuanced metrics for science and innovation.¹⁷² When combined with statistical modeling these analytical tools may allow for an assessment of the impact of policies in these areas.¹⁷³

More specifically, these network analysis tools include:

1. Collaboration Networks: These explore through a variety of descriptive statistics and visualize collaboration patterns between actors, including co-authorship of scientific or other publications, co-patenting, patentee-assignee relationships, licensing relationships and co-

¹⁷² Strotmann, A., Zhao, D., & Bubela, T. (2009). Author name disambiguation for collaboration network analysis and visualization. Proceedings of The American Society for Information Science and Technology 2009 Annual Meeting, November 6-11, 2009, Vancouver, British Columbia, Canada; Strotmann, A., Zhao, D., & Bubela, T. (2009). A multi-database approach to field delineation. Proceedings of the International Society for Scientometrics and Informetrics 2009 Conference, July 14-17, 2009, Rio de Janeiro, Brazil;

¹⁷³ Tania Bubela and Andreas Strotmann, *Designing Metrics to Assess Impacts and Social Benefits of Publicly Funded Research in Health and Agricultural Biotechnology. A Report to The International Expert Group on Biotechnology, Innovation and Intellectual Property* (The Innovation Partnership, 2008). Online: <http://www.theinnovationpartnership.org/en/ieg/cases/> (accessed March 1, 2009)

funding relationships, materials exchange and training. Network Statistics can indicate how central or important an actor is within the network.

2. Author Citation Networks: These explore formal knowledge flows in the form of co-citation or bibliographic coupling networks.¹⁷⁴ Such methods are well-established for analyzing the intellectual structure of a discipline, i.e., for determining and visualizing sub-fields and their inter-relationships, and for assigning individual authors to the various disciplines they have influenced (author co-citation analysis) or in which they have been actively publishing (bibliographic coupling).

3. Citation Trails: These resemble a branching family tree and track citations through generations of publications in a field. This method may be used to track or identify seminal research publications, technologies, or patents.

4. Geographic Information Systems: These may be used to track tacit knowledge flows, for example, by tracing the educational and employment history of individual actors.

5. Lexicographic Analyses: These can track the flow of text between documents by tracing keywords, phrases or concepts through different forms of documents originating from different sets of actors. For example, the diffusion of research may be tracked from research publications to patents, corporate documents, press releases, media coverage, websites, policy documents, and parliamentary or congressional sessions or hearings.

Other tools include patent landscaping for specific fields. Landscaping can provide information on actors and institutions which are patenting, when and what they are patenting and how much. These studies can assist policy makers in identifying local and national fields of

¹⁷⁴ H.D. White & B.C. Griffith, “Author co-citation: A literature measure of intellectual structure” (1981) 32 *Journal of the American Society for Information Science* 163 [White & Griffith, “Author co-citation”]; D. Zhao, “Towards all-author co-citation analysis” (2006) 42 *Information Processing and Management* 1578 [Zhao, “Towards all-author co-citation analysis”]; D. Zhao & A. Strotmann, “Evolution of research activities and intellectual influences in *Information Science* 1996-2005:

strength and leaders within those fields. This can be used to focus attention on supporting specific fields, especially when resources are limited. Landscape analyses are useful to industry in identifying potential partners, both nationally and internationally and in supporting a freedom-to-operate analysis.

Patent applications themselves contain information on a host of matters including the following: the subject matter of the patent, the scope of the patent as defined by the claims, the countries in which patents have been sought and/or granted, and the date when the invention passes into the public domain, being twenty years from the priority date/filing date in most instances.¹⁷⁵ Used in combination with network analyses, a comprehensive picture of a field emerges, tracking relationships between inventors, their institutions or companies, and patent holders (assignees).

Another innovative method combines advances in bioinformatics tools and databases to allow for matching between patented nucleotide and amino acid sequences, which must be disclosed in patents and genomics databases.¹⁷⁶ This last analysis enables a determination of the percentage of a genome that is patented.¹⁷⁷ The best known example of this method is a patent landscape of the human genome that found that approximately 20% of human genes are explicitly claimed in United States patents.¹⁷⁸

An excellent example of patent landscaping in the national interest is that undertaken by the policy branch of the Japanese Patent Office. This constitutes a labour-intensive effort to map the patents held by Japanese and foreign patent holders in Japan, the United States, Europe and

Introducing author bibliographic coupling analysis” (2008) 59:13 *Journal of the American Society for Information Science and Technology* 2070 [Zhao & Strotmann, “Evolution of research activities”].

¹⁷⁵ K. Bergman & G.D. Graff, “The global stem cell patent landscape: implications for efficient technology transfer and commercial development” (2007) 25:4 *Nature Biotechnology* 419.

¹⁷⁶ Kyle Jensen & Fiona Murray, “Intellectual Property Landscape of the Human Genome” (2005) 310 *Science* 239.

¹⁷⁷ *Ibid.*

China in a variety of strategic areas including biotechnology and nanotechnology. This mapping was undertaken in the interests of advancing Japanese knowledge-based sectors and research by identifying areas of high patenting activity (an indication of innovative activity) and potential competitors or markets. Such activities should be considered in Canada for the benefit of Canadian industries.

Unfortunately, patent landscaping has a number of limitations. First, there may be a distinction between the patent holder and the rights holder due to an exclusive license. Licensing information is very difficult to obtain. Licensing information from publicly-funded research should be compiled and made available to researchers of innovation systems as well as to policy makers.

Second, Canadian patent data is not held in commercially available patent search engines with sophisticated analytical capabilities such as Delphion. Reliance on available public databases makes patent landscaping and large-scale analyses for the Canada cumbersome and difficult. To respond to this concern, governments should facilitate the development of science and technology databases that permit robust searching (especially for patents), that link information between jurisdictions, and are more user-friendly. The NLM/NCBI (National Library of Medicine/National Centre for Biotechnology Information) and associated bio-medical research databases are an excellent model of data cohesion and availability. However, publically accessible databases should be promoted over commercial databases such as Elsevier's Scopus citation database and Thomson ISI's Web of Knowledge.

While responsibility for administering the patent system, and hence patent databases, rests with the Canadian Intellectual Property Office, both Health Canada and CIHR can promote

¹⁷⁸ *Ibid.*

the development of tools that will better enable data analysis to support policy formation. Further, by working with the Canadian Intellectual Property Office, Health Canada can encourage the development of an open and complete database over health-related patents.

Recommendation 9: Health Canada should provide all of its research data, data collected in the course of carrying out its regulatory duties (subject to confidentiality and data protection laws) in an open, accessible manner to researchers. It should encourage the Canadian Institutes for Health Research and the Canadian Intellectual Property Office to make their data similarly accessible and to work together to link health-related patents, research and data in an accessible manner.

h. Engage First Nations and Inuit Peoples in Access and Benefit Sharing

In order to allow Canada's aboriginal peoples to participate in health innovation drawing on their culture, tradition, history and knowledge, they need resources and training to assist them in developing methods to manage their heritage in the most appropriate manner to them. In practical terms, they would be greatly assisted by the development of model agreements that set out the terms and conditions for access to traditional knowledge and genetic resources.

However, even in the absence of such model agreements, Health Canada and CIHR could take the lead in re-aligning goals and actions to meet their missions. This includes partnering with Northern communities and aboriginal organizations to address research and capacity needs. Policies could be developed ensure negotiation of research agreements between institutional researchers and communities that meet community needs and interests and conform to the principles of prior informed consent and benefit sharing (monetary or otherwise). Further protections could be ensured if research councils adopted Ethics Guidelines specifically for research with Aboriginal communities that address relevance, prior informed consent, benefit

sharing, access and use of traditional knowledge and research relationships. The councils should continue to find ways to ensure that research grant programs are accessible to northern colleges, research institutions and aboriginal organizations as appropriate.

Recommendation 10: Health Canada should develop policies, in conjunction with the Canadian Institutes for Health Research, the Department of Indian and Northern Affairs, and Environment Canada with respect to access to and the use of traditional knowledge and genetic resources in health research and delivery.

i. Internal Health Canada IP Policies

While Health Canada both conducts a significant amount of intramural research – principally related to its regulatory mandate over the introduction of new substances – and contracts for research by third parties, it has not had a clear policy on whether and when to patent its inventions, whether, when and with whom to license those inventions and whether, when and with whom to openly share data. Recently, Health Canada began the process of developing such a policy.

In developing its policy, Health Canada needs to be mindful of the nature of its research, those who benefit from it and the costs involved in seeking to protect and license research results. Most of the research conducted by Health Canada revolves around the assessment and validation of tools to assist in the regulatory process, the use of those tools in the regulatory process and the development of processes to better examine products.

While some of the research sponsored by Health Canada may result in patentable inventions, it is unlikely that any have significant commercial value independently from the tools being assessed. Those companies whose tools are validated by Health Canada have, however, a commercial interest in the results of that validation if for no other reasons than to convince other

regulators internationally to use these tools. Health Canada also has an interest in ensuring that regulators around the world use the tools it has validated since this would facilitate the exchange of knowledge and data between regulators. Health Canada may therefore wish to consider ways to make its research regarding the validation of regulatory tools produced by Canadian companies available to those companies to assist in the commercial development of the tool for the benefit of Canadians and of the firm involved.

Given that most of the other inventions funded by Health Canada are unlikely to have commercial value, it would be inefficient for Health Canada to patent them or to set up an office to track, patent and license them. As at most universities, such an office would likely be a cost centre for the department and may, as the patenting and licensing of gene patents by university technology transfer offices illustrates, actually undermine access in certain circumstances.

Recommendation 11: Health Canada should develop an internal intellectual property that stresses the sharing of research materials, results and data. At this time, the costs of opening a technology transfer office within Health Canada do not seem to justify the benefits of doing so.

CONCLUSION

Health Canada has a critical role to play in policy development at the intersection of health and intellectual property as part of its mission of ensuring that new, safe and effective health-related technologies enter the Canadian health care system for the benefit of Canadians. Whether working alone, with agencies reporting to the Minister of Health or with other departments, such as Industry Canada and the Department of Foreign Affairs and International Trade, Health Canada brings knowledge, expertise and policy tools that can assist in the development and use of new technologies.

The health innovation landscape is complex whether one looks at the actors involved – research-based industries, generics, medical device manufacturers, universities, colleges, research institutes, government laboratories, provincial health departments, health agencies, regulatory authorities and so on – research and development funding, business models or national differences. Within this environment, Health Canada has both formal and informal policy tools at its disposal but many of these require the input and cooperation of other agencies and departments.

There are five principal types of tool available to assist Health Canada in addressing these issues: 1) the development of internal policies with respect, for example, to intellectual property created within Health Canada or by its contractors; 2) the provision of assistance (both technical and funding) to support the development of model agreements, analytical tools, data collection in areas related to health research and the commercialization of research; 3) the provision of data, background reports and other material accessible to the research community, the media and the public, for example, with respect to counterfeit medicines and licensing practices within Health Canada; 4) to encourage, through the Minister of Health, agencies reporting to the Minister to develop appropriate policies with respect to intellectual property (especially, for example, CIHR) and the collection and dissemination of data; and 5) inform other departments and agencies, in particular Industry Canada, Indian and Northern Affairs, Foreign Affairs and International Trade and the Canadian Intellectual Property Office, about the health implications of their intellectual property policies and cooperatively develop policies at the intersection of health and intellectual property.

Health Canada also provides a bridge to provincial health authorities and can work with them to identify their concerns, for example, with respect to genetic testing services, and bring

this to the attention of other departments and agencies. In fact, the main focus of the recommendations centres on Health Canada’s facilitating role in bringing together both agencies reporting the Minister of Health (while accepting that Health Canada has no jurisdiction over these agencies) and other departments. Health Canada has much to offer these agencies and departments in terms of knowledge about the health impacts of certain policies, data to support policy formation and identification of tools that these agencies and departments can produce that will benefit Canadian industry, researchers and policy-makers.