

WICKED ISSUES FOR CANADA AT THE INTERSECTION OF INTELLECTUAL PROPERTY AND PUBLIC HEALTH: MECHANISMS FOR POLICY COHERENCE

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This article focuses on the intersection of health and one of the main drivers of the global economy, intellectual property (“IP”). It is widely recognized that IP is an inter-sectoral issue with linkages to many other important public policy areas, such as health, agriculture, the environment, and education. In inter-sectoral issues such as IP, there is discussion on the need for governments around the world to achieve policy coherence not only across their various departments, but also between their domestic and international positions in important fora.

To appreciate better the complexity of achieving policy coherence, this article first gives a multi-disciplinary view of policy coherence and then provides the Canadian context for the debate. Next, it describes three examples at the border of public health and intellectual property in Canada and internationally: (1) health innovation and access to medicines in developing countries; (2) traditional knowledge (medicinal); and (3) pandemic influenza preparedness. Finally, the article discusses international experiences with a variety of mechanisms for achieving policy coherence in IP and health, including the practice of advisory groups, multi-stakeholder dialogue, inter-departmental coordination mechanisms, broad delegations for international meetings, and white papers. From this review, a few observations can be made. First, effective coordination requires two main factors: leadership and a permanent institution that can build trust. While inter-ministerial coordination is a widely used process for policy coherence, it is not always successful. Indeed, the lack of leadership in inter-ministerial coordination has strongly constrained policy coherence.

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Despite the importance of the task of developing policy coherence, achieving it has often been elusive. Many governments around the world have spoken of policy coherence, but few have developed mechanisms to implement it. Of these, fewer still have actually attained coherence, and empirical evidence of the actual impacts of coherence is lacking. One thing appears clear: a government department wishing to create policy coherence should avoid doing it alone. Trying to achieve coherence in the absence of a government-wide and politically supported mechanism is likely to do more harm than good as the department falls prey to those departments fixated on only furthering their own policy agendas. A department—or unit within a department—wishing to engage in policy coherence must therefore raise the importance of attaining coherence at the highest levels of government: the Cabinet. A clear statement of policy by the Cabinet, coupled with strong institutional mechanisms for the administration are likely the best way to ensure the development of policy coherence. While numerous mechanisms may assist in these processes, they can only do so with effective leadership and an environment of trust.

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| INTRODUCTION | 5 |
| I. A MULTI-DISCIPLINARY VIEW OF POLICY COHERENCE | 7 |
| II. THE CANADIAN CONTEXT—ROLES OF INDUSTRY CANADA & HEALTH CANADA | 9 |
| III. EXPERIENCES WITH POLICY COHERENCE IN IP AND PUBLIC HEALTH: THREE EXAMPLES | 11 |
| A. Innovation and Access to Medicines | 11 |
| 1. Canadian Response to Innovation and Access to Medicines | 13 |
| 2. Other Responses to Innovation and Access to Medicines | 14 |
| B. Traditional Knowledge and Traditional Medicines | 16 |
| 1. Canadian Protection of TK Suffers from the Lack of Coordination of Stakeholders | 17 |
| 2. Brazilian Responses Fail to Integrate Interests of Scientists and TK Holders | 19 |
| 3. Discussion of TK at the International Level Yields some Promise | 20 |
| C. Pandemic Influenza Preparedness | 21 |
| 1. Canadian Preparedness | 21 |
| 2. Other Country Preparedness | 22 |
| IV. INSTITUTIONAL MECHANISMS FOR GREATER POLICY COHERENCE USED INTERNATIONALLY | 24 |
| A. Advisory Committees and Expert Groups | 24 |
| B. Multi-Stakeholder Consultations | 26 |
| C. Intra-Governmental Coordination Mechanisms | 27 |
| D. Broader Delegations at Intergovernmental Meetings | 33 |
| E. White Papers | 34 |
| CONCLUSION | 36 |
| APPENDIX 1: FORA THAT ADDRESS THE INTERSECTION OF IP AND PUBLIC HEALTH | 40 |

INTRODUCTION

It is widely recognized that Intellectual Property (“IP”) is an inter-sectoral issue with linkages to many other important public policy areas, such as health, agriculture, the environment, and education.¹ Like other countries, Canada is increasingly engaged in the particular subset of international discussions that link IP with public health.² The intersection points between these two issues may occur at many levels, including local health delivery, health financing, innovation³ policy, science policy, health research funding and administration, access to health care innovation for marginalized communities and developing countries, research and development in neglected and emerging infectious diseases, traditional medicine, foreign investment, foreign trade, and development assistance.

This intersection of public health and IP may be thought of as a “wicked issue”: “a problem that is complex, difficult to define, with no immediate solution, and one where every wicked problem can be considered to be a symptom of another problem.”⁴ Accordingly, there is discussion on the need for governments to coordinate policies not only across their various departments but between their domestic and international positions in important fora. Such coordination may be termed policy coherence, whole-of-government coordination or joined-up government, depending on the country. This article discusses the particular challenges governments face in developing mechanisms through which to respond to health, economic, and social concerns in a coherent and coordinated manner.

The starting premise is that economic policies (including IP policies) should not impede health equity, for example by privileging access to healthcare for wealthier segments of the population. At the same time, we acknowledge that economic development (including the development of innovative or new drugs and other therapies in the pharmaceutical sector) is a major determinant of the overall health status of countries. At the international level, the right to health has been acknowledged as a human right in various instruments,⁵ while at the national level,

¹ Laurence R. Helfer, “Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking” (2004) 29 *Yale J. Int’l L.* 1 at 8; Ahmed Abdel Latif, “Developing Country Coordination in International Intellectual Property Standard-Setting” (2005) Trade-Related Agenda, Development and Equity (T.R.A.D.E.) Working Papers 24.

² To understand the complex nature of the relationship between public health and IP, it is first necessary to define “public health”. The Public Health Agency of Canada, in its *Sustainable Development Strategy 2007-2010: Toward Sustainable Development in Public Health*, recognized the 1948 World Health Organization (“WHO”) statement that “health is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity” ((Canada: PHAC, 2006) Catalogue No. HP5-17/2006, online: PHAC <http://www.phac-aspc.gc.ca/publicat/sds-sdd/pdf/sds-sdd_e.pdf> at 3 [*Sustainable Development Strategy*]). In this context, “Public health focuses on preventing diseases not just curing them. It pays attention to the economic inequalities, social problems, and environmental issues that cause many diseases and so addresses the root causes of disease. It does this by establishing policies, services, and education programs that can prevent many diseases from occurring in the first place” (UNESCO, “Educating for a Sustainable Future: A Transdisciplinary Vision for Concerted Action” (Background paper delivered at the International Conference on Environment and Society: Education and Public Awareness for Sustainability, Thessaloniki, Greece, 8 to 12 December 1997), online: UNESCO <http://www.unesco.org/education/tlsf/TLSF/theme_a/modo1/uncom01to5s01.htm> at para. 89, citing *Sustainable Development Strategy*, *ibid.* at 3).

³ Here, we rely on Schumpeter’s conceptualization of innovation that requires ideas to be successfully applied in practice. This distinguishes innovation from an invention, which is simply an idea made manifest (Joseph Schumpeter, *The Theory of Economic Development* (Boston: Harvard University Press, 1934)).

⁴ Mark Petticrew *et al.*, “Better Evidence About Wicked Issues in Tackling Health Inequities” (2009) 31:3 *Journal of Public Health* 453 at 454.

⁵ For example, *Universal Declaration of Human Rights* (GA Res. 217A (III), UN GAOR, 3d Sess., Supp. No. 13, UN Doc. A/810 (1948) 71); *International Covenant on Economic, Social and Cultural Rights* (993 U.N.T.S. 3, adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966, entered into force 3 January 1976, in accordance with art. 27 [*International Covenant*]). Several regional human rights instruments also recognize the right to health. See e.g. art.

recent Canadian Supreme Court jurisprudence has recognized, at least to some extent, *Charter* rights to timely access to healthcare.⁶ A second starting premise, discussed in this article, is that while IP is justified on the basis that rewarding inventors with property rights stimulates innovation from which society may benefit, it is highly debatable whether increased patent protection for health related products and processes has, in fact, stimulated innovation by the pharmaceutical industry in Canada.⁷

The issue of policy coherence and coordination for health and IP is further complicated by two factors. First, at a national level, it is likely that policies aimed at accomplishing policy coherence between IP and public health would have incidental impacts on other policy arenas. Second, given the proliferation of international fora in which these issues are discussed,⁸ when national objectives are promoted in international fora, they may be presented by different government departments and agencies with not only differing objectives and priorities, but also differing degrees of power and autonomy.⁹ Such a scenario, as discussed in this article, suggests that national coherence in IP and public health policies is desirable, but challenging. These spill-over effects with potential unintended negative consequences coupled with intensely competing interests make the IP-health intersection a wicked issue.

This article starts with a multidisciplinary review of the concept of policy coherence and a description of the key Canadian agencies responsible for IP, public health, or both. It then describes three examples at the border of public health and IP to illustrate the complexity of achieving policy coherence: (1) health innovation and access to medicines in developing countries; (2) access to genetic resources and traditional medicinal knowledge; and (3) pandemic influenza preparedness. Each of these examples illustrates how boundary issues cross departmental jurisdiction and require a coordinated approach.

11 of the *European Social Charter* (18 October 1961, 529 U.N.T.S. 89, Eur. T.S. 35 (entered into force 26 February 1965)); art. 16 of the *African Charter on Human and Peoples' Rights* (27 June 1981, OAU Doc. CAB/LEG/67/3 rev. 5, 1520 U.N.T.S. 217; 21 I.L.M. 58 (entered into force 21 October 1986)); and art. 10 of the *Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights* ("Protocol of San Salvador", 17 November 1988, O.A.S.T.S. 1988 No. 69, 28 I.L.M. 156 (entered into force 16 November 1999)). Furthermore, the right to health is echoed in the *Constitution of the World Health Organization*, which states: "The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being ..." (Off. Rec. Wld Hlth Org., 2, 100) adopted by the International Health Conference held in New York from 19 June to 22 July 1946, signed on 22 July 1946 by the representatives of 61 States, and entered into force 7 April 1948, online: WHO <<http://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf>>).

⁶ See e.g. *Chaoulli v. Quebec (A.G.)*, 2005 SCC 35, [2005] 1 S.C.R. 791 (three of four judges in the majority recognized that a denial of ability to seek private health insurance to access timely care (hip replacement) was a violation of s. 7 of the *Canadian Charter of Rights and Freedoms* (Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (U.K.), c. 11)). For a general discussion of *Charter* cases on access to health care see Nola M. Ries, "Charter Challenges" in Jocelyn Downie, Timothy Caulfield & Colleen M. Flood, eds., *Canadian Health Law & Policy*, 3d ed. (Markham, Ont.: LexisNexis Canada, 2007) at 539.

⁷ Mélanie Bourassa Forcier & Jean-Frédéric Morin, "Canadian Pharmaceutical Patent Policy: International Constraints and Domestic Priorities" in Ysolde Gendreau, ed., *An Emerging Intellectual Property Paradigm: Perspectives from Canada* (Cheltenham: Edward Elgar Publishing Limited, 2008) at 81; Matthew Herder & E. Richard Gold, *Intellectual Property Issues in Biotechnology: Health and Industry* (Report delivered at the 3rd Mtg. of the OECD, Steering Group for the International Future Project, The Bioeconomy to 2030: Designing a Policy Agenda, Paris 7-8 February 2008) at 5, online: OECD <<http://www.oecd.org/dataoecd/16/9/40181372.pdf>>).

⁸ See Appendix 1 at the end of this paper for details.

⁹ Latif, *supra* note 1.

The article then discusses mechanisms for achieving policy coherence through an examination of how other countries have managed policy coherence at the intersection of IP and public health. Specifically, the article outlines institutional mechanisms for greater coherence used in the U.S., the U.K., Switzerland, the Netherlands, Australia, Japan, Brazil, and India. This examination sets the stage for a discussion of mechanisms to achieve policy coherence in Canada. The article concludes with a discussion of the costs and benefits of attempting policy coherence on IP and health for Canada nationally and for the Canadian position in international fora. It discusses the appropriateness of a variety of mechanisms for achieving policy coherence based on international experiences.

I

A MULTI-DISCIPLINARY VIEW OF POLICY COHERENCE

Political scientists tend to favour a substantive definition of policy coherence as an outcome, (i.e., the degree of complementarity and consistency between logically-related policies generated by a political unit).¹⁰ Using this substantive definition, both coherence and incoherence could be the result of political dynamics. Increased coherence could be the result of internal power politics where one organization (a ministry for example) gains control and legitimacy over its peers.¹¹ Incoherence could also be an intended strategy to extract political gains with diverse and fragmented audiences.¹² Accordingly, two factors are positively correlated with policy coherence in the literature: first, the control of a lead organization within government and second, a united constituency with a shared policy perspective. This paper comes back to this point in the conclusion arguing that based on the countries surveyed, coherence was best accomplished in inter-sectoral issues with the adoption of a national approach, with clear and consensual policy objectives, organized and supported at the highest levels of government.

The reality, however, is that central decision-makers typically have limited control and agencies involved have multiples audiences and various interests. In this context, institutional and political constraints on policy-making may lead to “policies by the way”, a term coined by Dery in 1998 which refers to policies made incidentally in the making of other policies.¹³ In this sense, a policy promoted by an agency may be either a “substitute” or a “complement” for another policy that is not under the jurisdiction of this agency.¹⁴ A Canadian example of a substitute policy would relate to Federal and Provincial constitutional division of powers. Canadian provinces do not have constitutional jurisdiction over patent law but can nevertheless incentivize investments in research and development (“R&D”) through provincial research policies, periods of exclusive purchasing by provincial health systems, or selective coverage of pharmaceuticals and medical treatments. An example of a complementary policy is the creation of the Patented Medicine Prices Review Board (“PMPRB”) in 1987, the mandate of which is to compensate for the effect of new limitations in IP law on compulsory licenses for medicines to ensure that Canadian prices

¹⁰ R.A.W. Rhodes, “Shackling the Leader? Coherence, Capacity and the Hollow Crown” in Patrick Weller *et al.*, eds., *The Hollow Crown: Countervailing Trends in Core Executives* (New York: St. Martin’s Press, 1997) 198 at 222, n. 1.

¹¹ Alice Moseley, “Joined-Up Government: Rational Administration or Bureaucratic Politics?” (Paper delivered at the Public Administration Committee Annual Conference at the University of Glamorgan, 7-9 September 2009).

¹² Moseley, *ibid.*; Robin Pistorius, “Forum Shopping: Issue Linkages in the Genetic Resources Issue” in Robert V. Bartlett, Priya A. Kurian & Madhu Malik, eds., *International Organisations and Environmental Policy* (Westport: Greenwood Press, 1995) at 209.

¹³ David Dery, “Policy by the Way: When Policy is Incidental to Making Other Policies” (1998) 18:2 *Journal of Public Policy* 163.

¹⁴ *Ibid.*

for medicines are reasonable compared to those in other developed countries.¹⁵ Such substitutes and complements are more frequent than direct policies and produce much of the inconsistency. In Canada, this issue is particularly complex because of Canada's federal structure and the split jurisdiction over healthcare and health research and innovation. This complexity causes spill-over effects for Canada's positions on IP and public health internationally.

A further consideration, especially in light of Federal-Provincial relations and the relations between levels of government and Canada's First Nations, Inuit, and Métis, is that decentralization in policy-making may also lead to policy incoherence. Indeed, it is widely acknowledged that the rise of the "new public management" since the 1980s, which favoured decentralization to local authorities, empowerment of lower echelon employees, and creation of semiautonomous organizations, led to a decline in policy coherence.¹⁶ With increased fragmentation, motivated by enhanced effectiveness, governments lost control and expertise over complex and traversal issues. As the Organization for Economic Cooperation and Development ("OECD") observed, "constitutional, legal and political obstacles to policy coordination exist partly in order to maintain clear distribution of responsibilities and specialization of tasks among sectors and across levels of government."¹⁷ The Canadian example discussed below of decentralization of power and policy-making relates to discussions over Canada's policy on the Implementation of the Access and Benefit Sharing provisions of the UN *Convention on Biological Diversity* ("CBD").¹⁸

A second body of literature favours a procedural definition of policy coherence, namely, the degree to which institutions operate in a coherent and well-coordinated process of deliberation and decision-making. From this perspective, coherence in the process is always desirable, even when leading to incoherence in the outcome. For example, Jordan and Halpin argue that some level of incoherence in the outcome is necessary to avoid the hegemony of one issue-area of policy-making over all others, but that a rational "bargaining among informed and relevant participants" is an essential process of decision-making.¹⁹ One Canadian experience—largely a failure—with an emphasis on procedural coherence is the example of Canada's Access to Medicines Regime, also discussed below.

Notably, the pursuit of greater procedural coherence in a transparent and inclusive process may come at the expense of effectiveness. This compromise is acknowledged by the OECD: "[E]xcessive efforts to enhance coherence can result in a high degree of central control and a consequential loss of flexibility in the policy-making system."²⁰ The paradox, however, is that

¹⁵ *Patent Act*, R.S.C. 1980, c. P-4, ss. 88-89, 91; *Patented Medicines Regulations*, S.O.R./94-688, ss. 5-6. With respect to 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 existing Canadian medicines (*Patent Act*, *ibid.*, s. 85). For breakthrough medicines, the PMPRB will compare the Canadian price to the median price in seven reference countries: France, Germany, Italy, Sweden, Switzerland, the U.K. and the U.S. (*Patented Medicines Regulations*, *ibid.*, Schedule, s. 4(1)(f)(iii)). 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 (*Patent Act*, *ibid.*, s. 83).

¹⁶ Christopher D. Foster & Francis J. Plowden, *The State Under Stress: Can the Hollow State be Good Government?* (Buckingham: Open University Press, 1996); Rhodes, *supra* note 10.

¹⁷ OECD, "Improving Policy Coherence and Integration for Sustainable Development: A Checklist" *OECD Observer* 1 at 3, (October 2002) [OECD, "Improving Policy Coherence"].

¹⁸ *Convention on Biological Diversity*, 5 June 1992, 1760 U.N.T.S. 79, online: UN <<http://www.cbd.int/doc/legal/cbd-en.pdf>> [CBD].

¹⁹ Grant Jordan & Darren Halpin, "The Political Costs of Policy Coherence: Constructing a Rural Policy for Scotland" (2006) 26:1 *Journal of Public Policy* 21 at 21, 39.

²⁰ OECD, *Building Policy Coherence: Tools and Tensions* (Paris: OECD, 1996) at 8 [OECD, *Building Policy Coherence*].

effectiveness requires policy coherence in *outcome*. As stated by the OECD in the context of IP and public health,

[t]he issue of policy coherence is important in improving the availability of medicines since a number of policy areas need to be brought together in a coherent manner—including health, trade, science and technology, development co-operation and finance—in such a way as to create an environment that will spur both investments in, and efficiency of, research and product development.²¹

Accordingly, there is no consensus and limited practical examples on how to increase coherence in the *outcome* without unduly focusing on increasing coherence in the *process*, since a focus on the latter, while more immediately rewarding, may have detrimental or unintended effects on the former.

II

THE CANADIAN CONTEXT—ROLES OF INDUSTRY CANADA & HEALTH CANADA

This part sets the Canadian context, outlining the structural and economic issues at the IP-public health intersection. In Canada, patents are administered by the Canadian Intellectual Property Office and the *Patent Act*²² is under the purview of Industry Canada. The *Patent Act* governs patent protection for inventions that are new, useful, and non-obvious.²³ A patent is a limited monopoly that is granted for twenty years in exchange for the public disclosure of the invention.²⁴ The conventional wisdom is that by providing a legal (but not necessarily economic) monopoly, patents create an incentive or profit motive for the transformation of invention (the creation of ideas) into innovation (products and services that are made available on the market).²⁵ Patents constitute, however, only a small portion of the incentives that exist to promote invention and innovation; other incentives include tax credits, grants, good management, and simply being the first to market innovative products and services, which often leads to better established distribution channels, increased brand loyalty and decreased production costs associated with “learning by doing”.²⁶

Surprisingly, it is difficult from an economic and innovation perspective to determine Canada’s national interests for public health and IP rights. There is little consistent or coherent data available on Canada’s R&D environment, manufacturing capacity, domestic markets, and trade and investment flows for pharmaceuticals, biotechnology, and medical devices—all necessary information for calibrating IP protection with respect to the level of innovation.²⁷

²¹ OECD, *Coherence for Health: Innovation for New Medicines for Infectious Diseases* (Paris: OECD, 2009) at 56 [OECD, *Coherence for Health*].

²² *Patent Act*, *supra* note 15.

²³ *Ibid.* s. 2: “invention’ means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter”.

²⁴ Lionel Bentley & Brad Sherman, *Intellectual Property Law*, 2d ed. (Oxford: Oxford University Press, 2004) at 323.

²⁵ Edmund W. Kitch, “The Nature and Function of the Patent System” (1977) 20:2 J.L. & Econ. 265.

²⁶ See e.g. Frederic M. Scherer, “The Economics of Human Gene Patents” (2002) 77:12 *Academic Medicine* 1348 at 1350.

²⁷ 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, making it difficult to extract product or field specific data. 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

Nevertheless, our analysis²⁸ accords with the conclusion of Kaland and Shrier, who found that “[a]fter initially raising R&D spending to a previously determined level, the Canadian pharmaceutical industry has steadily lowered its expenditure. Further, based on available data, longer patent protection and increased R&D spending do not appear to have increased research productivity.”²⁹

In contrast to the importation into Canada of most brand name pharmaceutical products, the Canadian Generic Pharmaceutical Association claims that almost all generics are manufactured domestically.³⁰ It further contends that most of Canada’s pharmaceutical manufacturing capacity is generic.³¹ Canada’s generic drug industry generates 40% of its sales volume from exports, most of which goes to the U.S., but spends less than half the amount on R&D as brand name firms.³²

Aside from stimulating innovation, another argument in favour of patent protection for biomedical innovation is tied to the regulatory approval process for such products. Regulation—testing and monitoring the safety and efficacy of new drugs and medical devices—has a significant impact on health innovation in Canada and constitutes a non-patent barrier to entry into the Canadian market that complements the patent regime. One of the largest costs in drug development involves clinical trials. 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. There are three implications to regulatory activity. First, the cost of complying with regulatory requirements—including clinical trials—is used to justify existing patent rights. With high and increasing costs of clinical trials, companies need secure and exclusive market access in order to recoup their investments in R&D. Second, the cost of meeting regulatory requirements presents a significant barrier to market access in addition to that presented 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 paediatric medicines).³³ Third, linkages between market approval and patents lead to attempts by policy-makers to balance the interests of innovator companies in recouping their investments against the interests of the general public and generic companies in particular. We argue that the balancing of interests, in addition, needs to take into account the concerns of

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 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.

²⁸ The Innovation Partnership (co-author: T. Bubela), *Intellectual Property and Health, A Report to Health Canada: Bioethics, Innovation and Policy Integration Division* (2010), online: The Innovation Partnership <www.theinnovationpartnership.org>.

²⁹ Norman Kaland & Ian Shrier, “Research Output of the Canadian Pharmaceutical Industry: Where Has All the R&D Gone?” (2006) 1:4 *Healthcare Policy* 21 at 30.

³⁰ The two biggest players in the Canadian generic sector are Apotex (Canadian-owned) and Novopharm (Israeli-owned). They account for approximately 6% and 2% of the Canadian drugs market, respectively. See The Canadian Generic Pharmaceutical Association, “Resources” (2010), online: CGPA <http://www.canadiangenerics.ca/en/resources/economic_benefits.asp>.

³¹ *Ibid.*

³² Estimates are that generic manufacturers spent \$450 million on R&D, as compared to \$1,210 million for name brand firms: Canadian Generic Pharmaceutical Association, *The Role of the Generic Pharmaceutical Industry in Canada’s Economy* (Toronto: Canadian Generic Pharmaceutical Association, August 2010), online: CGPA <http://www.canadiangenerics.ca/en/advocacy/docs/The_Role_of_the_Generic_Pharmaceutical_Industry_in_Canada%27s_Economy.pdf>.

³³ *Regulations Respecting Food and Drugs*, C.R.C., c. 870, s. C.08.004.1.

the Canadian public about the sustainability and quality of the publicly funded healthcare system. The ever escalating costs of healthcare in Canada,³⁴ in part driven by the cost of pharmaceuticals and technological innovation, enhances the argument that IP policies should be informed by health policy concerns more than the reverse.

III

EXPERIENCES WITH POLICY COHERENCE IN IP AND PUBLIC HEALTH: THREE EXAMPLES

To appreciate better the complex environment in which public health and IP issues arise at the international level, this Part outlines three recent examples with direct relevance for Canada. Each of these examples illustrates how resolution of the issues required the participation of Health Canada and at least one other federal department. We then compare the Canadian experience to that of other countries attempting to achieve policy coherence at the intersection of public health and IP. While not all of these examples have been successful, they point to the different instruments available to governments to increase coherence without losing momentum in developing policy.

A. Innovation and Access to Medicines

On September 26, 2003, Canada became the first country to announce its intention to amend its *Patent Act* to authorize the export of generic drugs manufactured under compulsory licenses.³⁵ Briefly, the history of this amendment originates with the passage of *Trade-Related Aspects of Intellectual Property Rights* (“TRIPS”)³⁶—the most comprehensive multilateral agreement on IP that sets minimum standards of protection for copyright, trademarks, and patents, among other forms of IP rights. Most problematically, it required all WTO Members (the majority of the world’s countries including both developing and developed countries) to grant patents over pharmaceutical products, whether starting in 1995, 2005, or 2016. Up to that time countries such as India only granted process patents over pharmaceuticals and not product patents. However, there is also ongoing debate about the wording and application of TRIPS and what are known as TRIPS flexibilities.³⁷ These include flexibilities as to substantive standards of protection and the availability of compulsory licensing.³⁸

³⁴ Canadian Institute for Health Information, *National Health Expenditure Trends, 1975-2010* (Ottawa: CIHI, 2010), online: CIHI <<https://secure.cihi.ca/estore/productSeries.htm?pc=PCC52>>.

³⁵ Heather Scoffield & Steven Chase, “Ottawa Heeds Call on AIDS” *The Globe and Mail* (26 September 2003) A1. See also James Orbinski, “Access to Medicines and Global Health: Will Canada Lead or Flounder?” (2004) 170:2 *Canadian Medical Association Journal* 224 at 224.

³⁶ 1869 U.N.T.S. 299, 33 I.L.M. 1197 (Annex 1C of the Marrakesh Agreement establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994), online: WTO <http://www.wto.org/english/tratop_e/trips_e/t_agmo_e.htm> [TRIPS Agreement].

³⁷ The World Intellectual Property Organization states: “These [TRIPS flexibilities] aim to permit developing and least-developed countries to use TRIPS-compatible norms in a manner that enables them to pursue their own public policies, either in specific fields like access to pharmaceutical products or protection of their biodiversity, or more generally, in establishing macroeconomic, institutional conditions that support economic development.” The flexibilities fall within four broad categories: flexibilities as to the method of implementing TRIPS obligations, flexibilities as to substantive standards of protection, flexibilities as to mechanisms of enforcement, and flexibilities as to areas not covered by the TRIPS agreement (World Intellectual Property Organization, “Advice on Flexibilities under the TRIPS Agreement”, online: WIPO <http://www.wipo.int/ip-development/en/legislative_assistance/advice_trips.html>).

³⁸ Article 31 of the TRIPS Agreement, *supra* note 36, lists detailed conditions which must be complied with when a WTO Member chooses to use compulsory licensing. “A compulsory license is a license granted by an administrative or judicial body to a third party to exploit an invention without the authorization of the patent holder” (World Health Organisation, *Utilizing TRIPS Flexibilities for Public Health Protection Through South-South Regional Frameworks* (Geneva: The South Centre, 2004) at 12, online: WHO <<http://>

In this context, a transnational network of NGOs created the political momentum necessary to address some of the concerns raised by *TRIPS* on the issue of access to medicines for developing countries.³⁹ From the end of the 1990s, this network of NGOs capitalized on controversial cases of access to patented HIV/AIDS medications in Thailand, Brazil, and South Africa,⁴⁰ and later on the anthrax crisis of 2001, to communicate their message to media and WTO negotiators. This message was framed in a simple and highly successful formula equating patents with high prices, and therefore with the narrative of premature death.⁴¹ Demonstrations in the streets of Washington, Paris, and Bangkok cast pharmaceutical companies as greedy multinationals, and then juxtaposed these firms against images of the sick and dying in developing countries.⁴²

In response, the WTO reached the *Declaration on the TRIPS Agreement and Public Health* (“Doha Declaration”) in 2001.⁴³ The *Doha Declaration* called for international negotiations to address the need of countries without sufficient pharmaceutical manufacturing capacity to import generic medicines produced under compulsory licensing. Among other things, the *Doha Declaration* provided that countries could issue compulsory licenses to import needed medicines. This was necessary as *TRIPS* had provided that these licenses could only “be authorized predominantly for the supply of the domestic market.”⁴⁴ The *Doha Declaration* formally acknowledged that this situation was unacceptable and required WTO members to negotiate an “expeditious solution.”⁴⁵ After two years of difficult negotiations, WTO members adopted the *WTO Decision* defining conditions under which a country could manufacture and export pharmaceutical products to another under a compulsory license.⁴⁶

apps.who.int/medicinedocs/fr/d/Js4968e/6.1.1.html>).

³⁹ Debora J. Halbert, *Resisting Intellectual Property* (New York: Routledge, 2005); Ruth Mayne, “The Global Campaign on Patents and Access to Medicines: An Oxfam Perspective” in Peter Drahos & Ruth Mayne, eds., *Global Intellectual Property Rights: Knowledge, Access and Development* (New York: Palgrave MacMillan, 2002); Susan K. Sell & Aseem Prakash, “Using Ideas Strategically: The Contest Between Business and NGO Networks in Intellectual Property Rights” (2004) 48 *International Studies Quarterly* 143 at 163; Ellen ‘t Hoen, “Public Health and International Law: TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way From Seattle to Doha” (2002) 3 *Chicago J. Int’l L.* 27.

⁴⁰ The U.S. had attempted to impose trade sanctions under the “Special 301” process that authorized the U.S. Trade Representative (“USTR”) to undertake a review of IP laws and practices in other countries and impose sanctions if a country failed to revise their patent laws in accordance with TRIPS and other bilateral trade agreements with the U.S. that address IP protection. By a Statement of Administrative Action given to a WTO panel ruling on a dispute involving the Special 301 powers, the U.S. agreed to forego the unilateral imposition of sanctions (World Trade Organization, *United States – Sections 301-310 of the Trade Act of 1974*, WTO Doc. WT/DS152, online: WTO <<http://docsonline.wto.org/>>). Prior to that time, middle-income countries such as India, Brazil, and Thailand have been threatened with sanctions (Jillian Clare Cohen-Kohler, Lisa Forman & Nathaniel Lipkus, “Addressing Legal and Political Barriers to Global Pharmaceutical Access: Options for Remediating the Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Imposition of TRIPS-Plus Standards” (2008) 3 *Health Economics, Policy and Law* 229 at 240-241). The most egregious example of the use of “Special 301”, however, has been against South Africa after the South African government introduced its *South African Medicines and Medical Devices Regulatory Authority Act*, No. 132 of 1998, as rep. by *Medicines and Related Substances Amendment Act*, No. 59 of 2002 that allowed the Minister of Health “to revoke patents on medicines and to allow for broad-based compulsory licensing to manufacture generic versions of HIV/AIDS drugs” (Sell & Prakash, *ibid.* at 161). In addition, in 1998, 39 pharmaceutical companies filed a lawsuit against the government of South Africa over its *Act*. The suit was dropped in April 2001 under extreme international and NGO pressure: CPTEch, “Court Case Between 39 Pharmaceutical Firms and The South African Government”, online: CPTEch <<http://www.cptech.org/ip/health/sa/pharma-v-sa.html>>.

⁴¹ Sell & Prakash, *supra* note 39 at 161.

⁴² Mark Weisbrot, “A Prescription for Scandal” *The Baltimore Sun* (21 March 2001) A17.

⁴³ WTO Doc. WT/MIN(01)/DEC/2, 4th Sess., online: WTO <http://www.wto.org/english/thewto_e/minist_e/mino1_e/mindecl_trips_e.htm> [*Doha Declaration*].

⁴⁴ *TRIPS Agreement*, *supra* note 36, art. 31(f).

⁴⁵ *Doha Declaration*, *supra* note 43 at para. 6.

⁴⁶ WTO, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public*

1. *Canadian Response to Innovation and Access to Medicines*

This example illustrates the outcome of one Canadian attempt at policy coherence between IP and global health that brought together a number of government departments and was supported at the highest political levels by the Prime Minister, Cabinet, and the legislative process. Soon after the *WTO Decision*, the Canadian government announced that it would amend the *Patent Act* to permit the issuance of compulsory licenses for export of pharmaceutical products. During the implementation process, the government faced pressure from conflicting stakeholders who were well aware that the legislation would serve as a model for other jurisdictions. “Members of the government repeated in their speeches and press releases their goal of striking a ‘necessary balance’ between the ‘competing objectives’ of facilitating the flow of drugs to developing countries, complying with international obligations, and maintaining the integrity of the domestic patent regime.”⁴⁷

To this end, five departments with different perspectives (Industry Canada, Health Canada, International Trade Canada, the Canadian International Development Agency, and the Department of Foreign Affairs) were fully engaged in the process of drafting the legislation that eventually became Canada’s Access to Medicines Regime (“CAMR”). Moreover, the government integrated domestic and foreign non-state actors in the debate. Interestingly, each set of non-state actors was consulted separately rather than together. This led to a clearer picture of the different points of view, but left the work of overcoming differences to the government officials rather than to discussion between the stakeholder communities. Despite the difficult inter-ministerial dialogue and the extensive consultative process, the legislative process was rapid: Bill C-9 received its first reading in the House of Commons February 12, 2004 and received royal assent on May 14, 2004.⁴⁸

Canada was not only the first country to amend its patent legislation to implement the *WTO Decision*, but was also the first and only to use its compulsory licensing provisions. On September 20, 2007, the Commissioner of Patents granted a compulsory license to Apotex to produce and export 260,000 packs of TriAvir, an HIV/AIDS combination therapy, to Rwanda.⁴⁹ The negotiations and delays in the process, however, were lengthy, and another compulsory license is unlikely to be requested or issued in the near future.⁵⁰ To date, no other WTO member has issued a compulsory license for export, and the WTO has received no further notifications from any exporting or importing country of their intention to do so under the system set up by the *WTO Decision*.

Because of failures in CAMR, Canada may become the first country to amend its implementing legislation.⁵¹ On March 31, 2009, Senator Yoine Goldstein (since retired) introduced a private

Health (held on 30 August 2003), WTO Doc. WT/L/540 and Corr. 1, online: WTO <http://www.wto.org/english/tratop_E/TRIPS_e/implement_para6_e.htm> [*WTO Decision*].

⁴⁷ Tania Bubela & Jean-Frederic Morin, “Lost in Translation: The Canadian Access to Medicines Regime from Transnational Activism to Domestic Implementation” (2010) at 6 [unpublished, on file with authors]; Industry Canada, “Government of Canada Reinstates Legislative Proposals to Enable Export of Low-Cost Pharmaceutical Products to Least-Developed and Developing Countries” (12 February 2004), online: Government of Canada <<http://www.ic.gc.ca/eic/site/ic1.nsf/eng/02437.html>>; Privy Council Office, “Speech from the Throne to Open the Third Session of the 37th Parliament of Canada: Canada’s Role in the World” (2 February 2004), online: Government of Canada <http://www.pco-bcp.gc.ca/index.asp?lang=eng&page=information&sub=publications&doc=sft-ddt/2004_1-eng.htm>.

⁴⁸ Lalita Acharya & Kristen Douglas, “Legislative History of Bill C-9” (3 March 2004), online: Parliament of Canada <http://www2.parl.gc.ca/Sites/LOP/LegislativeSummaries/Bills_ls.asp?Parl=37&Ses=3&ls=C9>.

⁴⁹ Apotex, Press Release, “Canadian Company Receives Final Tender Approval from Rwanda for Vital AIDS Drug” (7 May 2008), online: Apotex <<http://www.apotex.com/global/about/press/20080507.asp>>.

⁵⁰ Indeed, at a University of Toronto/McGill University Workshop held in Ottawa in 2009, Apotex expressed significant concerns over CAMR, citing the length of the negotiations and the complexity of the process.

⁵¹ Frederick M. Abbott, “The WTO Medicines Decision: World Pharmaceutical Trade and the Protection

member's bill (S-232) to amend CAMR.⁵² Then, on May 25, 2009, a similar bill (C-393) was introduced in the House of Commons by the New Democratic Party Member for Winnipeg North, the Honourable Judy Wasylycia-Leis.⁵³ Both bills were intended to facilitate the issuing of compulsory licenses by simplifying the conditions and requirements provided in the original CAMR.

S-232 and C-393 are actively supported by a group of Canadian NGOs led by the Canadian HIV/AIDS Legal Network and the Stephen Lewis Foundation.⁵⁴ These NGOs (as well as Canadian generic companies) criticize the complexity of the process to obtain a compulsory license and consider it unlikely that another compulsory license will be granted soon. According to Richard Elliott, the Executive Director of the Legal Network, "the current system just doesn't work."⁵⁵ Stephen Lewis is even harsher, stating publicly, "We have failed lamentably."⁵⁶ The brand name pharmaceutical industry, on the other hand, fully supports CAMR and is not in favour of its amendment. The Canadian government supported this latter position in its 2007 review of CAMR, led by Industry Canada, which concluded that the case for making regulatory changes to CAMR had not been made out.⁵⁷

There is widespread agreement among neutral observers that the NGO community is correct in claiming that CAMR, in its attempt to deliver medicines to those who need them, can only be considered a failure.⁵⁸ While the idea of CAMR was laudable, the complex set of rules adopted in its implementation makes it among the most bureaucratically complex pieces of legislation administered by the Canadian Intellectual Property Office. The rules led to a quick consensus, but one that does not function in practice.

This discussion of CAMR illustrates that a consensus building *process* that brought together several government departments and stakeholders does not necessarily result in a coherent *outcome*. As will be discussed further in Part IV, coherence requires far more than adoption of the lowest common denominator.

2. Other Responses to Innovation and Access to Medicines

There are four other potential responses to the issue of policy coherence for innovation and access to medicines for developing countries. First, some level of coherence may arise from clarifying the responsibilities of national ministries. There is often a disagreement over the use of

of Public Health" (2005) 99 Am. J. Int'l L. 317 at 332.

⁵² Bill S-232, *An Act to amend the Patent Act (drugs for international humanitarian purposes) and to make a consequential amendment to another Act*, 2d Sess., 40th Parl., 2009.

⁵³ Bill C-393, *An Act to amend the Patent Act (drugs for international humanitarian purposes) and to make a consequential amendment to another Act*, 2d Sess., 40th Parl., 2009.

⁵⁴ Canadian HIV/AIDS Legal Network, News Release, "Move to Reform 'CAMR' Gains Momentum: New House of Commons Bill echoes Senate proposal, would ensure life-saving medicines reach people in developing countries" (25 May 2009), online: Canadian HIV/AIDS Legal Network <<http://www.aidslaw.ca/publications/interfaces/downloadFile.php?ref=1500>>; Canadian HIV/AIDS Legal Network, Press Release, "Dying for Lack of Medicines in Developing Countries: 43 organizations join in statement on the 5th anniversary of Canada's Access to Medicines Regime (CAMR)" (May 14, 2009), online: Canadian HIV/AIDS Legal Network <<http://www.aidslaw.ca/publications/interfaces/downloadFile.php?ref=1494>>.

⁵⁵ *Ibid.*

⁵⁶ Isabel Teotonio, "Clement Vows to Get Cheap Drugs Flowing; Health Minister Decries Lack of Aid. But Current Law Prevents Action" *Toronto Star* (14 August 2004) A1.

⁵⁷ Ministry of Industry, *Report on the Statutory Review of Sections 21.01 to 21.19 of the Patent Act* (Ottawa: Ministry of Industry, 2007), online: CAMR <http://www.camr-rcam.gc.ca/review-reviser/camr_rcam_report_rapport-eng.pdf>.

⁵⁸ Jean-Frédéric Morin & E. Richard Gold, "Consensus-Seeking, Distrust, and Rhetorical Action" (2010) 16:4 *European Journal of International Relations* 563, online: SSRN <<http://ssrn.com/abstract=1435747>> [Morin & Gold, "Consensus-Seeking, Distrust, and Rhetorical Action"].

TRIPS flexibilities and mechanisms that might provide a solution to access problems. For example, health ministries may favour the use of compulsory licensing (through mechanisms similar to CAMR), while trade ministries, under pressure from industry and trade partners, generally oppose compulsory licensing.⁵⁹ To protect trade ministries from this pressure coming from their constituency, and to allow them to keep their credibility in front of their partners, a country can give the exclusive authority over compulsory licensing for pharmaceutical products to health ministries. In South Africa, Thailand, Malaysia, and other emerging countries, it is the Ministry of Health that initiates requests for the grant of compulsory licenses. In Brazil, “the grant of patents for pharmaceutical products or processes must receive the prior approval of the Brazilian Sanitary Surveillance Agency (ANVISA).”⁶⁰ Canada has not adopted this approach and requests for compulsory licenses are managed by the CAMR office within Industry Canada.⁶¹

Second, coherence may be accomplished by balancing IP and health interests. As the Supreme Court of Canada has emphasized,⁶² IP laws represent a balance between the rights of creators or innovators and those of users in order to create a dynamic, creative, and innovative environment. Thus achieving balance could be a legitimate objective when specific changes at the national level are externally motivated. For example, in the context of the Free Trade Negotiations with the U.S., Canada amended its patent legislation in 1987 to allow patents for pharmaceutical products (as opposed to merely protecting the pharmaceutical processes) and introduced a deferral period of exclusivity (for the innovating brand name company), during which a compulsory license could not be issued.

In Canada, the PMPRB was introduced to compensate for these measures motivated by foreign policies and trade considerations. It is now generally acknowledged that the PMPRB is reasonably effective in keeping the price of Canadian patented drugs low (especially compared to the U.S. but not as effective as the U.K. or New Zealand) and there is no evidence that this action chilled R&D investments in Canada.⁶³

Third, policy coherence may be accomplished through addressing and distinguishing between push (incentives for research) and pull (incentives for development and manufacturing) mechanisms for incentivizing innovation and access to medicines. Push mechanisms include R&D tax credits and public-private partnerships. Pull mechanisms include international financing options and patent pools.

An example of a push mechanism is the U.S. paediatric exclusivity rule.⁶⁴ Drug companies receive an extra six months of patent protection if they test their product on children. However, this mechanism places “the entire burden of financing vaccine and drug development on patients who need the drug for which the patent has been extended,”⁶⁵ and it could even have a detrimental effect on access.

⁵⁹ Carolyn Deere, *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (Oxford: Oxford University Press, 2009) at 212.

⁶⁰ *Ibid.* at 213.

⁶¹ Health Canada plays a regulatory role by ensuring that all products destined for export under CAMR meet the same safety, efficacy, and quality requirements as products sold in Canada. Ministry of Industry, “Canada’s Access to Medicines Regime”, online: CAMR <http://www.camr-rcam.gc.ca/countr-pays/index_e.html>.

⁶² *Théberge v. Galerie d'Art du Petit Champlain Inc.*, 2002 SCC 34, [2002] 2 S.C.R. 336 at paras. 30-33.

⁶³ Bourassa Forcier & Morin, *supra* note 7.

⁶⁴ Steven Hirschfeld *et al.*, “Pediatric Oncology: Regulatory Initiatives” (2000) 5:6 *The Oncologist* 441; Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients, Final Rule” 63:231 Fed. Reg. 66631 (1998) (to be codified at 21 CFR Parts 201, 312, 314, 601).

⁶⁵ OECD, *Coherence for Health*, *supra* note 21 at 121.

An example of a pull mechanism is the Pneumococcal Vaccine Advance Market Commitment. In 2007, Canada, Italy, Norway, Russia, the U.K., and the Bill & Melinda Gates Foundation announced a \$1.5 billion Advanced Market Commitment for pneumococcal vaccines. It subsidizes the purchase of vaccines for use in developing countries.⁶⁶ Both push and pull mechanisms are necessary and complementary, but their respective objectives and utility should be kept in mind when designing programs and institutions for their implementation; one should not be used to accomplish the goals of the other.

Finally, policy coherence on the issue of access to medicines may be addressed through collaborative mechanisms. For example, Brazil has a *sui generis* mechanism of examining patent applications related to pharmaceutical products. Since 1999, the Brazilian intellectual property office (“INPI”) and ANVISA (Brazil’s regulatory authority for pharmaceutical products) share jurisdiction over examining patent applications for pharmaceutical products.⁶⁷ The concept was to foster coherence between patent policy and the right of access to medicines. In practice, what was meant to lead to stronger coherence has instead led to conflicts in positions between the two governmental bodies.⁶⁸ Nevertheless, the Brazilian experience still points to a mechanism that could be used to reconcile patent policy and health.

B. Traditional Knowledge and Traditional Medicines

Approaches to the recognition of traditional knowledge (“TK”) and traditional medicines provide an example of how the decentralization of negotiations and extensive consultation with stakeholders may actually lead to policy incoherence. This section will compare the Canadian and Brazilian experiences in this controversial area of the IP-public health interface. It will conclude with a few examples of international approaches to the issue.

The value of indigenous knowledge is recognized internationally in areas as diverse as conservation and agricultural practices, classification systems, land use practices and sustainable management of natural resources, healthcare practices, and medicinal properties of local species.⁶⁹ The value of this knowledge raises concerns about its exploitation by non-indigenous peoples, and about the diverse genetic resources found on indigenous lands. These concerns, in turn, have led to calls for the protection of indigenous or traditional knowledge, and for sharing the benefits derived from its exploitation. A number of international bodies and international treaties recognize the need to protect TK. These include, in the specific context of traditional

⁶⁶ On 23 March 2010, GAVI released a press release stating: “The governments of Italy, the United Kingdom, Canada, Russia, and Norway and the Bill & Melinda Gates Foundation welcome the first long-term agreements made by pharmaceutical firms to supply new, affordable vaccines against pneumococcal disease to the world’s poorest countries. GlaxoSmithKline (GSK) and Pfizer Inc. are the first companies to agree to supply pneumococcal vaccines through the Advance Market Commitment (AMC). These vaccines may be available as early as this year at a fraction of the price charged in industrialised countries.” GAVI Alliance, Press Release, “Update: Donors Welcome the Advance Market Commitment’s first long-term supply commitments from leading pharmaceutical companies”, online: AMC <http://www.vaccineamc.org/update/2mar23_10.html>.

⁶⁷ Edson Beas Rodriguez Jr. & Maristela Basso, “Legal Evaluation Reconciling Intellectual Property Rights and Human and Technological Development Demands: Challenges for Brazil on the Post-TRIPS/WTO Scenario” in Francisco Rossi, ed., *Technical, Economic and Legal Evaluation of Antiretroviral Production Capacity in Brazil* (Brazil: Ministry of Health, 2008) at 55.

⁶⁸ *Ibid.* at 87.

⁶⁹ *Convention Concerning Indigenous and Tribal Peoples in Independent Countries* (27 June 1989) 72 ILO Official Bull. 59, 28 I.L.M. 1382 (indigenous peoples are those who are regarded as indigenous on account of their descent from the population which inhabited the country, or geographical region to which the country belongs, at the time of conquest or colonization or the establishment of present state boundaries and who, irrespective of their legal status, retain some or all of their own social, economic, cultural, and political institutions).

medicines, the UN *Declaration on the Rights of Indigenous Peoples*⁷⁰ and the UN *Convention on Biological Diversity* (“*CBD*”).⁷¹

How protection and benefit sharing are to be accomplished,⁷² however, is a highly divisive and controversial topic, dividing resource rich developing countries from those with advanced industrial and research capacity.⁷³ The protection of traditional medicines is particularly controversial. In 2009, the WHO General Assembly adopted a resolution on traditional medicines urging member states “to further develop traditional medicine based on research and innovation, giving due consideration to the specific actions related to traditional medicine in the implementation of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.”⁷⁴

3. Canadian Protection of TK Suffers from the Lack of Coordination of Stakeholders

Canada has yet to achieve a coherent policy to govern Canadian TK. In particular, Canada has made little progress toward the national implementation of Access and Benefit Sharing (“ABS”) provisions. Moreover, it does not specifically recognize property or other rights in TK, despite being a signatory to the *CBD*. In Canada, protection of TK is tied up in broader socio-cultural issues, Canadian constitutional law, and self-determination for Aboriginal peoples. It is perhaps due in part to the nature of the issue then, that Canada has made so little progress in policy-making.

Canada’s failure to formulate coherent policies for TK, though, is also attributable to issues at the national and international levels. At home, there are multiple federal departments and stakeholders involved in the negotiations, rendering coordination difficult. At the international stage, these departments and stakeholders often present divergent positions at international meetings. The local and international factors will be dealt with in turn.

The Canadian TK experience illustrates how decentralization in policy-making may lead to policy incoherence. Policy-making has attempted to navigate the complexities of Federal-Provincial relations, and of relations between levels of government and Canada’s First Nations, Inuit and Métis, but with little success. The failure to implement ABS provisions in Canada has

⁷⁰ UN GAOR, 61st Sess., UN Doc. A/61/L.67 (2007), online: IWGIA <<http://www.iwgia.org/graphics/Synkron-Library/Documents/InternationalProcesses/DraftDeclaration/07-09-13ResolutiontextDeclaration.pdf>>.

⁷¹ *Supra* note 18.

⁷² The *CBD* provides an international framework for the conservation and sustainable use of biological diversity. While access to genetic resources should be granted, the benefits from the utilization of genetic resources must be shared through, for example, transfer of technologies (including biotechnology), rights over the resources and appropriate funding (*supra* note 18, art. 1). The *CBD* grants these rights to the sovereign nation in which those genetic resources are endemic, not to indigenous communities within its boundaries (*ibid.*, art. 15(1)). However, countries are encouraged to develop policies or national legislation to share, in an equitable way, the results of research and development benefits arising from the commercial and other uses of genetic resources (*ibid.*, art. 15(7)). These benefits may arise between Contracting Parties—supplier and receiver of genetic resource—for example, an indigenous community and a pharmaceutical company. For a full discussion of ABS principles and the potential application of contract law versus a *sui generis* legal regime for the protection of traditional knowledge, see Shakeel Bhatti *et al.*, eds., *Contracting for ABS: The Legal and Scientific Implications of Bioprospecting Contracts* (Switzerland: IUCN, 2009).

⁷³ Sylvia I. Martinez & Susette Biber-Klemm, “Scientists—Take Action for Access to Biodiversity” (2010) 2 *Current Opinion in Environmental Sustainability* 1 at 27; Kaitlin Mara “Mismatch On Traditional Knowledge Treaty Text, Negotiating Sessions at WIPO” *Intellectual Property Watch* (8 December 2009), online: IP-Watch <<http://www.ip-watch.org/weblog/2009/12/08/mismatch-on-traditional-knowledge-treatytextnegotiating-sessions-at-wipo/>>.

⁷⁴ World Health Organization, Executive Board, *Traditional Medicines*, 124th Sess. Agenda Item 4.5, WHO Doc. EB.124.R9 (26 January 2009).

occurred notwithstanding several years of concerted negotiations and consultations around the issue. In September 2004, the Federal/Provincial/Territorial Ministers responsible for Forests, Wildlife, Endangered Species and Fisheries and Aquaculture created a working group to advance policy discussions on ABS. The working group released a consultation document on ABS policies for Canada in 2005.⁷⁵ In 2008, a federal, provincial, and territorial task group⁷⁶ was established to develop policy to address access to genetic resources and a related ABS framework.⁷⁷ This policy will also consider TK and associated TK (TK associated with genetic resources such as medicinal plants) held by aboriginal and local communities.

These measures were accompanied by close consultation with stakeholders. Environment Canada, in collaboration with provinces and territories, organized a number of workshops between December 2004 and November 2006 to inform Canadian stakeholders of the on-going policy process in Canada, and to gather stakeholder views as they relate to ABS. Scientists, lawyers, academics, policy-makers, as well as representatives from industry, aboriginal communities and NGOs, were invited to attend these events. Moreover, in 2009, Environment Canada conducted an engagement process to seek views from aboriginal people and key stakeholders on the development of ABS policy in Canada.⁷⁸ The National Aboriginal Health Organization and the Inuit Tapiriit Kanatami were two of the key aboriginal organizations that participated in the process on health issues.

There is reason to doubt whether these discussions will result in coherent policy, given the divergent positions of the Canadian Government and key Aboriginal organizations on TK. In the international arena, these two camps have consistently voiced contrary views. Aboriginal organizations have supported enforceable ABS provisions to protect rights of TK holders in Canada, while the Government of Canada has opposed such measures.⁷⁹ The disagreement was evident in the recent negotiations on an ABS Protocol at the *CBD 10th Convention of the Parties (COP 10)* held in Nagoya, Japan in October 2010. As described by *Intellectual Property Watch*,

a group of Canadian indigenous peoples published a press release about Canada's alleged undermining of the biodiversity negotiations. They said that in an interview with the Aboriginal Peoples Television Network, John Duncan, Canadian minister of Indian affairs and northern development, "claimed the ABS issue was a diversion. What is being discussed in Japan is about intellectual property, so to think that has anything really significant to do with the UN Declaration on the Rights of Indigenous Peoples is inappropriate," he was reported saying.⁸⁰

⁷⁵ Federal/Provincial/Territorial Working Group on Access and Benefit Sharing of Genetic Resources, *ABS Policies in Canada: Scoping the Questions and Issues*, online: Environment Canada <http://www.ec.gc.ca/apa-abs/documents/ABS_policies_e.pdf>.

⁷⁶ 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 (Environment Canada, "Access and Benefit Sharing", online: Environment Canada <<http://www.ec.gc.ca/apa-abs/utilisant-using2/default.cfm?lang=eng>>).

⁷⁷ Environment Canada, "Canadian ABS Portal", online: Environment Canada <<http://www.ec.gc.ca/apa-abs/>>.

⁷⁸ As of May 2010, its report was not yet available on the website.

⁷⁹ Convention on Biological Diversity, Collation of Submissions Provided in Relation to Preambular Text, Definitions and Text for Inclusion in Annex II to the Report of the Eight Meeting of the Working Group on Access and Benefit-Sharing, 9th Mtg. (Cali, Columbia 22 to 28 March 2010) CBD Doc. UNEP/CBD/WG-ABS/9/2 (10 March 2010), online: CBD <<http://www.cbd.int/abs/documents.shtml>>. Note that the position of the government of Canada (one of two from developed countries) was in stark contradistinction to the two submissions from indigenous and local community organizations, international organizations, research institutions, non-governmental organizations and stakeholders, including the Quebec Native Women Inc.

⁸⁰ Catherine Saez, "Protocol on ABS Could Further Impoverish Indigenous Peoples, Groups Claim" *Intellectual Property Watch* (26 October 2010), online: IP Watch <<http://www.ip-watch.org/weblog/2010/>>

Canadian indigenous representatives claimed, *inter alia*, that indigenous peoples face the danger in the ABS negotiations that “indigenous peoples’ inherent right to genetic resources may be deemed to be contingent upon recognition by national legislation in each state.”⁸¹ In light of these disagreements on the international stage, then, it remains to be seen how widely the views of First Nations and Inuit will diverge from those of the Canadian government and other stakeholders in domestic consultation processes. That difference will likely be a key factor in whether the process will result in concrete action on recognizing and respecting TK, and on instituting an ABS regime in Canada.

Given the complex nature of the policy discussions in Canada, the multiple federal departments involved, and the divergent international positions on the issue, it may not be surprising that Canada has yet to achieve a coherent policy over TK. As opposed to CAMR, though, in which arriving at a quick decision was given priority over formulating a coherent position, discussions over TK have been inclusive, long, and without a clear path that will likely lead to a result.

4. *Brazilian Responses Fail to Integrate Interests of Scientists and TK Holders*

As in Canada, Brazilian policy-making in the area of traditional medicines has involved a complex mix of interests, fora, and government departments, combining to create policy incoherence rather than coherence. Brazil’s experience thus provides another example of lengthy negotiations which have failed to result in an ABS regime benefiting indigenous peoples, researchers, and local industry.

Brazil holds unique cultural diversity and the largest biogenetic heritage on Earth. This blending of biodiversity and cultural diversity favours the creation of medicinal know-how based on the knowledge of flora and fauna of local communities who inhabit the various Brazilian biomes. The combination could lead to a competitive advantage for Brazil’s R&D sector if appropriate innovation policies are put into place to further ethno-pharmacology while respecting the rights of aboriginal TK holders to a fair and equitable share of any benefits.

In Brazil, the main entity for managing TK is the Council for the Management of Genetic Patrimony (Conselho de gestao do patrimonio GENético [“CGEN”]), a special body attached to the Ministry of Environment. CGEN was created by *Provisory measure n°2.186-16*, adopted on August 23, 2001. CGEN makes decisions on access to Brazilian natural resources and acts as regulatory agency on the use of biodiversity and associated TK. It coordinates policies and monitors and manages Brazil’s genetic heritage. CGEN also develops technical binding guidelines for use, access, shipping, permits, and obtaining prior informed consent from communities.

CGEN includes a wide variety of stakeholders concerned with the use of natural genetic resources for commercial or research purposes. These stakeholders include representatives of governmental bodies and public research entities (nine ministries and ten federal public administrations), including the Brazilian Environment and Renewable Resources Institute (“IBAMA”), the Indigenous Affairs Body (“FUNAI”), and the Brazilian Patent and Trademark Office (“BPTO”).⁸² Since 2003, several non-governmental “permanent guest entities” have been invited to participate in debates. Representatives of the Indigenous and Other Local and Rural Communities, environmental NGOs, academic and industrial sectors, and the General Attorney’s Office figure among these guest entities. Although some scholars have argued that the variety of stake-

10/26/protocol-on-abs-could-further-impoverish-indigenous-peoples-groups-claim/>.

⁸¹ Cited in Saez, *ibid*.

⁸² Catherine Aubertin, Valérie Boisvert & Vanessa Nuzzo, “L’accès aux ressources génétiques et le partage des avantages : une question conflictuelle, exemples du Brésil et de la Bolivie” in Catherine Aubertin, Florence Pinton & Valérie Boisvert, eds., *Les marchés de la biodiversité* (Montpellier: Éditions de l’IRD, 2007) 121.

holders ensures policy coherence in the field of ABS,⁸³ caution should be taken in interpreting the Brazilian experience.

First, the CGEN's enabling statute and regulations demonstrate a lack of coordination between Brazil's IP and TK legal frameworks. As a result, there has been little integration amongst research areas on medicinal plants and TK holders. This lack of integration reflects a failure to consider the needs of Brazil's innovative science sector and has hampered technical and scientific progress in Brazil. It has also negatively impacted local and regional economic development, because benefits have not flowed back to TK holders to foster biological and cultural conservation.⁸⁴

Nowhere are these problems of integration more visible than in the CGEN's long delays in granting permits. As of 2009, CGEN had issued only thirty-six permits to access aboriginal TK since its creation in 2001.⁸⁵ Only two of these permits related to projects of technological development that might potentially bring monetary benefits to TK holders. Moreover, in early 2009, CGEN had twenty-eight applications for access to TK under consideration. Some of these applications had been filed over four years previously. This delay in granting permits is incompatible with the requirements of Brazil's scientific and innovation sectors; however, Bills before the Brazilian government to address the interests of Brazil's biotechnology sector have been stalled since 2003. In late 2009, the Bills had still not been brought before Congress, due to a lack of consensus among different stakeholder groups, especially the Brazilian innovation sector and NGOs representing indigenous and local communities.⁸⁶

In addition to the lack of integration between IP and TK frameworks, allegations of biopiracy provide a second reason for caution in assessing Brazil's approach to TK. Indigenous communities continue to be concerned that private companies are misappropriating health-related TK. Although documented occurrences of biopiracy are rare, some anecdotal cases are well known among indigenous communities and feed their suspicion.⁸⁷ A number of IP-related measures and initiatives could be developed to address these concerns. India's TK database is one possible model. The database is available internationally to patent examiners to assess the patent criterion of novelty. Other possibilities include the disclosure of origin of generic resources in patent applications, or an internationally adopted definition of novelty that takes into account inventions disclosed orally in any country. These measures, discussed later, could be crafted in a way that would reassure TK holders without significantly impacting the patent application process.

5. Discussion of TK at the International Level Yields some Promise

TK has been discussed both nationally and internationally for over a decade.⁸⁸ Yet negotiations over TK in international fora have yielded similarly limited results for a coherent policy

⁸³ *Ibid.*

⁸⁴ Edson Beas Rodriguez Jr. in a forthcoming book chapter on Brazil—unpublished manuscript on file with author.

⁸⁵ Maria Celeste Emerick, *Acesso aos Recursos Genéticos e aos Conhecimentos Tradicionais Associados: Legislação Vigente e Consulta Pública sobre APL* (São Paulo: FEBRAPLAME, September 1st, 2008).

⁸⁶ Beas Rodriguez Jr., *supra* note 84.

⁸⁷ The most often cited examples are Turmeric, Neem, Basmati Rice, Kava, Ayahuasca, Quinoa, and Hoodia according to the Traditional Knowledge Digital Library, "Bio-piracy of Traditional Knowledge", online: TKDL <<http://www.tkdl.res.in/tkdl/langdefault/common/BioPiracy.asp?GL=#Oth>> [TKDL]. For discussion of the agreement between the Brazilian Association for the Sustainable Use of Amazonian Biodiversity ((Bioamazônia) and the Swiss pharmaceutical company Novartis Pharma AG (Novartis)) that prompted the government of Brazil to establish a legal framework for ABS see Aubertin, Boisvert & Nuzzo, *supra* note 82.

⁸⁸ Kaitlin Mara, "Fate of Traditional Knowledge A Key Decision at WIPO Assemblies" *Intellectual Property Watch* (22 September 2009), online: IP Watch <<http://www.ipwatch.org/weblog/2009/09/22/>>

approach to TK. One recent development, though, is the work of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. In response to individual countries' mixed experiences with protection for traditional medicines,⁸⁹ the committee has considered a health-related exception for the use of TK "in government hospitals, especially by [TK] holders attached to such hospitals, or use for other public health purposes."⁹⁰ That committee is also currently working on a document entitled *The Protection of Traditional Knowledge: Revised Objectives and Principles*.

A second promising initiative is the compromise ABS protocol treaty against biopiracy, which was recently adopted at the UN *CBD* Conference of the Parties ("COP 10") in Nagoya.⁹¹ The instrument is aimed at preventing misappropriation of genetic resources and ensuring that benefits accrued from the use of those genetic resources are shared equitably with the provider country. It will come into force once ratified by 50 countries, but some countries, such as the U.S., are not parties to the *CBD*. The issue of biopiracy is also under discussion at the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, Folklore, which has been mandated by the 2009 WIPO General Assembly "to create an 'international legal instrument' on the protection of [TK]."⁹²

The examples of Canada and Brazil demonstrate that TK policy-making involves a complex mix of interests, fora, and government departments. Despite the length of TK discussions that have taken place in multiple settings, these discussions have resulted in policy incoherence rather than coherence. Unfortunately, none of the mechanisms adopted—such as Brazil's multi-stakeholder agency, CGEN—, nor the negotiations at any international fora, have yet resulted in an ABS regime that benefits indigenous peoples, researchers, and local industry.

C. Pandemic Influenza Preparedness

1. Canadian Preparedness

The Canadian example of influenza preparedness illustrates how privileging IP rules and industrial interests over public health may lead to the unintended consequence of tying the hands of policy-makers and politicians responding to public health crises. In the event of a pandemic or a national health emergency in Canada, the provisions of the *Patent Act* relating to compulsory licenses are available.⁹³ Under normal circumstances, the Commissioner of Patents will only consider an application for a compulsory license after the federal or provincial government has attempted to obtain authorization from the patentee under reasonable commercial terms. However, the government is exempted from this obligation in cases of "national

fate-of-traditional-knowledge-a-key-decision-at-wipo-assemblies/>.

⁸⁹ See e.g. South Africa, Traditional Health Practitioners Act, No. 35 of 2004 and Philippines, *Traditional and Alternative Medicinal Act (TAMA) of 1997*, Republic Act No. 8423.

⁹⁰ World Intellectual Property Organization, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *The Protection of Traditional Knowledge: Revised Objectives and Principles*, 9th Sess., (Geneva, 24 to 26 April 2006) WIPO Doc. WIPO/GRTKF/IC/9/5 Annex, (9 January 2006) at 33 art. 8 (Exceptions and Limitations).

⁹¹ Catherine Saez, "Compromise UN Protocol Treaty Against Biopiracy Adopted in Japan" *Intellectual Property Watch* (29 October 2010), online: IP Watch <<http://www.ipwatch.org/weblog/2010/10/29/compromise-un-protocol-treaty-against-biopiracy-adopted-in-japan/>>.

⁹² Kaitlin Mara, "WIPO Traditional Knowledge Committee Opens with Hope for Text-Based Talks" *Intellectual Property Watch* (3 May 2010), online: IP Watch <<http://www.ipwatch.org/weblog/2010/05/03/wipo-traditional-knowledge-committee-opens-with-hope-for-text-based-talks/>>.

⁹³ *Patent Act*, *supra* note 15. Sections 19 and 19.1 give the Commissioner of Patents the power to grant compulsory licenses under certain circumstances.

emergency or extreme urgency or where the use for which the authorization is sought is a public non-commercial use.”⁹⁴ Nevertheless, no Canadian government has exercised these rights.

These compulsory licensing provisions of the *Patent Act* in respect of medicines involve two government departments and one agency. Health Canada is likely to be the department requesting the compulsory license; Industry Canada is responsible for the *Patent Act* itself; and the Canadian Intellectual Property Office is responsible for granting and administering compulsory licenses. Nevertheless, there is no sustained discussion between these departments over whether the compulsory licensing provisions function as intended.

Following the September 11 terrorist attacks, Health Canada, fearing an attack on Canadian soil, placed an order for ciprofloxacin (“CIPRO”), a drug used to treat anthrax poisoning, with Apotex Inc., a generic drug company.⁹⁵ Apotex agreed to sell Health Canada a generic version of CIPRO for less than the price usually demanded by Bayer Inc., the owner of the CIPRO-related patents. Health Canada claimed that it had the authority to ignore the patents because Bayer appeared unable to meet its supply demands. The federal government ultimately negotiated a settlement with Bayer Inc., in order to avoid a domestic lawsuit or an international trade dispute before the WTO Dispute Settlement Body.⁹⁶

Similarly, during the avian flu outbreaks of 2005, Canada considered obtaining compulsory licenses to patented drugs used to treat the virus. Ultimately, Roche Pharmaceuticals, the patent holder over TAMIFLU, agreed to allow the production of a generic version of the product in Canada. However, had a pandemic occurred, a severe shortage would have nevertheless arisen; Roche management estimated that it would take generic manufacturers three years to prepare for production.⁹⁷

2. Other Country Preparedness

In the case of a global pandemic and associated drug or vaccine shortage, it is generally assumed that countries with manufacturing capacities will be better positioned than those without. During an outbreak, countries with production facilities would declare a national emergency and limit or ban the export of drugs and vaccines to other countries. Accordingly, those without sufficient manufacturing capacity would not be able to take advantage of the flexibilities granted by the *Doha Declaration* and the *WTO Decision* of August 30th, 2003, including the issuance of compulsory licenses for the importation of drugs and vaccines from countries with adequate manufacturing capabilities.

To avoid such a scenario where the lack of manufacturing capacity could pose significant problems, Brazil enacted *law n° 9279 of 14 May 1996*. It authorizes the grant of a compulsory license if the patent holder does not manufacture the product in Brazil.⁹⁸ This law prepared Brazil for facing a global pandemic by providing a strong incentive for foreign direct investment in drug manufacturing in Brazil. Although it is frequently criticized by the U.S. government on the ground that it discriminates between imported and locally manufactured products, the U.S. has never requested a WTO panel to settle the dispute (beyond the request for consultation with Brazil filed in 2001).

⁹⁴ *Ibid.* s. 19.1(2). Note that this section does not exempt the government from its obligation to fairly compensate the patentee.

⁹⁵ M.D. Penner & A. Abouali, “The Impact of Intellectual Property Rights on Health Care” (2008) 28:3-4 *Health L. Can.* 89 at 91.

⁹⁶ *Ibid.*

⁹⁷ *Ibid.*

⁹⁸ Art. 68 (regulates rights and obligations relating to industrial property).

Arguably, however, even countries with adequate manufacturing capability such as, the U.S., Canada, the E.U., Japan, Australia, and other countries that have opted-out of the *WTO Decision's* compulsory licensing mechanism as importing countries, could also suffer in the case of a global pandemic. For example, during the 2005 bird flu crisis, the U.S. had supplies of TAMIFLU available for less than 1% of its population. It did not have the capacity to switch all of its domestic manufacturing capacity to produce the medicine quickly enough if the crisis had worsened. Without the mechanism for compulsory licensing, the U.S. could not have imported the medicine from another country without the patent holder's consent, making it legally impermissible for the country to address its health crisis. Canada or another country that has opted-out of the *WTO Decision* could face a similar problem during a pandemic or other emergency situation. Therefore, the problem of countries with insufficient manufacturing capacity, a problem which the *WTO Decision* was aimed at addressing, is not necessarily limited to developing countries but also to developed countries that privilege IP over health interests. This possibility illustrates that a failure to understand the domestic health implications of trade policy could severely hamper a country's ability to effectively deal with a health crisis.

A more immediate connection exists between research using genetic resources, IP and pandemics. As described in *The Economist*:

[In 2006], the Indonesians stopped giving the WHO samples of the H5 virus which is responsible for avian flu, a disease that has forced a mass slaughter of poultry in many countries and could, if it mutates, cause a deadly epidemic among humans. Indonesia won some sympathy for its complaint that it was giving away precious intellectual property, while it might well be unable to afford the vaccines which are then developed. Indonesian officials put it bluntly: why should they hand over precious virus strains when the resultant vaccine may never benefit their people? There was little the WHO could do in response.⁹⁹

The international policy response was appropriate in the circumstances and privileged health over IP rights. At the WHA, in May 2007, developed countries agreed in principle that developing regions must have access to life-saving vaccines in the event of a pandemic.¹⁰⁰ As a result, Indonesia once again shared its virus samples, but negotiations continue on how to ensure this access through an inter-governmental working group.¹⁰¹ In 2009 the WHA adopted the resolution on *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits*.¹⁰² Among other things, it requested the Director-General to facilitate a transparent process to finalize the remaining elements, including the Standard Material Transfer Agreement ("SMTA") and its annex. A consultation on the SMTA, IP rights more generally, and benefit sharing was attended by seventy-four member states, a regional integration organization and two other international organizations. It resulted in broad support for a system for sharing virus samples and benefits that would be more sustainable, predictable, and structured than the current ad hoc arrangement for sharing of vaccines and other benefits. There was agreement on the need for an SMTA, some general agreement on an expanded list of potential benefits, disagreement on whether benefit sharing should be mandatory or voluntary, and a wide divergence of opinion on IP rights.¹⁰³ Negotiations are ongoing.

⁹⁹ "How Dr Chan Intends to Defend the Planet from Pandemics" (16 June 2007) 383 *The Economist* 67 at 67.

¹⁰⁰ World Health Assembly, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits*, WHA Res. 60.28, 60th Sess., (23 May 2007).

¹⁰¹ WHO, *Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property, Innovation and Public Health* (Geneva: WHO Press, 2006), online: WHO <<http://www.who.int/intellectualproperty/report/en/>> [*Report of the Commission on Intellectual Property, Innovation and Public Health*].

¹⁰² World Health Assembly, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits*, WHA Res 62.10, 62d Sess., WHA (22 May 2009).

¹⁰³ World Health Assembly, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access*

While pandemic preparedness would seem to give rise to a need for coherence only at the level of the delivery of medical care, it actually embodies a complex mix of industrial, trade, and health policy. It also raises the contentious issue of access to genetic resources and benefit sharing with developing countries. For the most part, both industrial and trade policy have been designed around “normal” circumstances, that is, the absence of a critical, short-term health need. These policies are not necessarily appropriate for the case of an extraordinary event, such as a pandemic, during which resources need to be quickly reallocated and access becomes paramount. It is exactly because trade and industrial policy do not consider extraordinary situations such as pandemics that it is of vital importance for public health authorities to be involved in establishing broader policy.

IV

INSTITUTIONAL MECHANISMS FOR GREATER POLICY COHERENCE USED INTERNATIONALLY

As the discussion of the three examples of innovation and access to medicines, traditional medicines, and pandemic influenza preparedness illustrate, both national and international policy at the border of public health and IP are “wicked issues”.¹⁰⁴ Because of their complex nature, these issues often engender policy responses that are quick but inefficient (as in the case of CAMR), slow and ineffective (as have been debates over TK), or undertaken in good faith but with a failure to anticipate the unexpected (pandemic influenza).

Given the prevalence of “wicked issues” at the public health-IP boundary, it is critical that countries such as Canada develop mechanisms to develop a coherent policy that avoid negative spillovers, are inclusive, and yet do not drown in unending debate. This section surveys mechanisms that Canada and other countries have employed to deal with these issues with the goal of assessing their feasibility, costs, and benefits.

A. Advisory Committees and Expert Groups

The practice of advisory groups is extensively developed in countries like the U.S. to address issue coherence. However, their composition, mandate, and interests may lead to widely divergent policy recommendations on similar issues. For example, in the U.S., the Secretary’s Advisory Committee on Genetics, Health and Society (“SACGHS”) recently released a report recommending additional exceptions to patent rights in order to increase patient access to genetic tests.¹⁰⁵ In contrast, the reports of the Industry Trade Advisory Committee on Intellectual Property Rights consistently recommend restricting exceptions to patent rights provided in free trade agreements.

Probably the most significant difference between these committees is in their membership: few pharmaceutical companies are represented on SACGHS, and few health advocates are represented on industry or trade focused committees. This imbalance in membership has led to criticisms and court challenges.

One solution that has been explored, particularly with respect to environmental issues, has been to appoint both representatives of NGOs and industry to the same committee. Most of the time, however, these groups fail to reach a consensus and submit two reports instead of one. This

to Vaccines and Other Benefits, Report by the Secretariat on the Outcome of the Process to Finalize Remaining Elements Under the Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits, 63d Sess., WHA A63/4, WHA (15 April 2010).

¹⁰⁴ Petticrew *et al.*, *supra* note 4 at 454.

¹⁰⁵ U.S. Department of Health and Human Services, *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests*, Report of the Secretary’s Advisory Committee on Genetics, Health, and Society (2010), online: SACGHS <http://oba.od.nih.gov/SACGHS/sacghs_documents.html>.

pattern of oppositional positions between NGOs and industry occurs at both the international and national levels. It is, for example, interfering with UNITAID's ability to implement a patent pool over HIV/AIDS medicines,¹⁰⁶ and has led to a deadlock in Canada over addressing the defects in CAMR.

Other countries have more workable models. Australia has an independent body, appointed by the government: the Advisory Council on Intellectual Property that advises the Federal Minister for Innovation, Industry, Science and Research on Intellectual Property Matters and the Strategic Administration of IP Australia. The Council's membership reflects a cross section of stakeholders of the IP system, and includes industry representation (SMEs and large firms) as well as representatives from the legal and academic communities. It is currently reviewing the test for patentable subject matter in Australia, in part based on the Australian Law Reform Commission's ("ALRC") report and recommendation on gene patenting and human health.¹⁰⁷ In the past, it has considered patents and experimental use exemptions, and the patentability of plants and animals.

In 2001, the U.K. Secretary of State for International Development established the Commission on Intellectual Property Rights ("CIPR") to develop a report on IP rights and development issues, including health. That commission was unusual in that it comprised members from a diversity of countries, backgrounds, and perspectives and incorporated voices from both developed and developing countries in the fields of science, law, ethics, economics, as well as industry, government and academia. Although appointed by the British Government, the CIPR was given freedom to set its own agenda, devise its own programme of work, and reach independent conclusions and recommendations. CIPR was granted the capacity and financial support to improve its understanding of the issues through commissioning studies, organizing workshops and conferences, and visiting officials and affected groups throughout the world.¹⁰⁸ The CIPR issued its report in September 2002.¹⁰⁹

The Canadian experience has been more similar to that of the U.S. For example, the Sectoral Advisory Groups on International Trade included mostly representatives from industry. This has led to criticism, and Blouin, Foster and Labonté recommended the inclusion of "more public health representatives in the Sectoral Advisory Groups on International Trade (SAGITs) which advise the government on trade policymaking."¹¹⁰

One solution may be for government to cease to select members of advisory committees on the basis that they represent a group of stakeholders. It is a mistake to consider that "industry" or "NGOs" are cohesive and monolithic groups.¹¹¹ Even among more specific groups such as "innovative industry" or "development NGOs", major disagreements exist. Therefore, more productive debates may emerge by focusing on selecting the right individuals rather than select-

¹⁰⁶ E. Richard Gold & Jean-Frédéric Morin, "The Missing Ingredient in Medicine Patent Pools" (2009) 374:9698 *The Lancet* 1329.

¹⁰⁷ Austl., Commonwealth, Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health* (Australian Government: ALRC 99, 2004), online: ALRC <<http://www.alrc.gov.au/publications/report-99>>.

¹⁰⁸ It visited Brazil, China, India, Kenya and South Africa and consulted with NGOs based in the U.K., Europe and the U.S. as well as the pharmaceutical industry in the U.K. It was supported by a Secretariat supplied by the U.K. Department for International Development ("DFID") and the U.K. Patent Office.

¹⁰⁹ U.K., Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* (London: Commission on Intellectual Property Rights, 2002), online: CIPR <http://www.iprcommission.org/papers/text/final_report/reportwebfinal.htm> [Commission on Intellectual Property Rights].

¹¹⁰ Chantal Blouin, John Foster & Ronald Labonté, *Canada's Foreign Policy and Health: Toward Policy Coherence* (Ottawa: North-South Institute, 2002) at 82.

¹¹¹ Jean-Frédéric Morin, "The Two-Level Game of Transnational Network" (forthcoming in 2010) *International Interactions*.

ing the right representatives. The idea here is to have fewer appointed lobbyists (either NGO or industry) and more appointees with practical experience in business, health care, and research.

However, Canada's experience with an advisory committee in areas of biomedical innovation and health—the now disbanded Canadian Biotechnology Advisory Committee—illustrates the dangers of such an approach. While the members may have been experts and may have represented a variety of interests without including lobbyists, the committee had little impact on policy development. Since the committee was considered little more than a group of experts, its recommendations were largely ignored by governments.¹¹²

B. Multi-Stakeholder Consultations

It is widely assumed that open exchanges among informed parties based on argumentative interaction will improve the coherence of a policy, its social acceptance and its normative acceptability. This is especially the case when ethical issues are at stake. In these circumstances, governments increasingly rely on multi-stakeholder dialogue to ensure that sufficient debate occurs to confront values, perceptions and views. The OECD has recognized the value of a breadth of viewpoints: “Innovative decision-making mechanisms that associate the private and public sectors as well as NGOs are in demand, and, increasingly, business is playing a positive role.”¹¹³

This model has potential if stakeholders share some norms, world-views, interest and trust each other.¹¹⁴ This may have been the case in India—the fact that “India ... stands out for its strategic and tailored approach to *TRIPS* implementation” might be the result of its extensive consultation process:

Starting in 1996-1997, the Commerce Ministry initiated one of the most comprehensive consultation processes among developing countries on *TRIPS*, involving industry and trade organizations, NGOs, research and academic institutions, political parties, and parliament.¹¹⁵

Similarly, Brazil instituted CGEN, discussed above, to include a wide variety of representatives, gathering all the stakeholders concerned by the use of natural genetic resources for commercial or research purposes. However, given the procedural complications and delays in obtaining aboriginal TK permits, CGEN exemplifies process trumping outcome.

There are, however, other risks and pre-conditions for deliberative approaches that are not well understood and require further research. One is the risk of groupthink.¹¹⁶ Conversely, when stakeholders have radically different views and interests and do not trust each other, there should likely be no attempt to reach consensus among them. In addition, the Canadian experience with the enactment of CAMR, discussed above, also illustrates that process might prevail over outcome.¹¹⁷ Every document published by the government on the original Bill before Parliament underlined “the concerted and sustained efforts of all relevant actors.”¹¹⁸ But Morin and Gold's interview-based study concluded that most bureaucrats recognized the regime would

¹¹² The Canadian Biotechnology Advisory Committee prepared reports on the patenting of higher life forms and made recommendations regarding research exemptions and plant breeders' exemptions. It is no longer active.

¹¹³ OECD, “Improving Policy Coherence”, *supra* note 17 at 3.

¹¹⁴ Morin & Gold, “Consensus-Seeking, Distrust, and Rhetorical Action”, *supra* note 58.

¹¹⁵ Deere, *supra* note 59 at 213.

¹¹⁶ Janis Irving, *Victims of Groupthink* (Boston: Houghton Mifflin, 1972); Janis Irving, *Groupthink: Psychological Studies of Policy Decisions and Fiascos*, 2d ed. (Boston: Houghton Mifflin, 1982).

¹¹⁷ Morin & Gold, “Consensus-Seeking, Distrust, and Rhetorical Action”, *supra* note 58.

¹¹⁸ Government of Canada, *Report on the Statutory Review of Section 21.01 to 21.19 of the Patent Act* (Ottawa: Industry Canada, 2007), online: CAMR <http://www.camr-rcam.gc.ca/review-reviser/camr_rcam_report_rapport_e.html> at 5.

most likely fail to reach its objective. For example, one Canadian government official, when asked whether he was surprised that the CAMR mechanism was not used, answered: “not particularly: it was a bit of a false issue right from the beginning.”¹¹⁹

C. Intra-Governmental Coordination Mechanisms

These mechanisms involve an institutional “catalyst” (a group, an office, a committee, etc.) in charge of intra-governmental coordination. To be effective, the institutional entity must be located within the government machinery and at the centre rather than at the margin of decision-making. It should have a mandate to favour coherence, such as reviewing laws and regulations, managing conflicting knowledge, expanding the number of scenarios and options, exploring “dissenting opinions”, conducting joint impact assessments, etc. Here, it is important to distinguish coordination from control. The goal is not higher control in the hand of one unit to achieve consistency in policy outcome: “[i]t is coordination among the parts rather than of the parts by some controlling body or person.”¹²⁰

Intra-governmental coordination mechanisms are important to IP given the disparate interests among different agencies and their stakeholders. In most countries, several agencies are responsible for different dimensions of IP. Copyright and patent are often dealt with by different agencies or departments as are domestic enforcement and international trade-related issues. What follows is a discussion of some country experiences with intra-governmental coordination mechanisms.

Switzerland presents an interesting example. An empirical study showed that Switzerland has one of the highest levels of policy coherence internationally when comparing communications on genetic resources and IP sent to the WTO, WIPO, and the CBD.¹²¹ There are two reasons for this finding. First, Switzerland may be the only country where one agency (the Swiss Federal Institute of Intellectual Property) is responsible both for domestic and international issues. This centralization facilitates coordination on IP-specific issues and enables coordination on cross-sectoral issues like IP and environment, IP and health, or IP and organized crime. Second, Switzerland has created an inter-departmental expert group.

[This] group – which includes people from the ministries responsible for economics and trade, health research, development, human rights, foreign affairs, drug approvals and intellectual property – covers a broad range of issues and has managed to expand the debate on IP and health in particular.¹²²

Similarly, the Netherlands has integrated development considerations (including health) into its economic and trade policies in what it terms “policy coherence for development”.¹²³ This policy, which was endorsed by the Dutch Cabinet, “implies that governments must always examine how decisions in other areas relate to goals and efforts in development cooperation” and that “policy areas should reinforce one another.”¹²⁴ The Ministry of Foreign Affairs increased its

¹¹⁹ Morin & Gold, “Consensus-Seeking, Distrust, and Rhetorical Action”, *supra* note 58 at 14.

¹²⁰ Martin Painter, *Steering the Modern State: Changes in Central Coordination in Three Australian State Governments* (Sydney: Sydney University Press, 1987) at 8.

¹²¹ Amandine Bled & Jean-Frédéric Morin, “Policy (In)coherence on Genetic Resources: Strategic Behavior, Bureaucratic Politics, or Socialization By-Product?” (Paper delivered at the REPI Workshop on Issue-Linkages and Regime-Complexes, Brussels, 21 May 2010).

¹²² Tove Iren S. Gerhardsen, “Swiss Initiative Seeks To Dispel ‘Black-And-White’ View Of Patents” *Intellectual Property Watch* (19 December 2006), online: IP Watch <<http://www.ip-watch.org/weblog/2006/12/19/swiss-initiative-seeks-to-dispel-black-and-white-view-of-patents/>>.

¹²³ World Intellectual Property Organization, Assemblies of the Member States of WIPO, *General Report*, 40th Series of Mtgs., WIPO Doc. A/40/7 (5 October 2004) at para. 71.

¹²⁴ The Foreign Ministry of the Netherlands, cited in Hirohisa Kohama, “Introduction: Aid, Trade, and

capacity to deal with coherence issues by establishing a Policy Coherence Unit in 2002. The task of the Unit is to ensure that the development dimension and the interests of developing countries are taken into account in the formulation of the Netherlands's positions in areas, such as trade, both at the European and international level, particularly through awareness raising and coordination with all relevant government departments and administrations. The Unit has played a role in coordinating the positions of the Netherlands's government departments and agencies during the negotiations on paragraph 6 of the *Doha Declaration on TRIPS and Public Health*, both at the national level and at the E.U. level. It is noteworthy that the Netherlands ranked first in the 2004 Commitment to Development Index.¹²⁵

In the U.K., a decade ago, the Labour Government instituted a policy of "joined-up-government". The principle here is to improve coordination in local public services and in central government and numerous initiatives and funding streams.¹²⁶ In the area of health, an independent inquiry was set up to address health inequalities under a "whole-of-government" approach. It considered both personal risk factors and the social determinants of health.¹²⁷ The inquiry conducted public consultations to identify programmes that were successfully addressing both the causes and effects of health inequalities. However, the experience with "joined-up-government" in the U.K. should also be treated with some caution because there is little empirical evidence on the effectiveness of these policies.¹²⁸

In the context of global health, the U.K. government released a Strategy in 2008 called *Health is Global*.¹²⁹ The Interministerial Group for Global Health is responsible for reviewing progress on the implementation of the Strategy, which follows on from the 2007 report discussed in the section on "White Papers" below.¹³⁰ The Interministerial Group for Global Health is supported by a cross-government steering group of senior officials. The impetus for the strategy and the Interministerial Group for Global Health is the recognition that in a globalized, interdependent world, health has become a global issue.¹³¹ In particular, the Strategy recognizes that global health is "determined by factors which themselves show scant respect for national boundaries—such as international trade, climate change, pollution, conflict, environmental degradation and poverty."¹³² Thus, the U.K. must partner with other countries, agencies and international organizations (e.g., the E.U. and UN) to improve global health. IP arises in the context of access to medicines in the strategy. The strategy promotes a "robust system of intellectual property rights, used innovatively and flexibly to promote access to medicines."¹³³ This includes

FDI for Economic Development in East Asia" in Hirohisa Kohama ed., *Asian Development Experience Vol 1: External Factors for Asian Development* (ASEAN Foundation: 2004) at 2.

¹²⁵ Latif, *supra* note at 1.

¹²⁶ Moseley, *supra* note 11 at 7.

¹²⁷ D. Nutbeam & A.M. Boxall, "What Influences the Transfer of Research into Health Policy and Practice? Observations from England and Australia" (2008) 122 *Public Health* 747 at 748-49.

¹²⁸ Jeannette Moore & Justin Keen, "Accounting for Joined-Up Government: The Case of Intermediate Care" (2007) 27 *Public Money & Management* 61.

¹²⁹ U.K., Department of Health, *Health is Global: A UK Government Strategy 2008-13* (London: Department of Health, 2008), online: Dept. of Health <http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_o88753.pdf> [*Health is Global*].

¹³⁰ U.K., Department of Health, *Health is Global: Proposals for a UK Government-Wide Strategy – A Report from the UK's Chief Medical Adviser Sir Liam Donaldson* (London: Department of Health, 2007), online: Dept. of Health <http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_o72696.pdf> [*Donaldson Report*].

¹³¹ The Strategy recognizes that a healthy population, as a cornerstone of a national economy and social development, is fundamental to global security and stability. Global health threats undermine the economic and political interests of all countries, and improving global health is a core component of meeting the United Nations Millennium Development Goals.

¹³² *Health is Global*, *supra* note 129 at 7.

¹³³ *Ibid.* at 10.

supporting the right of developing countries to use flexibilities built into *TRIPS* such as the use of compulsory licensing to improve access to medicines and innovative models such as patent pools for antiretrovirals. However, the strategy immediately cautions that “this should not be at the expense of damaging incentives to invest in research and development. Central to achieving this is agreeing to appropriate differential pricing policies for countries at different stages of development.”¹³⁴ In the context of policy coherence, the strategy calls for greater coherence and consistency between international and domestic policies that affect global health.¹³⁵ It specifically lays out departmental responsibilities.¹³⁶

Similar to the U.K., Australia has a broad policy framework and a number of initiatives to ensure policy coherence between areas of government, which come from the highest levels of government, the Department of the Prime Minister and Cabinet.¹³⁷ Senior executives within the Australian government are also expected to adhere to the Australian Public Service Senior Executive Leadership Capability Framework, which emphasizes relationship building, cooperation, and cross-government priorities.¹³⁸

Relating to IP and public health, specifically, the Australian Department of Health and Aging established the Intellectual Property and Trade Policy Section as part of its Regulatory Policy & Governance Division. The Section provides and implements advice on both domestic and international IP issues. Furthermore, it liaises with other departments and agencies on relevant issues, regardless of whether the Department of Health and Aging is the lead department, in formulating policy or Australia’s negotiating position in an international context. Other departments include those with industry and trade portfolios, as well as IP Australia. The goal is to outline issues from a health perspective to assist in overall policy formulation, including coordinating the development of IP and global health related positions at the WHO.

Japan is more similar to Canada in that it has privileged IP policy over health policy and has made little attempt to achieve coherence between the two. In terms of IP policy and Japan’s

¹³⁴ *Ibid.* at 28.

¹³⁵ *Ibid.* at 30-31 recommends that the government will work with a variety of partners domestically, as well as the WHO and EU, both of which are crucial players in global health research. The government plans to increase its investment in public-private product development partnerships for a range of neglected diseases and encourages health systems research. In addition, the U.K. strategy indicates the government’s willingness to “work effectively with non-governmental partners, especially when developing and implementing government policy; foster greater coherence and consistency of policy and action with non-governmental partners; and work more transparently with non-governmental partners”.

¹³⁶ The summary of departmental responsibilities is laid out in *Health is Global*, *supra* note 129 at Annex 5. Each of the five principles under the strategy: “better global health security”; “stronger, fairer and safer systems to deliver health”; “more effective international health organizations”; “stronger, freer and fairer trade for better health”; and “strengthening the way we develop and use evidence to improve policy and practice” lists a number of areas of action and ways of working. Each of these specific areas is designated a lead department and then lists supporting departments. Interestingly, the Intellectual Property Office is the lead department for an action item under the principle “stronger, freer and fairer trade for better health.” The action item is to “promote innovative ways to use the intellectual property system to encourage innovation and access to medicines, for example investigating patent pools for antiretrovirals.” The supporting departments are Department for Business, Enterprise and Regulatory Reform, DFID, and the Department of Health.

¹³⁷ The Department of the Prime Minister and Cabinet also provides guidelines and procedures to other Australian Government agencies on administration, the two most relevant being: the *Legislation Handbook* ((Commonwealth of Australia: Australian Government, 2000), online: DPMC <http://www.dPMC.gov.au/guidelines/docs/legislation_handbook.pdf>); and the *Cabinet Handbook* 6th ed. ((Commonwealth of Australia: Australian Government, 2009), online: DPMC <http://www.dPMC.gov.au/guidelines/docs/cabinet_handbook.pdf>).

¹³⁸ Austl., Commonwealth, Australian Public Service Commission, *Senior Executive Leadership Capability (SEL) Framework*, online: Australian Public Service Commission <<http://www.apsc.gov.au/selc/framework.pdf>>.

broader national interests, however, it has achieved remarkable coherence following the announcement by then Prime Minister Koizumi in 2002 that Japan would be an “IP-based nation”.¹³⁹ The Japanese government quickly followed on this statement by introducing and passing the *Intellectual Property Basic Act*, the objective of which was, according to article 1, “realizing a dynamic economy and society that is based on the creation of added values through the creation of new intellectual property and effective exploitation of such intellectual property.”¹⁴⁰ This Act created the Intellectual Property Strategy Headquarters within the Cabinet Office,¹⁴¹ and encouraged universities¹⁴² and businesses¹⁴³ to promote the dissemination of ideas and to develop strategies around the protection and licensing of IP.

The Diet (Japanese Parliament) and the Japanese Patent Office both took steps to implement the government policy, through legislative support or, in the case of the patent office, a labour-intensive effort to map the patents held by Japanese and foreign patent holders in Japan, the U.S., Europe, and China in a variety of strategic areas including biotechnology and nanotechnology.¹⁴⁴ 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. Officials were therefore conscious of the overarching government policy and were attempting as best they could to find ways to advance that policy. While this policy had little to say about global access to medicines, and thus is not a direct comparator for policy coherence in the IP-health nexus, it does illustrate how policy coherence can be constructed with high-level political support.

In India, policy coherence on IP and health requires not only coordination across federal or national governments, but also with the state/provincial or regional governments. In 2002, India put in place comprehensive legislation on biodiversity and IP rights at the local, national, and federal levels, to ensure policy coherence on the topic of traditional medicines. The *Biological Diversity Act* adopted in 2002 established several bodies to manage uses for biodiversity at the federal, national and local levels—the National Biodiversity Authority, the State Biodiversity Authority, and the Biodiversity Management Committee—as well as two funds to manage Access and Benefit Sharing in India (National and Local Biodiversity Funds).¹⁴⁵

The last version of India’s *Patent Act* (2005) recognized the patentability of plants and medicines but included several special clauses related to biodiversity management, such as disclosure of origin and of TK.¹⁴⁶ This last point has now been facilitated by the recent creation in India of a network of TK holders and databases at district, state, and national levels, such as the Traditional Knowledge Digital Library¹⁴⁷ and the Community Biodiversity Registers.¹⁴⁸ All these

¹³⁹ Hisamitsu Arai, “Intellectual Property Revolution: Japan’s Experience in Formulating a National IP Strategy” in *Intellectual Property Revolution* (Tokyo: Kadokawa Publishing Corporation, 2006), online: WIPO <http://www.wipo.int/export/sites/www/academy/en/research/research/pdf/national_ip_strategy.pdf>.

¹⁴⁰ Act 122 of 2002.

¹⁴¹ *Ibid.* at art. 24.

¹⁴² *Ibid.* at art. 7.

¹⁴³ *Ibid.* at art. 8.

¹⁴⁴ In October 2007, two of the authors of this article met with representatives from both the legislature office of the Diet (Japanese Parliament) and the Japanese Patent Office.

¹⁴⁵ Philippe Cullet & Jawahar Raja, “Intellectual Property Rights and Biodiversity Management: The Case of India” (2004) 4:1 *Global Environmental Politics* 97 at 103.

¹⁴⁶ *Patents (Amendment) Act 2005*, No. 15 of 2005.

¹⁴⁷ TKDL, *supra* note 87.

¹⁴⁸ R.V. Anuradha, Bansuri Taneja & Ashish Kothari, “Experiences with Biodiversity Policy-Making and Community Registers in India” in Krystyna Swiderska ed., *Participation in Access and Benefit-Sharing Policy* (London: International Institute for Environment and Development (IIED), 2001) Case Study No. 3, online: CBD <<http://www.cbd.int/doc/case-studies/abs/cs-abs-reg-in-en.pdf>>.

instruments aim to implement a coherent policy regarding the use of biological material in traditional medicines but do not, in themselves, constitute a legislative framework to protect TK.¹⁴⁹

More recently, the Department of Industrial Policy and Promotion (“DIPP”), the nodal agency for IP issues in India has set up a discussion forum on IP rights issues to facilitate a wider consultation on all IP issues, particularly those under discussion at WIPO.¹⁵⁰ However, legislation (under consideration but not yet passed) specifically aimed at protecting TK within a *sui generis* system is unlikely to be implemented by the DIPP, but rather by the Ministry of Environment.¹⁵¹ Shamnad Basheer, an Indian IP expert, questions the DIPP’s jurisdiction over issues under discussion at WIPO because these and other issues of international IP affairs were shifted by the Prime Ministers’ Office from the Ministry of Human Resource Development (“HRD”) to the Ministry of Commerce, except for copyright which remained with HRD. Indeed most WIPO meetings on copyright issues are attended by Mr. G. Raghavender, the current registrar of copyrights.¹⁵² From this, Basheer calls for coherent IP policy formulation in India, commencing with clarification of the jurisdictional bounds of the various ministries.¹⁵³ Further, Basheer concludes that there is increasing incoherence between India’s “domestic” and “international” positions on IP. In this context, pharmaceutical IP policy is likely to be particularly problematic, with the involvement of an increasing number of ministries.¹⁵⁴ The Ministry of Commerce can legitimately claim the greatest interest, given that it is in charge of patents overall. However, the Ministry of Health and Family Welfare could theoretically intervene and devise solutions, in so far as public health issues intersect with patents. That said, it has not been very active yet on the issue of pharmaceutical patents.

Basheer concludes by noting that the increasing number of government agencies involved at the intersection of IP and health, if combined with little coordination is a sure recipe for confusion.¹⁵⁵ The confusion is likely to increase unless jurisdictional issues are made clear. More

¹⁴⁹ Cullet & Raja, *supra* note 145.

¹⁵⁰ The website invites comments from individuals, organizations, stakeholders, and other interested parties, online: DIPP <www.dipp.nic.in>.

¹⁵¹ Shamnad Basheer, “Indian IP Policy Formulation: From Confusion to Coherence” (2010), online: Spicy IP Blog <<http://spicyipindia.blogspot.com/2010/03/indian-ip-policy-formulation-from.html>>. Text on India is adapted from Basheer (2010) with permission. Mr. Bhaskar’s task is to coordinate all IP issues that fall within the jurisdiction of the DIPP, including patents, trademarks Geographic Indications, and Industrial Design. However, it does not include copyright that falls under the exclusive domain of the HRD, new plant varieties that fall under the jurisdiction of the Ministry of Agriculture, and circuit topography that falls under the jurisdiction of the Ministry of Information Technology.

¹⁵² *Ibid.*

¹⁵³ *Ibid.*

¹⁵⁴ *Ibid.*

¹⁵⁵ For example, “the Ministry of Chemicals and Fertilizers is starting to play a larger role in pharmaceutical patent matters. Indeed, in 2008, the Department of Pharmaceuticals was set up to exclusively focus on pharmaceutical issues. And this department has already [begun] flexing its ‘patent’ muscle ... A recent notice announcing a [Federation of Indian Chambers of Commerce & Industry] patent round-table suggests that key personnel from [the Department of Pharmaceuticals] will hold forth on section 3(d) [of the *Patents Act*, 1970], a section that is yet to be conclusively interpreted by a court of law.” (Basheer, *supra* note 151); According to the Federation of Indian Chambers of Commerce & Industry, “[s]ection 3(d) was introduced in 2005. The section provides that mere discovery of a new form of a known substance which does not result in enhancement of the known efficacy of that substance or mere discovery of new property or new use for a known substance or of the mere use of a known process, etc., are not patentable” (Federation of Indian Chambers of Commerce & Industry, “Roundtable on Section 3d of the Patents Act, 1970” (New Delhi: Mar 29, 2010), online: Federation of Indian Chambers of Commerce & Industry <<http://www.ficci.com/events-page.asp?evid=20336>>); According to Basheer, *supra* note 151: “Apart from the above, the Ministry of Chemicals has a little more ‘IP’ say through its agency, the National Pharmaceutical Pricing Authority (NPPA), tasked with regulating pharmaceutical prices. With the creation of the [Department] of Pharmaceuticals, NPPA functions have now been moved to the [Department of Pharmaceuticals].”

importantly, it will be necessary to find effective ways of helping the agencies involved to coordinate better with each other, so as to make for coherent IP policy formulation, both domestically and internationally.

In Canada, the task of ensuring coherence on international matters traditionally fell to the Department of Foreign Affairs and International Trade (“DFAIT”). The Department of Foreign Affairs and International Trade Act provides that one of the duties of DFAIT is to “coordinate Canada’s international economic relations.”¹⁵⁶ However, with increasing internationalization of what was formerly understood as domestic issues, other departments developed extensive international activities. As a result, permanent and institutionalized inter-governmental coordination offices are sometimes useful. Canada has various Ministerial Coordinating Committees, including some on related issues, such as biotechnology and sustainable development. During the drafting of what eventually became CAMR, five departments with different perspectives (industry, health, trade, international development, and foreign affairs) were fully engaged in the process of drafting the legislation. Each official interviewed in the study by Morin and Gold confirmed that he or she was committed to reaching an inter-departmental consensus.¹⁵⁷ However, this experience has not led to a permanent inter-governmental committee on IP and health.

In general then, effective coordination requires two main factors: leadership and a permanent institution that can build trust. On the first point, inter-ministerial coordination is a widely used process for policy coherence, in particular for multidisciplinary issues such as traditional medicines—that involve trade, IP rights, relations with indigenous peoples and local communities, and environmental issues. However, this process is not always successful. Indeed, the lack of leadership in inter-ministerial coordination has been found strongly to constrain policy coherence. For example, in France, decisions relating to ABS are discussed by the General Secretariat to European Affairs (Secrétariat général des affaires européennes, “SGAE”). Coordination meetings include the main actors involved in regulating ABS, namely the ministries of research, environment, agriculture, and trade. But the lack of institutional leadership has impeded any clear decision on the topic.

Inter-ministerial coordination is a process that is also used at the European level of policy-making. In this case, the coordination meetings involve all the interested member states that are in turn often represented by different ministries. Despite the wide variety of the representatives gathered, these meetings are often successful thanks to the strong leadership of the European Commission—in particular, the Directorate General for the Environment is the leader on ABS issues.¹⁵⁸

However, there are exceptions to the requirement for leadership. One case of successful coordination without strong leadership has been pandemic influenza preparedness across the E.U. But a recent study concluded that this may be explained by special circumstances:

The EU’s powers in the field of pandemic influenza preparedness are limited to coordination, surveillance, monitoring and the issuing of recommendations. So far this soft method of inter-governmental cooperation has worked remarkably well. Although differences of influenza preparedness persist between member states, public fear and the media-frenzy about bird flu have enhanced the willingness of member states to cooperate.¹⁵⁹

¹⁵⁶ *Department of Foreign Affairs and International Trade Act*, R.S.C. 1985, c. E-22, s. 10.

¹⁵⁷ Morin & Gold, “Consensus-Seeking, Distrust, and Rhetorical Action”, *supra* note 58.

¹⁵⁸ Amandine Bled, *L’influence des firmes sur les négociations internationales, le cas de la Convention sur la diversité biologique* (D. en Science Politique, Université Montesquieu – Bordeaux, 2009) [unpublished manuscript].

¹⁵⁹ Oliver Wiechoczek, *The EU’s Contribution to Global Governance: The Case of Global Infectious Diseases* (Bruges: College of Europe, 2006) at 44.

The second factor for successful inter-ministerial coordination is a permanent institution that can build trust.¹⁶⁰ This is because coordination mechanisms do more than coordinate action. They help to improve the mutual understanding among bureaucrats from different departments by building trust. According to Felix Addord, the deputy director general and head of legal and international affairs of the Swiss Federal Institute of Intellectual Property, the goal of the Swiss Inter-Departmental Expert Group was “to build trust between the different players in the Swiss Federal Administration and to get all national experts around one table.”¹⁶¹

Furthermore, Christiansen has shown that collective identity, shared allegiance, increased knowledge, and informal relations increase coherence between institutions.¹⁶² This is especially important for issue-areas such as IP, which rely more on beliefs (on all sides) than solid empirical evidence; while the international IP system might appear rational, it is neither supported nor contested by clear empirical evidence.¹⁶³ Notwithstanding the availability of rich literature on the economics of patents, methodological constraints—especially the inability to control all the factors that drive innovation—prevent anyone from clearly establishing the optimal depth and breadth of patent protection.

D. Broader Delegations at Inter-governmental Meetings

At the 2009 WHO General Assembly, some countries (developed and developing) sent IP experts. The U.S. delegation included people from the U.S. Trade Representative (“USTR”), including an advisor for IP and an IP attaché from the Permanent Mission in Geneva. Kenya had a Patent Examiner from the Kenya Intellectual Property Institute. The U.K. sent an advisor from the Intellectual Property Office. Switzerland sent people from the Swiss Federal Institute of Intellectual Property.

Brazil is one of the few countries that systematically send people from its Health Ministry to IP related meetings, including the *TRIPS* Council, the WIPO Standing Committee on the Law of Patent, and the WIPO General Assembly. As observed in a recent study, “Brazilian diplomats serve key roles in health and other ministries to assure policy coherence across the government.”¹⁶⁴

Likewise, Switzerland has strong follow-up on international negotiations. For example, so that it can participate with greater precision and coherence in the different decision-making processes linked to the issue of traditional medicines, the Swiss government often sends the same representatives to different international negotiation processes. Indeed, an analysis of the Swiss delegation to WIPO and *CBD* revealed that Swiss representatives often have very intense follow-up sessions after international negotiations.¹⁶⁵ Moreover, several delegates specialized in both negotiation processes. Switzerland has also made efforts to send the same representatives

¹⁶⁰ A report from the International Expert Group on Biotechnology, Innovation and Intellectual Property, *Toward a New Era for Intellectual Property: From Confrontation to Negotiation*, (Montreal: International Expert Group on Biotechnology, Innovation and Intellectual Property, 2008), online: The Innovation <<http://www.theinnovationpartnership.org/en/ieg/report/>> [International Expert Group on Biotechnology, Innovation and Intellectual Property]; Morin & Gold, “Consensus-Seeking, Distrust, and Rhetorical Action” *supra* note 58.

¹⁶¹ Gerhardsen, *supra* note 122, quoting Felix Addord, the deputy director general and head of legal and international affairs of the Swiss Federal Institute of Intellectual Property.

¹⁶² Thomas Christiansen, “Intra-Institutional Politics and Inter-Institutional Relations in the EU: Towards Coherent Governance” (2001) 8:5 *Journal of European Public Policy* 747.

¹⁶³ International Expert Group on Biotechnology, Innovation and Intellectual Property, *supra* note 160.

¹⁶⁴ Ilona Kickbusch *et al.*, “Global Health Diplomacy: Training Across Disciplines” (2007) 85:12 *Bulletin of the World Health Organization* 971 at 971.

¹⁶⁵ Amandine Bled & Jean-Frederic Morin, “Strategic Behaviour, Socialization By-Product, or Bureaucratic Politics? The Case of Genetic Resources” (unpublished manuscript on file with authors).

to negotiation processes regarding IP and health, for example, the open-ended Working Group at WIPO and the Intergovernmental Meeting of the WHO on sharing of influenza viruses and access to vaccines and other benefits.¹⁶⁶

Another interesting case is that of the European Commission. According to the list of delegates sent to inter-governmental meeting, there was a specialized unit (Directorate General) taking the lead for each forum. However, such a division of labour is not put in place to the detriment of European policy coherence. To the contrary, there is evidence showing that the compartmentalization of the Commission's administrations is accompanied by strong inter-Directorate General coordination. One author already underlined this "apparent paradox: while intra-institutional politics are becoming increasingly fragmented, the relative coherence of inter-institutional relations in the EU is improving."¹⁶⁷ One explanation is that the institutional identification of European bureaucrats belongs to the Commission as whole. Specific Directorate Generals must hold together to resist the pressure and competition coming from the Council and the Parliament.¹⁶⁸ In a Europe that is still in construction, the bureaucratic politics is to be found among European institutions rather than within the Commission.

By way of contrast, at the 2009 WHO General Assembly, the Canadian delegation included mostly delegates from Health Canada, but also two delegates from CIDA (Population and Public Health, and Multilateral Institutions Division) and two from DFAIT (Health and Population Division). The delegation did not include a representative from Industry Canada or from DFAIT's Intellectual Property, Information and Technology Trade Policy Division. It is also very uncommon to have Health Canada representation at WIPO meetings such as the WIPO Standing Committee on the Law of Patent and the WIPO General Assembly, or at the Intergovernmental Working Group on TK, Genetic resources and Folklore. This may represent a missed opportunity for multi-sectoral policy development for Canada in IP and health at the international level.

E. White Papers

To ensure policy coherence, other countries have opted for the inclusion of health priorities in their national and international agenda. National efforts to develop health diplomacy are based on an "emerging recognition of the need for policy coherence, strategic direction and a common value base in global health."¹⁶⁹ Here, the assumption is that coherence could be created, not by new mechanisms or processes, but with a clearer collective vision spelled out in a single document. The emergence of the sustainable development paradigm, for example, changed the way economic and environmental issues are addressed. Following this paradigm shift, it became natural to conduct environmental impact assessments as part of trade agreements (while few think about conducting health impact assessments).

For example, in the U.K., in March 2007, the Department of Health published a report entitled *Health is Global: Proposals for a UK Government-Wide Strategy* that provided the rationale for a U.K. global health strategy.¹⁷⁰ The *Donaldson Report* recognized that, in today's globalized world it is not possible to consider a nation's health interests in isolation. This is true

¹⁶⁶ *Ibid.*

¹⁶⁷ Christiansen, *supra* note 162 at 747.

¹⁶⁸ Magdalena Frennhoff Larsén, "Trade Negotiations Between the EU and South Africa: A Three-Level Game" (2007) 45:4 *Journal of Common Market Studies* 857.

¹⁶⁹ Ilona Kickbusch, Gaudenz Silberschmidt & Paulo Buss, "Global Health Diplomacy: The Need for New Perspectives, Strategic Approaches and Skills in Global Health" (2007) 85:3 *Bulletin of the World Health Organization* 230 at 231, cited in Katherine Bond, "Commentary: Health Security or Health Diplomacy? Moving Beyond Semantic Analysis to Strengthen Health Systems and Global Cooperation" (2008) 23:6 *Health Policy and Planning* 369 at 377.

¹⁷⁰ *Donaldson Report*, *supra* note 130.

not only for infectious diseases that do not recognize national boundaries, but also for chronic diseases that are becoming a global rather than a developed country problem. In addition, globalization has led to new international governance structures that make decisions directly affecting the ability of national governments to respond to health challenges. The report makes the case for

concerted action on global health and for developing a global health strategy, one that will benefit the health of the UK population and those in the rest of the world. The report provides a framework for developing a strategy, and provides the basis for a public debate on what current global health priorities are, what the UK should focus on, and what the global health strategy should look like.¹⁷¹

A government-wide steering group was established to develop the strategy (as discussed above).

However, the report only dealt with IP issues briefly. In describing *TRIPS*, it concluded that “TRIPS strikes a good balance between the need to provide a return on the investment in research and development of new drugs and the need to secure access to medicines for poor people.”¹⁷² It expressed the U.K.’s commitment to promoting investment in pharmaceutical R&D. At the same time, however, the report recognized that “TRIPS should not prevent members from taking measures to protect public health and that, accordingly, it should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.”¹⁷³ The U.K. was a strong supporter of the compulsory licensing provisions in *TRIPS*.

An earlier report commissioned by the U.K. Secretary of State for International Development dealt more directly with IP rights, but in the context of development policy.¹⁷⁴ That report considered how national IP laws could be designed to benefit developing countries in the context of international agreements such as *TRIPS*. Chapter Two of the report examined the issue of IP rights and health. The primary issues canvassed and discussed in detail were access to medicines in developing countries and generating the resources necessary to develop pharmaceuticals and vaccines for diseases that primarily impact developing countries. It concluded with the recommendation that “[p]ublic funding for research on health problems in developing countries should be increased. This additional funding should seek to exploit and develop existing capacities in developing countries for this kind of research, and promote new capacity, both in the public and private sectors.”¹⁷⁵ Public funding is necessary because IP rights are not providing the incentives to the private sector to research in this area because there is no profitable market apparent.

On the issue of access to medicines, the report concluded that:

Countries need to adopt a range of policies to improve access to medicines. Additional resources to improve services, delivery mechanisms and infrastructure are critical. Other macroeconomic policies need to be in harmony with health policy objectives. But so also does the IP regime. Countries need to ensure that their IP protection regimes do not run counter to their public health policies and that they are consistent with and supportive of such policies.¹⁷⁶

In support of access to medicines, the report recommended that “[d]eveloping countries should establish workable laws and procedures to give effect to compulsory licensing, and

¹⁷¹ *Ibid.* at 7.

¹⁷² *Ibid.* at 46.

¹⁷³ *Ibid.* at 46.

¹⁷⁴ Commission on Intellectual Property Rights, *supra* note 109.

¹⁷⁵ *Ibid.* at 39.

¹⁷⁶ *Ibid.* at 46.

provide appropriate provisions for government use.”¹⁷⁷ Indeed, this last recommendation supports the enactment of laws that can take advantage of regimes such as CAMR.

In Switzerland, health has been included as a general policy objective in all governmental sectors to ensure better policy coherence.

Switzerland has prioritized health in foreign policy by emphasizing policy coherence through mapping global health across all government sectors. Through the Departments of Interior (Public Health) and Foreign Affairs, an agreement on the objectives of international health policy was submitted to the Swiss Federal Council to assure coordinated development assistance, trade policies, and national health policies that serve global health.¹⁷⁸

What would such a paradigm shift entail in the context of health in Canada? Blouin, Foster, and Labonté suggest a number of paradigm shifts to increase coherence on global health issues, such as a formal recognition of the right to health and a formal recognition of health as a global public good.¹⁷⁹ According to these authors, this approach would imply the

application of human rights commitments in a variety of subsidiary and related elements of health policy. It implies the development of a more effective monitoring and reporting agency within Canadian government structures, whether an enhanced role for the Canadian Human Rights Commission or some other body or process. It implies the human rights assessment of policies, whether domestic or international, which impinge on, potentially enhance or undermine Canada’s human rights obligations. We believe that such an approach would bring coherence and anchor to Canadian health policy and its future development.¹⁸⁰

CONCLUSION

Whether termed policy coherence, whole-of-government coordination, or joined-up-government, a central concern of governments around the world has been to coordinate policies not only across their various departments but between their domestic and international positions in important fora such as WHO, WTO, WIPO, OECD, *CBD*, and others. However, the pursuit of greater procedural coherence may come at the expense of effectiveness, specifically the loss of flexibility in the policy-making system as acknowledged by the OECD.¹⁸¹ The paradox is that effectiveness requires policy coherence in outcome.¹⁸² Nevertheless, there is no consensus and limited practical examples on how to increase coherence in the outcome without unduly focusing on increasing coherence in the process, since a focus on the latter, while more immediately rewarding, may have detrimental or unintended effects on the former.

The task of achieving policy coherence at the intersection of a “wicked issue” such as public health and IP has been especially important given that policy-making in this area affects so many domestic and international policies ranging from local health delivery, to health financing, innovation policy, science policy, health research funding and administration, marginalized communities, traditional medicine, links between health and socio-economic conditions, foreign investment, foreign trade, aid and humanitarian assistance, and so on.

Despite the importance of the task of developing policy coherence, achieving it has often been elusive. As this paper illustrates, many governments around the world have spoken of policy coherence, but few have developed mechanisms to implement it. Of these, fewer still have actually attained coherence and empirical evidence of the actual impacts of coherence is lacking.

¹⁷⁷ *Ibid.* at 53.

¹⁷⁸ Ilona Kickbusch *et al.*, *supra* note 164 at 971.

¹⁷⁹ Blouin, Foster & Labonté, *supra* note 110 at 28.

¹⁸⁰ *Ibid.* at 28.

¹⁸¹ OECD, *Building Policy Coherence: Tools and Tensions*, *supra* note 20 at 8.

¹⁸² OECD, *Coherence for Health*, *supra* note 21 at 4.

Some of the countries most held up as examples of having developed such coherence have not, in the end, been able to deliver. Of the countries surveyed, only Switzerland could be said to have a truly coherent policy on issues of IP and health.

Switzerland achieved its success through a coordinating body, the inter-departmental expert group on IP. Likely because it is a small country—Switzerland has a population under 8 million—and its history of international engagement, and of broad, public consultations, this coordinating committee has actually succeeded in providing a forum through which different IP positions are debated and a decision attained and implemented. As previously discussed, the success of Switzerland’s experience was likely due to the level of trust that it was able to achieve between departments and others involved with IP issues.

While not related specifically to health, the Japanese experience is instructive. Japan attained policy coherence around IP through a decision of the Prime Minister and Cabinet to make Japan “an IP nation”. The Prime Minister then formed the Intellectual Property Strategy Headquarters within the Cabinet office to oversee the creation and implementation of the country’s IP strategy. As a result, legislation was introduced and passed and a diverse set of departments and agencies, including the patent office, consulted with their stakeholders in order to build tools and develop policies to assist private and public actors to make Japan an IP nation. Nevertheless, attaining coherence in respect of IP alone is less complicated than achieving coherence with respect to health and IP together. The question remains, therefore, of whether the Japanese experience can be extended to intersecting issues of IP and public health.

The U.K. has attempted policy coherence in implementing its global health strategy through a high level Interministerial Group for Global Health. The impact of that approach and the overall strategy will be assessed in 2013, but the overall strategy calls for greater coherence and consistency between international and domestic policies that affect global health, including IP. The focus of the strategy, therefore, is assessing government policies, including IP, with respect to global health. The focus is therefore on global health and not the public health and IP nexus.

In Australia, the Department of the Prime Minister and Cabinet provides guidelines and procedures to government agencies. Senior executives within the Australian government are also expected to shape strategic thinking by operating “on the basis of a ‘whole of government’ framework and tak[ing] the broader context into account” and ensuring “portfolio effort contributes to cross-government priorities”, envisaging “what might be and how future possibilities balance with the ‘here and now’.”¹⁸³ Specifically relating to IP and public health, Australia established the Intellectual Property and Trade Policy Section as part of the Regulatory Policy & Governance Division of the Department of Health and Ageing, and tasked it with liaising with other government departments. The IP and Trade Policy Section provides and implements advice on both domestic and international IP issues and liaises with other departments and consults with other Ministries on relevant issues, regardless of whether the Department of Health and Aging is the lead department in formulating policy or Australia’s negotiating position in an international context.

In India, however, while there are some attempts to coordinate all IP issues that fall within the jurisdiction of the Department of Industrial Policy and Promotion, the nodal agency for IP issues, Basheer notes that the increasing number of government agencies involved at the intersection of IP and health, if combined with little coordination, is a sure recipe for confusion overall rather than coherence.¹⁸⁴

What, then, is to be learned from these examples? First, policy coherence is much easier said than done. Second, when it has been done, it has generally not achieved nearly the success that

¹⁸³ Australian Public Service Commission, *supra* note 138 at 3.

¹⁸⁴ Basheer, *supra* note 151.

was expected. Third, in many cases it is too soon to judge success or failure due to lack of empirical evidence—it is one thing to outline the number of processes and mechanisms, and another to determine their effectiveness in meeting their objectives. Finally, where it has succeeded, it has done so either because of the particular characteristics of the country—small and engaged in politics and debate as in Switzerland—, due to the adoption of a national policy organized through the highest offices in the land—as in the case of Japan and the U.K.—, or as a result of a strong internal champion and conditions of trust, as in the EU and in Switzerland.

While not dealing directly with the health-IP nexus, we can point to the relative success of Canada’s Science and Technology Strategy¹⁸⁵ in providing coherence between different government departments over science and technology. While some may criticize the policy itself for what it says or does not say, the fact is that most government departments do more than pay lip service to it: they try to justify their actions and policies in terms of it. While the strategy ostensibly is the responsibility of only one department, Industry Canada, its frequent mention by ministers and in Throne Speeches indicates that it was adopted and is supported at the very highest political levels in Canada.

Given these lessons, it seems that reaching full coherence requires both substantive and procedural coherence, or as Table 1 puts it, both a political commitment and the institutional capacity for greater coherence. Being politically committed to coherence means that a government has renounced “strategic ambiguity” or “strategic inconsistency”. But a number of studies suggest that most governments still rely on these strategies to extract simultaneous gains from diverse and fragmented audiences, especially in international IP debates.¹⁸⁶

However, as stakeholders motivated primarily by health issues become increasingly involved in IP fora, and IP experts learn to see the world from a health perspective, inconsistencies become more perceptible and reputational costs associated with these strategies rise. In this sense, multi-stakeholder consultations contribute to learning processes which may create pressure on the governments that set up these consultation processes to address problems of incoherence. As a result, an increasing number of governments, as this study has shown, are committed to policy coherence and have conceptualized their objectives. White papers and reports from expert groups are especially useful to identify the issues to be considered, conflicts to avoid, and synergies to seek. In some cases, the highest authorities in the country even gave an explicit impetus to pursue these objectives.

Table 1: Two conditions for policy coherence

| | | Political commitment (substantive coherence) | |
|--|------------|---|----------------------|
| | | No | Yes |
| Institutional Capacity (procedural coherence) | No | Full incoherency | Functional coherency |
| | Yes | Strategic incoherency | Full coherency |

¹⁸⁵ Industry Canada, *Mobilizing Science and Technology to Canada’s Advantage – 2007*, online: Industry Canada <[http://www.ic.gc.ca/eic/site/ic1.nsf/vwapj/S&Tstrategy.pdf/\\$file/S&Tstrategy.pdf](http://www.ic.gc.ca/eic/site/ic1.nsf/vwapj/S&Tstrategy.pdf/$file/S&Tstrategy.pdf)>.

¹⁸⁶ Raustiala Kal & David Victor, “The Regime Complex for Plant Genetic Resources” (2004) 32:2 International Organization 301; Helfer, *supra* note 1.

Political commitment, however, is not enough to reach full coherence, even when it comes from the highest authorities. IP and health policies rely heavily on bureaucratic administrations since they are quite technical issue-areas and are rarely controversial for the broader public beyond specific groups of informed stakeholders. Given the exceedingly technical issues, one could not necessarily expect the head of government or the cabinet alone to conceive and implement a strategy for greater coherence. Therefore, in addition to political commitment, full coherence requires the institutional capacity for bureaucrats to build trust, share experiences, and identify potential collaborations.

This study has discussed two mechanisms for countries like Canada to enhance this institutional capacity, namely intra-governmental coordination and broad delegation at inter-governmental meetings. Without similar mechanisms, the various agencies interested in IP and health have no choice other than to operate within policy silos, i.e. artificial boundaries between issue-areas to minimize conflicts between different authorities. We call this situation, where a government has the political commitment but not the institutional capacity, “functional coherence”. It is arguably more desirable that strategic incoherence remains but a second-best. Therefore, a clear statement of policy by the Cabinet coupled with strong institutional mechanisms for the administration are likely the best way to ensure the development of policy coherence for seemingly intransigent “wicked issues” such those found at intersection of IP and public health.

APPENDIX 1: FORA THAT ADDRESS THE INTERSECTION OF IP AND PUBLIC HEALTH

The need to deal with issues relating to IP and public health on an international level was first recognized in 1994 with the incorporation of minimum levels of IP protection in the World Trade Organization (“WTO”) *Agreement on Trade-Related Aspects of Intellectual Property Rights* (“TRIPS”),¹⁸⁷ followed by the WTO Ministerial Conference, *Declaration on the TRIPS Agreement and Public Health* (“Doha Declaration”),¹⁸⁸ and a decision of the WTO General Council that introduced a formal amendment to TRIPS to allow greater flexibility to developing countries on the issue of IP and health.¹⁸⁹

The WHO began work on IP and public health at about the same time as WTO members were debating the *Doha Declaration* and while the UN established the United Nations Millennium Development Goals and Project.¹⁹⁰ The WHO focused its attention on the interrelated issues of IP, health, and innovation, forming the Commission on Intellectual Property Rights, Innovation and Public Health in May 2003, at the Fifty-sixth World Health Assembly, by virtue of resolution WHA56.27, and released a report in 2006.¹⁹¹ On May 27, 2006, the Fifty-ninth World Health Assembly adopted Agenda 11.1 entitled “Public Health, Innovation, Essential Health Research and Intellectual Property Rights: Towards a Global Strategy and Plan of Action” and established an inter-governmental working group (“IGWG”) charged with drawing up the global action plan.¹⁹² The IGWG spent the next year or so elaborating a document entitled “Elements of a Global Strategy and Plan of Action” which it released on December 14, 2007.¹⁹³ In May 2008, the Sixty-first World Health Assembly adopted Resolution WHA61.21: Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (“GSPOA”).¹⁹⁴ Currently, the WHO’s focus is on implementing the GSPOA and other regional organizations such as the Pan American Health Organization.

Other international fora dealing with aspects of IP and public health include the Organization for Economic Cooperation and Development (“OECD”), which recognizes, on behalf of OECD countries, the need for greater coherence across sectors that affect developing countries, especially health, recognizing that aid alone cannot address the needs of the developing world. In this arena, the OECD has developed an initiative named Policy Coherence for Development.¹⁹⁵ The World Intellectual Property Organization (“WIPO”), fuelled by the rise of concerns about the

¹⁸⁷ 1869 U.N.T.S. 299, 33 I.L.M. 1197 (Annex 1C of the Marrakesh Agreement establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994), online: WTO <http://www.wto.org/english/tratop_e/trips_e/t_agmo_e.htm>.

¹⁸⁸ WTO Doc. WT/MIN(01)/DEC/2, 4th Sess., online: WTO <http://www.wto.org/english/theWTO_e/minist_e/mino1_e/mindecl_trips_e.htm>.

¹⁸⁹ WTO, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* (held on 30 August 2003), WTO Doc. WT/L/540 and Corr. 1, online: WTO <http://www.wto.org/english/tratop_E/TRIPS_e/implem_para6_e.htm>.

¹⁹⁰ UN Department of Economic & Social Affairs, “We Can End Poverty 2015 Millennium Development Goals” (2008), online: UN <<http://www.un.org/millenniumgoals/>>.

¹⁹¹ *Report of the Commission on Intellectual Property, Innovation and Public Health*, supra note 101.

¹⁹² WHO, “Public Health, Innovation and Intellectual Property”, online: WHO <<http://www.who.int/phi/en/>>.

¹⁹³ Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, *Elements of a Global Strategy and Plan of Action*, Doc. A/PHI/IGWG/1/4, 8 December 2006, online: WHO <http://apps.who.int/gb/phi/pdf/igwg1/phi_igwg1_5-en.pdf>.

¹⁹⁴ World Health Assembly, *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, Resolution WHA61.21, 24 May 2008, online: WHO <http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf>.

¹⁹⁵ OECD, “Policy Coherence for Development”, online: OECD <http://www.oecd.org/about/0,3347,en_2649_18532957_1_1_1_1_1,00.html>.

impact of increased IP protection in developing countries on health, has also adopted its own Development Agenda—launched by a group of developing countries that brought the issue to the fore at the 40th session of the WIPO Assemblies (September 20 to October 5, 2004).¹⁹⁶ In particular, the Agenda raises issues related to the welfare costs of increasing IP protection, the difficulty for developed and least developed countries to benefit from higher levels of protection, and the differences in economies and health status between developing countries and those countries proposing minimum standards of IP. WIPO also hosts negotiations on TK in its Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.

Finally, the UN *Convention on Biological Diversity* (“CBD”) provides an international framework for the conservation and sustainable use of biological diversity.¹⁹⁷ It is relevant in the context of IP and health because it contains provisions on access to genetic resources, the allocation of benefits from the utilization of genetic resources which must be shared through, for example, transfer of technologies (including biotechnology), and rights over the resources and appropriate funding.¹⁹⁸ There are also bilateral trade agreements that address IP and health, as well as current negotiations under the proposed Anti-Counterfeiting Trade Agreement that address counterfeit medicines.

¹⁹⁶ World Intellectual Property Organization, “Development Agenda for WIPO”, online: WIPO <<http://www.wipo.int/ip-development/en/agenda/>>.

¹⁹⁷ *Convention on Biological Diversity*, 5 June 1992, 1760 U.N.T.S. 79, online: UN <<http://www.cbd.int/doc/legal/cbd-en.pdf>> [CBD].

¹⁹⁸ *Ibid.*, art. 1.