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# Intellectual Property and Biomedical Innovation in the Context of Canadian Federalism

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# INTELLECTUAL PROPERTY AND BIOMEDICAL INNOVATION IN THE CONTEXT OF CANADIAN FEDERALISM

*Jeremy de Beer and Craig Brusnyk\**

## I. Introduction

The future of Canadian health care is being shaped by biotechnology. New technologies are providing patients with earlier diagnoses and superior treatment options. At the same time, developers of these technologies are seeking ways to maximize financial and strategic returns on their investments, and intellectual property is a primary vehicle for doing so. This has created new kinds of regulatory challenges for public officials and the biomedical technology industry.<sup>1</sup>

Innovation in the biomedical field has already triggered intellectual property related issues concerning the legal use and patentability of human genes, licensing and pricing of patented medicines, clinical trial data protection, and many more matters. Canadian policy makers now face the difficult task of shaping economic incentives for innovative research and product development while maintaining mechanisms to ensure public access to these health products and services. Moreover, a successful intellectual property regime must work within the broader regulatory context, especially in the health care field. In order to promote access to health technologies, law and policy makers must venture beyond traditional objectives of intellectual property and consider the multitude of other social, economic and political factors at play.

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1 See e.g. Colleen M Flood & Lorian Hardcastle, "The Private Sale of Cancer Drugs in Ontario's Public Hospitals: Tough Issues at the Public/Private Interface in Health Care" (2007) 1 McGill JL & Health 5.

Tania Bubela and colleagues<sup>2</sup> recently identified and discussed the need for policy coherence in addressing the persisting challenges at the intersection of intellectual property and health. This article adds to the ongoing dialogue by exploring the complex set of relationships that exist between intellectual property and other biomedical law and policy issues in the specific context of Canada's federal structure. While its primary focus is on the regulation and governance of intellectual property issues, the central thrust of our argument is that these intellectual property laws, policies, and practices cannot be isolated or divorced from broader regulatory issues. Intellectual property is deeply integrated in the network governance of biomedical technological innovation. Understanding intellectual property issues in this context has major legal implications, especially related to the constitutional division of powers, and, therefore, also has real practical and public policy significance.

The article has three parts. The first deconstructs and challenges assumptions about federal jurisdiction over intellectual property in the biomedical field by exploring the scope of Parliament's constitutional jurisdiction over patents and examining how the provinces also have a jurisdictional claim over the regulation of patented medicines and health technologies.

The second part investigates a series of case studies on issues of assisted human reproduction, gene patents and diagnostic testing, pharmaceutical pricing and intergovernmental relations, data exclusivity and intergovernmental relations, and finally, subsequent entry (generic) biologics. The conclusions that can be drawn from these case studies include: (i) intellectual property related jurisdictional overlap does exist in key areas of biomedical technology; (ii) a flawed and possibly unconstitutional federal regulatory framework will result if the provinces are not included in intellectual property decision making; (iii) the intersection of domestic and international intellectual property affairs further complicates federal-provincial relations in this field; and (iv) there is a need and opportunity for a cooperative intergovernmental approach in addressing federalism related to intellectual property.

The third part of this paper elaborates on this final conclusion by addressing possible strategies to manage complex relationships, in the

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2 Tania Bubela, E Richard Gold & Jean-Frédéric Morin, "Wicked Issues for Canada at the Intersection of Intellectual Property and Public Health: Mechanisms for Policy Coherence" (2011) 4 McGill JL & Health 3.

context of Canadian federalism, for better regulation and governance of biomedical technology innovation.

## II. Canadian Federalism and Biomedical Innovation

### A. Scope of Federal Jurisdiction over Patented Medicines

Most discussions in the academic literature, policymaking forums, and business community about intellectual property and biomedical innovation focus more on patents than any other issue, and in the area of biomedical patents, more on pharmaceuticals than anything else. That is one reason for the tendency to assume that the topic of intellectual property and biomedical innovation falls within the jurisdiction of the federal government to address; patents are specifically enumerated in Canada's Constitution as a federal matter. Industry Canada has, therefore, tended to deal with most patent policy issues in Canada, while Health Canada has become the primary regulator of the pharmaceutical industry. These federal departments are more active than any other, and than any provincial or territorial departments, on the matter of pharmaceutical patents. However, even in this area, jurisdictional questions are far less settled than many people have presumed. Patented pharmaceuticals are, therefore, a good place to begin this article's approach of deconstructing jurisdictional assumptions, revealing underlying complexities, and proposing possible solutions for coordinating intellectual property and biomedical innovation law and policy.

It is tempting to suggest that any intellectual property legislation related to patented biomedical technology – take pharmaceuticals as a concrete example – is always in pith and substance a matter concerning patents, and thus within the competence of Parliament. This, however, would ignore the wider constitutional legal landscape. In certain circumstances, the courts may recognize a law as presenting a “double aspect”, granting a valid jurisdictional claim to both the federal and provincial governments.<sup>3</sup> Or, in other conceivable circumstances, specific legislation might be more accurately regarded as pertaining to an exclusive matter of provincial concern.

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3 This is not to say that the double aspect doctrine should be used to avoid jurisdictional decisions. Rather, it should be used only in cases where the provincial and federal claims are equally important. See *Bell Canada v Quebec (Commission de santé et de la sécurité du travail du Québec)*, [1988] 1 SCR 749 at 765.

Canada's highest court has not yet considered the scope of Parliament's jurisdiction over section 91(22) of the *Constitution Act, 1867*,<sup>4</sup> "Patents of Invention and Discovery." However, a number of lower court decisions have helped to define Parliament's ability to legislate in the area of patented medicine. Two early cases, *Lilly v S & U Chemicals Ltd*<sup>5</sup> and *Smith, Kline & French Laboratories Ltd v Canada (Attorney General)*,<sup>6</sup> dealt with the constitutionality of compulsory licensing in respect of patents for medicine. In both cases, the plaintiff research-based pharmaceutical manufacturers sought a declaration that they were entitled to enjoy the economic benefits of their innovative medicines, free from the compulsory licensing system provided for under section 41(4) of the *Patent Act*.<sup>7</sup> They contended that the purpose and effect of the legislation was to regulate the price of drugs sold in Canada and that such regulation was a provincial matter falling under section 92(13) of the *Constitution Act, 1867*, being in pith and substance a law in relation to "Property and Civil Rights in the Province." The courts disagreed in both cases, finding that section 41(4) was a valid exercise of Parliament's legislative authority under section 91(22), since the provision was an integral part of the *Patent Act*. In *Smith, Kline & French*, Strayer J concluded: "Parliament is not precluded from creating or regulating property in the course of exercising its enumerated powers. And I can find no constitutional imperative that Parliament must exercise its authority over patents of invention and discovery in one way only."<sup>8</sup>

The enactment of legislation providing increased protection to pharmaceutical patent holders sparked another challenge to the constitutionality of federal price control. Bill C-22<sup>9</sup> purported to make significant changes to the patented medicine regulatory regime, guaranteeing patent owners a period of protection from compulsory licensing.<sup>10</sup> The bill also called for the creation of the Patented Medicine Price Review Board (PMPRB), an inde-

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4 (UK), 30 & 31 Vict, c 3, reprinted in RSC 1985, App II, No 5.

5 (1973), CPR (2d) 17 at 18 (FCA).

6 [1986] 1 FC 274 (FCTD), aff'd [1987] 2 FC 359 (FCA) [*Smith, Kline & French*].

7 RSC 1985, c P-4.

8 *Smith, Kline & French*, supra note 6 at 17. See also *Imperial Chemical Industries PLC v Apotex Inc*, [1989] FCJ No 11; and *Apotex v Tanabe Seiyaku & Nordic*, [1994] 59 OJ No 2613 (Ont Ct J (Gen Div)).

9 *An Act to amend the Patent Act and to provide for certain matters in relation thereto*, 2nd Sess, 33rd Parl, 1986 (as passed by the House of Commons 19 November 1987).

10 A brand-name drug manufacturer would thereafter be guaranteed 10 years

pendent quasi-judicial tribunal responsible for monitoring and reviewing the pharmaceutical market. The PMPRB was charged with establishing the maximum price(s) charged in Canada for patented drugs.

In 1989, the Manitoba Society of Seniors took the federal government to court, claiming that drug prices had soared since the enactment of the new legislation.<sup>11</sup> The group mounted their challenge, in part, based on the assertion that Parliament had exceeded its legislative authority and violated the constitutional right of the provinces to set their own drug prices. The challenge bore a striking resemblance to the aforementioned cases, and so did the decision. While the Manitoba Court of Queen's Bench conceded that, generally, legislation the purpose and effect of which is regulation of prices of a single industry is a provincial matter, it held that price review was merely one part of a broader regime of patent exclusivity.<sup>12</sup> In the decision, Justice Dureault quoted renowned constitutional law expert, Peter Hogg: "The pith and substance doctrine enables a law that is classified as 'in relation to' a matter within the competence of the enacting body to have incidental and ancillary effects on matters outside the competence of the enacting body."<sup>13</sup> Dureault J also returned to an earlier pronouncement by the Judicial Committee of the Privy Council in *Proprietary Articles Association v Attorney-General of Canada*, where Lord Atkin stated:

[If legislation] is authorized under one or other of the heads specifically enumerated in s. 91, it is not to the purpose to say that it affects property and civil rights in the Provinces. Most of the specific subjects in s. 91 do affect property and civil rights but so far as the legislation of Parliament in pith and substance is operating within the enumerated powers there is constitutional authority to interfere with property and civil rights.<sup>14</sup>

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of protection against compulsory licenses to import and seven years protection against compulsory licenses to manufacture.

11 "Drug law challenged by seniors" *The Globe and Mail* (16 February 1989) (QL).

12 *Manitoba Society of Seniors Inc v Canada (Attorney General)*, [1991] MJ No 22, 77 DLR (4th) 485 (Man QB).

13 Peter W Hogg, *Constitution Law of Canada*, 2d ed (Toronto: Carswell Legal Publishing, 1985) at 334.

14 [1931] AC 310 at 326-27 (PC).

On the basis of these authorities, the Court concluded that the pith and substance of the impugned amendments and the PMPRB was patents, not industry-specific pricing practices.

Canada's pharmaceutical regime has undergone further changes since the Manitoba Society of Seniors' constitutional challenge. *The Patent Act Amendment Act, 1992* (Bill C-91),<sup>15</sup> eliminated compulsory licensing for pharmaceutical products.<sup>16</sup> The same legislation introduced the *Patent Medicines Notice of Compliance Regulations (PM(NOC) Regulations)*,<sup>17</sup> a new regime linking the drug regulatory approval process and the patent system. The *PM(NOC) Regulations* permit the manufacturer of an innovator drug to submit certain patents for inclusion on the Patent Registry in connection with a New Drug Submission (NDS). A generic drug manufacturer must then "clear" any of the relevant patents prior to obtaining regulatory drug approval.

The *PM(NOC) Regulations* have faced their own constitutional challenges. In *Apotex Inc v Merck & Co*,<sup>18</sup> the Federal Court of Appeal addressed whether the "remedy clause" of the *PM(NOC) Regulations* was ultra vires federal regulatory powers. In 2003, Merck commenced proceedings prohibiting Health Canada from issuing drug approval to Apotex for a generic version of its osteoporosis drug, alendronate. The Court dismissed the application and in 2005 Apotex brought the first recovery action against Merck.

Section 8 of the *PM(NOC) Regulations* allows for a party to recover any loss suffered as a result of being held off the market by related legal proceedings. Facing substantial damages, Merck challenged that section 8 was ultra vires the authority of Parliament pursuant to section 91(22). Merck claimed that section 8 provided for "an independent cause of action unconnected to the *PM(NOC) Regulations*,"<sup>19</sup> falling within provincial legislative competence over property and civil rights. In familiar fashion, the Federal Court of Appeal acknowledged that in isolation section 8 does in fact create a civil right of action.<sup>20</sup> However, using the "ancillary doctrine test" set out in *General Motors*

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15 *An Act to Amend the Patent Act*, RSC 1993, c 2, amending RSC 1985, c P-4.

16 Under the legislation, compulsory licenses in existence before 20 December 1991 would continue in effect, subject to the seven and ten-year limitations established in Bill C-22. Compulsory licenses granted after 20 December 1991, but before the day the amendments came into force were terminated.

17 SOR 93-133.

18 2009 FCA 187, [2009] FCJ No 712.

19 *Ibid* at para 62.

20 *Ibid* at para 63.

of *Canada Ltd v City National Leasing*,<sup>21</sup> the Court determined that section 8 was “sufficiently integrated” into the federal legislative scheme and thus within Parliament’s jurisdiction.<sup>22</sup>

As a whole, the courts’ consideration of Parliament’s legislative authority over patented medicines has thus far failed to set out clear constitutional boundaries for federal patent laws. It is well established that Parliament may trench into provincial jurisdiction as an incidental consequence of legislating within its constitutional domains, including patents. At the same time, the frontier of provincial authority must be respected. The boundaries of relevant provincial powers, however, are somewhat poorly defined. It helps, at this stage in the article, to consider the latest legal developments regarding provincial jurisdiction over health and related matters.

## B. Provincial Regulation of Patented Biomedical Technology

The wide breadth of legislative powers provinces have in the field of health might lend credibility to a jurisdictional claim to the regulation of patented biomedical technology. Although health is not mentioned within the subject matters expressly assigned under the *Constitution Act, 1867*, and cannot be directly assigned to one level of government or the other, it is generally agreed upon that the Constitution affords the provinces broad and primary legislative jurisdiction in health-related matters.<sup>23</sup> In *Schneider v R*, Dickson J (as he then was) affirmed this presumption by revisiting the findings of the 1940 Royal Commission on Dominion-Provincial Relations: “[T]he view that the general jurisdiction over health matters is provincial (allowing for a limited federal jurisdiction either ancillary to the express heads of powers in s. 91 or the emergency power under peace, order, and good government) has prevailed and is now not seriously question.”<sup>24</sup>

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21 [1989] 1 SCR 641 at 641 – 42, 58 DLR (4th) 255.

22 A 2006 amendment to the *PM(NOC) Regulations* made this point moot by eliminating the right for a generic company to elect “profits” under s 8. As such, there is limited downside for a brand-name drug company to delay generic competition and no benefit to be gained by the generic in pursuing costly litigation, even in cases where there has been a misuse of the automatic stay provision.

23 See Martha Jackman, “Constitutional Jurisdiction Over Health in Canada” (2000) 8 Health LJ 95 at 105.

24 [1982] 2 SCR 112 at 136, 139 DLR (3d) 417.



Patented biomedical technologies, insofar as they represent a health matter, might fall within provincial jurisdiction over health. Undoubtedly legislation addressing or purporting to regulate such technology through tort, contract, or property law would be deemed, at least in part, to be within provincial constitutional authority. The net effect of other provincial powers may contribute to a larger zone of jurisdiction in the area of health technology, vesting the provinces with an even greater constitutional claim. Jackman explored this idea as part of the Royal Commission on New Reproductive Technologies:

[P]rovincial jurisdiction over public health under the property and civil rights clause, combined with the provincial jurisdiction over hospitals [under s. 92(7)], gives the provinces the prima facie authority with respect to [reproductive technologies] as a health matter. Levels of new reproductive health and hospital services; health requirements relating to the research, development, and application of [reproductive technologies] in hospital and non-medical settings; standards of medical ethics and practice; local public health information; and the insurability of [reproductive technologies] under provincial health insurance plans would be matters of valid provincial concern.<sup>25</sup>

A convincing argument could be put forward regarding other patented biomedical technologies, giving the provinces at least some authority over patented medicines.<sup>26</sup> To what extent however, will depend on the federal government's jurisdictional claim and the court's treatment of such constitutional assertions.

A recent dispute involving Vancouver's Insite – Supervised Injection Site, a downtown clinic that provides safe space for addicts to use intravenous drugs, addressed the need to protect provincial jurisdiction over health-

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25 Martha Jackman, "The Constitution and the Regulation of New Reproductive Technologies" in Royal Commission on New Reproductive Technologies, *Overview of Legal Issues in New Reproductive Technologies*, vol 3 of the Research Studies of the Royal Commission on New Reproductive Technologies (Ottawa: Supply and Services Canada, 1993) 1 at 14 – 15.

26 A similar proposal has been made with respect to "human research subjects". See Jennifer Llewellyn, Jocelyn Downie & Robert Holmes, "Protecting Human Research Subjects: A Jurisdictional Analysis" (2003) 11(Supp) Health LJ 207 at 212.

related matters from federal trenching. Initially, Parliament immunized the health institute from the *Controlled Drugs and Substances Act (CDSA)*<sup>27</sup> pursuant to section 52. In 2008, the federal government failed to extend the ministerial exemption leaving the initiative's future operations in jeopardy. PHS Community Service Society, the operator of Insite, and the Vancouver Area Network of Drug Users brought a series of actions seeking a range of declaratory relief on the basis that Insite was a provincial undertaking related to health, and therefore constitutionally immune from the *CDSA*.<sup>28</sup>

Valid legislation may be limited or "read down" so as not to touch matters within the exclusive jurisdiction of the other level of government. This doctrine, commonly referred to as interjurisdictional immunity, has typically come into play in situations where a generally worded provincial law is clearly valid in most of its applications, but arguably overreaches in others, subsequently affecting a matter falling within an area of federal jurisdiction. To put it another way, in those circumstances where the doctrine of interjurisdictional immunity applies, provincial laws are not allowed to have an effect on matters falling within core areas of federal jurisdiction.

The Supreme Court of Canada addressed the doctrine of interjurisdictional immunity in the division of powers framework in the 2007 companion decisions: *Canadian Western Bank v Alberta*<sup>29</sup> and *British Columbia (Attorney General) v Lafarge*.<sup>30</sup> First, the Court affirmed that the doctrine still has a place in legal analysis and that "its existence is supported both textually and by the principles of federalism."<sup>31</sup> Second, it acknowledged that the doctrine operates both ways, protecting federal *and* provincial legislative jurisdiction.<sup>32</sup> Third, it expressed concern that the doctrine is inconsistent with the "dominant tide" of constitutional interpretation, recommending that "the Court should favor, where possible, the ordinary operation of statutes enacted by *both* levels of government" and that, "[i]n that absence of conflicting enactments of the other level of government, the Court should avoid blocking the

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27 SC 1996, c 19.

28 The groups also argued that sections 4(1) and 5(1) of the *CDSA* should be struck down as a breach of section 7 of the *Charter of Rights and Freedoms* because they deprive a person addicted to a controlled substance access to health care at Insite.

29 2007 SCC 22, [2007] 2 SCR 3.

30 2007 SCC 23, [2007] 2 SCR 86.

31 *Canada Western Bank*, *supra* note 29 at para 33.

32 *Ibid* at para 34.

application of measures which are taken to be enacted in furtherance of the public interest.”<sup>33</sup> As part of its support for this holding, the Court pointed out that “a broad use of the doctrine of interjurisdictional immunity runs the risk of creating an unintentional centralizing tendency in constitutional interpretation” since as previously mentioned, “this doctrine has in the past most often protected federal heads of power from incidental intrusion by provincial legislatures.”<sup>34</sup>

In *PHS Community Services Society v Canada (Attorney General)* (PHS),<sup>35</sup> the British Columbia Court of Appeal acknowledged the Supreme Court of Canada’s claim that the doctrine of interjurisdictional immunity should not be used where the legislative subject presents a double aspect, but also held that the door should not be closed on the use of the doctrine in creating breathing room for provincial activity within its constitutional domain. Justice Huddart explained that relegating the doctrine of interjurisdictional immunity to the bottom of the “constitutional toolbox” would in practice jeopardize provincial legislative autonomy:

[J]udicial concern that legislative enclaves have been encouraged by the doctrine of interjurisdictional immunity, to the disadvantage of provincial activities touching on federal undertakings, has ignored the effect that this desire to encourage cooperative federalism has on provincial policies when a collision gives rise to federal paramountcy, regardless of the extent of the impact of the provincial activity on the federal power.<sup>36</sup>

In applying the doctrine so as to protect provincial legislative jurisdiction, the Court departed from the asymmetrical manner in which interjurisdictional immunity has been traditionally invoked to defend exclusive federal jurisdiction. While admitting it to be a novel approach, Justice Huddart suggested that it seems to be “precisely the restrained use of the doctrine that jurisprudence supports.”<sup>37</sup> Moreover, Huddart JA deemed the move to

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33 *Ibid* at para 37.

34 *Ibid* at para 45. See *Quebec (Attorney General) v Canadian Owners and Pilots Association*, 2010 SCC 39, [2010] 2 SCR 536; and *Quebec (Attorney General) v Lacombe*, 2010 SCC 38, [2010] 2 SCR 453.

35 2010 BCCA 15, aff’g 2008 BCSC 661.

36 *Ibid* at para 155.

37 *Ibid* at para 168.

be an imperative one since the current legal framework fails to preserve the intended balance in the division of powers and effectively grants Parliament “veto power” over provincial health care services.<sup>38</sup> In her decision, she queried:

The provision of health care services is what makes a hospital a hospital, what makes health care a provincially-regulated activity. It is the indisputable intrusion of the federal government into the provision of medical services *at the level of doctor and patient* that is happening at Insite. Could Parliament legislate to effectively prohibit a doctor from using a scalpel?<sup>39</sup>

On appeal, the Supreme Court of Canada dismissed the Court of Appeal’s decision and found that the doctrine of interjurisdictional immunity did not apply.<sup>40</sup> Writing for the unanimous court, Chief Justice McLachlin held that decisions regarding the treatment options offered in provincial health facilities do not constitute a protected power over health care and are not, therefore, immune from federal interference. McLachlin CJ offered three reasons for the holding. First, “the proposed core of the provincial power over health has never been recognized in the jurisprudence.”<sup>41</sup> Second, “[t]he federal role in the domain of health makes it impossible to precisely define what falls in or out of the proposed provincial ‘core’.”<sup>42</sup> Third, the “application of interjurisdictional immunity to a protected core of the provincial health power has the potential to create legal vacuums.”<sup>43</sup>

Pursuant to the Supreme Court’s above ruling, it seems unlikely that the provinces could immunize themselves from patent enforcement in the name of providing health care services. However, it is the practical fact that while the federal government has substantial authority to involve itself in the regulation of patented medicines and biomedical technologies, the actual effectiveness of such authority will likely require provincial support at an operational level. This is not to say that the provinces would or should have exclusive jurisdiction. It does, however, suggest that the federal

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38 *Ibid* at para 162.

39 *Ibid* at para 167 [emphasis in original].

40 2011 SCC 44.

41 *Ibid* at para 67.

42 *Ibid* at para 68.

43 *Ibid* at para 69.

government may want to seek and secure the backing of the provinces in designing a coordinated intergovernmental regulatory scheme. Moreover, officials should take time to understand which functions and instruments are best left solely to Parliament and which are best placed in the decentralized sphere of the provincial governments. A series of timely, interconnected case studies helps to demonstrate the practical impact of the legal issues that the foregoing introductory discussion has exposed.

### III. Case Studies

#### A. Assisted Human Reproduction

Canada's most recent division of powers decision concerns the federal *Assisted Human Reproduction Act (AHRA)*.<sup>44</sup> Considering the moral, social, and legal implications, Canadian policymakers have approached the regulation of assisted reproductive technologies with care and caution.<sup>45</sup> The aforementioned Royal Commission on New Reproductive Technologies was established in 1989 in response to increasing public demand for technologies such as in vitro fertilization.<sup>46</sup> The Commission ultimately concluded there was a considerable basis for seeking federal, rather than provincial legislation, pointing to the "Peace, Order and Good Government" clause in section 91 of the Constitution as justification. Following the Commission's recommendation, Parliament passed the *AHRA* on February 11, 2004. The legislation addressed a wide range of policy issues related to reproductive technologies and set in place a comprehensive regulatory framework.<sup>47</sup>

In September 2007, a few months before introducing similar legislation, Quebec referred to the Court of Appeal a question concerning the constitutional validity of *AHRA's* regulatory provisions on the basis that they were ultra vires federal jurisdiction, especially section 91(27) of the *Constitution*

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44 SC 2004, c 2.

45 See e.g. Erin L Nelson, "Legal and Ethical Outcomes in ART 'Outcome' Research" (2005) 13 Health LJ 165; and Vanessa Lentzm, "Asking the Inconceivable? Ethical and Legal Considerations Regarding HIV Seropositive Couples' Request to Access to ARTs" (2008) 18 Health LJ 237.

46 See "Fighting Infertility" *CBC News*, online: CBC Digital Archives <[http://archives.cbc.ca/health/reproductive\\_issues/topics/610-3370/](http://archives.cbc.ca/health/reproductive_issues/topics/610-3370/)>.

47 The *AHRA* also created a federal agency with a broad mandate to introduce new regulations – Assisted Human Reproduction Canada.

*Act, 1867, "The Criminal Law."* The Attorney General of Quebec asserted that the impugned provisions were an attempt to regulate the whole sector of medical practice and research related to assisted reproduction and that *AHRA* entered provincial jurisdiction. The Quebec Court of Appeal agreed, holding that the challenged sections were *ultra vires* the federal government, and instead a matter falling under health, an area of "provincial paramountcy."<sup>48</sup>

The Supreme Court of Canada accepted leave for appeal and in December 2010 issued a divided opinion in *Reference re Assisted Human Reproduction Act (AHRA Reference)*.<sup>49</sup> The reference offered the Court the opportunity to clarify the point at which regulatory provisions in the area of health lose their link to Parliament's criminal law power and become in pith and substance a provincial matter. The Court split three ways in its decision. Four judges – McLachlin CJ, joined by Binnie, Fish, and Charron JJ – upheld the entire legislation as valid under the criminal law power. Four different judges – LeBel and Deschamps JJ, joined by Abella and Rothstein JJ – found that the pith and substance of the impugned provisions was health, and struck them down as *ultra vires* the federal government's powers. Justice Cromwell, the tie-breaker, separately found the essence of the impugned provisions to be the "regulation of virtually every aspect of research and clinical practice in relation to assisted human reproduction."<sup>50</sup> Accordingly, Justice Cromwell held that the law as a whole was a matter best classified as relating to the establishment, maintenance, and management of hospitals, property and civil rights in the province, and matters of merely local or private nature in the province. However, he also held that certain provisions, specifically those concerning donor consent, the age of consent, and reimbursement for medical surrogacy expenses, fell within the "traditional boundaries of the criminal law."<sup>51</sup>

The impact that the *AHRA Reference* stands to have on Canadian federalism remains unclear. The reference's two main opinions are in fundamental disagreement as to whether or not the "criminal law must be circum-

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48 Renvoi fait par le gouvernement du Québec en vertu de la Loi sur les renvois à la Cour d'appel, LRQ, c R-23, relativement à la constitutionnalité des articles 8 à 19, 40 à 53, 60, 61 et 68 de la Loi sur la procréation assistée, LC 2004 c 2, 2008 QCCA 1167, [2008] RJQ 1551, 298 DLR (4th) 712 at para 89.

49 2010 SCC 61.

50 *Ibid* at para 285.

51 *Ibid* at para 289.

scribed to prevent trenching on provincial powers to regulate health.”<sup>52</sup> The Chief Justice stressed that “[t]he *Constitution Act, 1867*, allocates to Parliament jurisdiction over the criminal law precisely to permit Parliament to create uniform norms” and “[c]ircumscription of the ambit of the criminal law to avoid trenching on provincial regulation runs counter to this purpose.”<sup>53</sup> In contrast, Justices LeBel and Deschamps underscored that “administrative efficiency alone cannot be relied on to justify legislative action by Parliament” and “action must be taken within the limits of an assigned head.”<sup>54</sup> Furthermore, LeBel and Deschamps JJ asserted that “[n]either a desire for uniformity nor the very novelty of a medical technology can serve as the basis for an exercise of the federal criminal law power.”<sup>55</sup>

The Supreme Court of Canada did not address the Quebec Court of Appeal’s holding that health is an area of provincial paramountcy. In a recent article Newman contends that the court’s “recognition of the exclusivity of provincial powers has implicitly resulted in what amounts to provincial paramountcy in some contexts.”<sup>56</sup> Newman notes:

The possibility of areas of provincial paramountcy is also effectively raised by the new doctrine of provincial interjurisdictional immunity. Reciprocal interjurisdictional immunity otherwise gives rise to potentially paradoxical conclusions based on whether one first applies the doctrine of federal paramountcy or that of provincial interjurisdictional immunity. In a case where both apply, it may be that federal legislative provisions are inapplicable to a provincial work or undertaking operating under legislation that is allegedly inoperable. This paradoxical conclusion does not live out the intent of *Canadian Western Bank* to establish provincial interjurisdictional immunity ... [P]rovincial interjurisdictional immunity has to imply components of provincial paramountcy if the courts are to be able to engage in consistent legal decision-making.<sup>57</sup>

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52 *Ibid* at para 65.

53 *Ibid* at para 68.

54 *Ibid* at para 244.

55 *Ibid* at para 255.

56 Dwight Newman, “Changing Division of Powers Doctrine and the Emergent Principle of Subsidiarity” (2011) 74 Sask L Rev 21 at 30.

57 *Ibid*.

It is also interesting to note that in arriving at her decision, Chief Justice McLachlin reworked the current division of powers analytical framework, electing to examine the whole legislative scheme and the impugned provisions separately.<sup>58</sup> She stated:

Ordinarily, this Court would begin by examining the impugned provisions in order to determine if and to what extent they intrude on the provincial sphere of competence ... In this case, the Attorney General of Quebec is challenging the bulk of the *Assisted Human Reproduction Act* ... Under these circumstances, it is impossible to meaningfully consider the provisions at issue without first considering the nature of the whole scheme.<sup>59</sup>

Justices LeBel and Deschamps criticized McLachlin CJ's approach, suggesting that "[s]ince the purposes and effects of a statute's many provisions can be different, it is important to consider the impugned provisions separately before considering their connection with the other provisions of the statute."<sup>60</sup> One is left to ponder the effect of the Chief Justice's assessment on her final decision, whether or not the impugned provisions could have been deemed valid under the usual constitutional analysis, and if or when this inverted analytical approach might be used in future cases.

In a nutshell, the *AHRA* Reference resolves very little in terms of the acceptable balance between federal and provincial powers, leaving more questions opened than answered, in terms of the jurisdictional debate around biomedical innovation.<sup>61</sup> The following sections describe more examples of simmering issues in this complex and evolving area.

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58 For illustrative commentary on this approach, see Ubaka Ogbogu, "Latest 'Legislative Overreach' Analysis from SCC: Reference re Assisted Human Reproduction" (22 December 2010) (blog), online: University of Alberta, Faculty of Law Blog

<<http://ualbertalaw.typepad.com/faculty/2010/12/latest-legislative-overreach-analysis-from-scc-reference-re-assisted-human-reproduction-act-.html>>.

59 *AHRA* Reference, *supra* note 49 at para 16.

60 *Ibid* at para 194.

61 See Barbara von Tigerstrom, "Federal Health Legislation and the Assisted Human Reproduction Act Reference" (2011) 74 *Sask L Rev* 33.



## B. Gene Patents and Diagnostic Testing

Inheritable genetic abnormalities carried on the two genes known as BRCA1 and BRCA2 have been shown to be a factor in approximately 5 to 10% of breast cancer cases and carry an increased risk of developing ovarian cancer. Between October 2000 and April 2001, Myriad Genetics Inc (Myriad) was granted a series of patents in Canada giving the Utah-based biotechnology company exclusive control over the BRCA1/2 genes. Also claimed in the patent was a genetic test that Myriad had developed to identify deleterious mutations on the aforementioned genes.

In 2000, after partnering with MDS Laboratories (MDS), a Canadian-based private laboratory, Myriad approached government officials to pitch their services.<sup>62</sup> Provincial laboratories across the country were already offering research-based BRCA1/2 testing.<sup>63</sup> The existing programs had proven quite successful, making use of a variety of different tests other than Myriad's protocol.<sup>64</sup> In addition, these institutions also provided genetic counselling, follow-up monitoring, and when available, preventative treatment measures.<sup>65</sup> Switching to Myriad's commercialization model, whereby patient samples would be collected and sent outside the country to be analyzed, would have not only increased the cost of the testing by approximately three times, but also challenged the manner in which the provinces

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62 Myriad and MDS entered into a three year agreement in 2000 under which MDS would be responsible for both marketing the test in Canada and shipping samples to Myriad for sequencing in the US, since MDS lacked the expertise to conduct the test in Canada.

63 Heather Kent, "Popularity of Breast Cancer Program Leads to Referral Protocols in BC" (1998) 159 *Canadian Medical Association Journal* 832.

64 Genetic testing for mutations in the two BRCA genes was first available in Canada on a research basis. In 1996, British Columbia started provided clinical services through the hereditary cancer program at the British Columbia Cancer Agency. Similar public funded genetic testing programs and laboratories were subsequently established in Ontario and Alberta. Saskatchewan, Newfoundland, and Nova Scotia also started to provide the service, but sent blood services out for analysis by other provincial laboratories, usually Ontario. Alternatively, Quebec, with the exception of providing screening for high-risk groups, sent their patient samples for testing.

65 Bryn Williams-Jones, "History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing" (2002) 10 *Health LJ* 123 at 142.

provided these services. Worse, it could have left patients without a testing option altogether.<sup>66</sup>

The situation quickly escalated through a series of miscommunications and resulting misunderstandings.<sup>67</sup> Realizing that their decision on this issue might set the precedent for future dealings concerning genetic testing, the provinces consulted scientists and laboratory directors around the world.<sup>68</sup> The delays in the process frustrated Myriad and they began to look for ways to expedite a response.<sup>69</sup> In the spring of 2001, armed with a newly minted patent, Myriad sent cease-and-desist letters to the four provinces administering BRCA testing: Alberta, British Columbia, Ontario, and Quebec.<sup>70</sup> The letters demanded that all laboratories halt genetic testing services covered by the scope of their patents and that each province exclusively contract with MDS for future services.

Each province reacted uniquely to the cease-and-desist demands. The Ontario government challenged Myriad's right to stop Canadian laboratories from performing the genetic testing.<sup>71</sup> Tony Clement (then Ontario Health Minister, and interestingly, recent Federal Minister of Industry, which as mentioned above controls most patent law policymaking decisions) asserted that predictive breast and ovarian cancer testing should be available to all women who require it.<sup>72</sup> Mike Harris, the Premier of Ontario at the time,

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66 See E Richard Gold, "From Theory to Practice: Health Care and the Patent System" (2003) Special Edition Health LJ 22 at 36. See also Bryn Williams-Jones, "Reframing the Decision: Commercial Genetic Testing in Canada" (1999) 7 Health LJ 49 (advocates for private commercial genetic testing in Canada as a possible solution to access pitfalls).

67 E Richard Gold & Julia Carbone, "Myriad Genetics: In the Eye of a Policy Storm" (2010) 12 Genetics in Medicine S39.

68 For Ontario government officials, taking time to develop suitable and lasting policy was crucial. On-going concerns prompted the policy unit to work well into 2001.

69 Because they were not negotiating directly with the policy unit, but rather with the laboratory branch of the Ontario's Ministry of Health, MDS, and Myriad were not aware of the policy unit's concerns.

70 Timothy Caulfield, "Policy Conflicts: Gene Patents and Healthcare in Canada" (2005) 8 Community Genetics 223 at 224.

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

72 Carolyn Abraham, "Ontario to fight the gene test", *The Globe and Mail* (7 January 2003) (QL).

shared the sentiment and affirmed that the province would continue to provide BRCA genetic testing through its own system of laboratories in spite of the action taken by Myriad.<sup>73</sup> In August 2001, he brought the issue of gene patenting to the table at the Annual Premiers Conference where he voiced his concerns over genetic testing and affordable health care in Canada.<sup>74</sup>

British Columbia reluctantly complied with Myriad's demands forcing the British Columbia Cancer Agency to suspend testing for BRCA1/2.<sup>75</sup> The Ministry of Health decided that it would not reimburse patients who proceeded with the testing, leaving them to pay for it out of their own pockets.<sup>76</sup> In early 2003, after realizing their actions were putting patients at risk, the British Columbia Government elected to side-step the patent claim by transferring patient samples to Ontario for genetic testing.<sup>77</sup> A month later, British Columbia went a step further, fully reinstating in-house testing.<sup>78</sup>

Alberta and Quebec, both responded passively to the action, although with very different levels of compliance.<sup>79</sup> With the exception of continuing a screening program for at-risk population groups, Quebec began sending their samples directly to Myriad for sequencing.<sup>80</sup> Alberta, on the other hand, completely ignored the action and issued no orders to stop the funding of the genetic diagnostics.

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73 Harris argued that the benefits of the Human Genome Project should not be funneled to corporations like Myriad and advocated that the federal government address the situation immediately: Mike Harris, "Notes for Remarks by Mike Harris, Ontario's Premier" (19 September 2001) Toronto, Ontario Advisory Committee on Predictive Genetic Technology.

74 Caroline Mallan, "Gene tests for cancer won't stop; Harris pledges help with battle over U.S. Patent", *Toronto Star* (20 September 2001).

75 Lynn Hayley, "BC women left hanging by patent war over breast cancer test", *Canadian Press* (4 September 2001) (QL).

76 Heather Kent, "Patenting Move Ends BC's Gene-testing Program" (2001) 165 *Canadian Medical Association Journal* 812.

77 Heather Kent, "BC Sidesteps Patent Claim, Transfer BRCA Gene Testing to Ontario" (2003) 168 *Canadian Medical Association Journal* 211.

78 Lynn Hayley, "BC government ignores gene patent", *Medical Post* (4 March 2003) (QL).

79 David Kosub, "Canadian provinces defies threat of litigation over cancer test", *Diagnostic and Imaging Week* (27 February 2003) (QL).

80 Bryn Williams-Jones & Janice E Graham, "Actor Network Theory: A Tool to Support Ethical Analysis of Commercial Genetic Testing" (2003) 22 *New Genetics & Society* 271 at 286.

The Canadian Cancer Society and National Cancer Institute of Canada also responded to Myriad's action.<sup>81</sup> Both organizations took the position that Myriad's patents should not interfere with Canadian women's access to BRCA testing. They encouraged the provincial governments to collectively pursue court challenges on the breadth of the patents and on the manner in which they had been administered.

Despite holding a patent over BRCA diagnostic testing, Myriad had discovered that enforcing the exclusive right to the service in Canada would prove much more challenging than the company had anticipated. Provincial health care infrastructure had clearly not yet been established in the specific area of genetic testing. A much larger problem, however, was the division and disconnect that existed (and continues to exist) between federally enacted intellectual property regulations and the provincial health care system.

Industry Canada's Patent Policy Directorate (PPD), the federal government unit responsible for the *Patent Act*, remained silent during most of the Myriad controversy.<sup>82</sup> When provincial representatives, along with officials from Health Canada, met with the PPD to try and resolve the Myriad problem, negotiations were largely unsuccessful. The provinces were disturbed with the overreaching patents that had forced their health care systems to engage in *de facto* priority-setting, splitting patients into two groups: those who could and could not afford the diagnostic testing.<sup>83</sup> As such, provincial officials felt

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81 Canadian Cancer Society & National Cancer Institute of Canada, Media Release, "Positioning on the Patenting of BRCA-1 BRCA-2 Genes" (8 March 2002).

82 "Federal officials dismiss Ontario's concerns about gene patenting", *Canadian Press* (21 September 2001) (QL).

83 The general consensus was that every Canadian woman deserved equal access to this important and vital health information. See Julie White, "Why women deserve new gene patent laws", *The Globe and Mail* (15 March 2002). In February 2003, after reinstating in-house BRCA testing, the BC Minister of Health Services reported: "B.C. women and other future patients have a right to all the information that they need to stay healthy. It is completely unethical to sue patents based on genetic sequencing to block patients' access to their own genetic information, particularly when we already have the knowledge, ability, and equipment to provide women with this information" (Victoria: BC Minister of Health Services, 2003), cited in Bryn Williams-Jones & Michael M Burgess, "Social Contract Theory and Just Decision Making: Lessons from Genetic Testing for BRCA Mutations" (2004) 14 *Kennedy Institute of Ethics Journal* 115 at 120.

that an intervention was required and that policy needed to be generally restructured with respect to genetic patents. The PPD insisted that without clear evidence of an actual problem, there would be no response from the Department of Industry. This prevailing attitude angered provincial government officials who feared that if nothing was done to proactively address the problem, important health research and services would be at risk.<sup>84</sup>

In January 2002, the Ontario Ministry of Health and Long-Term Care issued a report examining the effect that emerging gene-based technologies were having on health care.<sup>85</sup> The main focus of the report was reform of Canada's health technology assessment process. It recommended the formation and implementation of various coordinated mechanisms that would better prepare both the health care sector and society for the impact of genetic science. Moreover, it called for a "comprehensive, patient-centred framework to assist jurisdictions in maximizing the benefits offered by new technologies and to set paths for collaborative work to better understand and address the risks."<sup>86</sup> The report noted "the rising rate of commercial development in genetics and the need for all jurisdictions to have access to high quality, objective health technology assessment and health economic analysis in the genetics field."<sup>87</sup> The report received unanimous support from the provinces when it was unveiled at the First Ministers' Conference in February 2002. The provincial health ministries, once again in unison with Health Canada, would go on to establish an inter-governmental committee, the Federal/Provincial/Territorial Advisory Committee on Information and Emerging Technologies. Part of the committee's mandate would be to support policy development and provide strategic advice on the effectiveness, appropriateness, and utilization of emerging health products and technologies.<sup>88</sup>

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84 Provincial-Territorial Premiers' Meeting, News Release, 850-085, "Provinces Pave the Way for the Future of Healthcare: Genetics and Preparing for Change", (25 January 2002) online: Canadian Intergovernmental Conference Secretariat <<http://www.scics.gc.ca/english/conferences.asp?a=viewdocument&id=1175>>.

85 Ontario, Ministry of Health and Long-Term Care, *Genetics, Testing, and Gene Patents: Charting New Territory in Healthcare* (January 2002).

86 *Ibid* at ii.

87 *Ibid*.

88 In 2005 the Federal/Provincial/Territorial Conference of Deputy Ministers of Health agreed to make the Advisory Committee on Information and Emerging Technologies dormant, and with it all of its priorities. In three years of operation the committee released a single report, see Health Technology Assessment Task

The concerted effort by the provinces demonstrated that, as a whole, they wanted to be more actively involved in the regulation of new and emerging health technologies.

Realizing that the conflict was more trouble than it was worth, Myriad abandoned the Canadian market. The lack of a common enemy, combined with a political shift in Ontario, no longer the outspoken leader of the patent policy challenge, would prove detrimental to the campaign for patent reform and tempered provincial demands for policy changes. Moreover, the unrelated SARS outbreak in 2003 soon attracted the bulk of the health care sector's attention. The provinces had seemingly won the battle against Myriad, however there was little resolution to the fundamental issues that had caused the problems in the first place – the patentability of genes and enforcement of gene patents.

On March 29, 2010 the United States District Court for the Southern District of New York issued its judgment in *Association for Molecular Pathology v US Patent and Trademark Office*<sup>89</sup> that stood to not only invalidate Myriad's BRCA1/2 patent rights, but also overturn the longstanding notion of DNA as patentable subject matter.<sup>90</sup> US Federal District Court Judge Robert Sweet held that laboratory-isolated genetic material was not sufficiently different from its intracellular form to be considered an "invention". His decision reignited the gene patent debate,<sup>91</sup> the discussion of which goes beyond the scope of this paper.

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Group, *Health Technology Strategy 1.0: Final Report* (2004) online: Health Canada <<http://www.hc-sc.gc.ca/hcs-sss/pubs/ehealth-esante/2004-tech-strateg/index-eng.php>>.

89 669 F Supp 2d 365 (SDNY 2009) online: <[http://graphics8.nytimes.com/packages/pdf/national/20100329\\_patent\\_opinion.pdf](http://graphics8.nytimes.com/packages/pdf/national/20100329_patent_opinion.pdf)>.

90 See Michelle M Mello, "Gene Patenting – Is the Pendulum Swinging Back?" (2010) 362 *New England Journal of Medicine* 1855. See also Mildred Cho, "Patently Unpatentable: Implications of the Myriad Court Decision on Genetic Diagnostics" (2010) 28 *Trends in Biotechnology* 548; and Howard Hoffenberg, "Will the Patentability of Genes Survive?" (2010) 28 *Nature Biotechnology* 925.

91 See e.g. Eileen Kane, "Patenting Genes and Genetic Methods: What's at Stake?" (2011) 6 *Journal of Business & Technology Law* 101; and Kathryn Claiborn, "Weighing in on the Future of Gene Patenting" (2011) 121 *J. Clinical Investigation* 3.

On appeal, the Federal Circuit overturned the District Court's finding that Myriad's claims covering the isolated gene sequences were invalid.<sup>92</sup> However the decision also included a dissenting opinion on this issue. In March 2012, the United States Supreme Court sent the case back to lower courts for reconsideration in light of its recent decision that the mere discovery, isolation or sometimes even application of laws of nature – the basis of many gene patents including Myriad's – is not protected subject matter.<sup>93</sup> The full effect of the on-going litigation on the multibillion-dollar medical biotechnology industry remains to be seen, as do the ramifications for Canadian technology law and policy.

The Myriad case study is particularly instructive in demonstrating the jurisdictional overlap that exists in the areas of health and biotechnology. The narrative demonstrates how current intellectual property governance prevents the provinces from maximizing the benefits of biotechnology research and innovation. Further, it indicates that Canada's present patent regulatory system might not be set up to deal with emerging intellectual property issues and warns of the pressing need for action. Provincial health care officials are becoming ever more frustrated by current patent laws. The federal government's seemingly exclusive jurisdiction inevitably bleeds into provincially designated powers, effectively limiting their authority to carry out responsibilities within their purview. Indeed, reconciliation in this constitutional area will be necessary to address budding federal-provincial conflicts.

### C. Pharmaceutical Pricing and Intergovernmental Relations

Although federal price control in the area of patented medicines has survived a number of constitutional challenges, as referenced above, the related issues remain generally unsettled and controversial. The problem of coordination is compounded by the fact that the federal government is almost completely insulated from the impact of its pricing policies because

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92 *The Association for Molecular Pathology v United States Patent and Trademark Office*, Case No 10-1406 (Fed Cir, 29 July 2011) online: United States Courts of Appeal for the Federal Circuit

<<http://www.cafc.uscourts.gov/images/stories/opinions-orders/10-1406.pdf>>.

93 *Mayo Collaborative Services v Prometheus Laboratories, Inc.*, 566 \_\_\_ (2012); and *The Association for Molecular Pathology v United States Patent and Trademark Office*, order list: 566 US (2012).

it does not purchase drugs for Canadians, other than for Aboriginal Peoples. This financial responsibility instead falls on the provincial governments, which fund public health care services. In other words, the provinces pay the consequences of federal regulation, footing the bill for pharmaceuticals without involvement in some of the key policy decisions that impact price, including specifically patent protection.<sup>94</sup> When the “well runs dry,” provincial health systems are forced to deal with resulting patient-led lawsuits for access to medicines.<sup>95</sup>

Canada’s national health insurance program, often referred to as “Medicare”, is designed to ensure that all residents have reasonable access to medically necessary hospital and physician services on a prepaid basis.<sup>96</sup> However, federal funding does not provide for outpatient prescriptions. The type and level of specific coverage is determined by the individual provincial legislatures and varies by region.<sup>97</sup> Each province/territory conducts a value-based analysis to determine whether a new medicine should be listed on its public formulary – a list of medicines that are eligible for reimbursement under the provincial/territorial drug plan.<sup>98</sup>

Unable to directly address brand-name drug pricing, the provinces have generally been forced to target unregulated generic substitutes in controlling health costs.<sup>99</sup> For example, the Government of Ontario announced on

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94 See Aslam H Anis, “Pharmaceutical Policies in Canada: Another Example of Federal-Provincial Discord” (2000) 162 *Canadian Medical Association Journal* 523.

95 See Amir Attaran, “Take Your Medicine?: The Risk of Patient-Led Litigation in Canada’s Medicine Access System” (2009) 3 *McGill JL & Health* 3.

96 Health Canada, “Canada’s Health Care System (Medicare)”, online: Health Canada <<http://www.hc-sc.gc.ca/hcs-sss/medi-assur/index-eng.php>>.

97 A Common Drug Review helps to inform and support drug plan decisions by providing equal access to timely evidence-based information and expert advice.

98 RA Bacovsky, *Drug Submission, Review and Approval Process for Provincial and Territorial Government Sponsored Prescription and Drug Plans in Canada* (Toronto: Joint Liaison Committee between the\* Pharmaceutical Industry and Ontario Government, 1997).

99 See e.g. Ann Silversides, “Ontario’s Law Curbing the Cost of Generic Drugs Sparks Changes for Pharmacies and other Canadian Buyers” (2009) 181 *Canadian Medical Association Journal* E43; and Ann Silversides, “Provincial Experiments Aim to Lower Public Drug Plan Costs” (2009) 181 *Canadian Medical Association Journal* E80.



April 7, 2010 that it would once again<sup>100</sup> reduce the price it will pay for generic pills by half, to a maximum of 25 per cent the brand-name price.<sup>101</sup> The government noted that by 2014, this price regulation would also apply to the private sector, bringing down the market price for Canadians who pay for or are insured by their employers.<sup>102</sup> Moreover, Ontario moved to do something that no other province has dared to do: eliminate professional allowances, which are the sums paid by generic drug manufacturers to pharmacies in return for selling their products.<sup>103</sup> The government took the stance that “eliminating professional allowances would increase the accountability of Ontario’s drug system, enable the government to more effectively compensate pharmacists for the care they provide to prescription drug users, and help reduce the cost of generic drugs.”<sup>104</sup>

Ontario’s proposed reforms were immediately met with strong resistance. The Canadian Generic Pharmaceutical Association (CGPA) announced that the new legislation would “undermine the future and current availability of low-cost generic prescription medicines as well as the economic contribution of Ontario’s generic pharmaceutical industry.”<sup>105</sup> Ontario’s pharmacists also reacted vehemently to the proposed changes, claiming that the reduced price of generic drugs would kill a business model that the industry had relied on for decades.<sup>106</sup> Unlike brand-name drug manufacturers, which

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100 In 2006, the government cut the price it paid for generic drugs to 50% of the brand price: “Canada: new formulary for New Year: Ontario introducing reform”, *Pharma Marketletter* (5 January 2007) (QL).

101 Ontario, Ministry of Health and Long-Term Care, News Release, “Reforming Ontario’s Drug System” (7 April 2010) online: Ontario <<http://news.ontario.ca/mohltc/en/2010/04/reforming-ontarios-drug-system.html>>.

102 Sarah Scott, “Ontario vs. the Pharmacists”, *Maclean’s* (22 April 2010) online: Macleans <<http://www2.macleans.ca/2010/04/22/ontario-vs-the-pharmacists/#more-120762>>.

103 Ontario had toyed with the idea of eliminating the professional allowances in earlier reform, however, abandoned the idea when faced with the prospect of drugstores shutting down. See Adam Radwanski, “Ontario to prescribe a bitter pill for pharmacies”, *The Globe and Mail* (7 April 2010).

104 Reforming Ontario’s Drug System, *supra* note 101.

105 CGPA, News Release, “Statement from the Canadian Generic Pharmaceutical Association Regarding Changes to Ontario’s Drug System” (8 April 2010) online: CGPA <<http://www.canadiangenerics.ca>>.

106 Marina Strauss, Grant Robertson & Karen Howlett, “A bitter pill to swallow”, *The Globe and Mail* (26 April 2010).

pitch their products directly to physicians, “generic manufacturers focus their marketing efforts on pharmacies that make the decisions about which generic substitute to dispense.”<sup>107</sup> Eliminating drug rebates, or professional allowances as they have come to be known, would deprive pharmacists of a key source of revenue.<sup>108</sup>

Fearing that Ontario’s reforms could have ripple effects across the country, the other provinces quickly joined the conversation. Ontario generally sets the benchmark for generic prices because of the size of the market.<sup>109</sup> A drop in drug prices in Ontario would likely lead to lower prices in Quebec and Manitoba, which have pricing schemes that mandate manufacturers offer their products at a price that is no higher than that offered elsewhere in the country. For the other provinces and territories, Ontario’s reforms risked creating new distinctions between jurisdictions, allowing the pharmacies to recoup their lost income in Ontario by increasing prices elsewhere. The mounting dispute ignited talks of a regulated national market for purchasing drugs. By remaining divided in pharmaceutical pricing reform, the provinces and territories would run the risk of impeding access to generic drugs from many consumers, especially with all of them uniformly grappling with tight budgetary restraints. National governance would ensure regional consistency in medicinal pricing and make sure Canadians have equal treatment options, no matter what their geographical location.

Nonetheless, lowering generic drug prices fails to address the primary cost driver of the provinces’ drug plans. Protected by robust patent laws, brand-name drug companies are able to sell their products at near-monopoly prices.<sup>110</sup> Brand-name and generic drugs are dispensed in approximately equal proportions in Canada, yet of the over \$20 billion that Canadians spent on prescription medicines in 2008, close to 80% went towards brand-name drugs, while generic substitutes accounted for only about 20%.<sup>111</sup>

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107 Palmer D’Angelo Consulting Inc, Media Release, “Generic Drug Prices: A Canada US Comparison” (August 2002) online: PDCI <<http://www.pdci.ca>>.

108 “Professional allowances and the price of generic drugs”, *The CBC* (9 April 2010).

109 Meagan Fitzpatrick, “Ont. policy on generic drugs could have national implications”, *The Ottawa Citizen* (12 April 2010).

110 See Thomas Walkom, “Ontario’s phony war against druggists”, *The Toronto Star* (13 April 2010).

111 CGPA, News Release, “The Real Story Behind R&D Spending by Brand-Name Drug Companies in Canada” (2009) online: CGPA <<http://www.canadiangenerics.ca>>.

Policy analysts suggest that reducing generic drug prices will likely prove a superficial step towards controlling drug spending in Ontario and the rest of the country.<sup>112</sup> The provinces could theoretically attempt to introduce their own price control legislation, however, without the involvement of the federal government, drug prices would likely end up fragmented across the nation, causing a new set of problems. In this light, it seems only a matter of time before the provinces and territories attempt to bring another constitutional challenge to Parliament's patented medicine price review scheme.

The federal government could avoid a constitutional challenge by embracing an intergovernmental approach to patented drug price review. To successfully control health care spending on pharmaceuticals, the provinces and territories, not just Parliament, need to be involved in setting and regulating patented medicine prices. The PMPRB should look to involve the provinces and territories in drug pricing consultations and secure the support of them in designing an intergovernmental regulatory scheme. Moreover, the factors considered by the PMPRB should be expanded to take into account regional health care concerns.

With administrative support from the provinces and territories, Parliament might also be able to enact a national system for regulating prices of non-patented drugs, complementing the existing scheme. As this case study illustrates, there are pressing reasons for the regulation of non-patented drugs in Canada. In a letter to Canada's provincial health ministers, Ontario's Minister of Health has called on her provincial and territorial colleagues to work together to develop a single system for generic prescription drugs. She warned that in the absence of such a system, "the pharmacy chains could go jurisdiction shopping for the best deal, by making bulk purchases at the new lower price and selling the drugs to consumers in other provinces."<sup>113</sup> British Columbia's Health Minister shared this perspective stating that British Columbia was aware of the "potential cross-jurisdictional impacts" and "open to working with other [provinces] to mitigate them."<sup>114</sup>

By remaining divided in pharmaceutical pricing reform, the provinces and territories run the risk of impeding access to pharmaceuticals for many

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112 See e.g. Joel Lexchin, "Targeting generic instead of brand-name drugs not the best way to lower Ontario's drug costs" (4 May 2010) online: Canadian Centre for Policy Alternatives <<http://www.policyalternatives.ca>>.

113 See Karen Howlett & Rheal Seguin, "Provinces join forces with plans to cut drug costs", *The Globe and Mail* (30 April 2010).

114 *Ibid.*

consumers. Unification and collective bargaining could provide an effective way to lower and stabilize pricing.

#### D. Data Exclusivity and International Obligations

Another area of controversy relating to the division of legislative powers is clinical trial data exclusivity. Data exclusivity guarantees additional market protection to originator pharmaceuticals and reinforces brand-name manufacturers' monopolies, independent of the patent regime. In basic terms, it prevents generic pharmaceutical manufacturers from using originator research data to assess drug safety and efficacy. This is not to say that generic medicines include data from the originator version in their registration application. Generic drugs are approved on their own merits, based on a particular manufacturers' own research and development. However, since generics contain similar ingredients to the respective originator drug, it is usually unnecessary to repeat time-consuming clinical testing and trials. Regulatory health authorities can instead usually assess safety and effectiveness by comparing the generic application against the brand-name documentation on file. Such an assessment is always carried out internally, and at no point does a generic manufacturer (or any other third party) get to see the data. Thus, contrary to popular opinion, data exclusivity may have very little to do with protecting research data. Data exclusivity merely prevents generic competitors from entering into the market by delaying the regulatory approval process.

Data exclusivity has had economic impact on Canada's pharmaceutical market and the public health care system. Introduced in 1995, Canada's first data exclusivity regime provided a five-year ban on generic drug approval commencing on the date of an innovator's first NOC for an "innovative drug."<sup>115</sup> The Governor in Council amended the *Data Protection Regulation (DP Regulation)* in October 2006, extending the exclusivity term to eight-years with the possibility of a further six-month period if studies are conducted in the pediatric population.<sup>116</sup> Under the current *DP Regulation*, a generic manufacturer must generally wait until the end of an eight-year exclusivity period before receiving drug approval, even if there is no existing patent protection. As such, Canada's exclusivity term has had the overall effect

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115 *Food and Drug Regulations*, CRC, c 870, s C.08.004.1.

116 *Regulations Amending the Food and Drug Regulations (Data Protection)*, SOR/2006-241.

of bestowing a commercial advantage to brand-name drug manufacturers. That commercial advantage is intended to provide a reward or incentive for investing time and money into the clinical trials needed to prove the pharmaceuticals safety and efficacy.

The *DP Regulation* was first enacted and subsequently amended so as to bring Canada into compliance with international obligations. Subsection 30(3) of the *Food and Drugs Act (FDA)*<sup>117</sup> gives the federal government the authority to enact regulations for the purpose of implementing specified data protection provisions of the *North American Free Trade Agreement (NAFTA)* and the *Agreement on Trade-Related Aspects of Intellectual Property (TRIPS)*.<sup>118</sup> The *DP Regulation* was intended to implement Article 1711 of *NAFTA* and Paragraph 3, Article 39 of *TRIPS* by providing the necessary market exclusivity term. Upon closer inspection, however, the terms of the *DP Regulation* may actually exceed Canada's trade commitments under these international agreements, leaving Canadian generic manufacturers at a potential competitive disadvantage since the US, their largest export market, mandates just 5 years of data exclusivity.<sup>119</sup>

Following the 2006 legislative amendments, Canada's generic pharmaceutical industry launched a legal challenge to the *DP Regulation*. Together the CGPA and generic drug manufacturer Apotex sought a declaration that both section 30(3) of the *FDA* and the *DP Regulation* were *ultra vires* and without legal force and effect. The Federal Court held however, that both were a valid exercise of the federal government's constitutional authority, falling under the second branch of the regulation of trade and commerce power, "General Regulation of Trade Affecting the Whole Dominion."<sup>120</sup> In doing so, the court followed Chief Justice Laskin's decision in *MacDonald v Vapour Canada Ltd*<sup>121</sup> whereby he mentioned in *obiter* that it might be open to Parliament to pass legislation to implement an international treaty obli-

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117 RSC 1985, c F-27.

118 *NAFTA*, 17 December 1992, Can TS 1994 No 2, 32 ILM (entered into force 1 January 1994); and *TRIPS*, 15 April 1994, 1869 UNTS 299, 33 ILM 1197 (entered into force 1 January 1996).

119 CGPA, Media Release, "Submission to the Stand Committee on Industry, Science and Technology: Study on Science and Technology" (16 April 2008) online: CGPA <<http://www.canadiangenerics.ca>>.

120 *Canadian Generic Pharmaceutical Association v Canada (Minister of Health)*, 2009 FC 725, [2009] FCJ No 938 [CGPA].

121 [1977] 2 SCR 134, 66 DLR (3d) 1.

gation into domestic law, even in areas of provincial jurisdiction, so long as that power is expressly manifested in the legislation and not left to inference.

That was an interesting and significant development since it overrules the long-standing accepted rule in *Canada (Attorney General) v Ontario (Attorney General)* (*Labour Conventions* case) whereby the Judicial Committee of the Privy Council held: “[T]here is no existing constitutional ground for stretching the competence of the Dominion Parliament so that it becomes enlarged to keep pace with the enlarged functions of the Dominion executive ... In other words, the Dominion, cannot, merely by making promises to foreign countries, clothe itself with legislative authority inconsistent with the constitution that give it birth.”<sup>122</sup>

The Federal Court of Appeal recently reviewed the Trial Division’s decision, in *Canadian Generic Pharmaceutical Association v Canada (Minister of Health)*.<sup>123</sup> Writing for the Court, Justice Nadon disagreed that the *DP Regulation* is, in pith and substance, and exercise of the trade and commerce power.<sup>124</sup> Instead, applying the three-part test from *RJR-MacDonald Inc v Canada (Attorney General)*,<sup>125</sup> Nadon JA held that the *DP Regulation* constitutes a valid exercise of the federal criminal law power under section 91(27) of the *Constitution Act, 1867*.<sup>126</sup>

The Federal Court of Appeal’s decision is especially interesting in light of the Supreme Court’s split in the *AHRA* Reference. In overruling the trial judge’s finding that data protection is not really about health and safety (or, therefore, criminal law), but rather about competing commercial interests (and therefore federal trade and commerce or provincial property and civil rights) the Federal Court of Appeal took a very broad contextual approach in assessing the pith and substance of the matter. Much emphasis was placed on the fact that the statutory provision enabling the creation of the data protection scheme happened to be contained in the *FDA*.

The Federal Court of Appeal’s approach aligns with Chief Justice McLachlin’s inverted process for characterizing the pith and substance of

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122 [1937] AC 326 at 355. See also *Thompson v Thompson*, [1994] 3 SCR 551, (concurring opinion of Justice L’heureux-Dubé provides recent affirmation of the rule).

123 *CGPA*, *supra* note 120.

124 *Canadian Generic Pharmaceutical Association v Canada* (Minister of Health), 2010 FCA 334 at para 102.

125 [1995] 3 SCR 199, 127 DLR (4th) 1, 62 CPR (3d) 417.

126 *Ibid* at para 118.

assisted human reproduction by looking first at the broad legislative context (i.e., the *FDA*) and only then at the particular impugned provisions (i.e., the *DP Regulation*). However, although Nadon JA acknowledged repeatedly in other parts of the judgment that this provision of the *FDA* was itself created by legislation to implement Canada's international trade obligations, he never really explained why that was not a strong signal that this matter is really about trade and commerce after all. Did the Federal Court of Appeal believe that *NAFTA* and *TRIPS* are in pith and substance about public health and safety, or that the exercise of contextualization stops at the Canadian border with the implementation of these international agreements through the *FDA*? The Trial Division's approach of concentrating on the pith and substance of the impugned regulation tracks more closely to the quite different, and more conventional, process endorsed by the majority of the Supreme Court in the *AHRA Reference*, through the decisions of Justices LeBel and Deschamps and Justice Cromwell.

This case regarding the *DP Regulation* definitely raises the problems of criminal law creep that divided not only the trial and appellate courts, but also the Supreme Court. The federal criminal law power is already broad, given its extension to cover public health and safety issues generally. Now, through the Federal Court of Appeal's decision, it has been extended even further to include commercial regulatory measures that are not health and safety measures, but are ostensibly designed to promote public health and safety (by providing economic incentives to develop new drugs, for example).

Notably, these constitutional challenges do not inherently favour either innovator or generic drug companies. Either camp can be, and has been, somewhat opportunistic in using constitutional arguments as the basis for their attacks on aspects of the law that disadvantage them. Recall that innovators have brought such a challenge against the compulsory licensing aspects of the patent system, as well as the remedies provisions of the *PM(NOC) Regulations*, arguing those were in pith and substance property and civil rights. Generic manufacturers' arguments about the data protection system are, boiled down to their essence, not that much different.

The timing of the decisions regarding data protection and assisted human reproduction – both issued in December 2010 – meant that the Federal Court of Appeal could not consider the Supreme Court's approach. Consequently, there is a significant need for the Supreme Court to consider these issues again. In the summer of 2011, an application for leave to appeal to the Supreme Court was dismissed. That marks the end of this particular case, but leaves the core issues still simmering.

The question of whether data protection is really about health or business is relevant not only in the context of the federal power over criminal law. It has major implications for Canada's implementation of international trade obligations. The Federal Court of Appeal made no comment on this issue, having found it unnecessary to do so as a result of its disposition of the matter as valid criminal law. The prior decision by the Federal Court suggests that the federal government may be able to justify provisions on the basis of their international obligations, but the holding also suggests that Parliament may also be able to mostly sidestep the division of powers in the *Constitution Act, 1867* and legislate in areas of provincial jurisdiction.

Canada's international trade law obligations in respect of pharmaceutical data exclusivity laws, like drug pricing and gene patents, broaden the areas where conflicts are borne out from property and civil rights (provincially) and patents (federally) to matters of criminal law and trade and commerce. So far, most health care related federalism cases have not dealt with these issues in much detail.

Federalism and the implementation of international treaties on data protection is also a very timely issue.<sup>127</sup> Canada and the European Union (EU) are presently in the midst of negotiations toward a Comprehensive Economic and Trade Agreement (CETA). These ambitious and wide-ranging negotiations could have lasting impact on Canada's data exclusivity period for biomedical technologies. Although negotiations are still ongoing, the European Commission is already pressing for the inclusion of stronger intellectual property governance, demanding changes be made to Canada's current legal framework.<sup>128</sup> Adopted in 2004, EU pharmaceutical legislation mandates a harmonized eight-year data exclusivity term that includes an additional two-year market exclusivity term.<sup>129</sup> This 10-year exclusivity period can be further extended by an additional one year maximum under certain circumstances. It is believed by many that a successful economic agreement between the two parties would require that Canada adopt the

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127 See Jeremy de Beer, "Implementing International Trade Agreements in Federal Systems: A Look at the Canada-E.U. CETA's Intellectual Property Issues," (2011) 38:4 LIEI (forthcoming).

128 See Michael Geist, "CETA Update: EU Pressures on IP Increases" (27 April 2010), online: Michael Geist's Blog <<http://www.michaelgeist.ca>>.

129 EC, *Commission Directive 2004/27/EC of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use*, [2004] OJ, L 136/34.



“8+2+1” formula of data exclusivity, in order to ensure that there is equal incentive for the development of innovative biomedical technology.<sup>130</sup>

The provinces and territories, as well as private health care insurers, would bear the brunt of the costs of the proposed data exclusivity provision. Extending data exclusivity would likely affect Canada’s generics drug manufacturers, eventually making prescription medicine more expensive.<sup>131</sup> It is estimated that the current data exclusivity regime already costs regional health care systems an additional \$100 million a year.<sup>132</sup>

Interestingly, the CETA negotiations have included both the federal and all provincial governments. Though one might expect the provinces to argue against the European position, because of its potentially significant costs, the opposite has happened. Alberta, Quebec, and New Brunswick have, surprisingly, sent letters supporting harmonization of intellectual property standards with the EU.<sup>133</sup>

## E. Subsequent Entry Biologics

Subsequent Entry Biologics (SEBs) are an emerging source of federalism-related controversy in the biomedical technology industry. Biologics are a subset of drugs derived and generated through the metabolic activity of living organisms. Such biological molecules tend to be more structurally complex than traditional pharmaceuticals or chemically synthesized drugs. Some common examples include: vaccines, antibodies, cytokines, protein hormones, and gene therapy products. The term SEB is used by Health Canada to describe a biologic that is similar to an approved innovator product.<sup>134</sup> However, it is widely conceded that a SEB is not a “generic biologic.”

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130 See e.g. BIOTECCanada, Media Release, “Re: Department of Foreign Affairs and International Trade Consultations on Possible Comprehensive Economic Agreement Negotiations with the European Union” (20 January 2009) online: BIOTECCanada <<http://www.biotech.ca>>.

131 India is currently worried that their own proposed EU-trade agreement could result in similar domestic hardships. Erika Kinetz, “EU trade deal jeopardizes generic drugs”, *The Morning Star* (30 April 2010).

132 CGPA, News Release, “Federal Court Decision on Extended Monopolies for Big Pharma will Cost Canadians More than \$100 Million Per Year” (22 July 2009) online: CGPA <<http://www.canadiangenerics.ca>>.

133 Tom Blackwell, “Trade deal would include increased protection for brand-name drugs”, *National Post* (25 October 2010).

134 The terms “biosimilar” or “follow-on biologic” are occasionally used in substitute.

Unlike generic pharmaceuticals, SEBs are not virtually identical to their reference product and various production factors can contribute to significant differences in immunogenicity and clinical response.<sup>135</sup> In the case of SEBs, the process is the product. This distinction necessitates that Canada's regulatory regime specifically addresses SEBs market authorization and approval. The existing *PM(NOC) Regulations* alone are insufficient under the present circumstances.

On March 8, 2010, Health Canada released the Final Guidance on SEBs.<sup>136</sup> The document was published to provide sponsors with guidance on how to satisfy the information and regulatory requirements under the *FDA* for approval of SEBs in Canada. The guidelines provide for a somewhat abbreviated SEBs approval process by accepting a reduced data package. At the same time, the guidelines state that a determination of similarity will not necessarily signify that the two products being compared are identical or even therapeutically equivalent. Instead it means only that: (i) the existing knowledge of both products is sufficient to predict that any differences in quality attributes should have no adverse impact upon safety or efficacy of the SEBs; and (ii) that non-clinical and clinical data previously generated with the reference biologic drug are relevant to the SEBs.

It is unclear as to whether or not SEBs may be deemed interchangeable with the reference biologic drug product. In the pharmaceutical industry, interchangeability generally refers to the act of interchanging a brand-name drug with a lower cost, generic version. Health Canada's finalized version of the SEBs guidance document provides no direct reference to interchangeability. According to Health Canada, interchangeability remains a provincial decision,<sup>137</sup> however, each of the provinces and territories has

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135 Some factors that might contribute include: cell line; type of growth media and supplements; incubation temperature; collection/harvesting protocol; purification technique; etc.

136 Health Canada, *Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics* (Ottawa: Public Works and Government Services Canada, 2010). See also Health Canada, *Draft Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics* (Ottawa: Public Works and Government Services Canada, 2008).

137 KA Nyarko, "Regulatory Approach for Subsequent Entry Biologics in Canada" (Presentation, delivered at the PMDA 3rd International Symposium on Biologics, 17 February 2009) online: Pharmaceuticals and Medical Devices Agency <[http://www.pmda.go.jp/2009bio-sympo/file/IV-2\\_Nyarko\\_\(Health%20Canada\).pdf](http://www.pmda.go.jp/2009bio-sympo/file/IV-2_Nyarko_(Health%20Canada).pdf)>.

different definitions of interchangeability and different levels of protection for dispensing interchangeable products. To date, there is no indication as to whether any of the provinces will consider SEBs as suitable for “interchangeable status.”

According to Alan West, the SEBs approval pathway creates potential liability problems for federal regulators.<sup>138</sup> West suggests that Health Canada holds two fundamentally incompatible stances with regards to SEBs. While not declaring SEBs to be “pharmaceutically or therapeutically equivalent”, federal regulators are effectively treating them as such with reduced approval requirements. This may form the basis of an allegation in negligence if a patient is harmed as a result of a SEB. As such, provincial and territorial decisions over interchangeability will not only effect provincial payors who list SEBs on formularies, but also have an important impact on the risk of federal legal liability.

SEBs are also subject to the *PM(NOC) Regulations* and the *DP Regulation*, and their respective guidance documents were amended concurrently with the release of the SEBs guidelines. Under the *PM(NOC) Regulations*, SEBs manufacturers that make “a direct or indirect comparison with, or reference to” a previously approved biologic in its submission will be required to either accept that market approval for the SEB will be delayed until the patents on the Patent Register expire or file a notice of allegation. Under the *DP Regulation*, SEBs manufacturers will be subject to the approval restrictions if their submissions rely on another innovative product that has been afforded data protection.<sup>139</sup>

The recent emergence of SEBs into the marketplace makes it even more imperative to consider the scope of Parliament’s jurisdiction over patented medicines. The application of the *PM(NOC) Regulations* and the *DP Regulation* fail to adequately address the specific nature of biologic molecules. Use of the same framework downplays the differences between SEBs and generic pharmaceuticals. A separate approval mechanism should be considered that recognizes the unique challenges posed by SEBs.

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138 Alan West, “Subsequent Entry Biologics: Legal Aspects of Interchangeability and Liability” (Presentation, delivered at the Canadian Agency for Drugs and Technologies in Health 2010 Symposium, 18 April 2010), online: Canadian Agency for Drugs and Technologies in Health <[http://www.cadth.ca/media/symp-2010/presentations/20100428-094354\\_cs17\\_-\\_a\\_west.pdf](http://www.cadth.ca/media/symp-2010/presentations/20100428-094354_cs17_-_a_west.pdf)>.

139 SEBs themselves cannot benefit from data protection.

Health Canada has a vested interest in bringing the provinces and territories into the conversation over SEBs approval. Representatives from the provincial governments made up 1% of the participants at the June 2008 Consultations on the Regulatory Framework for SEBs.<sup>140</sup> Considering the importance of their involvement and implications on their regional health care systems, this lack of provincial involvement appears to be a major oversight.<sup>141</sup> Indeed many of present stakeholders recognized the anomaly, expressing their interest in hearing what the provinces and territories had to say about the proposed approval pathway.<sup>142</sup> Their commentary stressed the need for further consultations, this time with greater provincial and territorial involvement.

#### IV. Working Together Toward Solutions

In their recent work, Bubela and colleagues recommend that Canada adopt a variety of mechanisms for achieving policy coherence in intellectual property and health, including an institutional “catalyst” in charge of intra-governmental coordination.<sup>143</sup> The authors suggest that effective coordination will require two important features: “leadership and a permanent institution that can build trust.”<sup>144</sup> In building both, this paper argues that particular attention must be paid to the Canadian federal structure.

The federal structure of the Canadian government has had an important and persisting impact on intellectual property law and policy making. There is a robust body of scholarly literature exploring federalism in Canada, yet little of this research directly addresses the complex relationship that exists between the “division of powers” and intellectual property. The *Constitution Act, 1867* grants Parliament the ability to pass legislation over copyrights, patents, and to some extent, trademarks. As such, many people assume intellectual property matters fall solely within federal jurisdiction and that

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140 Health Canada, Centre for Policy and Regulatory Affairs – Biologics and Genetic Therapies Directorate, *Consultations on the Regulatory Framework for Subsequent Entry Biologics – Summary Report* (Ottawa: Public Works and Government Services Canada, 2008).

141 It should be noted that Health Canada claims to have actively sought out provincial participation.

142 *Consultations on the Regulatory Framework for Subsequent Entry Biologics*, *supra* note 139.

143 *Supra* note 2 at 27.

144 *Ibid* at 32.

provincial officials have no role to play. Federal laws in the area of intellectual property, however, have a profound effect on matters of provincial jurisdiction. While some commentators have argued that, for example, “health-care affordability is an issue for social policy; the notion that government should use intellectual property as a tool for containing drug costs is both shortsighted and counterproductive,”<sup>145</sup> the case studies canvassed in this article prove that such issues are, rather, inseparable.

There are clear and obvious advantages from maintaining a centralized system of intellectual property law and policy-making, largely related to functional concerns for administrative and economic efficiency. Centralization eliminates variability, along with the associated conflicts and transaction costs. Moreover, centralization minimizes bureaucratic redundancy, reducing the coordination costs associated with intellectual property-related processes. Finally, centralization enhances accountability by making it easier for the public to monitor the handful of individuals responsible for relevant decision-making.

At the same, however, decentralizing power over intellectual property could yield a range of under-appreciated benefits. First, a locally tailored intellectual property framework could help to further specific regional objectives and create localized knowledge policies. Federally enacted intellectual property legislation and regulations often neglect regional interests and concerns. A decentralized system of intellectual property law and policy making would give provincial and territorial legislators the opportunity to pick and choose what they deem to be important. For example, a particular community might choose to prioritize low-cost pharmaceuticals over inducing drug research and development. Second, a decentralized system could help foster innovation by creating competition on a sub-national level, essentially allowing innovators to “forum shop” around political resistance. In a diverse regulatory marketplace, innovators are likely to seek out jurisdictions with the intellectual property governance regime that best caters to their needs and preferences. Decentralization would allow innovators to circumvent obstructing regulatory capture from special interest groups, a phenomenon that is more problematic with centralized state organization.<sup>146</sup> As a result, it is likely that

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145 John Manley & Russell Williams, “Enhancing trade by protecting intellectual property”, *National Post* (14 April 2011).

146 See Yingyi Qian & Barry Weingast, “Federalism as a Commitment to Preserving Market Incentives” (1997) 11 *Journal of Economic Perspectives* 83; and Barry

intellectual property norms would emerge from the bottom-up, according to local practices and industry demands, resulting in an overall higher level of regional economic development.<sup>147</sup> Third, decentralization could have a positive effect on democratic participation. Centralized legislative authority over intellectual property at the federal level may limit citizens' ability to participate in the democratic processes by which laws are made.

The Supreme Court of Canada's recent decisions in *AHRA Reference* and *PHS* are indicative of the persisting challenges facing the regulation of biomedical innovation in Canada. But most people have not yet realized the equally difficult jurisdictional issues surrounding the role of intellectual property in this context. The courts have so far pronounced on few, if any, of the fundamental constitutional principles that could answer these particular questions. The scope of Parliament's legislative authority over patented medicines with respect to federal patent laws remains unclear at best. Even more uncertain is the resulting implications when provincial regulation of patented biomedical technologies coincide with traditional intellectual property governance. As a result, courts' ad hoc prioritization of particular interests through litigation continues to prevail over government-led public policy coherence.

A collaborative approach to federalism could give provinces and territories the flexibility to deliver patented biomedical technologies in a manner that best meets the respective needs of Canadian citizens. Collaborative federalism is grounded in the idea that the federal and the provincial and territorial governments should work concurrently toward the development and implementation of both regional and national policy. Classical federalism supports the clear division of powers among different levels of governments. The modern approach is one of cooperative federalism, which advocates for different levels of government working together across jurisdictions, under federal leadership.<sup>148</sup> In contrast, collaborative federalism is defined by the principle of co-determination; the governance of Canada as a partnership in which no level of government is considered more important in terms of setting national priorities. Collaborative federalism breaks free of the traditional pattern of federal-leadership, sometimes even leaving

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Weingast, "The Economic Role of Political Institutions: Market Preserving Federalism and Economic Development" (1995) 11 *JL Econ & Org* 1.

147 See e.g. Daniel Drezner, "State Structure, Technological Leadership, and the Maintenance of Hegemony" (2001) 27 *Review of International Studies* 3.

148 See *Chatterjee v Ontario (Attorney General)*, 2009 SCC 19, [2009] 1 SCR 624.

provincial and territorial governments to collectively set the national agenda in the absence of the federal government.

The adoption of collaborative federalism in response to intergovernmental conflicts in the health care system is not a new idea. In late 2004, the federal government struck a long-term agreement with the provincial and territorial governments.<sup>149</sup> The Health Accord took steps to ensure that the federal government could not dominate the future of health care reform in Canada. An independent third-party panel was established to moderate federal involvement in the health care industry. Moreover, the agreement mandated that provinces and territories be treated as equal bargaining stakeholders and allowed to develop their own strategies independently. A 2008 submission to the House of Commons Standing Committee on Health concluded that:

The achievements contained in the 2004 Health Accord are important, and in some ways historic. The Agreement has provided clarity of roles, stability of funding, and timelines for deliverables. While there have important pockets of success where progress is being made – there is clearly room for improvement. While some of the ongoing improvement relates to the structural realignment of the health system, there are also financial considerations that relate to how the federal government – working collaboratively and in partnership with the provinces and territories – can improve the overall capacity of the health system to respond.<sup>150</sup>

The patented biomedical technology sector is one such area where improvements can be made. Many of the fundamental challenges surrounding the use of patented biomedical technologies in Canada remain unresolved. A more concerted effort towards intergovernmental collaboration could help address these contentious issues and develop beneficial public policy. More importantly, a collaborative approach could preemptively avoid new legal and policy problems from emerging.

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149 See David Cameron & Richard Simeon, "Intergovernmental Relations in Canada: The Emergence of Collaborative Federalism" (2002) 32 *Journal of Federalism* 49.

150 Association of the Canadian Academic Healthcare Organizations, *A 10-year Plan to Strengthen Health Care... Taking Stock of the 2004 First Ministers' Accord* (Ottawa: Association of the Canadian Academic Healthcare Organizations, 2008).