

# From Theory to Practice: Health Care and the Patent System

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## Introduction

Patents and biotechnology live in an unhappy – or at least contentious – marriage. Ever since the Supreme Court of the United States first agreed that a genetically-engineered organism could be patented,<sup>1</sup> researchers, industry, governments, courts and NGOs have discussed and argued over the wisdom, scope, nature, duration, validity and almost every other aspect of biotechnology patents without having arrived at any broad-based consensus. Given the division of views, in fact, consensus is unlikely.<sup>2</sup>

Despite the lack of consensus – or perhaps because of it – patent offices and courts have expanded patent rights over biotechnology's products to include almost all imaginable forms of biotechnological innovation.<sup>3</sup> Patent coverage is greatest in the United States, but other developed countries have generally followed suit.<sup>4</sup> Only Canada, among these nations, has resisted the trend to any extent when the Supreme Court of Canada found that the *Patent Act*<sup>5</sup> does not cover claims in respect of higher life forms.<sup>6</sup> Even this development should not be taken as a substantial diminution in Canadian patent rights: the Canadian Intellectual Property Office had already granted claims over the DNA sequence involved in that case, the cell culture containing that sequence and the process to make the mouse.<sup>7</sup> The effect of this holding is, given other jurisprudence,<sup>8</sup> to grant patent owners significant control over the use of higher life forms.

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<sup>1</sup> *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

<sup>2</sup> E. Richard Gold, "Finding Common Cause in the Patent Debate" (2000) 18 *Nature Biotechnology* 1217.

<sup>3</sup> Timothy A. Caulfield, E. Richard Gold & Mildred Cho, "Patenting Human Genetic Material: Refocusing the Debate" (2002) 1 *Nature Reviews Genetics* 227.

<sup>4</sup> See e.g. EC, *Directive 98/44 of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions*, [1998] O.J. L 213/13; Japanese Patent Office and European Patent Office, *Trilateral Project B3b Mutual understanding in search and examination: Report of comparative study on biotechnology patent practices* (2000), online: European Patent Office <[http://www.european-patent-office.org/tws/report/B3b\\_report\\_pdf/B3b\\_reachthrough\\_text.pdf](http://www.european-patent-office.org/tws/report/B3b_report_pdf/B3b_reachthrough_text.pdf)>.

<sup>5</sup> R.S.C. 1985, c. P-4.

<sup>6</sup> *Harvard College v. Canada* (Commissioner of Patents), 2002 SCC 76 [*Harvard Mouse*].

<sup>7</sup> Canadian Patent Application No. 484723 reproduced in Appendix – to *President and Fellows of Harvard College v. Canada* (Commissioner of Patents), [2000] 4 F.C. 528 (QL).

<sup>8</sup> See *Schmeiser v. Monsanto Canada Inc.*, 2002 FCA 309.

Patents currently cover a large range of traditional health products ranging from pharmaceutical products,<sup>9</sup> medical equipment,<sup>10</sup> test procedures, to bandages.<sup>11</sup> They also provide protection over new biotechnological products and processes such as DNA sequences,<sup>12</sup> proteins,<sup>13</sup> cell-lines<sup>14</sup> (including stem cells<sup>15</sup>) and processes used in bioinformatics.<sup>16</sup>

A relatively recent set of practical problems arising from the patent system threatens, however, to at least curtail the growing expansion of patent rights over biotechnological innovation. These challenges arise within health care systems and have been led by health care administrators. Where previous debates have failed to lead legislators to make any significant changes in patent law, the sheer importance of the health care system – not to mention its costs – provide substance to these challenges. Essentially, these challenges are two-fold. First, it is feared that patents diminish access to cutting-edge technology due to restrictive licensing practices. For example, a patent holder may prevent health care authorities from using the best or the most appropriate genetic predisposition test available for a given disease.<sup>17</sup> Second, health care administrators are concerned that patents will prevent them from implementing cost-effective screening and other health programs. This is not simply because the cost of the patented elements is high – this is true of many patented products and processes – but that patents will so restrict the flexibility of health care authorities that they will not be able to implement screening programs in an appropriate manner.<sup>18</sup>

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<sup>9</sup> See e.g. Canadian Patent No. 2210241, “Pharmaceutical Composition Containing Cyclosporin for Treating a Human with Nervous Insult”, online: Canadian Intellectual Property Office <<http://patents1.ic.gc.ca>>.

<sup>10</sup> See e.g. Canadian Patent No. 2068249, “Medical Support System”, online: Canadian Intellectual Property Office <<http://patents1.ic.gc.ca>>.

<sup>11</sup> See e.g. Canadian Patent No. 1225622, “Unitary Adhesive Bandage and Package”, online: Canadian Intellectual Property Office <<http://patents1.ic.gc.ca>>.

<sup>12</sup> See e.g. Canadian Patent No. 1302921, “Lymphotoxin DNA, Lymphotoxin Expression Vector, Lymphotoxin Resistant Cell, Transformant with Lymphotoxin Expression Vector and Process for Preparing Lymphotoxin”, online: Canadian Intellectual Property Office <<http://patents1.ic.gc.ca>>.

<sup>13</sup> See e.g. Canadian Patent No. 2171424, “Acylated Insulin”, online: Canadian Intellectual Property Office <<http://patents1.ic.gc.ca>>.

<sup>14</sup> See e.g. Canadian Patent No. 2137809, “A Genetically Engineered Cell Line for Detecting Infectious Herpes Simplex Virus and Method Therefor”, online: Canadian Intellectual Property Office <<http://patents1.ic.gc.ca>>.

<sup>15</sup> See e.g. Canadian Patent Application No. 2174746, “Embryonic Stem Cells Capable of Differentiating into Desired Cell Lines”, online: Canadian Intellectual Property Office <<http://patents1.ic.gc.ca>>.

<sup>16</sup> See e.g. Canadian Patent Application No. 2396495, “Method and System for Automated Inference Creation of Physico-Chemical Interaction Knowledge from Databases of Co-Occurrence Data.”, online: Canadian Intellectual Property Office <<http://patents1.ic.gc.ca>>.

<sup>17</sup> E. Richard Gold, Timothy A. Caulfield & Peter Ray, “Gene Patents and the Standard of Care” (2002) 167 Can. Med. A. J. 256.

<sup>18</sup> Government of Ontario, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare* (2002), online: <[http://www.gov.on.ca/MOH/english/pub/ministry/geneticsrep02/report\\_e.pdf](http://www.gov.on.ca/MOH/english/pub/ministry/geneticsrep02/report_e.pdf)> at 44.

We should not underestimate the importance of health care authorities' intervention into the patent debate. This article will outline the contribution that this intervention has made and how it has refocused the patenting debate not only about whether, but how, Canada and other countries ought to grant patents over biotechnological inventions. First some background is needed. Thus, in Part I, I provide an overview of the patent system. In Part II, I examine the traditional ethical concerns raised about biotechnology patents while in Part III, I discuss the particular contributions made to the debate by health care administrators.

## Part I: Nature of Patent Rights

Patent rights are essentially vetoes over the activities of others with respect to certain uses of inventions.<sup>19</sup> The Canadian patent holder can prevent anyone in Canada from making, using, selling or importing a patented invention without his or her permission.<sup>20</sup> This right is similar to the property rights countries grant in everything from houses to paperclips; there too, the property holder can prevent others from engaging in certain types of activity. While the range of the veto is wider when it comes to cars or to paperclips than to inventions, the veto itself is not different in nature. In both cases – tangible good or invention – nobody is permitted to do anything with respect to the good without the permission of the property holder. And the inventor is not required to grant this permission.

Like property in tangible goods, the patent holder does not necessarily have the right to do anything with the invention him or herself. Consider, for example, a building that has been condemned. In such a case, despite his or her property rights, the title holder is neither entitled to live in nor enter the building. Similarly, a patent holder over a pharmaceutical product is not entitled to sell that product without the approval from health authorities. In both cases, therefore, the property owner only has a privilege to use the good him or herself when there are no conflicting rights.

## National Nature of Patent Rights

Patents are granted on a country-by-country basis. There is thus no such thing as a world patent. To have a veto over activity relating to an invention in Canada, a person must have a Canadian patent. Similarly, to have a veto in the United States or Germany over the use of the invention, the person must have a patent in the

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<sup>19</sup> Even though s. 42 of the Act is written in positive terms, it does not give the patent holder the right to actually do anything. Per Binnie J. in *Harvard Mouse*, *supra* note 6 at para. 64: A patent does not exempt the owner from any relevant regulation or prohibition. While s. 44 (now s. 42) of the *Patent Act* gives the owner, as against the rest of the world, “the *exclusive* right, privilege and liberty of making, constructing and using the invention and selling it to others to be used ...” (emphasis added), and in that respect is framed as a positive right, its effect is essentially to prevent others from practising an invention that, but for the patent monopoly, they would be permitted to practise. In exchange for disclosure to the public, the patent protects the disclosed information from unauthorized use for a limited time.

<sup>20</sup> *Patent Act*, *supra* note 5, s. 42.

United States or Germany, as the case may be. Each country is entitled to apply its laws to determine whether the patent ought to be issued, the scope of the veto offered to the patent holder and the manner and ability of others to challenge the issued patent.

Despite the national nature of patent rights, international treaties coordinate the patent systems of countries generally by ensuring that these countries abide by a set of minimum standards. These standards include the requirement that residents of one country have the right to apply for a patent in all others (whether or not that person also applies for a patent in his or her country of residence)<sup>21</sup>, that the level of patent protection offered to a country's own residents is no different from that offered to the residents of other signatory countries,<sup>22</sup> that patents last for 20 years from the date of first application<sup>23</sup> and that countries grant patents over all inventions that are new, non-obvious and useful without discrimination.<sup>24</sup>

The minimum standards set out in international treaties provide countries with considerable wiggle room in terms of how they construct and operate their respective patent systems.<sup>25</sup> That is, while respecting the basic international framework for patent protection, countries can adapt their laws and processes to suit their needs. Thus, significant differences exist between even the patent regimes of the United States, Europe<sup>26</sup> and Canada. On a substantive level, while the United States grants patents over a greater range of innovation than do either Europe or Canada, the United States gives among the narrowest interpretations to those patents.<sup>27</sup> On a procedural level, Europe has incorporated an opposition procedure into its patent rules that neither Canada nor the United States have followed.<sup>28</sup> These examples only provide a taste of the real differences, both substantively and procedurally,

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<sup>21</sup> *Paris Convention for the Protection of Industrial Property*, 20 March 1883, 828 U.N.T.S. 307 (revised at Brussels on Dec. 14, 1900, at Washington on June 2, 1911, at the Hague on Nov. 6, 1925, at London on June 2, 1934, at Lisbon on Oct. 31, 1958 and at Stockholm on July 14, 1967) Art. 2 [*Paris Convention*].

<sup>22</sup> *Ibid.*

<sup>23</sup> *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments – Results of the Uruguay Round, vol. 31, 33 I.L.M. 81 (1994) Art. 33 [*TRIPS*].

<sup>24</sup> These are the Canadian names for these criteria, as permitted by *TRIPS*. The actual international criteria are novelty, inventive step and industrial application. *Ibid.*, Art. 27(1).

<sup>25</sup> J.H. Reichman, "From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement" (1996) 29 N.Y.U.J. Int'l L. & Pol. 11 at 28.

<sup>26</sup> Even though each country exercises jurisdiction over patents valid in its country, most European countries are members of the European Patent Convention that permits applicants to seek patents valid in each of the member countries from the European Patent Office. *European Patent Convention*, 5 October 1973, 1065 U.N.T.S. 199. Despite this centralization, there continue to exist significant differences between the patent regimes of the member countries to the European Patent Convention.

<sup>27</sup> See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831 (2002) (discussing the limiting effect of patent prosecution estoppel on patent scope); *Free World Trust v. Électro Santé Inc.*, [2000] 2 S.C.R. 1024 (QL) (discussing various strategies for interpreting the contents of patent scope in Canada, Japan and Europe).

<sup>28</sup> *European Patent Convention*, *supra* note 26, Part V.

that exist between the patent regimes of these three jurisdictions, let alone those that exist between these patent regimes and those of other countries.

### Reasons We Grant Patents

Although patent regimes seem to focus on protecting the interests of inventors and the companies they own or are employed by, in fact patent regimes aim at serving the public good.<sup>29</sup> It is simply a consequence of this more important aim that protection is provided to inventors.<sup>30</sup> While there are competing versions of the theory behind the award of patent rights, the predominant one is based on economic versions of utility. Essentially, this theory holds that patents are necessary either as a device to encourage inventors to invest their time and labour into creating inventions or as an inducement to encourage them to disclose their invention to the public.<sup>31</sup> The public good, on this theory, is served by not only having more innovation but by having knowledge of that innovation disseminated throughout society. Whether this definition of the public good is appropriate,<sup>32</sup> I leave for another day. What is essential is that patent rights are justified in terms of their consequences on society, and not because of any inherent moral right of the inventor to control his or her invention.

This normative underpinning of patent law has important implications for its interaction with health care. In terms of health care, we have some notion of what it means to serve the public good.<sup>33</sup> In this field, at least, not only academics, but policy-makers and the public can assess whether the patent system is attaining its goals.<sup>34</sup> As we will see below, it is because of this transparency that health care administrators have been able to change the nature of the debate over patents.

### Process to Attain Patent

There is no automatic right to a patent. In this respect, patents contrast with copyrights, which exist, for example, in literature, books and paintings. To obtain

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<sup>29</sup>Defining the public good is no easy task. Far too frequently, the public good is reduced to simple economic interest. See Audrey R. Chapman, "The Human Rights Implications of Intellectual Property Protection" (2002) 5 J. Int'l Econ. L. 861 at 867.

<sup>30</sup>That is, patents are not deserved, but are given to serve the public good. See e.g. per Binnie J. in *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77 at para. 37 [*Apotex*]: A patent, as has been said many times, is not intended as an accolade or civic award for ingenuity. It is a method by which inventive solutions to practical problems are coaxed into the public domain by the promise of a limited monopoly for a limited time.

<sup>31</sup>Harold I. Dutton, *The Patent System and Inventive Activity During the Industrial Revolution 1750-1852* (Manchester: Manchester University Press, 1984) at 17-20.

<sup>32</sup>One could ask, for example, why it is better to spend resources on creating new things rather than on simply using existing ones better.

<sup>33</sup>See e.g. Commission on the Future of Health Care in Canada, *Building on Values: The Future of Health Care in Canada* (Ottawa: Government of Canada, 2002), online: <[http://collection.nlc-bnc.ca/100/200/301/pco-bcp/commissions-ef/future\\_health\\_care-ef/building\\_values\\_future-e/hccfinalreport\\_e.pdf](http://collection.nlc-bnc.ca/100/200/301/pco-bcp/commissions-ef/future_health_care-ef/building_values_future-e/hccfinalreport_e.pdf)>.

<sup>34</sup>See *ibid.* at 208-9.

a patent, an inventor or the inventor's assignee must make application to the patent office in each country in which he or she desires protection. This necessity to apply in many countries arises out of the jurisdictionally bound nature of patent rights. It also means that the inventor must satisfy the requirements of each country's patent laws.

A series of international agreements simplifies the process of filing patents in several countries simultaneously. One convention permits an applicant, for example, to apply for a patent in one country and wait up to one year before applying in other countries. An applicant who does so benefits from the same priority date as the first application.<sup>35</sup> Another convention provides for the filing of an 'international' patent application. Under this option, a patent office reviews the application and reports back to the applicant before the latter must file separate applications in each member state.<sup>36</sup> There are two advantages to this approach. First it permits the applicant to postpone the cost of translating the application into the language of each country. Second, it provides the applicant with a better appreciation of the value of what kind of patent the individual countries would likely grant. Each of these options has time and cost implications to the applicants that I will not discuss further. The central point of this discussion is that, while patents remain national in nature, mechanisms exist to simplify the application process. Nevertheless, the cost of filing patent applications is significant: it is approximately US\$8,000 per patent per country.<sup>37</sup>

### Patent Examination

Once an application has been made, the patent office reviews it to ensure that it makes claims that satisfy the requirements of patent law. There are three types of requirements: that the invention is the kind of invention protected by that country's patent laws; that the invention satisfy the country's patent criteria; and that the invention is fully described. I will briefly examine each of these requirements in turn.

#### *Patentable Subject-Matter*

While international agreements state that patents must be granted without discrimination across all fields of technology, these agreements nevertheless provide countries with 'wobble-room' to determine which types of inventions to include within their patent regimes.<sup>38</sup> This wobble room arises from three points. First, there is no internationally accepted definition of invention. Essentially, an

<sup>35</sup> *Paris Convention*, *supra* note 21, Art. 4(C).

<sup>36</sup> *The Patent Cooperation Treaty*, 19 June 1970, 1160 U.N.T. S. 231.

<sup>37</sup> See John R.S. Orange, "Costs – an Issue for Whom" (Paper presented at the World Intellectual Property Organization Conference on the International Patent System March 25 - 27, 2002), online: <<http://patentagenda.wipo.int/meetings/2002/presentations/orange.pdf>> (this was based on a case study involving patent applications in a total of ten industrialized countries).

<sup>38</sup> *TRIPS*, *supra* note 23, Art. 27.

invention is something that would not exist but for human intervention. Given the vagueness of this definition, it is perfectly acceptable if different countries find different sorts of things to be inventions. Second, the treaties permit countries to exclude certain categories of inventions<sup>39</sup> some of which are particularly relevant to the health care sector. For example, countries need not grant patents over “diagnostic, therapeutic and surgical methods for the treatment of humans or animals.”<sup>40</sup> This is less generous than it may at first seem since the exclusion is generally thought to apply to only *in vivo* methods and not diagnostic or therapeutic procedures carried on outside the body.<sup>41</sup> This is certainly the case in Canada where the exclusion does not even include diagnostic procedures.<sup>42</sup>

The so-called Harvard oncomouse patent application amply illustrates this point concerning patentable subject-matter. The United States Patent and Trademark Office issued a patent comprising claims over all mammals containing a cancer-causing gene.<sup>43</sup> In Europe, this broad claim was rejected on the basis that the inventors had not demonstrated that the medical benefit from creating any non-human mammal predisposed to cancer outweighed the suffering to the animal. That is, the European Patent Office was not convinced that, say, an onco-elephant’s suffering would be outweighed by advances in medical knowledge arising from the commercialisation of such an elephant. The Patent Office thus restricted the claim to rodents in respect of which it was more convinced of the medical benefit.<sup>44</sup> In Canada, while the Supreme Court held that no patent could be granted over the entire animal, patents were granted over the DNA sequence, cells and the process involved in creating the mouse.<sup>45</sup> Thus, in three different jurisdictions, we get three different responses to the issue of what can be patented.

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<sup>39</sup> TRIPS, *ibid.*, Art. 27(3) permits countries to exclude plants and animals from patentability while 27(2) permits countries to withhold patents over inventions the commercialization of which would violate public order or fundamental ethical norms.

<sup>40</sup> *Ibid.*

<sup>41</sup> David Lange and J.H. Reichman, Comment on “Bargaining Around the TRIPS Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions” by Joseph Straus (1998) 9 Duke J. Comp. & Int’l L. 91 at 100.

<sup>42</sup> Government of Ontario, *supra* note 18 at 78.

<sup>43</sup> US Patent No. 4,736,866 “Transgenic non-human mammals”, online: United States Patent and Trademark Office <<http://patft.uspto.gov/netahtml/search-bool.html>>, claim 1 of which reads as follows:

A transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal, or an ancestor of said mammal, at an embryonic stage.

<sup>44</sup> European Patent No. EP0169672 “Method for producing transgenic animals”, online: The European Patent Office <<http://ec.espacenet.com/espacenet>>, claim 19 of which provides as follows (as amended by decision of the Appeal Board):

A transgenic rodent whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said oncogene optionally being further defined according to any one of claims 3 to 10.

<sup>45</sup> See *Harvard Mouse*, *supra* note 6.

### *Patent Criteria*

Once a patent examiner concludes that the invention is of a patentable nature, he or she must then review the claims to ensure that they satisfy the criteria of novelty, non-obviousness and utility. Given space restraints, I will only briefly describe each of the criteria. However, the subject has much subtlety, requiring me to gloss over many of the details.

The three criteria used to evaluate whether a particular invention is patentable have little to do with the theory underlying patent law; they relate much more to the haphazard development of caselaw and statutory reform than anything else. This gives the criteria a somewhat artificial nature that occasionally leads to confusion.<sup>46</sup>

Novelty refers to the idea that the exact invention as claimed – that is, the process or thing over which the patent applicant is claiming a veto – has never been previously published or made available in a single source. Depending on the country, these sources may include written material, oral presentations or merely displaying the invention in public.<sup>47</sup> For an invention to fail the novelty test, someone reading or looking at that previous source – called prior art – must be able to directly formulate the invention.<sup>48</sup> Essentially, this test makes it impossible to patent an invention that was already known; it thus prevents little else other than double dipping.<sup>49</sup> The novelty criterion can, however, cause problems for unsophisticated inventors. If the inventor discloses the invention at, for example, a scientific conference then the invention will no longer be new should the inventor later file a patent application. To avoid this problem, some countries, such as the United States and Canada, have instituted a one-year grace period, permitting an inventor to file an application within one year after her public disclosure of the invention.<sup>50</sup> This grace period does not exist everywhere: for example, in Europe.

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<sup>46</sup> Much criticism has been directed to gene patenting on the basis that isolating a gene is commonly understood to be obvious or lacking an inventive step. See e.g. Tewolde B.G. Egziabher, “The Inappropriateness of the Patent System for Life Forms and Processes”, online: Third World Network <<http://www.twinside.org.sg/title/gebne.htm>>. While there are many reasons to criticize the patenting of genes, this particular criticism – that patent offices are simply misunderstanding patent criteria – fails to recognize that the patent system has its own meanings which often do not accord with common understanding.

<sup>47</sup> See e.g. *Patent Act*, *supra* note 5, s. 28.2.

<sup>48</sup> *Beloit Canada Ltd. v. Valmet Oy* (1986), 8 C.P.R. (3d) 289 (F.C.A.) [*Beloit*].

<sup>49</sup> The predecessors to the modern patent acts did not worry about actual invention as much as bringing a known technology from another country into the country granting the patent. The purpose of the novelty requirement at that time was simply to prevent people from renewing their patent monopoly. See, for example, both the Venetian patent statute of 19 March 1474, discussed in Edward C. Walterscheid, “The Early Evolution of the U.S. Patent Law: Antecedents (5, Part II)” (1996) 78 *Journal of the Patent and Trademark Office Society* 665 at 667, and the *Statute of Monopolies 1624* (U.K.), 21 Jac. I, ch. 3, s. 6.

<sup>50</sup> See e.g. *Patent Act*, *supra* note 5, s. 28.2

The non-obvious criterion extends the concept of novelty further. Instead of asking whether the exact invention had previously been disclosed, the obviousness criterion revolves around the question of whether the invention would have been obvious to someone with knowledge in the scientific discipline given prior disclosures and general information in that discipline.<sup>51</sup> The central element here is one of creativity: did the inventor do more than simply put a few pieces of knowledge together? If yes, then what results is an invention. The standard is not a high one; any level of creativity will do.

The third criterion, that of utility, deals with whether the invention has some practical use. There is some divergence, here, between the tests applied in the various countries. The United States arguably has the most difficult test to meet: the invention must have a specific, substantial and credible utility.<sup>52</sup> The European Patent Convention has among the easiest tests to satisfy: the invention either must be capable of being made or used. In Canada, an invention is useful if it does what the inventor says it will do.<sup>53</sup> For the most part, the onus of meeting such a test is not high.

### *Description Requirement*

A patent applicant must also describe the invention in sufficient detail as to permit someone with skill in the discipline to make and use it.<sup>54</sup> Unlike the novelty, non-obviousness and utility criteria, the obligation to describe the invention is not a substantive requirement about the invention; rather it is a procedural requirement that, nevertheless, can be difficult to satisfy. As obvious as it may sound, a valid description includes only those things that the inventor has actually discovered. Thus, an applicant cannot claim a patent over inventions that are very similar to the one she created unless she can make a sound prediction that the object will also work.<sup>55</sup> The applicant must describe the utility of the invention although this need not be done in a single sentence but may be the result of reading the entire application.<sup>56</sup> If the claimed utility is based on a sound prediction of how the invention will work – rather than actual proof that it does work – then the applicant must set out her reasons for that sound prediction in the application.<sup>57</sup>

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<sup>51</sup> *Beloit*, supra note 48.

<sup>52</sup> *Patent Office's Utility Examination Guidelines*, 66 Fed. Reg 1097 (2001).

<sup>53</sup> *Mullard Radio Valve Co. Ltd. v. Philco Radio & Television Corp.* (1935), 52 R.P.C. 261 at 287 (U.K.C.A.).

<sup>54</sup> *Patent Act*, supra note 5, s. 27(3); Industry Canada, *Manual of Patent Office Practice* (Ottawa: Government of Canada, 1998) section 9.01.

<sup>55</sup> *Ibid.*

<sup>56</sup> *Ibid.*

<sup>57</sup> *Apotex*, supra note 30.

*Subject to review by courts*

Even if a patent applicant should receive a patent from the relevant patent office, this does not mean that the patent is valid. A granted patent can be challenged both before the patent office and before the courts. In some jurisdictions, such as in Europe, there is an explicit administrative procedure – called an opposition – that those dissatisfied with the grant of the patent can follow. In Canada, there is the opportunity to file prior art with the Canadian Intellectual Property Office in an attempt to have that office cancel a claim for a lack of novelty or because of obviousness.<sup>58</sup> A similar procedure exists in the United States.<sup>59</sup>

In Canada, individuals can both pre-emptively and defensively seek to invalidate an issued patent before the courts.<sup>60</sup> The grounds for finding a patent invalid are the same as those for refusing to grant a patent in the first place: the invention is not new, non-obvious and useful or was improperly described. Unlike the patent offices, however, the courts have the final word on these questions. Courts do not show deference to decisions of the patent examiners.<sup>61</sup> In fact, in the United States during the period 1989 to 1996, courts found 46% of those patents challenged to be invalid.<sup>62</sup> As these statistics show, the mere fact that a patent office has granted a patent over an invention does not mean that the patent is valid. Nevertheless, given the extraordinarily high costs of patent litigation – estimated to be between \$2 and \$4 million for each side in the United States<sup>63</sup> – a granted but invalid patent may be sufficient for the patent holder to prevent competition.

**Part II: Ethical Concerns Relating to Biotechnology Patents**

At least since the late 1980s, both academics and policy-makers have questioned the ethics of patenting the products of biotechnological innovation.<sup>64</sup> The nature of these concerns are varied, ranging from those arising directly from the fact that a patent right exists in respect of living matter, to the consequences of using patents as the regulatory tool to encourage innovation in the field of biotechnology.

Despite the abundance and variety of the concerns raised, none had any noticeable effect on public policy.<sup>65</sup> Patent offices continued to award patent rights over DNA sequences and the other products of biotechnology while academic and social debate raged. Even in Europe, where it was most vocal, the ethics debate had

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<sup>58</sup> *Patent Act*, *supra* note 5, ss. 48.1-48.5.

<sup>59</sup> See 35 U.S.C.A. § 301-307 (West 2003).

<sup>60</sup> *Patent Act*, *supra* note 5, ss. 57, 60.

<sup>61</sup> *Harvard Mouse*, *supra* note 6.

<sup>62</sup> John R. Allison & Mark A. Lemley, "Empirical Evidence on the Validity of Litigated Patents" (1998) 26 A.I.P.L.A. Q.J. 185 at 205.

<sup>63</sup> *Orange*, *supra* note 37.

<sup>64</sup> See E. Richard Gold & Alain Gallochat, "The European *Biotech Directive*: Past As Prologue" (2001) 7 Eur. L.J. 331 at 337-40.

<sup>65</sup> Caulfield, Gold & Cho, *supra* note 3.

little substantive effect on European policies toward biotechnology patenting.<sup>66</sup> It is only recently, with the intervention of public health authorities, that the tide has started to turn.

In this Part, I review the original ethical concerns raised in the literature. In doing so, I follow the advice of Schrecker *et al.* and examine first the deontological concerns arising from biotechnology patenting before turning to the consequences of patenting.<sup>67</sup> I will then examine how these concerns have metamorphosed to deal with the more tangible concerns of the health care system.

### Deontological Concerns

Deontological arguments regarding gene patenting take two forms. Both argue against the patenting of the products of biotechnological research. The first form of argument, which is usually but not exclusively religious in origin, holds that it is wrong for people to have proprietary rights in living beings and tissues.<sup>68</sup> The argument is usually put that only God can own life. While its advocates advance this argument with force, it is not a view that is generally shared or generalisable. Not all religions view, for example, proprietary rights in respect of life forms to be objectionable.<sup>69</sup>

The second form of argument finds fault with biotechnology itself. Since patents are meant to promote biotechnological development, anyone who believes that biotechnology is wrong would reasonably object to the award of patent rights over the products of this technology. This argument also runs into difficulty, as public opinion data demonstrates a generally positive attitude of Canadians toward biotechnology.<sup>70</sup> While this data is not determinative of the validity of the *ethical* concern raised, it does limit the impact of the argument on policy-makers.

I have only examined these deontological arguments in a general way. It may very well be that, in respect to certain forms of technology – for example xenotransplantation – deontological arguments against patenting would be favourably perceived.

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<sup>66</sup>Gold & Gallochat, *supra* note 64.

<sup>67</sup>Ted Schrecker *et al.*, *Ethical Issues Associated with the Patenting of Higher Life Forms* (Montreal: McGill Centre for Medicine, Ethics and Law, 1997), online: Industry Canada <<http://strategis.ic.gc.ca/pics/ip/schrecef.pdf>> (a paper published for the Intellectual Property Policy Directorate of Industry Canada).

<sup>68</sup>*Ibid* at 35.

<sup>69</sup>Gold, *supra* note 2 at 1218.

<sup>70</sup>See Lorraine Sheremeta, E. Richard Gold, & Timothy A. Caulfield, "Harmonizing Commercialization and Gene Patent Policy with other Social Goals" (Presented to the 3<sup>rd</sup> International DNA Sampling Conference, September 2002).

## Consequentialist Concerns

Most of the concerns raised about biotechnology patenting relate to the consequences of allocating rights over biotechnology innovation through the patent system rather than to a fundamental opposition to the patent system or biotechnology *per se*. The common theme in all of these concerns is that the regulation of who controls access to knowledge and innovation through the patent system has a negative effect either on research or on the commercialisation of health technology. I will briefly examine each in turn.

### *Consequences for research*

The theory behind patent law is that patents encourage innovation by providing a means through which researchers and their sponsors can recoup the costs of researching and developing inventions. Assuming that patent law achieves its mission of increasing innovation,<sup>71</sup> it may do so too well. That is, patents may so attract researchers to conduct work leading to patentable inventions that it leaves too few to conduct other health-related research, such as public health research, that may more effectively save lives.<sup>72</sup> Similarly, patents may be so attractive to researchers that they cause a loss of objectivity in research, thus creating conflicts of interest.<sup>73</sup> Alternatively, patents may cause researchers to take short-cuts with respect to obtaining fully informed consent from their research subjects.<sup>74</sup>

While patents may set up unanticipated – or at least unwanted – incentives, a second worry concerns their effect on second generation researchers. Remember that patents provide the inventor with a veto exercisable against all others, including other companies and researchers. Although limited exceptions may exist in Canada to permit non-profit research,<sup>75</sup> there is a fear that patents will slow down research by making it too expensive and difficult to obtain licenses to patented technology.<sup>76</sup> The problem is particularly acute in biotechnology, where researchers often require access to a large number of patented materials.<sup>77</sup>

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<sup>71</sup> But see E. Richard Gold *et al.*, “Needed: Models of Biotechnology Intellectual Property” (2002) 20 *Trends in Biotechnology* 327.

<sup>72</sup> E. Richard Gold, “Making Room: Reintegrating Basic Research, Health Policy, and Ethics into Patent Law” in Timothy A. Caulfield & Bryn Williams-Jones, eds., *The Commercialization of Genetic Research: Ethical, Legal, and Policy Issues* (New York: Kluwer Academic/Plenum Publishers, 1999) 14 at 63.

<sup>73</sup> Sheremeta *et al.*, *supra* note 70.

<sup>74</sup> Bartha M. Knoppers, Marie Hirtle & Kathy C. Glass, “Commercialization of Genetic Research and Public Policy” (1999) 286 *Science* 2277.

<sup>75</sup> The Supreme Court of Canada cast doubt on the scope of any ‘experimental use exception’ in Canada in *Harvard Mouse*, *supra* note 6.

<sup>76</sup> Michael Heller & Rebecca S. Eisenberg, “Can Patents Deter Innovation? The Anticommons in Biomedical Research” (1998) 280 *Science* 698.

<sup>77</sup> There is not, however, any evidence of a systematic breakdown in the patent system. OECD, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (Paris: OECD, 2002) 77, online: Organization for Economic Cooperation and Development

The patent system also sets up an incentive to keep secret research results until 18 months following the filing of a patent application. This is to ensure that the patent applicant does not lose the ability to file a new or revised application due to the novelty requirement. Of course, without the patent system, the inventor may never disclose the invention, so it may be that patents provide better disclosure than the alternative. This nevertheless assumes that the invention is only protected by patents and not by a combination of patents and trade secrets (simply not disclosing the invention). In the latter case, the inventor may be able to effectively prevent access to the valuable form of the invention despite patent law's disclosure requirement.

### *Consequences on commercialization*

In addition to affecting both the type and speed of biotechnology research, patents may also cause unwanted consequences with respect to the commercialization of biotechnology innovation. Here, I will discuss two such effects: the failure to share benefits and premature commercialization.

Much attention has been focussed on the equitable distribution of the financial rewards of innovation. The patent system, as it is set up, provides financial benefit only to the patent holder. Others who may have contributed to the research, such as tissue donors or indigenous peoples with knowledge concerning the use of plants and animals for medical purposes, receive no benefit.<sup>78</sup> There is a larger question, as well, as to whether there is a broader obligation to share the results of medical research regardless of the contribution of tissues.<sup>79</sup>

A second concern is that, because of the time-limited nature of patent rights, the patent system encourages patent holders to put their inventions on the market as soon as possible. The concern is that patent holders may do this before good data exists regarding the value of the invention. This issue has caused particular concern with respect to genetic testing.<sup>80</sup> Some genetic tests have been put onto the market, for example, before satisfactory data existed as to the risk that someone with a mutated gene would actually contract the genetic disease.<sup>81</sup>

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<<http://www.oecd.org/pdf/M00038000/M00038462.pdf>>. However, this does not mean that there are no difficulties or that a systematic breakdown will not be found one more biotechnological inventions are patented.

<sup>78</sup>Bartha M. Knoppers, "Biotechnology: Sovereignty and Sharing" in Timothy A. Caulfield & Bryn Williams-Jones, eds., *The Commercialization of Genetic Research: Ethical, Legal, and Policy Issues*. (New York: Kluwer Academic/Plenum Publishers, 1999) 1.

<sup>79</sup>Maria-Graciela de Ortúzar, "Towards a Universal Definition of "Benefit-Sharing" (Presented at 3rd International DNA Sampling Conference, September 5-8, 2002).

<sup>80</sup>Timothy A. Caulfield & E. Richard Gold, "Genetic Testing, Ethical Concerns, and the Role of Patent Law" (2000) 57 *Clinical Genetics* 370.

<sup>81</sup>*Ibid.*

### Part III: Health Care and the Refocusing of the Patent Debate

Despite over a decade of abundant academic discussion over the ethical concerns attaching to biotechnology patenting, very little came of it. Whatever changes were made to the patent system came about more to tidy up the internal workings of that system than as a response to the outside debate. While it is true that patent offices, such as the United States Patent and Trademark Office, started to apply patent criteria more strictly in 2001,<sup>82</sup> this was more a return to an established standard that the patent offices had earlier applied to other technology (and even biotechnology in its early days) than a reaction to the biotechnology patenting debate.

The situation seems, however, to be changing. Governments around the world now more readily question the application of patent law to biotechnology, particularly with respect to DNA sequences.<sup>83</sup> The reason for this change is that health care administrators recognised that DNA sequence patents posed not only theoretical, but very real, concerns for the health care system.<sup>84</sup>

#### The Breast Cancer Predisposition Case

To understand the motivation of health care administrators in entering this discussion, we need to go back a few years to the patenting of the BRCA1/2 genes. In the six month period starting in October 2000, the Canadian Intellectual Property Office issued four patents to Myriad Genetics, Inc. in respect of these two genes,<sup>85</sup> a mutation in which significantly increases the risk of a woman contracting either breast or ovarian cancer.<sup>86</sup> The patents covered not only the genes themselves, but mutations in the genes and in a generic diagnostic test to identify those mutations.<sup>87</sup> Myriad had previously obtained a US patent on these genes and was in the process of being issued similar patents in Europe under the European Patent Convention.

Having obtained its patents, Myriad issued cease-and-desist letters to most Canadian provincial governments in the summer of 2001.<sup>88</sup> These letters indicated

<sup>82</sup> *Patent Office's Utility Examination Guidelines*, *supra* note 52.

<sup>83</sup> E. Richard Gold, "Gene Patents and Medical Access" (2002) 49 *Intellectual Property Forum* 20.

<sup>84</sup> See e.g. Government of Ontario, *supra* note 18.

<sup>85</sup> Lori Sheremeta & E. Richard Gold, "Creating a Patent Clearinghouse in Canada: A Solution to Problems of Equity and Access?" (Poster presentation, GE<sup>3</sup>LS Winter Symposium 2003, February 6-8, 2003).

<sup>86</sup> Caulfield & Gold, *supra* note 80.

<sup>87</sup> Myriad obtained four important Canadian patents as follows:  
2,196,797, "*In-Vivo Mutations and Polymorphisms in the 17-Q Linked Breast and Ovarian Cancer Susceptibility Gene*";  
2,196,795, "*Method for Diagnosing a Predisposition for Breast and Ovarian Cancer*";  
2,196,790, "*17Q-Linked Breast and Ovarian Cancer Susceptibility Gene*" and  
2,239,733, "*Chromosome 13-Linked Breast Cancer Susceptibility Gene*".  
Sheremeta & Gold, *supra* note 85.

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that Myriad would only accept tests done through it in the United States or through an authorized licensee. Most provinces ignored Myriad's letters with the exception of British Columbia which initially ceased to provide or fund breast-cancer predisposition tests<sup>89</sup> but later reversed this decision.<sup>90</sup>

The BRCA1/2 controversy drew the attention of health administrators to two important factors. The first of these was cost. At C\$3,850, Myriad's tests cost approximately three times that of alternative tests.<sup>91</sup> This obviously caused concern, especially given that studies suggest that genetic predisposition tests will only add new expense to the healthcare system rather than replace any treatments or procedures.<sup>92</sup> The fact that patents provide an individual with the opportunity to charge monopoly rents for important medical procedures raised important ethical concerns for health care administrators in a country devoted to a public health care system.<sup>93</sup>

Despite the importance of cost, it was not, in fact, the most important issue facing health care administrators. The issue of central importance was the ability of health care administrators to determine which tests to make available to patients, when to make them available, and where to conduct them.<sup>94</sup> By providing the patent holders with a broad veto over the activities of public health administrators, biotechnology patents severely limit the ability of the public health care system to appropriately manage the introduction and use of genetic predisposition tests.<sup>95</sup>

The BRCA1/2 controversy also highlighted another aspect of DNA sequence patents: their effect on patients. While the earlier academic discussion had predicted some negative effects of gene patenting on patients, the Myriad case made these concerns tangible. As it turned out, the most immediate effect of the BRCA1/2 patents on patients was to threaten their ability to obtain those tests that were most appropriate for them.<sup>96</sup> This is because Myriad insisted that only its form of genetic predisposition test be used. However, an alternative test is thought to be more

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<sup>88</sup> Gold, *supra* note 83 at 23. It appears that Manitoba had not received such a letter. Sheremeta & Gold, *supra* note 85.

<sup>89</sup> Sheremeta & Gold, *supra* note 85.

<sup>90</sup> British Columbia Ministry of Health Services, Press Release 2003HSER0009-000160, "Federal Leadership Urged as Genetic Testing Resumes" (14 February 2003).

<sup>91</sup> *Ibid.*

<sup>92</sup> Ontario Ministry of Health and Long-Term Care, *Predictive Genetic Tests & Health Care Costs: Final Report* by Fiona Miller *et al.*, (Toronto: Ontario Ministry of Health and Long Term Care, 2002), online: Ontario Ministry of Health and Long-Term Care <[http://www.gov.on.ca/MOH/english/pub/ministry/geneticsrep02/chepa\\_rep.pdf](http://www.gov.on.ca/MOH/english/pub/ministry/geneticsrep02/chepa_rep.pdf)> (concluding that the genetic predisposition tests will increase health care costs).

<sup>93</sup> Timothy A Caulfield *et al.*, "Genetic technologies, health care policy and the patent bargain" (2003) 63 *Clinical Genetics* 15.

<sup>94</sup> Government of Ontario, *supra* note 18 at 44.

<sup>95</sup> Caulfield *et al.*, *supra* note 93.

<sup>96</sup> Gold, Caulfield & Ray, *supra* note 17 (arguing that DNA sequence patents impair physicians' ability to provide the best medical services to their patients).

accurate than the Myriad test for those most likely to have a large scale, rather than a pin-point, deletion in these genes.<sup>97</sup> Given the breadth of the patent claims awarded to it (and assuming the validity of those claims), Myriad has the power to prevent patients from using what may be a superior, alternative test.

The veto over the selection of an appropriate genetic test thus occurs on two levels. First, the veto prevents public health authorities from selecting the genetic testing methodology that they determine is most appropriate in the manner that they determine to best suit the health care system. Second, the veto prevents patients from selecting the genetic predisposition test that most suits their risk profile and needs. Thus, patents threaten to reduce choice both at the systemic level and at the individual level.

The veto also places physicians in a delicate position. Physicians have a duty of care to their patients that includes the duty to inform them of treatment options. Unfortunately, the most appropriate treatment option may not be available in Canada – due to the existence of the Canadian patent – thus forcing physicians to advise some of their patients to travel to countries where the patent is not being enforced.<sup>98</sup> Apart from complicating patient care management,<sup>99</sup> this result leads to two-tiered access to genetic predisposition tests that depends on one's ability to afford to travel abroad and pay for the alternative test.

## Responses

While there was little governmental action in the face of the earlier debate over biotechnology patenting, governments around the world quickly reacted to what they perceived to be the threat represented by Myriad's patents over the BRCA1/2 genes. This concern did not revolve solely around Myriad's test – this test represents only a tiny portion of the present health care system – but around what Myriad's test represents: the long term diminution of the power of public authorities to manage the public health care system.<sup>100</sup>

### *Europe*

While individual European countries have their own patent systems, most patents in Europe are granted by the European Patent Office. Nevertheless, the laws of each member state determine whether the patent is valid and enforceable within

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<sup>97</sup> Colin Perkel "Ontario defying American gene company by using new breast-cancer test" *The Canadian Press* (6 January 2003), online: Sympatico.ca <[http://mediresource.sympatico.ca/health\\_news\\_detail.asp?channel\\_id=7&menu\\_item\\_id=4&news\\_id=578](http://mediresource.sympatico.ca/health_news_detail.asp?channel_id=7&menu_item_id=4&news_id=578)>.

<sup>98</sup> Gold, Caulfield & Ray, *supra* note 17 at 257. A patient could travel to Europe, for example, to have the test. Currently, Myriad cannot enforce its patents in Europe because an opposition has been launched against the patent before the European Patent Office, (*ibid.*).

<sup>99</sup> *Ibid.*

<sup>100</sup> Government of Ontario, *supra* note 18 at 44.

that state.<sup>101</sup> Given this bifurcated jurisdiction, resistance to the Myriad patents occurred both at the level of the European Patent Office and in the individual member states.

### *Commencement of opposition proceedings*

Under the European Patent Convention, any individual may commence an opposition proceeding before the European Patent Office on the grounds that a patent was not properly issued.<sup>102</sup> Soon after the grant of Myriad's patents, several research organizations launched an opposition against them.<sup>103</sup> Until the opposition is finally determined – which may take several years – Myriad cannot enforce its patents (but may later claim damages in respect of use of the invention during this period if its patents are upheld).<sup>104</sup> This effectively permits European governments to ignore Myriad's patents for the time being.

### *Introduction of amendments re compulsory licensing*

In France, not only has the government supported the filing of oppositions against the Myriad patent, but it has introduced legislation that would provide the Minister of Health with the power to grant a compulsory licence in respect of genetic tests where public health is at risk.<sup>105</sup> This legislation broadens the Minister's current power to grant such licenses over other health-related products. The purpose of this power is to provide the government with bargaining power against reticent DNA sequence patent holders. In other words, it provides the Minister with a credible threat should industry not comply with the Minister's request. Because of the credibility of this threat, the Minister has never had to invoke the power with respect to other health products.

While Canada's *Patent Act* contains a compulsory licensing provision,<sup>106</sup> it is so broad that it does not provide a credible threat to industry. No provincial government is likely to invoke a broad and nebulous compulsory licensing provision for fear of losing the confidence of not only the biotechnology industry, but of the pharmaceutical and other industries. Thus, despite the formal existence of a compulsory licensing provision in Canada, it is ineffective.

### *Limiting patent scope*

While the German government has so far taken no official action in response to concerns over DNA sequence patents, it is studying a recommendation made by

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<sup>101</sup> Gold & Gallochat, *supra* note 64 at 348.

<sup>102</sup> *European Patent Convention*, *supra* note 26, Part V.

<sup>103</sup> Gold, *supra* note 83 at 23.

<sup>104</sup> *Ibid.*

<sup>105</sup> *Projet de loi relatif à la protection des inventions biotechnologiques*. France: Sénat. Session ordinaire de 2001-2002; 6 nov. 2001, No 55, Article 11, online: Sénat <[www.senat.fr/leg](http://www.senat.fr/leg)>.

<sup>106</sup> *Patent Act*, *supra* note 5, s. 19.

Joseph Straus, a leading European patent expert. Straus argues that, as a general rule, the patent office ought only to grant claims over DNA sequences that are limited to the particular function identified in the patent application.<sup>107</sup> While normally, an inventor must reveal only one function of the invention to capture a veto over all functions, Straus argues that there is simply not a sufficient level of invention to justify such a broad patent in respect of most DNA sequences. According to Straus, the only exception to this general rule is in respect of those DNA sequences that are truly original in nature. In such a case, he argues, it is appropriate to grant a veto over all uses of the sequence.<sup>108</sup>

## Other Countries

### *Exception for Medical Services*

Although not yet passed, a member of the United States Congress introduced a bill that would prevent a patent holder from bringing a patent infringement suit against a medical practitioner for providing a genetic test.<sup>109</sup> The bill suggests that this exclusion would only apply to patents issued after the date the bill is passed into law. Nevertheless, should the bill be passed, it would permit unrestricted access to genetic predisposition tests in the United States. Again, Canada has no equivalent provision in its *Patent Act*.

### *Commission to study gene patents*

Australia has decided to investigate the negative effects of patent rights over medical access more formally. To this end, the government asked the Australian Law Reform Commission to investigate “the impact of current patenting laws and practices – including licensing – related to genes and genetic and related technologies on research, the biotechnology industry and the cost-effective provision of healthcare in Australia.”<sup>110</sup> The government specifically asked the Commission to recommend changes needed to address any difficulties identified.<sup>111</sup>

Following the Ontario government’s issuance of its report entitled “Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare” in January 2002,<sup>112</sup> the Canadian provinces, territories and Health Canada have created a Federal/Provincial/Territorial Coordinating Committee on Genetics and Health.

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<sup>107</sup> Joseph Straus, “Produktpatente auf DNA – Sequenzen – Eine aktuelle Herausforderung des Patentrechts” Oktober [2001] Gewerblicher Rechtsschutz und Urheberrecht 10.

<sup>108</sup> *Ibid.*

<sup>109</sup> U.S. Bill H.R. 3967, *Genomic Research and Diagnostic Accessibility Act of 2002*, 107<sup>th</sup> Cong., 2d Sess., 2002.

<sup>110</sup> “Terms of Reference: Intellectual Property Rights Over Genetic Materials and Genetic Related Technologies”, online: Australia Law Reform Commission <<http://www.alrc.gov.au/inquiries/current/patenting/terms.htm>>.

<sup>111</sup> *Ibid.*

<sup>112</sup> Government of Ontario, *supra* note 18.

This Committee has met several times and, in conjunction with the Canadian Institutes of Health Research, are sponsoring research projects aimed at investigating the impact of human genetics on the Canadian health care system.<sup>113</sup> The federal government has not yet, however, created any body with a similar mandate as was given to the Commission in Australia.

## Conclusion

The introduction of public health administrators into the debate over the nature and scope of biotechnology patents turned a moribund discussion into a live political question. In the process, governments have moved from passive consumers of academic discussion to being proactive players in finding solutions to the more tangible, negative consequences of biotechnology patents. Government participation has gone even further than this, however. It has brought a level of experience and realism to the debate over biotechnology patenting. Instead of questioning the very foundations of patenting in this area, governments acknowledge that patents will continue to apply to biotechnology. What is important now is therefore not whether, but how and the extent to which patents will apply to biotechnology.

Canada can benefit from the international attention now given to biotechnology patents. The proposals that other countries are investigating – from limiting the scope of biotechnology patents, to creating exemptions, to creating targeted compulsory licences, to setting up blue ribbon panels – provides Canada with a wide choice of policy instruments with which to contend with the problems posed by biotechnology patents. Through a thorough examination of these options, Canada can ensure that its patent laws satisfy the fundamental goal of patent systems: to encourage innovation while serving the public good.

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<sup>113</sup> Canadian Institutes of Health Research, “Request for Applications: Staying Ahead of the Wave: Genetics, Health Services and Health Policy”, online: Canadian Institutes for Health Research <[http://www.cihr-irsc.gc.ca/services/funding/opportunities/institutes/2002/rfa\\_genetics\\_hsr\\_e.shtml](http://www.cihr-irsc.gc.ca/services/funding/opportunities/institutes/2002/rfa_genetics_hsr_e.shtml)>.

