Biomedical Patents and Ethics: A Canadian Solution

E. Richard Gold*

World Trade Organization member states are preparing for the upcoming renegotiation of the *Agreement on Trade-Related Aspects of Intellectual Property Rights*. One of the important elements of that renegotiation is the ethical considerations regarding the patenting of higher life forms and their component parts (*e.g.* DNA and cell-lines). The interface between the genetic revolution, patentability, and ethical considerations is the subject of this article.

The author identifies, explores, and critiques four possible positions Canada may adopt in respect of patentability of biomedical material. First, Canada could do nothing. This approach would mean keeping biomedical materials outside the patent system and outside the stream of commerce. Canada would simply wait for an international consensus to develop before adopting a position of its own. Second, Canada could go it alone. It could implement a policy that balances the incentive effects of patents with the need to incorporate ethical and social values into the decision-making process regarding the use of biomedical materials. In respect of this option, the author proposes a model whereby non-profit bodies would hold the exclusive rights to research, use, and exploit biomedical materials. Third, Canada could follow the United States, Europe, and Japan by providing for almost unrestricted patenting of biomedical materials. This would be the most industry-friendly alternative. The fourth and final option is to use the medicare system to promote discussion of ethical considerations involved in the use of biomedical materials. The power of provincial health agencies may be used as a lever to ensure discussion of ethical considerations concerning the use of biomedical materials. The author concludes that the fourth and final option is the best alternative for Canada while waiting for an international consensus to emerge.

Les États membres de l'Organisation mondiale du commerce se préparent à la renégociation prochaine de l'*Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce*. Celle-ci mettra en jeu des considérations éthiques concernant la possibilité de breveter des formes de vie supérieures et leurs composantes (par exemple l'ADN et les souches cellulaires). Cet article porte sur l'interaction entre la révolution génétique, le droit des brevets et les considérations éthiques soulevées.

L'auteur identifie, explore et critique quatre positions que le Canada pourrait adopter à l'égard de la possibilité de breveter le matériel biomédical. D'abord, il pourrait ne rien faire, ce qui reviendrait à maintenir le matériel biomédical hors des limites du système des brevets et du commerce. Le Canada attendrait ainsi l'émergence d'un consensus international avant d'adopter sa propre position. Ensuite, il pourrait mettre en œuvre une politique originale qui viserait à mettre en équilibre, d'une part, le caractère incitatif des brevets et, de l'autre, la nécessité d'intégrer des valeurs sociales et morales au processus décisionnel entourant l'utilisation du matériel biomédical. À cet égard, l'auteur propose un modèle par lequel des organismes à but non lucratif détiendraient le droit exclusif de faire de la recherche sur le matériel biomédical, de l'utiliser et de l'exploiter. En troisième lieu, le Canada pourrait suivre les États-Unis, l'Europe et le Japon en permettant de breveter, en l'absence presque totale de contraintes, le matériel biomédical. Cela constituerait l'option la plus favorable à l'industrie. La quatrième et dernière alternative serait d'utiliser le système existant de soins de santé pour promouvoir la discussion des considérations éthiques soulevées par l'utilisation du matériel biomédical. Le pouvoir des organismes provinciaux de soins de santé servirait ainsi de levier pour s'assurer que ces considérations soient prises en compte. L'auteur conclut que cette dernière solution est la meilleure pour le Canada, en attendant l'émergence d'un consensus international.

* Assistant Professor, Faculty of Law, The University of Western Ontario. I would like to thank Erin Rogozinski for her research and editorial assistance, Timothy A. Caulfield and Florence Dagicour for their comments, and the Law Foundation of Ontario and the Social Sciences and Humanities Research Council for their financial support.

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Introduction

If all the world is a stage, then the preparations now being undertaken in Ottawa and other world capitals in anticipation of the upcoming renegotiation of the World Trade Organization ("WTO") agreements[1], and the *Agreement on Trade-Related Aspects of Intellectual Property Rights*[2] in particular, must be the last rehearsals of a multilingual, multidisciplinary script. And what a script it is, full of suspense, intrigue, crime, and drama. There is something for everyone: bioprospeeting, biopiracy, biosphere, biodiversity, money, and information. Canada is in the midst of adding its part of the script, knowing, as it does, what the lead actors are likely to say.

The genetic revolution—the discovery and commercialization of our genetic inheritance—will be the subject of at least one act in the upcoming round of WTO negotiations. Issues such as the European moratorium on the introduction of genetically modified organisms[3] and the degree to which nations can block the importation of goods for health or environmental reasons[4] will bring discoveries resulting from the genetic revolution into trade debates around the world.

Although on a slower track than the general WTO negotiations,[5] the upcoming round of *TRIPs* negotiations will likely concern the question of whether patent law ought to apply to plants and animals, and if so, how. Under the existing *TRIPs Agreement*, each member of the WTO is free to establish its own policy with respect to the patentability of higher-life forms, but must grant patents in micro-organisms.[6] A country may, however, exclude an invention from patentability in order to protect life, morality, health, or the environment.[7] Therefore, not only is the question of the patentability of whole animals and plants unresolved, so too is the degree to which a country may exclude or limit patents over components (for example, DNA and cell-lines) of humans, animals, and plants.

Three of the lead actors in the drama, the United States, Japan, and the European Union, have already recognized patent rights in novel plants and animals. The United

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[1] *Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations*, 15 April 1994, 33 I.L.M. 1143, online: The Trading Floor <http://trading.wmw.com/gatt> (date accessed: 14 February 2000) [hereinafter *GATT*].

[2] *Ibid.* at 1197, Annex 1C: *Agreement on Trade-Related Aspects of Intellectual Property Rights* [hereinafter *TRIPs Agreement*].

[3] H. Kempf, "L'UE adopte sans le dire un moratoire sur les organismes génétiquement modifiés" *Le Monde* (26 June 1999) 3.

[4] *GATT, supra* note 1, Annex 1A, s. 4: *Agreement on the Application of Sanitary and Phytosanitary Measures*.

[5] "U.S. Sees No TRIPS Negotiations at Seattle, Focuses on Implementation" *Inside US Trade* (6 August 1999) 17.

[6] *TRIPs Agreement, supra* note 2, art. 27.

[7] *Ibid.*, art. 27(2).

States did so through court[8] and administrative[9] decisions, Japan through a change to its administrative rules covering the grant of patents,[10] and the European Union through a directive (a European Union policy that must be implemented in each member state) acknowledging patents in higher life forms.[11] Despite differences in form, the United States, Japan, and the European Union provide for almost unrestricted patenting of these life forms.[12]

Depending upon one's point of view, the villain or the hero in the negotiations is likely to be played by developing countries, in particular, India.[13] India is seeking greater access to technology and a recognition of the contribution that indigenous communities make to biotechnology.[14]

Non-profit groups, for their part, are largely taking a cautionary approach to increasing the scope of patent protection in the areas of agriculture and human health, arguing that increasing the scope of patent protection may cause further deterioration in north-south relations and may even result in environmental harm.[15]

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[8] *Diamond* v. *Chakrabarty*, 447 U.S. 144 (1980).

[9] See *e.g.* U.S. Pat. No. 4,736,866 (12 April 1988) (patent on onco-mouse); *Ex parte Hibberd, et al.* (18 September 1985 as corrected 24 September 1985) 227 U.S.P.Q. 443-48 (Patent and Trademark Offiee Board of Patent Appeals and Interferences), online: WL 71986.

[10] Japanese Patent Office, *Examination Guidelines for Patent and Utility Model in Japan* (Tokyo: 1994).

[11] 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 [hereinafter *Directive*].

[12] Both the *Directive* and the U.S. court decisions provide that any inventor can apply for and receive a patent in plant and animal (including) DNA, partial strands of DNA, and other genetic information with almost no restriction and without evidence of ethical practices, such as the demonstration of informed consent or attribution of DNA. Both U.S. and European law recognize that there may be some patents that are morally unacceptable. This is explicit in the *Directive* and the policy of the U.S. Patent Office; see *Directive, ibid.* at 18, art. 6(1); R. Weiss, "What is Patently Offensive? Policy on 'Immoral' Inventions Troubles Legal, Medical Professionals" *The Washington Post* (11 May 1998) Federal Page. While the *Directive*'s recitals discuss the need for informed consent and attribution (*Directive, ibid.* at 15, recitals 26 and 27), neither of these has any legal force.

[13] See generally T.S. Vishwanath, "Sleepless in Seattle? Well, not Quite" *The Economic Times of India* (5 September 1999), online: WL (ALLNEWS) 23697872; Gumisai Mutume, "Trade: Seattle Offers Opportunities for Developing Nations" *Inter Press Service* (25 August 1999), online: WL (ALLNEWS) 5950227; see also R. Hegde, Minister of Commerce (of India), "Address" (Second Ministerial Conference of the WTO, Geneva 18-20 May 1998), online: Ministry of Commerce, Government of India <http://www.nic.in/commin/wtofeb.html> (date accessed: 25 August 1999); "India Suggests WTO Help Amend TRIPS Section of Uruguay Round Pact" (1996) International Environmental Reporter, online: Trade News <http://www.enviroweb.org/publications/IATP/trade/vol5no8.html> (date accessed: 25 August 1999).

[14] Hegde, *ibid.*

[15] See *e.g.* D. Downes & M. Stilwell, "The 1990 WTO Review of Life Patenting Under TRIPS: Revised Diseussion Paper—November 1998" Center for International Environmental Law ("CIEL"), online: CIEL <http://www.igc.apc.org/ciel/trips.html> (date accessed: 25 August 1999) and Rural Advaneement Foundation International ("RAFI"), "Are Patents Out of Control? Human Rights and

Canada has yet to settle on a policy with respect to the patenting of higher life forms.[16] Currently, Canadian courts are grappling with the issue of the patentability of a genetically-engineered mouse,[17] an issue that has already been resolved in the inventor's favour in both the U.S. and the European Union.[18] And, while the patent office grants patents in genes, gene sequences, and cell-lines,[19] this practice has yet to be reviewed by a senior court. Meanwhile, the Canadian government continues to study the question of life-form patenting with no resolution yet in sight.[20]

The issue of patenting life forms and their components is a large one. It involves agricultural patents that will affect the food we eat, the introduction of genetically engineered plants and organisms into the environment (usually with unknown consequences), and the nature of the business of agriculture. But the issue also applies to the patenting of materials that are used to create new medications and develop new tests, and to the finding of the environmental and social bases of disease. Many of these materials are of human origin, but some may be derived from plants or animals. While these two large areas—agriculture and the pharmaceutical industry—have much in common (often the same companies are involved in both[21]) they also raise unique social and ethical questions given that their ultimate purposes, the provision of food or of health care, are so different. In this article, I deal only with materials used to promote human health.

In previous work, I have argued that, while we need to be mindful to establish appropriate economic incentives to encourage biomedical research and development (the traditional justification for awarding patents), we should not do so at the cost of

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Predatory Patents... The Right to Say 'No'", online: RAFI <http://www.rafi.org/misc/courtrips.html> (date accessed: 25 August 1999). Both are opposed to increasing the scopo of patent protection in these areas.

[16] Department of Foreign Affairs and International Trade, "Discussion Paper: Intellectual Property Trade Policy Issues" 1999), online: Department of Foreign Affairs <http://www.dfait-maeci.gc.ca/tna/nac/discussion/ip-e.asp> (date accessed: 26 August 1999).

[17] *President and Fellows of Harvard College* v. *Canada (Commissioner of Patents)* (1998), 146 F.T.R. 279, 79 C.P.R. (3d) 98, online: QL (FCJ).

[18] U.S. Pat. No. 4,736,866 (12 April 1988); E.P.O Pat. No. 169,672 (13 May 1992).

[19] Patent Rules (1996), SOR/96-423, s.111-13; Canadian Patent Office, *Manual of Patent Office Practice*, (1998), s. 16.05.

[20] "Canada and the Future of the World Trade Organization: Advancing a Millennium Agenda in the Public Interest" in *Report of the Standing Committee on Foreign Affairs and International Trade* (1999) (Chair: B. Graham), online: Parliamentary Internet <http://www.parl.gc.ca/infocomdoc/36/1/fait/studies/reports/faitrp09-e.htm> (date accessed: 20 September 1999); Department of Foreign Affairs and International Trade; Canadian Biotechnology Strategy Taskforce, "CBS Online: Resource Document 1: Other Related Activities" (1998), online: Industry Canada <http://strategis.ic.gc.ca/SSG/bh00185e.html> (date accessed: 20 September 1999).

[21] Rural Advancement Foundation International ("RAFI"), "The Gene Giants: Masters of the Universe?" RAFI Communique online: RAFI <http://rafi.org/communique/fltxt/19992.html> (date accessed: 25 August 1999).

endangering ethical principles and commodifying the human body.[22] I have sketched out an approach to regulating these materials that involves the establishment of independent boards to be composed of members of industry, the research community, patient groups, and the general community to decide how particular human biological materials should be used.[23]

The approach I proposed with respect to human biological materials can be applied to all biomedical material (whole plants and animals; human, animal, and plant DNA; cell-lines; and tissues used primarily in health-related research, prevention, and treatment). It is also an approach that is best implemented at the international level. This is so for two reasons. First, social and ethical concerns surrounding biomedical materials know no boundaries. While different communities around the world may take different approaches to the social and ethical value of these materials, we can agree that these values exist and that they are compromised by submitting these materials to an unregulated market. An international response to the biomedical materials would thus signal the universal importance of biomedical materials to human culture and society. Second, the biomedical industry is international, with research and development occurring around the globe. A patchwork solution to the ethical and social concerns surrounding biomedical materials will either result in a patchwork of ethical and social policies that will be hard for industry to follow or will lead to a flight of research and development to those countries with the least restrictive policies regarding these materials.

The model that I have proposed, or some other that provides a forum in which to debate the economic, social, and ethical importance of biomedical materials, could serve as a basis for Canada's position in the next round of *TRIPs* negotiations. Canada could put this model forward as a compromise between the rigidly market-based approach of the United States, Japan, and the European Union and the more interventionist approach of India. This position is in line both with Canadian policies on medical care (an approach based on a combination of a market and state intervention) and on the inclusion of ethical and social concerns in relation to the renegotiation of the *TRIPs Agreement*[24] as well as with Canada's reputation for mixing a U.S.-style economic approach with more egalitarian and communitarian concerns.[25]

Despite its economic and social importance, it will likely be years before the international community reaches a consensus on the patentability and scope of patent-

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[22] E.R. Gold, *Body Parts: Property Rights and the Ownership of Human Biological Materials* (Washington, D.C.: Georgetown University Press, 1996) [hereinafter *Body Parts*]; E.R. Gold, "Making Room: Reintegrating Basic Research, Health Policy, and Ethics Into Patent Law" in T. Caulfield & Williams-Jones, eds., *The Commercialization of Genetic Research: Ethical, Legal, and Policy Issues* (New York: Kluwer Academic/Plenum Publishers, 1999) 63 [hereinafter "Making Room"].

[23] "Making Room", *ibid.*

[24] Graham, *supra* note 20 at c. 9 ("Intellectual Property Rights in the Context of the WTO").

[25] Interview with J. Elisalde and L. Cordier (26 May 1998).

ability of biomedical materials.[26] In the meantime, Canada must settle on a domestic patent policy to deal with these materials. Canada's policy must not only be in accord with its negotiation stance at the *TRIPs* meetings, but be economically and ethically practicable while we wait for an international solution. Specifically, the position should achieve three goals. First, Canada should continue to provide its residents with access to a health care system that increases quality of life. Second, Canada should strive to encourage biomedical research and development work in Canada both to keep high-skilled, high-paying jobs in the country and to maintain independence in the health care field. Third, ethical, community, and religious views about biomedical materials ought not only to be respected, but reflected in the ways in which we deal with those materials in Canada.

In this article, I review several positions Canada could adopt while waiting for the international community to reach a consensus on the patentability of biomedical materials. There is a range of four options available: doing nothing (that is, leaving the question unresolved), implementing a model such as I have proposed, following the U.S. and European lead of placing these materials fully into the streams of commerce, or implementing a partial and transitional solution based on Canada's medicare system. I conclude that doing nothing offers the worst of all worlds: it submits biomedical materials to the market while doing nothing to encourage investment in biomedical research and development. At the same time, the options of unilaterally implementing my proposed model or of following the U.S., Japanese, and European lead are unappetizing: the first because it is unlikely to truly protect ethical and community values while disrupting the biomedical industry and the second because it would fully subject biomedical materials to the market. The only solution available, until an international consensus is reached, is to implement a partial solution based on our medicare system.

I. Option #1: Do Nothing (Non-Patentability of Human Biological Materials)

The easiest thing for Canada to do, while waiting for an international consensus to develop on the issue of patenting biomedical materials, is to do nothing. The purpose of this would be to keep these materials out of the stream of commerce until the international community has developed methods to preserve the ethical and social values inhering in them.

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[26] The current round of WTO negotiations, which began in Seattle, Washington in November 1999, are slated to continue for three years. K. Rockwell, Director, Information and Media Relations, World Trade Organization, "A Window to the World Trade Organisation: Progress and Opportunities" (Washington Council on International Trade, Seattle, Washington, 9 July 1999), online:<http://www.wtoseattle.org/internationaltrade/rockwell.htm> (date accessed: 20 September 1999); Washington Council on International Trade, "World Trade Organization (WTO): Q & A", online: WCIT Web <http://www.wcit.org/wtoq&a.htm> (date accessed: 14 February 2000).

The "do nothing" approach could be accomplished in one of two ways. The first is to simply permit the legal limbo in which these materials currently reside to continue through both legislative silence and resignation about the lengthy legal procedures that will be followed until the Supreme Court of Canada rules on the patentability of higher life forms. Even if the Supreme Court decides the issue, the uncertainty can be preserved through legislative debate or through the establishment of a committee to investigate the matter. Eventually, Canada would have to decide one way or another on patentability, but if it chose, it could probably wait for an international consensus. Alternatively, Parliament could explicitly provide that some or all biomedical materials were, at least temporarily, not subject to patent law. In either case, for the time being at least, biomedical materials would be unpatentable until it was determined, at the international level, what to do with those materials.

Unfortunately, neither of the alternatives examined above would remove biomedical materials from the realm of commerce. In fact, it is likely that by completely removing these materials from patent law, even temporarily, we risk subjecting them to greater commercial pressures than if they were patentable. The reason for this is that under a patent regime, the patent holder has an incentive to prevent others from using or selling the material. In terms of a breach of ethical or social value, the only person whose use of a patent we must worry about is the patent owner. And the patent owner has at least some (albeit not necessarily strong) incentive to ensure that its use of the material appears to the public to be in accordance with ethical standards.

If biomedical materials are unpatentable, nobody will have either the ability or the incentive to control the uses to which these materials are put. This is so because patent law provides only negative rights. Under patent law, the holder of a patent is given only the right to exclude others from using the invention, but not the right to actually use the invention him or herself. The right to use the invention comes from the general legal principle that what is not prohibited is permitted. To the extent that nobody has a specific right to prevent one from using an invention, one is free to do so. In the situation where there are no patent rights in biomedical materials, there will be nobody with a right to exclude anyone else. Thus, barring legislation or regulation, everyone will be entitled to use these materials as they will. In such an environment, no one would have an incentive to be careful about ethical principle.

Canada's current position of leaving the patentability of biomedical materials unresolved, at least if it continues for long, fails to remove these materials from commerce and from the potentially negative consequences of that commerce on ethical and social values. The situation is made even worse since industry would be left in a state of flux, not knowing whether these materials would eventually be held to be patentable. While industry may hope that strong patent rights will eventually become obtainable over these materials, it would likely prefer certainty to a long period of uncertainty.

The solution of keeping biomedical materials outside of the patent system, and thus out of commerce, does not work. Not only would industry be left unhappy, the lack of patents would actually lead to greater commercialization of these materials than if patents were available.

II. Option #2: Go It Alone

If the option of doing nothing is unappealing, Canada could consider implementing a policy that balances the incentive effects of patents with the need to incorporate ethical and social values into the decision-making process regarding the use of biomedical materials. Canada could, for example, implement a model such as I have proposed in my earlier articles or some other scheme where there exists a forum to explicitly consider ethical and social values.

The model that I have proposed uses one of the great strengths of the patent system: the fact that it places the exclusive right to use an invention in the hands of an individual, company, or organization. This person may use the invention for virtually any chosen purpose and also can prevent others from exercising the same right. In the ordinary course of events, patents are used to pursue a profit, but this need not be the case. A not-for-profit organization may, for example, use an invention for other purposes, such as providing services to the poor or preventing disease. One not-for-profit organization that holds a patent to a gene (BRCA2), a mutation of which is linked to an increased incidence of breast and ovarian cancer, decided to use its patent to ensure that genetic testing is provided free to those in the United Kingdom.[27]

In earlier articles, I proposed the establishment of a governmental or a non-profit body (or bodies) that would hold the exclusive rights to research, use, and exploit biomedical materials. Like the holder of a patent right, this body would be able to prevent others from using these materials without permission. Unlike ordinary patent holders, this body would have to adopt a mechanism to consider the ethical and social values inhering in biomedical materials, with respect to their intended use, in its decision-making processes. At the same time, economic incentives would be provided to researchers and industry to invent new therapies, diagnostic procedures, and preventive measures.

Under my proposal, all decisions of this body, with respect to the use of biomedical materials, would be made by a panel or board consisting of representatives from industry, the research community (scientists and managers of government or university laboratories), government (Industry Canada, Health Canada, the provincial health ministries, and the provincial health insurance plans), patient groups (particularly those whose illness or disease is linked to the particular material in question), and the general community (representatives from the general public, environmental groups, religious groups, etc.). The body may have one or multiple boards, depending on the degree of diversity of the materials controlled by the body. While too large a number of boards would be unwieldy, it seems preferable that the boards are at least somewhat specialised either by type of material or by use of material.

The board would need to make decisions fairly efficiently in order to respond to the needs of researchers and industry. Thus, the board should be kept small with em-

[27] Interview with M. Stratton (12 December 1998). Dr. Stratton was one of the investigators who discovered the BRCA2 gene.

phasis placed on general policy, rather than case-by-case reviews. These policies would, for example, establish the ethical requirements imposed on all researchers using the material (the nature of informed consent, compensation of donors, requirements for genetic counselling, etc.), the uses of any licensing revenue received (to assist patient groups, to conduct research into environmental or public health measures that could be undertaken to prevent the occurrence of disease, public education, etc.), and limitations on the uses of the materials (for example, prevention of sex selection, human cloning, etc.). Some of these policies would probably be appropriate for a wide range of materials and research; some will be more finely directed at the particular issues involved with a specific disease or material type.

So far, I have only discussed the role of these bodies and boards with respect to the ethical and social values inhering in biomedical materials. Of equal importance is the establishment of economic incentives for researchers and industry to conduct further biomedical research and to distribute the results (information, tests, medications) of that research to relevant communities. To accomplish this, we return to the bargain underlying patent law: through the grant of limited monopolies to exploit the commercial value of an invention, researchers and industry are motivated to invent more. At the same time, these monopolies must not be so large as to stifle research through the grant of too many overlapping rights (the so-called tragedy of the anticommons[28]) or to interfere with the board's ability to preserve ethieal and social values.

Appropriate economic incentives to encourage biomedical research need not be the broad rights granted to a patent holder. As I discussed in previous work, there are significant reasons to believe that the economic incentives granted to inventors of biomedical materials are too strong.[29] A more limited monopoly right would likely provide a sufficient economic incentive to conduct biomedical research without either stifling other research or compromising ethical and social values. This limited right could, for example, take the form of an automatic right held by the inventor to be granted a licence to use the invention in respect of certain fields of use. If sufficiently narrow, the licence could be exclusive; if broad, a non-exclusive licence would be more appropriate, perhaps with restrictions placed on the board's right to licence to competitors or with an accompanying right of first refusal over the grant of additional rights that the board may give from time to time.

The suggestion that more limited monopoly rights be granted instead of greater monopoly rights runs counter to industry requests to "strengthen" the patent system by giving industry greater rights.[30] Industry's general argument is that the stronger we

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[28] See M.A. Heller & R.S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research" (1998) 280 Science 698.

[29] "Making Room", *supra* note 22.

[30] See *e.g.* C. Ludlam, Vice President for Government Relations, Biotechnology Industry Organization ("BIO"), "Patent Term Amendments to Protect Diligent Patent Applicants and 18 Month Publication of Patent Applications" (Testimony before the Courts and Intellectual Property Subcommittee, House Judiciary Committee, 26 February 1997) online: <http://www.house.gov/judiciary/4125.htm>

make the patent system, the more innovation will take place in Canada. But stronger patent rights may actually undermine the amount of innovation that is likely to take place.[31]

The argument for greater patent protection should be understood for what it is: an attempt to maximize profit, not to maximize levels of innovation. Clearly, a company would prefer to have as large a monopoly as possible. This gives it ultimate control over how and when to market its product and the ability to garner monopoly profits.[32] But patent law is not about individual profit maximization; it is about maximizing the overall level of innovation in society. The two do not necessarily go together. We can, for example, maximize profit by extending patent terms and the nature of rights attached to patents, but we do so at the cost of impeding others from conducting research. Thus, our goal is to not to maximize profit, but to establish appropriate economic incentives to induce researchers and industry to invest in the research and development needed to invent and bring to market new health-enhancing discoveries.

The level of incentive required to induce sufficient research and development in the biomedical field is unknown.[33] Statements to the contrary are mere acts of faith based on uncertain or self-serving empirical evidence.[34] Nevertheless, I suspect that the grant of an exclusive licence in a narrow field of use (for example, using a gene to develop a screening test or to develop a vaccine) or a non-exclusive licence over a larger field of use (for example, all diagnostic uses of a gene) should be sufficient to achieve appropriate levels of investment in biomedical research.[35] This is because smaller biotechnology companies will, as part of their normal business planning process, focus on a narrow field of use anyway. Larger companies have several methods, besides patents, to protect their market shares, such as relying on their reputations, contacts, and existing distribution channels.

(date accessed: 25 August 1999); E.S. Micek, Chairman of Cargill, Inc., and Chairman of the Emergency Committee on American Trade (Testimony before the House Ways and Means Trade Subcommittee Hearing on U.S. Negotiating Objectives for the WTO Seattle Ministerial Meeting, 5 August 1999), online: WL 20011148.

[31] Heller & Eisenberg, *supra* note 28; "Making Room", *supra* note 22.

[32] While a company may use this control unwisely, and thus fail to profit as in the case of the monopolies held by Sony in Betamax videotapes or Apple with respect to its Macintosh computers, no company would admit that it would use its monopoly except to maximise profit for its shareholders. See P.H. Lewis, "Clan Macintosh Feels the Pain" *The New York Times* (2 April 1998) G1.

[33] See "Making Room", *supra* note 22.

[34] *Ibid.*; J. Mokyr, *The Lever of Riches: Technology Creativity and Economic Progress* (New York: Oxford University Press, 1990) at 251-52; R.C. Levin *et al.*, "Appropriating the Returns from Industrial Research and Development" in *Brookings Papers on Economic Activity* 783 (special issue vol. 3) reprinted in E. Mansfield & E. Mansfield, eds., *The Economics of Technical Change* (Brookfield, Vt.: Edward Elgar Publishing, 1993) at 247, 275; R.P. Merges, "Uncertainty and the Standard of Patentability" (1993) 7 High Tech. L.J. 1 at 5; D.C. Mowery & N. Rosenberg, *Technology and the Pursuit of Economic Growth* (New York: Cambridge University Press, 1989) at 293-94.

[35] Levin, *ibid.*; *contra,* R. J. Gilbert & C. Shapiro, "An Economic Analysis of Unilateral Refusals to License Intellectual Property" (1996) 93 Proceed. Nat'l Acad. Sci. U.S.A. 12749.

It will generally be appropriate for automatic licencees of biomedical materials to pay some form of licence fee. This fee may be low and simply cover operating costs, such as the legal expenses and government fees involved with prosecuting and maintaining the exclusive right over the material. It may also be appropriate to charge a higher licence fee: one that provides the board with the ability to fund other research projects.

The ability to sanction alternative research projects is one area in which the board can take affirmative steps to enhance ethical and social values. While its general policies with respect to research can help maintain these values, the board's ability to license and fund projects will ensure that the board contemplates broad health policy and social policy goals in its deliberations. For example, as I have explained elsewhere, market forces are likely to lead to an under-investment in finding ways to prevent disease, even though prevention has historically been a more efficient means of increasing health status than has therapy.[36] The board could, for example, use the fees it receives from a therapeutic licensee to fund research into environmental contributions to disease. The goal of this research would be to reduce environmental contribution to disease and thus prevent or reduce the occurrence of disease in the population. In this way, the board can balance the uses to which biomedical materials are put.

This model is not without its difficulties. One of the prime difficulties is the method of choosing representatives to sit on the board. The board must at once represent the different interests involved with the biomedical material without being so large that it fails to reach a decision. The board must also be protected from being taken over by interest groups who seek control to pursue a narrow set of goals. These difficulties are not unique to these boards and, in fact, are shared by many other decision-making bodies, from legislatures, to commissions, to ethics boards. Thus, while this concern is important, it is far from intractable.

I believe that this model is an appropriate one for Canada to advocate at the upcoming *TRIPs* negotiations. It provides both economic incentives and a forum in which to debate the ethical and social values inhering in biomedical materials. Further, it provides a way to use the power of exclusive use to pursue ethical and social goals rather than taking a passive regulatory approach to these goals.

Despite the strengths of this model in the international setting, I do not believe it is an appropriate route for Canada to follow unilaterally. Canada should only implement this model once it has been agreed upon at the *TRIPs* negotiations. The reason for this conclusion is not an obvious one. For example, the argument that people will simply avoid patenting biomedical materials in Canada to avoid this scheme is without merit. Inventors are unlikely to avoid patenting in Canada since these inventors will still get more protection by submitting to the scheme than by doing nothing. First, the inventor will be entitled to use the invention in its chosen field of use. Second, the fact that the board has exclusive rights over the material means that the inventor's

[36] *Body Parts*, *supra* note 22 at 36-37.

competitors will not automatically have the right to use the invention. This is, in itself, a market advantage. Even if inventors decided, however, not to submit to this scheme, Canada could provide in its legislation that the government could apply for the patent in the place of an inventor whenever the inventor applied for a similar patent elsewhere. This way, there would really be no way to avoid the scheme.

Nor is the reason for my reluctance to recommend this scheme for Canada while waiting for an international consensus to emerge based on any concern that the level of innovation would decrease in Canada. As argued before, there are sufficient rights being granted to inventors to encourage them to invent. But in the end, this does not matter because the patentability or non-patentability of a particular biomedical material in Canada is unlikely to affect levels of research and development in Canada. This is because those who are interested in commercially exploiting a biomedical invention will want to do so in the principal world markets: the United States, Europe, and Japan. Given the relative insignificance of the Canadian biomedical market, whether or not inventors get Canadian patents is almost irrelevant. Since an invention made in any country that is a signatory to the *Paris Convention for the Protection of Industrial Property*[37] or the *TRIPs Agreement* can be patented anywhere,[38] the real determinant of whether research is conducted in Canada is not Canadian patent rights but access to researchers, research facilities, and know-how within Canada. This lack of connection between the strength of patent rights and the level of innovation in Canada can be easily illustrated. In 1993, the pharmaceutical industry promised Canadian researchers that, in return for their support for Canada extending patent terms from 17 years to 20 years, the industry would invest $200 million in university research. Even though Canada extended patent terms, industry invested barely half of the promised amount.[39] This failure is hardly compatible with an assumption that with strengthened patent rights, industry will invest more in research and development in Canada.

Therefore, Canadian patent law is, at best, loosely connected with the amount of biomedical innovation occurring in Canada. The only exception to this may be in relation to treatments and procedures that are unique to Canada. In these limited cases, Canada may be a significant market for the product. These cases can, however, be treated separately from the ordinary patent system through orphan drug-type legislation.[40]

This lack of relevance of the Canadian market points, however, to the problem with Canada implementing the proposed model with respect to biomedical materials in the absence of an international consensus. The model would likely fail to truly promote the ethical and social values for which it is designed because research and development based on biomedical materials occurs throughout the world. In the absence of an international consensus to the contrary, research undertaken in the rest of the world may well be conducted without regard to ethical and social concerns. Nev-

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[37] 20 March 1883, 74 U.K.F.S. 44 as rev'd at Stockholm on 14 July 1967.

[38] *TRIPs Agreement, supra* note 2, art. 4.

[39] W. Kondro, "Drug Industry Misses Target for Funding Work on Campus" (1997) 275 Science 23.

[40] See *e.g.* 21 U.S.C.A. § 360cc.

ertheless, the results of that research would find its way into Canada as medications, services, and other end-products that do not, in and of themselves, violate ethical or social concerns.

The implementation of the proposed model will not, therefore, lead to harm, but simply be ineffective in ensuring that ethical and social concerns are addressed. Thus, while there is no danger to Canada by implementing such a scheme before other countries follow suit, there is also little advantage to doing so. Because the proposed model might not be implemented internationally, Canada might have to adopt a new model later on in conformity with whatever international consensus was reached. This problem, combined with the difficulties in establishing the model internally (the need for consultation, balancing of interests, drafting and passage of legislation, etc.) and the absence of tangible benefit, would make it unwise for Canada to implement the model unilaterally.

III. Option #3: Follow the American and European Leads

If industry had its way, Canada would neither adopt a "do nothing" approach nor implement a model that gives industry less than the most robust patent rights in the world. What the biomedical industry would prefer is for Canada to follow the leads of the United States, Japan, and the European Union in permitting the grant of patent rights over all biomedical materials.[41] Industry believes that patent rights as strong as those in the United States, Japan, and the European Union are necessary in order to stimulate biomedical research and development in Canada and to increase the ability of Canadian biomedical companies to compete worldwide. Patents stimulate innovation by offering those who invest in research and development a way of recouping their costs and making a profit during the time when they alone can market the innovation.[42] Patents also attract investors to small companies as they provide an objective standard of the science behind the innovation and provide for a monopoly period during which the investor can hope to profit.[43] While biomedical innovation does raise ethical and social issues, these issues do not relate to patenting, but to the manner in

[41] National Biotechnology Advisory Committee, Sixth Report, (1998) at c. 4 ("Market Access, Intellectual Property: Rights and Regulation"), online: Industry Canada <http://stragegis.ic.gc.ca/SSG/bo01254e.html> (last updated 29 May 1998); see also E. Blewett & J.D. MacDonald, "Potential Impacts of Patenting Lifeforms on the Aquatic Products Sector in Canada" at 4 ("Protecting Intellectual Property"), online: Industry Canada <http://strategis.ic.gc.ca/SSG/ip00047e.html> (last modified: 21 April 1998).

[42] See H.E. Bale, Jr., "Patent Protection and Pharmaceutical Innovation" (1996) 29 N.Y.U.J. Int'l L. & Pol. 95; Danish Council of Ethics, *Patenting Human Genes: A Report* (Copenhagen: Danish Council of Ethics, 1994) at 32-33.

[43] Blewett & MacDonald, *supra* note 41 at 5 ("Patenting Higher Life Forms").

which the innovation is used. Thus, patent law is not, according to industry, the place to deal with these ethical and social issues.[44]

This approach is probably best implemented through a combination of federal legislation and court decisions expanding the scope of patent coverage. Parliament could, for example, amend the *Patent Act*[45] in a manner similar to the European *Directive* on biotechnology.[46] This legislation would state that, provided that the patent criteria of novelty, utility, and non-obviousness are met, a biomedical invention is patentable in Canada. We may also wish to follow the European lead of acknowledging a morality clause in the *Patent Act* that would hold a very limited number of innovations to be unpatentable because they violate narrow moral principles (for example, innovations linked to eugenics).[47]

While the legislation may also address some technical aspects of patent law (the provision for the deposit of biomedical materials, refining the meaning of utility), the actual manner in which patent law would apply to biomedical inventions would be left to the courts. That is, courts would address issues such as the amount and nature of disclosure required, what constitutes novelty in the context of biomedical innovation, and the proper interpretation of the morality clause. Whether Canada proceeds by court decision alone or by a combination of legislation and court decision, Canada would soon conform with the standard of patent rights established in the United States, Japan, and the European Union with respect to biomedical materials. There are serious problems with this approach, stemming from its underlying assumptions and extending to the claim that ethical and social issues do not relate to the patenting of biomedical materials.

As discussed earlier, there is little reason to believe that the grant of patent rights in Canada will actually stimulate research and development in Canada. There are two reasons that this is so.

First, there is little evidence that patents actually increase the level of innovation at all;[48] for all we know, biomedical patents may actually decrease the overall level of innovation. There are many reasons why people invent and, while patents may encourage some, they may also prevent others who are discouraged by the patent anticommons discussed earlier. To the extent that evidence exists of a link between patents and innovation, it is based on the self-serving opinions of biotechnology and

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[44] *Ibid.* at 6 ("Conclusions and Recommendations"); A. Marcus, "Owning a Gene: Patent Pending" 2:7 Nature Medicine (July 1996) 728.

[45] R.S.C. 1985, c. P-4.

[46] *Directive*, *supra* note 11.

[47] *Ibid.* at 18, art. 6.

[48] Mokyr, *supra* note 34 at 247-52; Levin *et al.*, *supra* note 34 at 275; Merges, *supra* note 34 at 5; Mowery & Rosenberg, *supra* note 34 at 294.

pharmaceutical leaders who would evidently personally benefit from an increase in patent protection.[49]

There are, in fact, some concrete examples of biomedical innovation proceeding, and proceeding quickly, at the costs of many millions of dollars, without the availability of patents. The Human Genome Project, the international project to map all the genes in human beings, was originally scheduled for completion in 2005.[50] Due to severe competition from the private sector, that schedule has been moved up to 2000 for a preliminary draft and 2001 for a final draft of the human genome.[51] All this is being done without the likelihood of patents being available on the vast majority of the genes discovered through this study. A consensus has emerged within the patent community that genes will be unpatentable unless the discoverer can point to a concrete use of these genes.[52] Since the current stage of the Human Genome Project aims at sequencing the genes, but not describing their function, most genes will be unpatentable.

Second, given the global nature of biomedical knowledge, even if patents do encourage research and development, Canadian patent rights are unlikely to have a significant incentive effect given the small size of the Canadian economy. Canadian enterprise will be far more affected by United States, Japanese, and European patent rights than by Canadian patent rights. Provided that Canada stays on-side of the WTO agreements, there is no reason to believe that these other countries will withhold patent rights in biomedical materials from Canadian companies even if those rights are not granted here. So far, even though Canada does not issue patents on higher life forms, there is nothing to stop a Canadian from applying for and being granted a patent on a higher life form in the United States.

The assumption that investors are drawn to companies with patents is also overstated. It is generally assumed that a public company's stock price increases when that company announces the grant of a patent.[53] But like any other phenomenon in the market, this should be taken with a grain of salt. Almost any event may lead to short-term fluctuations in the market; what is important is not a short-term gain, but long-term trends in a stock. Isolating the effect of any one event, like the grant of a patent, on this long-term trend is impossible. And it is the long-term trend with which we should concern ourselves, not the profit available to arbitragers or day-traders from a public announcement that a patent has been granted.

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[49] "Making Room", *supra* note 22.

[50] C. Wills, *Exons, Introns, and Talking Genes: The Science Behind the Human Genome Project* (New York: Basic Books, 1991) at 10.

[51] N. Wade, "One of 2 Teams in Genome-Map Race Sets an Earlier Deadline" *The New York Times* (16 March 1999) A21.

[52] See *Directive, supra* note 11 at 18, art. 3(1) & 5(3).

[53] See *e.g.* "BIOSPHERICS INC.: Stock Price Soars on News of Patent for D-Tagatose" *The Wall Street Journal* (7 September, 1995) Business Brief.

Investors look at a large number of factors in deciding whether to invest.[54] Highest on the list of factors is the background and skill of management.[55] A company with a wonderful invention, strong patents, and good market prospects but poor or inexperienced management is probably a bad investment choice. Some of the other factors that investors look for in choosing a company in which to invest include market size, marketing strategy, distribution channels, and exit strategy.[56] Patents certainly are a factor, but so too are any market advantages (tradename, market lead, backing by an established company, etc.).[57] While the failure to hold a patent in a field where all one's competitors hold patents may discourage some investment, the same is unlikely in areas where patents are rare or unavailable.

It is also wrong to conclude that there is no link between the patent system and the ethical and social values inhering in biomedical materials. For example, as I have discussed elsewhere,[58] the patent system deeply affects health policy in a number of ways. One area where this occurs is genetic testing. These tests tell a patient whether she or he carries a genetic mutation that, statistically, increases that patient's chances of contracting a particular illness. Patent law encourages those who hold patents over the underlying gene to create these tests and to distribute them as widely as possible. While good health practice would place significant limits on the use of the tests (so that only those that are at a substantial risk of carrying the genetic mutation receive the tests and that all those who take the tests receive genetic counselling to help them interpret the results) the patent holder has a strong incentive to ignore or at least push these limits.[59]

A patent owner can only profit from a patent if he or she sells a good or service based on that patent. In biomedical research, this means that the owner of a biomedical material will profit only if he or she uses that material to create a medication, a test, or a service that can be sold to patients, or if the owner sells the material to researchers who in turn use it to develop a medication, test, or service. Thus, patent owners have a strong economic incentive to pursue research that is most likely to lead to profit. Unfortunately, not all necessary and good health research is likely to deliver this profit. Public health measures such as better sanitation, ensuring that children eat

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[54] See P. Standeven, "Financing Canadian Software Company Development: Observations and Trends" in *Financing Your Software or Multimedia Company* (Ottawa: Industry Canada, 1998), online: Industry Canada <http://strategis.ic.gc.ca/SSG/it02334e.html> (date accessed: 9 September 1999).

[55] *Ibid.*

[56] *Ibid.*; Industry Canada, *Demonstrate Your Investment Potential*, online: Industry Canada <http://strategis.ic.gc.ca/pics/is/mod3fnl.pdf> (date accessed: 16 September 1999).

[57] Industry Canada, *ibid.*

[58] "Making Room", *supra* note 22.

[59] In E.R. Gold, "Hope, Fear, and Genetics: Judicial Approaches to Biotechnology" 83 Judicature 132 at 134-35, I discuss the example of the test for a mutation in the BRCA1 and BRCA2 genes, both linked with breast and ovarian cancer. The example illustrates that where the patent owner is a for-profit company, these limits are much more likely to be stretched.

well, and education do not lead to profit, at least not profit linked to a patent. But public health measures have done far more to increase health than has treatment.[60] The patent system is, unfortunately, blind to this. It merely encourages research into areas where profits can most easily be made, not research most likely to increase overall health.

Following the lead of the United States, Japan, and the European Union is not only unlikely to encourage biomedical research and development in Canada, it also threatens the construction of a sound health policy within Canada. This approach perpetuates and entrenches the very market forces that endanger the ethical, health, and social concerns related to biomedical materials. In addition to these negative consequences, this approach would undermine Canada's ability to argue for a more careful approach to biomedical materials in the upcoming *TRIPs* negotiations. If Canada supported a purely economic approach to patenting biomedical materials within its own borders, it could hardly call on other countries to incorporate ethical and social considerations into international patent law.

Option #4: Use the Medicare System

As discussed in previous sections, the right of exclusive use is one of the strongest provided by the patent system. It provides the patent owner with the ability to prevent competitors from entering the field for a period of twenty years, thus opening up the opportunity to recoup costs and make a profit without fear of direct competition. In Canada there is, however, another regulatory scheme that impacts on the patent holder's ability to sell her product or service: the medicare system.

The largest purchasers of medications and health tests and services in Canada are the provincial medicare systems. While patients, in consultation with their physicians, actually decide which medications, tests, and services to use, it is the provinces that determine which of these medications, tests, and services will be covered by the provincial health insurance plans.[61] There will be a financial incentive for physicians and patients to choose medications, tests, and services covered by these plans. Thus, where there is a choice between a medication, test, or service listed for payment or reimbursement by the provincial plan and a medication, test, or service not listed by the plan, patients will tend to choose the former. So while nothing prevents a patient from choosing any medication, test, or service (provided that it has been approved for use in Canada[62]), for practical reasons, patent owners will find it more difficult to sell medications, tests, and services that are not covered by the provincial health plans.

Given the purchasing power of the provincial health insurance plans, vendors of medications and biomedical tests and services will have a strong incentive to ensure that their medications, tests, and services are listed for payment or reimbursement by

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[60] *Body Parts*, *supra* note 22 at 37.

[61] For example, in Ontario see *Health Insurance Act*, R.S.O. 1990, c. H.6, ss. 10-11.

[62] See *Food and Drugs Act*, R.S.C. 1985, c. F-27, s.12.

those plans. This practical need for provincial-government approval provides Canada with a unique (at least as compared with the United States) opportunity to incorporate ethical considerations into debates over the use of biomedical materials. The provincial insurance plans could, as a condition to listing a medication, test, or service, require the vendor of that medication, test, or service to conform to requirements designed to encourage discussion of ethical considerations.

There are two sets of ethical considerations that apply to a particular test, service, or medication. First, there are ethical concerns arising from the research that led to the test, service, or medication. These include standard concerns over informed consent, environmental safety, and animal welfare.[63] Given the nature of human biological materials, these concerns also include the rational development of health policy, equity of access to health services, and the commodification of the human body.[64] Second, there are ethical concerns that arise from the administration of the test, service, or medication itself. For example, the provision of genetic testing raises ethical issues such as the premature implementation of the test, the population that ought to receive the test, who (family, employers, insurers) ought to have access to the results of the test, and how the test results ought to be communicated and interpreted.[65] Any scheme that we develop ought to address both sets of ethical considerations.

To a certain degree, the question of to whom a medication, test, or service ought to be offered is already one of the foci of decisions related to the listing of new tests, services, and medications under the guise of medical necessity.[66] While vague, the notion of medical necessity means that only those tests, services, and medications with a demonstrated level of utility to the patient ought to be covered by the health insurance plans. The vagueness of the notion becomes apparent once one starts asking what level of utility must be demonstrated, how that utility is to be demonstrated, what counts as utility to the patient, and whether it is appropriate for society to place any limits (for financial reasons, for example) on providing that level of utility to patients.[67]

What I suggest here is that we apply a broader standard than medical necessity in determining whether a test, service, or medication is approved for coverage under the provincial health insurance plans. I believe that it would be appropriate for us to look

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[63] See *e.g.* Tri-Council Policy Statement, *Ethical Conduct for Research Involving Humans* (Ottawa: Medical Research Council, August 1998); Canadian Council on Animal Care, *Guide to the Care and Use of Experimental Animals*, vol. 1, 2d ed., (Ottawa: Canadian Council on Animal Care, 1993); Health Canada, *Laboratory Biosafety Guidelines*, 2d ed. (Ottawa: Minister of Supply and Services Canada, 1996) (Editor: M.E. Kennedy).

[64] See generally, *Body Parts*, *supra* note 22.

[65] See T.A. Caulfield, "The Commercialization of Human Genetics: A Discussion of Issues Relevant to the Canadian Consumer" (1998) 21 J. Consumer Pol'y 483; K. Birmingham, "Myriad's Rationale for Wider Testing" 3:7 Nature Medicine (July 1997) 709; O. Smith, "Breast Cancer Susceptibility Tests Still Valid, Companies Argue" 3:7 Nature Medicine (July 1997) 709.

[66] T.A. Caulfield, "Wishful Thinking: Defining 'Medically Necessary' in Canada" (1996) 4 Health L.J. 63 at 84 [hereinafter "Wishful Thinking"].

[67] *Ibid.* at 70-85.

at the overall contribution of a test, service, or medication to the health care system as a whole, and not simply to the individual receiving the test, service or medication before deciding to list it as an insurable expense. In particular, I suggest that tests, services, and medications based on or produced using biomedical materials only be listed if the person having patent rights (directly or through licence from the patent holder) to the biomedical material demonstrates that ethical concerns have been appropriately dealt with. These concerns would include requirements related to the conduct of the research leading to the development of the medication, test, or service (informed consent, animal welfare, etc.), to the availability of the biomedical material to other researchers on an equitable basis, and to the manner in which the medication, test, or service is marketed and distributed. For example, the vendor may be required to demonstrate that university researchers and competitors have access to the biomedical material to develop preventative measures or alternative therapies to the illness in question. In the case of genetic tests, vendors could also be required to establish that their marketing is limited in scope, that all those who take the test will be given genetic counselling, and that issues of family access to the results of the test be discussed with patients prior to the administration of the test.

The advantage of using the medicare system rather than domestic patent legislation is that the former permits us to address a wider scope of ethical concern than does patent law. The reason for this is that domestic patent legislation is territorially limited since it can only deal with activities taking place in Canada. The medicare system is not so inherently limited: we could, for example, deal with ethical breaches in both the research and development stage as well as in the sale and administration of medications, tests, and services whether occurring in Canada or elsewhere. Thus, unlike the patent system, medicare policy can effectively catch unethical activity regardless of where it takes place.

The medicare system can respond to ethical concerns through the process of listing medications, tests, and services for payment or reimbursement under provincial health insurance plans. In particular, provincial legislation could address both types of ethical concern raised earlier, namely, those related to the research and development of the underlying biomedical material (informed consent, equitable sharing of the financial and other benefits of the research, and prevention of harm to animals and the environment) and those attaching to the actual marketing and sale of the medication, test, or service (definition of population to receive the medication, test, or service, requirements for genetic counselling, and sharing of results with family and other interested parties). If the vendor of the medication, test, or service cannot establish that the biomedical material underlying its medication, test, or service meets both sets of ethical concerns, the medication, test, or service would not be listed for payment or reimbursement.

There are two potential hurdles to overcome in implementing a medieare-based solution to the ethical concerns raised in this article. The first is the anticipated reaction of patients who suffer from an illness that may benefit from treatment from the medication, test, or service. The result of the solution proposed above is that a medication, test, or service can be effectively denied (through non-coverage) to a Canadian patient even where that medication, test, or service is medically necessary from that

patient's point of view. That is, patient groups will most likely, and quite naturally, focus on their own needs and will measure medical necessity in terms of that.

The response to these patients groups is that medical necessity ought not to be defined solely in terms of individual patient needs, but also in terms of the health care system as a whole. While the needs of patients is certainly of high importance, of equally high importance is the stability of the entire system. That is why we accept rationing of services and wait lists. Nobody likes to wait to receive an operation or treatment, but we accept it because we cannot do everything for everyone at the same time. We accept that it is in the interests of the health care system as a whole, and thus in our own interests in the long run, that the system be operated for the benefit of all rather than each and every individual. On this view then, it is appropriate not to list a medication, test, or service where to do so undermines the integrity of the health care system as a whole. Given the trust relationship implicit in the provision of health services, a breach of ethical considerations may well result in undermining public confidence in the health care system.

Despite the force of this argument, several trial-level court decisions place it in doubt. In Canada, both legislation and court decisions make it clear that medical necessity, narrowly defined, is to be considered in determining whether a particular medication, test, or service is to be listed for payment or reimbursement under provincial health insurance plans.[68] Courts have interpreted the notion of medical necessity to be synonymous with whatever the physician recommends[69] and are unsympathetic to claims that the health care system has insufficient resources to provide all services.[70] One recent Ontario decision required, for example, the provincial government to pay for genetic tests for mutations in the two genes related to breast cancer despite the significant costs of the test.[71] If provincial governments, therefore, agree to include factors other than patient benefit in the decision to list a medication, test, or service under provincial health insurance plans, they will need to pass clear legislation to specify that these factors are to be considered.

The second difficulty presented by the proposal of using the medicare system to resolve ethical concerns is one of harmonisation. Given that health care falls within provincial legislative jurisdiction, each province could, in theory, set up its own scheme under which different standards are set with respect to the ethical concerns raised in this article. While the list of insured services varies from province to prov-

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[68] *Canada Health Act*, R.S.C. 1985, c C-6, s. 2.; *Regulations under the Health Insurance Act*, R.R.O. 1990, Reg. 552; *Stein* v. *Québec (Régie de l'Assurance-maladie)* [1999] Q.J. No. 2724 (Sup. Ct.), online: QL (QJ); C. Abraham, "Tenacious Woman Scores Medical Victory: Fiona Webster's Fight Opens Access to Genetic Breast-Cancer Test" *The Globe and Mail* (27 August 1999) A1.

[69] "Wishful Thinking", *supra* note 66 at 76.

[70] See *Estate of Law* v. *Simice* (1994), 21 C.C.L.T. 2d 228, B.C.J. No. 979 (S.C.), online QL (BCJ).

[71] Abraham, *supra* note 68.

ince today,[72] the situation would likely be worse if provinces were to adopt different ethical standards. This could give rise to a real patchwork of health care coverage across the country and a concomitant movement of patients from one province to another to take advantage of the differential standards.

Federal legislation could provide some assistance in bridging the gap between provinces. While health care is not within federal jurisdiction, the federal government can, through its spending powers, influence provincial policy on health care. A more direct approach, and one less likely to raise provincial ire, would be for the federal government to pass enabling legislation should the provinces agree to participate. This legislation could establish a framework of ethical considerations or, better still, a process to reach consensus on the ethical considerations that provincial health insurance plans could adopt in deciding whether to list a particular medication, test, or service. Those provinces wishing to participate could then, as a condition to listing a medication, test, or service involving biomedical materials, require that those materials meet the ethical standards adopted through the federal legislation.

By using the power of *de facto* control on the sale and distribution of medications, tests, and services within the province, provincial health insurance plans can go a long way to ensure that ethical concerns have been addressed with respect to research and development, and marketing and distribution of the products of biomedical materials. While not all provinces may opt to participate in the plan, one can hope that the presence of a federal standard will at least alleviate great differences between the provinces.

Conclusion

In the period leading up to the renegotiation of the *TRIPs Agreement*, Canada must formulate a policy with respect to rights in biomedical materials that satisfies three goals. The first is to provide Canadians with ongoing access to health medications, tests, and services where this access is likely to increase quality of life. This means that there must either be an economic incentive to sell these medications, tests, and services in Canada or some non-market mechanism to ensure that they are distributed within Canada. The second goal is that Canada continue to foster a strong biomedical research and development community. This is important not only because it provides Canada with a level of independence in the health care field, but also because it is a source of well-paying, highly-skilled jobs. The third goal is to take into account the diversity of ethical and social concerns regarding biomedical materials in any decision about these materials.

At first glance, there appears to be a contradiction between economic efficiency and accounting for diverse values. Economic efficiency does not generally coincide with actively taking into account a diverse set of views and values. The options of ei-

[72] See *e.g.* Ontario's list of covered services in *Regulations under the Health Insurance Act*, *supra* note 68.

ther doing nothing (holding that biomedical materials are not subject to intellectual property rights) or following the U.S., Japanese, and European lead in holding these materials to be unreservedly subject to patents do much to allow the market to work its magic, but undermine any real chance to discuss the values inhering in these materials. The option of implementing my proposed model, under which biomedical materials are controlled by non-profit organizations, does better but, in the end, will be unlikely to address ethical concerns should Canada be the only country to implement the model. The best option is to use the market power held by provincial health insurance agencies to negotiate with those supplying biomedical materials or medications, tests, or services based on those materials for the inclusion of ethical considerations in the research, marketing, and distribution of those materials, tests, and services.