PATENTING OF BIOTECHNOLOGICAL INNOVATIONS CONCERNING ANIMALS AND HUMAN BEINGS

Prepared for The Canadian Biotechnology Advisory Committee Project Steering Committee on Intellectual Property and the Patenting of Higher Life Forms

Ted Schrecker * and Alex Wellington **

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* **Consultant, 450, rue de la Congrégation, Montréal, Québec H3K 2H7; Phone: 514 932 5386 Fax: 514 932 5230 E-mail: tschrecker@sympatico.ca**

** **Department of Philosophy, Ryerson Polytechnic University, 350 Victoria Street, Toronto, Ontario M5B 2K3; Phone: 416 516 4808 Fax: 416 535 1093 E-mail: alex.wellington@sympatico.ca**

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I. Introduction

The twenty-first century may well be the century of biotechnology, much as the latter part of the current century belonged – in a technological sense -- to the transistor and the integrated circuit. To continue with this comparison, just as today's leading-edge computer and communications technologies now make Dick Tracy's original comic strip wrist radio look distinctly old fashioned, so it may be hard today to imagine the future applications of a variety of advances in biology.

These prospects fill some people with enthusiasm, some with dread, and still others with emotions that reflect a combination of both (Box 1). In any event, they present a number of challenge to a legal regime of intellectual property (IP) protection that developed during earlier Industrial Revolutions, and which was organized primarily around mechanical, electrical and chemical innovations. Today, however, the most valuable forms of intellectual property are likely to involve quite different disciplines and potential end products -- the latter including human cell lines, genes (the sequences of DNA that enable an organism to produce a particular protein), and living organisms themselves.

Box 1: The Biotechnological Future

"Microsoft chairman Bill Gates has said that the computer revolution is unfolding at an exponential rate. But with respect to genetically engineered plants and animals, there are many reasons to think that we are on the eve of a biotechnological revolution that will unfold even faster."

> U.S. patent lawyer Breffni Baggot, "Legislating a Transgenics Revolution," *IP Frontline*, (Manning & Napier Information Services), December 1998.

"We are making a shift from the industrial revolution to the biotech century and from fossil fuels, metals and minerals as the primary raw resource for economic activity to genes as the raw resource for economic activity in the new era. The computer is the management tool to decipher, download and organize genes."

> Jeremy Rifkin, "Mouse Cloning Begins Bio-Industrial Era," interview in *New Perspectives Quarterly* 15 (Summer 1998): 48-53, at 49. Rifkin started the Foundation on Economic Trends, which actively opposes a variety of biotechnology applications, and in particular the issuance of "patents on life".

The issue of patenting human cell lines first drew widespread public attention because of the case of John Moore, a surgical patient whose spleen was removed at the University of California hospital in 1976. His oncologist and other researchers were subsequently able to culture cells from Moore's cancerous spleen that produced a class of substances (lymphokines) with considerable therapeutic, and therefore commercial, potential.[1] They obtained a patent on the cell line, from which both they and the University expected to earn substantial royalties over time. When Moore became aware of this fact, he sued both the oncologist and the university, seeking a share of the royalties from the patent.[2] Moore's lawsuit was ultimately rejected by the California Supreme Court for a number of reasons. To oversimplify considerably, one was that whatever the provenance of the cells from which the cell line originated, neither the genetic material responsible for the production of lymphokines nor the lymphokines themselves were in any way unique to Moore's body.[3] However, the strongest considerations prompting the court to reject the idea that Moore retained a property right in 'his' cells or their biochemical products appear to have involved public policy considerations: the possible chilling effects on medical research and the associated industries.[4]

Microorganisms have been considered patentable subject matter in Canada since 1982, when the Patent Appeal Board (an internal tribunal of what was then the Patent Office and is now the Canadian Intellectual Property Office, or CIPO) concluded, in *Re Abitibi*, that Canada should no longer refuse to issue patents on any form of living matter.[5] In making this ruling the Patent Appeal Board relied in part on the reasoning of the U.S. Supreme Court in *Diamond v. Chakrabarty*, a landmark 1980 decision involving a patent on a genetically engineered bacterium capable of degrading crude oil.[6] The United States Patent and Trademark

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1. The term "cell line" refers to cells that will grow indefinitely in the appropriate culture medium. Differentiated human cells (as distinct from embryonic cells) will not usually do this, but cells from cancerous tissue are more likely to do this than normal cells. Such cell lines are valuable for research purposes in themselves; it is even more unusual to isolate and propagate a cell line that will produce substances that are potentially valuable for commercial purposes. "Consequently, the discovery of a particular cancerous tissue that will generate a cell line is highly prized commercially." S. Pepa, "International Trade and Emerging Genetic Regulatory Regimes," *Law & Policy in International Business* 29 (1998): 415-450, at 420.

2. For discussion of this case see G. Annas, "Outrageous Fortune: Selling Other People's Cells," *Hastings Center Report* 20 (November/December 1990): 36-39; I.J. Churchill, "Patenting Humanity: The Development of Property Rights in the Human Body and the Subsequent Evolution of Patentability of Living Things," *Intellectual Property Journal* 8 (July 1994): 273-279; B. Hoffmaster, "Between the Sacred and the Profane: Bodies, Property and Patents in the *Moore* Case," *Intellectual Property Journal* 17 (1992): 115-148; T. Wells, "The Implications of a Property Right in One's Body," *Jurimetrics Journal* 30 (Spring 1990): 371-382.

3. See discussion by Hoffmaster, *ibid.*, at 123-124.

4. *Ibid.*, at 124-126; Annas, *supra* note 2, at 37; Churchill, *supra* note 2, at 276-278.

5. 62 C.P.R. (2d) 81.

6. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). For commentaries on this ruling and its effects see among many other sources J. Hudson, "Biotechnology Patents After the 'Harvard Mouse': Did Congress Really Intend 'Everything Under the Sun' to Include Shiny Eyes, Soft Fur and Pink Feet?" *Journal of the Patent and Trademark Office Society* 74 (1992): 510-537; L. Kass, *Toward a More Natural Science* (New York:

Office (USPTO) had initially rejected the application, on the grounds that "micro-organisms are 'products of nature'" and "as living things, micro-organisms are not patentable subject matter."[7] The patent applicant, microbiologist Ananda Chakrabarty, appealed the ruling all the way to the US Supreme Court, which in a split 5-4 decision held that a living organism was patentable subject matter. Indeed, the majority quoted a 1952 Congressional committee report on the recodification of the *Patent Act*, to the effect that Congress intended patentable subject matter "to 'include anything under the sun that is made by man'."[8] After *Abitibi*, the Canadian Patent Office's policies were modified to permit claims to microorganisms and cell lines -- although as noted *infra*, at least one Canadian patent on a human cell line was granted well in advance of *Abitibi*.

The Harvard mouse or Onco-mouse is a mouse that has been genetically modified by the insertion of a gene that confers high susceptibility to tumours (an 'oncogene sequence'), making the mice extremely useful in laboratory studies of cancer.[9] The United States Patent and Trademark Office (USPTO) issued a patent on the Harvard mouse in 1988; the patent covers the processes for 'creating' a Harvard mouse as well as the creature itself, and interestingly applies not only to mice but to any non-human mammal that has been modified in the specified fashion. In the flurry of law journal articles that followed the granting of the Harvard mouse patent, one writer wondered: "Did Congress really intend *everything under the sun* to include shiny eyes, soft fur, and pink feet?"[10] He concluded that it did, "at least so far as the patent incentive is concerned."[11] Others were not so sure whether Congress could have intended such an outcome, or whether such an outcome would constitute sound and defensible public policy, even if it were consistent with the outlines of existing patent law. Such doubts, which apparently are shared by some key Canadian administrative and judicial decision-makers,[12] are a primary reason for the present paper.

Free Press, 1985), at 128-153.

7. For a critical commentary on the "product of nature" doctrine see M. Gollin, "Patenting Recipes from Nature's Kitchen," *Bio/Technology* 12 (1994): 406-407.

8. *Diamond v. Chakrabarty*, at 309.

9. The creature is often referred to as the Harvard mouse because the patent was assigned by the inventors to the President and Fellows of Harvard College, where the genetic engineering research was carried out; Onco-mouse is a trademark of the firm that now sells the mice to researchers. For a brief history of the Harvard mouse as well as its scientific significance and some of the issues raised for the scientific community by the patenting of such research resources, see National Research Council, *Sharing Laboratory Resources: Genetically Altered Mice*, Summary of a Workshop Held at the National Academy of Sciences, March 23-24, 1993 (Washington, DC: National Academy Press, 1994); <http://www.nap.edu/readingroom/books/mice>. Other useful commentaries include R. Dresser, "Ethical and Legal Issues in Patenting New Animal Life," *Jurimetrics Journal* (Summer 1988): 399-435; Hudson, *supra* note 6; D. Manspeizer, "The Cheshire Cat, the March Hare, and the Harvard Mouse: Animal Patents Open Up a New, Genetically-Engineered Wonderland," *Rutgers Law Review* 43 (1991): 413-55.

10. Hudson, *supra* note 6.

11. *Ibid.*, at 537.

12. See the discussion of the Canadian history of the Harvard mouse patent application accompanying notes 28-32, *infra*.

The outline of the paper is as follows. In section II we briefly explain what patents are and aren't, and explain the general case for patenting biotechnology applications. In section III we outline the major concerns that have been raised about animal patenting. In section IV we carry out the same exercise with respect to patents on human biological material.[13] The issues discussed in sections III and IV are not isolated or unconnected. In fact, some of the most widespread concerns about patenting are often stated in similar terms whether the context involves animal patenting or the patenting of human biological materials. For this reason, section V of the paper is devoted to an exploration of these 'cross-cutting concerns,' as we call them.

With respect to the concerns identified in sections III, IV and V, it is important to ask three sets of questions.

First: what principles, values or intuitions[14] are at issue?

Second, do the principles, values or intuitions at issue primarily involve the consequences of a particular biotechnology application, or of the issuance of a patent, or do they primarily involve the intrinsic rightness or wrongness of a particular action? In other words, are they primarily deontological or consequentialist in form,[15] keeping in mind the understandable difficulty in separating the two forms of argument — each of which draws on a long tradition in Western philosophy — at the level of applied ethical reasoning (Box 2)?

Third, to what extent is patenting actually relevant to the concerns being expressed or the outcomes being anticipated? In other words, is the issue one of IP law and policy, or one that involves the nature or consequences of a particular biotechnology application, quite apart from the structure of intellectual property rights that applies? And would the absence of patents in connection with a particular application genuinely address the values at issue, or might it in fact offend against them in ways that patenting would not? With apologies to Tina Turner, this third set of questions might be summarized as: "What's patenting got to do with it?"

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13. We have used the phrase 'biological material' rather than 'genetic material' because some of the more vocal objections to patenting have actually involved cell lines rather than genes, and in these cases it is important to be clear with respect to what the patent does and does not cover; see (citation to follow). In addition, whether genetic material should be treated differently from (say) tissues, organs and cells for purposes of IP law and policy is arguably a question that deserves more careful attention.

14. Philosopher Thomas Nagel points out that: "To trust our intuitions, particularly those that tell us something is wrong even though we don't know exactly what would be right, we need only believe that our moral understanding extends farther than our capacity to spell out the principles which underlie it. .... Intuitive dissatisfaction is an essential resource in political theory. It can tell us that something is wrong, without necessarily telling us how to fix it." *Equality and Partiality* (New York: Oxford University Press, 1991), at 7.

15. For examples of how this distinction has been used in actual policy analyses related to biotechnology, see e.g. Danish Council of Ethics, *Patenting Human Genes: A Report* (Copenhagen, 1994), at 27-35; Ministry of Agriculture, Fisheries and Food [U.K.], *Report of the Committee to Consider the Ethical Implications of Emerging Technologies in the Breeding of Farm Animals* (London: HMSO, 1994), at 8-18.

Box 2: Forms of Ethical Argument

Ethical critiques and defences of IP rights in biotechnology can be classified into two basic forms, each of which draws on a distinct tradition in western ethics or moral philosophy.

One form of argument, referred to by philosophers as *deontological* (or sometimes as 'duty ethics'), appeals to duties, obligations, rights or principles that supply the basis for evaluating an action, choice or policy. A simple example is the axiom that one must always tell the truth, or that one must always treat other human beings as ends in themselves, rather than as means to an end. (This is one formulation of the philosopher Immanuel Kant's 'categorical imperative,' which is central to many versions of duty ethics.). When such axioms are invoked in order to justify or reject a particular action, it is usually important to ask: where do such duties or obligations come from? And who says?

A second form of argument links the ethical status of an action or policy with an assessment of its consequences -- hence the term *consequentialist* to describe such an argument. The simplest and most familiar kind of consequentialist position is utilitarianism, in which the action that is right is the one that produces the greatest good for the greatest number. However, consequentialism must not be used as a loose synonym for cost-benefit analysis, which is just one particular application of utilitarianism that attempts to convert all the relevant values into dollar terms for purposes of simplifying comparison. The consequences taken into account in a consequentialist ethical argument may be environmental, social or even spiritual, and they need not be converted to a common unit of measurement.

Distinctions between deontological and consequentialist claims are indispensable for analytical purposes because they require clarity with respect to what is being defended, or objected to. The distinctions also have significant policy consequences. "If deontological theorists are right, they can establish the moral status of human activities -- such as genetic engineering -- quite independently of the expected consequences of those activities."* Conversely, consequentialist arguments invite exploration of possible policy interventions, in a way that deontological arguments do not.

In practice, ethical reasoning normally combines the two categories of argument, for at least three good reasons.

(i) The choice of whether to define consequences as beneficial or harmful is not always self-evident, and always takes place against a pre-existing ethical background. For example, high-priced treatments for human infertility can be viewed as enhancing reproductive choice, as generating unsustainable demands on a finite pool of health care resources, or as doing both of the above, with the result that a balancing of values is required. In other words, just identifying consequences tells us nothing about their ethical significance.

(ii) Not only the nature of consequences, but also their distribution may be ethically significant. Once again to use an example from the health care field, a medical intervention derived from biotechnology that resulted in the ability to prolong a few lives at immense cost to a health care system with finite resources, might legitimately be questioned on grounds of distributive justice -- particularly in a society like Canada's that attaches a high value to providing access to health care independently of ability to pay.

(iii) Perhaps most importantly, abstract principles tend to lose some of their attractiveness when proponents confront consequences. To be a bit provocative, the idea that Canada should never allow patents on laboratory animals might lose some of its lustre were Canadian researchers thereby to lose access to transgenic animal models of serious diseases, leaving them with no option apart from the costly and time-consuming process of re-creating the models from scratch based on the information in foreign patent applications, and perhaps also leaving them to contend with trade sanctions against whatever marketable products their research were to yield.

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* M. Häyry, "Categorical Objections to Genetic Engineering -- A Critique," in A. Dyson and J. Harris, eds., *Ethics and Biotechnology* (London: Routledge, 1994), at 202.

Section VI situates debates about patenting animals and human biological material in the context of the international regime of trade law, policy and politics. This is an essential element in any analysis of intellectual property policy, given Canada's situation as a trade-dependent nation with a relatively small domestic market. Finally, in section VII we present an illustrative list of policy responses to the concerns raised in sections III, IV and V that have been proposed or actually undertaken, either in Canada or elsewhere. The point here is to indicate that the problems many people associate with the extension of IP rights into new biological areas may be remediable in a variety of ways, some within the domain of IP law and many others outside it.

The approach we have taken is not the only conceivable one. The intellectual starting points, or "initial presumptions,"[16] from which any intellectual inquiry begins have an important influence on the conclusions at which one eventually arrives, and we have started from the position that current law and policy on biotechnology patenting are not altogether illegitimate. We might, instead, have begun with a *prima facie* presumption against the patenting of most or all living organisms, tissues, cells and genes; this is in fact the presumption that has been advocated by some non-governmental organizations. However, we have tried to make the analysis and its underlying premises as transparent as possible for those readers who do not share our initial presumption. Most importantly of all, the approach taken in this report reflects a conviction that the development of sound public policy requires that all stakeholders meet a consistently high and demanding standard of analytical clarity in defining their positions and elaborating on them with reference to competing perspectives.

16. T. Schrecker and M. Somerville, "Making Ethically Acceptable Policy Decisions: Challenges Facing the Federal Government," in *Renewal of the Canadian Biotechnology Strategy Roundtable Consultation: Background Documents* vol. 3.4.1 (Ottawa: Canadian Biotechnology Strategy Task Force, Industry Canada, 1998; <http://strategis.ic.gc.ca/SSG/bh00195e.html>): 73-133, at 120-122.

II. The Case for Intellectual Property Protection of Biotechnological Innovations

II.A Patents: What They Are and Aren't

Patents are one of several ways in which legal protection can be sought for intellectual property (IP). Others include copyright, trademarks and trade secrecy, although only trade secrecy is likely to be relevant to biotechnological innovation. A patent confers on the inventor the right to exclude others from using the patented invention for a specified period of time: since the latest round of modifications to Canadian patent law to bring it into line with other countries, 20 years from the date of filing a patent application. Often, the inventor will assign this right to another party, such as an employer or a firm that has agreed to invest the resources needed to commercialize the invention. A patent does *not* represent a seal of official approval, or carry with it any right to exploit a particular invention; this possibility may be dependent on regulatory, administrative or other approvals. It also does not guarantee a return on investment, although having invested the substantial amounts required (especially in biological research) not only to arrive at a potentially patentable end point but also to pursue the patent application itself, patent holders normally have strong motivation to seek approval for commercialization. Otherwise, with one key exception[17] there would normally be little point in going to the trouble and expense of seeking a patent.

Patents can be issued either on products or on the processes for making them; "generally, the most effective commercial protection, and therefore the most powerful incentive to invest in product development, is provided by a patent on an end product that is sold to consumers."[18] Among other advantages, product patents protect both against independent invention and against reverse engineering, which involves "starting with the known product and working backward to divine the process which aided in its development or manufacture."[19] In other words, even if another inventor has come up with the same invention, she is prohibited from making, using, or selling the invention without authorization from the patent owner.

What are the legal preconditions for patentability? First of all, the claimed invention must constitute patentable subject matter. The *Patent Act* expressly precludes patents for "any mere scientific principle or

17. The situation in which an inventor seeks a patent in order to increase the chances that an invention will be widely used, for instance by offering non-exclusive, royalty-free licences on certain terms and conditions, while retaining some control over the invention's potential uses. That control would be lost were the details of the invention simply to be published in an academic journal.

18. R. Eisenberg, "Technology Transfer and the Genome Project: Problems with Patenting Research Tools," *Risk* 5 (1993): 163-176.

19. Chief Justice Burger, writing for the United States Supreme Court in *Kewanee Oil v. Bicron* (1974) 416 U.S. 470.

abstract theorem".[20] Other kinds of unpatentable subject matter include schemes, plans, or methods for doing business.[21] A patent for a human cell line was issued in Canada as long ago as 1976.[22] As noted earlier, microorganisms have been considered patentable by CIPO since 1982. In addition, DNA sequences -- including those derived from human biological materials -- are now considered patentable by CIPO, reflecting a position that is uncontroversial at least within the IP and scientific communities.

What qualifies as an invention? Canadian patent law defines an invention as "any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter."[23] The relevant criteria are novelty (the invention must be new, and with some exceptions must not have been disclosed publicly before the date of filing an application);[24] utility (defined with reference to industrial or commercial value);[25] and non-obviousness (the invention must not be obvious to someone with the relevant specialized skills).[26] In these respects, Canadian patent law is substantially similar to the regimes that are in place elsewhere in the industrialized world.

Both the definition of an invention and the distinction between product and process patents are important to understanding the saga of the application for a Canadian patent on the Harvard mouse, first filed in 1985. As in other jurisdictions, the application consisted both of product and process claims. The final decision of the patent examiner, in March 1993, rejected the product claims on the basis that "a higher life form, like an animal, is outside the definition of invention as given is Section 2 of the *Patent Act*."[27] After an appeal to the Patent Appeal Board, the Commissioner of Patents upheld the decision in 1995, primarily for reasons having to do with the interpretation of the words "manufacture or composition of matter."

> ... I cannot extend the meaning of 'manufacture' or 'composition of matter' to include a non-human mammal. On the plain and ordinary meaning of the words ... I do not find that non-human mammal like a mouse falls within the definition of 'invention'. The inventors do not have full control over all the characteristics of the resulting mouse since the intervention of man ensures that reproducibility extends only as far as the cancer forming gene.[28]

The patent applicants appealed to the Federal Court of Canada, which in April 1998 upheld the Commissioner's decision, noting with respect to the issue of a patent on the creature itself:

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20. *Patent Act,* R.S.C. 1985 c. P-4, as amended, s. 27 (3).

21. See D. Vaver, *Intellectual Property Law* (Toronto?: Irwin Law, 1997), at 128-130 for elaboration.

22. Patent no. 999546, on a process for culturing a human liver cell line and the products of that process, was issued in 1976 to The Wellcome Foundation Limited, UK

23. *Patent Act*, s. 2.

24. *Ibid.*, s. 28.2

25. *Ibid.*, s. 2.

26. *Ibid.*, s. 28.3.

27. Patent application no. 484,723, Final Action, March 24, 1993, at 1 (see also 3).

28. Decision of the Commissioner of Patents, Patent application no. 484,723, at 6-7.

> [I]t may be that there is a logical place at which one can draw a line and say definitively that a certain percentage of characteristics must be controlled before one can claim the entire life form as an invention. However, that line was not shown to me in the present case and the complexities of the issue make it unlikely that the court is the forum in which to decide where the line should be drawn. On even the broadest interpretation I cannot find that a mouse is 'raw material' which was given new qualities from the inventor.[29]

Significantly, the Federal Court explicitly adopted the reasoning of the minority in *Chakrabarty*, to the effect that determining the patentability of higher life forms "involves the balancing of competing values and interests," which is the responsibility of politicians rather than the courts, and noted that "if Parliament so wishes, it clearly can alter the legislation so that mammals can be patented."[30] The court thus rejected the applicants' position that in the absence of a prohibition on patenting animals in legislation or case law, they should be considered patentable subject matter.[31]

Patents can be granted on very narrowly defined and specified inventions, or on a broad and generalized basis. Belgian medical scientist Désiré Collen, whose research has by his own account led to "a successful patent on the one hand, and several patents not worth the paper on which they are printed on the other hand," observes that: "If you have a good patent agent, the first claim of your patent will ask half the world, and the following claims will progressively restrict this."[32] Sometimes, this strategy results in a situation in which one jurisdiction grants far broader patent protection than another, in response to a similar or identical application. In its most recent report, Canada's National Biotechnology Advisory Committee (NBAC) points to a case in which CIPO granted far broader patent protection than the United States or the signatory countries to the European Patent Convention[33] for the synthesis of a gene that produces human Epidermal Growth Factor (EGF), with the result that a Canadian firm abandoned plans to commercialize the invention because a multinational firm had been awarded broader patent protection in Canada than in other jurisdictions.[34] This case illustrates that at least in a rapidly developing field like biotechnology, decisions about the appropriate level of IP protection are by no means self-evident or uncontestable. Further, although the fact that CIPO has issued a patent creates a presumption in favour of the patent's validity,[35] the presumption is just that -- a

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29. President and Fellows of Harvard College v. Commissioner of Patents, Docket T-275-96 (Federal Court of Canada), April 21, 1998, at 15.

30. *Ibid.* at 22.

31. See e.g. K. Kaminski, Smart & Biggar [lawyers for the applicants] to Commissioner of Patents, August 16, 1990, at 2 ("Had the Legislature intended to preclude patentability of animals, it could and would have done so in express prohibitory language in the Act"); J. Morrow and M. Gravelle, Smart & Biggar, to Commissioner of Patents, September 24, 1993, at 1-2.

32. D. Collen, "Biomedical Applications of Biotechnology," in S. Sterckx, ed., *Biotechnology, Patents and Morality* (Aldershot, UK: Ashgate, 1997): 72-81, at 72-73.

33. See the discussion in section VI.C, *infra* for an explanation of the Convention's significance.

34. National Biotechnology Advisory Committee (NBAC), Leading in the Next Millennium, Sixth Report (Ottawa: Industry Canada, 1998), at 53-54; also available at <http://strategis.ic.gc.ca/bio>.

35. *Patent Act*, s. .

presumption -- and it is not necessarily the case that all the claims in a patent that has been issued would survive judicial scrutiny.

The nature of the intellectual property right conferred by a patent is noteworthy in several respects. We have already noted that a patent does not confer the right to exploit or market a particular invention, but only the right to exclude others from doing so. Further, disclosure is of the essence in the patent application process; the application must provide sufficient detail to enable an individual with the skills that are ordinary in the field in question to reproduce the invention. In Canada, the contents of a patent application must be disclosed no later than 18 months after the application is filed;[36] in the United States, by contrast, disclosure is not required until and unless the patent is awarded.

II.B Why Patents?

Patents, then, are government grants of a limited monopoly, awarded in exchange for disclosure of the invention, which is a crucial element of the patenting process. They represent a bargain between the state and the inventor, a *quid pro quo*, whereby the inventor agrees to divulge the details of his invention, for the ultimate public use and benefit in return for the grant of a monopoly of the exploitation of his invention for the duration of the patent. Paul Lucas, Chair of the Intellectual Property Protection Issues Committee of the Pharmaceutical Manufacturers' Association of Canada, noted the importance of disclosure in 1997 by arguing that:

> Since patents are publicly available for review by researchers and competitors, their commercial importance in stimulating innovation is obvious. They become a key industrial tool to track research developments and identify trends, discover new product lines, avoid duplicative and unproductive research avenues, find solutions to technical roadblocks, and gain new ideas for competitive research. In short, they advance society's knowledge.[37]

But why permit the creation of such exclusive IP rights in the first place?

One argument for IP protection in biotechnology, as in other areas of scientific and intellectual endeavour, relies on the premise is that inventors are entitled to receive a return on their own investments of time, money and intellectual effort. This argument reflects a line of philosophical reasoning that goes back at least as far as John Locke,[38] and is ultimately rooted in considerations of fairness:

> The consideration of *justice* (or morality, if you like -- this is the ethics of the patent system) is that it would be unfair to the inventor to allow his competitors to exploit the invention which is the fruit of

36. *Ibid*, s. 28.2(1)

37. P. Lucas, "Innovation and Intellectual Property Protection," *PMAC 1997 Annual Review*, <http://www.pmac-acim.org/review/review97/e-chap1.html>.

38. For discussion see O. Funke, "Biotechnology and Patent Rights: Seeking the Common Good?" in T. Schrecker, ed., *Surviving Globalism: The Social and Environmental Challenges* (London: Macmillan, 1997), at 216-26.

> his own substantial intellectual effort and financial investment. .... This is the basic ground of intellectual property as a whole ...[39]

Another, more frequent set of arguments involves the role of patents as a necessary incentive to continued innovation, and to undertake the often lengthy and expensive process of bringing an invention forward from lab bench to marketplace. "The consideration of *utility* is that patents are an indispensable motor of technological innovation."[40] Thus, the intellectual property strategy of the Canadian Genetic Diseases Network, a national network of scientific researchers funded by the federal Networks of Centres of Excellence (NCE) program, is based on the premise that:

> Commercialization of biomedical discoveries requires strong intellectual property. Investors need the confidence that the multi-million dollar investments will provide economic returns at the end of what is often a 5-10 year development horizon for new diagnostics and therapeutics.[41]

This is just one statement of a position whose essentials have been repeated by scientists, intellectual property lawyers and others in Canada, the United States and the European Union.[42] Particularly worth quoting is the comment of Graham Strachan, Chair of the NBAC and President of Allelix Biopharmaceuticals:

> I can tell you from many first hand experiences that the intellectual property status is one of the first questions asked of the biopharmaceutical CEO when out trying to raise money from the financial gatekeepers -- be they investment bankers, institutional players or potential pharma partners. Anything less than a positive response, preferably involving product patents, inevitably causes problems.[43]

Indeed, a portfolio of patents can represent the principal asset of startup firms, or divisions within firms that must operate as independent profit centres, seeking capital for a lengthy research and development process that may take years to generate returns. Similar first-hand observations, both from the scientists whose work

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39. U. Schatz, "Patents and Morality," in Sterckx, ed., *supra* note 32: 159-170, at 166-167, emphasis in original.

40. *Ibid*., at 167.

41. Canadian Genetic Diseases Network, "Intellectual Property Strategy," <http://www.cgdn.generes.ca/Property.html>.

42. See e.g. B. Healy, testimony in *The Genome Project: The Ethical Issues of Gene Patenting,* Hearing Before the Subcommittee on Patents, Copyrights and Trademarks, Committee on the Judiciary, United States Senate, 102nd Congress, 2nd Session (Washington, D.C.: U.S. Government Printing Office, 1993), at 24-5; C. Venter, testimony in *ibid.,* at 55; P. Leder [co-inventor of the Harvard mouse], testimony in *Transgenic Animal Patent Reform Act* of 1989, Hearings Before the Subcommittee on Courts, Intellectual Property and the Administration of Justice and the House Committee on the Judiciary, 101st Congress, 1st Session (Washington, D.C.: U.S. Government Printing Office, 1990) at 194-195, 219-220; D. Quigg (U.S. Commissioner of Patents and Trademarks), testimony in *ibid.*; G. Strachan, "Patents: The Lifeblood of the Evolving Canadian Biopharmaceutical Sector," speech to CPIC (mimeo, November 27, 1996). For a comparable European view see F. Logan [Chairman, Association of Medical Research Charities] et al., "Patent Protection in Genetic Research" [letter], *The Times*, October 17, 1997: 21.

43. Strachan, *supra* note 42.

provides the basis for patentable innovations and from the businesspeople whose task is to commercialize those innovations, will be a valuable resource for policy formation and public education in this area.

On this line of argument, the benefits to be gained by providing reliable and effective patent protection include not only such anticipated outcomes as improved agricultural yields, new capabilities in the area of environmental remediation, and new diagnostic tools and therapies for debilitating diseases,[44] but also the straightforwardly economic rewards associated with a thriving domestic biotechnology industry: jobs, domestic business opportunities, export earnings and tax revenues. Creating the policy environment for a strong domestic biotechnology industry may be necessary if Canada wishes to avoid relying on imports in order to gain access to the benefits of biotechnological innovation within its own borders. For all these benefits to be realized, effective IP protection is often viewed as a prerequisite.

There is some suggestion in the economic literature that the actual benefits of IP protection in terms of the rate of innovation are less substantial than claimed.[45] Economic historian Joel Mokyr, who has expressed scepticism about the role of patents in stimulating technological progress during the Industrial Revolution, also argues that the patent system "encourages ideas that represent radical departures from accepted practice," which he calls macroinventions, and thus that patenting is important in generating "the occasional spectacular breakthrough," one that results from a tremendous investment of resources against a low probability of success.[46] Arguably, this describes many current and anticipated ventures in biological research. In addition, the cost structure of some of the industries to which biotechnological innovation can be expected to contribute, such as the pharmaceutical industry, may make patent protection especially significant: the costs of research and clinical trials are high, potential dead ends are numerous, and lead times before a product can be commercialized are long.[47]

In response, those who question the merits of expansive IP protection for biotechnology innovation might distinguish between the role of patent protection in commercialization and its role in generating the funds needed to support basic research. Most industrialized countries have traditions of public investment in such

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44. In addition to the examples cited later in this report in discussions specific to the patentability of animals or human genetic material, illustrations include the prospect of a gene therapy for clogged arteries; the possibility of being able to use information about an individual's genotype for more precise targeting of drug therapies; and the availability of tissues and even organs grown *in vitro* rather than transplanted from donors. T. Ohno et al., "Gene Therapy for Vascular Smooth Muscle Cell Proliferation After Arterial Injury," *Science* 265 (1994): 781-4; D. Housman and F. Ledley, "Why Pharmacogenomics? Why Now?" *Nature Biotechnology* 16 (1998): 492-3; C. Arnst and J. Carey, "Biotech Bodies," *Business Week*, July 27, 1998: 56-63.

45. J. Barton, "Patenting Life," *Scientific American* 264 (March 1991): xx-xx, at 40; J. Mokyr, *The Lever of Riches: Technological Creativity and Economic Progress* (New York: Oxford University Press, 1990), at 247-252.

46. Mokyr, *ibid*., 252.

47. M. Ryan, *Knowledge Diplomacy: Global Competition and the Politics of Intellectual Property* (Washington, D.C.: Brookings Institution Press, 1998), at 26-31 (explaining the economic basis for the pharmaceutical industry's key role in shaping U.S. efforts to integrate intellectual property policy with trade policy).

research, for good economic reasons: societies will *always* under-invest in basic research if the sole determinant of the level of investment is the anticipation of profitability. The positive externalities from such investments may not be readily captured in the price of new products or services, and profound uncertainty exists until after the fact about the future commercial benefits of basic research. The urgency now attached to IP protection may in part be connected to governmental decisions to reduce public funding for scientific research, or not to increase funding at a rate sufficient to keep up with demand, meaning that private financing has emerged as a necessary complement or substitute.

A more fundamental point, which is central to understanding how and why patenting issues have come to serve as a lightning rod (some would say a target of opportunity) with respect to public concerns about biotechnology, is that some people have misgivings about the products of the biotechnology enterprise, or indeed about the justifiability of the enterprise itself. Health-related applications of biotechnology may be viewed as contributing to the medicalization of problems that are fundamentally social in origin, and ultimately to "geneticization" of health care decision making.[48] In the agricultural field, claims that biotechnology will help to feed the more heavily populated world of tomorrow are met with the argument that food insecurity today has less to do with agricultural productivity (markets for some products are in fact glutted by persistent overproduction relative to the available market) than with inequalities in the distribution of purchasing power.[49] And modifying the genomes of living organisms may be viewed as an impermissible interference with the natural order, as defined in any one of several ways. Many more examples could be provided, but these are enough to show how and why arguments for maintaining or expanding the scope of patent protection for biotechnological innovations carry little weight with people who are profoundly sceptical about whether those benefits are really benefits at all, or who believe that some applications are unacceptable under any circumstances.

48. The term used by A. Lippman, "Prenatal Genetic Testing and Screening: Constructing Needs and Reinforcing Inequalities," *American Journal of Law & Medicine* 17 (1991): 15-50.

49. S. George, *Ill Fares the Land: Essays on Food, Hunger and Power* (San Francisco: Institute for Policy Studies, 1984) at 3-15; A. Sen, *Poverty and Famines: An Essay on Entitlement and Deprivation* (New York: Oxford University Press, 1981).

III. Animal Patenting

Many of the most dramatic applications of advances in biotechnology involve genetically modified mammals.[50] The Harvard mouse exemplifies one set of applications: animals that have been modified to make them distinctively useful as models for the study of debilitating human diseases, including cancer, cystic fibrosis, and amyotrophic lateral sclerosis (ALS, or Lou Gehrig's disease).[51] The general principle is that genetic modification of laboratory animals makes possible the study of both normal and diseased physiology in ways that are simply not possible in human subjects.[52]

Genetic modifications are also being undertaken with a view (a) to making non-human mammals, specifically pigs, more useful as sources of organs for transplantation into humans by introducing human gene sequences,[53] and (b) to the use of mammals, such as sheep and goats, as bioreactors for the production of human proteins including human insulin and tissue plasminogen activators (TPAs).[54] It is now possible to envision the production of a wide variety of therapeutically valuable proteins in this manner, in much larger quantity (and perhaps at lower cost) than with existing methods. Finally, genetic modifications to livestock offer the prospect of reduced time to market; increased yields of milk, meat or eggs; and 'designed-in' characteristics such as leaner pork. Faster-growing fish, for purposes of aquaculture, represent a similar application.

Sheldon Krimsky, who has written extensively on the social and political controversies that surround biotechnology, notes that the granting of the Harvard mouse patent suggested to animal rights advocates and others that "society was regressing to an extreme Cartesian view of animals as soulless, unfeeling creatures that may be treated like machine parts."[55] With continued growth in the number of animal patents issued

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50. For a generic overview, see S. Krimsky and R. Wrubel, *Agricultural Biotechnology and the Environment* (Urbana: University of Illinois Press, 1996), at 191-211.

51. P. Aldhous, "Transgenic Mice Display a Class (Switching) Act," *Science* 262 (1993): 1212-1213; R. Brown, "A Transgenic Mouse Model of Amyotrophic Lateral Sclerosis," *New England Journal of Medicine* 331 (1994): 1091-1092; Reuters, "New Mice Created to Fight a Disease," *The New York Times*, June 21, 1994: C6; A. Shuldiner, "Molecular Medicine: Transgenic Animals," *New England Journal of Medicine* 334 (1996): 653-655.

52. Cf. Aldhous, *ibid*., at 1212: "Over the past decade, genetically engineered mice have transformed immunology."

53. See e.g. L. Fisher, "Down on the Farm, A Donor: Genetically Altered Pigs Bred for Organ Transplants," *The New York Times*, January 5, 1996: C1, C6.

54. J. Hodgson, "Whole Animals for Wholesale Protein Production," *Bio/Technology* 10 (1992): 863-866.

55. S. Krimsky, *Biotechnics & Society: The Rise of Industrial Genetics* (New York: Praeger, 1991), at 49.

Table 1: An Oversimplified Framework for Analyzing Concerns about Animal Patenting

Concern about Animal Patenting	Values or Principles at Issue
Impact on the structure of agricultural production	Self-reliance; respect for rural community and the values it purportedly embodies, symbolic significance of the 'family farm' Distributive justice: should highly capitalized dairy or livestock producers enjoy a further competitive advantage?
Increased animal suffering	Avoiding [unnecessary, unjustified] suffering to non-human sentient organisms.
Risks of xenotransplantation	Protecting public health against the spread of animal pathogens. Distributive justice: high costs of xenotransplantation, including long-term surveillance of at least the first cohort of organ recipients, place unwarranted demands on finite health care resources.

outside Canada,[56] this is just one of several objections that have arisen to the granting of patents on transgenic animals.

In an important article published a decade ago, Rebecca Dresser classified these objections under five headings: undesirable distributional consequences in terms of the structure of agricultural production and the survival of the family farm; increased animal suffering; devaluation or commodification of life; interference with the natural world; and the undesirable infusion of commercial imperatives into the organization and priorities of academic research.[57] The last three of these headings represent concerns that arise with equal, if not greater immediacy when the research and applications in question involve human genetic material. As indicated earlier, we have reserved discussion of these 'cross-cutting concerns' for section V the paper. In the

56. In mid-1998, it was reported that since the Harvard mouse "some eighty-five transgenic animal patents have been issued and, according to the USPTO about ninety more transgenic animal patents have been allowed and will issue soon." W. Feifer, "Patent Aspects of Human Cloning in the US," *Patent World* no. 102 (May/June 1998): 20-23, at 22.

57. Dresser, *supra* note 9

intervening years, at least one additional concern has arisen: the potential animal welfare and human health effects of xenotransplants (transplants of organs from non-human species into human beings), whose viability is likely to rely heavily on the commercial production of genetically modified donor animals.[58]

Table 1 provides an oversimplified and non-exhaustive framework for analyzing the values at stake with respect to each of three primary concerns about animal patenting. It is a heuristic (that is, a problem-solving) device, and that's all it is. Other concerns and other values might well be added, and any characterization of the values at stake is of course itself the topic of legitimate disagreement. The table is nevertheless useful as a starting point for further discussion, and as a matrix into which additional issues or values can be incorporated.

Concern about the impact of biotechnology patenting on farm input costs has focused primarily on crop production, and specifically on the prospect that a small number of transnational firms might control the rights to numerous genetically modified crops and be able to exploit synergies with their fertilizer and chemical businesses.[59] However, there are also reasons for concern that farmers with limited resources might be unable to afford the animals genetically engineered for higher milk yields, faster growth or higher quality meat that would give their larger and wealthier competitors a decisive advantage in the marketplace.[60] Conversely, given the gradual liberalization of North American agricultural trade a parallel concern may involve Canadian farmers' potential lack of access to patented animals developed outside Canada, in the absence of strong IP protection. Thus, a study carried out at the University of Guelph raised the possibility that "Canadian developed biotechnologies may be available in the U.S. long before they become available in Canada," and further that uncertainties about IP protection could mean that "Canadian bio-engineered products patented in the U.S. may not be available in the Canadian market. This can have significant impacts on the competitiveness of the Canadian agri-food sector,"[61] although the problem is not in fact confined to that sector.

The infliction of suffering on animals is a matter of considerable concern to Canadians, as shown by the strong public response to Department of Justice proposals in 1998 to increase the *Criminal Code* penalties for cruelty to animals. Some forms of genetic modification are likely to have few implications for animal suffering; for instance, there is little reason to think that sheep or goats that produce a human protein in their

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58. For an overview of these issues see *Report of the National Forum on Xenotransplantation: Clinical, Ethical and Regulatory Issues*, Ottawa, November 6-8, 1997 (Ottawa: Health Canada, 1998; <http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/btox/reports/frmrptx_e.pdf >.

59. See e.g. F.H. Buttel and J. Belsky, "Biotechnology, Plant Breeding, and Intellectual Property: Social and Ethical Dimensions," *Science, Technology & Human Values* 12 (1987): 31-49; C. Fowler and P. Mooney, *Shattering: Food, Politics, and the Loss of Genetic Diversity* (Tucson: University of Arizona Press, 1990), at 123-139; "Seed Industry Consolidation: Who Owns Whom?" *RAFI Communiqué*, July/August 1998.

60. C. Carpenter, in *Transgenic Animal Patent Reform Act Hearings*, *supra* note 42, at 594; Fowler and Mooney, *ibid*., at 115-123.

61. V. Amanor-Boadu, M. Feeman and L. Martin, *The Potential Impacts of Patenting Biotechnology on the Animal and Agri-Food Sector*, draft final report (Guelph, Ontario: George Morris Centre, University of Guelph, March 1995), at 90; see also 136 on the economic advantages to Canada of taking a leadership role in facilitating farm animal patenting.

milk suffer as a consequence. On the other hand, increased suffering could clearly result from the development of more transgenic animal models to study debilitating human diseases: it could be argued that suffering is in some sense the point of the exercise.[62] (This point was central to the case made by European opponents of the Harvard mouse patent.[63]) In the case of farm animals, innovations like the insertion of a human growth hormone gene into pig embryos may also lead to increased suffering -- in this case, pigs that grew faster but suffered from crossed eyes, severe arthritis and increased susceptibility to disease.[64] At least in university laboratories, institutional controls exist to minimize such suffering, in the form of federal granting agency requirements and Animal Care Committees. A more subtle, and perhaps more far-reaching problem involves the attitudinal changes that might result as genetically modified animals came to be viewed as "manufactures or compositions of matter." Once again, this is just one element of a much larger cluster of issues, discussed in section V of the report.

As for xenotransplantation, the prospect of alleviating the severe shortage of organs for transplantation is undeniably attractive, since more than 54,800 people in North America were awaiting donor organs for transplantation in 1997. Some have died while waiting, and will continue to do so given the current shortage of donor organs.[65] At the same time, in addition to animal welfare considerations – our society's routine use of animals as sources of food does not self-evidently justify their modification as sources of organs for transplantation -- substantial uncertainties exist about the potential (and perhaps unpredictable) risks from animal pathogens. The issues have been characterized in terms of individual benefit (to the transplant recipient) versus collective risk to public health[66] Resource allocation questions also arise because of the potential need for lifelong surveillance of at least the initial cohort of xenotransplant recipients, suggesting the need to balance individual and community priorities, against a background of limited health care resources.

What is the relevance of patenting to each of these concerns? In some cases, the same issues would arise in the absence of patents, and indeed might arise with greater urgency (consider, for example, trade secrecy with respect to modifying animals for purposes of xenotransplantation.) In this example as in others, the debate is really about whether, or under what conditions society should permit the particular application of biotechnology -- or, alternatively, how the application should be regulated to protect the values in question. An adaptation (Table 2) of the Table used previously can serve as a useful starting point for this discussion. Once again, it must be emphasized that the table is illustrative, rather than exhaustive. The table does, however, suggest that the link between patenting and the outcomes that some people regard as undesirable is considerably more direct with respect to the structure of agricultural production. With respect to the other

62. See e.g. S. Donnelley, C. McCarthy and R. Singelton, Jr., "The Brave New World of Animal Biotechnology" (special supplement), *Hastings Center Report* 24 (January-February 1994), at S11-S12.

63. See text accompanying notes 150-153, *infra*.

64. S. Krimsky, *Biotechnics & Society, supra* note 55 at 55; see also Donnelley et al., supra note 62, at S21.

65. G. Levy, "Overview of the Need for Xenotransplantation in Canada" (abstract), in *National Forum*, supra note 58, at 8-9.

66. F.H. Bach et al., "Uncertainty in Xenotransplantation: Individual Benefit versus Collective Risk," *Nature Medicine* 4 (1998): 141-144; see also D. Butler, "Briefing: Xenotransplantation," *Nature* 391 (1998): 321-325.

Table 2: Concerns about Animal Patenting: What's Patenting Got to Do With It?

Concern about Animal Patenting	Significance of Patenting
Impact on the structure of agricultural production	Perhaps substantial: patents are preferred mechanism for enforcing intellectual property rights on agronomically desirable animal genomes, meaning that many smaller scale or undercapitalized producers cannot pay the price and remain competitive.
Increased animal suffering	Limited: perhaps availability of patents on genetically modified animals provides an incentive to undertake further research and commercialization that may increase animal suffering.
Risks of xenotransplantation	Limited: perhaps availability of patents on animals genetically modified to increase their suitability as sources for xenotransplants contributes to commercially motivated pressures to promote xenotransplants.

concerns identified, if a link exists with patenting at all it is by way of the role that IP protection is likely to play in speeding up the commercialization or diffusion of the particular biotechnology application, by providing an incentive for private investment ... so as noted, the point at issue is really the desirability of the application, or the conditions under which it can be regarded as desirable.

This is, in itself, a useful provisional conclusion. Whether the damping effects on diffusion that might result from the difficulty or impossibility of obtaining patent protection would be a good thing or a bad thing depends, of course, on one's approach to the issues and values outlined in Table 2. Two further points must be made. First, neither patenting nor genetic engineering is a prerequisite for changing animal phenotypes in ways that reduce their welfare:

> Our homes and kennels are full of companion animals that have breed-related welfare problems, produced by selective breeding to satisfy often trivial human needs, that cause significant suffering. .... Thus, while the welfare concerns raised by genetic engineering are real, they are certainly not new.[67]

67. S. Blair and A. Rowan, "Of Mice and Men: Patents and Social Policy Issues," *Patent World*, January 1990: 36-38, at 38.

Second, the difficulty or impossibility of obtaining patent protection might lead to situations in which (a) IP protection was sought through other avenues, most probably trade secrecy, or (b) innovations rapidly entered the public domain, with the result that they would be easily accessible but also, perhaps, much more difficult to commercialize with financing from private investors. We return to these questions in section V.

IV. Human Biological Material

The Human Genome Project is an ambitious international effort to map and sequence all 100,000 or so genes that comprise the human genome.[68] In 1991 the U.S. National Institutes of Health (NIH) brought the issue of patents on human genetic material into the public eye by filing patent applications for more than 2,000 gene sequences identified as part of the Human Genome Project. These were not entire genes but rather DNA sequences whose functions were unknown. U.S. patent authorities rejected the application in September 1992, on a number of grounds that apparently had to do with the conventional requirement of utility.[69] In February 1994, NIH withdrew these and subsequent patent applications rather than appealing the initial rejection; the British Medical Research Council did the same with the applications it had filed.[70]

However, the Human Genome Project is now facing intensive competition from private firms that are also involved in human gene sequencing on a parallel track,[71] and which are aggressively pursuing IP protection for their findings. This is just one part of a picture in which various kinds of human biological material are now potentially patentable. These include tissue cultures, cell cultures, and -- as in the Moore case -- commercially valuable cell lines; innovations related to human gene therapy, which have been patented with increasing frequency at least in the United States[72]; and individual human genes with an identified function and potential commercial significance for diagnostic or therapeutic purposes. The BRCA1 and BRCA2 genes, which confer high hereditary susceptibility to breast cancer, are probably the most familiar examples in this

68. On the history of the Human Genome Project, see R.M. Cook-Deegan, "Origins of the Human Genome Project," *Risk* 5 (1993): 97-119.

69. For an argument supporting rejection of the NIH patent applications based on failure to demonstrate utility, see S. Maebius, "Novel DNA Sequences and the Utility Requirement: The Human Genome Initiative," *Journal of the Patent and Trademark Office Society* 74 (1992): 651-658.

70. C. Anderson, "NIH Drops Bid for Gene Patents," *Science* 263 (1994): 909-910.

71. On recent developments in this area see L. Belkin, "DNA is His Pay Dirt," *New York Times Magazine*, August 23, 1998: 26-31, 56-61; K. Jegalian, "The Gene Factory," *Technology Review* 102 (March/April 1999): 64-68; E. Marshall and E. Pennisi, "Hubris and the Human Genome," *Science* 280 (1998): 994-995; J. Shreeve, "The Code Breaker," *Discover*, May 1998: 44-51.

72. B. Baggot, "Human Gene Therapy Patents in the United States, January 1, 1992 to December 31, 1993," *Human Gene Therapy* 9 (1998): 1117-1118; "Human Gene Therapy Patents in the United States, January 1, 1994 to June 30, 1995," *Human Gene Therapy* 9 (1998): 977-979; "Human Gene Therapy Patents Issued in the United States, July 1, 1995 to June 30, 1996," *Human Gene Therapy* 9 (1998): 605-606; "Major Human Gene Therapy Patents Issued in the US: July 1-December 31, 1996," *Human Gene Therapy* 9 (1998): 449-452; "Major Human Gene Therapy Patents Issued in the United States: January 1 - June 30, 1997," *Human Gene Therapy* 9 (1998): 277-281; "Human Gene Therapy Patents in the United States," *Human Gene Therapy* 9 (1998): 151-157; "Major Human Gene Therapy Patents Issued in the United States: October 15 - December 31, 1997," *Human Gene Therapy* 9 (1998): 759-763; "Major Human Gene Therapy Patents Issued in the United States: January 1 to March 31, 1998," *Human Gene Therapy* 9 (1998): 1389-1392.

last category, but they are by no means the only ones. By 1996, more than a thousand patents for human DNA sequences had been granted worldwide, with 76 percent of those patents granted to private firms.[73] The article from which this figure is drawn noted that more than half of these patents have been issued by the European Patent Office (EPO) because "both the United States and Japan have been vigorously patenting human DNA in Europe."[74] A survey by the same authors using a different database, however, has identified a significantly larger role for non-profit research institutions -- specifically U.S. universities and charitable foundations -- in patenting human DNA sequences.[75] In any event, human genetic material is now the basis for a rapidly growing sector within the pharmaceutical industry,[76] and one heavily reliant on IP protection for reasons identified earlier.

As a matter of law, the patentability of human genes and gene sequences appears to have been affirmed in most of the industrialized world, including Canada,[77] with one partial exception: a consensus is rapidly emerging that patents should not be allowed on gene sequences whose utility, in industrial or commercial terms, has not been identified by the researcher or applicant.[78] There are a number of reasons for this consensus, which have to do more with the potential of such patents to inhibit subsequent research than with the perception that there is any fundamental ethical problem with patenting human biological material. Beyond this consensus, some important questions remain, as matters of ethics and public policy. Canadian geneticist Patricia Baird has cautioned that:

> There does not seem to be a mechanism within the legal system for the broader ethical, social and distributional implications of patenting human genes to be properly addressed and responded to, yet there is a need for realistic and balanced policy and law in this area. .... The issues are complex and difficult, and it is important to avoid simplistic positions. We need to seek legislative and regulatory approaches that safeguard privacy and respect human dignity, yet allow enough intellectual property protection so that innovative research is not discouraged, to the detriment of future human well being.[79]

Particularly important for purposes of the present paper is Baird's warning that:

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73. S.M Thomas et al., "Ownership of the Human Genome," *Nature* 380 (1996): 387-8.

74. *Ibid*., at 387.

75. S.M. Thomas et al., "Public-Sector Patents on Human DNA," *Nature* 388 (1997): 709.

76. "Capitalizing on the Genome" (Editorial), *Nature Genetics* 13 (1996): 1-5.

77. As noted *supra*, this does not mean that the specific claims in any particular patent on human genetic material would necessarily survive judicial scrutiny. Neither does it preclude legislative action to limit the scope of subsequent patents, within the constraints imposed by international agreements as discussed in section VI *infra*.

78. See e.g. "First North-South Human Genome Conference Adopts Declaration on Patenting of Human DNA Sequences," International Digest of Health Legislation 44 (1993): 362-3; "International Council of Scientific Unions Adopts Statement on Gene Patenting," *ibid.*: 363; C.T. Caskey et al., "HUGO Statement on the Patenting of DNA Sequences" (January, 1995); available at <http://www.gdb.org/hugo/patent.htm>; NBAC, *supra* note 34, at 52.

79. P. Baird, *Should Human Genes Be Patented*? CIAR Program in Population Health Working Paper No. 68 (Toronto: Canadian Institute for Advanced Research, 1997), at 19.

> The issues are not going to go away, and there is a need to deal with them now -- the human genome will be completely sequenced within the next seven or eight years. Simply avoiding these issues *is* a policy, in that the current interpretation of patent laws, developed to deal with inert matter, will continue to be applied.[80]

As in the case of animal patenting, we have outlined these issues in a table (Table 3), and have deferred consideration of cross-cutting concerns until the next section of the paper. It is important to emphasize, however, that one such concern -- genetic reductionism -- may arise with particular force when the subject matter in question is the human genome and by extension, at least potentially, our very definition of humanity.[81]

Probably no areas of biological and medical research has received as much attention to their ethical, legal and social dimensions as genetic diagnosis and therapy. This report cannot possibly provide a comprehensive survey of the extensive literature;[82] all we can do is extract a few key issues. The results of genetic testing or screening could be demanded, or even obtained and used by third parties without the knowledge or consent of the person in question, as the basis for discriminatory treatment in access to employment, life and disability insurance, or (in the United States) health insurance. Such discrimination based on genetic status might target either particular individuals or members of groups perceived to be at higher

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80. *Ibid.* (emphasis in original).

81. Those who think this concern overstated should consider the discussion of patenting human/non-human hybrids quoted at note 100, *infra*.

82. Among the most important recent sources are: G. Annas and S. Elias, eds., *Gene Mapping: Using Law and Ethics as Guides* (New York: Oxford University Press, 1992); P. Boyle, ed., "Public Priorities for Genetic Services," special supplement, *Hastings Center Report* 25 (no. 3, May-June 1995); T. Caulfield, "The Commercialization of Human Genetics: A Discussion of Issues Relevant to the Canadian Consumer," prepared for Office of Consumer Affairs, Industry Canada (Edmonton: Health Law Institute, University of Alberta, August 23, 1997); T. Caulfield, "The Allocation of Genetic Services: Economics, Expectations, Ethics and the Law," *Health Law Journal* 3 (1995): 213-234; E. Draper, "Social Issues of Genome Innovation and Intellectual Property," *Risk* 7 (1995): 201-230; R. Dreyfuss and D. Nelkin, "The Jurisprudence of Genetics," *Vanderbilt Law Review* 45 (1992): 313-348; E. Fox Keller, "Genetics, Reductionism and the Normative Uses of Biological Information," *Southern California Law Review* 65 (1991): 285-291; "The Genetic Privacy Act: Roundtable Panel Comments," *Journal of Law, Medicine & Ethics* 23 (1995): 360-381; M. Hall, "Insurers' Use of Genetic Information," *Jurimetrics Journal* 37 (Fall 1996): 13-22; T. Lemmens, "'What About Your Genes?' Ethical, Legal, and Policy Dimensions of Genetics in the Workplace," *Politics and the Life Sciences* 16 (1997): 57-75; Lippman, *supra* note 48; T. Murray, M. Rothstein and R. Murray, Jr., eds., *The Human Genome Project and the Future of Health Care* (Bloomington: Indiana University Press, 1996); E. Parens, "The Goodness of Fragility: On the Prospect of Genetic Technologies Aimed at the Enhancement of Human Capabilities," *Kennedy Institute of Ethics Journal* 5 (1995): 141-153; M. Rothstein, ed., *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (New Haven: Yale University Press, 1997); "Symposium: The Genome Imperative," *Journal of Law, Medicine & Ethics* 23 (1995): 309-359; N. Wivel and L. Walters, "Germ-Line Gene Modification and Disease Prevention: Some Medical and Ethical Perspectives," *Science* 262 (1993): 533-538. This is necessarily a far from exhaustive list.

Table 3: An Oversimplified Framework for Analyzing Concerns about Patenting Human Biological Materials

Concern about Patenting Human Materials	Values or Principles at Issue
Misuses of genetic diagnosis	Avoidance of harm (potential for mis-application of tests before their reliability and validity have been clearly determined). Distributive justice (potential for discriminatory use of diagnostics in employment, insurance, etc.); concern about freedom of reproductive choice, reproductive control and, at the extreme, the need to guard against eugenic applications. Avoiding discrimination: what if disabilities come to be regarded as "defects" that could have been prevented?
Privacy and confidentiality	Autonomy, privacy: Researchers may not protect anonymity when samples of genetic material are taken and become part of a data base and/or a type culture collection.
Informed consent	Autonomy (the principle of biomedical ethics from which the requirement of informed consent is derived): individuals who provide biological material may not be made aware of possible subsequent commercial uses; provisions to ensure that informed consent is obtained before samples are taken may be inadequate.
Effects on health care costs	Distributive justice; equality (e.g. as embodied in *Canada Health Act* principles) as cost of patented diagnostics and therapies puts further pressure on public health insurance budgets

'genetic risk'. The economics of the private financing of health care in the United States[83] make some such uses a virtual certainty once the technology has reached a certain stage of diffusion, and although Canada's system of universal, public health insurance largely eliminates the potential for one set of abuses, potential uses in the workplace and with respect to other forms of insurance remain a concern. Illustrating this latter point,

83. D. Light, "The Practice and Ethics of Risk-Rated Health Insurance," *JAMA,* 267 (1992): 2503-2508.

in the United Kingdom access to genetic information has been the focus of considerable conflict between official advisory bodies and the country's insurance industry.[84] A more subtle problem involves the potential misinterpretation of genetic susceptibility data in a clinical setting, where they may be used inappropriately as predictors of individual, rather than group risk; they may also be marketed directly to potential users, once again without a clear explanation or understanding of the limits of the information provided by a test result.

A separate set of privacy, confidentiality and informed consent issues arises with respect to the collection and storage of biological materials from large populations, as in the highly publicized proposals to establish a centralized genetic database involving much of the population of Iceland.[85] Because of the clarity with which most Icelandic genealogies can be traced, the population is of special interest for research purposes. The norm of informed consent to participation in biomedical research, which is a keystone concept in biomedical ethics,[86] is challenged by the prospect that data collected in such a project may at some point be used for purposes remote from the original objective of research, and indeed beyond the imagination of researchers at the time the data were collected. The problem is not unique to Iceland; it arises with respect to large scale genetic epidemiological research in general,[87] including some research efforts in Canada.[88] It may be further complicated by the overlay of considerations associated with permitting access (in the Icelandic case, temporarily exclusive access) to the database for commercial purposes,[89] either with or without the possibility of retrospective individual identification. It is also further complicated because identifying certain genetic characteristics of a population may also, by extension, link those characteristics with particular individual members of the population who may or may not ever have been consulted prior to disclosure.[90]

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84. T. Wilkie, "Genetics and Insurance in Britain: Why More than Just the Atlantic Divides the English-Speaking Nations," *Nature Genetics* 20 (October 1998): 119-121.

85. J. Hodgson, "Iceland Considers Its Genetic Future," *Nature Biotechnology* 16 (1998): 696-697; E. Masood, "Iceland Poised to Sell Exclusive Rights to National Health Data," *Nature* 396 (1998): 395; M. Specter, "DeCoding Iceland," *The New Yorker*, January 18, 1999: 40-51; S. Lyall, "A Country Unveils Its Gene Pool, and Debate Flares," *New York Times*, February 16, 1999: D1, D4.

86. T. Beauchamp and J. Childress, *Principles of Biomedical Ethics*, 4th ed. (New York: Oxford University Press, 1994), at 142-188.

87. E. Clayton et al., "Informed Consent for Genetic Research on Stored Tissue Samples," *JAMA* 274 (1995): 1786-1792; R. James, "Data Protection and Epidemiologic Research," *Science of the Total Environment* 184 (1996): 25-32; B. Knoppers and C. Laberge, "Research and Stored Tissues," *JAMA* 274 (1995): 1806-1807; M. Wadman, "'Group Debate' Urged for Gene Studies," *Nature* 314 (1998): 391; M. Wadman, "Genome Panel Defends Researchers' -- and Families' -- Interests," *Nature* 314 (1998): 826.

88. C. Abraham, "A World Gene Hunt Targets Canada," *The Globe and Mail*, November 28, 1998: A1, A12-A13 (on genetic predispositions to psoriasis in some Newfoundland communities); C. Abraham, "Let's Make a DNA Deal," *The Globe and Mail*, December 7, 1998: A1, A13 (on research on diabetes in Sandy Lake, Ontario).

89. Interestingly, one major U.S. workshop on this question recommended only that "people should be told whether they will share in the profits of any commercial products that might be developed based on findings from the research." Clayton et al., *supra* note 87.

90. This point is made with particular clarity in M. Foster,, A. Eisenbraun and T. Carter, "Communal Discourse as a Supplement to Informed Consent for Genetic Research," *Nature Genetics* 17 (November

Such questions have given rise to particular controversy with respect to collection of human biological material among isolated populations in developing countries where, as in Iceland, individual pedigrees are relatively easy to establish.[91] Such research has at times occurred with limited safeguards for research subjects, and questionable standards of informed consent.[92] The result has been intense criticism from organizations like the Rural Advancement Foundation International (RAFI) on two counts: (a) the circumstances of interactions with the populations being studied, and (b) applications for patents on human biological material obtained from such research.[93] Such problems are familiar from other contexts in biomedical ethics, but incorporate new dimensions as well, such as the need for special recognition of a distinction between biological samples as "sources" and "participants in human research [as] persons."[94] Furthermore, a key issue when genetic research crosses cultural boundaries and national borders is the appropriate definition of consent: should individual informed consent suffice, or should group consent of some sort also be required? If the latter, when and how may group refusal preclude individual participation?[95]

Financial and ethical considerations converge in terms of the potential effect on health care costs of the commercialization of human genetics. A particularly striking example comes from the United Kingdom, where one group opposed to the expansion of IP protection for biotechnology commented in 1997 on

> ... the implications of patenting for breast cancer screening. The US company, Myriad Genetics, has applied for a European patent on the breast cancer gene BRCA1, as well as on all therapeutic and diagnostic applciations resulting from the knowledge of the gene.
>
> If the patent is granted, Myriad Genetics will be able to charge patietns or the health service every time a diagnostic screening test is carried out. It currently costs the NHS some £600 to screen fo rthe two breast cancer genes which have been discovered, BRCA-1 and 2, and some £30-35 for each subsequent test: in the US, Myriad Genetics charges $2,400 (£1,500 to screen for the genes and some $500 (£300) for each subsequent test. Were similar charges to operate in the UK, the National Health Service would be unable to bear the royalty payments.[96]

1997): 277-279; see also E. Clayton, "Why the Use of Anonymous Samples for Research Matters," *Journal of Law, Medicine & Ethics* 23 (1995): 375-377 [this article appears as part of the "Genetic Privacy Act Roundtable," *supra* note 82] and S. Stolberg, "Concern Among Jews Is Heightened As Scientists Deepen Genetic Studies," *The New York Times*, April 22, 1998: A24.

91. L. Belkin, "The Clues are in the Blood," *New York Times Magazine*, April 28, 1998: 46-54, 120-1; V. Brower, "Mining the Genetic Riches of Human Populations," *Nature Biotechnology* 16 (1998): 337-40.

92. Brower, *ibid.* at 337-8; P. Kahn, "Genetic Diversity Project Tries Again," *Science* 266 (1994): 720-2.

93. Kahn, *ibid.*; J. Christie [Director of International Liaison, RAFI], "Whose Property, Whose Rights?" *Cultural Survival Quarterly* 20 (Summer 1996): 34-38. See also the responses to RAFI by J. Friedlaender and H. Greely, *Cultural Survival Quarterly* 20 (Summer 1996): 38-39.

94. Knoppers and Laberge, *supra* note 87.

95. H. Greely, "The Control of Genetic Research: Involving the 'Groups Between'," *Houston Law Review* 33 (1997): 1397-1430.

96. A. Simpson, N. Hildyard and S. Sexton, "No Patents on Life! A Briefing on the Proposed EU Directive on the Legal Protection of Biotechnological Inventions" (Sturminster Newton, Dorset, UK: Genetic

Table 4: Concerns about Patenting Human Biological Materials
What's Patenting Got to Do With It?

Concern about Patenting Human Materials	Significance of Patenting
Misuses of genetic diagnosis	Limited, although patenting can be viewed as integral to commercialization in ways that encourage inappropriate or premature promotion of genetic diagnostics, or promotion for ethically inappropriate uses.
Privacy and confidentiality	Limited, although anticipation of high returns from patented human biological materials may create an incentive for non-compliance or minimal compliance with normal standards of research ethics.
Informed consent	Limited, although patents may be part of a broader shift in norms of research and the culture of research institutions that indirectly encourages taking short-cuts.
Effects on health care costs	Patent protection may be partially responsible for the high costs of new diagnostic techniques and therapies, but may also be necessary to finance their development in the first place.

In and of itself, this example will only go so far: public health insurance programs have, after all, adapted in the past to new and costly (but beneficial) techniques. A longer-term problem may involve the possible cumulative impact of multiple, patented diagnostics and therapies at a time when cost containment is a central concern for health policy -- and the question of whether the private returns generated are defensible, as a matter of distributive justice. In the Canadian context, the prospect that rising costs might undermine governments' ability to maintain the egalitarian values that are central to the *Canada Health Act* is likely to create particular concern. At the same time, it is essential to consider the counter-argument that without patenting and the financial incentives it provides, genuinely beneficial diagnostic and therapeutic techniques may not become available at all, or (if they do) will take longer to reach the market.

As in the case of animal patenting, the preceding discussion and Table 4 both suggest that many of the concerns are not IP issues *per se*, and are best dealt with in other policy arenas. For example, it is the pressure

Engineering Monitoring Project, September 1997).

to generate returns on substantial investment, rather than any characteristic of patenting per se, that is likely to lead to inappropriate marketing and promotion of genetic diagnosis and therapy[97]; similarly, insufficient attention to privacy and informed consent in medical genetic research probably have more to do with changes in the corporate culture of universities in response to resource constraints, and a general "pro-commercialization environment,"[98] than they do with patenting *per se*.

This having been said, a much broader and perhaps more fundamental range of apprehensions includes the possibility that logical extrapolation from existing conceptual categories may lead us to accept applications of biotechnology that we might otherwise reject, perhaps eventually including such outcomes as the chimaeric, disposable companion in Joan Bernott's enigmatic story "The Test-Tube Creature, Afterward"[99] or the eugenic practices depicted in Aldous Huxley's *Brave New World*. Such speculations are not confined to the world of science fiction. A particularly thought-provoking recent law journal article on the links among IP, biotechnology and international trade observes that:

> Industry is presently engaged in developing technological improvements in order to blur distinctions between species. If stringent legal requirements are not immediately developed, the term 'human being' is likely to become inherently ambiguous. The definition of 'person' should be under-inclusive in order to maximize potential industrial applications while reinforcing humanity's present notions of existence. Presently the [U.S.] PTO grants patents only to non-human transgenic animals. If industry were to develop a hybrid mammal, simultaneously playing down physical and intellectual human genetic traits, then presumably the PTO would be confronted with an ever encroaching rejection of its former patent policies. This process could occur either through the downward genetic manipulation of human embryos or through the upward engineering of mammals. Upward engineering of genetic material is already patentable. Downward patentability should also exist; otherwise, other countries could adopt strategic behavior by designing domestic regulatory regimes that take into account hybrid mammals involving significant human genetic material.
>
> The implication of the above proposition is clear -- future transgenic humanoids and hybrid derivatives could end up constituting a human underclass. Although this sis morally repugnant, there does not seem to be a better outcome. The prevailing international climate of strategic behavior and the enormous profit potential of product development for industrial application dictates [*sic*] such a situation.[100]

This is perhaps an appropriate note on which to turn to the discussion of cross-cutting issues that arise with respect to IP protection for higher life forms more generally.

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97. Caulfield, "Commercialization," *supra* note 82, at 18-33.

98. *Ibid*., at 8-9; see also 33-36.

99. J. Bernott, "The Test-Tube Creature, Afterward," in H. Ellison, ed., *Again, Dangerous Visions*, v. 2 (New York: New American Library, 1972): 24-28.

100. Pepa, *supra* note 1, at 445-446, citations omitted.

V. Cross-Cutting Social and Ethical Issues

Outcomes like the creation of disposable chimaeras for specific purposes exemplify what people are concerned about when they claim that allowing the patenting of higher life forms will lead to the devaluation of life, or the inappropriate commodification or objectification of life and living organisms. Commodification refers to the association of something or some practice with attitudes that ordinarily accompany a certain subset of commercial transactions.[101] Objectification similarly refers to the act of treating someone, or something, as a commodity, but what is disturbing is not so much the exchange of money as it is the notion that a subject, a moral agent with autonomy and dignity, is being treated as if it can be used as an instrument for the needs or desires of others without giving rise to ethical objections.[102] This can mean equating the 'worth' of the subject with her, or its, market value; it can also mean treating or thinking of the person or creature as the kind of entity that can be acquired or traded by way of market exchanges *or* transactions that look like market exchanges (in other words, they are governed primarily by the norms of reciprocity) even if no money changes hands. Thus, the concern is that with the widespread patenting of animals or of human biological materials we might come to think of both in ways more appropriate to the "manufactures" referred to in patent legislation. The language of some discussions of genetically modified animals appears to lend weight to this concern[103] ... but so does the language used in describing some animals bred using strictly conventional methods.[104]

A further set of concerns involves the potential for genetic reductionism, in which human beings and non-human creatures alike will come to be seen as "gene machines," in Margaret Somerville's words,[105] whose characteristics and behaviour are mechanically and straightforwardly determined by genetic makeup. People concerned about genetic reductionism are not reassured by claims that "the development of a human being is guided by just 750 megabytes of digital information [which] could be stored on an single CD-ROM," or by

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101. S. Altman, "(Com)modifying Experience," Southern California Law Review 65 (1991): 293-340; M. Radin, "Reflections on Objectification," *Southern California Law Review* 65 (1991), 341-354; M. Radin, "Justice and the Market Domain," in R. Pennock and J. Chapman, eds., *Markets and Justice* (New York: New York University Press, 1989): 165-197.

102. M. Shapiro, "Fragmenting and Reassembling the World: Of Flying Squirrels, Augmented Persons, and Other Monsters," *Ohio State Law Journal* 51 (1990): 331-374, at 351; Radin, "Reflections," *supra* note 101, at 345.

103. For instance, references to genetically modified animals as "production systems" or "production vessels" for human proteins: Hodgson, *supra* note 54, at 866.

104. Cf. the advertisement promoting one cattery's Bengals as having "tomorrow's wilder look today," *Cat Fancy*, April 1999, at 64.

105. M. Somerville, "Are we Just 'Gene Machines' or Also 'Secular Sacred'? From New Science to a New Societal Paradigm?" *Policy Options* 16 (March 1996): 3-6.

references to genes as "cassettes" that control the behaviour of an organism.[106] Concerns about reductionism and about objectification may both be magnified by the high-profile prospects of cloning numerous genetic copies of a single organism. In the context of medicine and public health, an additional concern is the diffusion of simplistic genetic explanations for phenomena that are more appropriately viewed in terms of complex interactions of biological, social and environmental factors.[107]

There are, in fact, two distinct forms of the arguments from commodification, objectification or genetic reductionism, although critics of IP protection for animals and human biological material often fail to draw a clear distinction between the two forms.[108] The deontological form of the argument is exemplified by the 1995 statement that announced the formation of a coalition of religious bodies to call for reversal of the US policy of allowing patents on genetically modified animals and on human biological materials. The statement said, in part: "We believe that humans and animals are creations of God, not humans, and as such should not be patented as human inventions."[109] Philosopher Barry Hoffmaster has been strongly critical of this position, noting that it is intellectually unsatisfactory because it amounts to stating a conclusion as a substitute for argument, and indeed has called it "moral sloganeering."[110] To this he might have added its questionable appeal for agnostics.

However, arguments that biotechnology patenting is intrinsically wrong need not rely on creation science or on specifically religious grounds. They could instead assert the inappropriateness of interfering with what Margaret Somerville has called the "secular sacred,"[111] and rely on the premise that living organisms, as the end points of a lengthy process of evolution, should not be patentable as human inventions even if genetically altered through human intervention. More difficult than recasting the objection in these terms is constructing it in a form that is, in fact, an argument -- that is, a form susceptible to refutation.

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106. M. Olson, "A Time to Sequence," *Science* 270 (1995): 396; see generally D. Kevles, "Vital Essences and Human Wholeness: The Social Readings of Biological Information," *Southern California Law Review* 65 (1991): 255-278.

107. Dreyfuss and Nelkin, *supra* note 82; Fox Keller, *supra* note 82; Lippman, *supra* note 48; S. Wolf, "Beyond 'Genetic Discrimination': Toward the Broader Harm of Geneticism," *Journal of Law, Medicine & Ethics* 23 (1995): 345-353. [This article appears as part of the symposium on "The Genome Imperative," *supra* note 82].

108. As, for example, when a spokesperson for Greenpeace International states that: "We consider the patenting of living beings and genetic resources as such to be immoral. Therefore, we request a ban on the patenting of life. Our concerns are actually based on several reasons. Among others, we think that allowing the patenting of life leads to the classification of life as the product of an industrial process, an artificial commodity. We believe patents should only be granted for inventions that are in the public interest ..." I. Meister, commentary in Sterckx, ed., *supra* note 32: 185-188, at 185.

109. Quoted in R. Stone, "Religious Leaders Oppose Patenting Genes and Animals," *Science* 268 (26 May 1995): 1126; see also E. Andrews, "Religious Leaders Prepare to Fight Patents on Genes," *The New York Times*, May 13, 1995: A1, A19.

110. C.B. Hoffmaster, "The Ethics of Patenting Higher Life Forms," *Intellectual Property Journal* 4 (1989): 1-24, at 4.

111. Somerville, *supra* note 105.

Table 5: An Oversimplified Framework for Analyzing Cross-Cutting Concerns about Patenting Animals and Human Biological Materials

Cross-Cutting Concern	Values or Principles at Issue
Commodification or objectification; devaluation of life (In either the consequentialist or deontological form of the argument)	Respect for life and living organisms, either on religious grounds or with reference to the "secular sacred" Treating human beings and other sentient organisms as ends in themselves, rather than means to an end (*and thus*) guarding against exploitation or the infliction of undue suffering.
Genetic reductionism	Respect for life and living organisms as more than "gene machines" Avoiding distractions from the social and environmental dimensions of disease causation in human beings in favour of mechanistic genetic explanations.
Effects on the scientific enterprise	Beneficence: commercially motivated delays in disclosing research results may limit the benefits from research. Beneficence: restrictions on the availability of research materials (e.g. genes, transgenic animal models for study of human disease) as well as research results limit the benfits from research, may even inflict harm.

The consequentialist version of the concerns just identified is easier to construct in such a form, starting with the idea that patenting genetically modified animals or human biological materials, along with the associated transformation of these into routine objects of commerce, will over time lead to a change in people's attitudes toward life and living organisms. Here, too, an appeal can be made to the idea of the "secular sacred," so the values and principles at stake are broadly the same as in the deontological objection, although the form of the argument is not. Such claims, which Scott Altman has called "modified-experience claims," are extremely difficult to evaluate until after the events that will supposedly lead to a change in attitudes have actually occurred.

Perhaps, then, such claims should not be used as the basis for public policy,[112] since at least according to some observers the available precedents suggest that worries about the erosion of respect for life are overstated.[113] On the other hand, consider the fact that couples in both Canada and the United States can already choose, for purposes of implantation, among embryos created *in vitro* using gametes provided by donors whose characteristics are known.[114] Although uncommon and now very expensive, the technique could well become more broadly popular as a way of 'improving' offspring. Especially when combined with the prospect of modifying embryos *in vitro* as well as selecting them the result could be a transformation of such "noncontingent bonds" as those between parents and children, mediated by technology and purchasing power.[115] This example suggests that some available precedents may no longer be relevant in a world of patented mice and human genes, a world in which leading scientists can talk of men with wings.[116] Conversely, it could be argued that expanded scientific knowledge of the common genetic heritage shared by humankind with other species will actually enhance our respect for life, including human life, and its complexity.[117] From this perspective the explosion of scientific knowledge that underpins human capacity for genetic modification and manipulation may lead either to reductionism or to reverence.

For better or for worse, scientific research has been transformed by the infusion of commercial considerations. The growth of mutually beneficial university-industry collaboration in the life sciences, whose

112. Altman, *supra* note 101, at 308.

113. *Ibid*., at 308-334.

114. G. Kolata, "Clinics Enter a New World of Embryo 'Adoption'," *The New York Times*, November 23, 1997, s. 1: 1,18; R. Harvey, "Human eggs sold to rich couples: They pay up to $27,000 to conceive test-tube babies," *Toronto Star*, February 22, 1998.

115. Altman, *supra* note 102, at 305, is not particularly sympathetic to this argument, but describes it clearly and fairly: Once it has been demonstrated that parents can control the characteristics of their children, at least if they have enough money, then: "Control over the characteristics of their children could lead those who fail to control their children's characteristics to reject, emotionally or physically, the imperfect child. The ability to increase the intelligence, attractiveness, or talent of one's offspring might create a taste for perfection. Noticing that one wants better children could make clear that people want children with certain qualities for selfish reasons, leaving observers in the cynical cycle of viewing relations as instrumental."

116. "If enough money and research are put into human and bird genome research, we could no doubt put a bird's wings on a man." C. Venter and D. Cohen, "The 21st Century: The Century of Biology," *New Perspectives Quarterly* 1997 (special issue): 26-31, at 29. The authors are among the world's leading innovators in sequencing the human genome. In *Modest_Witness@Second_Millennium: FemaleMan©_Meets_OncoMouse™* (London: Routledge, 1997), historian of science Donna Haraway provides a thoughtful and eclectic exploration of how familiar conceptual frameworks might change in such a world.

117. Cf. The comment of a biologist quoted by J. Levine and D. Suzuki, *The Secret of Life: Redesigning the Living World* (Toronto: Stoddart, 1993), at 10-11: "We all knew that evolution was true, but now, every time I pick up a cell, I have the same amazement. These genes really are there, and they are the same genes across species. A little bit of tinkering here and there, that's all. We really are connected to all these organisms."

most conspicuous feature may be the increasing number of startup firms arising from those collaborations,[118] is potentially exciting in both intellectual and economic terms. On the other hand, a leading biotechnology trade journal warns life scientists against conducting even informal conversations that might jeopardize the subsequent patentability of their findings.[119] Michael Heller and Rebecca Eisenberg of the University of Michigan Law School recently commented on the consequences of "a spiral of overlapping patent claims in the hands of different patent owners, reaching ever further upstream in the course of biomedical research."[120] One example of such "upstream" consequences is the effect of patenting on the availability of research tools, whether those 'tools' are techniques of DNA sequencing or new varieties of genetically modified laboratory mice.[121]

The effects of IP protection on research are not always clear or predictable. A 1996 workshop held by the U.S. National Academy of Sciences found that in some situations, such as those involving protein and DNA sequencing instruments, strong patent protection had actually promoted broad access.[122] Other situations suggest the value of an observation made at the workshop by Leon Rosenberg of Bristol-Myers Squibb: "The biomedical research community has not yet truly grappled with the possibility that a large number of genes could be controlled by the rights of a relatively small number of parties who could not possibly hope to fully exploit their potential value."[123]

In contrast to upstream effects, delays in publishing research results might be called a 'downstream effect' of commercial considerations. In the United States, recent national surveys of life science company executives and university faculty have found that both considerations of patentability and other commercial

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118. See e.g. "Capitalizing on the Genome," *supra* note 76; NBAC, *supra* note 34, at 38-42.

119. K. Williams, "When is a 'Private' Conversation 'Public' Disclosure?" *Bio/Technology* 12 (May 1994): 523-525.

120. M. Heller and R. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research," *Science* 280 (1998): 698-701, at 698. This question was also the topic of a session at the 1998 Annual Meeting of the American Academy for the Advancement of Science; see A. Hopen, "1998 AAAS Annual Meeting Debates Human Gene Patents: Promoting Innovation or Strangling Research? (Coral Gables, FL: Lott & Friedland, <http://patentfla.com/genetic.htm>).

121. National Research Council, *Sharing Laboratory Resources*, *supra* note 6; National Research Council, *Intellectual Property Rights and Research Tools in Molecular Biology*, Summary of a Workshop held at the National Academy of Sciences (Washington, D.C.: National Academy Press, 1997) <http://www.nap.edu/readingroom/books/property>.

122. National Research Council, *Intellectual Property Rights*, *ibid*., chapter 5 (note that pagination is not available because the electronic version of this source document was used for purposes of this report).

123. *Ibid*.; cf. Pepa, *supra* note 1, at 427-428 (citations omitted): "Major pharmaceutical companies now pay a premium for important discoveries because the acquisition of certain genes can help them to generate new products. As a corollary, large corporations are developing DNA data banks in human tissue in order to strategically target important discoveries. As a result, outside researchers wishing to use the proprietary information in the data banks are essentially forced to cede commercial rights to any discoveries that may result.".

concerns have often delayed publication of research results.[124] Delays in publication are not necessarily reprehensible.[125] Furthermore, it is important for purposes of public policy to consider the broader interactions among the requirements of IP protection, the decline in public sector support for basic research, and the associated reorganization of university priorities around fund-raising. Since the start of the decade, the gap between levels of federal funding available in Canada and south of the border, in particular for medical research, has widened dramatically.[126] However the transformation of research and education priorities has important implications for the public interest, almost regardless of how one defines that vexatious phrase, because "in the end, the commercialization of university-based research may rob Canadian consumers of a valued and unique quality control mechanism -- the independent academic researcher."[127]

Asking about the significance of patenting with respect to these cross-cutting concerns yields a variety of answers, as shown in Table 6. For those whose concern is rooted in what they see as an intrinsic conflict between patenting and respect for life, patenting *is* the problem. For those whose concerns are primarily consequentialist in nature, patenting is one element of a potentially undesirable trend of commodification or commercialization, albeit perhaps an integral part because of its role in attracting investment to this field of endeavour. The key here is to consider particular situations rather than generalizing about the consequences of IP protection for biotechnological innovations, always keeping in mind both the multiple values that must be balanced and the fact that many issues commonly linked to patents on biotechnology are, in fact, best dealt with outside the IP policy arena.

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124. D. Blumenthal et al., "Relationships between Academic Institutions and Industry in the Life Sciences -- an Industry Survey," *New England Journal of Medicine* 334 (1996): 368-73; D. Blumenthal et al., "Withholding Research Results in Academic Life Science: Evidence from a National Survey of Faculty," *JAMA* 277 (1997): 1224-8. The survey of faculty found that almost 20 percent of respondents "reported that publication of their research results had been delayed by more than 6 months at least once ... Of those, 46% reported delays to allow time for patent application; 33% to protect the proprietary value of research results by means other than patent applications; 31% to protect their scientific lead; 28% to slow dissemination of undesired results; 26% to allow time to negotiate licence agreements: and 17% to resolve disputes over intellectual property." Blumenthal et al., "Withholding Research Results," at 1226. On the other hand, effects on overall productivity were ambiguous: "On average, faculty members who withheld research results published 4 more articles in the last 3 years than nonwithholding faculty." *Ibid.*, at 1228.

See also E. Campbell, K. Louis and D. Blumenthal, "Looking a Gift Horse in the Mouth: Corporate Gifts Supporting Life Sciences Research," *JAMA* 279 (1998): 995-999; Caulfield, supra note 83; Haraway, *supra* note 116, at 89-101.

A European perspective is provided by Collen, supra note 33, at 73, who notes: "My personal attitude has always been, when we make contracts with the industry, to insist that we can publish and communicate our results *as soon as possible*, meaning usually not more than one month *after the submission of a patent application*" (emphasis added).

125. See text accompanying notes 129-132, *infra*.

126. NBAC, *supra* note 34, at 34-37.

127. Caulfield, "Commercialization," *supra* note 82, at 36.

Table 6: Cross-Cutting Concerns about Patenting Animals and Human Biological Materials: What's Patenting Got to Do With Them?

Cross-Cutting Concern	Significance of Patenting
Commodification or objectification; Devaluation of life; Genetic reductionism (deontological form of arguments)	Critical: patenting, or the policy of allowing patents, *are* the acts or policies that offend against the values or principles at issue
Commodification or objectification; Devaluation of life; Genetic reductionism (consequentialist form of arguments)	Limited; related to the incentive that patenting provides for commercialization of genetically modified animals and human biological materials, and the resulting changes in human attitudes and perceptions.
Effects on the scientific enterprise	In some cases, patent protection as it is now provided may substantially inhibit scientific research, e.g. by restricting access to research materials. In other instances, the problem does not involve IP protection, but rather such factors as (a) inappropriate commercialization, for reasons that have nothing to do with the availability of patent protection, or (b) inadequate, or inadequately enforced, standards of research ethics. In any event, even critics of the effects of patenting on scientific research suggest not abandoning patents, but rather modifying the rights they confer.

Two illustrations may help to clarify these points. The first is a hypothetical example, albeit one modeled closely on a real case,[128] in which university-based medical researchers who think they have made a major breakthrough that could lead to the development of an AIDS vaccine hold off publishing their findings for several months until a patent application can be drafted and filed. It could be argued that the delay is ethically reprehensible, since immediate publication would place the findings in the public domain, making them more rapidly available to other researchers. In fact, patent law in most jurisdictions (including Canada and

128. As reported by J. Sher, "London Team Seeks Patent on Potential AIDS Vaccine" *London Free Press*, October 16, 1998: A1, A16.

the United States) now allows a patent application to be filed up to one year after publication.[129] However, as Rebecca Eisenberg points out, "research may yield publishable results before it yields a patentable invention. In this situation publication of early results could prevent patenting of later-developed inventions emanating from the same research if the publication makes the subsequent inventions 'obvious'."[130] Commercial prudence, in such a situation, might dictate erring on the side of non-publication -- particularly since if early publication were to render subsequent inventions unpatentable, the effect would be to undermine the ability of any firm to raise the financing needed to bring any resulting vaccine to the commercial market. It is far from clear that any government or non-profit agency could or would mobilize the necessary resources to do so.[131] Among the IP protection options, only trade secrecy constitutes a viable alternative, and it is an inferior option for a whole range of reasons, starting with the fact that trade secrecy rests on a presumption of *permanent* non-disclosure. In other words, the short-term unavailability of the research findings pending the filing of a patent application may be an essential prerequisite for the commercialization of the findings, and hence for the realization of their long-term benefits.

In the second illustration, Stanford University law professor Henry Greely[132] has examined the undoubtedly serious problem of the potential commercial exploitation of biological materials obtained from indigenous or remote populations.[133] He concludes that a "no patents" policy is probably not a solution to the problem of achieving distributive justice in apportioning whatever financial returns might be involved, and in any event would be extremely difficult to achieve. (It should be added that such a policy, in and of itself, does nothing to address norms of informed consent or appropriate restrictions on disclosure, which could be treated just as cavalierly in a no-patents environment.) Entrusting sovereignty over indigenous peoples' genomes to national governments is, he says, an even worse option given the track record of such governments, despite this option's central place in the 1992 Biodiversity Convention. Other approaches would insist that biological

129. *Patent Act*, s. 28.2(1); on the U.S. "grace period" see *Sharing Laboratory Resources*, *supra* note 9, at ch. 2.

130. R. Eisenberg, "Patent Rights in the Human Genome Project," in Annas and Elias, eds., *supra* note 82: 226-245, at 230.

131. Or if it did, it would thereby be giving up the opportunity to invest in some other, equally worthwhile health protection venture. A strong ethical case could, in fact, be made for an international, intergovernmental consortium to finance an AIDS vaccine -- perhaps under the auspices of the WHO -- because of the special significance to some of the poorest countries in the world. The point is that only the private sector can *consistently* mobilize the needed resources across a whole range of potentially valuable biopharmaceutical products.

132. Greely chairs the ethics subcommittee of the North American Committee of the Human Genome Diversity Project (HGDP). HGDP is a loosely organized international collaboration of scientists who share the aim of surveying genetic diversity among the world's human populations. It has been the target of much criticism from groups like RAFI, even though the research they have criticized was carried out independently of HGDP and Greely himself has been highly critical of some of that research. See Brower, *supra* note 91, at 339.

133. H. Greely, "Genes, Patents, and Indigenous Peoples," *Cultural Survival Quarterly* 20 (Summer 1996): 54-57. See also Greely, *supra* note 95 and, for further explication, A. Wellington, "'Rewriting Genesis': Intellectual Property Rights and Global (In)Justice" (in press).

materials be uncompensated gifts to researchers, or else would rely on negotiations between researchers and individual members of a study population. The approach Greely regards as preferable would be organized around group decisions both about participation in research and about the terms of compensation. "The community could decide to allow patents or to ban patents, to prohibit commercialization or to benefit from it, to participate in the research or not participate in it."[134] This is, of course, not an IP policy in itself, but rather a solution in which IP policy flows from the implementation of a more general set of principles concerning the relationships between researchers and subjects.

Here, as throughout the report, it needs to be emphasized that patenting is neither the only, nor even the most significant issue of concern. If patenting of all contentious biological material were banned or renounced tomorrow, that would do nothing to resolve the fundamental questions about what constitutes appropriate consent, or about how to maintain appropriate levels of respect for human dignity, while ensuring technological progress and development in the biomedical field. Likewise, allowing for expansive IP protection will not obviate the need to ensure the protection of privacy, or the need to treat research subjects and participants with proper care and concern.

Those who resist increasing commercialization in the health care sector, as in other parts of society, will reject broader patenting practices, but their real (and legitimate) concern is the overall speed and scope of commercialization. Those who actively promote patenting may be doing so from a perspective that, at least from the point of view of their critics, identifies the 'public interest' too uncritically with the expansion of opportunities for profitable investment. Against this background, uncompromising clarity in analyzing the connections between values and the implications of particular legal and public policy options is especially important.

134. Greely, "Genes ...", *ibid.*, at 57.

VI. The International Context: Trade Policy and Market Access Considerations

VI.A NAFTA and TRIPs Commitments

Canadian IP policy is constrained by the provisions of several international agreements -- most importantly, NAFTA and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), which is a component of the GATT and which has been described by Georgetown University's Michael Ryan as "the first agreement of the new knowledge diplomacy."[135] The two agreements contain virtually identical provisions on potential exclusions from patentability, quoted below from Article 27 of TRIPs (the parallel provisions are found in Article 1709 of NAFTA):

> 1. Subject to paragraphs 2 and 3, patents shall be available for any new inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. .... [P]atents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

This provision might create problems were any IP regime to create special preconditions for patenting biotechnology innovations that are not applied to innovations of other kinds, and do not fit clearly within one of the following categories of permissible exclusions:

> 2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by domestic law.
>
> 3. Members may exclude from patentability:
>
> (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
>
> (b) plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this sub-paragraph shall be reviewed four years after the entry into force of the Agreement Establishing the WTO.

TRIPs incorporates in a footnote, and NAFTA in the text of the agreement itself, the equation of the terms "inventive step" and "capable of industrial application" with non-obviousness and utility.

Although both NAFTA and TRIPs may now be regarded as *faits accomplis*, it is important to recall that NAFTA and its predecessor agreement, the Canada-U.S. Free Trade Agreement, were the subject of considerable political controversy in Canada at the time of their adoption, and that the same continues to be

135. Ryan, *supra* note 47, at 201.

true of TRIPs in a number of developing countries.[136] S.K. Verma argues that "the conclusion of the TRIPs Agreement was made possible by the strong-arm tactics used by the United States in the form of the 'Section 301' action under its Trade Act, 1974, against the developing countries, particularly the NICs who were the reluctant partners in the negotiation."[137] Indian philosopher and social commentator Vandana Shiva has gone even farther in her critique of TRIPs, contending that: "Five hundred years after Columbus, a more secular version of the same project of colonization continues through patents and intellectual property rights .... The vacancy of target lands has been replaced by the vacancy of target life forms and species manipulated by the new biotechnologies."[138]

As Shiva's comments suggest, developing country policies toward IP protection are likely to reflect deeply divergent views of what such countries have to gain, or to lose, by implementing such protection -- views that are in turn linked to both domestic and international political economy. Such divergent approaches reflect not only considerations of political economy, but also competing perspectives at the level of economic theory. On the one hand, Robert Sherwood assumes for purposes of a comparative study of IP regimes in 18 developing countries,

> ... that a national intellectual property regime which works well serves public welfare by upgrading the technical base of the country, preparing the ground for creation and exchange of advancing technology, and fostering greater human resource development in technical fields. In short, the stimulus to expanding a country's stock of technical knowledge is materially increased and the stimulus to investment in useful development of that knowledge is likewise increased.[139]

On the other hand, Michael Trebilcock and Robert Howse of the University of Toronto suggest reasons for scepticism about the presumed benefits of international harmonization of IP protection:

> [A] requirement of strengthened protection, in the case of at least some sectors, could increase economic welfare in some countries while reducing it in others. Mandated stronger protection for intellectual property rights is not necessarily, therefore, Pareto-superior -- and must be justified instead as a fair bargain or trade-off between the competing or conflicting economic interests of different states.

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136. See e.g. Pepa, *supra* note 1, at 431-432 (on India's position); Ryan, *supra* note 48, at 109-110 (on the Indian and Brazilian positions).

137. S.K. Verma, "TRIPs – Development and Transfer of Technology," *IIC* 27 (1996): 331-364, at 334.

138. V. Shiva, *Biopiracy: The Plunder of Nature and Knowledge* (Boston: South End Press, 1997), at 81. For a somewhat less polemical corroboration of many aspects of the preceding analyses, specifically the role of key U.S.-based transnational corporations in shaping U.S. policy before and during the TRIPs negotiations and the U.S. strategy of using Section 301 sanctions in bilateral relations with its trading partners as a way of making TRIPs look like the less unpalatable alternative, see Ryan, *supra* note 48.

139. R. Sherwood, "Intellectual Property Systems and Investment Stimulation: The Rating of Systems in Eighteen Developing Countries," *IDEA: Journal of Law and Technology* 37 (1997): 261-370, at 262 (citation omitted).

> In addition, it is highly questionable whether increased protection is even Kaldor-Hicks efficient -- i.e. whether the gains to economic welfare to countries who benefit from stricter protection outweigh the losses to those countries who lose by it.[140]

In other words, there may be a sound basis in economic theory for the reluctance of many developing countries to implement the same kind of IP protection available in the industrialized world. Because of that reluctance, from a commercial point of view a formal national commitment to TRIPs at the level of IP law is only part of the picture, and indeed may turn out to be less significant than implementation and enforcement in developing countries. This is, in turn, likely to vary substantially among, and even within, jurisdictions all of which are signatories to TRIPs.[141]

VI.B Trade Policy, Reciprocity and Market Access

Quite apart from the letter of the law, intellectual property policy and trade policy are increasingly interconnected, as are trade policy and policy with respect to foreign investment. In both areas, reciprocity is an important consideration that underpins not only agreements like NAFTA and TRIPs, but also the ongoing politics of trade. As the National Biotechnology Advisory Council pointed out in its most recent annual report: "A country does not provide IP protection to foreigners for altruistic reasons; it provides that protection to guarantee access for its own important inventions in foreign markets."[142] A highly trade-dependent nation like Canada, in particular, cannot realistically make policy on biotechnology patenting in isolation from the policies of its major trading partners and potential investors.

For purposes of the Canadian biotechnology industry the market of most immediate concern is the United States. In terms of the commercial prospects for Canadian biotechnology, the availability of patent protection in the United States may be considerably more significant that its availability in Canada, simply

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140. M. Trebilcock and R. Howse, *The Regulation of International Trade* (London: Routledge, 1995), at 253. In economic theory, "Pareto superiority" refers to moving closer to the ideal state in which all the mutually beneficial voluntary exchanges (of goods, services or individuals' own labour) have been consummated. At this point, the society's allocation of resources is 'optimal' in the sense that it maximizes the welfare of all members; otherwise, they wouldn't have engaged in the exchanges.
Given any initial distribution of resources, there is only a limited number of voluntary exchanges in which both parties will win, and few public policies are 'win-win' situations for everyone involved. Consequently, economists who are trying to assess the effects of public policy often substitute the Kaldor-Hicks criterion of *potential* Pareto improvement in welfare, usually as measured by increases in national income or product. The rationale for this shift is that the increase in society's (or the province's, or the region's) available resources means that the winners from any policy change could fully compensate the losers, and still have some net gains left over. This neatly shifts questions of distributive justice into the political realm, where resources are unequally distributed just as they are in the marketplace.

141. Sherwood, *supra* note 139.

142. NBAC, *supra* note 34, at 51.

because of the relative size of the two markets.[143] However, were Canadian firms perceived as enjoying a competitive advantage by virtue of substantially weaker or less extensive patent protection than they enjoy in south of the border, the discrepancy would soon draw political attention. Given the extensive array of trade remedies available under U.S. legislation,[144] as well as the United States' demonstrated willingness to deploy these sanctions on a bilateral basis,[145] we could anticipate substantial adverse effects on Canadian industry and on private sector research investment. Indeed, to some degree the same may be true with respect to the Canadian regulatory environment:

> Industrial strategy, both on the national and international level, will not be arrested by moral difficulties. .... Government regimes designed to limit or eliminate certain biotechnology research are shortsighted when viewed through the wider lens of trade considerations. In the end, anti-genetic regulatory regimes will achieve little in the way of maintaining the moral high ground if industry simply moves elsewhere.[146]
>
> Industry is in the process of becoming global. Countries must be conscious of the fact that domestic biotechnology firms may be wholly owned subsidiaries of foreign-based corporations. Thus, trad disputes will no longer be based on protecting national positions arising out of private commerce. Rather, private commerce will make use of multiple jurisdictions in order to obtain comparative advantage. .... Thus, a country's strategy must look simultaneously inward and outward when structuring a domestic regulatory regime on genetic research.[147]

It is therefore very important that any discussion of the social and ethical dimensions of patenting animals and human biological material distinguish between (a) the IP regime that we might wish to implement were a similar regime to be in place elsewhere in the world, and (b) the IP regime that appears most desirable given those regimes currently in place elsewhere, particularly among our major trading partners and competitors for capital investment.

VI.C European IP Law: A Study in Contrasts

European patent law provides an intriguing contrast to the U.S. and Canadian regimes, in a number of ways.[148] Article 53(a) of the European Patent Convention (EPC), to which all EU countries are now signatories, requires that patents not be granted on "inventions the publication or exploitation of which would be contrary to 'ordre

143. James G. Heller Consulting, *Background Economic Study of the Canadian Biotechnology Industry*, prepared for Industry Canada, Environment Canada and Health Canada (Ottawa: Industry Canada, 1995), at 119-20, 198-9.

144. Ryan, *supra* note 47, at 42-46; Trebilcock and Howse, *supra* note 140 at 259-62.

145. Pepa, *supra* note 1, at 430-431; Ryan, *supra* note 47, at 73-88. The dispute early in 1999 over Canadian legislation to prevent the spread of split run editions of U.S. magazines is another case in point.

146. Pepa, *supra* note 1, at 416.

147. *Ibid*., at 436.

148. See the overview by Sigrid Sterckx, "European Patent Law and Biotechnological Inventions," in Sterckx, ed., *supra* note 32: 1-54.

public' or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States." In dealing with the Harvard mouse application, an Appeal Board of the European Patent Office (EPO), which is responsible for administering and interpreting the EPC, took the position that "EPO Examining Divisions," responsible for the initial evaluation of patent applications, "are not permitted to avoid the evaluation of ethical provisions" under Article 53(a).[149] This represents a direct contrast with the North American situation, in which no statutory basis exists for evaluating a patent on ethical grounds. The Examining Division thereupon took the position that although considerations of animal suffering were relevant, but also that Article 53(a) permitted a balancing of benefits against harms, and that the basic interest of mankind in remedying dangerous diseases outweighed considerations of animal suffering.[150] This conclusion was in keeping with the reasoning of the patent applicants[151] but not, at least for some time thereafter, with that of the European Parliament.[152] The EPC also provides for an opposition procedure in which interested parties have nine months following the grant of a patent to file objections;[153] this procedure has been used by 'public interest' intervenors like Greenpeace,[154] as well as those motivated by commercial concerns.

149. L. Gruszow, "Types of Invention in the Field of Genetic Engineering, Arising in the Practice of the European Patent Office," in Sterckx, ed., *supra* note 32: 149-158, at 150. Gruszow is a patent lawyer with more than 20 years' experience in the EPO.

150. B. Baggot, "Patenting Transgenics in the European Union," *Biotech Patent News* <http://biotechpatent.com/biotech/baggot_eu.html>; Gruszow, *supra* note 149, at 150; R. Teschemacher, "Legislation, Existing Practice in the EPO, Japan and USA," Conference Document for the Symposium Biotechnology and Intellectual Property, Stockholm, November 23-24, 1993 (Munich: EPO, mimeo), 7-8. On the inadequacy of the guidance provided by the EPC with respect to this balancing exercise, see Sterckx, *supra* note 148, at 42-45.

151. "Although some animal subject matter may be 'immoral,' our position has always been that the Harvard mouse is the essence of a moral invention because it offers the possibility of more expeditious development of potential new cancer treatments (surely a desirable aim), and allows overall for a reduction in the amount of animal testing and the extent of animal suffering.... Using animals for testing purposes (in a strictly controlled manner) is a 'necessary evil,' given the requirements of drug clearance authorities. The provision of a type of animal which might actually reduce the amount of experimentation has, we feel, rightly to be regarded as moral." R. Bizley, "Patenting Animals in Europe," *Bio/Technology* 9 (July 1991): 620-621, at 620.

152. Sterckx, *supra* note 148, at 14-15.

153. *Ibid*., at 19-20.

154. As it has been in the case of the Harvard mouse. "In the US," on the other hand, "the Animal Legal Defense Fund (ALDF) sued the US Patent Commissioner; the case was summarily dismissed because the ALDF was told it had no standing to sue. That is why the Harvard mouse patent did not face the same opposition that it faced in Europe." Baggot, "Patenting Transgenics," *supra* note 150 at n. 2. For a more detailed discussion of the ALDF's initiative, see D. Kell, "The Furore over the Patenting of Animals: Animal Legal Defense Fund v. Quigg," *European Intellectual Property Review* 8 (1992): 279-283.

Exclusions from patentability are also provided for in the European Union's recent Directive on the legal protection of biotechnological inventions (Directive 98/44), which was passed by the European Parliament in 1998 after more than a decade of sometimes acrimonious debate.[155] The relevant provisions are as follows:

> Article 5:
>
> 1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
>
> 2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.
>
> 3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

This third section is intended to prevent the speculative patenting of gene sequences that do not meet the criterion of utility.[156]

> Article 6:
>
> 1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
>
> 2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:
>
> (a) processes for cloning human beings
>
> (b) processes for modifying the germ line genetic identity of human beings;
>
> (c) uses of human embryos for industrial or commercial purposes;
>
> (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

155. On the history of this debate see e.g. B. Dixon, "Who's Who in European Antibiotech," *Bio/Technology* 11 (1993): 44-48; C. Ho, "Building a Better Mousetrap: Patenting Biotechnology in the European Community," *Duke Journal of Comparative and International Law* 3 (1992): 173-201; J. Hodgson, "Europe, Maastricht and Biotechnology," *Bio/Technology* 10 (1992): 1421-1422; N. Jones, "Biotechnological Patents in Europe -- Update on the Draft Directive," *European Intellectual Property Review* 14 (1992): 455-457; S. Crespi, "The European Biotechnology Patent Directive is Dead," *Trends in Biotechnology* 13 (May 1995): 162-164.

156. See the discussion of this point in text accompanying note 78, *supra*.

Thus, both the EPC and Directive 98/44 repudiate the North American pattern of providing minimal exclusions from patentability.[157] Commenting on the European situation, one U.S. patent lawyer has argued "that the American view should be the world view, so to speak, that morality should practically speaking have nothing to do with patents."[158] A similar view has been expressed by at least one European academic specializing in patent law,[159] reflecting the view of some members of the IP law and policy community that the grant of a patent is "*ethically neutral*" because it is logically and legally independent from actual commercialization of an innovation as well as from public policy decisions about particular uses.[160]

What do these contrasts mean in practice, in terms of what is likely to constitute patentable subject matter? The short answer is: with one possible exception,[161] probably not much. Ulrich Schatz, a lawyer with more than 20 years' experience in the EPO, points out that no patent has ever been refused or revoked on grounds related to Article 53(a),[162] and there are good reasons to suppose that this will continue to be the case. Both the EPC and Directive 98/44 clearly indicate that it is the exploitation of an invention, rather than the nature of the invention per se, that is at issue with respect to assessment of the implications for "ordre public and morality". In the *Plant Genetic Systems* case, which involved an opposition filed by Greenpeace to a patent on herbicide-resistant plants and seeds, the EPO's Technical Board of Appeal held that evidence "that the exploitation of the invention ... would seriously prejudice the environment" might provide grounds for revoking a patent, but that the law requires "that the threat to the environment be sufficiently substantiated at the time the decision to revoke the patent is taken by the EPO". However the evidence of environmental harm brought forward by Greenpeace was, said the Board, not "conclusive".[163]

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157. Cf. the comment of Baggot, "Patenting Transgenics," *supra* note 150, at n. 2: "[T]he directive's prohibition on patents against public policy will continue to give Greenpeace legal standing to challenge biotechnology patents."

158. R. Schapira, "Biotechnology Patents in the United States," in Sterckx, ed., *supra* note 32: 171-172, at 172.

159. "I feel that the European Patent Office should ... model itself on the American Supreme Court, which stated explicitly — in the Chakrabarty case — that it is not competent to rule on ecological and ethical matters and that such issues should be addressed by the political branches of government." G. Van Overwalle, "Biotechnology Patents in Europe: From Law to Ethics," in Sterckx, ed., *ibid.*: 139-148, at 147.

160. S. Crespi, "Biotechnology Patenting: The Wicked Animal Must Defend Itself," *European Intellectual Property Review* 9 (1995): 431-41, at 435 (emphasis in original); see also S. Crespi, commentary in "The Case For and Against the Patenting of Biotechnological Inventions," in Sterckx, ed., *supra* note 33: 219-238.

161. The patentability of plant and animal "varieties" is allowed for by the Directive while proscribed by the EPC. I. Fürst, "EU and EPC Prepare for Patent Fight," *Nature Biotechnology* 16 (1998): 321. However, even before the Directive's passage the EPO had demonstrated considerable flexibility in the definition of a "variety" for purposes of applying the exclusion.

162. U. Schatz, "Patents and Morality," in Sterckx, ed., *supra* note 32: 159-170, at 159.

163. Decision of the Technical Board of Appeal, *Greenpeace Ltd. v. Plant Genetic Systems N.V., et al.* (February 21, 1995), IIC 28 (1997): 75-90, at 80.

Such issues of the standard of scientific proof are familiar from the context of environmental regulation, and can be expected to come up with some frequency in controversies about biotechnology. Schatz argued in 1998 that the provisions of the EPC would probably render a technique of human germ line gene therapy unpatentable under the EPC, because even in countries where such therapy is not actually prohibited it is now regarded at ethically unacceptable, although this might not always be the case.[164] Directive 98/44 has now rendered that particular example moot, along with a few more potentially controversial areas involving human biological material. It is difficult, however, to envision a situation in which the Article 5 and Article 6 exclusions will extend beyond the enumerated examples.

164. U. Schatz, "Patentability of Genetic Engineering Inventions in European Patent Office Practice," *IIC* 29 (1998): 1-16, at 13.

VII. Potential Policy Initiatives and Responses

Introduction

The discussion that follows is divided into (A) policy initiatives and responses in the domain of IP law and policy, and (B) those outside that domain. This reflects the provisional conclusion, stated at a number of points in preceding sections of the report, that some of the concerns associated with IP protection for higher life forms genuinely involve IP issues, but many others are best dealt with in other ways and in other policy arenas. A number of these responses challenge the presumption that any regime of IP protection can be "ethically neutral"[165] when it involves certain kinds of living subject matter; each of them could well be the topic of considerably more detailed investigation.

VII.A Responses Involving IP Law and Policy

VII.A.1 Subject Matter Exclusions

The European Union has now adopted the approach of defining a number of specific categories of subject matter that may not be patented: the human body; processes for cloning human beings; processes for germ line modification; the use of human embryos for industrial or commercial purposes;[166] and processes for genetic modification of animals that "are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes." It remains to be seen whether or not these restrictions will be seen as exhausting the range of inventions excluded by the reference to "ordre public or morality." The EPC's decision in *Plant Genetic Systems* suggests that (for instance) inventions whose exploitation would demonstrably result in major environmental damage would not be considered patentable subject matter. The decision further suggests that the standard of proof demanded from those challenging EPC patents on such grounds will be sufficiently demanding that no one would seek to patent such an invention, given the slender prospects of commercialization.

Canada currently has no analogous statutory restrictions, which means (for example) that decisions about whether processes for human cloning and germ-line modification constitute patentable subject matter, like the decision about the Harvard mouse, are up to CIPO in the first instance and ultimately to the courts. Is this a satisfactory situation? Alternatively, should certain kinds of subject matter be excluded by statute,

165. See the text accompanying notes 159-161, *supra*.

166. Although the Directive does not refer to human gametes, applications for patents on modified gametes would probably be rejected on the basis that they constitute processes for modifying the human germ line.

with reference to considerations of ordre public or morality, or under the provisions of NAFTA and TRIPs that permit the exclusion of animals or methods of medical diagnosis and treatment from patentability? If so, should the exclusions be general (e.g., simply incorporating the language of ordre public and morality into the *Patent Act*) or specific, as in the EU Directive? (In either scenario, CIPO and the courts will obviously continue to play an interpretive role.) Should there be explicit statutory provision for a balancing test involving animal welfare and potential human benefit, of the kind applied (without adequate statutory guidance) in the case of the EPC patent on the Harvard mouse?[167] What are the chances that a statutory subject matter exclusion, introduced with the best of intentions, might subsequently have consequences that were socially, ethically or financially destructive? These are among the hard questions that must be asked with respect to subject matter exclusions.

VII. A.2 Infringement Exemptions

As a response to concerns about the potential inhibiting effects of patents on scientific research, infringement exemptions constitute an alternative to outright subject matter prohibitions. In the U.S. context, Rebecca Eisenberg has suggested that one approach would be "to protect researchers who later use patented research tools developed with government funds from liability." Another "would be to deny patent holders an injunctive remedy against research users, but permit them to recover a reasonable royalty as damages."[168] She concedes that both approaches "amount to compulsory licenses for research users of patented inventions, although only the latter is a royalty-bearing compulsory license. If they are perceived as such, they may be opposed throughout the industry."[169] It is not clear at what point the expansion of exemptions related to research uses would come into conflict with the provisions of NAFTA and TRIPs.[170] Nevertheless, Eisenberg argues, concern about the vitality of the research enterprise should make governments wary of over-protecting intellectual property, as well as of under-protecting it.

Infringement exemptions have also been used to address other concerns about the negative social and ethical impacts of expansive IP protection. The United States has moved towards this approach for patents relating to medical procedures,[171] by way of a provision that specifically denies to the owners of patents on medical procedures patents "the right to seek remedies from medical practitioners, i.e., doctors and

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167. See discussion accompanying notes 150-153, *supra*.

168. Eisenberg, *supra* note 19

169. *Ibid.*

170. Article 30 of TRIPs and Article 1709.6 of NAFTA each provide for "limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not *unreasonably* conflict with a *normal* exploitation of the patent and do not *unreasonably* prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties" (in the TRIPs wording) or "other persons" (in NAFTA; all emphases added).

171. P.L. 104-208, passed in 1996. On the trend toward patenting medical procedures see S. Chartrand, "Why Is this Surgeon Suing? Doctors Split over Patenting of Their Techniques," *The New York Times*, June 8, 1995: D1, D5.

hospitals."[172] Inventors and their employers can still obtain patents for medical procedures, but cannot rely upon them to sue doctors and hospitals. All the other rights arising from patent ownership remain intact. The amendment responded, in part, to the well publicized case of Dr. Samuel Pallin, who was awarded a patent for "no-stitch" cataract surgery and subsequently filed suit against other surgeons, claiming royalties. The suit and the resulting outcry "stimulated a campaign to introduce legislation preventing the grant of such patents."[173] The American Medical Association had recommended even stronger measures: precluding medical procedure patents, along with patents for new uses of known compounds for therapy and diagnosis and gene therapy applications.[174] The bill that was eventually passed was considerably weaker than these recommendations. Although medical procedures in and of themselves are outside the scope of this report, it is certainly conceivable that continued advances in human genetics will in time make it difficult clearly to distinguish what constitutes a 'procedure' as distinguished from a diagnostic or therapeutic product.

VII.A.3 Opposition Procedures

Like the United States, but unlike the EPC countries, Canada lacks an opposition procedure through which interested parties can challenge the grant of a patent once issued. On purely commercial grounds, there are reasons to want such a procedure: Graham Strachan of Allelix has noted that:

> Such a system would introduce a degree of rigor into the Canadian patent examination process that would enhance both the quality and the strength of granted patents. Few of the emerging Canadian biopharmaceutical companies can afford the expense of a court action for patent impeachment, the only avenue presently available to remove suspect patents.[175]

With reference to the example of a broad patent for epidermal growth factor, which had the effect of eliminating important business opportunities for a Canadian firm,[176] the NBAC's *Sixth Report* recommends the introduction of an opposition procedure with a six-month time limit (rather than the nine months allowed under the EPC), with the observation that: "An effective opposition process would have provided an opportunity to restrict the scope of the Canadian claims to be similar to those in the United States."[177]

Should Canada institute an opposition procedure? If such a procedure were to be put in place, two critical questions about its content and design would arise. The first of these, of course, relates to the substantive bases for opposition, and its resolution depends in part on whether legislative amendments have specified certain categories of subject matter as unpatentable. Even if this has not happened, however, one can

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172. M. Kaminski, "United States - Legislative Update: What Happened in 1996?" *Patent World*, January 1997: 8.

173. "International News," *Patent World*, June/ July 1996: 10-11.

174. Kaminski, supra note 172.

175. Strachan, *supra* note 42. .

176. See discussion in text accompanying notes 34-35, *supra*.

177. NBAC, *supra* note 34, at 54.

envision a situation in which 'public interest' groups objected to the issuance of a particular patent, for instance on the grounds that the claims in question were excessively broad. Hence, the second question: who should have standing to oppose the awarding of a particular patent? Should standing be limited to those with an actual or potential commercial interest? At one extreme, the EPC's procedure is essentially wide open as regards issues of standing, allowing opposition by "any person". At the other extreme in the United States, which as noted has no opposition procedure, the Animal Legal Defense Fund (ALDF) tried to sue the U.S. Commissioner of Patents to block the issuance of the Harvard mouse patent on procedural grounds, but the Federal Circuit court held that ALDF could not establish standing in the case[178] -- a barrier that is familiar from numerous efforts at 'public interest' litigation in the field of environmental law.

VII.A.4 'Upstream' Ethics Review Requirements

Some concerns about the social and ethical implications of biotechnology patenting might be addressed by requiring that compliance with certain standards be demonstrated at the time a patent application is filed. For example, the European Parliament's Committee on Development and Cooperation proposed that Directive 98/44 include the requirement that patent applications identify the origins of plant or animal materials that are the subject of an invention, and "provide[] evidence to the patent authorities that the material was used in accordance with the legal access and export provisions in force in the place of origin." Further, it was proposed to require applicants for patents involving biological material of human origin to identify "the name and address of the person of origin," and to show "that the material has been used and the patent applied for with the voluntary and informed agreement of the person of origin, their legal representative or relatives," although this information would not be publishable.[179] In the event, these proposals were not adopted, although their intent was reflected in a number of preambular sections ("Recitals") of the Directive.

It is certainly conceivable that a number of social and ethical concerns about the patentability of animals, or of inventions derived from human biological materials, could be addressed by way of analogous upstream conditions. With respect to animal welfare, where there are some controls on use for laboratory purposes but no formal controls on marketing, such upstream conditions might involve the requirement that a patent application incorporate an ethics preclearance signed off on by animal care specialists, with reference to such items as humane practice with respect to the use of the animal on which a patent was sought (perhaps including impermissible uses). Required elements of the patent application package might include the text of a 'user manual' that would specify humane practice and would be required to accompany a particular, genetically modified animal.[180] With respect to human biological material, it is possible to envision a similar preclearance procedure that would make reference to codes of conduct with respect to research involving

178. Kell, *supra* note 154, at 281.

179. European Parliament Committee on Legal Affairs and Citizens' Rights, Report on the Proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions, A4-0222/97 (25 June 1997).

180. The ideas in this paragraph rely largely on M. Keaney (Director of Animal Care and Veterinary Services, University of Ottawa), personal communication, March 1999.

human subjects, including the proposed model protocol for collection of human DNA samples under the auspices of the Human Genome Diversity Project (HGDP),[181] and the Policy Statement on research involving human subjects recently released by Canada's three federal granting councils.[182] Since each of these codes engages a much broader range of ethical considerations than those specific to IP issues, they are discussed separately in the next section of the report.

VII.B Responses Not (Directly) Involving IP Law or Policy

VII.B.1 Codes of Research Ethics

The model ethical protocol for the HGDP,[183] which was drafted at least partly in response to intense criticism of researchers who collect human biological material from indigenous populations, is organized under nine headings: what should be done before contacting the population; how contact should be made; the requirements for informed consent, with special reference to the potential tensions between individual and group consent; the basis on which benefits should be provided to participating populations; medical services for participating populations; privacy and confidentiality; the responsibilities of researchers to combat the racism that is almost inescapably associated with research on human genetic differences by way of educational initiatives; questions of ownership and control of biological material; and the nature of partnerships with participating populations. It is complex, potentially demanding, and a brief summary cannot possibly do it justice.

The model protocol also, at present, has no binding force apart from the commitment of individual researchers. By contrast, the Tri-Council Policy statement will in time, subject to the vagaries of implementation at individual institutions,[184] will bind all research institutions receiving funds from any of the three granting councils. Philosopher Michael McDonald of the University of British Columbia, who was co-chair of the working group that drafted the Policy Statement, has been strongly critical of a number of the changes that were made by the granting councils subsequent to the working group's final report.[185] Some of

181. "Model Protocol: Proposed Model Ethical Protocol for Collecting DNA Samples," *Houston Law Review* 33 (1997): 1431-73; on the reasoning behind the protocol see Greely, "The Control of Genetic Research," *supra* note 95. (Greely chaired the committee that drafted the protocol.)

182. *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (Ottawa: Medical Research Council of Canada, 1998); <http://www.mrc.gc.ca/ethics/english/index.htm>.

183. *Supra*, note 181.

184. Which may constitute a fatal flaw in some cases; see "Protecting and Promoting the Human Research Subject: A Review of the Function of Research Ethics Boards in Canadian Faculties of Medicine," *NCBHR Communiqué* 6 (no. 1, Winter 1995): 3-32.

185. M. McDonald, "The Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans," *Canadian Bioethics Society Newsletter* 3 (October, 1998). The earlier report, "Code of Ethical Conduct for Research Involving Humans" (Prepared by the Tri-Council Working Group, July 1997) is available at <http://www.ethics.ubc.ca>.

these criticisms may be directly relevant to the ethical dimensions of IP protection. For example, a portion of the working group's draft requiring that "researchers and REBs [research ethics boards] must endeavor to distribute equitably the potential benefits of research,"[186] which admittedly invites considerable debate around the notion of equity, was removed from the Policy Statement. Another of McDonald's criticisms is that the chapter of the working group's draft that dealt with the ethics of research involving vulnerable groups or collectivities was replaced by a chapter of general principles for research involving aboriginal peoples, without any corresponding specific requirements.[187] Notes McDonald, "there is much less concern with cultural and other types of group difference in the PS [Policy Statement] than in the Code. This move toward reductive individualism has serious negative implications not only for social science research, but also for research in other areas, e.g., genetics and population health research."[188] He further observes, in a comment that illuminates the hard politics of research ethics, that "university research offices were cool to the proactive provisions of the Code" because "empowering REBs might make it harder to attact researcher dollars."[189] Perhaps most significantly, the Policy Statement will have no effect on research conducted outside institutions that receive federal funds, or outside Canada.

In and of themselves, codes of research ethics are of great value *if* they go beyond codifying present practices, and can go a long way toward addressing misgivings about the (mis)applications of the biotechnology enterprise. However, if a connection between such codes and the patenting process were institutionalized, their effectiveness could be leveraged by (a) attaching sanctions, in the form of denial of IP protection, to codes that might otherwise be strictly advisory, and (b) extending the scope of application of such codes beyond institutions receiving funding from specified sources, and indeed possibly outside Canadian borders. Whether this is a good thing or a vexatious impediment to commerce is likely to be topic of considerable debate if and when more specific proposals emerge.

VII.B.2 Genetic Privacy Legislation

In the United States, generic concerns about the discriminatory use of genetic information are magnified by the reliance of much of the population on private health insurance. Insurance companies survive and prosper by minimizing actuarial risk, using whatever information is available.[190] In response to concerns about genetic privacy, three professors of health law drafted a proposal for a national Genetic Privacy Act (GPA), which would have imposed a national prohibition on the collection and use of human DNA samples without the detailed informed consent of the individual in question or her representative.[191] The proposed Act,[192] which was

186. *Ibid*., Article 6.2.

187. *Ibid*., chapter VII; *Policy Statement*, *supra* note 183, s. 6.

188. McDonald, *supra* note 185, at 14.

189. *Ibid*.

190. Light, *supra* note 83; Wolf, *supra* note 107.

191. For the provisions of the proposed Act, see G. Annas, L. Glantz and P. Roche, "Drafting the Genetic Privacy Act: Science, Policy and Practical Considerations," *Journal of Law, Medicine & Ethics* 23 (1995):

unsuccessfully introduced into at least one state legislature (Maryland's), itself "[did] not prohibit the use of genetic information by employers and insurance companies," although the authors (in their words) believed "it would be reasonable public policy to prohibit both employers and health insurance companies from using genetic information in making employment and coverage decisions."[193] Ironically, the Act's organization around the concept of privacy rather than the concept of discrimination may mean its authors failed to address the primary economic motivations for the erosion of genetic privacy.

Canadian jurisprudence on genetic information and privacy under federal and provincial human rights statutes and under the *Charter of Rights and Freedoms* is underdeveloped. At the policy level, in 1992 a report by the office of the Privacy Commissioner of Canada argued that the ethical principle of autonomy entailed an expectation of genetic privacy.[194] The report recommended general prohibitions on employer collection of personal genetic information, with some exceptions, but did not clearly recommend separating access to services or benefits from consent to genetic testing.[195] The report recommended strong protection against third-party use of information collected in the course of ordinary medical care,[196] but did not propose principled restrictions on governmental collection of genetic information.[197] The report did warn that "the private sector has at least as much leeway as government, and likely significantly more, to intrude on personal privacy" with respect to genetic information.[198]

A detailed analysis of genetic privacy issues is outside the scope of this report, and for the most part it is safe to conclude that they are probably not amenable to resolution through IP law and policy. They are out there, however. Defining the appropriate uses of a body of human genetic information that is likely to expand exponentially in the near future represents an important legal and ethical challenge, which includes not only the identification of appropriate uses but also acknowledging the potential need to balance privacy

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360-366 [this article appears as part of the "Genetic Privacy Act Roundtable," *supra* note 82]; P. Roche, L. Glantz and G. Annas, "The Genetic Privacy Act: A Proposal for National Legislation," *Jurimetrics Journal* 37 (Fall, 1996): 1-11.

192. Available electronically at <http://www-busph.bu.edu/Depts/Health Law/>.

193. Annas et al., "Drafting," *supra* note 191, at 361. On the weaknesses of existing U.S. federal law in the area of employment, see Draper, *supra* note 82; on health insurance, see H. Davis and J. Mitrius, "Recent Legislation on Genetics and Insurance," *Jurimetrics Journal* 37 (Fall 1996): 69-82; K. Hudson et al., "Genetic Discrimination and Health Insurance: An Urgent Need for Reform," *Science* 270 (1995): 391-393; K. Rothenberg, "Genetic Information and Health Insurance: State Legislative Approaches," *Journal of Law, Medicine & Ethics* 23 (1995): 312-319 (this article appears as part of the "Genome Imperative" symposium, *supra* note 82).

194. Privacy Commissioner of Canada, *Genetic Testing and Privacy* (Ottawa: Supply and Services Canada, 1992), at 30-31.

195. *Ibid*., at 32-34. Such exceptions or qualifications call into question the entire notion of uncoerced consent.

196. *Ibid*., at 42.

197. *Ibid*., at 59-69.

198. *Ibid*., at 79.

considerations against legitimate medical research objectives.[199] As a matter of public perception, such issues are unlikely to remain separable from IP concerns if the challenge is not met by way of initiatives in other policy fields.

VII.B.3 The "Transgenics Agency" Proposal

In 1996 political scientist William Leiss, who has recently specialized in issues of risk definition and communication, argued that "the creation of transgenic entities through science and engineering is a sufficiently distinctive process that it could itself be the subject of a regulatory agenda under separate legislation,"[200] under the control of an agency that would be a joint venture of Health Canada and Environment Canada.[201] This proposal relies on two assumptions: (a) that transgenic entities *prima facie* require a specialized regulatory regime with respect to health, safety and environmental impact and (b) that inadequacies have been demonstrated, or can be anticipated, in the existing regime. Both assumptions are highly contentious. At the same time, intriguing items of information such as the fact that biopharmaceuticals derived from transgenic animals "cannot be terminally sterilized and [therefore] great attention must be paid to the safety and quality of the starting materials, the manufacturing process, and the quality and safety testing of the final product"[202] suggest that such proposals are not inherently unreasonable.

The transgenics agency proposal, whatever its specific merits within the existing Canadian framework of regulatory institutions, is important as an indication that the distinctive capabilities of today's (and tomorrow's) biotechnologies may demand novel policy responses that demonstrate government's ability to articulate the 'public interest,' however it may be defined. Some of the attention patenting has attracted is undeniably due to the simple novelty of the idea that the particular genome of living, sentient organisms can be the subject of IP protection. That novelty, in turn, is just one indication of the transformative potential of new ways of placing biological processes at the service of human ends.

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199. See e.g. James, *supra* note 87; P. Reilly, "The Impact of the Genetic Privacy Act on Medicine," *Journal of Law, Medicine & Ethics* 23 (1995): 378-381 (this article appears as part of the "Genetic Privacy Act Roundtable," *supra* note 82).

200. W. Leiss, in *Minutes of Proceedings and Evidence*, House of Commons Standing Committee on Environment and Sustainable Development (June 11, 1996), at 4.

201. *Ibid.*, at 16.

202. "Production of Biopharmaceuticals from Transgenic Animals," in *Overview and Background Breakout Session Papers*, *supra* note 16, at 16.

Appendix A: Potential Plan for a Public Consultation on Patenting of Animals and Human Biological Materials

Day One

8:30 - 8:45	Welcome and Initial Announcements
8:45 - 12:00	Plenary Session Four presentations on key issues and challenges
	Lunch
1:15 - 3:45	First set of concurrent breakout sessions (Four — two each on animal patents and patents on human biological materials, with the understanding that concurrent issues will be dealt with in the second set of breakout sessions)
3:45 - 4:15	Break
4:15 - 5:15	Reports back from breakout sessions
7:00	Reception and dinner (possibly including keynote speech)

Day Two

9:00 - 12:00	Second set of concurrent breakout sessions (Four — all addressing the concurrent issues identified in this paper, along with any new ones identified in reports back from first breakouts)
	Lunch
1:15 - 2:15	Reports back from breakout sessions
2:15 - 2:30	Break
2:30 - 4:00	Plenary discussion, including comments by at least some of the speakers from Day One's morning session.
4:00	General conclusions, indications of next steps, etc.