Patenting of Higher Life Forms and Human Biological Materials: An Introduction to the Issues

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Authors' Preface

In January, 2000 this paper was revised in response to three external reviews as well as comments from several government sources. In January and February, 2001 it was revised to take into account developments during the year 2000 in the litigation involving the Harvard mouse patent, to update a number of other points, and to reflect the comments of an additional reviewer.

Both academic reviewers of the previous draft expressed concern about the brevity of the paper, given the range of issues to be covered; a communications strategist, conversely, worried about the difficulty of some of the material. We are sympathetic to both perspectives, but view this paper as a manageable introduction to a complicated field of law, public policy and ethics that has until recently been the domain of specialists. It is a starting point, a point of entry into the debate, and only that. Readers interested in more information – and we hope there are many such readers – are encouraged to start by consulting the list of resources at the end of the paper.

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I. Introduction

The twenty-first century may well be the century of biologically based industry, just as the last decades of the twentieth century were driven, in a technological sense, by the integrated circuit. Canadians have a particular stake in the development of knowledge based industries like those arising from biological research, because of our historically high (and precarious) reliance on commodity exports.

Intellectual property (IP) protection is currently a focus of legal reform around the world, indicative of the crucial role of knowledge based industry in modern economies. Many industrialized countries are pinning their hopes of competitiveness in the new international political economy on an expansion of intellectual property rights. Contemporary business interests have set out to expand the purview of patents, in particular, into areas of recent technological innovation and application, such as biotechnology. These efforts have not gone uncontested. Social activists and academics have been strongly critical of many aspects of the expansion of IP rights. One of the most prominent sites of contestation presently is the issue of patenting transgenic animals (see Box 1). In addition, some scholars question the evidence linking patent protection either with economic gains, or with the widespread diffusion of socially beneficial research findings.

Canada needs to develop a comprehensive policy position on the patenting of higher life forms and human biological materials.[1] Because we do not now have such a policy, an important

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1 For purposes of this document, "higher life forms" are defined as multicellular organisms, and "human biological materials" as biological materials or products of human origin or intended for incorporation into the human phenotype or genotype, including but not necessarily limited to DNA sequences, cell lines, tissues, and organs.

dispute about the scope of patent protection for one particular transgenic animal, the so-called Harvard mouse, has been left to the courts to resolve without any guidance beyond that provided by current legislation. Future patent applications could involve not only transgenic animals, but also such innovations as human tissues or organs grown in the laboratory from human embryo stem cells (Box 3). Thus, a proactive approach to the social and ethical issues involved in patenting the results of advanced biological research is needed.

Box 1: Transgenic animals: Transgenic animals are those whose normal genetic makeup has been changed by the incorporation of one or more genes from another species.

The genetic makeup of the Harvard mouse, perhaps the best known such animal, has been modified by the incorporation into a mouse embryo of a gene that confers high susceptibility to tumours (an 'oncogene sequence'). The mice that carry the gene, which is transmitted to future generations in accordance with the principles of Mendelian inheritance, are valuable in laboratory studies of cancer. Genetically modified animals are also under development as sources of human proteins in relatively large quantities, and of organs for transplantation into human beings ('xeno-transplantation').

Patent protection for transgenic animals attracts criticism both from those who think that it is inherently wrong to claim intellectual property rights over the genetic blueprint of animals, and from those who worry that such a practice would lead to such undesirable outcomes as a decline in respect for the sanctity of life. Apprehensions of this second kind are invoked as an objection to many areas of biotechnology research and development. Thus, the criticism involves more than just patenting transgenic animals.

An element of urgency is present, as well, because IP issues are part of the ongoing agenda in negotiations to create a Free Trade Area of the Americas (FTAA). These negotiations began in 1994 and are scheduled for completion by the year 2005; as of January, 2001, Canada had made no submissions to the FTAA Negotiating Group on Intellectual Property Rights. IP issues are also likely to be central to any future multilateral trade negotiations under the auspices of the World Trade Organization (WTO), as national governments seek to improve their competitive position in the global economy.

This discussion paper was prepared as one step in a long history of federal government initiatives to explore the social and ethical implications of biotechnology. These initiatives began with research commissioned in 1993/94, and included a series of national consultations on renewal of the Canadian Biotechnology Strategy. One result of those consultations was the establishment of the Canadian Biotechnology Advisory Committee (CBAC), which advises the Biotechnology Ministerial Coordinating Committee – consisting of the Ministers of Industry, Agriculture and Agri-Food Canada, Health, Environment, Natural Resources, Fisheries and Oceans and Foreign Affairs and International Trade – on the full range of policy issues related to the development and application of biotechnology in Canada.

II. Understanding Intellectual Property and Biotechnology

II.1 Patents and Intellectual Property: Nuts and Bolts

In simplified terms, an inventor who applies for a patent is applying for the grant of a limited monopoly. If a patent is awarded, the patent holder may be either the inventor or an 'assignee' such as a university or a for-profit corporation to which the inventor has agreed to turn over rights to the patent. The patent holder is entitled to *exclude others* from making, selling or using the invention covered by the patent for a specified period of time (currently 20 years) from the date of filing. In return for that limited term monopoly, a patent application must provide sufficient detail to enable the ordinarily skilled worker in the field to reproduce the invention, which can legally be done either through licensing arrangements or once the patent has expired. In Canada, the contents of a patent application must be disclosed no later than 18 months after the application is filed, whether or not a patent is awarded.

Canada's *Patent Act* 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." The applicant for a patent must demonstrate:

- *novelty*: the invention must be new, and with some exceptions must not have been disclosed publicly before a patent application was filed;
- *utility* or usefulness: the invention must have some potential industrial or commercial application; and
- *non-obviousness:* the invention must not be obvious to someone with the relevant specialized skills.

In these respects, Canadian patent law is substantially similar to the regimes that are in place elsewhere in the industrialized world.

Box 2: Expressed sequence tags (ESTs) are short sequences of DNA used by scientists to identify much longer sequences of which they are a part, even though what the sequence does in the human body may not yet be known.

In November 1998, the U.S. Patent and Trademark Office issued the first U.S. patent for an EST, thus intensifying concerns that were already widespread within the scientific community about whether researchers would have to negotiate licences for each EST they wish to use for purposes of their own work: a time-consuming and costly process.

It was once thought that patent applicants' inability to demonstrate the utility of ESTs would prevent the granting of patents. However, the potential for use as a research tool may now be sufficient to demonstrate utility, and at least in the United States attention is shifting instead to the appropriate scope of patent claims involving ESTs: will a subsequent patent claim to a much longer, functional DNA sequence that includes a patented EST be disallowed?

An important distinction exists in patent law between discoveries, which are not patentable, and inventions. A DNA sequence in a purified and reproducible form, which makes it commercially useful, is considered patentable, although some critics argue that this should not be the case because the inventive step is not substantial enough to justify granting IP protection to the products that result. A similarly contentious issue, having to do with utility rather than with the distinction between discoveries and inventions, involves the granting of patents on expressed sequence tags, or ESTs (Box 2). In January 2001, the US Patent and Trademark Office issued new guidelines to the effect that: "You can patent a gene but only if it meets a three-prong test of utility – that is, having specific, credible and substantial uses," in the words of a US official.

Patents cannot be granted for "any mere scientific principle or abstract theorem." Also not patentable are: medical or surgical treatments; schemes or plans, or methods for doing business. Previously, Canada's *Patent Act* contained an exclusion from patentability applicable to "an invention that has an illicit object in view." This exclusion was not meant to be a 'morality clause,' and the passage was removed from the *Patent Act* as part of a package of legislation aimed at bringing various Canadian statutes into compliance with the provisions of the North American Free Trade Agreement (NAFTA). The *Patent Act* also provides that the Canadian Nuclear Safety Commission (CNSC) must receive notice of any patent application related to nuclear energy, although the section does not appear to give CNSC a role in rejecting patents on grounds not elsewhere specified in the *Act*.

A patent application consists of several parts: the disclosure and the claims. In the disclosure section, the applicant describes the invention, and provides background information, often including drawings. Disclosure must show how to make and use products, or must set out the various steps and sequence of any process. The claims, on the other hand, mark out the boundaries of the innovative territory over which the applicant wishes to stake a claim. Each claim is independently evaluated, and any one claim in a patent application may be rejected or modified without affecting the validity of the others.

The government agency responsible for granting patents in Canada is the Canadian Intellectual Property Office, or CIPO, which is part of Industry Canada. In legal terms, patents are granted not by CIPO but rather by the Commissioner of Patents, a senior public servant who also serves as the chief executive officer of CIPO. Decisions on patent applications are made by patent examiners, who may engage in extensive consultation and discussion with the applicant's patent agent; the discussion may lead to redrafting and resubmission of some or all of the patent claims. If all or part of a patent application is rejected, the applicant may request review by the Patent Appeal Board, an internal tribunal of CIPO that advises the Commissioner of Patents. After such a review, either party may appeal the decision of the Commissioner to the Federal Court of Canada, and ultimately to the Supreme Court of Canada.

Patents may be granted for products and for processes. In the case of the Harvard mouse, the application for a patent on the "transgenic non-human mammal" was denied by a patent examiner, the Patent Appeal Board and the Commissioner of Patents, although the process claims were accepted. The applicants appealed the matter to the courts, and the results are discussed in section II.3 of this paper. The United States granted a patent for the animal itself in 1988, the first such patent ever awarded.

II.2 Patents and Intellectual Property: Philosophy

The patent system in industrialized countries has historically been designed around what political scientist G. Bruce Doern has called a "trade-off between protecting creations and inventions of the mind and disseminating such creations for the broader good of society."[2] Two distinct philosophical justifications exist for the system of law that implements the trade-off.

The first involves a line of reasoning that can be traced back at least to the seventeenth century English philosopher John Locke, for whom "justice [gave] every man a title to the product of his honest industry";[3] depriving inventors of that return would be unfair. The motivation for intellectual property protection, on this account, is to give inventors what is their due.

The second relies instead on the argument that without intellectual property rights to protect "creations and inventions of the mind" from being appropriated by others, inventors and investors would be less likely to bring those creations forward from the basement workshop or the lab bench to the marketplace. The prospect of a patent offers at least the chance of a return on their commitments of time, effort and money. Otherwise, it would be too easy for imitators to reap the rewards with little actual outlay of their own. The result, so the argument goes, would be a climate in which socially desirable innovation of various kinds would be inhibited.

Informed policy choices must therefore be guided by accurate information about how patent protection actually affects research and innovation. Graham Strachan, the president of Canada's Allelix Biopharmaceuticals, notes that "intellectual property status is one of the first questions asked of the biopharmaceutical CEO when out trying to raise money from the financial gatekeepers."[4] On the other hand, the multiplication of patents and patent applications may actually slow down biological research, if scientists find it necessary to enter into costly licensing arrangements in order to avoid possible subsequent liability for patent infringement.

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2 G.B. Doern, *Global Change and Intellectual Property Agencies: An International Perspective* (London: Pinter, 1999), at 6.

3 J. Locke, *Two Treatises on Government* (1698), Book 1, ¶42; see also Book 2, ¶26-36, 134.

4 G. Strachan, "Patents: The Lifeblood of the Evolving Canadian Biopharmaceutical Sector," speech to CPIC, November 27, 1996.

In a play on words, it has been suggested that expansive patent protection may result in a "tragedy of the anticommons" in biomedical research: the direct opposite of Garrett Hardin's tragedy of the commons, in which inadequate specification of property rights leads to destructive results.[5] The concern is that over-protecting intellectual property could actually inhibit innovation over the longer term. A related concern, which involves more general issues of the appropriate relations between commercial concerns and the scientific enterprise, arises when scientists delay publication of research findings that may have commercial potential until a patent application has been filed.

II.3 Patents and Living Matter

Most practitioners and scholars in IP law hold that the granting of a patent implies no conclusion about the desirability of a particular invention, or of its commercialization. A patent does not carry with it official approval to market a particular invention or the products of a patented process. Depending on the nature of the product or process, that approval may require a number of other governmental decisions. For instance, in Canada novel varieties of crop plants, whether produced by genetic modification or by conventional plant breeding methods, must receive approval from Agriculture Canada. Veterinary biopharmaceuticals and prescription drugs must be approved by Health Canada before being marketed. Neither does a patent ensure commercial success; that is ultimately up to the market.

Against this claim, it can be argued that patenting of higher life forms or human biological materials implies willingness to live with a variety of possible consequences that would occur if a patented invention met with widespread commercial acceptance, even though such consequences may be ethically disturbing. It can also be argued that patenting implies rejecting apprehensions about the intrinsic wrongness of establishing intellectual property rights to the genetic blueprint of living organisms.

Canadian patent law makes no explicit reference to ethics. Although the *Patent Act* says nothing about living matter, a patent for a human cell line was issued in Canada as early as 1976, and microorganisms have been considered patentable subject matter since 1982 by virtue of a decision of the Patent Appeal Board.[6] Patents on human DNA sequences ('human genes') have been issued in most of the industrialized world, including Canada. Bartha Maria Knoppers, a legal scholar who is both a member of CBAC and chair of the Ethics Committee of the international Human Genome Organization, has noted that it would take "a total revolution

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5 M Heller and R. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research," 280 *Science* (1998) 698.

6 *Re application of Abitibi Co.* (1982), 62 C.P.R. (2d) 81.

of traditional patenting criteria" to restrict the patenting of human genetic material beyond prohibiting the granting of patents on a DNA sequence "in the natural state."[7]

Courts in Canada and the United States have taken similar approaches to interpreting the two countries' patent legislation. In *Diamond v. Chakrabarty*, a case that involved a patent on a genetically engineered bacterium capable of degrading crude oil, the US Supreme Court ruled in 1980 that a living organism could indeed constitute patentable subject matter. The majority of the justices held that if Congress had meant to restrict the scope of patent protection, it would have said so in legislation. In August 2000, Canada's Federal Court of Appeal, placing considerable reliance on the *Chakrabarty* decision, held that the *Patent Act* does not preclude treating a living mammal as patentable subject matter, and that: "The provisions of the *Patent Act* have been cast in broad terms to fulfil Parliament"s objective -- to promote invention. If anyone is of the opinion that the scope of patentability should be narrowed, it is open to that person to ask Parliament to do so."[8] The Supreme Court of Canada has now been asked for leave to appeal this decision. Interestingly, in both the Canadian and US court decisions, dissenting justices argued that the patent in question should not be granted. In September, 2000, CBAC encouraged "the Government of Canada to take all reasonable and feasible steps to facilitate Parliamentary review of the issue of patenting of biological products and processes."

A 1998 poll commissioned by the Canadian Biotechnology Strategy Task Force found that 94 percent of respondents thought ethical considerations should be taken into account when determining whether or not to grant a patent. An earlier (1994) poll found that Canadians' views about the acceptability of patents on "life forms created through biotechnology" varied with the intended uses of the plants, animals or human genes that were covered by patents. Only 24 percent of those surveyed agreed that "patents on any form of life developed through biotechnology are acceptable," and 51 percent regarded patents on altered human genes as unacceptable "if it would lead to commercialization of the human body."[9] It must be noted that, for some critics, that commercialization has already begun to occur with the proliferation of patents on human DNA sequences.

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7 B.M. Knoppers, "Status, Sale and Patenting of Human Genetic Material: An International Survey," 22 *Nature Genetics* (May, 1999) 23, at 25.

8 *President and Fellows of Harvard College* v. *Canada (Commissioner of Patents)* (C.A.), [2000] 4 F.C. 528. The full text of the decision, which includes a detailed history of the patent application in both Canada and the United States, is available electronically at <http://www.fja.gc.ca/en/cf/2000/vol4/html/2000fca27094.p.en.html>.

9 The sardonically minded might wonder whether these Canadians regard Calvin Klein advertisements as unacceptable for similar reasons, and what – if anything – they think public policy should do by way of a response.

II.4 The European Legal Approach

In the countries that comprise the European Union, two distinct legal frameworks identify ethical considerations that might justify the refusal of a patent.

The first of these is the European Patent Convention (EPC), to which all EU countries are signatories; the EPC is administered and implemented by the European Patent Office (EPO).[10] The EPC prohibits the granting of patents on

> ... inventions the publication or exploitation of which would be contrary to '*ordre 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.

"*Ordre public*," translated literally, means simply public order. However, in international law the concept has a somewhat broader meaning, which includes elements of public policy not related to order in the English sense of the word.

The EPC also allows for third party opposition, a procedure in which "any person" has nine months following the grant of a patent to file an objection. This procedure has been used on numerous occasions by 'public interest' intervenors like Greenpeace, as well as by those motivated by commercial concerns. No comparable procedure exists in Canada or the United States.

The implementing regulations of the EPC have now been modified in order to bring them into line with the second framework: EU Directive 98/44 on the legal protection of biotechnological inventions. Directive 98/44, which was aimed at harmonizing patent protection for biotechnology across the EU's member countries, not only incorporates the provisions of the EPC related to "*ordre public* or morality," but also specifically rules out patents on:

- the human body, at the various stages of its formation and development;
- processes for cloning human beings;
- processes for modifying the germ line genetic identity of human beings;
- uses of human embryos for industrial or commercial purposes; and
- 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.

The provisions of the EPC relating to "*ordre public* or morality" have been used unsuccessfully under the opposition procedure to challenge several key biotechnology patents, including the

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10 The text of the EPC is available on the European Patent Office web site at <http://www.european-patent-office.org/legal/epc/index.html>.

patent on the Harvard mouse. However, in December 1999 the EPO awarded a patent to Edinburgh University and an Australian biotech firm for a way of genetically altering the cells of mammals, which could then be used to create embryos. As awarded, the patent would have included processes for 'cloning' human beings. Numerous oppositions were quickly filed, and the patent applicants responded by revising their claims to exclude application to human beings. As a result of the controversy, the Administrative Council of the EPO noted in June, 2000:

> Internal measures have been taken to prevent similar situations occurring in future. The 'early warning system' for applications filed in this sensitive area of technology has been improved. All [patent] examiners in this field have been reminded of the heavy responsibility they bear, especially when examining whether an invention should be excluded from patentability on the grounds that it is contrary to 'ordre public' or morality within the meaning of Article 53(a) EPC or because it does not meet those requirements set out in the Implementing Regulations which were incorporated into European patent law from the Biotechnology Directive.[11]

Thus, despite the lack of success associated with formal oppositions to European patents based on the "*ordre public* or morality" exclusion, the exclusion apparently is far from being a dead issue in terms of affecting EPO decision making.

Apart from such cases, the wording of Directive 98/44 illustrates the problems of interpretation that must be confronted in efforts to draft descriptions of unpatentable subject matter, in any jurisdiction. For example, will human organs grown *in vitro* from human embryo stem cells (Box 3) be considered patentable subject matter, or would they instead be viewed as constituting a commercial use of the human embryo? What about steps involved in producing such organs from human embryo stem cells?

II.5 Canada's International Commitments

In making policy related to patents on higher life forms and human biological materials, Canada is constrained by a variety of international obligations. Perhaps the most important are NAFTA and the agreement on Trade-Related Aspects of Intellectual Property (TRIPs); TRIPs is part of the WTO Agreement reached in 1994. These agreements for the first time incorporated the idea that IP issues affect economic competitiveness in the same way as the tariffs and subsidies that were the more familiar concerns of trade policy and law.

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11 Report on the 80th Meeting of the Administrative Council (6-8 June 2000), 7 *Official Journal of the European Patent Organization* (July); <http://www.european-patent-office.org/epo/pubs/oj000/ 7_00/ 7_3070.pdf>.

Box 3: Embryonic Stem Cells (ES cells), which are present only in the very early stages of embryonic development, have the special ability to develop into almost any type of tissue or organ. That is, they are 'pluripotent'. In November 1998, a US scientist showed that ES cells, in this case taken from an embryo donated by a couple who had received treatment for infertility, could be cultured in the laboratory – opening up a range of possibilities for research on human biological development.

It is possible that stem cells could eventually be used to generate a variety of human tissues and organs in the laboratory, for purposes of treating injury or disease. Controversies surrounding stem cell research have so far focussed on the source of the cells, which can be obtained from embryos 'left over' from *in vitro* fertilization of human ova. Somatic cell nuclear transfer – the process used to 'clone' the famous sheep Dolly – could also be used to generate such cells. Both the United States and the United Kingdom have recently relaxed their national governments' controls on stem cell research, citing the potential therapeutic benefits of such research. Given the immense clinical and research possibilities, it seems likely that patent protection will be sought for many scientific advances, as is the case in the area of xenotransplantation.

The two agreements contain virtually identical provisions on what kinds of subject matter governments may exclude from patentability (subject matter exclusions), 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.

The dispute resolution mechanisms established under the WTO Agreement and under NAFTA have not yet addressed the interpretation of this provision as it relates to biotechnology. However, problems would almost certainly arise if Canada were to impose special requirements on applications for patents on higher life forms and human biological materials, unless those requirements could be defended with reference to one of the following categories of permissible exclusions under NAFTA and TRIPs:

> 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.

It is not certain what evidence would be needed to defend such an exclusion, but the hurdle has clearly been set very high.

Other kinds of exclusions from patentability are permissible, as well:

> 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 micro organisms, 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.

TRIPs provides for a review of plant variety protection four years after the entry into force of the WTO Agreement. That review will focus attention on how the economic benefits of strong IP protection for crop plants will be distributed, both within and among nations (see Box 4).

Canada has also signed the Convention on Biological Diversity (CBD). The CBD established the principle of national sovereignty over biological resources, but set up no dispute resolution mechanisms like those in NAFTA or the WTO Agreement. CBD does, however, link technology transfer to recognition of expansive intellectual property rights in biological material – a provision that gave rise to many objections from developing countries at the time the agreement was being negotiated.

Quite apart from the letter of the law, intellectual property policy and trade policy are increasingly interconnected. Reciprocity is an important consideration that underpins not only agreements like NAFTA and TRIPs, but also the ongoing politics of trade. A trade-dependent nation like Canada may not be able to make policy on biotechnology patenting in isolation from the policies of major trading partners – at least if our policy is perceived as giving domestic industry a competitive advantage. It may, therefore, be important to distinguish between the policy toward patenting higher life forms and human biological materials that we would prefer in an ideal world and the one we would prefer given the need to take into account the IP regimes in place elsewhere in the world.

III. Ethical Questions About Patenting Higher Life Forms and Human Biological Materials

III.1 First Steps

When considering the ethics of patenting higher life forms, it is important to ask three sets of questions.

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

Second, do the ethical issues primarily involve the consequences of a particular application of biotechnology, or of the issuing 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? (These terms are explained in the next section of the paper.)

Third, how relevant is patenting to the concerns being expressed or the outcomes being anticipated? Is patenting really the issue, or are the concerns in question best addressed in another way: for example through regulatory controls on how a particular invention is marketed or used?

An example serves to illustrate the interplay of these questions. When the Harvard mouse patent was issued in the United States Sheldon Krimsky, who has written extensively on the social and political controversies that surround biotechnology, noted that the granting of the patent suggested that "society was regressing to an extreme Cartesian view of animals as soulless, unfeeling creatures that may be treated like machine parts."[12]

The value in question was respect for life, as reflected in our ability to make the distinction between living, sentient organisms and Cartesian machines. The concerns expressed might have to do with the effects of patenting and the associated commercial use of animals on public attitudes and animal welfare, or they might reflect a conviction that patenting in and of itself constitutes a transgression against the value of respect for life. In this case, patenting was clearly the issue: it was seen as simultaneously reflecting and reinforcing a particular set of unacceptable attitudes and beliefs. In other situations, however, patenting may serve as a lightning rod (some would say, a target of opportunity) for a variety of apprehensions about the biotechnology enterprise itself.

III.2 The Conceptual Framework: Forms of Argument

Arguments for and against permitting patents on higher life forms can be classified into two basic forms, each of which draws on a long and distinct tradition in western ethics or moral philosophy.

One form of argument, referred to by philosophers as *deontological* (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 treat other human beings as ends in themselves, rather than as means to an end. When such axioms are invoked in order to justify or reject a particular action, it is usually important to ask about the *source* of such duties or obligations: where do they come from?

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

Figure 1: Schematic View of the Ethical Issues Associated with Patenting Higher Life Forms and Human Biological Materials

	Primary Topic of Discussion	
Form of Argument	*The biotechnology enterprise*	*Patenting*
Deontological: arguments addressing inherent or intrinsic rightness or wrongness	Pro: Advanced biological research fulfils humanity's obligation to expand the range of scientific knowledge, which is valuable its their own right. Con: Respect for life means that there are some things we can do that we ought not to do; modifying the genome of living organisms is one of these things.	Pro: Patenting higher life forms is required in order to be fair to inventors and investors, who otherwise will lose the opportunity to earn a deserved return on their intellectual efforts and financial commitments. Con: The simple act of assigning intellectual property rights to parts of the genome of living organisms denigrates them by equating them with mere "manufactures or compositions of matter" (the words of Canada's *Patent Act*).
Consequentialist: Arguments addressing harmful or beneficial consequences	Pro: Biological research will lead to new ways of treating debilitating diseases; increases in crop yields and livestock productivity will enable humanity to produce more food at the same or lower cost. Con: Applications of agricultural biotechnology may involve long-term risks (e.g. of gene transfer) that are imperfectly understood; genetic screening will invariably provide the basis for ethically impermissible forms of discrimination.	Pro: Expansive patent protection is needed to encourage investment in a strong biotechnology industry; without that incentive, the social benefits will be slow to materialize, and/or the economic ones will be captured by other jurisdictions. Con: Patenting will lead us to treat living creatures as objects ("objectification"); patenting may actually discourage research by comparison with an alternative scenario in which the relevant basic research is publicly financed and results are placed in the public domain.

Source: Adapted from T. Schrecker, C.B. Hoffmaster, M. Somerville and A. Wellington, *Biotechnology, Ethics and Government*, Report to the Interdepartmental Working Group on Ethics (Ottawa; Industry Canada, 1998; completed 1996); on Industry Canada's Strategis web site at <http://strategis.ic.gc.ca/SSG/bh00195e.html>

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. How 'the good' should be defined remains a topic of philosophical dispute. For many contemporary philosophers, the consequences that must be taken into account in ethical reasoning are environmental, social, economic or even spiritual.

Distinctions between deontological and consequentialist positions on patenting higher life forms and human biological materials are indispensable for analytical purposes because they demand 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."[13] Conversely, consequentialist arguments invite exploration of ways to mitigate the undesired effects of a particular choice, and to enhance the desired ones, in a way that deontological arguments do not.

Figure 1 shows the importance both of the distinction between these two forms of argument and of the distinction between ethical arguments that address the biotechnology enterprise as a whole and those that address issues directly related to patenting.

In practice, ethical reasoning routinely and justifiably combines the forms of argument, for at least two reasons. First, 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. Just identifying and listing consequences tells us nothing about their ethical significance. Still less does it tell us how best to balance a number of potentially conflicting values, such as animal welfare and potential advances in understanding human diseases.

Second, not only the nature of consequences, but also their distribution may be ethically significant … and distribution can only be evaluated with reference to principles of fairness or justice that are part of that pre-existing ethical background. For example, it is possible that the holders of a few patents on diagnostic techniques based on molecular genetics could accumulate fortunes while driving up costs to public health care systems like Canada's. In such a situation, we might consider distributive justice as providing a sound case either for limiting the intellectual property rights in question or for redistributing the profits they generated using some other policy instrument, such as a combination of dedicated taxes and subsidies.

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

III.3 The International Dimension

Redistributive polices of this kind are far more difficult to implement when they would need to cross national borders in order to achieve their intended objective. The government of India, say, cannot tax a US corporation that holds a crop plant patent, or a Swiss one that holds a pharmaceutical patent; subsidies of many kinds are increasingly likely to be the target of trade policy objections. Building on this insight, several economists point out that developing countries may have good reasons to want different kinds of intellectual property protection from industrialized countries. In particular, knowledge-poor countries may be rich in biological diversity and in botanical wisdom derived from traditional or indigenous knowledge, both of which provide the material for many patented inventions. Their industries may have little to gain, at least in the short term, from adopting rich-country standards of IP protection for subject matter such as crop plants (Box 4), and their populations may have much to lose if patented, cutting-edge pharmaceuticals are only available at prices geared to the health care budgets of the industrialized world.

Some of the strongest critiques of patent protection for higher life forms and human biological materials are therefore rooted in considerations of distributive justice at the international level. The 1999 edition of the United Nations' *Human Development Report* warns that new intellectual property rules may entrench the industrialized world's research agenda, in which "money talks louder than need," and make technology transfer unaffordable.[14] On this view, harmonized intellectual property protection may be one of several reasons for a widening economic gap between knowledge-rich and knowledge-poor countries. The 2000 *Human Development Report* provocatively speculated that the TRIPs agreement may actually be incompatible with provisions of international human rights agreements that recognize a right to share in scientific progress.[15]

Canada may not be able to do much about such situations by way of domestic patent policy. However, our position in future multilateral negotiations might be defined at least partly with reference to such considerations of distributive justice at the international level. We might, for instance, argue that international agreements should recognize and accommodate the differential impacts of strong intellectual property protection regimes on countries at different stages of economic development.

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14 United Nations Development Programme, *Human Development Report 1999: Globalization with a Human Face* (New York: Oxford University Press, 1999), at 66-72.

15 United Nations Development Programme, *Human Development Report 2000: Human Rights and Human Development* (New York: Oxford University Press, 2000) at 84.

Box 4. Exhaustion of rights: Historically, there have been no legal barriers for farmers wishing to use saved seed for future crops ('farmer's privilege'). However, patent protection for plant varieties may extinguish this right.

The prospect that agricultural input suppliers in the industrialized world might take legal action against farmers who have used saved seed for the next year's crops was an important factor contributing to resistance to TRIPs in developing countries, especially India, and to earlier versions of Directive 98/44 in the EU. The final version of the Directive permits farmers to use saved seed from patented crop plants, and the progeny of patented animals, in their own agricultural operations but not to use them in other ways for commercial purposes.

Such issues are likely to become progressively more significant if in the future, as some observers predict, most of the crops and livestock used in commercial agriculture worldwide are bioengineered and protected by patents or patent-like forms of protection.

IV. Policy Options and Responses

For purposes of argument, let us assume that ethical and social policy considerations have a legitimate place, somewhere, in decisions about granting patents on higher life forms or human biological materials. A number of legislative or regulatory responses have been either proposed or tried; what follows is not an exhaustive list.

IV.1 The Status Quo: Canada could make no changes to the *Patent Act* or to existing CIPO policy. Resolution of such questions as the nature of patentable subject matter would therefore be left up to CIPO and the courts, based on the *Patent Act* and relevant case law as they now stand. CBAC has rejected this position, agreeing with the Federal Court of Appeal that "Parliament, not the Courts, should determine Canada's policy with respect to the patenting of higher life forms (and the distinction between 'lower' and 'higher' life forms)." What restrictions, if any, might Parliament consider?

IV.2 Subject Matter Exclusions: Canada could amend the *Patent Act* either to allow or to require CIPO to refuse patents on certain kinds of subject matter. Were Canada to take this route, should the exclusions be stated in general terms, or should they be stated in terms of outright prohibitions on patents for certain kinds of innovations?

Directive 98/44, which the EU thinks is compatible with TRIPs, does both. Generic subject matter exclusions and outright prohibitions on patenting certain kinds of innovations are not mutually exclusive. However, either category of exclusion must be compatible with the provisions of NAFTA and TRIPs. Exclusions that appear to single out biotechnology for special consideration will need to be clearly defensible because of the prohibition against discrimination as to the field of technology. A national government's say-so with respect to categories of

innovations that are unpatentable on grounds related to "*ordre public* or morality" is unlikely to be decisive in the absence of considerable supporting evidence and argument.

Subject matter exclusions raise challenges for drafting and implementation, especially when stated in generic terms. For example: who would decide whether or not the commercial exploitation in Canada of a particular patent would threaten "*ordre public* or morality": CIPO? The courts? Since any refusal of a patent on such grounds would almost certainly be challenged in the courts, we must be prepared to consider how the courts would interpret the wording of such exclusions. Is CIPO equipped to make such a determination, even in the first instance? Can either legislative drafting or the development of policy that interprets subject matter exclusions be expected to keep pace with the rapid advance of biological science?

IV.3 Opposition Procedures: In its *Sixth Report* (1998), the National Biotechnology Advisory Committee recommended the introduction of an opposition procedure with a six-month time limit for commercial reasons: it would provide a way for Canadian firms to challenge CIPO's acceptance of excessively broad patent claims without the expense of a lawsuit to impeach the patent.

The legislated establishment of such a process is logically independent from any incorporation of ethical or other non-commercial concerns into Canadian patent law, although if such a procedure existed it would probably be used as a way of articulating those concerns. It is therefore important to consider whether challengers on 'public interest' grounds would, *or should*, be granted standing. In the United States, where the courts are the only forum in which a patent can normally be challenged, organizations objecting to biotechnology patents on 'public interest' grounds have been denied standing. Under Canada's *Patent Act*, only the Attorney General of Canada and those whose activities might leave them open to lawsuits for patent infringement have standing to sue for patent impeachment.

The administration of any opposition procedure would need resources, as well as an organizational 'home'. Is CIPO or any other federal agency, as presently constituted, equipped to provide these?

IV.4 Infringement Exemptions and Compulsory Licensing: 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. Canadian legal scholar Richard Gold argues for expanding the conditions under which scientific researchers may make use of human biological materials for which patents have been granted or applied for, without risking lawsuits for patent infringement. He has also suggested the introduction of a regime of compulsory licensing for certain kinds of research tools, such as genes and cell lines. This

would "prevent prohibitive or anti-competitive licensing terms with respect to basic technology." Such changes, says Gold, "can be accommodated within existing patent law."[16]

Compulsory licensing has also been proposed as a way of controlling the costs of patented drugs and diagnostic techniques, perhaps as an alternative to price controls at the national level. Indeed, Canada had provisions for compulsory licensing until the early 1990s for this reason. Here as in other areas of IP protection, trade law and policy constraints are important. Articles 30 and 31 of TRIPs seriously restrict the conditions under which infringement exemptions or compulsory licensing may be used. For instance, "exceptions to the exclusive rights conferred by a patent" are only permissible if they

> ... 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.

Compulsory licensing is only permissible after "efforts [have been made] to obtain authorization from the right holder on reasonable commercial terms and conditions," and must be accompanied by "adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization".

IV.5 Upstream Conditions: Biological material used in research that generates patent applications is obtained in many ways. Human materials may be obtained in the course of field research, diagnosis or treatment, from people who are unaware of their subsequent use. The *Moore* case (see Box 5) exemplifies such a situation. Non-human materials may have been obtained in the course of bioprospecting, or from collections of biological material that are in the public domain.

What standards of consent, confidentiality and sharing of commercial revenues are ethically appropriate in these situations? What role, if any, should the patent system play in ensuring that such standards are maintained? One approach to such questions involves specifying upstream conditions. For example, patent applicants might be required to submit ethics approvals before receiving patents on certain kinds of subject matter, just as university-based researchers must receive approval from their institution's Research Ethics Board (REB) before Canada's federal granting councils will support research involving human subjects.

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16 E.R. Gold, "Making Room: Reintegrating Basic Research, Health Policy, and Ethics into Patent Law," in T. Caulfield and B. Williams-Jones, eds., *The Commercialization of Genetic Research: Ethical, Legal, and Policy Issues* (New York: Plenum, 1999) at 72.

Box 5. Confidentiality, informed consent, and ownership of human biological materials: The question of who owns human biological materials obtained during diagnosis or therapy came to public attention because of the case of John Moore, a California man whose spleen was removed in 1976. Moore's oncologist and other researchers then cultured cells from Moore's cancerous spleen that produced a class of substances (lymphokines) with considerable therapeutic (and therefore commercial) potential. They obtained a patent on the cell line, from which both they and the University expected to earn substantial royalties. After learning about these developments, Moore sued both the oncologist and the university for a share of the royalties from the patent. His claim was ultimately rejected by the courts.

More recently, bioethicists have devoted considerable attention to requirements for informed consent as they apply to research uses of human biological materials. Key questions include: the circumstances under which identifiers may (or must) be removed; whether, or under what circumstances, commercial use of either such anonymized samples of biological material or of identifiable samples collected during prospective research is permissible; whether research subjects may (or must) share in the revenues from such uses; and how research that identifies genetic characteristics that occur more frequently among members of a particular ethnic group might result in the stigmatization of all members of the group.

The Human Genome Diversity Project (HGDP), a loosely organized international collaboration of scientists who share the aim of surveying genetic diversity among the world's human populations, has been the target of intense criticism for lack of foresight on these questions. In response, project researchers have developed a detailed model protocol for collection of human DNA samples that recognizes the importance of such issues as disclosure of possible commercial uses and cultural differences in the relative significance of group and individual consent to participation in research.

Standards for ethical review required as a precondition for the grant of a patent might be relatively general in nature. Alternatively, specific reference could be made to such documents as the Canadian Council on Animal Care *Guidelines on Transgenic Animals;* the new *Tri-Council Policy Statement* on Canadian federally funded research involving human subjects,[17] or the model protocol for collecting human DNA samples developed for the HGDP.[18] In addition, patent applicants might be required to demonstrate compliance with provisions of the CBD requiring that: "Access to genetic resources shall be subject to prior informed consent of the Contracting Party" – meaning the national government within whose jurisdiction the resources were obtained. Upstream requirements would thus use Canadian intellectual property law to achieve outcomes that reflect the spirit of Canadian commitments in superficially unrelated areas, such as animal welfare, the protection of human research subjects and the protection of biodiversity.

IV.6 Regulation, Old and New: Most, if not all of the preceding responses would require changes both in the *Patent Act* and to the practices of the agencies that administer it. However,

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17 *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, available at <http://www.nserc.ca/programs/ethics/english/policy.htm>.

18 "Model Protocol: Proposed Model Ethical Protocol for Collecting DNA Samples," *Houston Law Review* 33 (1997): 1431-73.

it has been argued that ethical concerns about the patenting of higher life forms and human biological materials, although legitimate, are best addressed in other areas of law and public policy, or by institutions that have no direct connection with IP.

We therefore need to ask the always-contentious question of whether Canada's existing statutes, procedures and institutions can credibly articulate the 'public interest' with respect to the emerging capabilities of biological science. Perhaps not surprisingly, the key players in some existing institutions tend to say yes. On the other hand, political theorist William Leiss has 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," with a separate agency administered jointly by Health Canada and Environment Canada.[19] In its November 1996 report on regulating biotechnology, the House of Commons Committee on the Environment and Sustainable Development recommended further study of proposals for such an agency.

Regulatory issues are complicated. Organizations as dissimilar as the Canadian Food Inspection Agency (CFIA), which is responsible for enforcing federal food safety standards, and the REBs that approve research protocols within each Canadian university, can all be thought of as regulators for purposes of some applications of biotechnology. Partly for this reason, the present paper does not provide a complete list of such institutions, and of course does not assess their adequacy. Such issues nevertheless need to be explored, because without doing so it is impossible to answer a key question: Do the ethical issues associated with patenting higher life forms and human biological material require fundamental changes in Canadian patent law, or can they be addressed by "minor tweaks" (in the words of one reviewer of an earlier draft of this paper) in combination with policy initiatives in other areas?

V. Conclusion

Patent law is meant to provide social benefits by encouraging scientific and commercial creativity; recognizing the fruits of inventive activity; and, crucially, enriching the public domain. Some critics of patenting call into question whether those benefits could, or would, be realized with the advent of patents for higher life forms and human biological materials. Other critics assert that the inherent wrongness of IP rights involving certain kinds of living matter supersedes any consideration of benefits. Conversely, proponents of patenting insist that the field of biotechnology is especially appropriate for the incentive framework and reward structure provided by patents.

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

Canadian debates over the merits and demerits of patents for higher life forms and human biological materials are just beginning, in many ways. The positions people take on the issues tend to reflect a variety of influences, including their views about what the balance between public investment in research and reliance upon typically profit-driven commercial investment should look like. Thus public discussion of biotechnology patenting issues will unavoidably touch on broader issues of the appropriate relation among science, business and society. This is almost certainly a good thing.

VI. Resources: For Further Information

The web site of the Canadian Biotechnology Advisory Committee <http://cbac.gc.ca> offers an expanding range of information about the Committee's work on biotechnology related issues, as well as the reports of research commissioned by the Committee.

The Biotechnology Gateway on Industry Canada's Strategis web site, <http://strategis.ic.gc.ca/SSG/bo01376e.html>, offers access to information on many aspects of Canada's biotechnology industry.

Trade and intellectual property issues often intersect. Canada's Department of Foreign Affairs and International Trade (DFAIT) offers a range of information on such topics as trade negotiations and agreements, why trade matters and current trade policy issues. Go to <http://www.dfait.gc.ca/trade/menu-e.asp>.

A web site maintained by the University of Pennsylvania's Center for Bioethics, <http://www.bioethics.net>, is a particularly useful gateway for information and late breaking news on biotechnology patenting in the United States.

The web site of the European Patent Office, <http://www.european-patent-office.org/index.htm>, provides extensive links to official documents related to patents in the EPC countries.

Some of the best European reporting on biotechnology issues can be found in *The Guardian*; go to <http://guardianunlimited.co.uk/genes>.

The web site of the World Trade Organization, <http://www.wto.org> is an excellent source on trade policy, including trade related aspects of intellectual property rights.