ETHICAL ISSUES ASSOCIATED WITH THE PATENTING OF HIGHER LIFE FORMS

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EXECUTIVE SUMMARY

I. The United States and European Experiences

In both the United States and the European Union, the patenting of the so-called Harvard mouse marked a turning point in public perceptions of the issues surrounding patenting of higher life forms. A key issue was that of whether patenting higher life forms represented acceptance of a Cartesian world view that, in effect, treated higher life forms as mere "manufactures or compositions of matter" (the phrase used in both Canadian and U.S. patent law to describe patentable subject matter). In the United States, policy entrepreneurs like Jeremy Rifkin's Foundation on Economic Trends (FET) played an important role in setting the terms of the debate. Other interest groups involved in opposition to patenting included farm organizations, religious groups and organizations concerned with animal welfare.

The European situation was and is different because of the existence of Green or ecology parties in a number of countries and at the EU level. It was and is different, as well, because of specific provision in the European Patent Convention (EPC), which covers patenting in most EU countries, for denial of patents on public interest grounds. No comparable statutory provision or authority exists in the United States. In addition, the EPC precludes the issuance of patents on "inventions the publication or exploitation of which would be contrary to *ordre public* or morality".

A draft directive recently adopted by the European Parliament precludes patents on:

(a) the human body or parts of the human body *per se*;
(b) processes for modifying the genetic identity of the human body for a non-therapeutic purpose which is contrary to the dignity of man;
(c) processes for modifying the genetic identity of animals which are likely to inflict suffering or physical handicaps upon them without any benefit to man or animal.

The European Commission has attempted to commit EU countries to expansive patent protection for biotechnological innovations. However, it has run into substantial opposition both because of the apprehended effects on farmers and for range of ethical reasons. The directly elected European Parliament has shown itself more sceptical of arguments in favour of expansive patent protection than the Commission and the biotechnology industry.

II. Canadian Policy and Politics

Both the United States and Europe have experienced relatively high-profile public debates about the ethics of patenting higher life forms. This has not happened in Canada. The Canadian Patent Office (CPO) has so far stated a policy of not granting patents on higher life forms, based on an interpretation of existing case law. There is no legislation supporting this position, and court

decisions are ambiguous. In the absence of a catalyst like the announcement of a patent on a transgenic animal or the activities of high-profile policy entrepreneurs, debate about the ethical implications of intellectual property rights in higher life forms has been minimal in Canada, with two exceptions.

The first exception is the passage of the *Plant Breeders' Rights Act* in 1990, and the Parliamentary hearings that preceded it. The second exception is the work of the Royal Commission on New Reproductive Technologies (RCNRT), which actually paid little attention to patenting issues. The absence of such public debate is one of the reasons for the process-based approach proposed in Section XII of the report.

III. Analysing Arguments For and Against Patenting Higher Life Forms

Arguments about patenting higher life forms can be classified based on two factors: the topic of discussion, and the nature of the argument being made. With respect to what is being discussed, patenting higher life forms can be seen either as derivatively wrong or as wrong in itself. The former view is based on the claim that genetic engineering, certain applications of genetic engineering or certain kinds of research in molecular genetics are morally wrong.

Another line of criticism is directed at patenting *per se*. Even if genetic engineering is morally acceptable and should be allowed to proceed, some of the outcomes ought not to be patentable.

Under each of these headings, arguments assume two forms that correspond to the two main traditions in Western moral philosophy. On the one hand, an activity (such as genetic engineering, or the patenting of all or some higher life forms) is held to be intrinsically wrong, or wrong in principle. Philosophers refer to such arguments as deontological. On the other hand, an activity such as genetic engineering or patenting could be wrong because it causes bad or harmful consequences. Philosophers call such arguments consequentialist. These categories of arguments about genetic engineering and patenting are schematically depicted in Figure 1.

Consequentialist arguments need not be strictly utilitarian in form or content. The consequences taken into account need not be solely economic ones. They may be environmental, social or even spiritual, depending upon how harms are defined and identified. As this observation suggests, basing decision-making on consequentialist arguments does not mean decisions should be made simply by aggregating individuals' preferences. What we want as individual consumers may differ from what we consider, as citizens, to be a desirable social policy choice. Finally, when we decide what is to count as a beneficial or a harmful consequence of a particular policy, such as allowing patents on genetically engineered laboratory animals or on a particular animal, we rely on pre-existing values or ethical commitments. Simply pointing to a particular set of consequences of that policy does not itself constitute an ethical argument.

Figure 1

	Topic of Discussion	
Form of Argument	*Genetic Engineering*	*Patenting*
Deontological (arguments dealing with inherent or intrinsic rightness or wrongness)	Pro: Genetic engineering is part of humanity's obligation to expand the range of scientific knowledge and technological capability. Con: Genetic engineering, or certain kinds of human gene therapy, amount to "Playing God".	Pro: Patenting of higher life forms is justified on grounds of fairness to inventors and investors. Con: Ownership of life, or property rights in portions of the human genome, are inherently wrong.
Consequentialist (arguments dealing with harmful or beneficial consequences)	Pro: Genetic engineering will make possible new kinds of therapies for debilitating diseases, and substantial increases in farmers' ability to produce more food at the same or lower cost. Con: A slippery slope leads inexorably from such medical techniques as pre-implantation diagnosis and embryo cloning to the dire consequences that would follow from a revival of eugenics.	Pro: Patenting is necessary in order to create an incentive for investing in research and development that will lead to the various benefits that can be realized from genetic engineering; without the incentive provided by patenting that investment will not be made, or will be made at lower levels. Con: Patenting will have destructive economic effects on family farms; will enable patent holders to reap monopoly profits even from lifesaving therapies and diagnostic techniques; will lead us to objectify life and living creatures, human and otherwise.

IV. Of Slippery Slopes and Accumulated Consequences

Claims about "slippery slopes" are often encountered in discussions of biotechnology policy and intellectual property rights. The "thin edge of the wedge" is another image that communicates the same idea. Among several frameworks for assessing slippery slope arguments, political theorist Richard Vernon provides one of the clearest and simplest: such arguments must "contain a genuine causal element linking the top of the slope with the bottom," or in other words they must specify the lubricant that makes the slope slippery.

One such lubricant is "precedential force." A second is involved where "previous expenditures of effort are regarded as an investment which it would be costly to abandon." A third type of lubricant can be identified in situations where particular actions or policies either create altogether new actors, or strengthen the commitment and expand the resources of existing ones. Finally, there is what Vernon calls "cumulative effects on our political culture." The key questions with respect to slippery slope arguments of all kinds are: what is the lubricant? how slippery will the lubricant in fact make the slope? how sure are we about the preceding answer? It is also useful to ask whether the effects of the lubricant can be offset, for example by spreading sand, ashes, or some other traction aid on the slippery slope at a particular point.

Slippery slope arguments must be distinguished from claims about the cumulative effects of large numbers of seemingly insignificant or isolated decisions. Decisions that are defensible viewed in a local or small-scale context may be indefensible and even irrational when the system-wide consequences of large numbers of similar decisions are taken into account., which may be unanticipated and/or perverse. The discipline of economics and the domain of environmental policy provide a number of useful and cautionary examples.

V. Generic Arguments About Patenting Higher Life Forms

At least three distinct arguments in favour of patenting higher life forms can be identified. First, patenting is viewed as an incentive necessary to motivate the profit-motivated private sector to meet public needs like the provision of increased agricultural yields and life-saving therapies and diagnostic techniques. This argument has been prominent in the U.S. debates about patenting, especially as they relate to patents on portions of the human genome. Second, countries that offer weak or limited patent protection can expect to suffer economic losses as investors in the biotechnology industry simply look elsewhere. The power of this claim depends both on the overall economic significance of biotechnology and on the intra-national distribution of its benefits. A third argument is based on considerations of fairness: people deserve the fruits of their intellectual work. Fairness or justice is valued in and of itself, apart from socially beneficial consequences.

It seems hard to argue against patenting if, for instance, it will actually provide an incentive for major medical breakthroughs. However, some commentators view the accumulation of scientific knowledge through genetic research as a mixed blessing, and argue that will in the end

be socially destructive. If one regards genetic engineering and its applications as ethically troubling to begin with, then patenting becomes ethically suspect in direct proportion to the strength of the incentive it provides for such research and development. Further, some recent developments suggest that patenting may in fact hinder the pursuit of lines of inquiry with potentially lifesaving results, by substituting self-interested preservation of confidentiality for the norm of open and immediate sharing of results that supposedly governs scientific communication.

The national income and employment possibilities associated with a thriving biotechnology industry are themselves desirable, and provide an argument for expansive patent protection *if* the economic benefits are as substantial as claimed by promoters of the industry. However, there are reasons to take a sceptical view of those claims. Jobs and income are not the only relevant ethical considerations; claims about economic benefits may be driven by the interests of industry promoters, and deserve more careful examination.

VI. On Playing God

A familiar objection to genetic engineering is that genetic engineers are playing God. Although some argue that genetic engineering is not fundamentally different from the natural process of selective breeding, there are abundant reasons to treat genetic engineering as a special and distinctive kind of phenomenon. These reasons, however, do not make explicit the basis of the claim by opponents that it is wrong to exercise the control over biological processes represented by genetic engineering.

This distinction is important because our ethical intuitions are often in conflict. A basic antagonism toward biotechnology, expressed in the argument from playing God, conflict with a equally strong conviction that everything possible should be done to find cures or palliative measures for debilitating and fatal diseases, including (for instance) the creation of transgenic animals that serve as laboratory models for the study of such diseases. A number of similar instances of conflicting intuitions can be found in debates about the ethics of biotechnology; their existence strengthens the case made in this report for emphasizing procedure rather than "right answers" in resolving ethical conflicts about biotechnology.

Three variants of the playing god argument deserve separate attention. The first appeals to the notion of species integrity, which some observers see as problematic. Second, there is the claim that patenting tends to reduce the value of life to that assigned to it by the economic system. Third, it can be argued that a loss of a sense of the mystery of life may accompany the scientific ability to define life in terms of genetic information. Here again, however, a counterargument can be made that such an ability actually enhances our sense of wonder with respect to life and living things.

VII. Some Distributional Implications of the Ownership of Genetic Resources

The prospect of patents on genetic resources raises a number of distributional questions that emerge most immediately as they affect agriculture. Patents on the genetic makeup of crops and livestock could exacerbate the concentration of economic power in the global agri-food industry. Advocacy groups are concemed that this is already happening as large firms develop plant varieties resistant to the particular herbicides they market. They are further concerned that "species patents" on genetically engineered crops will hasten the corporate domination of global agriculture, perhaps impairing the economic viability of agriculture in poorer countries. The chance that such patents will survive legal challenges, and the implications if they do, are flagged as an area of high priority for further research.

In addition, the extension of the intellectual property regimes of developed countries to cover genetic resources could allow scientists and investors in those countries to appropriate both genetic resources and indigenous knowledge from the Third World. This phenomenon has been termed "bio-piracy" by critics, especially when human genetic materials are involved. In this context, the Rio Convention on Biodiversity raises complex issues involving not only the ownership of genetic resources already in depository collections, but also the meaning and implications of the concept of national sovereignty over genetic resources.

Finally, there is the potential for monopoly profits associated with the ownership of intellectual property rights. Arguably, this potential is inherent in the nature of a patent system, but it becomes ethically troubling when it involves access to lifesaving diagnosis and therapy. If the benefits of genetic research in terms of diagnosis and treatment are as dramatic as some enthusiasts believe, the question of excessive profits will invariably arise.

VIII. The Control of Environmental Hazards

In North America, public concern about the negative consequences of biotechnology began with environmental effects, including those of genetically modified organisms (GMOs). The relevance of environmental concerns to the issue of patenting is not immediately obvious. However, opponents of patenting might respond by arguing that the regulatory regime is either (a) inherently incapable of dealing with the hazards posed by GMOs, or (b) incapable of dealing with them at present. In either instance, the potential hazards may be serious enough that the incentive provided by patenting should not be provided.

This argument has been made with reference to characteristics of GMOs, such as the ability to reproduce and interbreed with native, unmodified species, which make them unlike other environmental hazards. A further concern is the possibility of unanticipated gene transfer among organisms. These issues exacerbate the scientific disagreements and uncertainties that are already part of environmental regulation. If people's views on how uncertainty about environmental risks should be dealt with reflect competing attitudes toward technology, the social system and social

interactions as a whole, as some social theorists claim, then conflicts about the environmental risks associated with biotechnology are likely to be both ethically and politically intractable.

IX. Animal Welfare

At least since the early nineteenth century, the public has become less willing to tolerate the infliction of suffering on animals. Genetic engineering of animals for agricultural or laboratory purposes could be harmful to them in a variety of ways, some of which have already been documented. According to both opponents and supporters of patenting, if patents on genetically engineered animals were not available, it would be less likely that such creatures would be developed for commercial purposes.

There are existing regulatory controls on the use of animals in laboratories and (to some extent) in agriculture, but critics might challenge both their ethical adequacy and their effectiveness. Further, regulatory controls may not be adequate where the patented characteristics or traits are *in and of themselves* likely to cause suffering, or where the suffering produced by the engineering of particular reproducible traits into animals is different in kind from that dealt with under current controls.

X. Patenting and Human Beings

Private firms in the United States are now applying for patents on human gene sequences. Ethical disputes about patenting a portion of the human genome are inextricably linked with conflicting views about the entire enterprise of genetic research involving human beings. With specific reference to patenting, the key questions are:

(1) **Should human beings themselves be patentable?** It is taken for granted that they should not be, but the line between the human and the non-human may not be clear for purposes of patent law. In addition, there is not an explicit legal prohibition of patents on human beings. An argument can therefore be made that Canada should both adopt a specific statutory prevention on patenting human beings, and attempt to arrive at a definition of a human being for purposes of this exclusion.

(2) **What about patents on portions of the human genome?** Despite the argument that patents are necessary incentives for private investment in research, many people are uncomfortable with the idea that someone might have the right to exclude others from using a portion of the human genome covered by a patent.

(3) **What about the conditions under which human genetic material is obtained?** This issue was brought to public attention by the *Moore* case, in which a hospital patient unsuccessfully tried to collect a share of the royalties from a cell line

obtained from his spleen. In another case, a patent application on a cell line "collected" from an indigenous Panamanian woman by U.S. researchers was eventually dropped after an international outcry. There should be a basic presumption that informed consent and equitable arrangements for distributing returns are essential ethical conditions for commercialization or patenting of genetic materials of human origin.

XI. Commodification and Objectification

Among the most potent objections both to genetic engineering itself and to patenting higher life forms is the diminished moral respect for life and living organisms that either or both might engender. This could occur by way of "commodification," the set of attitudes that ordinarily accompany commercial transactions, or "objectification". To objectify something is related to treating it as a market commodity, but what is disturbing about objectifying a person or organism is not the exchange of money but rather the notion that a subject, a moral agent with autonomy and dignity, is treated like an object.

The charge of commodification or objectification captures one of the most widely voiced criticisms of patenting: the failure of patent law to distinguish between living and non-living things. We need to ask precisely *how* patenting is likely to diminish respect for life, for example through commodification or objectification, and whether that diminished respect is of enough significance to justify restrictions on the patentability of living organisms. One of the key questions is that of people's ability to make the appropriate ethical distinctions in situations where commodification and objectification might occur. There are reasons to believe both that people can make these distinctions much of the time; there are also reasons to believe they cannot. Here even more than in other situations involving ethics and patenting of higher life forms, there are no easy answers.

XII. Conclusions: On Process and Substance

For this reason, we have taken a process-based approach to our recommendations. One approach to public policy choices about technologies that are unfamiliar and incompletely understood is to leave them up to the experts. However, societies are increasingly unwilling to do this, for a variety of reasons. Failing to have an informed public debate about the ethics of patenting higher life forms effectively prejudges the questions raised in this report in favour of a point of view that is relatively sanguine about potential hazards, and in favour of an incremental approach to dealing with those hazards. More particularly, with respect to matters such as the patenting of transgenic animals or of human cell lines and the products derived from them, any pretence to moral neutrality is itself not neutral because it predisposes public policy toward accepting the status quo and an incremental approach to policy formation that may not be justified. "Patent now, deal with the ethical questions later" is simply not a defensible approach, yet the Canadian Patent Office as presently constituted has neither the statutory mandate nor the capacity

to deal with them.

Any effort adequately to address the ethical questions outlined in this paper will involve two institutional stages. The first stage should involve hearings by a Parliamentary committee given a mandate specifically to examine the ethical issues associated with the patenting of higher life forms and to recommend legislative, regulatory and policy changes. A key ethical question addressed should be whether the baseline or starting point for decisions about patenting higher life forms should be a presumption in favour of patenting or a presumption against it.

Until the public debate we envision has occurred, Canada should preserve the viability of as many policy options as possible, and should therefore resist pressure to adopt policies on intellectual property that might create additional restrictions on the ability to deny patents on higher life forms.

Assuming that some ethical constraints on the patentability of higher life forms are recognized and embodied in legislation, the application of general principles to specific cases will not be self-evident. Indeed, some ethical issues probably can be decided only on a case-by-case basis. There will therefore be a need for some institution to make those determinations. Our preferred option is that of an appointed ethical review board or panel that would operate at arm's-length from the CPO, but the options of requiring certification of ethical review by patent applicants and of leaving the meaning of statutory exclusions from patentability to the courts to resolve are also outlined. Many further details of course remain to be considered.

Finally, at present there is no provision in Canadian patent law for a challenge to patents on public interest grounds. We recommend attention to this matter if exclusions from patentability are adopted.

I. The United States and European Experiences

On April 12, 1988 the U.S. Patent and Trademark Office (PTO) issued its first patent on a living animal: the Harvard mouse or Onco-Mouse.[1] This announcement marked a turning point in a debate about the patenting of living organisms that had gone on for some years, beginning with a 1974 application for a patent on a genetically engineered bacterium capable of "digesting" crude oil. The Patent and Trademark office initially rejected the application, on the grounds that "micro-organisms are `products of nature'" and that "as living things, micro-organisms are not patentable subject matter" under the relevant sections of U.S. patent law.[2] The patent applicant, microbiologist Ananda Chakrabarty, appealed this ruling all the way to the U.S. Supreme Court, which ruled in 1980 that life forms were indeed patentable.[3] There followed an expansion of patent activity in a number of areas related to micro-organisms and cells: one such patent, "covering the process for producing biologically functioning molecular chimeras" (the Cohen-Boyer patent) became Stanford University's "top earning patent".[4] However, until 1987 biotechnology-related U.S. patents applied only to microorganisms, to processes involving them, and to tissue and cell culture processes and products. Among the most controversial patents in this latter category was one issued to the Regents of the University of California for a cell line originating in the diseased spleen of a surgical patient named John Moore. After patents had been granted for both the cell line and the methods of producing several products from it, Moore sued the University seeking a share of the proceeds.[5] His lawsuit was ultimately rejected by the California Supreme Court, based on legal reasoning that at least some commentators find strongly suspect.[6]

In April 1987, as the result of a ruling by an internal review board (the Board of Patent Appeals and Interferences), PTO announced that it subsequently would consider "nonnaturally occurring nonhuman multicellular living organisms, including animals, to be patentable subject

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1 Harvard mouse because the patent was issued to the President and Fellows of Harvard College, where the genetic engineering research was carried out; Onco-Mouse, a registered trademark of the firm that now breeds the mice and sells them to experimenters, because the mouse's genome has been modified by the insertion of a human gene that confers high susceptibility to cancerous tumours and consequently makes the mouse highly useful for purposes of cancer research. U.S. Congressional Office of Technology Assessment, *New Developments in Biotechnology: Patenting Life* (New York: Marcel Dekker, 1990), 99.

2 *Ibid.*, 8, 30. For a critical commentary on the "product of nature" doctrine see Michael Gollin, "Patenting Recipes from Nature's Kitchen," *Bio/Technology* 12 (1994), 406-407.

3 *Ibid.*, 51-55.

4 *Ibid.*, 56.

5 For discussion of this case see George Annas, "Outrageous Fortune: Selling Other People's Cells," *Hastings Center Report* 20 (November/December 1990), 36-39; C. Barry Hoffmaster, "Between the Sacred and the Profane: Bodies, Property, and Patents in the Moore Case," *Intellectual Property Journal* 7 (August 1992), 115-148; I. Jane 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; T. Wells, "The Implications of a Property Right in One's Body," *Jurimetrics Journal* 30 (Spring 1990), 371-382.

6 Annas, "Outrageous Fortune," 37; Churchill, "Patenting Humanity," 276-278.

matter ...."[7] The announcement provoked a moral maelstrom. Typical of the reaction was a petition by a coalition of animal rights groups and an organization known as the Foundation on Economic Trends (FET) asking the PTO to reverse its policy because it is "morally reprehensible."[8] Jeremy Rifkin, the founder of FET, remarked that "the new patent policy raises moral and ethical issues that are mind-boggling."[9] In response to such criticisms, the PTO imposed a moratorium on animal patents until September 30, 1987.[10] Shortly after the end of that moratorium period, the Harvard mouse patent was granted. It is indicative of the biotechnology research community's interest in patenting animals that as of late 1991, 120 animal patent applications were pending in the United States.[11] As of early 1994, only three additional animal patents have been granted.[12] This may be read either as a consequence of the backlog of applications for biotechnology patents in general,[13] or as a consequence of PTO's reluctance to fuel the political controversy surrounding patenting of higher organisms by, for instance, providing patent protection to genetically engineered farm animals as well as to animals used in laboratory experiments.

The flavour of the controversy about patenting animals is described by Sheldon Krimsky, who has investigated and written about biotechnology and public policy for almost 20 years:[14] "The decision to patent a mammal brought many of the advocacy groups that opposed the patented bacterium into the latest policy fray. It also attracted another formidable constituency, animal rights groups. The concept of a patented animal signalled to these groups that society was regressing to an extreme Cartesian view of animals as soulless, unfeeling creatures that may be treated like machine parts."[15] Legislators acted on these interest group concerns even before the

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7 OTA, *Patenting Life*, 93.

8 See BNA's *Patent, Trademark and Copyright Journal* 33, No. 827 (April 23, 1987), 664; quoted in K. Bozicevic, "Distinguishing `Products of Nature' from Products Derived from Nature," *Journal of the Patent and Trademark Office Society* 69 (1987), 418.

9 *Ibid.*

10 "Clash Looming on Patenting of Animals," *The New York Times*, July 23, 1987, 10.

11 U.S. Congressional Office of Technology Assessment, *Biotechnology in the Global Economy* (Washington, D.C.: U.S. Government Printing Office, October 1991), 214.

12 S. Chong, "The Relevancy of Ethical Concerns in the Patenting of Life Forms," *Canadian Intellectual Property Review* 10 (1993), 193.

13 *Ibid.*, 211.

14 S. Krimsky, *Genetic Alchemy: The Social History of the Recombinant DNA Controversy* (Cambridge, MA: MIT Press, 1982); Krimsky and A. Plough, *Environmental Hazards: Communicating Risks as a Social Process* (Dover, MA: Auburn House, 1991), ch. 3; Krimsky, *Biotechnics & Society: The Rise of Industrial Genetics* (New York: Praeger, 1991); Krimsky, "The Role of Theory in Risk Studies," in Krimsky and D. Golding (eds.), *Social Theories of Risk* (New York: Praeger, 1992), 3-22.

15 Krimsky, *Biotechnics & Society*, 49. See also Andrew Kimbrell, *The Human Body Shop* (New York: Harper Collins, 1993), 188-202. For a detailed discussion of the political history of humane treatment of animals as an issue and the rise of animal rights interest groups, see F. Barbara Orlans, *In the Name of Science: Issues in Responsible Animal Experimentation* (New York: Oxford University Press, 1993), 44-60.

1988 patent decision was issued. A subcommittee of the House of Representatives' Committee on the Judiciary held hearings on proposed legislation to impose a moratorium on the patenting of animals in 1987,[16] and on essentially the same legislation in 1989.[17] In neither case was the proposed legislation passed.[18]

This discussion of U.S. policy on patenting higher life forms is necessarily incomplete; it does not, for example, include legislative activity in the area of plant patenting or the related field of plant breeders' rights. However, it does indicate quite effectively that the high-profile actors have fallen into three categories: an administrative agency (PTO) with a restricted statutory mandate; the courts; and interest group leaders and individual legislators. The key actors in this last category are best described as "policy entrepreneurs." The most prominent among these entrepreneurs is Rifkin, who established FET in 1977 "to pursue his campaign against what he saw as an unreflective headlong rush for scientific progress at the expense of other values."[19] Like other advocacy groups in the United States, FET has made aggressive and often successful use of litigation to advance its policy positions.[20] Most notably, a lawsuit filed by FET led to a 1984 federal court injunction that temporarily prohibited approval of field tests of genetically engineered microorganisms, on the grounds that the U.S. National Institutes of Health (NIH), the agency responsible for issuing such approvals, had failed to meet the environmental impact assessment requirements imposed by federal legislation. Although the tests were eventually approved, the litigation resulted in years of delay.[21] FET subsequently used litigation to oppose other field trials.[22]

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16 For discussion of these hearings, see B. Hanson and D. Nelkin, "Policy Responses to Genetic Engineering," *Society*, November/December 1989, 76-80.

17 *Transgenic Animal Patent Reform Act of 1989*, Hearings on H.R. 1556 Before the Subcommittee on Courts, Intellectual Property and the Administration of Justice of the House Committee on the Judiciary, 101st Cong. 1st Sess. (1989) (Washington, D.C.: U.S. Government Printing Office, 1990), subsequently cited as *TAPRA '89 Hearings*. For discussion see D. Mark "All Animals Are Equal, But Some Are Better Than Others: Patenting Transgenic Animals," *Journal of Contemporary Health Law and Policy* 7 (1991), 245-268.

18 The 1987 legislation was passed by the House, but not the Senate. In order to understand the significance of the legislation's failure to achieve enactment, it helps to note a basic difference between the U.S. and Canadian legislative processes. Since party discipline is fragile and limited, individual U.S. legislators are most effective when they can build coalitions at the committee stage, in their own chamber and (in particular) in both the House and Senate. By comparison, in Canada the legislative agenda is primarily under the control of the executive, and private members' bills that are not part of the government's legislative program are rarely enacted into law. When they are, they tend either to deal with non-controversial issues or to deal with issues (like capital punishment) on which public opinion is so highly polarized that Cabinet has decided the most politically advantageous course is to take no position, at least for public consumption, and allow government members a "free vote".

19 B. Pletenik and P. Cooper, "Administration at the Cusp of Science: The Case of Recombinant DNA," *Administration & Society* 24 (1992), 141.

20 Krimsky, *Biotechnics & Society*, 120-124.

21 Pletenik and Cooper, "Administration at the Cusp of Science," 139-149; Krimsky, *Biotechnics & Society*, 120-132. For critical commentaries on Rifkin's role in U.S. biotechnology policy, see C. Anderson, "Evolution of a gadfly," *Nature* 353 (1991), 686-687; R. Hoyle, "Rifkin Resurgent," *Bio/Technology* 10 (1992), 1406-1407.

22 Krimsky and Plough, *Environmental Hazards*, ch. 3.

Additional interest groups opposed to patenting of higher life forms participated in the 1987 legislative hearings. They included farmers' organizations worried that expansion of patenting would lead to intensified corporate control of agriculture, and would thereby threaten the already tenuous viability of the family farm. The National Council of Churches and a variety of animal rights organizations were concerned about the potential for a "shift in how humanity relates to the natural environment."[23] To this list of actors one must add, of course, the biotechnology industry itself and the expanding number of academic researchers with a direct or indirect economic stake in the fortunes of that industry.[24] Two observers of the 1987 hearings do not, however, see the controversy as predominantly economic:

> The dispute reflected in part the concerns of those with direct economic interests. But opposition to the patenting decision was mainly driven by values and beliefs--about the moral rights of animals, the threat to democratic values, the repugnance of commodifying living things, and the ethics of tampering with life.[25]

Similar conflicts have unfolded in the European Union (EU). In most EU countries, although not all, patenting decisions are broadly governed by the provisions of the European Patent Convention (EPC), to which some non-EU countries are signatories as well. Decisions about patentability under the EPC are made by the European Patent Office (EPO). Once again, the Harvard mouse is a central character in the story. The application for a patent on the mouse was originally rejected by the Examining Division of EPO, on the grounds that animal varieties were excluded from patentability under Article 53(b) of the EPC.[26] On appeal to the EPO's Technical Board of Appeal, an internal tribunal roughly analogous to the PTO Board of Appeals in the United States, the case was returned to the Examining Division with the finding that animals *per se* were not excluded from patentability by the EPC prohibition on patenting of animal varieties. In addition, according to one of the lawyers for the patent applicants, "in differing from the Examining Division, the Appeal Board took the view that use of oncogenes in the Harvard animals does raise questions of animal suffering which make it critically important to reconsider the morality issue.... This issue was thus also remitted to the Examining Division for reassessment."[27]

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23 Quoted in Hanson and Nelkin, "Public Responses," 78. Daniel Kevles has referred to opponents of patenting as "a disparate collection of overlapping groups ... united by a common dissatisfaction with the reductive manipulation of living organisms, as well as with what they regard as a deplorable disassembly and exploitation of nature." "Vital Essences and Human Wholeness: The Social Readings of Biological Information," *Southern California Law Review* 65 (1991), 271.

24 *Ibid.*, 77; M. Kenney, *Biotechnology: The University-Industrial Complex* (New Haven: Yale University Press, 1986); S. Krimsky *et al.*, "Academic-Corporate Ties in Biotechnology: A Quantitative Study," *Science, Technology & Human Values* 16 (1991), 275-287; J. Rule, "Biotechnology: Big Money Comes to the University," *Dissent*, Fall 1988, 430-436.

25 Hanson and Nelkin, "Public Responses to Genetic Engineering," 80.

26 Article 53 deals with Exceptions to Patentability, and provides that: "European patents shall not be granted in respect of ... (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof."

27 R. Bizley, "Patenting Animals in Europe," *Bio/Technology* 9 (July 1991), 620.

As a result of that reassessment, the Examining Division decided that the Onco-Mouse was patentable, at least partly on the basis that granting the patent would not offend against the ethical exclusion in Article 53(a) of the EPC. That exclusion provides that patents shall not be granted 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...." According to one of the lawyers for the patent applicants, "hundreds of moral objections" to granting the Harvard mouse patent were received by the EPO's examining division.[28] Canadian patent legislation provides no analogous exclusion from patentability based on considerations of morality or public policy.[29] In addition, under Article 99(1) of the EPC, notices of opposition may be filed for up to nine months after a patent is granted. There is no comparable procedure for objections to be registered in Canada--a point emphasized by the Canadian Intellectual Property Office in a recent presentation on patenting life forms,[30] and one we consider extremely important.

The EPO's approach to resolving the ethical questions raised about patenting the Onco-Mouse involved identifying the relevant values and balancing them. According to Rudolf Teschemacher of EPO:

> [T]he Division identified three different interests which were involved and required balancing: there is the basic interest of mankind to remedy widespread and dangerous diseases, on the other hand the environment has to be protected against the uncontrolled dissemination of unwanted genes and, finally, cruelty to animals should be avoided. The latter two considerations may well justify regarding an invention as immoral and therefore unacceptable, unless the advantages, i.e. the benefit to mankind, outweigh the negative aspects.
>
> On overall balance the Examining Division concluded that the invention cannot be considered immoral or contrary to "ordre public". The provision of a type of test animal useful in cancer research and giving rise to a reduction in the amount of testing on animals together with a low risk connected with the handling of the animals by qualified staff can generally be regarded as beneficial to mankind.[31]

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28 *Ibid.*, 619.

29 This may be a consequence of the distinction between the civil law systems of continental Europe and the common law systems of North America, but there is no reason to think that such policy-based exclusions are necessarily incompatible with other aspects of intellectual property law in a common law jurisdiction.

30 "Patents for Lifeforms," notes for presentation (Ottawa, January 5, 1994).

31 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.

This conclusion was in keeping with the reasoning of the patent applicants, who argued that:

> 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.[32]

The EPO decision clearly left the door open to denying patents in situations where different values were involved or different weights were attached to those values. Indeed, the EPO "recently opposed a similar mouse patent designed to study hair growth because the study was not deemed to be sufficiently important to outweigh animal suffering."[33]

Even before the initial rejection of the Harvard mouse patent application by the EPO's Examining Division, the Commission of the European Communities had proposed a draft Directive that would have provided for expansive patent protection of biotechnological innovations within the nations of the European Union.[34] An amended proposal was released in December 1992, after consultations with the European Parliament.[35] According to the amended draft:

> Parliament concentrated mainly on the ethical dimension of biotechnological inventions. As the discussions progressed, it became clear that a mere reference to the concepts of public policy ("*ordre public*") and morality was not enough and that this traditional framework for exclusion from patentability needed to be supplemented by more precise

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32 Bizley, "Patenting Animals in Europe," 620.

33 C. Ho, "Building a Better Mousetrap: Patenting Biotechnology in the European Community," *Duke Journal of Comparative and International Law* 3 (1992), 188.

34 At present, all member nations of the EU except Portugal are signatories to the EPC.

35 The relations among the various Euro-institutions are best summarized this way: "The European Commission initiates and supervises European Community policy" through its "23 Directorates-General with responsibilities approximately aligned with those of European National Ministries or U.S. Cabinet Departments....

For a given piece of legislation, the Commission drafts a proposal in consultation with member state authorities. The proposal goes before the European Parliament (518 elected members), which reply with an `opinion' suggesting to the Commission any number of amendments (45 in the case of the Biotechnology Patents Directive). Those amendments may (or may not) be included in the proposal which reaches the Council of Ministers....

The Council is the supreme decision-making body of the Community and comprises the twelve member state ministers with responsibility for the policy area under discussion." J. Hodgson, "Europe, Maastricht, and Biotechnology," *Bio/Technology* 10 (November 1992), 1421-1422; see also L. Maher, "The Patent Environment: Domestic and European Community Frameworks for Biotechnology," *Jurimetrics Journal* 33 (1992), 101-102.

guidelines for national patent offices and courts.[36]

A number of elements of the amended draft resulted from tensions between the European Commission and the European Parliament.[37] Of these, two are of particular importance as background for our study of ethical issues.

First, "the vast majority" of the members of the European Parliament supported adding to the directive a section on "farmer's privilege,"[38] which would enable farmers to use seeds from crops grown from patent-protected seeds, and to breed patent-protected livestock, without incurring a further financial obligation to the patent-holder. However, such use would be for their own purposes only, and not for resale.[39] Second, the amended Draft Directive explicitly excluded from patentability, "*inter alia*,":

(a) the human body or parts of the human body *per se*;
(b) processes for modifying the genetic identity of the human body for a non-therapeutic purpose which is contrary to the dignity of man;
(c) processes for modifying the genetic identity of animals which are likely to inflict suffering or physical handicaps upon them without any benefit to man or animal.[40]

This exclusion is ambiguous in several respects. For instance, it is not clear how it will be determined whether a particular non-therapeutic purpose is contrary to the dignity of man. In addition, although the amended Draft Directive prohibits patents on parts of the human body, this provision "means parts of the human body as found inside the human body" and clearly was *not* intended to preclude patenting "certain products or parts of the human body which are already covered by patents granted in connection with the development of medicinal products."[41]

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[36] Commission of the European Communities, COM(92)589, final, "Amended Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions" (Brussels, December 16, 1992), Explanatory Memorandum, 1. The explanatory memorandum provides commentary on the actual text of the draft directive.

[37] For background on these modifications, see Ho, "Building a Better Mousetrap," 191-194; N. Jones, "Biotechnological Patents in Europe--Update on the Draft Directive," *European Intellectual Property Review* 14 (1992), 455-457.

[38] Commission of the European Communities, COM(92)589, final, "Amended Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions" (Brussels, December 16, 1992), Explanatory Memorandum, 16.

[39] *Ibid.*, Amended Proposal, 21 (Article 13).

[40] *Ibid.*, 13 (Article 2).

[41] *Ibid.*, Explanatory memorandum, 7. These include "a human lymphoblastoid cell line ... a recombinant DNA molecule capable of inducing the expression in a unicellular host of a polypeptide displaying the immunological and biological activity of human B-interferon ... a human hepatocyte culture process ... the molecular cloning and characterization of a gene sequence coding for human relaxin ... a method for producing human antibody ... and a process for producing a human protein of therapeutic value," all of which are the subject of European patents granted between 1989 and 1991. *Ibid.*

A revised (yet again) version of the Draft Directive was adopted by the EU Council of Ministers in February 1994.[42] The Council of Ministers, "the supreme decision-making body of the Community,"[43] accepted some but by no means all of the revisions proposed by the European Parliament. A number of minor modifications were made to the exclusions from patentability mentioned in the preceding paragraph. At least one of these modifications would expand the range of biotechnological inventions excluded from patentability by requiring that genetically modified animals and processes for carrying out such modification offer "substantial benefit to man or animal" before they are considered patentable.[44] On the other hand, the Council extended farmer's privilege only to seeds and not to livestock,[45] arguing that although farmer's privilege is already provided for in forthcoming Community regulations on plant breeders' rights, there is no justification for creating an exception from "the fundamental principle of patent law according to which the holder of a patent may prohibit any third party from using the protected invention."[46] In other words, the reasoning is that farmers do not deserve special treatment simply because of the distinctive nature of the economic activity in which they engage.

This is not the end of the issue, for two reasons. First, the Council of Ministers adopted what is referred to as a "Common Position adopted by qualified majority," rather than a unanimous position, which means the proposed Directive must now be returned to the European Parliament for approval. (Ministers from Denmark, Spain and Luxembourg voted against the Directive.) "If Parliament rejects the `common position,' the Council must act unanimously."[47] Since elected members of the European Parliament are not necessarily committed to the policies of their respective national governments, such approval is by no means a foregone conclusion. Second, although Directives are binding on EU member nations, they "lay down the ends but not the means," and must be implemented by the adoption of legislation or regulations by each member state.[48] Given the widespread opposition to various provisions of the Directive, political conflict over some of its key provisions is likely to intensify rather than abate at the national level within at least some EU nations.

The coalition opposing patenting of higher life forms in Europe is similar to that in the United States. Farmers' organizations are concerned about the possible economic impacts of patents on higher life forms. Although studies on the topic are not available, it is probable that the intense politicization of this issue is at least loosely related to the tension between protectionist

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42 Common Position adopted by the Council on 07/02/94, session document C3-0087/94.

43 Hodgson, "Europe, Maastricht, and Biotechnology," 1422.

44 Article 2.3.

45 Session document C3-0087-94, Common Position of the Council, 4065/1/94, Article 12. For commentary see No Patents on Life! European Coordination, Mail Out no. 19, February 1994.

46 *Ibid.*, Addendum 1 (Statement of the Council's Reasons), s. III.3.2.

47 Hodgson, "Europe, Maastricht and Biotechnology," 1422.

48 *Ibid.*

agricultural policies in the EU and the trade-liberalizing objectives of the recently concluded General Agreement on Tariffs and Trade (GATT) negotiations.[49] In many European countries, new advocacy organizations have been formed specifically to support more restrictive biotechnology policies, and have been joined by some existing organizations such as Greenpeace. Among their key activities at the European level has been a "No Patents for Life!" campaign organized in response to the EPO decision on the Harvard Mouse.[50] The political issues include not only patenting, but also regulation of biotechnological research and applications. Efforts to achieve a unified regulatory framework at the Community level have come into conflict with sharply differing national approaches and attitudes. Germany, for instance, has enacted a regulatory regime the stringency of which has provoked considerable complaint from academic researchers and industry, and apparently has led to decisions by at least two chemical firms to locate new plants outside Germany.[51]

A crucial difference between the North American and European situations is the existence in Europe of vocal and strategically influential Green or ecology parties, not only at the national level but also in the European Parliament.[52] Whereas in the United States opponents of patenting are limited to the courts and to asserting influence through policy networks and communities that exist largely outside formal legislative institutions, ecology parties provide an additional conduit through which European policy outcomes can be influenced. Superimposed on these political dynamics is the "democratic deficit" created by the increased authority acquired by the European Commission as part of the process of European integration; according to some critics, that increased authority has not been accompanied by increased accountability.[53] The effect has been to create a relatively high-profile public debate that highlights a number of the key conflicts surrounding the patenting of biotechnological innovations, in a way that has not happened in Canada.[54]

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49 "Grotesque: A Survey of Agriculture," *The Economist*, December 12, 1992.

50 B. Dixon, "Who's Who in European Antibiotech," *Bio/Technology* 11 (January 1993), 44-48.

51 *Ibid.*, 48; S. Shackley and J. Hodgson, "Biotechnology Regulation in Europe," *Bio/Technology* 9 (1991), 1056-1061; P. Kahn, "Germany's Gene Law Begins to Bite," *Science* 255 (1992), 524-526.

52 For example, the president of Zurich-based coalition SAG (Schweizerische Arbeitsgruppe Gentechnologie) sits as a Green member of the Swiss parliament. Dixon, "Who's Who in European Antibiotech," 44. The Green contingent in the European Parliament has also been active in extra-legislative contexts: it has, for instance, filed protests with the EPO against the granting of patents on human genes. D. MacKenzie, "Greens go to law to block human gene patent," *New Scientist*, 1 February 1992, 18.

53 D. Dinan, "The European Community, 1978-93," *Annals of the American Academy of Political and Social Science* 531 (January 1994), 23; J. Lodge, "The European Parliament and the Authority-Democracy Crises" *Annals of the American Academy of Political and Social Science* 531 (January 1994), 69-83; Hodgson, "Europe, Maastricht, and Biotechnology."

54 A revealing anecdote was related to one of the authors (T.S.) by a colleague who visited what was then the Federal Republic of Germany for an extended period in 1988, and observed that genetic engineering and its implications were often the topic of television talk shows. This is not necessarily the most appropriate forum for debating bioethical issues, but it is at least an indication of a potentially high level of awareness of them.

II. Canadian Policy and Politics

In contrast to the European and U.S. experiences, the Canadian Patent Office (CPO) has stated a policy of not granting patents on higher life-forms (beyond the bacterial micro-organism level).[55] This prohibition is based on the CPO's interpretation of existing Canadian case law. It is important to note that this policy statement is merely an interpretation of the law; the matter has not been dealt with expressly either in legislation or in a court decision that can be regarded as setting a precedent. Further, it is arguable that the CPO has, to a large degree, misinterpreted the rulings of both the Federal Court of Appeal and the Supreme Court of Canada in the *Pioneer Hi-Bred* case,[56] which "left open the question of whether a plant or animal altered by an intervention at the gene level could be the subject of patent protection,"[57] while ignoring two previous decisions handed down by the Commissioner of Patents (and Patent Appeal Board) that make explicit statements about the patenting of higher life-forms.[58]

In the absence of a catalyst like the announcement of a patent on a transgenic animal or the activities of a high-profile policy entrepreneur, debate about the ethical implications of intellectual property rights in higher life forms has been minimal in Canada, with two exceptions. First, the passage of the *Plant Breeders' Rights Act* in 1990 followed hearings of both a House of Commons Legislative Committee and the Standing Senate Committee on Agriculture and Forestry. Whereas "consistent and strong support" was expressed "from groups representing just about every aspect of the industry that uses seeds,"[59] concerns were expressed about such potential implications as the declining perceived value of publicly supported agricultural research, reduced genetic diversity, and the slippery slope allegedly leading from plant breeders' rights to animal patents,[60] notably by representatives of a coalition of farm and environmentalist organizations known as Genetic Resources for Our World (GROW). Such arguments and others related to national and global effects on agriculture and biodiversity have subsequently been advanced as well by the Rural Advancement Foundation International (RAFI), a non-governmental organization which has been

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55 S. Avisar, "The Ethics of Biotechnology--The Argument in Favour of Patents," *Canadian Intellectual Property Review* 10 (1993), 209.

56 *Pioneer Hi-Bred Ltd. v. Commissioner of Patents* (1987), 14 C.P.R. (3d) 491 (F.C.A.); (1989), 25 C.P.R. (3d) 257 (S.C.C.)

57 Avisar, "The Ethics of Biotechnology," 211.

58 These are the *Abitibi* (1982) 82 C.P.R. (2d) 32 (Patent Appeal Board and Commissioner of Patents) and *Connaught Laboratories* (1982) 62 C.P.R. (2d) 81 (Patent Appeal Board and Commissioner of Patents) decisions. A memorandum detailing this argument by Sunny Handa, LL.M. is on file with the Westminster Institute and the McGill Centre.

59 Sen. Joyce Fairbairn, in *Senate Debates*, 2nd Sess., 34th Parl., June 14, 1990, 2052.

60 "Once we have allowed property rights to be applied on plants we will find ourselves granting exclusive rights on animals, human cell lines and individual genes, as has been the case in the United States." Genetic Resources of Our World (GROW) brief to Senate Standing Committee, quoted by Fairbairn, *ibid.*, 2054. Cf. the claim of Pat Mooney, then of the Canadian Council on International Cooperation, that: "If Bill C-15 is passed and becomes law in Canada, it will be again recognition by Parliament that a life is patentable." *Minutes of Proceedings and Evidence*, House of Commons Legislative Committee on Bill C-15, 2nd Sess., 34th Parl. (October 24, 1989), 2:13 [subsequently cited as *House C-15 Hearings*].

active on development policy issues for many years and which collaborates with a variety of non-governmental organizations in developing countries as well as with agencies of the United Nations and other international bodies.

Second, late 1993 saw the release of the two-volume report of the Royal Commission on New Reproductive Technologies (RCNRT).[61] The creation of the Commission was the result of considerable political pressure from Canadian women's organizations, which had its counterparts internationally in such developments as the formation of FINNRAGE (Feminist International Network of Resistance to Reproductive and Genetic Engineering), whose founders also edited a now-discontinued journal on *Issues in Reproductive and Genetic Engineering*. The Commission was dogged by political controversy, and its work has already been the topic of at least one scathing critique and retrospective.[62]

Based in part on what it saw as public apprehension about the role of the profit motive in driving the development and provision of new reproductive technologies, RCNRT

> ... recommended stringent legislation against the buying and selling of [human] gametes, zygotes, embryos and fetal tissue. This legislative prohibition would set the boundaries within which any patenting of microbial life forms would operate. Provided such a prohibition is in place, patent protection for cell lines may not, by itself, lead to the commodification of human life. However, if a law prohibiting the sale of gametes, zygotes, embryos and fetal tissue were not in place, withdrawing patent protection from cell lines would not by itself eliminate the problem of commodifying human life. Patents are not the only reason why people might buy and sell gametes or fetal tissue.[63]

The report's brief and inconclusive discussion of specific issues surrounding patenting was accompanied by a recommendation for further study of these issues.[64] This recommendation has already been acted upon, in the form of the present paper as well as other activities on the part of Industry Canada.

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61 *Proceed With Care*, Final Report of the Royal Commission on New Reproductive Technologies, 2 vols. (Ottawa: Supply and Services Canada, 1993).

62 G. Basen, M. Eichler and A. Lippman, (eds.), *Misconceptions: The Social Construction of Choice and the New Reproductive and Genetic Technologies*, vol. 1 (Hull, Québec: Voyageur Publishing, 1993).

63 RCNRT, *Proceed With Care*, 723.

64 *Ibid.*, 724.

In addition, in response to a request from the authors of this report, the co-chairs of the New Reproductive Technologies Committee of the National Action Committee on the Status of Women (NAC) prepared a position paper on patenting of biotechnology inventions.[65] With the exception of this position paper, the organized Canadian women's movement (like its counterparts in other jurisdictions) has until recently paid relatively little attention to patenting and commercialization of human biological material or of biotechnological innovations in general. However, greater attention can be expected on the part of the women's movement given the argument that genetic engineering "directly implicates women's health and autonomy through the interrelated research priorities and industries of reproductive technologies and biotechnologies."[66]

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[65] Gwynne Basen and Christine Massey, "National Action Committee on the Status of Women (NAC) Background/Briefing Paper: Patenting of Biotechnological Inventions" (mimeo, April 1994), on file with the Westminster Institute.

[66] *Ibid.*, 1

III. Analysing Arguments For and Against Patenting Higher Life Forms

A fourfold classification of the arguments we will be analysing helps to distinguish and clarify them. This classificatory scheme is based on two factors: the topic of discussion, that is, whether what is at issue is the moral legitimacy of patenting or of genetic engineering more broadly; and the nature of the argument being made, that is, whether moral legitimacy is seen as a function of the inherent nature of the activity in question or the likely consequences of engaging in that activity. For purposes of convenience, the discussion which follows is organized around objections to patenting higher life forms, but the same classification can also be used for arguments in support of patenting.

With respect to the topic of discussion, patenting higher life forms can be seen as wrong in itself or as derivatively wrong: wrong, in other words, because it would encourage and foster developments in genetic engineering that are morally unacceptable. The latter view assumes that genetic engineering, or at least certain applications of genetic engineering or certain kinds of research in molecular genetics, are morally wrong. Patenting the processes and products of genetic engineering is rejected because it is taken to constitute either an endorsement of the technology and the research on which it is based, or an incentive for continued research and development of a kind that is morally wrong. Indeed, the argument that patenting is a necessary incentive for genetic engineering research is often made by the biotechnology industry. Although that claim may well be overstated, making it impossible to patent the results of this research is an appealing strategy to opponents. The target of this line of criticism is, however, genetic engineering rather than patenting; the wrongness of patenting is derived from the wrongness of genetic engineering.

The importance of keeping this distinction in mind can be illustrated with reference to the EPO decision on the Harvard Mouse patent. The EPO examined the consequences of applying a particular innovation for which a patent was being sought. It did not, however, examine the ethics of patenting in and of itself. Instead, it started from the presumption that patenting higher life forms is acceptable, just as intellectual property law (at least in North America) operates on the presumption that an inventor is entitled to a patent as long as certain standard conditions are met. As we shall see later in the paper, this presumption is not likely to remain uncontested, and arguably should not. To illustrate with a topical recent example, researchers who have isolated the BRCA1 gene, which in some families is responsible for an inherited predisposition to breast cancer, have not only applied for a patent on the gene but also negotiated a licensing agreement with the major pharmaceutical firm of Eli Lilly and Co.[67] It is possible to applaud the use that could be made of the gene in diagnostic screening, although such approbation is not universal,[68] while at the same time bitterly opposing the grant of a patent because of the resultant potential for monopoly

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[67] R. Nowak, "Breast Cancer Gene Offers Surprises," *Science* 265 (23 September 1994), 1796-1799; D. Butler and D. Gershon, "Breast cancer discovery sparks new debate on patenting human genes," *Nature* 371 (22 September 1994), 271-272; R. Nowak, "NIH in Danger of Losing Out on BRCA1 Patent," *Science* 266 (14 October 1994), 209; "Dispute Arises Over Patent for a Gene," *The New York Times*, October 30, 1994: 10.

[68] G. Kolata, "Should Children Be Told If Genes Predict Illness?" *The New York Times*, September 26, 1994: A1, A7.

profits and for exacerbated inequalities in access to health care (because of the high price of testsand therapies developed using the patented gene).

Figure 1

	Topic of Discussion	
Form of Argument	*Genetic Engineering*	*Patenting*
Deontological (arguments dealing with inherent or intrinsic rightness or wrongness)	Pro: Genetic engineering is part of humanity's obligation to expand the range of scientific knowledge and technological capability. Con: Genetic engineering, or certain kinds of human gene therapy, amount to "Playing God".	Pro: Patenting of higher life forms is justified on grounds of fairness to inventors and investors. Con: Ownership of life, or property rights in portions of the human genome, are inherently wrong.
Consequentialist (arguments dealing with harmful or beneficial consequences)	Pro: Genetic engineering will make possible new kinds of therapies for debilitating diseases, and substantial increases in farmers' ability to produce more food at the same or lower cost. Con: A slippery slope leads inexorably from such medical techniques as pre-implantation diagnosis and embryo cloning to the dire consequences that would follow from a revival of eugenics.	Pro: Patenting is necessary in order to create an incentive for investing in research and development that will lead to the various benefits that can be realized from genetic engineering; without the incentive provided by patenting that investment will not be made, or will be made at lower levels. Con: Patenting will have destructive economic effects on family farms; will enable patent holders to reap monopoly profits even from lifesaving therapies and diagnostic techniques; will lead us to objectify life and living creatures, human and otherwise.

With respect to these two topics, the arguments about moral legitimacy exemplify the two main traditions in Western moral philosophy. On the one hand, it is claimed that the activity in question, whether genetic engineering or the patenting of (certain kinds of) higher life forms, is intrinsically wrong,or wrong in principle. (Philosophers refer to claims of this kind as deontological arguments.) Such arguments characteristically appeal to duties, obligations or principles in virtue of which an activity is right or wrong regardless of the good or bad

consequences of that activity. Even if the activity would lead to a net balance of benefits over harms or costs, however one wishes to define these, it nevertheless would be wrong, in this view, if a moral duty, obligation or principle were violated. Comparing the likely benefits and harms, even if they can be determined and agreed upon, is irrelevant if an action or policy is intrinsically wrong. Perhaps the most common argument of this type in the context of patenting, although by no means the only one, is the appeal to "playing God."[69] To allow the genetic engineering of higher life forms would, it is alleged, mean "that the entire creative process in higher forms of life, including human life, is going to be redirected or controlled to satisfy purely human ends. ... We are not only playing God, we are assuming dominion over God."[70]

On the other hand, an activity such as genetic engineering or patenting could be wrong because it causes bad or harmful consequences. (Philosophers call this kind of argument consequentialist.) Such an objection requires that the likely benefits and harms of the particular activity or policy in question be identified and then compared; the activity or policy is judged to be wrong if its harmful consequences outweigh the beneficial ones, and right if the beneficial consequences outweigh the harmful ones.

A consequentialist approach was adopted by EPO in granting the patent for the Harvard mouse. The reasoning used there suggests some extremely important points about such arguments. Sometimes, as in the application of cost-benefit analysis to public policy decisions, benefits and harms are defined and assessed on a narrowly economic basis. The (mis)application of cost-benefit analysis to issues of public policy has been extensively (and properly) criticized.[71] Within philosophy, the most familiar consequentialist argument is "utilitarian," according to which the action that is right is the one that produces "the greatest good for the greatest number." *Consequentialist arguments need not be strictly economic in content or utilitarian in form, however.* First of all, the consequences taken into account need not be solely economic ones. They may be environmental, social or even spiritual, depending upon the criteria used to define, identify and measure benefits and harms. Indeed, some of the most powerful arguments against patenting higher life forms have to do with the potential for commodifying all forms of life, with the attendant loss of respect or even reverence for living things. Further, as this observation suggests, arguing that decision-making should be based on consequentialist arguments is not the same as arguing that

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69 Rebecca Dresser, "Ethical and Legal Issues in Patenting Animal Life," *Jurimetrics Journal* 28 (Summer 1988), 410-412.

70 Cited in "New Animal Forms Will be Patented," *The New York Times,* April 17, 1987, 1.

71 Among many other references, see A.B. Lovins, "Cost-Risk-Benefit Assessments in Energy Policy," *George Washington Law Review* 45 (1977), 911-943; Mark Sagoff, "Economic Theory and Environmental Law," Michigan Law Review 79 (1981), 1393-1419; T. Schrecker, "Risks versus Rights; Economic Power and Economic Analysis in Environmental Policy," in D. Poff and W. Waluchow (eds.), *Business Ethics in Canada* (Scarborough, ON: Prentice-Hall, 1987), 265-284; Peter Self, "Nonsense on Stilts: The Futility of Roskill," *New Society,* 2 July 1970, 8-11; Peter Self, *Econocrats and the Policy Process: The Politics and Philosophy of Cost-Benefit Analysis* (London: Macmillan, 1975); Kristin Shrader-Frechette, *Science Policy, Ethics, and Economic Methodology* (Boston: Reidel, 1985).

decisions should be made simply by aggregating individuals' preferences.[72] Although this process is characteristic of modern economics, Cass Sunstein has made an extremely important case against such "subjective welfarism" as a universal basis for public policy decisions.[73] He puts forward a catalogue of arguments based on (for instance) the difference between people's preferences as private consumers and the collective choices they wish to make as citizens, and their realization that current desires and preferences themselves deserve scrutiny.[74] In the environmental context, Mark Sagoff has made a similar argument, emphasizing that not all preferences have the same moral status. For example, we may as individuals prefer strongly prefer vacationing in theme parks to hiking or canoeing in wilderness areas, yet at the same time we may find ethically unacceptable a public policy decision to allow the destruction of a wilderness area for the construction of a theme park.[75]

Consequentialist arguments, it is important to recognize, occur against a preexisting moral background. When we decide, as individuals or as a society, what is to count as a beneficial or a harmful consequence of a particular policy, such as allowing patents on genetically engineered laboratory animals or on a particular animal, we rely on pre-existing values or ethical commitments. In other words, simply pointing to a particular set of consequences of that policy does not itself constitute an ethical argument. For instance, even if we could demonstrate convincingly that allowing such patents would lead to increased use of laboratory animals in painful experimental procedures, someone without a pre-existing commitment to avoiding animal suffering as a value might simply reply: "so what?" A number of similar examples where the ethical significance of anticipated consequences of patenting higher life forms is itself contested will be cited throughout this report. Because choosing criteria for what constitutes a benefit or harm itself involves value judgements, the question then becomes one of who decides, according to which procedures, and on the basis of whose values. For this reason among others, we have emphasized procedural issues in the recommendations made in section XII of the report.

These categories of arguments about genetic engineering and patenting are schematically depicted in the matrix in Figure 1. Why is this kind of analysis important? Let us give an example. Arguments about the spiritual consequences of certain applications of genetic engineering or patenting sometimes are confused with arguments that genetic engineering or patenting is intrinsically wrong. The difference is subtle, but important for purposes of public policy, because the first kind of argument, but not the second, suggests the value of debate about the probability

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[72] Odelia Funke, "Can a Technocratic Culture be a Democratic One?" presentation to Symposium on Ecological Risk Assessment: Use, Abuse and Alternatives, Center for the Analysis of Environmental Change, Oregon State University, Corvallis, OR, November 1994.

[73] Cass Sunstein, "Preferences and Politics," *Philosophy and Public Affairs* 20 (no. 1, Winter 1991), 3-34.

[74] *Ibid.*, 6-27.

[75] Mark Sagoff, "We Have Met the Enemy and He is Us, or Conflict and Contradiction in Environmental Law," *Environmental Law* 12 (1982), 283-315; Sagoff, "At the Shrine of Our Lady of Fatima, or Why Political Questions are Not All Economic," *Arizona Law Review* 23 (1981), 1283-1298; Sagoff, "Economic Theory and Environmental Law," 1411-1418.

and seriousness of the alleged spiritual consequences. More generally, consequentialist arguments against patenting higher life forms, unlike deontological ones, can be answered for purposes of public policy by demonstrating that anticipated negative consequences can be addressed by way of policies to mitigate them or regulatory regimes to keep them from happening. *If* such measures can be put in place, and if they can be expected to be effective in practice, then the ethical force of the consequentialist objection is reduced.

The framework or matrix in Figure 1 should be used with caution, as an analytical tool to stimulate worthwhile questions rather than as a set of pigeonholes within which particular arguments can be neatly classified. Ethical arguments about biotechnology cannot always be definitively placed into a single cell of the matrix. (This is why the cells of the matrix are separated by dotted lines.) For instance, if one has ethical objections to certain consequences of genetic engineering, one's opposition to patenting is likely to hinge on the question of whether patenting will exacerbate those anticipated negative consequences by providing an incentive to carry out the research, therapy or product development associated with the objectionable consequences. On the other hand, claims involving genetic engineering and the commodification of life may take the form of an argument that ownership of intellectual property rights in life is intrinsically wrong, "as life is not a commodity on which monopoly rights can be granted and exercised."[76] They may also take the form of assertions that patenting and commercialization will lead to certain kinds of ethically unacceptable consequences, such as the commodification of life, of animals or of human traits.

Another value of the matrix is that it enforces clarity about the distinction between deontological and consequentialist arguments, a distinction which is important for purposes of public policy. If ways can be found to avoid or mitigate harmful consequences effectively, then the practices in question may be acceptable provided that such measures are in fact taken. But if the practice is intrinsically wrong, no such policy response is possible. The distinction also directs our attention to the fact that often we do not know how probable the consequences of a particular biotechnology development will be, or indeed even what they will be.

Finally, the matrix is valuable for the kind of intellectual activity it symbolizes. The enterprise of applied ethics is not a science. Ethicists, especially those working in the field of applied ethics, as here, are not oracles and cannot provide "right answers" in the way that careful experimenters can provide right answers to questions about, for instance, the requisites for heavier than air flight. This is why some readers will, no doubt, find this paper frustratingly inconclusive. Moral decision-making is a dynamic, pluralistic process that involves an ongoing accommodation among conflicting values. "No moral theory or argument has been able to establish a rigid hierarchy of values or the dominance of one value over all others in every conceivable case of

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[76] "4736866: Please take note of this number," leaflet produced by the Rainbow Group, European Parliament, n.d. 4736866 is the number of the U.S. patent on the Harvard mouse.

conflict."[77] The classification exemplified by the matrix can nevertheless be helpful in identifying the values and interests that are in conflict in complex areas of public policy, and in clarifying the nature of the conflicts themselves.

[77] C. Barry Hoffmaster, "The Ethics of Patenting Higher Life Forms," *Intellectual Property Journal* 4 (1988), 9.

IV. Of Slippery Slopes and Accumulated Consequences

Before exploring the arguments for and against patenting in greater detail, some further distinctions should be made. Claims about "slippery slopes" are often encountered in discussions of biotechnology policy and intellectual property rights. The "thin edge of the wedge" is another image that communicates the same idea: "a series of gradual steps from an acceptable to an unacceptable position, where it is difficult to determine the exact point at which the crucial transition is made."[78] For example, in June, 1990 a GROW spokesperson told the Senate Committee holding hearings on Bill C-15, Canada's plant breeders' rights legislation, that the bill "should be regarded as simply the tip of the wedge" that will eventually lead to the unrestricted patentability of higher life forms.[79] He pointed to the progression in the United States from the *Plant Variety Protection Act* of 1970, to the granting of full patent rights on micro-organisms in 1980, to the granting of full patent rights on plants in 1986, and finally to granting full patent rights on animals in 1987.

How can the soundness of slippery slope arguments be assessed? A number of philosophers and social scientists have examined this problem, sometimes in great detail.[80] With specific reference to the controversial aspects of human genetic engineering,[81] Krimsky has distinguished two versions of the argument:

> The slippery-slope argument may be framed in a deterministic or probabilistic form. However, it is more convincing as a probabilistic thesis.
>
> Suppose that there are *n* types of human genetic engineering (HGE) scaled such that the first level (HGE-1) is least objectionable and the nth level (HGE-*n*) is most objectionable (according to current norms), with increasing states of 'objectionableness' between 1 and *n*.[82]

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78 D. Lamb, *Down the Slippery Slope: Arguing in Applied Ethics* (London: Croom Helm, 1988), vii.

79 R. Munroe (Genetic Resources for our World (GROW) Co-Chairman), Evidence presented to the Standing Senate Committee on Agriculture and Forestry, June 11-12, 1990; see also testimony of R. Munroe in *House C-15 Hearings*, 7:6. 7:12.

80 See *e.g.* Lamb, *Down the Slippery Slope*; W. van der Burg, "The Slippery Slope Argument," *Ethics* 102 (1991), 42-65.

81 This term is used to refer to a variety of practices ranging from pre-implantation diagnosis (PID) to modification of the human germ line.

82 Krimsky, *Biotechnics & Society*, 163.

The deterministic position is "that once HGE-1 is permitted, we will inevitably draw closer to HGE-*n*."[83] The probabilistic position, by contrast, maintains that once HGE-1 is permitted,

> [A]ny decision, say HGE-*k* (where $k<n$), makes HGE-*n* more likely, but does not causally determine it. It allows for the possibility of human intervention at any point in the chain. Thus, while there is no law of iron necessity that links the treatment of a thalassemic patient by transplanting genetically engineered cells and the implantation of genes in a human egg, these two events are united by a similar technological process and impelled by similar economic forces and professional motivation. The former event gives shape to the latter event without `determining' it. The probabilistic thesis implies that we are treading on ethically sensitive ground. For this reason there must be clarity about the justification for HGE-*k* and the ethical boundaries between each class in the series of possible human genetic engineering events.[84]

Wibren van der Burg draws a different distinction, that between logical and empirical versions:

> The logical form of the argument holds that we are logically committed to allow B once we have allowed A. The empirical form tells us that the effect of accepting A will be that, as a result of psychological and social processes, we sooner or later will accept B.[85]

Political theorist Richard Vernon provides one of the clearest and simplest tests of the strength or weakness of slippery slope arguments. Whether the arguments are cast in deterministic or probabilistic terms, whether logical or empirical, they must "contain a genuine causal element linking the top of the slope with the bottom".[86] It may help to think of the process of searching for this causal element as looking for the lubricant that makes the slope slippery and deprives us of traction as we slide down it.

One such lubricant is what Vernon calls "precedential force": the creation of precedents that will subsequently be applied in ways whose consequences are undesirable.[87] "Precedents," says Vernon, "erode what we may term argumentative space." Vernon uses the example of the infamous neo-Nazi march through Skokie, Illinois, and notes that:

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83 *Ibid.*

84 *Ibid.*

85 van der Burg, "The Slippery Slope Argument," 43.

86 R. Vernon, "Slippery Slopes and Other Hazards," draft MS (London: University of Western Ontario, mimeo, February 1994), 18.

87 *Ibid.*, 5.

> If municipalities or local magistrates are debarred from prohibiting any public assemblies at all, we can at least predict that they will not prohibit any inappropriately: open the door by allowing one community to prohibit a demonstration--even a clearly loathsome one--and we no longer have the assurance that we had before. This, I think, is a clear case of a slippery slope argument. It arises because while we may believe that we can manage to distinguish between objectionable and innocuous demonstrations, we do not believe that the line will be clear enough to others.

However, precedent provides a credible lubricant only "when the action which we are to take runs the risk of being mistaken, by other people, as a precedent for other kinds of action, of an undesirable sort. It is a reminder about the `frailty' of others."[88] This definition of a slippery slope thus has both logical and sociological elements.

In a common-law legal system, in which decision-making is explicitly organized around precedents, that frailty is arguably institutionalized: the rule of *stare decisis* provides lubrication for the slide down the slippery slope. The weight of a slippery slope argument in such a legal context depends primarily on how predictable one believes that judicial decisions actually are in terms of the relevant precedents, and why one believes this. There exists a surprising degree of agreement among social scientists who study the legal process that in practice judges exercise considerable discretion in selecting precedents, and considerable creativity in supporting their conclusions by distinguishing the case at hand from previous cases in which the precedents would seem to imply contrary conclusions.[89] The notion of a precedent does not have to be understood in strictly legal terms, however; there are moral and political precedents as well as legal precedents. Having accepted a particular situation, people may view themselves as logically bound to accept a subsequent situation if its key elements seem relevantly similar. In some circumstances, stepping onto the slope itself may be viewed as the relevant precedential change: once a threshold is first crossed or a prohibition broken, its subsequent power may be lost.

Another kind of lubricant may be involved in situations where "previous expenditures of effort are regarded as an investment which it would be costly to abandon,"[90] for any one of a number of reasons. The costs may be financial, political, or emotional. Governments which have made a commitment to support failing industrial enterprises, or to pursue unpopular wars like the U.S. campaign in Vietnam, may attempt to justify additional investments in the firm or the war with reference to the need to salvage some return on the financial or political resources already committed. The likelihood that this may happen can be invoked as a credible argument against

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88 *Ibid.*, 7.

89 Rainer Knopff and F.L. Morton, *Charter Politics* (Toronto: Nelson Canada, 1993). Consider, for instance, the dramatically different conclusions reached by the justices of the Supreme Court of Canada in such recent cases as *Morgenthaler* and *McKinney*, and the distinctive logics by which various justices came to their respective conclusions: *Morgenthaler, Smoling and Scott v. R.* (1988), 37 C.C.C. (3d) 449; *McKinney v. University of Guelph* (1990), 76 D.L.R. (4th) 545.

90 Vernon, "Slippery Slopes," 9.

initiating such ventures in the first place, when the ultimate costs in the event of failure may be substantial and the probability of success is uncertain. This version of the slippery slope argument has been made by opponents of U.S. military involvement in Bosnia and was made prior to the U.S. intervention in Haiti, to give but two topical examples.

A third, related type of lubricant can be identified in situations where particular actions or policies either create altogether new actors, or strengthen the commitment and expand the resources of existing ones. For example, granting intellectual property rights in higher life forms may encourage the investment of researchers' time and governments' and shareholders' money in particular lines of research based on anticipated commercial returns that could not be realized in the absence of patents on the products of the research. Researchers would be motivated by the desire to protect the returns on their investments of dollars and years, and the financial strength of the emerging industry could provide the basis for effective opposition to regulatory measures that might be identified as justified at a later date. If patenting does indeed facilitate successful (i.e. profitable) commercialization, it could enhance the resources available to the firms and researchers in question for purposes of resisting regulation or evading subsequent ethical scrutiny, as well as bolster their motivation to do so. A version of this argument might be: do we want to create the preconditions for an industry based on the patenting of segments of the human genome?

A final kind of lubricant involves what Vernon calls "cumulative effects on our political culture: if we become accustomed to seeing government as a parenting institution in one area, will we not tend to lose our resistance to seeing it this way in other areas? If we inure ourselves to the toleration of some vices, will we not tend to lose our hatred of all vice?"[91] A useful parallel can be drawn with the argument that exposure to violence on film and on television gradually desensitizes the audience, increasing its toleration of violence as a solution for problems quite apart from the context in which televised and filmed violence was originally depicted. Even in retrospect, it is difficult empirically to demonstrate the existence of this effect in a way that will convince sceptics. This is at least partly because of the problems that are encountered in trying to identify a control group sufficiently isolated from the pervasive cultural influence of television to make one's findings unequivocal.

With reference to biotechnology, thinking about this lubricant suggests questions such as: If our society becomes accustomed to treating animals as protein factories, will we treat them in a similarly instrumental way in other contexts? If we become accustomed to the use of prenatal diagnosis followed by selective abortion with respect to a limited range of devastating genetic disorders which can presently be screened for, will we in time accept the use of these procedures to screen embryos for a much broader range of supposedly undesirable traits? The fact that such questions are difficult to answer does not mean we should pay less attention to them.

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[91] *Ibid.*, 18; see also M. Shapiro, "Fragmenting and Reassembling the World: Of Flying Squirrels, Augmented Persons, and Other Monsters," *Ohio State Law Journal* 51 (1990), 361.

To summarize, the key questions with respect to slippery slope arguments of all kinds are: what is the lubricant? how slippery will the lubricant in fact make the slope? how sure are we about the preceding answer? For purposes of public policy, it is also useful to draw attention to another question about slippery slopes: can the effects of the lubricant be offset, for example by measures directed at preventing or mitigating the likely negative impacts in a particular context. We may think of this process in terms of spreading sand, ashes, or some other absorbent on the slippery slope at a particular point, or alternatively in terms of erecting barriers that can be relied upon to arrest further progress down the slope. Even if this *could* happen, in the sense that it is not precluded by prohibitive administrative complexity or enormous cost, or is not physically impossible because it contravenes the two basic laws of thermodynamics, is it reasonable to believe that it *will* happen, given what we know about the constellation of interests promoting the policies that created the prospect of the slippery slope in the first place? So the question in its simplest form is: what can individuals, societies and governments use to put traction on the slippery slope, or to ensure that solid and reliable barriers are put up at certain points on the slope to indicate boundaries between the permissible and the impermissible? (The barrier may, of course, be placed at the very top of the slope, corresponding to a situation in which *any* departure from a particular norm is impermissible.)

Slippery slope arguments of all kinds must be distinguished from a number of superficially similar arguments, most importantly those about the cumulative effects of large numbers of seemingly insignificant or isolated decisions, which may be unanticipated and/or perverse. In the context of biotechnology, consider a hypothetical situation in which patents on transgenic animals are allowed on the basis that, in a large number of individual cases, the benefits outweigh the harms. This is, it will be recalled, the reasoning adopted by the EPO in allowing the Harvard mouse patent. The result of a host of similar decisions could be a substantial increase in the attractiveness of using animals in general and transgenic animals in particular in laboratory experiments.[92] Each individual decision considered alone will appear rational and defensible, yet the combined effect of the decisions, which was neither planned nor necessarily anticipated, is contrary to the broader policy objective of reducing animal experimentation and the associated suffering. (It is assumed, for purposes of this example, that this is in fact a societal objective on which consensus exists.)

This is not a slippery slope argument, since no causal or probabilistic progression of the type identified by Krimsky is involved. It is, rather, an argument that decisions which are defensible viewed in a local or small-scale context may be indefensible and even irrational when the system-wide consequences of large numbers of similar decisions are taken into account. In the environmental policy context, many small-scale individual projects involving wetland drainage by farmers or road widening by municipalities may be justified on the basis that the environmental damage in each individual case, considered in isolation, is outweighed by the benefits. (Once

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[92] There is some evidence for this latter effect in the United Kingdom, where between 1990 and 1991 alone "the number of tests involving animals bred with harmful genetic defects rose by 28,000, to 170,000, and transgenic creatures were subjected to 62,000 procedures, 14,000 more than in 1990." "Animal tests," *New Scientist*, 14 November 1992, 12.

again, the contested nature of definitions of damage and benefit must be considered as well.) The cumulative effect of these decisions over time, however, is that a large percentage of the wetlands in a given geographic region may be converted to pastures or parking lots, with the associated ecological consequences, or that a region's reliance on a highway-based transportation system is literally cast in concrete, with the associated (and unexamined) implications for energy consumption, pollution levels and settlement patterns.[93]

The discipline of economics provides an interesting conceptual approach to this question of cumulative or connected actions, by way of the concept of negative externalities. When a highway is carrying rush hour traffic at or near its peak design capacity, each additional user may cut her own commuting time relative to alternative routes while at the same time slightly increasing commuting time for all other users of the highway. It does little good in such cases to judge the decision of each additional user by comparing it to the decisions of previous users. As isolated individual choices, they all make sense; the cumulative consequences may nevertheless be highly undesirable, and call for public policy intervention using instruments as diverse as higher fuel taxes (to discourage commuting by car and encourage car-pooling) and explicit pricing of road use at peak hours.

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[93] Cf. K. Shrader-Frechette, "Environmental Impact Assessment and the Fallacy of Unfinished Business," *Environmental Ethics* 4 (1982), 37-47.

V. Generic Arguments About Patenting Higher Life Forms

At least three distinct arguments in favour of patenting higher life forms can be identified. The first, and probably most powerful, was stated by Philip Leder, the coinventor of the Harvard mouse, in the course of 1989 Congressional hearings on proposed U.S. legislation to restrict the patenting of transgenic animals:

> [T]he great and costly engine for invention can only be effectively driven with the support from the private sector, motivated to serve a public need.
>
> The patent system offers the only protection available for the intellectual product of this research, and thus, the only hope of a fair return against the great financial risks that investment in biotechnology entails.[94]

This argument can be construed as an appeal either to the inherent fairness of compensating those who take risks, or to the assumption that patent protection provides an incentive without which beneficial scientific and technological developments will be delayed or foregone.[95] The beneficial consequences of research in biotechnology could include less expensive and more abundant food; more effective pharmaceutical products; or expanded opportunities for life-saving medical research.

Dr. Leder provided some examples. He argued that the Harvard mouse had great potential for public benefit "as a vehicle for the development of further therapies" as well as "an early warning system for the detection of carcinogens and mutagens" in chemical testing,[96] and he pointed out that:

> In the past few weeks, the gene for cystic fibrosis has been identified and the ability to replace this gene, for example, in a mouse, with the defective human cystic fibrosis gene would constitute an extremely powerful model system for the development of an effective treatment.

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94 P. Leder, testimony in *Transgenic Animal Patent Reform Act of 1989 (HR 1556)*, Hearings before Subcommittee on Courts, Intellectual Property and the Administration of Justice, Committee on the Judiciary, U.S. House of Representatives, 101 Cong. 1st Sess., September 13 and 14, 1989, Serial No. 76 (Washington, D.C.: USGPO, 1990), 195 [subsequently cited as *TAPRA '89 Hearings*].

95 Thus Leder pointed out that DuPont Corporation, "the industrial concern that provided the financial support for this research," had received the rights to the patent on the Harvard mouse under licence from Harvard University. *Ibid.*, 194; see also 219.

96 *Ibid.*, 219-220.

For individuals and families at risk for this and other diseases, this would represent a priceless asset.[97]

In a similar vein Bernadine Healy, then Director of the U.S. National Institutes of Health, argued during 1992 Congressional hearings on the patent application policy of the Human Genome Project that: "The success of Government-funded human genome research is of critical importance to our Nation's public health" as the basis for "understanding the genetic basis for health, disease, and life functions" as well as for developing therapies. "The supportive and symbiotic relationship must be assured between emerging scientific developments and the intellectual property system."[98] "Patent protection for biotechnology and pharmaceutical industries is critical," she continued. "Bringing new therapies to the public is a lengthy and expensive process. Not surprisingly, companies are reluctant to invest the resources and take risks unless some market protection can be obtained."[99] Similar arguments have been made by spokespeople for Myriad Genetics, a firm involved in the discovery and prospective commercialization of the BRCA1 gene.[100]

A second argument moves beyond judgments about the social or humanitarian desirability of particular innovations for which the availability of patents provides an incentive to more general economic considerations. In a world where private sector investment, including research support, flows across national borders with increasing ease, those jurisdictions offering weak or limited patent protection can expect to suffer in terms of lost employment opportunities and national income: investors will simply look elsewhere. A patent agent with Allelix Biopharmaceuticals Inc., who has by his own account "experienced the ebb and flow of investor interest," has emphasized the importance of strong and predictable patent protection given the fragile state of the Canadian biotechnology industry.[101] In the U.S. context, Patents and Trademarks Commissioner Donald Quigg argued against restrictions on patenting transgenic animals based on anticipated harm to "the

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97 *Ibid.*, 194-195. See also comments of Philip Chen, Chairman, Patent Policy Board, National Institutes of Health, to the effect that "the NIH has initiated an active cooperative research program" involving "over 100 cooperative research and development agreements ... mostly with chemical and pharmaceutical corporations and biotechnology companies....

A primary incentive to industry to collaborate with the Government is the promise of patent rights to inventions developed under a cooperative research and development agreement. This has been a very important consideration to our corporate collaborators on transgenic and nontransgenic products." Restrictions on patenting would limit this incentive, and thus impede future advances in medical technology. *Ibid.*, 155.

98 Testimony of B. Healy 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, 102 Cong., 2 Sess., September 22, 1992, Serial No. J-102-83 (Washington, D.C.: USGPO, 1993), 24 [subsequently cited as *Genome Project Hearings*].

99 *Ibid.*, 25.

100 Butler and Gershon, "Breast cancer discovery," 271; "Dispute Arises," *The New York Times*, October 30, 1994: 10.

101 H.S. Duncan, "Canadian Biotechnology Patents--An Industry Perspective," *Canadian Intellectual Property Review* 10 (1993), 347-355.

competitive position of our industry in this area,"[102] and a spokesman for the Industrial Biotechnology Association argued against a moratorium on transgenic animal patents by saying: "I can think of no better way to throw a bucket of cold water on America's high-tech industries than to suggest that scientists and inventors cannot count on our patent system until Congress debates whether the new technology should qualify for patent protection."[103]

The ethical weight attached to such claims depends on two factors. First, the flourishing of the biotechnology industry must actually benefit "society," rather than just a select universe of users and promoters. To give an example, the use of bovine somatotropin (BST) to increase the milk production of dairy cattle arguably fails to meet this test, since at present the primary problem facing dairy farmers is that of excess productive capacity rather than excess demand. Second, there must be an unambiguous causal connection between the availability of patent protection and the economic viability of the biotechnology industry. Of course, if one defines what genetic researchers and the biotechnology industry are doing as intrinsically wrong, such a consequentialist approach will be seen as irrelevant at best, and ethically corrosive at worst.

A third argument is based on considerations of fairness: people deserve the fruits of their intellectual work. To the inventor goes the right to the invention. Just as we are entitled under ordinary circumstances, as a matter of justice, to the products of our physical labour, so we are entitled to the products of our creative and intellectual labour. As Leon Kass writes, "justice requires protecting the labours of the imaginative and industrious against theft by the sly and lazy".[104] This is not a consequentialist argument because fairness or justice is valued in and of itself. It is important to note that although the vocabulary is similar, there is a difference between this argument and Philip Leder's invocation of the beneficial consequences for society that can arise only if inventors and investors retain the "hope of a fair return".

How compelling are these arguments? It seems hard to argue against patenting if it will be conducive to the kinds of outcomes identified by Leder. Nevertheless, some commentators view the accumulation of scientific knowledge through genetic research as a mixed blessing, at best. They are concerned, for instance, that the "geneticization" of human health associated with the accumulation of knowledge about the human genome will be socially destructive.[105] Numerous disturbing ethical questions are raised by the predicted expansion of "molecular medicine, in which the risk of disease can be accurately assessed by DNA-based diagnostic procedures."[106] How would

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102 Testimony in *TAPRA '89 Hearings*, 145.

103 Testimony of S. Holtzman, Vice-President for Corporate Development, DNX Inc., on behalf of Industrial Biotechnology Association, in *TAPRA '89 Hearings*, 70.

104 L. Kass, *Toward a More Natural Science: Biology and Human Affairs* (New York: The Free Press, 1985), 135.

105 See *e.g.* Evelyn Fox Keller, "Genetics, Reductionism, and the Normative Uses of Biological Information," *Southern California Law Review* 65 (1991), 290-291; Abby Lippman, "Prenatal Genetic Testing and Screening: Constructing Needs and Reinforcing Inequities," *American Journal of Law and Medicine* 17 (1991), 18.

106 C.T. Caskey, "Presymptomatic Diagnosis: A First Step Toward Genetic Health Care," *Science* 262 (1993), 48.

this capability be used? Would it become a basis for subtle, but effective discrimination against the genetically "weak"?[107] The potential for human germ line therapy has provoked even stronger ethical objections. If one regards particular applications of genetic engineering or the basic research that supports it as sufficiently troubling or pernicious to call the social desirability of the entire enterprise into question, then the argument that patenting will facilitate its expansion and commercialization loses its appeal. Indeed, on this view patenting becomes ethically suspect in direct proportion to the strength of the incentive it provides for such research and development.

Further, some recent developments suggest that patenting may in fact hinder the pursuit of lines of inquiry with potentially lifesaving results. Scientists in Australia are reportedly concerned that a patent awarded by the Australian Patent Office covering the hepatitis-C virus as well as any vaccine or product derived from the growth of cells infected with the virus will create a disincentive for research on the disease; one research project has reportedly already been abandoned "after potential investors became nervous because of the uncertainty surrounding the patent."[108] Researchers in the United States are becoming uneasy about restrictions on access to a database of gene sequences compiled by the Institute for Genomic Research (TIGR). TIGR is headed by J. Craig Venter, a former senior scientist with the U.S. National Institutes of Health (NIH), whose work with the Human Genome Project provides the basis for what appears to be a uniquely fast and efficient approach to gene sequencing.[109] Although itself a nonprofit institution, it has contractual and financial links with for-profit firms including Human Genome Sciences Inc. (HGS) and the pharmaceutical firm SmithKline Beecham.[110] "TIGR is offering to share much of its data with universities and other nonprofit institutions--if they sign contracts promising to respect TIGR's and HGS's proprietary rights and to provide previews of relevant publications."[111] U.S. researchers are also being warned about some kinds of conversations at scientific conferences, since they may involve disclosures that compromise subsequent patent applications.[112] These developments suggest that there exists at least the potential for direct conflict between the profit imperative and the pursuit of potentially lifesaving research.

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[107] E. Draper, *Risky Business: Genetic Testing and Exclusionary Practices in the Hazardous Workplace* (Cambridge: Cambridge University Press, 1991); N. Holtzman, *Proceed With Caution: Predicting Genetic Risks in the Recombinant DNA Era* (Baltimore: Johns Hopkins University Press, 1989).

[108] D. Talbot, "Hepatitis C: now a US company owns the virus in Australia," *Sydney Morning Herald*, July 12, 1994.

[109] L. Fisher, "Profits and Ethics Collide in a Study of Genetic Coding," *The New York Times*, January 30, 1994, 1, 16; N. Wade, "A Bold Short Cut to Human Genes," *The New York Times*, February 22, 1994, C1, C9; prepared statement of J. Craig Venter in *Genome Project Hearings*, 58-59.

[110] E. Marshall, "Showdown Over Gene Fragments," *Science* 266, 14 October 1994: 208-210.

[111] *Ibid.*, 208.

[112] Kathleen Madden Williams, "When is a `Private' Conversation `Public' Disclosure?" *Bio/Technology* 12 (May 1994), 523-525.

Quite apart from these issues, it can be argued that the national income and employment possibilities associated with a thriving biotechnology industry and with the applications of its various products and processes are *prima facie* desirable as objectives of public policy, just as are income and employment growth in any other sector. Whenever the welfare of people is at stake, as it is with the prospect of employment and what that means for one's economic and personal well-being, ethical concerns are present. Particularly given the fragility of Canada's position in an increasingly open and interdependent economic world, such arguments should not be dismissed lightly if Canada's biotechnology industry lags well behind that of the United States,[113] and *if* the economic benefits are as substantial as promoters of the industry would have us believe.

This is a big "if," and two reasons for caution should be kept in mind. First and more obviously, it is one thing to say that the economic benefits associated with the applications of biotechnology have to be taken into account; it is quite another to treat these as the *only* relevant considerations. Doing so would amount to making employment and income the only values of concern: "jobs at any cost". Claims about economic benefits, even if they stand up to factual scrutiny, are always just one factor among many to be taken into account. There is nothing irrational in a society's deciding that some such benefits are not worth the price in terms of damage to any one of a number of ethical principles.

Second, industry's perception and promotion of the importance of patenting may be inflated by self-interest: attempts to secure subsidies or favourable regulatory treatment from government by promising jobs that never materialize are hardly new in the Canadian context. The pursuit of self-interest is not confined to investors in biotechnology firms; it extends to the careers of individual academic researchers, particularly as they are affected by the status and funding of their university departments.[114] Would the industry and the careers of those who provide its scientific basis wither and die without a high level of patent protection, or would they merely not flourish as much as they otherwise might? Is the question really one of national survival in the global marketplace? How strong a claim, in other words, can be defended about the relationship between patenting and the future of a country's biotechnology industry?

According to John Barton, "The empirical evidence that patents actually favour innovation is limited but moderately supportive."[115] Economic historian Joel Mokyr, who has specialized in analysing the role of technological innovation in economic growth, reaches a similar conclusion with respect to the role of patents in stimulating technological progress during the Industrial

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[113] B.J. Spalding, "Canadian biotech lags behind U.S. biotech," *Bio/Technology* 12 (August 1994), 756-757 (reporting on an Ernst & Young study that found the revenues of the Canadian biotechnology industry to be just three percent of those of the U.S. industry).

[114] Nancy (Ann) Davis, "Morality and Biotechnology," *Southern California Law Review* 65 (1991), 360; Kenney, *Biotechnology*.

[115] J. Barton, "Patenting Life," *Scientific American* 264 (March 1991), 40.

Revolution.[116] He does, however, argue 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 which results from a tremendous investment of resources against a low probability of success.[117] Arguably, this describes many current and proposed ventures in genetic research and biotechnology, including not only capital-intensive laboratory research but also the effort to discover wild genetic resources with potential commercial utility.[118] In addition, the cost structure of at least some of the industries to which biotechnological innovation may be expected to contribute, such as the pharmaceutical industry, is likely to make patent protection especially significant: research costs are high, potential dead ends are numerous, and lead times before a product can be marketed are long because of the regime of clinical trials necessary to demonstrate safety and efficacy. Conversely, it has been argued that patenting historically has encouraged incremental improvements based on "practical knowledge and mechanical ingenuity,"[119] whereas today's emergent industries are increasingly reliant on scientific knowledge generated in different institutional settings within which scientists respond to a different set of incentive structures.[120]

In other words, the empirical status of the connections among patenting, scientific research and social benefits (however defined) is contested and at least sometimes unclear. However, even if claims about the need for patent protection are inflated by considerations of self-interest, *within the existing legal framework of intellectual property rights* that fact in itself would not justify withholding patent protection for higher life forms as long as they met the standard criteria for patentability. Similarly inflated claims by other science-based industries probably would not be met with proposals to limit the patent protection to which those industries are entitled. Indeed, one of the rationales for patenting--the inherent fairness of compensating those who take risks and invest resources--is logically independent of considerations of socially beneficial consequences.

The argument from the inherent fairness of patent protection seems unproblematic at first. It can be elaborated either on the basis "that man [*sic*] has a natural property right in his own ideas" or that "justice requires that a man [*sic*] receive reward for his services in proportion to their usefulness to society," presumably as reflected in the returns from licenses and royalties.[121]

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116 J. Mokyr, *The Lever of Riches: Technological Creativity and Economic Progress* (New York: Oxford University Press, 1990), 247-252.

117 *Ibid.*, 252.

118 R. Sedjo, "Property Rights, Genetic Resources, and Biotechnological Change," *Journal of Law and Economics* 35 (1992), 204.

119 Nathan Rosenberg, *Technology and American Economic Growth* (White Plains, NY: M.E. Sharpe, 1972), 117-119; Bernard Barber, *Science and the Social Order* (New York: Free Press, 1952), 256-257.

120 Barber, *Science and the Social Order*, 154-155, 206-207.

121 "An Economic Review of the Patent System," Study of Subcommittee on Patents, Trademarks and Copyrights, Committee on the Judiciary, U.S. Senate, 85th Cong., 2nd Sess., (Washington, D.C.: U.S. Government Printing Office, 1958), 21.

However, in at least some cases involving patents on living matter, it has been argued that the intellectual labour in question involves at best collection, cultivation or purification (for instance, of human cell lines or soil microorganisms) rather than invention as conventionally understood by way of analogy with the development of a new mechanical device. Policy director Andrew Kimbrell of FET explained the Foundation's opposition to gene patenting: "when you have a cell, a gene, an organ--if that has not been turned into a therapeutic device, when you are trying to patent the thing in itself what you are basically doing is patenting part of life itself. You are not patenting your own invention. You are patenting something that was discovered. That's like patenting the moon once it was discovered."[122]

A further ethical issue is rooted in the concern that the economic reward provided by a patent might be out of proportion to the effort expended. It may be unfair. To use a deliberately provocative formulation of the issue, patenting of higher life forms may amount to granting title to the entire iceberg in return for having helped to develop the tip, or even just for having described it with previously unachievable precision (as in the case of BRCA1). In other words, not enough human effort or ingenuity has been involved to justify a potentially far-reaching claim to intellectual property rights in the result: although "[e]very living organism is a product of millions of years of natural evolution," the availability of patents on living organisms has made it possible, "by generating a relatively very small change in an organism ... to gain legal control over the exploitation of the modified organism and all of its progeny ...".[123] A similar argument has been made against allowing patents on modifications of genetic material collected in developing countries with a long tradition of plant breeding in response to local conditions.

This situation is admittedly not unique to the products and processes of biotechnology. Most inventions, be they mechanical, chemical or microbiological, rely on an extensive body of earlier innovation which may or may not be covered by patents or other forms of intellectual property rights. For an example in another area of intellectual property law and policy, consider an annotated bibliography. Clearly the work of compiling and annotating the bibliography, however substantial it may have been, pales in comparison to the task of writing all the books, articles and theses. Nevertheless, the producer of the bibliography would not be denied copyright protection on this basis. As noted earlier, radical breakthroughs or macroinventions remain the exception rather than the rule, yet is it suggested by opponents of extending intellectual property rights to higher life forms that only such inventions are worthy of patent protection? In addition, at this point in the history of intellectual property law and policy, accepting this objection to the fairness argument would have implications going far beyond higher (multicellular) life forms. It could mean repudiating a body of administrative decisions and case law having to do with the patentability of microorganisms and human cell lines that is now relatively well established. This is not, of course, a conclusive ethical argument; precedent and established practice do not necessarily carry any ethical weight in and of themselves. Finally, it should be pointed out that

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122 *Genome Project Hearings*, 193.

123 B. Belcher and G. Hawtin, *A Patent on Life: Ownership of Plant and Animal Research* (Ottawa: International Development Research Centre, 1991), 22.

almost by definition, the value added to a naturally occurring microorganism or cell line by cultivation or purification can hardly be deemed insubstantial, if it represents a step in the absence of which the cell line or organism would not have had commercial utility.

In conclusion, we are sceptical about arguments that rely on the existing principles of intellectual property law to support the conclusion that patents should not issue on higher life forms or biological materials such as human cell lines. However, this is quite different from making an ethical argument that such patents should be available, or should be unrestricted. Indeed, as noted in the remainder of the report, arguments exist to justify a variety of restrictions. Arguments could also be made, based on independent considerations of distributive justice, for restricting or imposing conditions on intellectual property rights in biotechnological innovations. Suppose for the sake of argument that discoveries or innovations leading to drugs that arrest the progress of AIDS or diagnostic tests that predict susceptibility to breast cancer are protected by patents. Might there be an ethical case for combining intellectual property rights in the relevant discoveries or innovations with policy measures that would broaden access to the fruits of those innovations? Such measures could include regulatory control of product pricing or compulsory licensing, among other policy instruments.

VI. On Playing God

A familiar objection to genetic engineering in and of itself is that genetic engineers are playing God. Perhaps the most eloquent statement of this view, made outside the context of the patenting debate, is provided by William McKibben: "It is the simple act of creating new forms of life that changes the world, that puts us forever in the deity business. We will never again be a created being; instead we will be creators."[124] Yet opponents of genetic engineering do not object to at least some of the multitude of other ways in which people redirect or control events for their own purposes. Indeed, they often distinguish quite clearly between ethically acceptable and ethically unacceptable uses of genetic engineering. During the 1992 Congressional hearings on the Human Genome Project, FET's Kimbrell noted that "the Foundation has supported the research ongoing in the human genome project. It has also not opposed any gene therapies being undertaken to cure fatal disease. However, we do feel strongly that we must assess the long term risks of this technology along with recognizing its benefits."[125] Moreover, the Foundation, as noted earlier, had no objection to the patenting of therapeutic devices developed as a result of the research in question. On what basis, then, is the human creativity manifested by genetic engineering or specific uses of genetic engineering to be morally condemned as an instance of "playing God"?

One defence of genetic engineering sees it as not fundamentally different from the "natural" process of selective breeding. In the words of a U.S. lawyer who specializes in patent, trademark, and copyright law : "Breeding may have the advantage of forcing us to do things a bit more slowly, and thus a bit more deliberately. But switching genes around strikes me as little more than expedited breeding...."[126] As well, it has been pointed out in response to criticisms of genetic engineering based on its potentially harmful consequences for animals that: "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."[127]

Analogous replies can be made to many other criticisms of genetic engineering. However, genetic engineering is unlike selective breeding not only because it drastically accelerates the process of achieving outcomes that might in time be achieved by selective breeding, but also because it makes possible the creation of new kinds of organisms.[128] Inserting genes from another species into plant germ cells or animal embryos can produce transgenic organisms about which

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124 W. McKibben, *The End of Nature* (New York: Random House, 1989), 166.

125 *Genome Project Hearings*, 178.

126 L. McAulay, "Letter to the Editor," *The New York Times*, May 11, 1987, 16.

127 S. Blair and A. Rowan, "Of Mice and Men: Patents and Social Policy Matters," *Patent World*, January 1990, 37.

128 See e.g. the comments of John Hoyt, President, Humane Society of the United States, in *TAPRA '89 Hearings*, 109: "Clearly, genetic engineering is of a wholly different order of magnitude [from selective breeding], in that in traditional breeding practices, genes cannot be exchanged between unrelated species. Furthermore, genetic changes can be wrought very rapidly through genetic engineering while in selective breeding, such changes occur over a long period of time."

conventional breeders can only fantasize. The Harvard mouse is such a creature, as is (for instance) "a mouse [genetically] engineered to secrete in its milk a human blood protein called TPA, which dissolves blood clots in heart attack victims."[129] Genetic engineering makes possible not only entirely new kinds of biological products, but also new kinds of biological production processes. This point was dramatically brought to the public's attention in October 1993, when it was announced that the cloning of human embryos had been achieved in the laboratory using "methods that are commonly used to clone animal embryos."[130]

In other words, even if the argument about "playing God" is overstated and (as McKibben's formulation suggests) of little appeal to agnostics, there are abundant reasons to treat genetic engineering as a special and distinctive phenomenon. John Fletcher has tried to explain the basis of this feeling:

> It's the reluctant recognition that human beings have discovered how to deliberately change and alter biological evolution....Before, this appeared to be totally beyond the realm of human control and in the realm of natural or divine forces. It raises questions about the limits and possibilities of human control over life.[131]

Ethical objections to genetic engineering are directed not so much toward intervention in the "natural" course of evolution as toward the speed, scope and power of interventions that were once inconceivable. Such objections are rooted in moral doubts to which we should arguably pay heed. With specific reference to the application of genetic engineering to human reproduction, Michael Shapiro has said that the "fragmentations" of human identity associated with these applications are not "flatly unprecedented .... But most of the older fragmentations are less striking than the new ones, which deal with the threshold questions of whether and how one is to come into existence, continue in existence, and exist in a certain form, and with whether species identity is to maintain its integrity.[132] Observations like this one express, often in eloquent ways, the admittedly disquieting nature of this profound control over biological processes. Still, they do not make explicit the basis of the implied claim that it is wrong to exercise such control.

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129 Hanson and Nelkin, "Public Responses," 76.

130 G. Kolata, "Research Clones Embryos of Human in Fertility Effort," *The New York Times*, October 24, 1993, 1, 12. It should be emphasized that the creation of a new product was not the intent of the experimenters. Their work nevertheless illustrates the technological potential.

131 "Patenting Life," *The New York Times*, April 18, 1987, 6.

132 Shapiro, "Fragmenting and Reassembling the World," 337.

The importance of elaborating such objections can be understood by way of a provocative example. The creation of transgenic laboratory mice that can serve as experimental models for the study of AIDS and cystic fibrosis could increase scientific understanding of the diseases;[133] and mice have been genetically engineered for susceptibility to amyotrophic lateral sclerosis (ALS) as a way of testing potential therapies.[134] ALS is, of course, the incurable degenerative disease that led Susan Rodriguez to petition the Canadian courts for the right to terminate her life at a time of her own choosing.[135] The claim that it is ethically reprehensible to create transgenic organisms *regardless of the consequences,* even though those consequences might include achieving a scientific basis for treating a horrible disease such as ALS, is inconsistent with our basic humanitarian intuitions.

Examining this claim leads, in turn, to a point that is important for purposes of understanding arguments both for and against patenting higher life forms. It may often be the case that ethical intuitions conflict, particularly when it comes to defining and applying abstract principles of the kind that can be embodied in public policy. Even a basic deontological antagonism toward biotechnology, on the grounds that it involves "playing God," may conflict with an equally strong conviction that everything possible should be done to find cures or palliative measures for diseases that kill or torment those whom they afflict. The conflict may pit a conviction that new kinds of organisms should not be created by way of genetic manipulation against an equally intense conviction that all possible scientific and technological resources should be mobilized to avoid or mitigate human suffering. This is yet another argument for the procedural approach taken in section XII of the report, which focuses on *how* the tension between such conflicting intuitions can be reduced, or at least lived with, for purposes of public policy.

To return to substantive matters, three variants of the "playing God" argument deserve separate attention. The first appeals to the notion of species integrity. Rifkin has argued for "the right of a species to exist as a separate, identifiable creature,"[136] and a variety of European opponents of modifying the human germ line have invoked the integrity of the human genetic patrimony or genetic endowment.[137] Intuitively, we have a reasonably clear idea of what a species is, and of why the concept is important. The U.S. Congressional Office of Technology Assessment counters, however, with the argument that "there is no universal or absolute rule that all species are discretely bounded in any generally consistent manner." Further, says OTA, the right or

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133 J. Levine and D. Suzuki, *The Secret of Life: Redesigning the Living World* (Toronto: Stoddart, 1993), 150-157; J. Snouwaert *et al.*, "An Animal Model for Cystic Fibrosis Made by Gene Targeting," *Science* 257 (1992), 1083-1088.

134 "New Mice Created to Fight a Disease," *The New York Times*, June 21, 1994, C6; Robert Brown, "A Transgenic Mouse Model of Amyotrophic Lateral Sclerosis," *New England Journal of Medicine* 331 (1994), 1091-1092.

135 Margaret A. Somerville, "'Death Talk' in Canada: The *Rodriguez* Case" (Montréal: McGill Centre for Medicine, Ethics and Law, 1994).

136 Cited in OTA, *Patenting Life*, 101.

137 Cited in A. Mauron and J.-M. Thévoz, "Germ-Line Engineering: A Few European Voices," *Journal of Medicine and Philosophy* 16 (1991), 654.

expectation asserted by Rifkin on behalf of individual species "... has no known foundation in biology. Species exist in nature as reproductive communities, not as separate creatures, and these reproductive communities are, by standards of geologic time, temporary."[138] The ability or inability to produce offspring nevertheless provides an important way of defining "reproductive communities" within a time frame shorter than the geologic. Along these lines, Stephen Jay Gould has argued that "species are almost always objective entities in nature."[139] The emergence of new species, he says, can be compared to the growth of new branches on a bush, and "[a] branch on a bush is an objective division."[140] Further, "species emerge relatively quickly, compared with their period of later stability, and then live for long periods ... with minimal change."[141] This necessarily superficial treatment of a complex set of questions does not mean that Rifkin's arguments about the rights of species are sound. It does suggest that there are sound reasons to consider the concept of a species as more than just an arbitrary construct. It also suggests that there are sound ethical reasons to consider the extinction or wholesale transformation of a species as something qualitatively distinct from the fate of large numbers of organisms belonging to a particular species.[142]

A second elaboration of the "playing God" argument can be presented in less stark terms that may have more general appeal. NAC, for instance, has argued that "there is an inherent value to life beyond that which our economic system assigns (or fails to assign) it."[143] This point is undeniably an important one, and introduces a distinctively complex set of issues having to do with patenting's potential contribution to what various authors have called the commodification of life, human and otherwise. Nevertheless, there is no inconsistency in accepting the NAC point about the value of life, while at the same time accepting arguments that patenting of higher life forms should be allowed in situations where (for example) it is associated with such beneficial effects as the creation of new animal models for studying debilitating diseases. Here again, the potential tension between conflicting intuitions comes into play.

We take up the question of commodification at some length later in our report. For the reasons outlined, though, we doubt that the claims that genetic engineering involves "playing God," or that it involves the deliberate alteration of "nature," a "nature" that may itself be socially constructed, constitute compelling moral criticisms. More needs to be said. This is why we generally favour a consequentialist approach to evaluating the desirability of patenting higher life

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138 OTA, *Patenting Life*, 100-101.

139 S.J. Gould, "What Is a Species?" in D. VanDeVeer and C. Pierce (eds.), *The Environmental Ethics and Policy Book* (Belmont, CA: Wadsworth, 1994), 474.

140 *Ibid.*, 475.

141 *Ibid.*

142 *Cf.* Lilly-Marlene Russow, "Why Do Species Matter?" in VanDeVeer and Pierce (eds.), *The Environmental Ethics and Policy Book*, 478-484.

143 Massey and Basen, "Patenting of Biotechnological Inventions," 1.

forms. At the same time, the range of potentially relevant consequences must be sufficiently broad and inclusive to encompass, for instance, consideration of the effects that allowing patents on higher life forms is likely to have on attitudes toward life and toward its symbolic and moral significance.

Along these lines, a third and more nuanced variant of the "playing God" argument, one which is consequentialist in form, invokes the loss of a sense of the mystery of life that may accompany the scientific ability to define life in terms of genetic information, and the technological ability to manipulate that information. Arguably the effect will be a loss of a sense of the sacred character of life, although the term "sacred" need not be understood in a narrowly religious sense. It could be argued in response that increased scientific understanding of the molecular "building blocks" of life, and of the common genetic heritage shared by humankind with other species, may actually serve to enhance our respect for life and its complexity. As one biologist has stated: "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."[144] Scientific knowledge can thus lead either to reductionism or to reverence. A useful analogy may be that simply contemplating the concept of a light-year, based on knowledge of the speed at which light travels, may engender a more profound sense of awe and mystery than any number of cosmologies that attempt to provide an explicit account of order in the universe.

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[144] G. Fink, quoted in Levine and Suzuki, *The Secret of Life*, 10-11; see generally chapters 1-2. For an elaboration of this point with specific reference to the relatively minor genetic differences between human beings and the so-called great apes, see as well Richard Dawkins, "Gaps in the Mind," in P. Cavalieri and P. Singer (eds.), *The Great Ape Project* (New York: St. Martin's, 1993), 80-87.

VII. Some Distributional Implications of the Ownership of Genetic Resources

The prospect of patents on genetic resources raises a number of distributional questions that perhaps emerge most immediately as they affect agriculture. Patents on the genetic makeup of crops and livestock could exacerbate the concentration of economic power in the global agri-food industry. In addition, the extension of the intellectual property regimes of developed countries to cover genetic resources could allow scientists and investors in those countries to appropriate from the Third World both genetic resources and knowledge about their characteristics that is distinctive to indigenous people.

During House of Commons Committee hearings on Bill C-15, a GROW spokesperson argued that expansion of intellectual property protection to plant varieties had already created incentives for the acquisition by chemical companies of a number of major seed companies.[145] Potential negative consequences include not only the economic threat to relatively small-scale, low-budget agriculture, but also the environmental implications of entrenching farmers' commitment to a pesticide- and herbicide-intensive agriculture. This line of argument is supported by rural sociologists Frederick Buttel and Jill Belsky, who state that "the most important impact" of the U.S. Plant Variety Protection Act (PVPA) of 1970

> ... may have had nothing to do with the stimulation of private investments. Rather, the perception that PVPA would increase the profitability of seed companies was an important factor in galvanizing a massive acquisition and merger movement involving many American seed firms.
>
> ....
>
> The significance of the acquisition of seed companies by large multinational agroinput firms lies less in increased profitability and monopoly power (which have generally not been realized) than in the potential synergies in R&D and marketing that were made possible by the rise of commercial biotechnology in the late 1970s and early 1980s.[146]

In other words, chemical companies bought seed companies at least partly so they could ensure that seed companies' research and development priorities emphasized the design of plant varieties with enhanced tolerance to the particular pesticides or herbicides marketed by the parent company, as a way of increasing the markets for those products.

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[145] R. Munroe in *House C-15 Hearings*, November 21, 1989, 7:10. See also documentation provided by Patrick Mooney, Canadian Council for International Cooperation, *House C-15 Hearings*, October 25, 1989, 2A:1-2A:10; C. Fowler and P. Mooney, *Shattering: Food, Politics, and the Loss of Genetic Diversity* (Tucson: University of Arizona Press, 1990), 123-139.

[146] F.H. Buttel and J. Belsky, "Biotechnology, Plant Breeding, and Intellectual Property: Social and Ethical Dimensions," *Science, Technology, & Human Values* 12 (1987), 35.

The 1985 decision that plants constitute patentable subject matter in the United States might be expected to magnify this and related effects because patenting is, according to Buttel and Belsky, likely to be "the preferred means of protecting plant-related inventions by private companies in the United States" given that patenting provides a broader range of protection and costs less.[147] A similar argument was made by the president of the National Farmers' Union in U.S. Congressional Hearings on the proposed Transgenic Animal Patent Reform Act. He said that the price of competitiveness in particular crop markets might rise to levels that would be prohibitive for many family-operated farms, and he foresaw a similar outcome in the livestock sector if the U.S. PTO decision to permit animal patenting were allowed to stand.[148] Thus 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 cost or quality advantage in the marketplace.

Recent developments in patent policy as applied to genetically engineered plants have at least partly justified these concerns, and suggest the need for more public policy attention to the concentration of economic power in the agri-food sector on at least two counts. First, 34 percent of all the field trials of genetically modified plants approved in the European Union, and 41 percent in the United States, involve "crops that have been modified to tolerate proprietary herbicides."[149] Second, in October 1992 a firm called Agracetus, a division of W.R. Grace & Co., was granted a U.S. patent on genetic engineering of cotton plants and lines. According to RAFI:

> [T]he Agracetus claim, if upheld in the courts, would largely surrender the future of global cotton development to a single enterprise and its licensees. While only valid in the United States at present, it is likely that Agracetus could prevent any other country from exporting genetically-manipulated cotton to the United States. It may also be possible for Agracetus to prevent the importation of cotton clothing or other finished products containing engineered cotton.[150]

These misgivings are now shared by at least one executive in the biotechnology industry, who recently argued that: "This is equivalent to someone saying that if you invent the assembly line, you get the right to any product that is made with the assembly line."[151] They are also shared

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147 *Ibid.*, 40.

148 Cy Carpenter, President, NFU, *TAPRA '89 Hearings*, 594. See also Fowler and Mooney, *Shattering*, 115-123.

149 Mike Ward, "Analyzing EU and U.S. agbiotech field trials," *Bio/Technology* 12 (October 1994), 967-968.

150 P. Mooney, *The Conservation and Development of Indigenous Knowledge in the Context of Intellectual Property Systems*, United Nations Development Program contract INT/92/209 (Ottawa: RAFI, 1993), 14-15. See also George Kidd and James Dvorak, "Agracetus' cotton patent draws opposition," *Bio/Technology* 12 (July 1994), 659.

151 D. Holzman, "UDSA Files to Re-examine Recombinant Cotton Patent," *Genetic Engineering News* 14 (no. 13, July 1994), 1, 13.

by the U.S. Department of Agriculture, which has now sought re-examination of the patent.[152] The patent was revoked by India in February 1994.[153] The breadth of these and similar species patent claims is apparently based on the applicants' use of a proprietary method for genetic modification, which itself has been patented.[154] In March 1994, the EPO granted Agracetus a similarly broad "species patent" on genetically engineered soybeans. According to RAFI, which is mounting a challenge to this patent in Europe: "The sweeping patent claim extends to all forms of genetically-transformed soybeans, regardless of the technique employed or the germplasm involved. ... The patent is also pending in the United States."[155] Broadly worded patent claims like those made in the cotton and soybean species patents are referred to by one author as "patent blitzkrieg," which "involves taking out a large number of patents or wording claims very broadly in order to suppress competition through the use of infringement suits, or at least the threat of them."[156] The tactic is not confined to patents on biotechnological innovations. However, should the cotton and soybean patents be upheld, the consequences would be unsettling in at least two respects.

First, if RAFI's analysis of the potential for sanctions against countries failing to provide species patent protection is accurate, then the global control that patent-holders in industrialized countries would be able to exert in the production of a variety of agricultural commodities, and the competitive advantage they would thereby gain, would be unprecedented.[157] The price of patented, genetically engineered seeds might place them out of reach of many developing-country producers, particularly in the absence of a farmer's privilege exception covering saved seed. The effect might be not only to reduce the competitiveness of developing-country exports of agricultural commodities, but also to reduce the economic viability of production for domestic consumption as developing countries are pressured to open their agricultural product markets to imports. Especially because of Canada's traditional commitment to supporting economic development in the South, these potential effects deserve careful consideration by lawyers, agricultural economists and trade policy specialists before Canada makes any commitment to supporting similarly broad patent protection.

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152 *Ibid.*

153 D. Ravi Kanth, "Gov't to revoke seed patent of US firm," [Calcutta] *Business Standard*, 18 February 1994, 1.

154 "`Species' patent on Transgenic Soybeans Granted to Transnational Chemical Giant W.R. Grace," *RAFI Communiqué* March/April 1994, 4.

155 *RAFI Communiqué* March/April 1994, 1-2.

156 Michael S. Hart, "Getting Back to Basics: Reinventing Patent Law for Economic Efficiency," *Intellectual Property Journal* 8 (July 1994), 243.

157 According to RAFI, "the total commodity value of the six crops" on which species patent applications have been filed by W.R. Grace and its subsidiaries--soybeans, rice, maize (corn), cotton, peanuts, and livestock breeding--"exceeds $139 billion per annum worldwide. But the real value lies in the importance of these crops to global food security and the well-being of small farmers. Half of the world's population subsists on rice." "Out of Control," RAFI Press Release, 28 March 1994.

Second, there is no reason to expect that if species patents on plants are upheld, the practice of granting such patents will be restricted to applications involving plants. The implications of this second point are perhaps even more unsettling, given the variety of ethical concerns that surround patents on animals and on human genetic material. Unfortunately, we lack the specialized expertise and time to undertake a detailed study of the species patent applications, to assess the probability that they will be upheld, and to predict the full range of future legal consequences. This should be flagged as an area of highest priority for ongoing study by Industry Canada.

A related concern, which also has to do with economic and political inequalities between rich and poor countries but is not restricted to the agricultural sector, is that some forms of intellectual property rights create the basis for what RAFI has called "bio-piracy" in the global context.[158] This concern arises when government research laboratories, transnational corporations and their agents, including freelance or contract "biodiversity prospectors," appropriate genetic resources which have traditionally been treated as public goods and held in the public domain and then seek patent protection based on modification or cultivation (in the case of cell lines) of those resources.[159] The American Type Culture Collection (ATCC) is the world's largest depository collection or archive of cultured biological material, ranging from soil microorganisms to plant, animal and human cell lines. Based on a search of the computer database maintained by the ATCC, RAFI has identified literally hundreds of examples of commercially useful biological materials that were collected in developing countries. Although only a few of these materials have so far been involved in patent applications, the allegation of bio-piracy is nevertheless relevant to public policy on patenting higher life forms.

The rapidly expanding capabilities of biological science mean that commercial utilization of collected materials, including those already in the ATCC and 25 smaller such collections around the world, will almost certainly expand. That expansion will raise in various specific contexts the general question identified earlier of whether, or under what circumstances, intellectual property regimes that grant title to the entire iceberg in return for contributing the tip are justified. The issue becomes especially important when commercially significant genetic resources are identified in the first instance based on the uncompensated use of local knowledge, accumulated over long periods of time, about the qualities of particular organisms.

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158 RAFI, "Bio-Piracy Survey: Preliminary List for Selected Countries" (Ottawa: RAFI, 1994); For additional statements of this or similar arguments, see Fowler and Mooney, *Shattering*, 174-200; Mooney, *Conservation and Development of Indigenous Knowledge*, 15-19; V. Shiva, "The Seed and the Earth: Biotechnology and the Colonization of Regeneration," *EcoDecision* no. 10 (September 1993), 30-35; V. Shiva and R. Holla-Bhar, "Intellectual Piracy and the Neem Tree," *The Ecologist* 23 (1993), 223-227.

159 W. Reid *et al.*, "A New Lease on Life," in W. Reid *et al.*, *Biodiversity Prospecting* (Washington, D.C.: World Resources Institute, 1993), 6-22.

The question of who owns these resources and is entitled to benefit from them in the future has arguably been made more complicated by the United Nations Convention on Biological Diversity,[160] one of the agreements emerging from the Rio Summit in 1992. Article 15.1 of the Rio Convention specifies that "the authority to determine access to genetic resources rests with the national governments and is subject to national legislation."[161] However, Article 15.3 states that the genetic resources covered by the convention "are only those that are provided by Contracting Parties that are countries of origin of such resources or by the parties that have acquired the genetic resources in accordance with this Convention."[162] One commentator notes that Article 15.3 "has been interpreted by some as meaning that all genetic resources currently in collections are not covered by the Convention," entailing that they are the property of the individual or corporate depositor. "The concern is that countries of origin will not benefit from materials already collected,"[163] and indeed that patent protection might specifically exclude their people from access to such benefits. For example, a patented drug, genetically engineered plant variety or diagnostic technique developed from human or plant biological material might be priced out of reach of most people in the jurisdiction where the material was collected. As the wording of the commentary implies, this is a contested point; however, it is one whose implications are potentially far-reaching given (for instance) the amount of material of human origin that is on deposit in the ATCC. This amount is likely to expand further because of the work of the Human Genome Diversity Project, associated with the NIH's Human Genome Project, whose aim is to collect genetic materials from more than 700 indigenous communities and store these materials in the ATCC.[164] A particularly striking patent application involving human genetic material collected in a developing country is described later in this report.

In economic terms, which admittedly do not take into account all the relevant ethical dimensions, the charge of bio-piracy can be recast as "a conflict over the distribution of rents generated by genetic resources and associated product development," principally although not exclusively in the area of crop plants and pharmaceuticals.[165] It is often extremely difficult for the "owners" of genetic resources, however ownership is defined, to capture a return from them that is in any way commensurate with the benefits those resources provide to the world at large, *or*

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160 Reproduced in Reid *et al.*, *Biodiversity Prospecting* as Annex 4.

161 *Ibid.*, 309.

162 *Ibid.*, 310.

163 B. Belcher, "Review" of the Convention on Biological Diversity, in T. Carroll-Foster, ed., *Action 21: Abstracts, Reviews and Commentaries* [on Agenda 21 and related documents] (Ottawa: IDRC, 1993), 291.

164 P. Mooney, *The Conservation and Development of Indigenous Knowledge in the Context of Intellectual Property Systems*, prepared under United Nations Development Program contract INT/92/209 (Ottawa: Rural Advancement Foundation International, November 1993), 47-49

165 Sedjo, "Property Rights, Genetic Resources, and Biotechnological Change," 201-202.

might provide in the future.[166] Among these benefits are those associated with the conservation of genetic diversity or biodiversity, which has consistently been identified as one of the most pressing global environmental issues.[167] Almost by definition, the value of such potential future benefits is unknown, as is the identity of the beneficiaries, most of whom (as in the case of drugs developed from tropical forest plant species) may be outside the boundaries of the jurisdiction where the resources are located.

There are several ways to ensure that at least a portion of the rents generated by appropriation of local knowledge and local genetic resources is returned to the national government or the citizenry in question.[168] One approach to this problem is based on creating a regime of property rights that enables national governments or other actors to earn an economic return from genetic resources.[169] According to some commentators, this position is implicit in the Rio Convention.[170] Perhaps the best known application of such an approach is Costa Rica's creation of a national non-profit authority, INBio, whose mandate includes both biodiversity conservation and commercialization.[171] Few such policies have been implemented. This may be partly because they depend on governments' willingness and ability to devise and enforce an intellectual property rights framework for biodiversity prospecting, starting with effective regulation of the collection and export of genetic material,[172] and partly because of the highly speculative nature of the investments in biodiversity conservation on which the success of such a regime is likely to depend.

Consequently, even leaving aside the unavoidable spectre of corruption, emulating the Costa Rican model is likely to be a difficult task in many of the jurisdictions in which genetic resources are of greatest commercial interest from a global perspective. In any event, the establishment of such policies is of course outside the control of governments like Canada's that must nevertheless make decisions about the scope of intellectual property rights within their own

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166 See *e.g.* Sedjo, "Property Rights, Genetic Resources, and Biotechnological Change," 203-205; T. Swanson, "Economics of a Biodiversity Convention," *Ambio* 21 (1992), 250-257; M. Wells, "Biodiversity Conservation, Affluence and Poverty: Mismatched Costs and Benefits and Efforts to Remedy Them," *Ambio* 21 (1992), 237-243.

167 P. Ehrlich and A. Ehrlich, "The Value of Biodiversity," *Ambio* 21 (1992), 219-226; P. Ehrlich and G. Daily, "Population Extinction and Saving Biodiversity," *Ambio* 22 (1993), 64-68; N. Myers, "Biodiversity and the Precautionary Principle," *Ambio* 22 (1993), 74-79; C. Perrings et al., "The Ecology and Economics of Biodiversity Loss: The Research Agenda," *Ambio* 21 (1992), 201-211.

168 *Ibid.*, 23-52.

169 L. Roberts, "Chemical Prospecting: Hope for Vanishing Ecosystems," *Science* 256 (1992), 1142-1143; Swanson, "Economics of a Biodiversity Convention," 254-255.

170 M. Gollin, "The Convention on Biodiversity and Intellectual Property Rights," in Reid *et al.*, *Biodiversity Prospecting*, 289-302.

171 R. Gamez *et al.*, "Costa Rica's Conservation Program and National Biodiversity Institute (INBio)" and A. Sittenfeld and R. Gamez, "Biodiversity Prospecting by INBio," in Reid *et al.*, *Biodiversity Prospecting*, 53-97.

172 M. Gollin, "An Intellectual Property Rights Framework for Biodiversity Prospecting," in Reid *et al.*, *Biodiversity Prospecting*, 159-197.

national jurisdictions. Ethical concerns about the implications of Canadian patent policy for international equity cannot be dismissed based on the presumption that poorer countries, when they are the source of commercially significant genetic resources, will have the scientific, technical and institutional capacity necessary to implement effective policies to capture a share of the economic returns.

To make the distributional questions associated with ownership of genetic resources yet more complicated, the Costa Rican example is widely regarded as relatively benign. However, there is little reason to presume that national governments will consistently exercise the control over access to genetic resources specified by the Rio Convention in ways that will benefit their citizens. It is at least as plausible to suggest that they may use that control to reward supporters and assemble private fortunes. Indeed, some people might view national governments' monopoly control over access to genetic resources under the Rio Convention as at least as outrageous as the monopoly control over certain genetic resources enjoyed by inventors and investors under the patent laws of the industrialized countries. It is not obvious, for instance, that vesting property rights in the depositors of biological material in the ATCC is less ethically objectionable than vesting them, under the rubric of national sovereignty, in the governments of some of the countries where the material was originally collected.

A distributional issue that is not distinctive to genetic engineering and its products but nevertheless should be considered in any discussion of ethical issues associated with patenting is that of the potential for monopoly profits associated with the ownership of intellectual property rights. Arguably, this potential is inherent in the nature of a patent system. For some, it becomes ethically troubling when the effect is to drive up the cost of diagnostic tests or therapeutic agents, access to which may mean the difference between life and death. This was part of the rationale behind Canada's legislation providing for compulsory licensing of patented pharmaceuticals in exchange for royalty payments to the patent holder. Ironically, although Canada recently repealed this legislation, at least two similar (although unsuccessful) proposals were made in 1993 as part of the U.S. government's efforts to control spiralling health care costs.[173] Opponents of the proposals "characterized such legislation as an attempt to treat drug companies much like a crucial social service or public utility rather than as a private profit-seeking business and have expressed concern that the proposals to indirectly control prices would cripple research budgets for critical drugs."[174]

If the benefits of genetic research in terms of diagnosis and treatment turn out to be as dramatic as some enthusiasts believe, the issue of excessive profits is bound to re-emerge, for example, should applications of the isolation of the BRCA1 gene turn out to be very effective but also very expensive and profitable for licensees. As in a previous example, one way of conceptualizing this issue is in terms of conflicting conceptions of fairness. We may think it unfair

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173 R.H. Kjeldgaard and D. Marsh, "Health-Care Reform and Intellectual Property," *Bio/Technology* 12 (June 1994), 639-640.

174 *Ibid.*

that researchers are restricted in their ability to profit from their discoveries and inventions, but also think it unfair that potential beneficiaries of life-saving technologies are denied access because of failure to restrict that ability.

VIII. The Control of Environmental Hazards

In North America, public concern about the negative consequences of genetic engineering began with environmental effects: first, the apprehended potential for accidental release of organisms from the laboratory[175] and later, the intentional release of genetically engineered plants or microorganisms in field trials and ultimately in full-scale commercial usage. As mentioned earlier, one of the highest-profile controversies over genetic engineering in the United States involved concerns about the possible environmental effects of field-testing genetically modified bacteria.

The relevance of environmental concerns to the issue of patenting is not obvious. Granting a patent does not imply approval of any particular use of the patented product or process, or indeed approval of any use at all. Consequently, any argument linking the environmental implications of genetically modified organisms (GMOs), be they microbes, plants or animals, to patenting must run as follows. Patenting will create incentives for biotechnology research and development (precisely the claim made by firms and researchers in the field). The effect will be to create a client group of investors with an economic stake in recovering their investments through commercialization of the patent, and therefore with an interest in playing down the potential environmental consequences of commercialization. Normally, we would expect the environmental implications of the release of GMOs to be addressed through environmental protection statutes and regulations, just as we would expect the safety implications of other kinds of patented devices to be addressed through appropriate statutes and regulations. However, opponents of patenting might respond with an argument that the regulatory regime is either (a) inherently incapable of dealing with the hazards posed by GMOs, or (b) incapable of dealing with them at present. In either instance, the potential hazards may be serious enough that, in the absence of promising alternatives, the patent system should be used to check the development of the technology.

Just such an argument was made by Margaret Mellon of the [U.S.] National Wildlife Federation in the 1989 Congressional hearings on transgenic animal patenting. Warning that we need to "look before we leap" into biotechnology, she went on to say:

> In a nutshell, patenting will encourage scientists to produce large numbers of genetically engineered animals and we believe that the release of those animals, either accidentally or intentionally, poses uncertain but real environmental risks. It is our view that we are not ready to stimulate the engineering of animals; that is, we are not ready for patenting until we have in place a system of laws and regulations to oversee the environmental releases of the organisms the technology will produce.[176]

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[175] Krimsky, *Genetic Alchemy*, provides a detailed history of these concerns and the initial institutional responses on the part of both local governments and the scientific research community.

[176] Mellon, testimony in *TAPRA '89 Hearings*, 226-227.

This is one instance among many in which we can see the importance of whether or not the basic presumption underlying law and public policy is in favour of patenting. An alternative presumption would place the burden of proof on applicants for patents on GMOs to demonstrate safety according to a previously specified standard as a precondition for the grant of a patent. Indeed, acording to critics like Mellon there are several reasons to treat the environmental hazards of GMOs as special.

For one thing, "the products of biotechnology are often living organisms themselves. They are consequently capable of movement and reproduction. This makes an accurate prediction of the likely level of exposure," a standard and indispensable element of conventional risk assessment methodology, "extremely difficult."[177] Increasing the number of carefully monitored experimental field trials is unlikely to reduce that difficulty.[178] Mellon asks what might happen if fish that have been genetically engineered to grow faster or to survive in extremely cold water escape from their holding tanks. Will the faster-growing fish

> ... displace native species? Will the extra hormones have altered the nutritional quality of their flesh? Will the novel fish breed with other fish and transfer the new gene into wild populations with further and even more unpredictable effects?
>
> What about warm-water fish that are newly equipped with anti-freeze genes? Will they be able to survive in waters where they previously might have died? Will they displace existing populations of cold-water fish?[179]

Similar problems could be envisioned with genetically engineered insects, such as honeybees and ladybugs.[180]

An additional difficulty is the possibility of gene transfer among organisms, which, according to Mellon, "poses a particularly important issue in the risk assessment of genetically engineered organisms released to the environment:"

> For example, genes for antibiotic resistance engineered into one bacterium may, under certain circumstances, be transferred to animal or human pathogens. Our ability to combat these pathogens would be compromised if the antibiotics to which they had become resistant were the same ones used to control them. Similarly, it would be a problem if genes

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177 B. Mausberg et al., "Growing Safely? Concerns About Biotechnology and the Regulatory Process," Report to Agriculture Canada (Ottawa: Biotechnology Caucus, Canadian Environmental Network, December 15, 1993).

178 H. Miller and D. Gunary, "Serious Flaws in the Horizontal Approach to Biotechnology Risk," *Science* 262 (1993), 1500-1501.

179 Testimony of M. Mellon, *TAPRA '89 Hearings*, 227.

180 *Ibid.*, 235.

> for pest resistance introduced into bacteria associated with crops were transferred into bacteria that became associated with weeds. The results could be `superweeds' which would require ever higher doses of chemical herbicides to control.[181]

Possibilities such as gene transfer among organisms exacerbate the scientific disagreements and uncertainties that already characterize environmental regulation. For instance, a March 1994 research report in *Science* indicated that after plants have been genetically modified for resistance to particular viruses, the inserted genetic material may recombine with viruses in the natural environment to produce new viruses that could, in theory, prove highly infectious.[182] A commentary in the same issue conceded that such "recombination in the field ... does not have a zero probability,"[183] but went on to argue that "the potential benefits of engineered resistance genes far outweigh the vanishingly small risk of creating new and harmful viruses in significant excess over those being created by natural processes."[184] The U.S. biotechnology industry has also been highly critical of claims about environmental hazards associated with transgenic crops.[185]

Environmental health and safety concerns constitute a good reason for proceeding cautiously with particular applications of any new technology, quite independently of the issues surrounding patenting. One way of approaching the implications of those concerns for patenting, as we have suggested in other sections of the report, is to ask whether these concerns are serious enough, and difficult enough to deal with in other ways, that they justify replacing the presumption in favour of patenting with a presumption against patenting, until and unless certain conditions can be met. Since neither zero risk nor definitive proof of safety is attainable in practice, risk-benefit comparisons are a crucial and unavoidable component of environmental regulation.[186] They are also ultimately subjective even when not bedeviled by highly incomplete information. Even more than the hazards with which environmental policy and law have generally dealt, the hazards associated with genetic engineering are a matter of profound disagreement, and the topic of much informed but necessarily inconclusive scientific debate.

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[181] M. Mellon, "Risk Assessment and the Release of Genetically Novel Organisms," Appendix to *Biotechnology and the Environment*, National Biotechnology Policy Center, National Wildlife Federation (1988), included in *TAPRA '89 Hearings*, 578.

[182] A. Greene and R. Allison, "Recombination Between Viral RNA and Transgenic Plant Transcripts" *Science* 263 (1994), 1423.

[183] B. Falk and G. Bruening, "Will Transgenic Crops Generate New Viruses and New Diseases?" *Science* 263 (1994), 1395.

[184] *Ibid.*, 1396.

[185] Jeffery L. Fox, "Do transgenic crops pose ecological risks?" *Bio/Technology* 12 (February 1994), 127-128; Russ Hoyle, "A quixotic assault on transgenic plants," *Bio/Technology* 12 (March 1994), 236-237.

[186] Odelia Funke, "Can a Technocratic Culture Be a Democratic One? Biotechnology, Risk and Public Policy," prepared for presentation at the XVIth World Congress of the International Political Science Association, Berlin (Washington, D.C.: Information Management Division, Environmental Protection Agency, mimeo, August 1994).

What is the appropriate response to such profound uncertainty on the part of experts? The choice of approaches is likely to be a function of one's more general attitude towards risk, which may in turn be associated with an optimistic or pessimistic view of the relative hazards and benefits of technological innovation.[187] According to some social theorists, such views are closely connected with competing conceptions of the social system and social interactions as a whole.[188] Responses to uncertainty and risk, in other words, can be interpreted as manifestations of global moral conceptions of the nature of society and the place of science and technology in it. This line of reasoning suggests that conflicts about the environmental risks associated with biotechnology are likely to be both ethically and politically intractable, regardless of what presumptions are adopted about patentability of higher life forms.

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[187] Davis, "Morality and Biotechnology," 355; J. Krier and C. Gillette, "The Un-Easy Case for Technological Optimism," *Michigan Law Review* 84 (1985), 405-429.

[188] Mary Douglas, *Risk and Blame: Essays in Cultural Theory* (London: Routledge, 1992).

IX. Animal Welfare

At least since the early nineteenth century, there has been a gradual decline in the Western public's willingness to tolerate the infliction of suffering on animals.[189] This is due at least partly to acceptance of the view that animals, at least some animals, are part of a "community of sentient beings" that also includes humankind.[190] It is important to note that non-human creatures have not always been thought to share consciousness and the ability to suffer with human beings. The seventeenth-century philosopher René Descartes regarded all animals other than human beings as mechanisms or "automata"--exquisitely designed mechanisms, to be sure, but without consciousness (for they had no souls) and therefore without the ability to experience pain.[191] It is also important to emphasize that a contemporary consensus does not exist about the ethical implications arising from the extension of the boundaries of the "community of sentient beings." For instance, some might argue that those implications include vegetarianism;[192] others might tolerate meat-eating by human beings under certain conditions (*e.g.* humane slaughter) but would severely restrict the use of animals for laboratory experiments, perhaps prohibiting altogether experiments involving the so-called great apes.[193]

Against this background, important ethical issues are raised by the fact that genetic engineering of animals could be harmful to them in a variety of ways, both direct and indirect. In Congressional hearings on proposed U.S. transgenic animal patent reform legislation, spokespeople for the Humane Society of the United States (HSUS) suggested that genetic intervention could produce suffering for animals through the introduction of developmental abnormalities, designed-in vulnerability to human diseases (in the case of transgenic animal models of human diseases), and the emergence of unanticipated health problems in mature animals.[194] Examples give credence to this concern. Researchers have inserted a human growth hormone gene into pig embryos; the pigs that result grow faster and are leaner than naturally bred pigs, but they suffer from crossed eyes and severe arthritis in the joints and are susceptible to disease.[195] Dairy cows that have been treated

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189 Rod Preece and Lorna Chamberlain, *Animal Welfare and Human Values* (Waterloo: Wilfrid Laurier University Press, 1993), 34-43.

190 *Ibid.*, 243-263.

191 See the selections from Descartes' work excerpted as "Animals are Machines" in T. Regan and P. Singer (eds.), *Animal Rights and Human Obligations*, 2nd ed. (Englewood Cliffs, NJ: Prentice-Hall, 1989). For commentary, see William R. Shea, *The Magic of Numbers and Motion: The Scientific Career of René Descartes* (Canton, MA: Watson Publishing International, 1991), 182-187; Peter Singer, *Animal Liberation* (New York: Avon, 1977), 206-211.

192 Singer, *Animal Liberation*, 163-191.

193 For a brief yet provocative exploration of these issues see Stephen R.L. Clark, "Apes and the Idea of Kindred" and Raymond Corbey, "Ambiguous Apes," in Cavalieri and Singer (eds.), *The Great Ape Project*, 113-125 and 126-136 [respectively].

194 M. Fox, Vice-President, Bioethics and Farm Animals Division, HSUS, "Animal Welfare Concerns of Genetic Engineering Biotechnology," reproduced in *TAPRA '89 Hearings*, 125-128.

195 Krimsky, *Biotechnics & Society*, 55.

with BST, which improves milk yields by 20 to 40 percent, pay a price for their enhanced commercial value: they "tend to keel over after two years of gargantuan production"; moreover, "pigs, injected with a similar wonder drug, can freeze to death because they grow so much lean meat they can't keep warm."[196] The enthusiasm of the biotechnology industry for profitable genetically engineered livestock heightens this concern. A two-part 1989 series in the magazine *Agricultural Research* began: "Broilers blooming to market size 40 percent quicker, hens cranking out eggs in double time, a computer `cookbook' of recipes for custom designed creatures--this could well be the face of animal production in the 21st century."[197] Suffering also could be imposed on transgenic animals engineered for laboratory use, such as "a mouse that has problems remembering where it is, thanks to the targeted destruction of a single gene."[198]

The link between ethically troubling consequences and patenting of higher life forms is clearer with respect to animal suffering than it is in some other cases. According to both opponents and supporters of patenting, if patents on genetically engineered animals were not available, it would be less likely that such creatures would be developed for commercial purposes. Sandra Keegan argues: "Patenting animals will encourage research with animals. In this connection, we should re-examine whether greater rigour should be instilled in the current rules on animal research, not whether we should preclude patenting so as to avoid encouraging animal research."[199] As Keegan's position demonstrates, there are responses other than a restriction on patenting. Some uses of animals in the laboratory might be avoided by ingenuity, diligence, and perhaps a slightly greater cost. If research with animals is necessary, once agreement has been reached about the nature and level of suffering it is permissible to inflict, or about the way suffering should be weighted against potential benefits (the kind of judgment reached in the case of the Harvard mouse patent in Europe), regulatory controls could be put in place to guard against practices that create unacceptable suffering to animals.

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196 J. Ehrlichman, "Just Who Will Cash in on the Brave New World of Life Forms Created Purely for Profit?" *Financial Guardian*, April 25, 1987, 20.

197 "Farm Animals of the Future," *Agricultural Research*, April and May 1989, reproduced in *TAPRA '89 Hearings*, 166-175.

198 G. Vines, "Guess what's coming to dinner?" *New Scientist* 136 (14 November 1992), 14.

199 S. Keegan, "The Proposed Directive on the Legal Protection of Biotechnological Inventions," in *Patenting Life Forms in Europe*, Proceedings of an International Conference at the European Parliament, Brussels, 7-8 February 1989 (Barcelona: International Coalition for Development Action, 1989), 13.

Such controls, admittedly limited in application, already exist in Canada's *Criminal Code*[200] and in the European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes,[201] to give just two examples.[202] Although Canada lacks national legislation covering animal experimentation,[203] the care and treatment of experimental animals in Canadian university laboratories receiving government funds is controlled, albeit indirectly, by requirements imposed by granting agencies and by guidelines developed by the Canadian Council on Animal Care (CCAC).[204] However, there are limits to the effectiveness of this regime. [205] Animals used in private sector laboratory research in Canada do not appear to benefit from comparable protection; neither do livestock in commercial farming operations. In the United States, both federal legislation (the *Animal Welfare Act*) and National Institutes of Health funding guidelines govern the use of animals for laboratory research.[206] However, despite strengthening amendments passed in 1985, actual implementation has been slow, and "[t]he academic and commercial institutions that either do not receive federal funding or that use species of animals that are exempted are still outside the provisions of any national policies. How many such institutions there are is unknown, but the number probably runs to several thousands."[207] In addition, agricultural animals are excluded from the provisions of the legislation, as well as the rats and mice which "comprise about 80 to 90 percent of all laboratory animals used."[208]

Although existing controls are incomplete and imperfect, it can be argued that improving these controls is preferable to using patenting as a proxy for more direct efforts to limit animal suffering. However, existing controls may not be adequate where the patented characteristics or traits are *in and of themselves* likely to cause suffering, or where the suffering produced by the engineering of particular reproducible traits into animals is different in kind from that dealt with under current controls.[209] In these situations, it may be ethically appropriate to incorporate a risk-

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200 R.S.C. 1985, c. C-46, s. 446. However, it is not clear how frequently, if ever, these provisions have been used to control the treatment either of laboratory animals or of livestock.

201 Cited in Commission of the European Communities, COM(9)589 final, 10-11.

202 But *cf.* the claim by HSUS that "the two major groups of animals utilized in genetic engineering studies--livestock and mice and rats--are not now covered by the Animal Welfare Act." Addendum to testimony of J. Hoyt, President, HSUS and A. Kimbrell, Policy Director, Foundation for Economic Trends, *TAPRA '89 Hearings*, 140-141.

203 Preece and Chamberlain, *Animal Welfare and Human Values*, 96.

204 *Ibid.*, 97-101.

205 *Ibid.*

206 Orlans, *In the Name of Science*, 44-58.

207 *Ibid.*, 58.

208 *Ibid.*

209 A case that may constitute such a situation, which we have so far been unable to document in greater detail, comes from a recent newspaper report of an experiment in which "scientists interested in colouring the hair and eyes of an albino strain of mice injected the gene for a pigment; unexpectedly, they created a strain of mice whose viscera--heart, stomach, liver, and the like--were all turned around. These mice were unable to live long after birth; the added gene had inadvertently

benefit or cost-benefit test into the criteria for awarding a patent. That is what the EPC did in the case of the Harvard mouse, and that is the justification for the European Union's effort to restrict the patentability of processes for modifying the genetic identity of animals without substantial offsetting benefits.

A more diffuse and intractable question is whether allowing patents on higher life forms might contribute to a decline in animal welfare by coarsening social attitudes toward suffering. This claim is an example of an argument from cumulative effects. In other words, it could be that substantial numbers of animal patents are in future awarded, after demonstrating that the benefits outweigh the risks (in terms of animal suffering) in a way that is plausible and persuasive when viewed in isolation. However, having approved large numbers of such patents, we might find ourselves living in a society in which attitudes toward life and living organisms had been subtly but pervasively transformed. Such possibilities are taken up in section XI of the report.

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damaged a gene responsible for the usual positioning of the internal organs." R. Pollack, "Beyond Cloning," *The New York Times*, November 17, 1993, A15.

X. Patenting and Human Beings

The issue of patents on human genetic material was brought to public attention dramatically in 1991, when the U.S. National Institutes of Health filed patent applications for more than 2,000 DNA sequences identified as part of the Human Genome Project, an ambitious international effort to map the entire human genome, in which NIH functions as the lead agency. (These were not, it should be emphasized, entire genes but rather DNA sequences whose function remained unknown.) The PTO rejected the application in September 1992, on a number of grounds that apparently had to do with the conventional requirements of novelty, utility and nonobviousness that must be satisfied by every patent application rather than with the complex ethical issues raised by a claim for intellectual property rights in a portion of the human genome.[210] 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.[211] This step may have gratified opponents of NIH's patenting strategy, but it left in limbo the legal questions associated with the patentability of portions of the human genome.

The resulting uncertainty is particularly important because even in North America, NIH is not the only applicant for such patents. At least two private firms involved in human gene sequencing have applied for patents on human gene sequences.[212] As noted earlier one such firm, Human Genome Sciences Inc., is attractive to investors because of its relationship with Craig Venter's Institute for Genomic Research (TIGR). In U.S. Congressional hearings on NIH's gene patenting policy held in September 1992, Venter defended the patentability of portions of the human genome on several grounds. First, he argued that in the absence of patent protection academic and industry researchers would seek trade secrecy as an alternative route to intellectual property protection, while "[s]cientists in other countries, who will not be subject to this constraint, will continue to publish their work and reap its benefits."[213] In addition:

> A moratorium on patents would prevent U.S. companies, but not our foreign competitors, from obtaining the intellectual property protection necessary to raise capital and develop products. The American public would be denied the benefits of pharmaceuticals and other products of the biotechnology industry, and American companies could be forced to move their markets and their operations overseas.[214]

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210 L. Roberts, "Rumours Fly Over Rejection of NIH Claim," *Science* 257 (1992), 1855; Comments of B. Healy, Director, National Institutes of Health in *Genome Project Hearings*, 25. For an argument that the NIH patent applications should have been rejected based on failure to demonstrate utility, see Stephen B. Maebius, "Novel DNA Sequences and the Utility Requirement: The Human Genome Initiative," *Journal of the Patent and Trademark Office Society* 74 (1992), 651-658.

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

212 *Ibid.*

213 *Genome Project Hearings*, 55.

214 *Ibid.*

> The biotechnology industry must raise enormous amounts of capital to develop products and bring them to market. Developing a new human pharmaceutical typically requires at least five years, costs several hundred million dollars, and involves the very considerable risk that a competitor, either in the U.S. or abroad, will develop and market a competing product. The capital required to develop new products can only be raised if the risks are balanced by adequate patent protection. ... The key starting materials for product development are synthetic copies of human genes. The prospect of all human genes being identified in the course of the Human Genome Project, therefore, emphatically raises the issue of how human genes can be protected so that they will be useful as starting materials for the development of new human therapeutics and other useful products.[215]

Ethical disputes about patenting a portion of the human genome are inextricably linked with conflicting views about the entire enterprise of genetic research involving human beings. The same is true for patents on human cell lines (which have already been issued in the United States, Canada and Europe), as well as for patents on tissues and organs. Once again, the importance attached to the availability of patents by supporters of human genetic research has the effect of deepening opposition on the part of sceptics. Although a comprehensive outline of the ethical issues raised by (for instance) human gene therapy and germ line modification[216] or by the uses of genetic information by employers and insurers[217] is beyond the scope of this paper, three issues with a specific connection to patenting deserve further examination.

(1) Should human beings themselves be patentable? It is taken for granted that they should not. For a variety of ethical reasons, we recoil from the proposition that intellectual property rights should be granted with respect to human beings who have been genetically modified in a particular way. Interestingly, in Canada there is no clear statutory basis for that exclusion, although it is possible that a challenge to such a patent might be successfully mounted under section 7 of the *Charter of Rights and Freedoms* (security of the person). In the United States, it is widely presumed that patents on human beings are precluded by the Thirteenth Amendment to the Constitution, which provides: "Neither slavery nor involuntary servitude, except as a punishment for crime whereof the party shall have been duly convicted, shall exist within the United States." In the countries of the European Union, the patenting of human beings *per se* is prohibited by the language of the EU Directive.

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215 *Ibid.*, 57.

216 N. Wivel and L. Walters, "Germ-Line Gene Modification and Disease Prevention: Some Medical and Ethical Perspectives," *Science* 262 (1993), 533-538; J. Fletcher, "Evolution of Ethical Debate about Human Gene Therapy," *Human Gene Therapy* 1 (1990), 55-68; C. Tauer, "Does Human Gene Therapy Raise New Ethical Questions?" *Human Gene Therapy* 1 (1990), 411-418.

217 Draper, *Risky Business*; Holtzman, *Proceed With Caution.*

But what constitutes a human being for purposes of patent law? Steven Wise, President of the Animal Legal Defense Fund in the United States, argues that "there is no `fixed genetic definition of a human being',"[218] and Canadian patent lawyer Stephanie Chong points out that "[e]ach time it is sought to exclude human beings from the scope of patentability, it becomes necessary to come up with a workable definition of `human being' which will clarify what is to be covered by the prohibition."[219] The U.S. PTO has not yet answered this question, even to its own satisfaction.[220]

This lack of clarity may not be significant for policy purposes, at least in the foreseeable future. It seems clear, for instance, that a laboratory animal into which a single human gene has been transferred would not be regarded as human by any definition of the term in common usage, and should not thereby be excluded from patent protection. It seems equally clear that a human being whose somatic cells contain a single non-human gene, or multiple non-human genes, introduced for a therapeutic purpose would not be considered non-human and thereby patentable. On the other hand, technologies that make possible the creation of transgenic higher organisms are now relatively well understood, at least for purposes of laboratory application, and a general characteristic of public policy toward biotechnology is that scientific developments have forced redefinition of concepts and relationships that once seemed relatively clear-cut. The question, "How many characteristics may be transplanted before an animal is considered a `human being,' or a human being considered an animal?"[221] could soon become urgent, and between the extremes that seem clear, answers to it will be controversial.

An argument can therefore be made that whatever decisions are reached in other areas of patent law with respect to higher life forms, Canada should (a) adopt a specific statutory exclusion of human beings from patentability, and (b) attempt to arrive at a definition of "human being" for purposes of interpreting this exclusion. Rachel Fishman has suggested such a definition for U.S. patent legislation:

> The term "human being" means:
>
> (i) any genetically altered animal possessing one or more higher faculties such as: the ability to reason (including, but not limited to, the ability to use facts and argue them, to arrive at conclusions from premises in a logical manner, to explain

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218 Cited in Mark, "All Animals Are Equal," 259. More recently, the Council for Responsible Genetics expressed concern that legislative exemption of human beings from patentability "falls afoul of ambiguities in the definition of biological characteristics and is, therefore, unenforceable." *TAPRA '89 Hearings*, 209.

219 Chong, "The Relevancy of Ethical Concerns," 193; see also 200-202.

220 J. Langford, Industry Canada, personal communication based on interviews with PTO officials. See also Kimbrell, *The Human Body Shop*, 190-191.

221 R. Fishman, "Patenting Human Beings: Do Sub-Human Creatures Deserve Constitutional Protection?" *American Journal of Law and Medicine* 15 (1989), 480.

observed phenomena and to form beliefs based on facts); the ability to evaluate principles and observations to arrive at reasoned decisions; the ability to formulate speech and communicate; the ability to write; the ability to develop meaningful personal relationships with other human beings on the basis of equality; the demonstration of awareness of self as a unique and separate being; the ability to feel concern for others; or any other higher faculty; or

(ii) any creature born of the ovum and sperm of parents who are human beings, whether or not the union of ovum and sperm was *in utero*, and whether or not the genetic material of the resulting embryo was scientifically altered.[222]

Among this definition's strong points is the apparent preclusion of patents on human embryos or fetuses,[223] although it could be argued that the phrase "born of the ovum and sperm" contradicts the subsequent attempt to include the union of ovum and sperm *ex utero*. It is not clear how it would affect applications for patents on processes for modifying human embryos, either *in utero* or *in vitro*, with the aim of achieving specific characteristics, or how it would affect processes for modification of germ lines that have potential applicability to human reproduction.[224] Moreover, Fishman's reference to higher faculties might create more problems of legal interpretation than it would solve. The definition nevertheless represents a useful contribution to the more extensive public discussion of ethical issues that we recommend in section XII.

(2) **What about patents on portions of the human genome?** Whether patenting portions of the human genome should be permissible depends, in large part, upon a determination of what it is that would be patented. Craig Venter, who supports the granting of patents on portions of the human genome, sees a sharp distinction between genes and human or animal life:

> I am strongly against patenting human cells, tissues, organs or any animal. There is, however, a major difference between the patenting of genetic information and the patenting of animals or other life forms. Genetic reductionists argue that genes are life forms or equivalent to life. I strongly believe that we are much more than the sum total of our genetic composition. Genes are *merely* chemical entities that contain the coded information which is translated into a protein, much in the way that a computer stores the information to print a word.[225]

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222 *Ibid.*, citations omitted.

223 George Annas has asked: "Since cloned embryos are not persons protected by the [U.S.] Constitution and theoretically at least could be as 'immortal' as cloned cell lines, could a particularly 'novel' and 'useful' human embryo be patented, cloned, and sold?" "Of Monkeys, Man [*sic*], and Oysters," *Hastings Center Report* (August 1987), 22.

224 This has seemed a distant prospect until recently; however, see G. Kolata, "Gene Technique Can Shape Future Generations," *The New York Times*, November 22, 1994: A1, B9.

225 *Genome Project Hearings*, 67 (emphasis added).

However, the distinction between patenting genetic information and patenting life forms is not quite as clear-cut as Venter implies. The importance of this issue stretches beyond patents on portions of the human genome because the same questions arise in discussions of how ownership of portions of an animal's genotype, or of the genotype of a transgenic animal, differs from more familiar forms of property rights in specific individuals of the species. What troubles many critics of patenting is the extension of rights of ownership, in a new way, over living things. For instance, although we have a long tradition of regarding animals as property, we do not have a tradition of considering them as patentable *types*. The authors of a study prepared for IDRC suggest that a defense of patenting based on the widely accepted practice of owning particular animals or organisms "confuses the concept of physical property, the buying and selling of individual animals, with the very different concept of intellectual property and the extension of that idea that vests exclusive rights of exploitation and all its progeny to an `inventor' who has `modified' that organism."[226] Although we might be comfortable with owning particular living things, that is not the same as granting property rights over a type of living thing or to the information comprising even a portion of the distinctive genome of that living thing. As Leon Kass points out, we have no ethical problem with a person owning "a mule", but we would probably start to worry if he owned "mule".[227]

To issue a patent for a new type of living organism does not mean the holder of the patent owns organisms of that type that exist or that might come into existence. The owner does, however, have the right, for a limited time, to prevent other people from making, using or reproducing that organism.[228] The property rights in question are perhaps best understood by analogy with copyright in written works, films or sound recordings: even if someone were granted a patent for "mule," or for a genetically modified mule or mouse, that person would not have rights of ownership over all creatures whose distinctive genome is covered by the patent. But that person would have the right to exclude others from using the distinctive version of the genetic code that constitutes the "program" for that particular creature, and the right to benefit financially from all such uses by way of licensing, royalties and the like. For example, a farmer might own a herd of cattle, but be prohibited from selling the calves to other farmers (at least without a contractual provision requiring sterilization to prevent the possibility of further breeding) because the genotype of the cattle is patented.

Such general concerns are, quite understandably, magnified when the subject of a patent is a portion of the human genome. Among the merits of the decision-making framework and procedural approach we recommend in section XII is that it would provide a context within which an informed public debate about the ethics of human gene patenting could occur.

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226 B. Belcher and G. Hawtin, *A Patent on Life: Ownership of Plant and Animal Research* (Ottawa: IDRC, 1991), 20-21.

227 Kass, *Toward a More Natural Science*, 151.

228 J. Sharp. "The Patenting of Transgenic Animals," in R. Blank and A. Bonnicksen (eds.), *Emerging Issues in Biomedical Policy: An Annual Review* vol. 1 (New York: Cambridge University Press, 1992), 203.

(3) What about the conditions under which human genetic material is obtained? In at least one case a patent has been sought on a human cell line "collected" in the developing world: a human T-lymphocyte line collected from a Guaymi native woman in Panama. This application, filed by the U.S. Secretary of Commerce, was eventually dropped following protests by native organizations in Panama and by RAFI.[229] Such applications raise issues of informed consent similar to those in the *Moore* case, but with the additional elements of language problems and North-South power differentials. According to a RAFI report: "U.S. officials who took the cell line reported that they had her `oral informed consent,' but Guaymi leaders doubt that she was told that her cell line would be taken out of Panama, or that it would be patented. Panamanian medical doctors who participated in the drive to collect Guaymi cell lines have told Prof. Acosta," the President of the Guaymi General Congress, "that they were unaware of the patent claim."[230] The commercialization of human genetic material obtained from indigenous people is likely to arise as an ethical issue with increasing frequency because of the Human Genome Diversity Project, associated with the NIH's Human Genome Project, whose aim is to collect genetic materials from more than 700 indigenous communities and store these materials in the ATCC.

More than matters of informed consent are involved in determining whether the collection and development of human genetic material is morally permissible, though. Four distinct questions need to be asked. First, should human biological material be patentable under any circumstances at all? Second, should human biological material be patentable in the absence of evidence of informed consent to both the collection and the subsequent commercial use of those materials? Third, how meaningful is informed consent when there are wide disparities of wealth and power, such as exist between scientists from industrialized countries and aboriginal women in Panama? Fourth, assuming that the answers to the first three questions do not preclude patenting human cell lines or other biological materials, what constitutes an equitable arrangement for sharing the returns from the commercialization of human cell lines or other biological materials?

In Canada the first question has been answered affirmatively, at least with respect to cell lines,[231] although in specific cases there is still room for debate about whether enough human ingenuity or intervention has been exercised to justify conferring intellectual property rights. Our answer to the second question is unequivocally negative: the principle of informed consent is widely accepted and deeply entrenched in scientific research and medical interventions involving human subjects,[232] and there seems no justification for departing from it here. To implement the principle of informed consent in this context, however, requires new institutional mechanisms because the procedures used to collect genetic materials might not have undergone the ethics

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229 Mooney, *The Conservation and Development of Indigenous Knowledge in the Context of Intellectual Property Systems*, 47-49.

230 *Ibid.*, 48.

231 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, U.K.

232 Margaret A. Somerville, "Structuring the Issues in Informed Consent," *McGill Law Journal* 26 (1981), 740-808.

review normally conducted in clinical or university settings. The third and fourth questions, in our view, cannot be answered except on a case-by-case basis. They therefore lead to the same conclusion implied by the answer to the second question: an institutional mechanism is needed to ensure that minimum ethical standards have been adhered to in situations involving patents on human genetic material. An outline of such a mechanism is suggested in section XII. There should, however, be a basic presumption that free and fully informed consent and clearly equitable arrangements are essential conditions for the acceptability of any scheme involving commercialization or patenting of materials of human origin. It is important to note that neither requisite was present in the landmark *Moore* case.

XI. Commodification and Objectification

Among the most potent objections to both genetic engineering and patenting higher life forms is the diminished moral respect for life and living organisms that either or both might engender. This diminished respect could be manifested in tolerance for the increased suffering of livestock or laboratory animals (which are among the principal candidates for genetic modification). More profoundly, it could be manifested in the spiritual impoverishment of all of us as human and non-human life alike are progressively reconceptualized in terms of genetic information.[233] This complex of concerns involves "several overarching themes: the reduction of vital processes to physics and chemistry, the treatment of organisms as collections of matter definable in physical and chemical terms, and the corresponding exposure of living systems to medical manipulation or utilitarian engineering."[234]

The term "commodification" generally refers to the association of something or some practice with the attitudes that ordinarily accompany commercial transactions.[235] The processes by which commodification can occur, as well as the results of those processes, are diverse, particularly with respect to human beings. According to Scott Altman:

> The term "commodification" has many meanings; it can refer to actions that (1) violate a duty of respect for persons by treating the person as a thing that can be sold; (2) alter a person's moral status so that the person becomes a thing without a will; (3) alter the sensibilities of people directly involved in market transactions by causing them to regard each other as objects with prices rather than as persons; and (4) alter the sensibilities of people who learn about or live in a society that permits the sale of persons but who do not participate in such transactions themselves.[236]

New technologies like genetic engineering can lead to commodification either because they result in "dramatic changes in the sensibilities of participants and observers," or because such technologies "entrench, reinforce, or make seem more natural and inevitable, attitudes or beliefs that are already widely held."[237]

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233 See for instance Kevles, "Vital Essences"; Baruch Brody, "An Evaluation of the Ethical Arguments Commonly Raised Against the Patenting of Transgenic Animals," in W. Lesser (ed), *Animal Patents: The Legal, Ethical and Economic Issues* (New York: Stockton Press, 1991), 141-153.

234 Kevles, "Vital Essences," 255.

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

236 Altman, "(Com)modifying Experience," 295-296.

237 *Ibid.*, 294-295.

A closely related but perhaps more inclusive concept is that of objectification. According to Michael Shapiro:

> [I]t may be better to talk of"objectification" rather than "commodification," which suggests the presence of commerce--exchange of value. Paying money for a child may well be a feature of the child's status as a commodity, but more generally, it suggests that the child is an object, and one can become an object without commerce as the prime element of the objectification process. We might, for example, give a child growth hormone to enhance short stature or increase athletic ability. We might even insert genes that code for growth hormone into the early embryo for similar purposes. Long-term commercial rewards may be expected, but such expectations are not essential to the objectification process.[238]

To objectify something is implicit in treating it as a market commodity, but what is disturbing about objectifying a person or organism 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.[239] Treating either some person or some creature as a commodity can mean equating the "worth" of the person or creature with his, her or its market value. Alternatively, it can also mean treating or thinking of the person or creature as the kind of entity which can be acquired or traded by way of market exchanges *or* transactions that look like market exchanges, even if no money changes hands.

Both commodification and objectification involve what Shapiro calls the "association of ideas": shaping or reconfiguring the *schemata* we use to organize our thinking about living things of all sorts.[240] Concerns about commodification and objectification are frequently expressed by feminist philosophers and social scientists who criticize new reproductive technologies on the grounds that they introduce financial considerations into the social relationships of reproduction.[241] By treating reproduction as an activity that can be purchased, manipulated and contracted for, these technologies encourage the attitude that women are instruments for reproduction, and that children are commercial products. As Christine Overall observes, "the embryo/fetus is becoming a type of consumer good that can be made to order and purchased on the open market. Parents thus become

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238 Shapiro, "Fragmenting and Reassembling the World," 351 (citations omitted).

239 Radin, "Reflections on Objectification," 345.

240 On schemata and their significance for understanding cognition and moral judgement see William Brewer and Glenn Nakamura, "The Nature and Functions of Schemas," in R. Wyer and T. Srull (eds.), *Handbook of Social Cognition*, vol. 1 (Hillsdale, NJ: Lawrence Erlbaum Associates, 1984), 119-160; David E. Rumelhart, "Schemata and the Cognitive System," in *ibid.*, 161-180; Ronald W. Casson, "Schemata in Cognitive Anthropology," *Annual Review of Anthropology* 12 (1983), 429-462; Shelley Taylor and Jennifer Crocker, "Schematic Bases of Social Information Processing," in E.T. Higgins *et al.* (eds.), *Social Cognition: The Ontario Symposium, vol. 1* (Hillsdale, NJ: Lawrence Erlbaum Associates, 1981), 89-134.

241 C. Overall, *Ethics and Human Reproduction: A Feminist Analysis* (Boston: Allen and Unwin, 1987), especially ch. 3; B.K. Rothman, *Recreating Motherhood: Ideology and Technology in a Patriarchal Society* (New York: Norton, 1989).

the consumers of special reproductive services designed to enhance the quality of the fetus-product."[242] The discourse associated with assisted human reproduction also provides illustrations of objectification: the success of in vitro fertilization (IVF) clinics is often assessed in terms of their "take-home baby rate". And the editors of a recent volume of feminist essays on new reproductive technologies warn, as well, about "the `one-ness' of these technologies ... Body parts, whole persons, now the human genome itself--all are commercial property."[243]

With specific reference to intellectual property, the charge of commodification or objectification captures one of the most widely voiced criticisms of patenting: the failure of patent law to distinguish between living and non-living things, thus opening up the potential for commercializing aspects of life and characteristics of living organisms in new and unprecedented ways. Canadian and U.S. patent law allow patents on any new "machine, manufacture or composition of matter." Whichever of these categories a patentable living organism is considered to fall under, for the purpose of patenting (although not necessarily for other purposes), it would be treated in the same way as a non-living thing, meaning that "there would no longer be any distinction between material objects and living organisms."[244] Patent law thereby, it is argued, reduces living organisms to the level of things to which no respect is due,[245] thus subtly embodying the Cartesian view of all non-human organisms as automata devoid of consciousness or the ability to suffer.

Various strands of this critique can be found in Rifkin's response to the 1987 U.S. decision to allow patenting of higher life forms. He claimed that patenting would inescapably commercialize life, to the point where "[l]iving beings are to be considered no differently than chemical products or automobiles or tennis balls,"[246] and saw the decision as "`a harbinger of a brave new future where pigs and primates, dogs and cats, birds and beasts are suddenly reclassified, stripped of their species integrity, robbed of their special biological bonds, and reduced to the level of chemical compositions.'"[247] Similarly, in a debate about property rights in the human body provoked in part by the *Moore* case, Andrew Kimbrell argued that "the body is not a factory. The body is not a machine. That is the pathetic fallacy in reverse. The original pathetic fallacy had the unruly passions of the human spirit inhabiting stones, trees, and rivers. Now we seem to believe that nothing has soul: we are all *inanimata*, analogous to machines or factories, and can be treated

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242 Overall, *Ethics and Human Reproduction*, 149.

243 Basen, Eichler and Lippman, (eds.), *Misconceptions,* vol. 1, Introduction to Part I, "Setting the Context," 25.

244 Massey and Basen, "Patenting of Biotechnological Inventions," 4.

245 Statement of the American Humane Association, on behalf of American Society for the Prevention of Cruelty to Animals, Animal Protection Institute, Committee for Humane Legislation, and Massachusetts Society for the Prevention of Cruelty to Animals: "It troubles us that animal patenting reduces the animal kingdom to the same level as laundry detergent and toasters. Animals are not objects." *TAPRA '89 Hearings*, 288.

246 "New Animal Forms Will be Patented," *The New York Times*, April 17, 1987, 9.

247 As quoted in Kevles, "Vital Essences," 269.

as such."[248] Finally, consider William McKibben's rhetorical question: "What will it mean to come across a rabbit in the woods once genetically engineered `rabbits' are widespread? Why would we have any more reverence for such a rabbit than we would for a Coke bottle?"[249] Like Kimbrell, McKibben is here drawing our attention to what he sees as the ethical dangers of reviving a Cartesian approach to living beings.

For analytical purposes, it is important to once again invoke two earlier distinctions. One differentiates the claim that certain kinds of ethically troubling consequences will (or may) follow from the ownership of intellectual property rights in higher life forms from the claim that the existence of such property rights is intrinsically wrong. To illustrate this distinction, consider how an enthusiast of the Human Genome Project views its potential:

> Three billion bases of sequence can, if packed unusually densely, actually be put on a single compact disc. So once the human sequence is complete, one will in fact be able to stick one's hand in a pocket, draw out a compact disc, and say, `Here's a human being. It's Joe Blow.'[250]

This fanciful prospect can be viewed as ethically troubling either because of the intrinsically undesirable nature of doing so ("people *are not* just collections of information"), or because of the various anticipated negative effects of doing so ("if we treat people as collections of digitized information, even for purposes of illustration, it is likely negatively to affect the way people are treated in other contexts"). When scrutinized, most arguments from commodification or objectification are of this second, consequentialist kind even if they do not appear to be.[251] And as noted, we regard this approach as more likely to yield valid objections both to the enterprise of genetic engineering and to the patenting of higher life forms, as long as consequences are identified and assessed in terms that are sufficiently broad.

As an example of such a broad approach, a key concern of opponents of genetic engineering as applied to the genetic makeup of human beings is that it will lead to a society of "designer human beings" or, at the very least, of designer features. Moreover, were this to occur, access to such features would be rationed by price.[252] In an extreme version of this argument, Rifkin warns that:

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248 A. Kimbrell, in "Forum: Sacred or For Sale?" *Harper's Magazine* October 1990, 47-55.

249 McKibben, *The End of Nature*, 211.

250 Kevles, "Vital Essences," 257.

251 Altman, "(Com)modifying Experience," 295.

252 D. Brock, "The Human Genome Project and Human Identity," *Houston Law Review* 29 (1992), 8-13.

> Increasingly, we are going to see the disabled as defective products. I can see a day coming very soon in the 1990s when people will look at someone walking down the street, a young person, and say, 'Why did that young person have a cleft palate? He must have come from a lower class. His parents couldn't afford to program that trait out at conception. Why is that person disabled? Obviously she comes from a class that couldn't afford genetic screening or genetic engineering.'[253]

Thus, new technology is seen as leading to new and disturbing dimensions of economic inequality. *Contra* Rifkin, it has been argued that genetic engineering to improve the characteristics of children cannot be rejected on ethical grounds because our society not only permits but actively encourages parents to invest effort and money in improving their children's chances of success in ways that do not involve genetic engineering,[254] even though many such investments are accessible to rich parents but not to poor ones. This reply assumes, however, that the existing distribution of economic opportunity is ethically defensible. It also neglects the obvious but important point that the social and distributional consequences of permitting such genetic modification would be *superimposed on* existing inequalities. Even if we consider existing economic inequalities to be ethically tolerable, we might not consider tolerable the additional inequalities that could result from economically differentiated access to genetic screening or engineering of offspring.

The second distinction separates arguments against genetic engineering *per se* from those directed specifically against patenting. With respect to patenting, we need to ask precisely *how* patenting might diminish respect for life, and what the consequences of that diminished respect might be. Although Altman does not refer directly to patenting, he provides a number of illustrations of how new technologies might have this effect. For example, permitting the practice of surrogate motherhood (characterized by its opponents as the sale of children) might change the way in which society regards all children, even if surrogate motherhood remained uncommon. It might also change the way we view our bond to children (our own or others') and our responsibility for them. The ability to determine the sex or other characteristics of children using new reproductive or genetic technologies might reduce the strength of "noncontingent" relationships like those between parents and children:

> If technologies reveal that some relationships are more contingent on people's characteristics than is usually recognized, observers might accept this fact. Learning that affection and duty are contingent on certain properties could lead people to view relationships merely as means to possess those properties, and therefore nothing more than instrumental.
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253 Quoted in Levine and Suzuki, *The Secret of Life*, 217.

254 Nils Holtug, "Human Gene Therapy: Down the Slippery Slope?" *Bioethics* 7 (1993), 411.

> 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.[255]

The concern that patenting higher life forms will modify our experience--change our attitudes and sensibilities towards life--in unwelcome ways gains credence from the language of manufacture and production used to describe the genetic alteration of animals for commercial purposes. A recent article in the trade journal *Bio/Technology* states that: "Transgenic animals and transgenic plants could provide production systems for" a variety of proteins.[256] One firm is reportedly "looking to transgenic goats as its bulk production system" for proteins;[257] more generally, a key question associated with "transgenic animal production systems" is identified as that of "which species is the most appropriate production vessel?"[258]

Treating not only individual animals but also animal species (or genetically engineered variants thereof) as "production systems" or "production vessels" is precisely the kind of outcome abhorred by critics of patenting. It represents a magnification or intensification of the attitudes already expressed, at least some of the time, in the context of today's commercial farming operations.[259] Like the reference to take-home baby rates, this example illustrates that language is significant not only because of the attitudes it might engender, but also because of the attitudes it might reinforce. Language both reflects and forms us; we are the names we use and the stories we tell about ourselves and the world around us, in many respects. To provide another example, this one involving laboratory animals, a recent advertisement in *Science* for DNX-Transgenic Services offers:

> Custom Transgenic Rat and Mouse Production
> Transgenic Mice and Rats Guaranteed
> Mice Delivered in Less than 12 Weeks
> ....
> Shipments to Locations Worldwide
> Transgenic Rat Production Now Available.

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255 *Ibid.*, 305; see also Shapiro, "Fragmenting and Reassembling the World," 348-349.

256 J. Hodgson, "Whole Animals for Wholesale Protein Production," *Bio/Technology* 10 (August 1992), 863.

257 *Ibid.*, 864.

258 *Ibid.*, 866.

259 Singer, *Animal Liberation*, 92-162.

Because they are developed through a distinctively powerful form of human intervention motivated specifically by commercial opportunity, may we come to speak and think of genetically altered animals as commodities[260] rather than as beings or subjects with interests of their own, to which we owe at least some duties of care and respect?[261] To continue the argument, the fact that some kinds of animals are regarded, at least in one legal context, as "manufactures or compositions of matter" might be conducive to viewing *all* animals (and, for that matter, human beings themselves) in that way.

One reaction to these fears is to preclude the patenting of any form of living creature or living matter in virtue of patenting's possible contribution to the commodification or objectification of human life or life in general. Implicit in this approach is the view that no set of beneficial consequences would offset the damage done by allowing patenting. For reasons explained earlier in the paper, we are sceptical about such blanket rejections of patenting, and argue instead for an approach that is tailored to responding to the particular moral difficulties that arise in different areas of this heterogeneous policy field.

Even without introducting extreme cases of the type imagined by Rifkin, though, it is clear why commodification or objectification of human beings or human characteristics would be objectionable. To the extent that patenting human genetic material or even cell lines would have this effect, a strong (although rebuttable) presumption exists against it. But the commodification or objectification of human life or human traits could also occur indirectly, as a result of allowing patents on higher but non-human life forms. If the genetic information coding for certain specific animal traits were to become patentable subject matter, the commodification of human traits and the objectification or devaluation of human beings and human life could follow, even if human beings and/or human traits *per se* were not eligible for patent protection. Were the evidence to support this eventuality sufficiently strong, it would provide a compelling argument against allowing patents on genetically engineered animals. Allowing such patents, or even continuing to allow the patenting of microorganisms, might reinforce or alter undesirable attitudes toward both animals and human beings. Attitudes toward both animals and human beings (indeed, all forms of life) might change if they came to be thought of *either* as mere collections of biological information, or as objects (manufactures or compositions of matter), rather than as conscious beings and subjects of experience.

What about the objectification or commodification of animals themselves? Whether one worries about this depends in large part on one's reaction to practices such as factory farming. Many people apparently are not bothered; on the other hand, some clearly find such treatment intensely objectionable.[262] For our purposes, a more important question is how seriously to take the claim that patenting would worsen these situations. Would allowing patents for higher life forms erode

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260 Shapiro, "Fragmenting and Reassembling the World," 350.

261 For discussion of some of these objections, see Sharp, "The Patenting of Transgenic Animals," 269-70.

262 See *e.g.* Singer, *Animal Liberation*, 92-162.

or jeopardize attitudes about the moral status of animals and what constitutes humane treatment of them? Comparable questions can be asked with respect to allowing patents on portions of the human genome. The issue of whether allowing patents for higher life forms would have indirect effects on our attitudes toward human beings, even if exclusions of the type specified in the EU Draft Directive were specifically incorporated into patent law, merits careful consideration.

We have a long tradition of treating animals as property. We buy and sell pets and livestock, breeding them to produce desirable characteristics and pricing them according to their possession of valued characteristics, but this does not prevent us from developing feelings of affection for them (in the case of pets) or from feeling that it would be wrong to mistreat them.[263] Our commitment to treat animals humanely is sufficiently strong that criminal liability is imposed for serious mistreatment. Thus although there may be nothing wrong with treating non-human animals as means to our ends, assuming the ends themselves are justifiable, there is nevertheless something wrong with treating them as "things." They are sentient creatures, and as subjects capable of conscious experience, they have interests, for example, interests in avoiding pain, in being healthy and well-nourished, and in not being disabled. To treat an animal morally is at least partly to take the animal's interest into consideration in deciding how it will be treated. It is, minimally, to recognize that animals are sentient beings, capable of suffering and feeling pain, not objects like rocks or houses.

Patenting animals (or animal genotypes) could make us more ready to think of animals as things rather than as subjects of experience; it could also magnify or intensify existing tendencies to do so, for instance, in the context of research. On the other hand, allowing patents on higher life forms might enhance our ethical sensitivity towards animals--it could make us more aware of ethically questionable dimensions of our current attitudes. Recognizing both possibilities emphasizes a major difficulty in evaluating arguments about commodification or objectification: they are largely empirical in form. These arguments, in other words, rest on predictions that if a practice is adopted, a given state of affairs will result.

A high degree of uncertainty is inescapably associated with such predictions, however, not least because the way in which new technologies like genetic engineering are treated by governments and professionals helps to determine whether people scrutinize their social consequences or simply accept those consequences as the price of progress.[264] Our understanding of social processes, such as those that surround the introduction of new technologies, and the formation of human belief systems, such as the emergence of public attitudes towards new scientific and technological developments, remains (to put it mildly) imperfect. We cannot be sure how our attitudes towards animals and human beings would be affected by genetic engineering and patenting. They might be shaped by prevailing general conceptions. On the other hand, our attitudes might be sensitive to complexities, nuances, and the richness of particular situations, as

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263 Altman, "(Com)modifying experience," 310-312.

264 Davis, "Morality and Biotechnology," 367-368.

Radin notes happens with respect to human beings: "We see wage labour as commodifying and alienating workers, sometimes, in some senses; and we see workers as resisting commodification and alienation, sometimes, in some senses."[265]

This empirical uncertainty does not mean that less attention should be paid to the concerns about commodification and objectification. The connections between new technologies and the way we view the world and the creatures that inhabit it may well be subtle rather than obvious:

> For people to be commodified (in the relevant morally distressing sense), it is not necessary for us to come to view each other *just* the way we view items we buy and sell. Given the ways that human norms and psyches work, it is far more reasonable to think that, though people may continue to mouth the familiar Kantian platitudes about worth and dignity, they will not treat each other accordingly. People's thoughts and feelings about people--both themselves and others--may thus remain significantly different from their thoughts and feelings about mere objects, and yet people may still be commodified (in a morally significant, non-trivial sense of the notion).[266]

Both for this reason and because concerns about commodification and objectification strike an intuitive, or even emotional, chord with us, it can be argued that particularly close attention to ethical and social implications is warranted precisely where uncertainty about the potential impact of technologies upon attitudes, values and behaviour is most pervasive.

The importance of such close attention is heightened by the fact that large numbers of people can fail to make distinctions that seem ethically appropriate in the circumstances. There are legitimate and conscientious pet breeders, but there are also unscrupulous operators of puppy mills. Some feminists argue that the popularity of pornography and the prevalence of the attitudes toward women that it embodies indicate a widespread failure or inability to distinguish between sentient human beings and pieces of meat.[267] This warning should not be taken lightly. The soundness of distinctions, and of the practices they legitimate, also needs to be assessed. For instance, in ethnographic studies of scientists and technicians involved with animal research, sociologist Arnold Arluke

> ... concluded that there are two views of animals used for experimentation.

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265 *Ibid.*

266 *Ibid.*, 370-371.

267 See *e.g.* Andrea Dworkin, *Letters from a War Zone* (New York: E.P. Dutton, 1988), 197-322; Catharine MacKinnon, *Feminism Unmodified: Discourses on Life and Law* (Cambridge, MA: Harvard University Press, 1987), 127-213.

> The more predictable and prevalent view is that these animals are objects devoid of unique personality or even animate nature. They are considered tools, models, data, material, or supplies. They are batched, numbered, used, and dispatched in a disassembly process reminiscent of the mechanical and routine work of factory mass production. Far less commonly, laboratory animals are viewed as pets, often set aside from experimentation and sacrifice to become mascots or household adoptees. Viewing laboratory animals as pets morally elevates their status compared with that of their depersonalized peers. The pet will be treated as a living entity rather than as a collection of tissues; it will be perceived to have a unique identity and a will; and it will be a source of human pleasure.[268]

Many animal rights advocates would argue that the distinctions observed by Arluke are thoroughly inappropriate, and some social theorists would probably argue that wage labour in a market economy is virtually *always* commodifying and alienating. Radin is aware of the latter problem, because she recognizes that relying on precedents for moral decision-making about existing social practices and relations "encourages us to take the status quo as given *morally*, not just empirically."[269] Perhaps the ways we do things now are morally suspect, and the prospect of a new practice could "awaken us, or re-awaken us, to the problematic nature of the objectifications that we have previously--perhaps uneasily--tolerated."[270]

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[268] A. Arluke, "The significance of seeking the animal's perspective," Behavioral and Brain Sciences 13 (1990), 13-14; see also Arluke, "Sacrificial Symbolism in Animal Experimentation: Object or Pet?" *Anthrozoös* 2 (1988), 98-117.

[269] Radin, "Reflections on Objectification," 343.

[270] *Ibid.*

XII. Conclusions: On Process and Substance

A distinguishing characteristic of democratic institutions is that their acceptability is determined as much by how they make decisions (process) as by the nature of the decisions they produce (outcome). At least as important as the outcome of policy decisions about patenting higher life forms is the process by which such decisions are reached. Indeed, democracy is largely *about* process, and about the willingness of all parties involved to live with the uncertainty of the outcome in any particular case.[271]

How should societies and governments make choices about technologies that are unfamiliar and incompletely understood? One approach is to leave such decisions up to the experts: those who "know best." However, democratic societies appear increasingly unwilling to do this with respect to choices involving science and technology, whether those choices concern the siting of hazardous waste disposal facilities or the environmental hazards of genetically engineered plants.[272] The controversies that have surrounded the marketing of food preserved using irradiation and milk from cows given bovine growth hormone provide two apt examples. Such mistrust is fuelled in part by experts'(as well as so-called laypersons') often incomplete enumeration of technological risks,[273] and in part by straightforward misuses of the authority that accompanies the specialized knowledge of experts. Brian Wynne argues, in this regard, that "the heart of risk perceptions and risk conflicts [is] not the issue of technical risk magnitudes, but rather trust in institutions."[274] The nature of trust has also changed. Whether in the clinical or the political context, trust based on status, power and expertise has been replaced by a more egalitarian conception of earned trust. By definition the latter cannot be demanded; it must be continually earned and justified.

Questions of trust and appropriate mandate are especially important in the context of genetic engineering and its products. Because of, for instance, the uncertainty associated with the environmental health and safety impacts of the release of genetically engineered organisms, biotechnologies are at best imperfectly amenable to conventional techniques of risk assessment. According to Nancy Davis, because new biotechnologies "may radically change the way people can and will live their lives, some of the risks they pose are *special*. It is not clear that such risks can be adequately assessed, or even properly understood, within the confines of a consequentialist framework."[275] The definition of a consequentialist framework used by Davis is narrower than ours, and excludes some effects of biotechnological advances on human attitudes that we have included.

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271 A. Przeworski, *Democracy and the Market* (Cambridge: Cambridge University Press, 1991).

272 On genetically engineered plants, see the discussion of environmental impacts earlier in this report; on nuclear waste, see *e.g.* Paul Slovic, James H. Flynn and Mark Layman, "Perceived Risk, Trust, and the Politics of Nuclear Waste," *Science* 254 (1991), 1603-1607.

273 Baruch Fischhoff *et al.*, *Acceptable Risk* (Cambridge: Cambridge University Press, 1981), 31-35.

274 B. Wynne, "Risk and Social Learning: Reification to Engagement," in Sheldon Krimsky and Dominic Golding (eds.), *Social Theories of Risk* (Westport, CT: Praeger 1992), 277-278.

275 Davis, "Morality and Biotechnology," 357; see also 360-367.

Nevertheless, her warning should be heeded.

Many of the points made in the preceding paragraphs are reflected in the findings of a 1993 survey on public attitudes toward biotechnology in Canada conducted by Decima Research for the Canadian Institute of Biotechnology. A summary of that survey is worth quoting at length:

> First, there is recognition that biotechnology is extremely powerful, and that while two-thirds of respondents believe that it offers "some/a lot of benefit", two-thirds also believe that biotech poses "some/a lot" of danger to society. Two global domains of public concern were identified: first, that there is potential for the misuse of biotechnology, and secondly, that biotechnology amounts to tampering with nature.

The same survey found that the public has varying degrees of resistance to the idea of gene transfer, and that resistance is greatest when the technology is not linked to a specific goal. By contrast, public acceptance increases significantly when gene transfer is linked to a goal such as preventing a fatal illness, or increasing the nutritional value of foods. Beliefs about God and nature are highly associated with beliefs about the acceptability of gene technology, and whether biotechnology is perceived as being harmful or beneficial.

Finally, the survey indicated that public confidence in biotechnology companies is moderately low, and trust in government to ensure the safety of biotechnology is only moderate. A majority of respondents do not believe that the established [industrial biotechnology] sector takes account of the human consequences of biotechnology.[276]

The survey results are broadly consistent with those from similar surveys in a number of other jurisdictions.[277]

Gillian Turner and Brian Wynne have identified as a key element of so-called cultural theories of risk the insistence that "risk definition ... is a social process, and no framework can claim a privileged status over others. Risk definitions have to be negotiated."[278] This point is extremely important, as are the questions it leads us to ask. With specific reference to human germ

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[276] Michelle Mullen, *Biotechnology: Social & Ethical Issues, Industry's Commitment and Public Policy* (Toronto: Ontario Biotechnology Advisory Board, 1994), 10-11. This summary is quoted for convenience; see also Decima Research, "Executive Summary: Survey for the Canadian Institute of Biotechnology" (Toronto, September 1993).

[277] See *e.g.* Sam Martin and Joyce Tait, "Attitudes of Selected Public Groups in the U.K. to Biotechnology" and Eric Marlier, "Eurobarometer 35.1: Opinions of Europeans on Biotechnology in 1991," in J. Durant (ed.), *Biotechnology in Public: A Review of Recent Research* (London: Science Museum for the European Federation of Biotechnology, 1992), 28-41, 52-108 [respectively].

[278] Gillian Turner and Brian Wynne, "Risk Communication: A Literature Review and Some Implications for Biotechnology," in Durant (ed.), *Biotechnology in Public*, 122.

line modification, Krimsky has argued:

> The implications of genetically modifying germ cells are far from understood. Many agree that there are profound consequences associated with initiating such experiments, but few can even begin to anticipate the scope of these consequences. Therefore, to begin such a process without understanding its broader implications, without a reasonable idea about whether it is possible to control the process once it is begun, and without a strong consensus from an informed electorate would be socially irresponsible.[279]

In a similar vein, Daryl Macer has recommended that research involving the genetic manipulation of human embryonic stem cells "should be deferred until society has come to a consensus on the time and developmental limits of human embryo experimentation."[280] An opposing viewpoint might question the need for social debate about biotechnological innovations, in particular the claim that consensus is required before particular directions should be followed or permitted. Why are the implications of this technology so morally significant, unique and far-reaching as to warrant moratoria on patenting or, as some have argued, restrictions on research pending the establishment of a society-wide consensus? Is it not the case that the public remains to be informed, or has indeed remained uninformed, about the implications of a variety of contemporary scientific and technological developments which have had or are likely to have more immediate and extensive impacts?

Viewed this way, the argument against patenting is an instance of a more general argument for the social control of technology, and perhaps even of a mistrust of technology. How relevant is this position to patenting? Why should consensus about patenting be required when a variety of other human activities are permitted despite bitter conflicts that do not appear amenable to easy or rapid resolution (*e.g.* clearcutting the forests of British Columbia's Clayoquot Sound, raising and trapping animals for fur, building nuclear power stations)? An answer to this hypothetical challenge depends crucially on just how special the potential hazards associated with genetic engineering and patenting higher life forms really are ... and this, in turn, depends on the resolution of any number of factual questions that can only be answered as the technology develops and as social scientific research into its implications continues.

Although consensus may never be achieved, failing to have an informed public debate about such questions effectively prejudges them in favour of a point of view that is relatively sanguine about potential hazards, and in favour of an incremental approach that cannot accommodate long-term, sweeping and unique hazards. To repeat Radin's observation, the effect is to "take the status quo as given *morally*, not just empirically." Patent lawyers who opposed the temporary 1987

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279 Sheldon Krimsky, "Human Gene Therapy: Must We Know Where to Stop Before We Start?" *Human Gene Therapy* 1 (1990), 173.

280 D. Macer, "New Creations? Commentary," *Hastings Center Report* 21 (January-February 1991), 33.

moratorium in the United States argued that the PTO should be "morally neutral" and should not function "...as a forum for assessing the consequences of introducing new technology."[281] A similar argument has been made in Europe:

> The ethical concerns currently raised in conjunction with biotechnology patents are misplaced because they stem from a lack of understanding of the patent system. A patent system is not a means of safeguarding the public interest. It is primarily a commercial and industrial tool that encourages innovation, divorced from social and ethical concerns.[282]

The contention that a government agency with a statutory mandate to implement a system of intellectual property rights can be "divorced from social and ethical concerns" is, however, disingenuous at best. With respect to matters such as the patenting of transgenic animals or of human cell lines and the products derived from them, any pretence to moral agnosticism or moral neutrality is itself not neutral because it predisposes public policy toward accepting the status quo and an incremental approach to policy formation that may not be justified in the circumstances.

This line of reasoning is elaborated in a landmark article on constitutional decision- making by the judiciary in which Cass Sunstein argues that the concept of neutrality is unintelligible except when understood with reference to a set of socially and culturally specific baseline assumptions that together define the natural, the good and (perhaps most importantly) the normal.[283] At least in North America, the basic principles of patent law can be traced historically to an underlying, not always explicit, equation of the public interest with the furtherance of commercial and industrial innovation. Once we accept, even provisionally or for purposes of argument, the claim that advances in biotechnology might create serious tensions between the public interest and the furtherance of commercial and industrial innovation, the patent system's claim to moral neutrality is called into question. This is particularly true if there are intrinsic ethical problems with granting patents on certain higher life forms. In this situation "patent now, deal with the ethical repercussions later" is simply not a defensible approach. Patent offices, as presently constituted, cannot deal with those ethical repercussions and should not be expected to. They lack both the statutory mandate (at least in Canada and the United States) and the requisite institutional capacity.

Any effort to address the ethical questions outlined in this paper adequately will involve two institutional stages or "tiers". Given the potentially far-reaching consequences of patents on higher life forms, particularly if the claims of promoters about the role of patenting as an incentive to research and development are accurate, there has been remarkably little public debate in Canada about when such patents are ethically acceptable. The first stage should therefore involve a forum for public debate about the general principles that should guide policy responses to this question.

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281 "Clash Looming," *New York Times*, July 23, 1987.

282 Ho, "Building a Better Mousetrap," 195.

283 Sunstein, "*Lochner*'s Legacy," *Columbia Law Review* 87 (1987), 873-919.

There are several institutional options for conducting such a debate. One is to establish a Royal Commission, analogous to the RCNRT, but this approach has the obvious disadvantages of being both costly and time-consuming. These are serious drawbacks given the financial constraints on government and the pace of developments in biotechnology. Another option is a process of informal consultations analogous to the one that will shortly begin on the federal discussion paper on *Improving Social Security in Canada.* However, these consultations involve issues that already have a very high profile, rather than issues about which the level of public information and awareness needs to be raised. Further, unless it is eventually concluded that no further change or elaboration of current public policy with respect to patenting higher life forms is necessary (a conclusion with which we would strongly disagree), the ethical issues will ultimately have to be addressed within a legislative framework specifically designed by Parliament to deal with those issues. The exclusions contained in the EU Directive constitute one example of such a framework, although it is possible to envision a framework that would be more specific as well as one that would be even more general. In Canada, this would take the form of amendments to the *Patent Act,* and quite possibly to other statutes and regulations as well. The two sets of changes might well be interdependent. For instance, it might be concluded that the ethical acceptability of patenting certain kinds of genetically engineered organisms depends on the strengthening of existing regulatory controls on such matters as the treatment of laboratory animals or the use of genetically modified plants in agriculture.

Both for this reason and because of the public profile often associated with such proceedings, we recommend that hearings be held by a Parliamentary committee given a mandate specifically to examine the ethical issues associated with the patenting of higher life forms and to recommend legislative, regulatory and policy changes. Obviously, such a committee will have considerable latitude in choosing its own approach to the issues. However, as suggested at several points in this report, a key question (perhaps *the* key question) is whether the baseline or starting-point for purposes of making decisions about patenting higher life forms, both at a policy level and in specific cases, should be a presumption in favour of patenting or a presumption against patenting. The former presumption is implicit in Canadian intellectual property law, and manifests itself in the absence of any statutory authority to deny a patent on what might be called public-interest grounds. The latter presumption is similar to that which operates (at least in theory) with respect to the regulatory screening of prescription drugs and pesticides, where demonstrations both of safety and of efficacy are required before approval is granted. In other words, under the latter presumption patent applicants would need not only to meet the conventional tests of novelty, utility and innovation, but also a variety of other tests designed to reflect the ethical issues distinctive to intellectual property rights in higher life forms. Beyond and apart from this initial choice of baselines, the analytical framework presented in this paper should provide a useful basis for framing questions, if not for arriving at easy, uncontroversial answers.

Until the public debate we envision has occurred, Canada should preserve as much public space as possible for that debate, and protect the viability of as many policy options as possible. This issue arises with some urgency because of the concern that industry and government may seek to limit that space, and the concern that governmental decisions may unintentionally have that

effect. Both the final text of the GATT agreement dealing with intellectual property[284] and the final text of NAFTA, the North American Free Trade Agreement,[285] leave considerable space for national action. Neither appears to preclude exclusions like those in the EU Directive. However, the Clinton administration and its key private-sector advisory committees on trade policy have indicated their intention to seek further entrenchment of intellectual property protection through bilateral trade and investment negotiations.[286] This development would preclude the kind of national debate and initiative we see as essential. For this reason, it is important that, for now, Canada not make any commitments in new bilateral or multilateral agreements that would limit our ability to restrict patenting of higher life forms based on non-commercial criteria.

Regardless of the substantive conclusions that are ultimately reached by a Parliamentary committee (or some other body) and eventually embodied in legislation, the application of general principles to subsequent specific patent applications will not be self-evident, and their implementation will not be automatic. Indeed, in many situations it is likely that the ethical acceptability of patenting can and should be decided only on a case-by-case basis, although with reference to a set of general principles. (The EPO's approach to the Harvard mouse patent is an example.) The institutional framework within which that decision-making will take place is itself of considerable importance. Obviously, some of its features will depend on the general principles around which the institution is designed, and our approach is not intended to entail specific decisions or to entrench particular value positions in advance of public debate. As with the public debate that we envision preceding it, though, the institution that makes decisions in specific cases must be as open and public as possible, recognizing patent applicants' legitimate expectation that

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284 Article 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights [TRIPS] provides that:

"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 also 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. ... "

285 NAFTA Article 1709(2) provides that:

"A party may exclude from patentability inventions if preventing in its country the commercial exploitation of the inventions is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to nature or the environmentfor reasons including the protection of human, animal or plant life, provided that the exclusion is not based solely on the grounds that the Party prohibits commercial exploitation in its territory of the subject matter of the patent."

Article 1709(3 also provides for the same further exclusions as the TRIPS Agreement, and likewise requires intellectual property protection for plant varieties.

286 Ecumenical Coalition for Economic Justice, *Intellectual Property Rights in NAFTA: Implications for Health Care and Industrial Policy in Ontario* (Toronto: Ecumenical Coalition for Economic Justice, October 1993), 27; "U.S Industry Advisors Press for Bilateral IPR Pacts Based on NAFTA," *Inside NAFTA*, January 26, 1994, 20.

delays will be minimized and the confidentiality that must be maintained until patent applications are laid open to public inspection.[287] We have already argued that the CPO, in its present form, is not an appropriate forum for such debate and decision-making. Three options, which by no means exhaust the range of possibilities and combinations, can be considered as alternative mechanisms for public, accountable review and decision-making.

Option A involves an appointed ethical review board or panel that would operate at arm's-length from the CPO, yet would be called upon for decisions in cases where the denial of a patent might be justified on ethical grounds. A key issue for this option is the composition of the board. How large should it be, and who should be a member? Should such a board or panel contain scientists, business people, laypersons, and ethicists? What about the danger that ethicists may become a new and special category of experts, with their own institutionalized biases? Should an attempt be made to achieve "representation" of the various constituencies with a stake or an interest in patenting policy? If so, what would a search for representativeness imply for the nature of ethical decision making? Would it erode the distinctiveness and the prominence that are generally accorded to ethical issues, by reducing their resolution to a process of lobbying and interest-group accommodation?

Instead of creating a national review body, option B establishes a statutory or regulatory requirement that applications for certain categories of patents on higher life forms be accompanied by a certificate of compliance with ethical criteria analogous to those that must be satisfied by applicants for federal funds to support research involving human subjects. Key issues with this option include: What body would supply such certificates? Do the committees that now provide ethics review for university-based research have the resources and capacity (or, in some instances, the independence) to expand into this new area? How, for instance, would an animal care committee or an institutional review board that reviews research on human subjects deal with some of the far-reaching implications of patenting explored in this report?

Option C takes no further action beyond legislative amendment, leaving to the courts the task of resolving conflicts in specific cases. This alternative has the apparent advantage of minimizing additional costs to government.[288] Were this option selected, the parties or groups who have standing to object to the issuance of a patent on ethical or public-interest grounds would have to be clarified. But this will need to happen in any case, for reasons explained later in this section. More basic issues include whether the only mechanism for ethical scrutiny of patenting decisions should be the costly, time-consuming and adversarial path of litigation, and whether courts are

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[287] This latter requirement means that in some situations, where a patent is awarded in a situation where an ethical exclusion might be justified, the requisite "transparency" with respect to decisions on individual patent applications will only be available after the fact, in the form of carefully documented reasons for whatever decision is eventually reached.

[288] We say "apparent" because it is a matter of speculation as to whether the costs of implementing options A or B would in fact be lower than the additional costs imposed on the court system were substantial volumes of litigation to occur. The volume of litigation is, in turn, a function both of the rules of standing adopted and of the fund-raising abilities of potential "public interest" litigants.

really the best forum for resolving the "polycentric" questions associated with patenting higher life forms.[289]

Among the merits of option A, which lead us cautiously to favour it, are: the probability of a greater degree of consistency in decision-making and interpretation than would be likely if those tasks were left either to a number of separate bodies or to the courts; the fact that it may be easier to make provision for ongoing consultation and public participation when a single national body is responsible for ethical review; and the fact that there are no existing bodies whose mandate is to provide ethical clearance for research carried out in the private sector or (in some cases) under direct contract to governments. The unavailability of ethics review bodies outside universities and hospitals, and the varied composition and effectiveness of these bodies even where they do exist, could create substantial difficulties in implementing Option B.

The recommendation that a single national body with a mandate for ethical review be established resembles the far more ambitious proposal of the Royal Commission on New Reproductive Technologies (RCNRT) to establish a National Reproductive Technologies Commission "charged with the primary responsibility of ensuring that new reproductive technologies are developed and applied in the public interest."[290] The Commission's own work arguably corresponded to the first tier of the approach we recommend here. The proposed National Commission corresponds to the second tier; it would "permit the creation and implementation of coherent, comprehensive, and effective nation-wide standards and monitoring devices" and could "apply an ethical framework in decision making and ensure that the interests of all concerned groups and individuals are considered in setting policy and standards and assuring adherence to them in practice."[291] The responsibilities of the National Commission would include licensing practitioners of a variety of new reproductive technologies; developing national guidelines and standards of practice for research and delivery, based on the work of permanent subcommittees; and collecting, evaluating and disseminating information about new reproductive technologies and their use.[292] Our recommendation is also similar to the approach proposed by GROW, which during the debate on Bill C-15 suggested the appointment of a board of public-interest representatives to advise on intellectual property issues as they apply to agriculture.[293]

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289 Lon Fuller, "The Forms and Limits of Adjudication," *Harvard Law Review* 92 (1978) [originally circulated in 1961], 395.

290 RCNRT, *Proceed With Care*, 112.

291 *Ibid.*, 113.

292 *Ibid.*, 115-121, 1023-1033.

293 R. Munroe, in *C-15 Hearings*, November 21, 1989, 7:10.

With respect to the composition of its proposed National Commission, RCNRT favoured "diverse representation of interests"[294] and recommended that the Commission's subcommittees include, as well as members of the Commission itself, outside members who could represent "the views and interests of governments, professional bodies, consumers, and other groups with particular interest in the area of sub-committee activity in question."[295] It is premature to make recommendations on such points; further, although we are concerned with issues of representation at the decision-making level, we are even more concerned with the openness and transparency of the process by which decisions are reached.

One important issue that requires further consideration is accountability. Let us assume for purposes of argument that there will be some form of arm's length ethical review of at least certain categories of patent applications on higher life forms. In deciding whether to issue a patent, should the CPO be bound by the decisions of its ethical advisors, or should those decisions remain advisory in nature? The RCNRT's proposed National Reproductive Technologies Commission would have an explicitly regulatory role, rather than just an advisory one. Another issue is that of standing. Suppose that a patent were granted in Canada on the Harvard mouse, or on a particular genetically modified agricultural animal. Would an individual or organization seeking to challenge this decision on such grounds as the impact on animal welfare or on our attitudes toward life and living beings be granted standing to do so, either in the courts or in some other forum?[296]

In addition to being an important practical problem, this is also a philosophical and a legal/procedural problem. As noted earlier, independent third parties do have a vehicle for challenging the grant of a patent in Europe, although this mechanism comes into play only after the patent is granted. Under Canada's *Patent Act*, no express standing is granted to the public or other third parties. Section 10 is the only place where the public is recognized in the patent application process: "... all patents, applications and documents filed in connection with patents or applications for patents shall be open to public inspection at the Patent Office, under such conditions as may be prescribed."[297] Current CPO practice is that members of the public may file a protest with the Patent Office. Although there is no specific mention of such protests in the *Patent Act*, section 15 of the *Patent Rules* states that "the receipt of a protest against the granting of an application shall be acknowledged by the Office, but no information shall be given as to the action taken thereon," meaning that a protest cannot be followed up meaningfully. Section 2.07 of the Manual of Patent Office Practice expands upon this and states that a protest may develop "as a result of public inspection of an opened application."

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294 *Ibid.*, 122.

295 *Ibid.*

296 This discussion of standing is based on research conducted by Sunny Handa, LL.M.

297 R.S.C. 1985, c. P-4, s. 10.

These provisions would not appear to preclude a public interest protest. However, CPO has no statutory basis for refusing a patent on public interest or ethical grounds. An extensive search of patent cases at both the administrative and judicial levels fails[298] to uncover a single case where a member of the public (or interested third party) has sought standing in the courts to challenge a patent on public interest grounds. Once a patent has been issued, the lack of any statutory basis for refusing a patent application on public interest grounds means the validity of the patent can be challenged only on a technical point of patent law. This would not be the case if exclusions of the type embodied in the EU Directive were added to the *Patent Act*. The *Patent Act's* failure to provide any formal mechanism for opposition to the issuance of patents is a particularly serious deficiency given the ethical concerns raised in this paper and the importance of public discussion of ethical issues. Specific attention should be paid to the issue of standing if ethics- or public interest-based exclusions are added to Canadian patent law.

298 Conducted by Sunny Handa, LL.M. at the McGill Centre for Medicine, Ethics and Law.

XIII. Epilogue

To some readers, our conclusions may seem maddeningly inconclusive. This is partly because, as emphasized earlier in the paper, applied ethics does not provide an algorithm for practical moral decision-making. It is also because sound ethical decisions about patenting higher life forms must be made on the basis of factual information about a wide variety of matters, ranging from the incentive effects of patenting to the effects on human attitudes of issuing patents on higher life forms. In some cases, the facts are not yet available; in others, they are likely to be hotly contested; and in still others, the facts will change as scientific and technological capabilities develop.

What we have tried to do is provide a framework for further discussion, involving the various stakeholders and informed by the results of the other studies currently being carried out for Industry Canada, about (a) what the ethical issues are and (b) how they should be dealt with in public policy and law. Once again, we feel the need to emphasize the importance of process and of further discussion. To use an analogy that is overworked but which nevertheless seems appropriate in this context, the analysis we have provided represents the road map, not the end point of the journey.

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