PATENTING LIFE-FORMS & OWNING HUMAN TISSUE*

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^{*} This text represents the author's personal views and does not necessarily reflect those of the Law Reform Commission of Canada

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I. PATENTING LIFE-FORMS¹

Tremendous advances have been made in the field of biotechnology over the past few decades. It is now possible to create forms of life that cannot be found in nature. One of the corollaries of such developments has been an increased potential for the commercial application of biotechnological principles. Yet humankind has only begun to realize the immense scientific and economic potential of the new technology. Patent protection for man-made life-forms could contribute to their profitable exploitation and possibly provide an important stimulus for continued research.

At an October 1988 meeting hosted by the World Intellectual Property Organization² and the International Union for the Protection of Industrial Property,³ delegations of some 35 nations, including Canada, generally approved the following principle:

¹I would like to thank Dr. Burleigh Trevor-Deutsch, Coordinator of the Protection of Life Section; Derek Jones, Consultant; and Sam Levine, summer student; for their contribution to this work.

²See text accompanying note 69, <u>infra</u>.

³See text accompanying notes 75, 76, <u>infra</u>.

"A product shall not be excluded from patent protection or regarded as unpatentable for the mere reason that it constitutes or includes living matter."

However, some delegations, even in accepting the general principle, "expressed some reservations with respect to inventions concerning higher life-forms."

If patenting life is permissible, where and on what grounds should society draw lines for the patenting of different life forms--micro-organisms, plants, animals and humans? Canada and other nations are currently grappling with the dynamics raised by this question. In July 1989, the Supreme Court of Canada decided its first case on the patenting of life-forms, Pioneer Hi-Bred Limited v. The Commissioner of Patents⁶.

Most developed countries provide more extensive options for intellectual property protection of new life-forms than is available in Canada. They appear also to be more active in international efforts to provide for standardized policies on intellectual property protection for man-made life-forms. A review of foreign efforts to furnish such protection suggests policy options, and demonstrates the uniqueness of the Canadian situation.

⁴See World Intellectual Property Organization (WIPO), International Union for the Protection of Industrial Property, Committee of Experts on Biotechnological Inventions and Industrial Property <u>Draft Report of Fourth Session Geneva</u>, 17 (28 Oct, 1988) and <u>Revised Suggested Solutions Concerning Industrial Property Protection of Biotechnological Inventions</u>, 9 (24 June, 1988).

⁵<u>Id.</u> (Draft Report) at 17.

⁶Infra, note 42. Judgment rendered June 22, 1989, reasons for judgment by The Hon. Mr. Justice Lamer.

The effect that divergent national policies might have on international trade, and the probable link between intellectual property protection for man-made life-forms and the development of this industry, indicate the need for a review of prevailing Canadian law.

The serious ethical considerations raised by biotechnology itself, and the possibility of patenting biotechnological products, are factors that will have to be taken into account in any policy review. An examination of major ethical concerns indicates that those which are most pressing relate to the technology rather than the prospect of patenting the technology.

Neither prohibition nor general patent protection for genetically altered life-forms appears to be the most appropriate means of dealing with the ethical issues associated with biotechnology. Accordingly, more comprehensive efforts will be necessary if the biotechnology industry is to be effectively regulated.

1.1 Biological Background and Ethical Considerations

It is widely felt that the less an organism is like a human, the more likely it is to be an acceptable subject for biotechnological alteration and patenting. But what are the real differences among the major groups of life forms? Consider these differences from an evolutionary standpoint:

All life on Earth shares a common ancestry. Its diversity is the result of the evolutionary process. Micro-organisms, like bacteria and protozoa, are our most distant relatives. Our ancestral lines are thought to have diverged relatively soon after the advent of life on Earth. The common ancestors of plants and animals are more recent but still very ancient; the divergence of the plant and animal lines probably occurred billions of years ago. Plants are different from animals, not only because the former can photosynthesize, but also because they are not capable of consciousness and in particular, they can't feel pain.

Animals have undergone complex evolutionary changes since their divergence from plants. The first fish appeared 500 million years ago. Amphibians have existed for 350 million years and reptiles for 280 million years. Birds and mammals are a mere 150 million years old. Most mammalian species that now inhabit the Earth (extant species) evolved less than 200,000 years ago. Therefore, in the greater light of the evolutionary process, we humans are very closely allied with all other mammals.

Considering evolution from a different angle, there is more concern about the biotechnological manipulation and patentability of more "advanced" creatures than of "primitive" ones. What, then, is the distinction between advanced and primitive? In the simplest sense, a primitive physical characteristic in an extant organism is one which existed in its distant ancestors. An advanced characteristic is more recent.

For example, the most primitive land creatures, the amphibians, have five fingers and five toes. It is a characteristic which humans share with amphibians. In this regard, we are primitive; our direct ancestors have not changed in 350,000 years. On the other hand, we have advanced tongues which allow us to speak, and we walk upright which liberates the hands for other things. These are two of our advanced characteristics. And of course there has been an explosive development of the key to our species' success thus far: the brain. From an evolutionary viewpoint, then, humankind is a blend of advanced and primitive characteristics.

All of this tells us that despite the diversity of life forms on Earth, in many respects we are not all that far removed from our mammalian cousins and we share many advanced and primitive evolutionary characteristics with our more distant relatives, the fish, amphibians, reptiles and birds. Also, we bear strong biochemical resemblances to plants as well as other "simpler" organisms.

On what basis, then, can humankind rationalize the patenting of life, even if it has been genetically altered in the laboratory? As we learn to manipulate evolution through genetics, should matters formerly subject to the laws of nature, now be controlled by the laws of humankind? These are questions which do not lend themselves to scientific solution. They will have to be addressed by those who engage in a policy review of Canadian law regarding the patenting of life-forms.

The patenting of life question also raises ethical considerations for Canadian society. The debate appears to center on such issues as (i) whether patent protection for life-forms violates the sanctity of life and may lead to the patenting of human beings, (ii) whether patenting life forms threatens "species integrity" or constitutes cruelty to animals.

The patenting of life-forms is often criticized for violating the sanctity of life. To respond to the criticism, some counter that the prospect of patenting life-forms is merely an extension of existing norms: namely, it is not inconsistent with the rights that humankind has traditionally exerted over other creatures. This response, however, does little to address concerns about patenting human life forms.

From an anthropocentric perspective, it is understandable that one of the more emotionally charged objections to patenting life is that such a policy could lead to patenting humans. 9 Some

⁷See Lauroesch, <u>infra</u>, note 31, at 114, Merges, Intellectual, <u>infra</u>, note 109 at 1058, and Rebecca Dresser, J.D., Ethical and Legal Issues in Patenting New Animal Life. (1988) 28:4 Jurimetrics, 399, at 410 for further discussion of such views.

⁸See Lauroesch, <u>infra</u>, note 31, at 114-5, Barry Hoffmaster, The Ethics of Patenting Higher Life Forms. (1988) 4:1 Intellectual Property J., 1, at 5 and 11, Dresser, <u>supra</u>, note 7, at 412 and 414, and C. Keith Boone, "Bad Axioms in Genetic Engineering" (1988) 18:4 Hastings Center Report 9 at 411, for discussions of such a counterpoint. The strength of such an argument is dubious, however; as the traditional rights that man has had over animals might also be questioned.

Lauroesch, <u>infra</u>, note 31, at 115, Hoffmaster, <u>supra</u>, note 8, at 11, Dresser, <u>supra</u>, note 7, at 407 & 416, all discuss such allegations. It is also interesting to note that Current Topics, "The Patenting of Animal Forms With New Traits" (1987) 61:7 The Aus. L.J. 324 at 325, and George J. Annas, "Of Monkeys, Man, and Oysters" (1987) 17:4 Hastings Center Report 20 at 22 both suggest that the granting of patent protection to a claim involving a human

some argue that current practice indicates patent protection is unlikely to be applied to whole human beings, even if it is allowed for cell lines or organs. They contend that the patenting of human beings concern is a "slippery slope" argument; that it would never be allowed because of ethical and legal prohibitions against slavery. On the other hand, many commentators consider the application of biotechnology to human beings to be a positive development, so long as it is used in an appropriate manner (for the eradication of disease rather than for eugenics). This argument suggests that if the patenting of microbial human life forms (i.e. genetically altered human cell lines) is not ethically or legally intolerable, the focus will be on where to draw lines to limit the patenting of higher, or even human, life forms.

being is a development that may be foreseen by the U.S.P.T.O.

¹⁰Hoffmaster, <u>supra</u>, note 8, at 12-13 makes such an argument.

¹¹The U.S.P.T.O. Policy Statement of April 4th, 1987 indicated that a patent claim "including within its scope a human being would not be considered patentable subject" in part because it is prohibited by the U.S. constitution. See OTA, infra, note 30, at 93. See also Lauroesch, infra, note 31, at 115-6, and Merges, Intellectual, infra, note 109, at 1058 for discussions of such a point of view.

¹²Boone, <u>supra</u>, note 8, at 11, although he stops short of suggesting that the positive applications of genetic engineering on human beings should allow for patent protection, certainly supports the possibility of genetically engineered human beings. While Dresser, <u>supra</u>, note 7, at 417, by pointing out that appropriate regulation could render impossible the improper use of genetic engineering on human beings, implicitly adopts a stance that supports the possibility of patent protection for inventions that involve genetic engineering on humans.

Critics of biotechnology also argue that it threatens "species integrity" by altering the natural genetic identity of the organism. Thus, the new biotechnology allows humankind to "play God." These objections are countered by "legitimizing" claims that we have been cultivating and manipulating animal and plant species for centuries, and that in modern life society permits, condones, or even encourages the "playing of God", as occurs, for example, in modern medicine. 16

It is also suggested that the patenting of animal life-forms will encourage inhumane treatment of animal life. 17 Supporters of patent protection respond by pointing out that a patent ban will not affect the incidence of such treatment, 18 and allege

¹³See "Science of Sin," Globe & Mail 30 April 88, at D1. See also Merges, Intellectual, <u>infra</u>, note 109, at 1058-1059, and Dresser, <u>supra</u>, note 7, at 410 for discussions of such views. The Complaint in <u>Foundation on Economic Trends</u> v. <u>Block</u> at 18, in H. Edgar & R. Nelson, "Colloquium On Biotechnology. Installment Two Regulatory Issues. Volume Two: Deliberate Release And Food & Drug Law" (Spring 1988) (Privately Printed for the Exclusive Use Of Students At The Columbia University School of Law), at 516, presents such an argument.

¹⁴See Hoffmaster, <u>supra</u>, note 8, at 4; Dresser, <u>supra</u>, note 7, at 410; Boone, <u>supra</u> note 8, at 10.

¹⁵See, supra, note 8, and accompanying text.

¹⁶Hoffmaster, <u>supra</u>, note 8, at 4 severely criticizes such arguments against biotechnology. But see Boone, <u>supra</u>, note 8, at 10.

¹⁷Lauroesch, <u>infra</u>, note 31, at 117, Hoffmaster, <u>supra</u>, note 8, at 8, and Annas, <u>supra</u>, note 9, at 22. Susan L. Goodkin, The Evolution of Animal Rights. (1987) 18:2 Columbia Human Rights L. Rev., 259 provides a good indication of the position of the animal rights movement, while Hoffmaster, <u>supra</u>, note 8, at 8-9 contains a criticism of the stance taken by the movement.

¹⁸See Lauroesch, <u>infra</u>, note 31, at 118.

that the economic incentives provided by a policy that allows new life-forms to be patented would lead to the development of animals that might be less affected by the conditions encountered in factory-style farming. 19

There are also a number of related concerns that are ancillary to the ethical debate. One has to do with the impact on scientific norms. It is suggested that patenting life-forms would be likely to discourage the free dissemination of scientific information, and cause genetic scientists to pursue only avenues of profitable research.²⁰ The counter argument is that patent law requires disclosure - which is conducive to further innovation²¹ - and that prestige, recognition, and the discovery of the truth are more important forms of reward for many scientists than is the procurement of wealth.²²

A second important concern centers on the environmental risks of biotechnology, which are frequently cited as major

¹⁹See Dresser, <u>supra</u>, note 7, at 423.

²⁰See Lauroesch, <u>infra</u>, note 31, at 101, Dresser, <u>supra</u>, note 7, at 420, and R.S. Eisenberg, "Proprietary Rights and the Norms of Science in Biotechnology Research." (1987) 97:2 The Yale L.J. 177 at 218.

²¹See Dresser, <u>supra</u>, note 7, at 421, Eisenberg, <u>supra</u>, note 20, at 214 and Current Topics, <u>supra</u>, note 9, at 325 for discussion of this.

²²See Lauroesch, <u>infra</u>, note 31, at 107, Hoffmaster, <u>supra</u>, note 8, at 10-11, and Amnon Goldworth, "The Moral Limit to Private Profit in Entrepreneurial Science" (1987) 17:3 Hastings Center Réport 8, at 10. See Eisenberg, <u>supra</u>, note 20, at 204-205, for a discussion of "conflicting incentives within the reward structure of science itself."

hazards.²³ Proponents of patenting emphasize that serious environmental risks are speculative.²⁴ They also maintain, perhaps persuasively, that a ban on patenting would not necessarily reduce any such risks because it would not eliminate research or industrial exploitation.²⁵ Finally, proponents argue that patenting new life-forms may lessen the risk of environmental mishap, in part, because patenting gives rise to publication, scrutiny by experts and related public policy initiatives, as demonstrated by the international scientific community's self-imposed moratorium on biotechnological research in the mid-seventies.²⁶

²³See Dresser, <u>supra</u>, note 7, at 410 and Lauroesch, <u>infra</u>, note 31, at 125 for discussions of such concerns.

²⁴Compare Merges, Intellectual, <u>infra</u>, note 109, at 1067, Hoffmaster, <u>supra</u>, note 8, at 6 and 9, as well as Dresser, <u>supra</u> note 7, at 411.

²⁵Lauroesch, <u>infra</u>, note 31, at 125 makes such an argument. See generally Hoffmaster, <u>supra</u>, note 8, at 10, and Harold P. Green, "Chakrabarty: Tempest in a Test Tube", in "Commentaries on Recombinant DNA: From the Moratorium to Patenting Life" (1980) 10:5 The Hastings Center Report 10 at 13. But see Dresser, <u>supra</u>, note 7, at 409, R.H. Guthrie, DNA Technology: Are We Ready? (1981) 6:3 Dalhousie L.J. 659 at 673, and Hoffmaster, <u>supra</u>, note 8, at 17-18.

²⁶See Key Dismukes, "Life is Patently Not Human-Made", in Commentaries, <u>supra</u>, note 25, at 12, for a discussion of the importance of "scrutiny by the broad scientific community." See Norton D. Zinder "The Berg Letter: A Statement of Conscience, Not of Conviction" in Commentaries, <u>supra</u>, note 25, at 14 and David Baltimore, "The Berg Letter: Certainly Necessary, Possibly Good" in Commentaries, <u>supra</u>, note 25, at 15 for a critical discussion of how the scientific community imposed the moratorium on itself.

1.2 <u>Intellectual Property Protection For New Life-Forms in</u> Canada: Patent Law and Man-Made Life-Forms in Canada

The Canadian biotechnology industry is not large. As of 1985 Canada ranked last amongst OECD countries in per capita investment.²⁷ However, the industry is growing rapidly.²⁸ According to some estimates it might eventually grow to rival electronics in size and importance.²⁹

Various laws affect the developing industry. Environmental laws as well as the health and safety regulations at the federal and provincial levels are significant here. Both criminal law and the law of civil liability touch the biotechnology industry indirectly—either in the form of statutory sanctions or directly as redress for negligence.

²⁷J. Keon, "Intellectual Property Protection in Canada: The Technology Challenge" (1986) 11:19 Can.-U.S. L.J., 27 at 48.

²⁸See <u>1988 Canadian Biotechnology Industry Source Book</u>.

²⁹See D.M. Stotland, Patenting Novel Life-Forms. The Scope of The Abitibi-Price Decision. Canadian Intellectual Property Review. 1:2 (1984) 250 at 250.

³⁰M.A. Valiante and P.R. Muldoon, "Biotechnology and the Environment: A Regulatory Proposal" (1985) 23:2 Osgoode Hall L.J. 359 considers existing provisions for the regulation of the biotechnology industry in Canada and examines means of improving the current state of affairs. J.N. Gibbs, I.P. Cooper, B.F. Mackler, Biotechnology & the Environment: International Regulation. (New York: Stockton Press, 1987.) at 212 et seq. deals with the impact that such environmental forms of legislation might have upon the manner in which industrial property can be protected and used in Canada. United States Congress, Office of Technology Assessment. New Developments in Biotechnology: Patenting Life (hereinafter cited as "OTA"), at 102-110 contains a good discussion of how other areas of the law interact with industrial property law, in the American context.

In the absence of specific legislation in Canada, the protection of intellectual property rights in biotechnological inventions depends largely on the common law of trade secrecy and on Federal patent law. While effective maintenance of a trade secret may allow for perpetual enjoyment of an exclusive right to intellectual property, the patent system provides distinct incentives and benefits to the patent holder. On the other hand, the public disclosure requirements of the patent process may yield products, information and innovation that would otherwise remain undeveloped. Such considerations suggest that patent protection for biotechnologically-derived life forms may

³¹ See H.G. Fox, The Canadian Law of Trade Marks & Unfair Competition (Toronto: Carswell, 1972) at 652-658 for an in depth look at the law of trade secrecy in Canada. R. Saliwanchik, Legal Protection for Microbiological and Genetic Engineering Inventions. (Massachusetts: Addison-Wesley Publishing Co., 1982) at 9-18 provides a relatively detailed assessment of the applicability of trade secret law to biotechnological inventions. S.A. Bent, et al., Intellectual Property Rights In Biotechnology Worldwide. (New York: Stockton Press, 1987) at 346 et seq. also contains a good general discussion of the application of the law relating to trade secrecy to biotechnological products and processes. The same work also reviews various countries' laws (Canadian approaches are conspicuously absent) regarding trade secrecy at 555-586. M.W. Lauroesch, Genetic Engineering: Innovation And Risk Minimization. (1988) 57:1 George Washington L. Rev., 100 at 107-109, John Woodley, Capitalizing on the Wealth Buried Deep in Living Matter. Canadian Intellectual Property Review. 2:1 (1985) 128 at 128-131, OTA, supra, note 30 at 117 et seq., and Statement by Dr. Ann Sorenson, American Farm Bureau Federation, Hearings before the House Committee on the Judiciary, Subcommittee on Courts, Civil Liberties, and the administration of Justice, on the Patentability of Higher Life Forms, July 22, 1987 at 39 all discuss, in a comparative manner, patent protection and trade secrets in the field of bio-technology.

stimulate the development of biotechnological products in Canada. 32

To what extent, then, does federal patent law protect biotechnologically-derived life-forms? To qualify for a patent under Canadian law an inventor must meet several basic requirements. The applicant must present a novel, 4 useful, 5 non-obvious, 6 invention that is capable of being reproduced by

³²See United States Congress, Office of Technology Assessment, Commercial Biotechnology: An International Analysis (Washington D.C.: U.S. Government Printing Office, 1984) for a well researched effort to support such a point of view - with regard to the biotechnology industry in the United States.

³³For much more thorough treatment of the subject of Patent Law, than that which is provided here, see J.A. Blanco White, Patents For Inventions and the Protection of Industrial Design" (London: Stevens, 1974), Immanuel Goldsmith, "Patents of Invention: A Revision of Fox's Digest of Canadian Patent Law" (Toronto: Carswell, 1981), and H.G. Fox, "The Canadian Law and Practice Relating to Letters Patent for Inventions" (Toronto: Carswell, 1969).

³⁴See <u>Patent Act</u>, R.S.C. 1985, c. P-4, s. 2. Important amendments to the <u>Patent Act</u> have been passed, but not yet proclaimed in force. See Bill C-22, 35-36 Eliz. II, 1986-87.

³⁵Supra, note 34, s. 2.

³⁶This requirement is of judicial origin.

someone other than the inventor. 37 An invention is defined as follows:

...any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter; 38

An applicant who meets these requirements is granted "...the exclusive right, privilege and liberty of making, constructing, using" and selling the invention for 17 years from the date that the patent is granted. 40

The traditional position in Canadian law, was that living matter could not be patented, although processes that employed living matter could be. 41 Developments in biotechnology since

 $^{^{37}}$ This requirement is found in <u>supra</u>, note 34, s. 36(1), which states that the applicant

^{...}shall in the specification correctly and fully describe the invention and its operation or use..., and set forth clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science...to make construct compound or use it...; he shall particularly indicate and distinctly claim the part, improvement or combination which he claims as his invention.

³⁸See <u>supra</u>, note 34, s. 2.

³⁹See <u>supra</u>, note 34, s. 46.

⁴⁰See <u>supra</u>, note 34, s. 48.

⁴¹See, for example, <u>American Cyanamid v. Frosst</u> (1965), 47 C.P.R. 215. <u>Supra</u>, note 34, s. 41(1), explicitly provides for such an approach where a micro-biological process gives rise to an invention "intended for food or medicine." Though the Canadian Patent Office is apparently revising the language of its policy on patenting living matter, the current <u>Manual for Patent Office Practice</u>, s. 12.03.01, states a general prohibition on the patenting of higher life forms:

the mid-seventies have motivated patent applicants to attempt to extend the scope of the law to the inventions themselves, as well as the processes.

When presented with the issue of whether man-made life-forms are patentable subject matter, Canadian courts and patent authorities have tended to focus on the invention and reproducibility requirements of the <u>Patent Act</u>, as illustrated in the Supreme Court decision in <u>Pioneer Hi-Bred</u>, below. The prospect of patenting living products was recognized by the Patent Office as early as 1977. In <u>K. Apostolov's Application</u>, 43

[&]quot;(a) Subject matter for a process for producing a new genetic strain or variety of a plant or animal, or the product thereof, is not patentable. This exclusion does not include a micro-biological process or the product thereof.

^{...,} the Commissioner of Patents has indicated that inventions for new microbial life forms such as bacteria, yeasts, molds, fungi, actinomycetes, algae, cell lines, viruses, protozoa, and processes for preparing them may be patentable. To be patentable such inventions must relate to new man-made life forms which previously did not exist in nature, they must..."

See also A.J. Manson, The Process Claim For Biological Inventions, Canadian Intellectual Property Review 1:2 (1984) 240 at 245 et seq.; E.J. McKhool, Lifeform Patentability Advisory Committee Presentation, Canadian Intellectual Property Review 2:1 (1985) 119 at 120; Effat Maher, Patenting of Life Forms, Canadian Intellectual Property Review 2:1 (1985) 125 at 125; Re: Application of Abitibi Co. (1982) 62 C.P.R. (2d) 81 at 86-87; and W.L. Hayhurst, Patenting Life (1980) 5 Can. Bus. L.J. 19 at 25-26 all discuss this policy.

⁴²Pioneer Hi-Bred Limited v. The Commissioner of Patents (June 22, 1989) #20388 (S.C.C.) (as yet unreported).

⁴³Re Application No. 086,556 (Now Patent No. 999,546) (1977), 35 C.P.R. (2d) 56 at 59 "(t)he development of a cell line may give rise to patentable subject-matter satisfying the requirement of a new and useful invention, under s. 2 of the Patent Act, R.S.C. 1970, c. P-4, provided the applicant can also satisfy the requirements of s. 36 of the Patent Act...". Stotland, supra, note 29, at 257 and Manson, supra, note 41, at 247, discuss this

the Patent Appeal Board rejected the product claim for a human liver cell line because it failed to satisfy the reproducibility requirement. The Board found that the specification that accompanied the application was not "...full, clear, concise and exact..." enough to permit a person skilled in the art to reproduce the invention. Mere deposit of a culture of the new cell line was not sufficient to meet the reproducibility requirement.44

1.2.1 The Abitibi Case

In 1982, the Patent Appeal Board and Commissioner of Patents took a contrary view on the reproducibility issue. In <u>Re</u>

<u>Application of Abitibi</u>, 45 the Board held that depositing a microorganism in an accredited culture collection was sufficient to
satisfy the reproducibility test. 46 Although <u>Abitibi</u> concerned a
micro-organism, the Board's language and reasoning made reference
to higher life-forms, such as plants and animals:

If an inventor creates a new and unobvious insect which did not exist before (and thus is not a product of

case.

^{44&}lt;u>Supra</u>, note 43, at 59-60.

⁴⁵Supra, note 41. McKhool, <u>supra</u>, note 41, A.G. Creber and E.J. McKhool, Recent Developments In Protecting Plants And Seeds Under The Canadian Patent Act. Canadian Intellectual Property Review 3:1 (1987) 27 and Stotland, <u>supra</u>, note 29 all contain insightful treatment of the decision and its ramifications.

^{46&}lt;u>Supra</u>, note 37, at 91.

nature), and can recreate it uniformly and at will, and it is useful..., then it is every bit as much a new tool of man as a micro-organism. With still higher life forms it is of course less likely that the inventor will be able to reproduce it at will and consistently.... But if it eventually becomes possible to achieve such a result, and the other requirements of patentability are met, we do not see why it should be treated differently.⁴⁷

The <u>Abitibi</u> decision was significant in that it effectively extended patent protection to product claims involving microorganisms and cell lines. The reasoning of <u>Abitibi</u> was subsequently followed by the Patent Board in <u>Re Application for Patent of Connaught Laboratories</u>, 48 where a claim for a new bovine cell line was granted. However, even after <u>Abitibi</u> and <u>Connaught</u>, the Patent Office still maintained a general prohibition against the patentability of higher life-forms. 49

As of the early eighties, Canadian patent law was still in the process of evolving a clear policy with regard to the reproducibility requirement in the patenting of life-forms question. The law appeared to accept that some lower life-forms were patentable. But the contrast between the <u>Abitibi</u> language and the Patent Office's policy on patenting higher life-forms⁵⁰

⁴⁷Supra, note 41, at 90.

⁴⁸Re Application for Patent of Connaught Laboratories (Now Patent No. 1,139,691) (1982) 82 C.P.R. (2d) 32.

⁴⁹See Michael E. Wheeler, Patenting In The Bio-Technology Field. Canadian Intellectual Property Review. 4:2 (1988) 295 at 297-298 and Creber and McKhool, <u>supra</u>, note 45, at 29 for a discussion of this policy.

⁵⁰ See Patent Office Manual, supra, note 41.

suggests that opinions on the patenting of higher life-forms were still strongly divided.

In 1986, in the early stages of a dispute which would eventually be heard by the Supreme Court of Canada, the Commissioner of Patents refused to grant a claim for a new variety of soya-bean on the grounds of its failure to meet the requirement of "invention". The decision, Pioneer Hi-Bred v. The Commissioner of Patents, was appealed to the Federal Court of Appeal in 1987. 52

1.2.2 The Pioneer Hi-Bred Case

The Federal Court of Appeal upheld the Commissioner's refusal to grant a patent on a "new" variety of soybean plant. The denial was based on the failure to meet the requirements for a new invention and the requirements of reproducibility—disclosure. Marceau, J., writing for himself and another member of the court, acknowledged that Canadian Patent Law does not expressly exclude living organisms from patentability. He, nonetheless, questioned whether "...a soybean variety developed

⁵¹See Wheeler, <u>supra</u>, note 49 and especially Creber and McKhool, <u>supra</u>, note 45 for a discussion of the decision. The "annex" to Creber and McKhool, is a reproduction of the Commissioner's decision.

⁵²<u>Pioneer Hi-Bred Limited v. Commissioner of Patents</u>. (1987) 11 C.I.P.R. 165 (Fed. C.A.). See Wheeler, <u>supra</u>, note 49, for a critical discussion of the Federal Court of Appeal's ruling.

⁵³ Supra, note 52, at 168, citing Abitibi.

by crossbreeding can be said to be an invention..." He acknowledged that the definitions of "manufacture" and "composition of matter" as dealt with by analogous U.S. case law might allow for the patenting of micro-organisms, but he declined to follow U.S. precedent:

It seems to me that the common ordinary meaning of the words "manufacture" and "composition of matter" would be distorted if a unique but simple variety of soybean were to be included within their scope. 56

Marceau went on to say that since plant breeding technology was already established when the <u>Patent Act</u> was passed, the absence of such words as "strain", "variety" or "hybrid" from the definition of invention suggests that Parliament did not contemplate plant life-forms as patentable subject matter.⁵⁷ He concluded that the protection of such plant forms could be provided by Parliamentary enactment of "special legislation, as was done long ago in the United States and in many other industrialized countries."

Pratte, J. upheld the patent denial on the basis of the reproducibility-disclosure requirement. ⁵⁹ He interpreted the reproducibility section as requiring the description to be such

⁵⁴Supra, note 52, at 169.

⁵⁵<u>Diamond v. Chakrabarty</u> 477 U.S. 303 (1980).

⁵⁶Supra, note 52, at 169.

⁵⁷Supra, note 52, at 170.

⁵⁸Supra, note 52, at 170.

⁵⁹Pratte's decision can be found at <u>supra</u>, note 52, at 170-171.

that third persons, without access to the invention or anything produced by it, be able to reproduce the invention. He found that, where written specifications are inadequate without a deposit of the "invention", the deposit of the organism will not save the application.

On appeal, the Supreme Court of Canada affirmed the Federal Court of Appeal. In its decision on <u>Pioneer Hi-Bred</u>, 60 rendered 22 June 1989, the Supreme Court held that patentees of particular plant forms must do more than deposit the claimed invention to satisfy the reproducibility-disclosure requirements of the <u>Patent Act</u>. 61 Speaking for the Court, Lamer J. said that

"... More than a century ago Darwin developed the theory that only species and individuals that can adapt and acquire new characteristics can survive and reproduce. The same principle underlies the experiments which through genetic engineering now make possible adaptation to specific environments or new uses of known living organisms.

The real issue in this appeal is the patentability of a form of life. This is in fact a claim for a new product developed in the field of biotechnology, an area of activity taking in all types of techniques having a common purpose, 'the application of scientific and engineering principles to the processing of material by biological agents to provide goods and services' (A.T. Bull, G. Holt and M.D. Lilly, Biotechnology: international trends and perspectives, Paris, O.E.C.D., 1982, p. 21). This is regarded by many as the latest technological system to be developed in the 20th century and the harbinger of a new era, and we must therefore be very cautions regarding the scope of our pronouncements.

Genetic engineering can occur in two ways. The first involves crossing different species or varieties by hybridization, altering the frequency of genes over successive generations. ...

⁶⁰ Supra, note 42.

^{61&}lt;u>Supra</u>, note 42, at 20.

- ... This procedure differs from the second type of genetic engineering, which requires a change in the genetic material an alteration of the genetic code affecting all the hereditary material since in the latter case the intervention occurs inside the gene itself. The change made is thus a molecular one and the 'new' gene is thus ultimately the result of a chemical reaction, which will in due course lead to a change in the trait controlled by the gene. While the first method implies an evolution based strictly on heredity and Mendelian principles, the second also employs a sharp and permanent alteration of hereditary traits by a change in the quality of the genes. ...
- ... The genetic engineering performed by Hi-Bred is of the first type. Hi-Bred obtained this new soybean variety by hybridization, that is by crossing various soybean plants so as to obtain a unique variety combining the desirable traits of each one. ...
- The intervention made by Hi-Bred does not in any way appear to alter the soybean reproductive process, which occurs in accordance with the laws of nature. Earlier decisions have never allowed such a method to be the basis for a patent. The courts have regarded creations following the laws of nature as being mere discoveries the existence of which man has simply uncovered without thereby being able to claim he has invented them. Hi-Bred is asking this Court to reverse a position long defended in the case law. To do this we would have, inter alia, to consider whether there is a conclusive difference as regards patentability between the first and second types of genetic engineering, or whether distinctions should be made based on the first type of engineering, in view of the nature of the intervention. ...
- ... In view of the complexity presented by the question as to the cases in which the result of genetic engineering may be patented, the limited interest shown in this area by the parties in their submissions, and since I share the view of Pratte J. that Hi-Bred does not meet the requirements of s. 36(1) of the Act, I choose to dispose of this appeal solely on the latter point."

⁶²Supra, note 42, at 8, 9, 11.

Accordingly, the case was decided on the narrow grounds of reproducibility.

There is no ambiguity in the wording of s. 36(1): the inventor must describe not only how the invention can be used but also how a third party can make it; nowhere does it say that the deposit by itself of a sample of the invention will meet the disclosure requirement. To adopt the language of Rand J. in Commissioner of Patents v. Winthrop Chemicals Co. Inc., [1948] S.C.R. 46, at 57, cited by Pigeon J. in Tennessee Eastman v. Commissioner of Patents, [1944] S.C.R. 111, at 121:

The intention of a legislature must be gathered from the language it has used and the task of construing that language is not to satisfy ourselves that as used it is adequate to an intention drawn from general considerations or to a purpose which might seem to be more reasonable or equitable than what the language in its ordinary or primary sense indicates.

While it is true that competitors may obtain the new variety by this means and exploit it commercially for a fraction of the original cost borne by appellant, deposit of the seed by itself does not comply with the applicable law. It might be that in certain circumstances, the deposit may contribute to complete the description; I do not rule out this possibility but I do not find it applicable to the case at bar. 63

...Having found that there was not sufficient disclosure of this soybean variety and that it therefore cannot be a patentable matter within the meaning of the <u>Patent Act</u>, it is neither necessary nor desirable for the reasons already given to consider in this appeal whether this new soybean variety can be regarded as an invention within the meaning of s. 2. I would accordingly dismiss the appeal.

Thus, while both the invention and the reproducibility-disclosure questions were at issue, the Court elected to decide the appeal on the basis of reproducibility. As a result, the

⁶³Supra, note 42, at 20-21.

question of whether life-forms higher than micro-organisms are inventions was not addressed.⁶⁴

The Court appears to have limited the scope of its disclosure analysis to higher life-forms. It declared that its "observations should not be taken to be directed at patent applications for micro-organisms." The Court held that because the disclosure required by s. 36(1) in the appellant's patent application did not allow someone skilled in the art to "...arrive at the same result as the inventor without further explanation", 66 the appeal would fail.

What life forms may be patented after <u>Pioneer Hi-Bred</u>? The decision leaves some aspects of the question clearer than others. Lower life-forms would still appear to be patentable. The Supreme Court's intention to limit its holding to higher life-forms, ⁶⁷ previous case law, ⁶⁸ and Canadian Patent Office

⁶⁴Supra, note 42, at 11. Some language in the opinion may extend to higher life forms generally:

[&]quot;...since the Patent Act contains no provisions relating directly to biotechnological inventions and new forms of life in particular, this new soybean variety will only be patentable if it meets the traditional conditions and requirements for a patent." (See <u>supra</u>, note 42, at 20.)

⁶⁵Supra, note 21, at 21.

⁶⁶Supra, note 42, at 18.

⁶⁷See text accompanying note 65, <u>supra</u>.

⁶⁸ See Abitibi, supra, note 41.

construction of the <u>Patent Act</u>⁶⁹--all suggest that microbial and cell line life-forms are patentable subject matter in Canada.

The patentability of plants, animals and other such higher life-forms is less clear. Both the Supreme Court⁷⁰ and the Federal Court of Appeal⁷¹ seem to agree that Canadian patent law does not expressly preclude the patenting of higher life-forms. Both nonetheless insist that patent applicants meet the basic requirements for patenting.⁷² Since the Patent Office is always first to evaluate a patent claim, its view on whether a particular higher life-form satisfies the invention requirement, for example, will continue to carry considerable weight. Thus, absent legislative clarification, the lines on which forms of biotechnologically-manipulated plant and animal life may be patentable in Canada appear likely to be drawn by the Patent Office, with occasional scrutiny by the Courts.⁷³

1.3 <u>International Law: Patenting of Micro-organisms & Protection of New Varieties of Plants</u>

⁶⁹See MPOP, supra, note 41.

⁷⁰See, <u>supra</u>, note 42.

⁷¹ See the text accompanying note 47, supra.

⁷²See note 64 and text accompanying notes 53-54, <u>supra</u>. <u>Pioneer Hi-Bred</u> at both the Federal Court of Appeal and the Supreme Court of Canada makes this much clear.

⁷³P. 20-21 of the judgment.

Canada's present international commitments, do not require the recognition of a foreign applicant's life-form as patentable subject matter. However, an emerging international trend towards the patenting of higher life forms is of interest to Canadian society. Those nations of the international community that have responded to the trend have helped create a preliminary international network of patent law protection for biotechnologically derived life-forms.

The importance of uniform standards of patentability among trading partners has long been evident. So, too, has the requirement that national patent protection be available on an equal basis, to citizens of a nation and citizens of other jurisdictions. The International Union for the Protection of Industrial Property (Paris Union) Convention, ratified in 1884, was the first international agreement to provide for the harmonization of national patent laws and the entitlement of foreigners to treatment equal to that afforded to nationals. This is the only major international agreement, pertaining to biotechnological patent protection, to which Canada is a party.⁷⁴

Convention article 1(4) contains a definition of "patents".

It is couched in terms general enough to support a claim for the patenting of life-forms:

...the various kinds of industrial patents recognized by the laws of the countries of the Union, such as patents of importation, patents of improvement, patents and certificates of addition....

⁷⁴The Convention is discussed in greater detail in Bent, <u>supra</u>, note 31 at 399-407, OTA, <u>supra</u>, note 30 at 155-157 and Philip W. Grubb, Patents in Chemistry and Biotechnology. (Oxford: Clarendon Press, 1986) at 24-26.

With such an open ended definition, governments have been free to establish their own policies.

Two treaties, to which Canada has yet to subscribe, indicate how widespread the international recognition of intellectual property rights in man-made life forms has become. One is the Budapest Treaty on the International Recognition of the Deposit of Micro-organism for the Purpose of Patent Procedure of 1980.75 Administered by the World Intellectual Property Organization (WIPO), the treaty provides for uniform national requirements for depositions, depositories and the patenting of micro-organisms. While Canada is not a signatory, it participates in WIPO deliberations. Member countries include Japan, the United States, and most of the countries in Western Europe. The treaty has created a series of International Depository Authorities (IDAs) located in member countries. Perhaps the most important stipulation of the treaty obliges parties to the treaty to recognize single deposits made in any IDA. This eliminates the need for deposits in each country where patent protection is sought. Since Canada is not a party to the Budapest Treaty, it has no depository institution holding IDA status.

The full name of the treaty is "The Treaty on the International Recognition of the Deposit of Micro-organism for the Purpose of Patent Procedure." It is examined in F.K. Beier, R.S. Crespi, J. Straus, Bio Technologie Et Protection Par Brevet. (Paris: OECD, 1985), at 63-64, Grubb, supra, note 74, at 153, Bent, supra, note 31, at 407-421, and OTA, supra, note 30, at 158-159.

⁷⁶See "Draft Report," supra, note 4, page 1, at 7.

patentees must therefore make separate deposits with the authorities of all Budapest Treaty countries in which they wish to have patent protection.

A second treaty relates specifically to biotechnology. The 1968 International Convention for the Protection of New Varieties of Plants (UPOV), is designed to recognize and protect the rights of breeders of new plant varieties. Though Canada is not a party to the convention either, several western industrial nations are, including West Germany, France, Japan, Sweden, the U.S. and the U.K. The determination of the particular form such protection is to take is left to the individual signatory. Since the protection offered by each country may vary widely, consensual reciprocity between member states is an important factor in allowing for effective international protection. The such protection of the particular form the protection of the particular form the protection of the protection of the particular form the protection of the pro

1.4 Comparative Law: Which New Forms of Life Can Be Patented?

⁷⁷Heitz, "Intellectual Property in New Plant Varieties & Biotechnical Inventions," (1988) 10 Europ. Intellectual Prop. Rev. 297.

⁷⁸Id.

⁷⁹Judith R. Curry, The Patentability of Genetically Engineered Plants and Animals in the US and Europe. (London: Intellectual Property Publishing Limited London, 1987) at 12-15, OTA, <u>supra</u>, note 30 at 159, and Bent, <u>supra</u>, note 31, at 436-470 all provide a more detailed discussion of the UPOV.

The threshold question is to what extent, if any, new forms of life - micro-organisms, plants life, animal life - can or should be patentable?

1.4.1 Patenting of Micro-organisms

The Canadian practice of permitting the patenting of microorganisms, 80 parallels the national practices of Germany, France,
England, Australia, and the U.S. It differs from those of Brazil
and Chile.

In 1980, the United States Supreme Court decided the landmark case of <u>Diamond v. Chakrabarty</u>, ⁸¹ and overruled U.S. Patent and Trademark Office policy on living organisms. The decision resulted in the granting of a patent on a genetically engineered bacterium capable of breaking down crude oil. The major issue before the court was whether the organism met the statutory requirements for an "invention".

The definition of "invention" in the United States parallels that in Canada:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may

⁸⁰See text accompanying notes 67-69, <u>supra</u>.

 $^{^{81}}$ Supra, note 55. Both McKhool, supra, note 41 at 120 et seq., as well as OTA, supra, note 30 at 51-54 summarize and discuss the decision.

obtain a patent therefor, subject to the conditions and requirements of this title. 82

The majority held that a live, human-made micro-organism was patentable subject matter as a "manufacture" or "composition of matter". The Court construed the statute broadly on the basis of its plain meaning and legislative history. Speaking for the majority Chief Justice Warren Burger stated that:

...the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork but his own; accordingly, it is patentable subject matter...⁸⁴

The fact that genetic technology was unanticipated when the law was enacted, was not seen as disqualifying micro-organisms as patentable material. Regarding the hazards associated with genetic research, the Court found that such concerns were best addressed by the regulatory powers available to the legislative and executive branches of government. 86

The European Patent Convention (EPC) explicitly states that although plant and animal varieties and "essentially biological"

 $^{^{82}}$ 35 U.S.C. 101. The Canadian definition is found in s. 2 of the <u>Patent Act</u>, reproduced on page 13 above.

^{83&}lt;u>Supra</u>, note 55, at 307-308.

⁸⁴Supra, note 55, at 310. The minority in <u>Chakrabarty</u> argued that since Congress had passed legislation for the protection of plant varieties it was clear that it understood that living things were not able to be protected by patent. <u>supra</u>, note 55, at 318-322.

^{85&}lt;u>Supra</u>, note 55, at 310-316.

^{86&}lt;u>Supra</u>, note 55, at 316-318.

inventions are not patentable subject matter, ⁸⁷ the exclusion does not extend to micro-organisms. Indeed, several EPC countries have been at the forefront of the international trend toward granting patent protection for micro-organisms. West German law initially recognized the possibility of patent protection for micro-organisms in 1969, ⁸⁸ and expressly held them to be patentable subject matter in 1975. ⁸⁹

Over the past two decades legislative, jurisprudential and administrative developments in other jurisdictions have granted patent protection for micro-organisms. France has provided patent protection for micro-organisms since the early 1970s. 90 When it amended its <u>Patent Act</u> in 1977, the United Kingdom adopted the EPC definition of patentable subject matter. 91 By 1979, the Japanese Patent Office had established guidelines that

⁸⁷EPC Article 53(b). Norris M. Eades, International Patenting of Biotechnology. Canadian Intellectual Property Review. 2:1 (1985) 137, at 138-140 discusses the article.

⁸⁸See the "Rote Taube" decision of March 27, 1969, German Federal Supreme Court, 1969 GRUR 672, 1 <u>IIC</u> 136 (1970). It is discussed in OTA, <u>supra</u>, note 30 at 161, Bent, <u>supra</u>, note 31 at 487, Saliwanchik, <u>supra</u>, note 31, at 148-9, and Beier, <u>supra</u>, note 75 at 25. The case is summarized in Beier, appendix C.

⁸⁹See the "Baker's Yeast" decision of March 11, 1975, German Federal Supreme Court, 1975 GRUR 430, 6 <u>IIC</u> (1975). Saliwanchik, <u>supra</u>, note 31 at 148-149, Bent, <u>supra</u>, note 31 at 487, OTA, <u>supra</u>, note 30 at 161, and Beier, <u>supra</u>, note 75 at 24 all discuss it. Beier appendix C. summarizes the case.

⁹⁰See Bent, <u>supra</u>, note 31 at 492, OTA, <u>supra</u>, note 30 at 161, Beier, <u>supra</u>, note 75, at 53-4 for a discussion of the French position.

⁹¹OTA, <u>supra</u>, note 30 at 161-2, Bent, <u>supra</u>, note 31 at 531-2, Beier, <u>supra</u>, note 75 at 53, and Salinwanchik, <u>supra</u>, note 31, at 150-153 all discuss the state of the law in the United Kingdom.

allowed for the patenting of micro-organisms⁹² while the Australian Commissioner of Patents has recognized micro-organisms to be patentable subject matter since 1976.⁹³

As indicated above, certain problems are posed by patent claims for biotechnological products that cannot be described so that a person skilled in the art can replicate them. The Canadian position following the <u>Abitibi</u>⁹⁴ decision permitted the depositing of a culture of a micro-organism to satisfy the reproducibility requirement. The recent Supreme Court of Canada <u>Pioneer Hi-Bred</u> decision appears to have left <u>Abitibi</u> undisturbed. 95

Many other developed countries have adopted a similar approach on the reproducibility requirement for micro-organisms. In West Germany, for example, long-standing practice was changed in 1987, when the Federal Supreme Court held that patenting is permitted where the culture is deposited, even if the process creating the culture cannot be reported in a way that allows repetition. American and Japanese practice also allow

⁹²Eades, <u>supra</u>, note 87, at 137-138, Bent, <u>supra</u>, note 31 at 505, Beier, <u>supra</u>, note 75, at 53 and Saliwanchik, <u>supra</u>, note 31 at 156-7 all discuss the Japanese position.

⁹³ In Re Ranks Hovis McDougal Ltd. 1976 Austral. Off. J. Pat. 3915, 8 IIC 453 (1977). The Australian position is discussed by Bent, supra, note 31, at 473, Beier, supra, note 75, at 54, and OTA, supra, note 30, at 162.

⁹⁴ Supra, note 41.

⁹⁵ See text accompanying note 21, supra.

⁹⁶The Rabies Virus case, 1987 GRUR 231. Bent, <u>supra</u>, note 31 at 487, Peter A. Rauh, Hans-Rainer Jaenichen, Novelty and Inventive Step in Inventions having Proteins or DNA Sequences as their Subject Matter. (1988) 70:5 J. of the Patent and Trademark Office

deposit of a micro-organism where a written description is not sufficient. By contrast, while British law requires deposits in certain instances, the requirements regarding disclosure and reproducibility cannot be satisfied by a deposit alone. 99

1.4.2 Patenting of Plants

While the patentability of new varieties of plants is a relatively recent development, other forms of intellectual property protection, that may extend to new, "man-made" forms of plant life, have been in existence for decades. Trade secrets law is a prime example. Special plant variety protection legislation is another example. Some foreign jurisdictions

Soc. 313 at 327-328, and Wheeler, <u>supra</u>, note 49, at 300 all discuss this case.

⁹⁷John M. Czarnetzky, Altering Nature's Blueprints for Profit: Patenting Multicellular Animals. (1988) 74:7 Virginia L. Rev. 1327 at 1336, OTA, <u>supra</u>, note 30, at 141-151, Eades, <u>supra</u>, note 87, at 140-141 as well as Bent, <u>supra</u>, note 31, at 536, all discuss the American position on deposits.

⁹⁸See Bent, <u>supra</u>, note 31, at 505 and Eades, <u>supra</u>, note 87, at 138 for a discussion of Japanese practice.

⁹⁹See Bent, <u>supra</u>, note 31, at 533 for a more complete discussion.

¹⁰⁰ Maher, <u>supra</u>, note 41, at 127, Wheeler, <u>supra</u>, note 49, at 295 and Hayhurst, <u>supra</u>, note 41, at 22, as well as the Commissioner of Patent's decision in <u>Pioneer Hi-Bred</u>, cited as the "annex" to Creber and McKhool, <u>supra</u>, note 45, all discuss previous, unsuccessful efforts made to enact such legislation in Canada. Parties to the Union for the Protection of new Varieties of Plants as well as Argentina, and possibly Australia, allow nonpatent protection for new plant varieties. For a discussion of the situation in Argentina see Bent, <u>supra</u>, note 31, at 472, OTA, <u>supra</u>, note 30, at 164, and Martin A. Etcheverry, Recent

have invoked such special legislation, or trade secrets law in conjunction with administrative interpretation, to afford some protection to new plant varieties.

The recent Supreme Court of Canada ruling declaring the non-patentability of a plant life-forms and the absence of special legislation in Canada contrasts sharply with the positions of some nations. For example, West Germany¹⁰¹ and France¹⁰² provide patent protection for plants that would otherwise not benefit from specific legislation designed to protect proprietary rights in new plant life.¹⁰³ The Australian Patent Office has allowed new plant varieties to be patented since 1980.¹⁰⁴ By contrast, the situation regarding the patentability of new plant varieties in Japan is not clear. Some commentators indicate that new plant

Development of Industrial Property Rights in Argentina. (1987) 17:1 California Western Int'l L.J. 310 at 316. The state of the law in Australia is not entirely clear. Curry, supra, note 79 at 22 states that Australia has no plant variety protection law. Bent, supra, note 31, at 475 discusses Australian efforts to adhere to UPOV, and provide for comprehensive legislation, while OTA, supra, note 30, at 162 suggests that non-patent protection for new plant varieties is currently available in Australia.

¹⁰¹See Bier, <u>supra</u>, note 75, at 73, Bent, <u>supra</u>, note 31 at 487, and OTA, <u>supra</u>, note 30 at 161.

¹⁰² See Bent, supra, note 31, at 492, OTA, supra, note 30, at 161 and Beier, supra, note 75, at 73.

¹⁰³ It is of interest to note that there is an explicit EPC prohibition against providing patent protection for plants. A Commission of the European Communities proposal of October 17, 1988 indicates that this position is currently under review.

¹⁰⁴ See OTA, <u>supra</u>, note 30, at 162, Beier, <u>supra</u>, note 75, at 174, and Bent, <u>supra</u>, note 31, at 473-4.

varieties are capable of receiving patent protection, 105 while others suggest that protection extends only to the processes used to develop them. 106

The United States allowsg both patent protection and express legislative (non-patent) protection for new plant varieties to overlap. The <u>Plant Patent Act</u> of 1930 and the <u>Plant Variety</u> <u>Protection Act</u> of 1970 provide for legislative protection to new plant varieties. Non-legislative patent protection emerged more recently; although <u>Chakrabarty</u> did not specifically address whether normal ("utility") patents could be issued for plants, the Board of Patent Appeals ruled five years later, that plants were capable of qualifying for them. 107 The Board concluded that the existence of legislative, non-patent protection should not result in an applicant being denied patent protection. 108

1.4.3 Patenting of Animals 109

¹⁰⁵ Eades, <u>supra</u>, note 87, at 137-8, OTA, <u>supra</u>, note 30 at 163-4, and Beier, <u>supra</u>, note 75, at 73-74.

¹⁰⁶Bent, <u>supra</u>, note 31, at 504-505.

¹⁰⁷Ex Parte Hibberd, 227 USPQ 443 (PTO Bd. Pat. App. & Int.
1985).

¹⁰⁸ Supra, note 107, at 444-445. It is interesting to compare this approach to that taken by Marceau in Pioneer Hi-Bred. It is also evident that Hibberd indicates that Marceau J's interpretation of American law was at fault. See text accompanying notes 57 and 58, supra.

¹⁰⁹OTA, <u>supra</u>, note 30, at 121 et seq., Statement by Ann Sorenson, <u>supra</u>, note 31, at 40, and particularly Robert P. Merges, Intellectual Property In Higher Life Forms: The Patent System and Controversial Technologies. (1988) 47:4 Maryland L. Rev. 1051 at 1068 et seq. and Statement by Rob Merges, Julius Silver Fellow,

The development of new forms of animal life is at the cutting edge of the biotechnological revolution. The most promising candidates for patenting are so-called "transgenic animals." These are the product of crossing and cloning the DNAs of different species of animals. They are often designed for use in biomedical research and agriculture. Indeed, transgenic livestock and poultry have been amongst the earliest biotechnology "products".

Most countries have only begun to think about the legal, ethical and regulatory ramifications of such revolutionary technologies. In Canada, it is open to question whether the patenting of animals is permitted. Yet, even nations that allow patenting of these new animal "products" acknowledge the need for further government action. Thus, it is difficult to provide more than a sketch of the state of the law.

Columbia Law School, Hearings before the House Committee on the Judiciary, Subcommittee on Courts, Civil Liberties, and the administration of Justice, on the Patentability of Higher Life Forms, July 22, 1987 at 45-52, all raise the important point that even if patent protection can be obtained for animal life, the possibility of enforcing the patent is likely to be especially difficult - given the fact that animals procreate.

¹¹⁰ See text accompanying note 64, <u>supra</u>; the Manual of Patent Office Practice, <u>supra</u>, note 41; and text accompanying note 47, <u>supra</u>.

¹¹¹By their actions if by nothing else - as indicated by the amount of time the Office of Technology Assessment is devoting to the issue in the United States - even after Ex Parte Allen, 2 USPQ 2d 1425 (PTO Bd. Pat. App. & Int. 1987).

The United States has witnessed the most interesting developments in this area. The possibility of obtaining a patent for a multicellular animal was first acknowledged in 1987, seven years after the landmark Chakrabarty decision. In the same year, the U.S. Patent and Trademark Office issued a notice that "it considers non-naturally occurring, non-human, multicellular organisms, including animals, to be patentable subject matter within the scope of patent laws. In 1988, the first U.S. patent for a transgenic animal was issued to Harvard University. The subject was a strain of laboratory mouse that had been genetically engineered to have an increased propensity to develop cancer. In 1988.

Outside the United States, trends are more difficult to identify. The Japanese Patent Office appears to be in the process of amending its practice, to allow for the patenting of animals. There is some authority, as discussed previously, for the proposition that it is possible to patent animals in

¹¹²Curry, <u>supra</u>, note 79, at 40, Bent, <u>supra</u>, note 31, at 536 discuss recent American developments. OTA, <u>supra</u>, note 30, Chapter 6 reviews the American position on the patenting of animals. Merges, Intellectual, <u>supra</u>, note 109 and Czarnetzky, <u>supra</u>, note 97, survey the current state of affairs in the States, discuss some of the problems associated with the development of new forms of animal life, and examine possible options for law reform.

¹¹³ Ex parte Allen 2, supra, note 111. The application, for polyploid Pacific oysters, failed because the invention was judged to be obvious.

¹¹⁴ See OTA, supra, note 30 at 93.

¹¹⁵N.Y. Times, 13 Apr., 1988, at A6.

¹¹⁶See Eades, <u>supra</u>, note 87, at 137, and OTA, <u>supra</u>, note 30, at 164.

Australia. Finally, although the European Patent Convention specifically rules out the possibility of patenting animal life in article 53(b), that policy is currently under review. 118

1.5 Options for Reform: Is There a Need for Legislative Reform?

Much of the debate over patenting life-forms is a microcosm of the debate over the forms and limits of biotechnology itself. How should society sort through these patenting, biotechnology and risk-benefit questions—through case-by-case development of jurisprudence, by regulation, by prohibition? Some commentators have argued that patent offices and courts are not equipped to deal with the ethical issues biotechnology raises. They suggest that the preferred approach would be to establish specially constituted regulatory bodies. 121

¹¹⁷OTA, <u>supra</u>, note 30 at 162, and Curry, <u>supra</u>, note 79, at 22 substantiate this. Bent, <u>supra</u>, note 31, at 473-4, although indicative of the fact that it is possible to patent animals in Australia, suggests that considerations of public policy may block certain applications.

¹¹⁸ See, supra, note 103.

¹¹⁹ See Green, supra, note 25, at 13 and Annas, supra, note 9, at 22 for such an allegation.

¹²⁰ See generally Lauroesch, <u>supra</u>, note 31, at 126, Merges, Intellectual, <u>supra</u>, note 109, at 1061-1068, Dresser, <u>supra</u>, note 7, at 4094, Current Topics, <u>supra</u>, note 9, at 325, Annas, <u>supra</u> note 9, at 22, and Green, <u>supra</u>, note 25, at 13.

¹²¹ See Merges, Intellectual, <u>supra</u>, note 109, at 1068, Hoffmaster, <u>supra</u>, note 8, at 7, and Dresser, <u>supra</u>, note 7, at 414 & 417. The Supreme Court of the United States, in <u>Chakrabarty</u>, <u>supra</u>, note 55, also adopts such a point of view.

The more centralized control that might follow from a new regulatory approach to biotechnology may give rise to positive results. 122 The opposite extreme is a simple prohibition on the patenting of some or all life-forms. But will a ban on patenting hinder or stop ethically unacceptable research? Some analysts claim that a ban may itself prove to be hazardous; such a policy might result in unjustified complacency about risks. 123

The alternatives 124 regarding patenting life-forms can be summarized as follows:

Non-Patenting: Adopt a policy by which granting of a patent protection for living matter of any kind, is not allowed.

This option would reverse existing policy.

<u>Patenting</u>: Permit the patenting of some <u>or</u> all life-forms which meet the general requirements of the <u>Patent Act</u>.

a. <u>Micro-organisms</u>: Consistent with existing policy,
permit the patenting of micro-organisms. This option
involves potential extension to higher life forms:
forms of plant and animal life can be used to create

¹²² See (Canadian) National Biotechnology Advisory Committee 1987-88 Annual Report. See also Beak Consultants Limited, "Regulatory Policy Options For Canadian Biotechnology: A Report for Biotechnology Unit Ministry of State for Science and Technology." (March 1987) at 4.1 et seq., (discussing centralized oversight).

¹²³ See Hoffmaster, <u>supra</u>, note 8, at 7 and 23, and Dresser, <u>supra</u>, note 7, at 424 & 434.

¹²⁴ See Consumer and Corporate Affairs Canada, in collaboration with Science and Technology Canada and Agriculture Canada, "Patenting Life Forms & Processes" at 30-37. See OTA, supra, note 30, at 22-26, for an analogous review of U.S. policy options.

- cell lines which, through a complicated process, may be used to create complete plants. 125
- b. <u>Plants</u>: To remove existing legal ambiguity on the patenting of plants, the government should adopt a policy that some (e.g. genetically engineered) or no man-made life-forms are patentable subject matter. Alternatively, Parliament might enact special, protective legislation for man-made plants (and non-human animals) by analogy with the UPOV.
- c. Animals: To remove existing legal ambiguity on the patenting of animals, the government should adopt a policy that animals are not or are patentable subject matter. If the decision is that animals are patentable subject matter, the policy may be effected by explicit Patent Office policy, Parliamentary amendment of the Patent Act, or Court decision.
- d. <u>Human Life-Forms</u>: To make patenting policy on human life-forms explicit, the government might
 - i) proscribe the patenting of all human living matter, or

 - iii) proscribe or permit the patenting of higher human life-forms.

¹²⁵ Stotland, supra, note 29, at 259 points out this interesting problem.

Whatever options are adopted, it is critical that ethical and environmental concerns be addressed, perhaps by regulation and appropriate prohibition. A comprehensive regulatory scheme may analyze the application of existing laws, highlight the need for further regulatory measures, and generally provide for an efficient and effective regulatory apparatus that minimizes risks and maximizes the benefits of biotechnological development. Covernment may help orchestrate national policy by outlining goals in precise or general terms, 27 and by generally coordinating voluntary guidelines, certification systems, specific legislation, and/or licensing systems. One regulatory body might generally coordinate policy development, or various regulatory bodies, which are either entirely independent or subject to the coordinating efforts of a single office, might occupy themselves with the task.

CONCLUSION

¹²⁶ See Beak Consultants, <u>supra</u>, note 122, at 1.3, for a discussion of the general requirements for a regulatory scheme.

¹²⁷See Beak Consultants, <u>supra</u>, note 122, at 2.11-2.12 for a discussion of such options and a recommendation that a more general, and thereby more flexible approach be adopted as a result of the "many scientific uncertainties involved...."

¹²⁸See Beak Consultants, <u>supra</u>, note 122, at 4.1-4.3 for further discussion of this matter.

¹²⁹ See Beak Consultants, <u>supra</u>, note 122, at 4.1 et seq. for further discussion of such options along with recommendations.

What emerges from this survey of the initial responses of Canada and other nations to the patenting of life question? In my view, the survey suggests at least three general observations. First, Canada and many developed nations generally appear to accept the principle that some biotechnologically-derived life-forms are patentable. Once this principle accepted, the debate and scrutiny seems to focus on where and how to draw the lines on the patenting of plants, animals, human life-forms, and other living matter beyond the microbial level.

Secondly, the survey suggests that societies rely on a handful of means to make the substantive decisions on patenting life. The recent Supreme Court of Canada ruling indicates the role of the courts. The increasing attention biotechnology receives from diverse quarters of the international community suggests that Canada's foreign relation and treaty powers may influence domestic policy in the future. The Canadian Patent Office provides the means to administer the provisions of the Patent Act in the context of biotechnological products. And, of course, Parliament and the public share a fundamental role.

Finally, this survey suggests that Canada and different nations are drawing lines on the patenting of life at different levels. Many countries appear to permit the patenting of microorganisms. Several others have permitted the patenting of plant life-forms. While the United States is the clearest example of a jurisdiction that authorizes the patenting of mammals and other animals, the novelty and complexity of the issue suggest that we have just begun serious deliberation.

How high in the scheme of life should patenting extend? This remains to be seen. Canada and other nations permit the patenting of cell lines including those of the human. Yet, even nations that permit the patenting of higher life-forms insist that the patenting of human beings per se is not acceptable. Thus, the debate and decisions in the foreseeable future will focus on where lines should be drawn in the spectrum between micro-organisms and humankind.

II. RECONCEIVING BODILY PROPERTY 130

The patenting of human cell lines has recently been related to the fundamental question of property rights and interests in the human body. A series of recent international cases, combined with biomedical and biotechnological developments, have begun to challenge traditional notions about property in the human body. In that area, we do not speak of intellectual property, but of property in a broader sense.

In 1985, a tribunal in France ruled that a French sperm bank must return the frozen semen of a deceased depositor, a Mr. Parpalaix, to his wife. Mr. Parpalaix had deposited his sperm

¹³⁰This section is largely excerpted from an ongoing internal draft of a Law Reform Commission Working Document, by Derek J. Jones, on tissue transfer law.

¹³¹ Parpalaix v. CECOS, judgment of 1 Aug. 1984, Trib. Gr. Inst. Creteil, 16-17 Sept. 1984, Gaz. Pal. (2 Sem.) 560. For an English discussion of the case, see Jones, "Artificial Procreation, Societal Reconceptions: Legal Insight From France," (1988) 36 Am. J. Comp. L. 525. See also Jansen, "Sperm and Ova as Property,"

for preservation, after learning he would undergo chemotherapy treatments that might make him sterile. In the U.S.--where there have been a number of bodily property disputes--a case currently before the California Supreme Court is commanding international attention. In Moore v. University of California et al., 132 a leukemia patient claims that, without his knowledge or consent, his university doctor used Mr. Moore's cells and tissue to develop and patent a biotechnologically produced, commercially valuable, human cell line. Moore has sued on a theory of conversion. He argues that he is owed a rightful share of the money generated by the patent, due to the misappropriation of his bodily tissues.

Moore and Parpalaix are, in many senses, extraordinary.

Such circumstances do not arise on a daily basis. In other ways, however, they signify trends and questions in law and medicine. Applied to the banking of blood, tissues and reproductive matter, and to biotechnological developments in Canada, the cases may suggest that the ownership or control of valuable human bodily parts and substances is an issue that Canadian society will also have to address over the next decade. Therefore, it is appropriate to explore some of the questions provoked by these issues as they may affect the law, doctors, patients, hospitals, and tissue banks. In doing so, I am sharing with you some of the deliberative process of the Protection of Life Project of the Law

^{(1985) 11} J. Med. Ethics 123.

^{132 249} Cal. Rptr. 494 (Cal. App. 2d Dist. 1988).

Reform Commission of Canada, which has begun to examine the broader issues of tissue procurement and transfer law.

2.1 Ambivalence of the Law

Our initial research suggests that the law speaks rather ambivalently on notions of property in the body. The property concept we are exploring focuses not on human tissues or organs; rather, it focuses on the legal rights and duties between individuals in reference to these "things". We have found that a focus on rights and duties is helpful in clarifying law and public policy considerations.

2.1.1 <u>Cadavers as Property</u>

Moore and Parpalaix largely concern the control of bodily tissues or substances from patients alive at the time specimens were taken. Yet, much of the supply of therapeutic tissues, organs, and bodily parts come from recently deceased donors, usually with the consent of the next-of-kin. Are property notions helpful to clarifying rights and duties vis-à-vis human tissue in this area?

The common law has traditionally frowned upon formally recognizing property rights in the bodies of the deceased. The "no-property in a corpse" rule derived from 17th-19th century

British Jurisprudence on burial rights, control of corpses, and payment of funeral expenses. The no-property rule discourages the withholding of corpses for payment and likely discourages commerce in corpses.

Despite this rule, the common law has also traditionally granted relatives or executors of the deceased a possessory interest in the corpse. Relatives of the deceased are entitled to possession of the body for the purpose of burial. 135

Interference with the right of possession, in the form of an unauthorized autopsy or a hospital's undue delay in returning a body, may give rise to liability for mental distress of the family. 136 The next-of-kin right of possession facilitates societal burial customs and accords respect to survivors' sensibilities and religious beliefs.

The practical workings of these rules are clear. But are they coherent? If a right of possession is technically a property interest, is it not accurate to say that the next-of-kin have a limited property interest in the body of the deceased? The question and its answer would appear to be definitional.

¹³³ See Matthews, "Whose Body? People as Property," (1983) 36 Current Legal Problems 193 at 196, discussing 3 Cokes Institutes 203 (1644) and Williams v. Williams, 20 C.H.D. 659 (1882).

¹³⁴See <u>R v. Fox</u> (1841) 2 Q.B. 246.

¹³⁵ Hunter v. Hunter (1930) 4 D.L.R. 255 (Ont. H.C.).

¹³⁶ See Edmonds v. Armstrong Funeral Home (1931) 1 D.L.R. 676 (Alta. S. C. App. Div.), and Strachan v. JFK Memorial Hosp., 538 A.2d 346 (N.J. 1988); for the Quebec approach, see Phillips v. Montreal Gen. Hosp. (1908) 33 Que.S.C. 483.

2.1.2 Living Donors and Bodily Property

Does the no-property rule encompass live "donors"? In Canada, there appears to be no case that specifically addresses the issue. American cases seem to suggest that the courts have molded the no-property in a corpse rule to a no-property in bodily parts rule. In cases involving eye tissue lost prior to being examined for cancer and the unconsented disposal of reproductive matter in an infertility clinic, the courts have avoided grounding of judgments on the basis of property; instead, they have preferred to ground them on claimed mental distress. Similarly, in Parpalaix, the French Court expressly rejected an argument that the frozen semen was property, on grounds that human reproductive material was not a subject of commerce or inheritance. 138

Commentators, including Professor Bernard Dickens, have critiqued the "no-property in a live body" tendency. He and others suggest that while a claim for mental damages may afford some recovery in jurisdictions where it is available, mental damages do not address instances when return of the human tissue or material is what is being sought. The suggestion is that

¹³⁷ See Del Zio v. Manhattan's Columbia Presbyterian Medical Center, No. 74-3558 (S.D.N.Y. Nov. 14, 1978), described in Andrews, "My Body, My Property," 16(5) Hastings Ctr. Rpt. 28 (Oct. 1986); Mokry v. University of Tex. Health Science Ctr. 529 S.W. 2d 802 (Tex. App. 1975).

¹³⁸See Jones, <u>supra</u>, note 131, at 528-529.

¹³⁹ See Dickens, "The Control of Living Body Materials," (1977) 127 Univ. Toronto L. J. 142. See also, <u>Andrews</u>, <u>supra</u>, nost 128.

¹⁴⁰<u>Id.</u>, at 147 - 149.

property concepts might better protect the individual's autonomy and person, in addition to clarifying legal rights and duties in particular circumstances. A U.S. couple is currently suing for the control of and right to transfer a frozen embryo from an east coast infertility clinic to another on the west coast. 141

Parpalaix suggests that agreements between tissue banks and depositors might resolve such conflicts. 142 Indeed, well-drafted informed consent forms might help eliminate conflicts based in contract. However, when an institution unconsentingly destroys valuable human tissue in a jurisdiction that limits mental damages, common law property principles on the destruction or spoilage of materials rightfully in one's possession might prove helpful in defining legal rights, duties, and grounds of recovery (e.g. the doctrine of waste).

The proposition that property may also serve as a legal instrument to promote and protect patient autonomy was broached in a recent Supreme Court of Canada decision involving constitutional law. In R v. Dyment, 143 a physician's unconsented taking and use of a patient's blood sample was held to be an unreasonable seizure under the Canadian Charter of Rights and Freedoms. A physician had taken a blood sample from an unconscious, hospitalized patient who had been injured in an automobile accident. The blood was eventually given to a police

¹⁴¹ York v. Jones Institute, No. 89-373N (E.D. VA 1989),
described in National L. J., 12 June, 1989, at 1.

¹⁴²See Jones, <u>supra</u>, note 131, at 529.

¹⁴³(1988) 2 S.C.R. 417

officer, analyzed, and later offered as evidence of drunken driving. The opinion may suggest a relationship between property in the body and human dignity:

As I have attempted to indicate earlier, the use of a person's body without his consent to obtain information about him, invades an area of personal privacy essential to the maintenance of his human dignity. . . . It was a perfectly reasonable thing for a doctor who has been entrusted with the medical care of a patient to do. However, I would emphasize that the doctor's sole justification for taking the blood sample was that it was to be used for medical purposes. He had no right to take Mr. Dyment's blood for other purposes. I do not wish to put the matter on the basis of property considerations, although it would not be too far-fetched to do so. Some provinces expressly vest the property of blood samples in the hospital, a matter I consider wholly irrelevant . . . Specifically, I think the protection of the Charter extends to prevent a police officer, an agent of the state, from taking a substance as intimately personal as a person's blood from a person who owns it subject to a duty to respect the dignity and privacy of that person. (emphasis added) 144

2.1.3 Statutory and Civil Law Reflections on Sales

The civil code and applicable statutory law reflect similar notions of bodily property. The <u>Quebec Civil Code</u> authorizes the gratuitous transfer of non-regenerative human tissue and the non-gratuitous transfer or sale of regenerative tissue. The <u>Uniform Gift Tissue Act</u> prohibits the sale of "tissue" except for

^{144&}lt;u>Id.</u>, at 432. Reasons for Judgment, the Hon. Mr. Justice LaForest.

¹⁴⁵Art. 20 Que.Civ.C.

blood. The Federal <u>Food and Drug Act</u> regulates the processing, manufacture, and sale of blood products. Thus, the statutes and civil law seem to tolerate the sales of regenerative bodily substances, while denying the right to alienate, nongratuitously, organs and like non-regenerative tissues.

The statutes also raise the important distinction between property and commerce. Both a housing tenant and the next-of-kin of a deceased have rights of possession, which do not include the right to sell. Both have a property interest short of the right to sell. Thus, while property and commerce often overlap, the right to sell may or may not be added to the bundle of property interests that the law confers.

2.2 Bodily Property Reconceived

The foregoing reveals some of the principles and some of the ambivalence of the "law of human bodily property." The common law of cadavers denies proprietary but recognizes possessory interests in human corpses. The common law of <u>inter vivos</u> tissue transfers depends on important, but sometimes limited principles of informed consent and damages for mental shock or distress, to govern tissue transfers and deposits. Biotechnology, as the

¹⁴⁶Uniform Human Tissue Gift Act., s.10. [The Act is currently being studied for revision].

¹⁴⁷See R.S.C. 1985, c. F-27 and Canada Gazette Part I at 3660 (3 Sept. 1988).

Moore case illustrates, appears to be accelerating the rate at which medical science may convert formerly useless human tissue, cells or bodily parts into commercially valuable entities. In the face of these new trends and challenges, should society and the law formally recognize any or some property interests in the human body? Our research suggests that the answer depends on how ownership or property is conceived and defined and for what purposes:

In western societies the property right is no longer regarded as absolute if, indeed, it ever was....

... The term "property" is used in a wide variety of meanings. It may refer to a person's physical assets, to his real property, or to the totality of his wealth which consists of physical objects and various incorporeal rights which he is entitled to exercise, such as debts due to him, rights in a trust fund, stocks, patent rights, and so on. Thus it may refer to physical objects and to rights. It may also refer to the legal relations between persons and such objects and rights....

right, namely, the several rights, privileges, powers and immunities which comprise it, that is of significance in law and not the physical thing or right itself. The physical objects or rights may, after all, be multifarious, while the powers or rights are definite. ... This simple generic list can be broken down further to give a list of specific powers, rights, privileges and immunities with respect to property. Property, therefore, is not just a single right, but a bundle of rights or powers. (emphasis added)

In its study on tissue transfer law, the Protection of Life Project has begun to examine these issues and their implications for such laws as the Federal <u>Food and Drug Act</u>, the <u>Criminal</u> <u>Code</u>, and laws relating to the national tissue and organ

¹⁴⁸A. Oosterhoff and W. Rayner, 1 <u>Law of Real Property</u> 3102 at 5, 6 (1985).

scarcity. We have not concluded our deliberations. Indeed, we have only begun to define what seems to be important preliminary questions:

- . Is it helpful to distinguish property interests from commercial interests?
- Do or should property notions apply differently to living and dead individuals, and to whole bodies, bodily tissues, parts, cells?
- . What might existing property notions -- the doctrines of accession, conversion, abandonment, waste--contribute to clarifying rights and duties in particular circumstances?

While such issues are just beginning to receive broader public attention, it is our view that these questions are increasingly of national importance. They implicate doctor/patient relations, the biotechnology industry, university research and medical practice and facilities management, provincial and federal health care, and legal institutions.

CONCLUSION

The challenge of <u>Moore</u> and <u>Parpalaix</u> is to reconceptualize, rationalize, and perhaps assess basic notions regarding property interests in the human body. The question has prompted international commentary and federal legislative attention in the United States and in France, the jurisdictions of <u>Moore</u> and <u>Parpalaix</u>. Initially, at least, both cases would seem

¹⁴⁹ See R. Scott, <u>The Body as Property</u> (1981); United States Congress, Office of Technology Assessment, <u>New Developments in Biotechnology: Ownership of Human Tissues and Cells</u> (1987);

consistent with the protection of individual rights. While individual rights cannot be absolute in a pluralist society, will recognizing bodily property interests help keep human rights sovereign? Viewed from an 18th century perspective, the body as property seems ethically and legally abhorrent. Both law and medicine are dynamic enterprises, however. A Canadian commentator has written that "the meaning of property is not constant. The actual institution and the way people see it, and hence the meaning they give to the word, all change over time." Viewed at this end of the 20th century, through a human rights perspective, we might consider whether a legal notion of property interests in our bodies may serve to protect physical integrity, individual autonomy, and fundamental values of personhood.

Conseil d'État, <u>De l'Éthique Au Droit</u> (La Documentation Française, 1988).

¹⁵⁰C.B. Macpherson, <u>Property: Mainstream and Critical</u> <u>Positions</u> 1 (1978).