

Harvard College v. Canada (Commissioner of Patents), [2002] 4 S.C.R. 45, 2002 SCC

76

**Commissioner of Patents**

*Appellant*

v.

**President and Fellows of Harvard College**

*Respondent*

and

**Canadian Council of Churches,  
Evangelical Fellowship of Canada,  
Canadian Environmental Law Association,  
Greenpeace Canada, Canadian Association  
of Physicians for the Environment, Action  
Group on Erosion, Technology and  
Concentration, Canadian Institute for  
Environmental Law and Policy,  
Sierra Club of Canada, Animal Alliance  
of Canada, International Fund for Animal  
Welfare Inc. and Zoocheck Canada Inc.**

*Interveners*

**Indexed as: Harvard College v. Canada (Commissioner of Patents)**

**Neutral citation: 2002 SCC 76.**

File No.: 28155.

2002: May 21; 2002: December 5.

Present: McLachlin C.J. and L’Heureux-Dubé, Gonthier, Iacobucci, Major, Bastarache,  
Binnie, Arbour and LeBel JJ.

on appeal from the federal court of appeal

*Patents — Patentable subject matter — Standard of review — Standard of review applicable to Commissioner of Patent's decision to refuse patent.*

*Patents — Patentable subject matter — Biotechnology — Patentability of higher life forms — College seeking to patent genetically altered mouse for cancer research — Whether "invention" encompasses higher life forms — Meaning of "manufacture" and "composition of matter" — Patent Act, R.S.C. 1985, c. P-4, s. 2 "invention".*

The respondent applied for a patent on an invention entitled "transgenic animals". According to the application, a cancer-promoting gene ("oncogene") is injected into fertilized mouse eggs as close as possible to the one-cell stage. The eggs are then implanted into a female host mouse and permitted to develop to term. After the offspring of the host mouse are delivered, they are tested for the presence of the oncogene. Those that contain the oncogene are called "founder" mice. Founder mice are mated with mice that have not been genetically altered. Fifty per cent of the offspring will have all of their cells affected by the oncogene, making them suitable for animal carcinogenic studies. In its patent application, the respondent seeks to protect both the process by which the oncomice are produced and the end product of the process, i.e. the founder mice and the offspring whose cells contain the oncogene. The process and product claims extend to all non-human mammals. The process claims were allowed by the Patent Examiner, while the product claims were rejected. The appellant Commissioner confirmed the refusal of the product claims. The Federal Court, Trial

Division, dismissed the respondent's appeal from the appellant's decision. The respondent's further appeal to the Federal Court of Appeal was allowed.

*Held* (McLachlin C.J. and Major, Binnie and Arbour JJ. dissenting): The appeal should be allowed. A higher life form is not patentable because it is not a "manufacture" or "composition of matter" within the meaning of "invention" in s. 2 of the *Patent Act*.

*Per* L'Heureux-Dubé, Gonthier, Iacobucci, Bastarache and LeBel JJ.: This appeal raises the issue of the patentability of higher life forms within the context of the *Patent Act*.

A. *The Commissioner's Power to Refuse a Patent Under Section 40*

The standard of review applicable to the Commissioner's decision in this case is correctness. The courts are as well placed as the Commissioner to decide whether the definition of invention in s. 2 of the *Patent Act* encompasses higher life forms, since the *Patent Act* contains no privative clause, gives applicants a broad right of appeal, and the question approaches a pure determination of law that has significant precedential value. Section 40 of the *Patent Act* does not give the Commissioner discretion to refuse a patent on the basis of public policy considerations independent of any express provision in the Act. Since the Commissioner has no discretion independent of the *Patent Act* to consider the public interest when granting or denying a patent, the Commissioner's decision in this case, given its nature, is not owed deference.

B. *The Definition of Invention: Whether a Higher Life Form Is a "Manufacture" or a "Composition of Matter"*

The sole question in this appeal is whether the words “manufacture” and “composition of matter”, within the context of the *Patent Act*, are sufficiently broad to include higher life forms. It is irrelevant whether this Court believes that higher life forms such as the oncomouse ought to be patentable. The words of the *Patent Act* “are to be read in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament”. Comparisons with the patenting schemes of other countries will therefore be of limited value. The best reading of the words of the Act supports the conclusion that higher life forms are not patentable.

(1) The Words of the Act

For a higher life form to fit within the definition of “invention”, it must be considered to be either a “manufacture” or a “composition of matter”. While the definition of “invention” in the *Patent Act* is broad, Parliament did not define “invention” as “anything new and useful made by man”. The choice of an exhaustive definition signals a clear intention to exclude certain subject matter as being outside the confines of the Act. The word “manufacture” (“*fabrication*”), in the context of the Act, is commonly understood to denote a non-living mechanistic product or process, not a higher life form. The words “composition of matter” (“*composition de matières*”) as they are used in the Act do not include a higher life form such as the oncomouse. The words occur in the phrase “art, process, machine, manufacture or composition of matter”. A collective term that completes an enumeration is often restricted to the same genus as the terms which precede it, even though the collective term may ordinarily have a much broader meaning. Just as “machine” and “manufacture” do not imply a living creature, the words “composition of matter” are best read as not including higher life forms.

While a fertilized egg injected with an oncogene may be a mixture of various ingredients, the body of a mouse does not consist of ingredients or substances that have been combined or mixed together by a person. Moreover, “matter” captures only one aspect of a higher life form, generally regarded as possessing qualities and characteristics that transcend the particular genetic material of which it is composed. Higher life forms cannot be conceptualized as mere “compositions of matter” within the context of the *Patent Act*. Just because all inventions are unanticipated and unforeseeable, it does not necessarily follow that they are all patentable. It is possible that Parliament did not intend to include higher life forms in the definition of “invention”. It is also possible that Parliament did not regard cross-bred plants and animals as patentable because they are better regarded as “discoveries”. Since patenting higher life forms would involve a radical departure from the traditional patent regime, and since the patentability of such life forms is a highly contentious matter that raises a number of extremely complex issues, clear and unequivocal legislation is required for higher life forms to be patentable. The current Act does not clearly indicate that higher life forms are patentable.

## (2) The Scheme of the Act

The above interpretation of the words of the Act finds support in the fact that the patenting of higher life forms raises unique concerns which do not arise in respect of non-living inventions and which are not addressed by the scheme of the Act. The fact that the Act is ill-equipped to deal appropriately with higher life forms as patentable subject matter is an indication that Parliament never intended the definition of “invention” to extend to this type of subject matter. While some policy concerns, such as the environmental and animal welfare implications of biotechnology, are more

appropriately dealt with outside the patent system, other concerns are more directly related to patentability and to the scheme of the Act. These concerns illustrate the fact that the *Patent Act* in its current form is not well suited to address the unique characteristics possessed by higher life forms. The issue of the patenting of human life forms is a complex one that cannot be readily dismissed by reference to the *Charter*. It is not an appropriate judicial function of the courts to create an exception from patentability for human life given that such an exception requires one to consider both what is human and which aspects of human life should be excluded. The lack of direction currently in the Act to deal with issues that might reasonably arise signals a legislative intent that higher life forms are currently not patentable. This Court does not possess the institutional competence to deal with issues of this complexity, which presumably will require Parliament to engage in public debate, a balancing of competing social interests, and intricate legislative drafting.

(3) The Object of the Act

Although the *Patent Act* is designed to advance research and development and encourage broader economic activity, it simply does not follow from the objective of promoting ingenuity that all inventions must be patentable. A product of human ingenuity must fall within the terms of the Act in order for it to be patentable; the issue of whether a proposed invention ought to be patentable does not provide an answer to the question of whether that proposed invention is patentable. In any event, the manner in which Canada has administered its patent regime reveals that the promotion of ingenuity has at times been balanced against other considerations.

(4) Related Legislation: The *Plant Breeders' Rights Act*

The interpretation of an ambiguous law may be informed by the substance and the form of subsequent legislation. The *Plant Breeders' Rights Act* is of significance to the interpretation of the *Patent Act* and the issue of its applicability to higher life forms. Although Parliament enacted special legislation for the protection of plant breeders, it did not address other higher life forms. Moreover, the passage of the *Plant Breeders' Rights Act* demonstrates that mechanisms other than the *Patent Act* may be used to encourage inventors to undertake innovative activity in the field of biotechnology. Many of the issues that arose with respect to intellectual property protection for plant varieties also arise when considering the patentability of other higher life forms. If a special legislative scheme was needed to protect plant varieties, a subset of higher life forms, a similar scheme may also be necessary to deal with the patenting of higher life forms in general. It is beyond the competence of this Court to address in a comprehensive fashion the issues associated with the patentability of higher life forms.

C. *Drawing the Line: Is it Defensible to Allow Patents on Lower Life Forms While Denying Patents on Higher Life Forms?*

The patentability of lower life forms is not at issue before this Court, and was in fact never litigated in Canada. The distinction between lower and higher life forms, though not explicit in the *Patent Act*, is nonetheless defensible on the basis of the common sense differences between the two. The non-patentability of human life is not explicit in the *Patent Act*. If the line between lower and higher life forms is indefensible and arbitrary, so too is the line between human beings and other higher life forms. It is now accepted in Canada that lower life forms are patentable but this does not necessarily lead to the conclusion that higher life forms are patentable, at least in part for the reasons that it is easier to conceptualize a lower life form as a “composition of matter” or “manufacture” than it is to conceptualize a higher life form in these terms.

Patentable micro-organisms are formed in such large numbers that any measurable quantity will possess uniform properties and characteristics. The same cannot be said for plants and animals. It is far easier to analogize a micro-organism to a chemical compound or another inanimate object than it is to analogize an animal to an inanimate object. Moreover, several important features possessed by animals distinguish them from both micro-organisms and plants and remove them even further from being considered a “composition of matter” or a “manufacture”. Given the complexity of the issues involved, it is not the task of the Court to situate the line between higher and lower life forms. Also, the specific exception for plants and animals in trade agreements demonstrates that a distinction between higher and lower life forms is widely accepted as valid.

*Per McLachlin C.J. and Major, Binnie and Arbour JJ. (dissenting):* The oncomouse is patentable subject matter. The extraordinary scientific achievement of altering every single cell in the body of an animal which does not in this altered form exist in nature, by human modification of the genetic material of which it is composed, is an inventive “composition of matter” within the meaning of s. 2 of the *Patent Act*.

#### A. *Statutory Interpretation*

Once it is acknowledged, as does the majority of this Court, that the fertilized, genetically altered oncomouse egg is an invention under the *Patent Act*, there is no basis in the statutory text to conclude that the resulting oncomouse, that grows from the patented egg, is not itself patentable because it is not an invention. Since the respondent has fulfilled the other statutory criteria for an invention, it is entitled to the patent.



The context and scheme of the *Patent Act* reinforce the expansive sense of the words “composition of matter” to render the oncomouse patentable. The proper question is not whether Parliament intended to include “oncomice” or “higher life forms” or biotechnology generally in patent legislation, but whether Parliament intended to protect “inventions” that were not anticipated at the time of enactment of the *Patent Act*, or indeed, at any time before the claimed invention. While Parliament did not contemplate the oncomouse in 1869 when it enacted the definition of “invention”, it did not contemplate moon rockets, antibiotics, telephones, e-mail or hand-held computers either.

The intent that can properly be attributed to Parliament, based on the language it used and the context of patent legislation generally, is that it considered it to be in the public interest to encourage new and useful inventions without knowing what such inventions would turn out to be and to that end inventors who disclosed their work should be rewarded for their ingenuity. The Commissioner of Patents was given no discretion to refuse a patent on the grounds of morality, public interest, public order, or any other ground if the statutory criteria are met.

#### B. *The International Context*

The mobility of capital and technology makes it desirable that comparable jurisdictions with comparable intellectual property legislation arrive at similar legal results. The expression “composition of matter” is found in the U.S. *Patent Act*, under which the oncomouse was patented in 1988. The oncomouse is also patented in jurisdictions that cover Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden and the United

Kingdom. A similar patent has been issued in Japan. New Zealand has issued a patent for a transgenic mouse that has been genetically modified to be susceptible to HIV infection. The Commissioner's approach to this case sounds a highly discordant note. The massive private sector investment in biotechnological research is exactly the sort of research and innovation that the *Patent Act* was intended to promote. Healthcare is the major beneficiary of biotechnology. At the same time, vast amounts of money must be found to finance biomedical research. The *Patent Act* embodies the public policy that those who directly benefit from an invention should be asked, through the patent system, to pay for it, at least in part.

C. *The Line-Drawing Exercise*

The Commissioner is unable to show any statutory authority for drawing a line between those life forms that he acknowledges to be patentable and those he rejects. "Composition of matter" is an open-ended expression and is not confined to inanimate matter. While as a matter of law there can be no patent on a human being, the *Patent Act* does not distinguish, in its definition of "invention", between "lower" and "higher" life forms. None of the proposed dividing lines between "lower" and "higher" life forms arise from the text of the *Patent Act*. Whether to carve out a subject-matter exception for "higher life forms", and how "higher life form" is to be defined, is a policy matter for Parliament.

As to the contention that growth from a single fertilized cell to the complete mouse has nothing to do with the inventors and everything to do with the "laws of nature", it must be said that the "laws of nature" are an essential part of the working of many and probably most patented inventions. Pharmaceutical drugs utilize the normal

bodily processes and functions of animals and humans and are not on that account regarded as less patentable. Medications, like the oncomouse, could not be brought into existence without reliance on the “laws of nature” in general and the processes of biochemistry in particular.

D. *The Plant Breeders’ Rights Act*

The adoption of the *Plant Breeders’ Rights Act* in 1990 does not mean that the subject matter of patents excludes plants and, by extension, other “higher” life forms such as seeds and animals. The rights available under the *Plant Breeders’ Rights Act* fall well short of those conferred by patent, both in comprehensiveness and duration. In addition, the *Patent Act* language reaches back prior to Confederation. There was no repeal by implication in 1990 since it cannot be said that the two Acts are inconsistent.

E. *Other Objections*

As to the lack of a regulatory framework for “higher life form” inventions, there are as many areas of potential regulation as there are areas of invention. These regulatory regimes cannot and should not all be put under the inadequate umbrella of the *Patent Act*. It is normal that regulation follows, rather than precedes, the invention.

The scientific accomplishment manifested in the oncomouse is profound and far-reaching. Every cell in the animal’s body has been altered in a way that is highly important to scientific research. While the oncomouse is deliberately designed to grow painful malignant tumours, animals will continue to be used in laboratories for scientific research whether patented or not. With respect to the commodification of human life,

the patentability of humans is precluded by law and the broadest claim here specifically excepts humans from the scope of transgenic mammals. Environmental concerns which include the diversity of the gene pool and the potential escape of genetically modified organisms into the environment are serious. They have little to do, however, with the patent system. The *Patent Act* has always had the modest and focussed objective of encouraging the disclosure of the fruit of human inventiveness in exchange for the statutory rewards. The balance between the other competing policy considerations is for Parliament to strike.

F. *The Court's Moratorium*

Neither the Commissioner of Patents nor the courts have the authority to declare a moratorium on “higher” life patents until Parliament chooses to act.

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By Bastarache J.

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*parte Al-Mehdawi*, [1989] 1 All E.R. 777; *Diamond v. Chakrabarty*, 447 U.S. 303 (1980); *Moreau-Bérubé v. New Brunswick (Judicial Council)*, [2002] 1 S.C.R. 249, 2002 SCC 11; *Pushpanathan v. Canada (Minister of Citizenship and Immigration)*, [1998] 1 S.C.R. 982; *Canada (Director of Investigation and Research) v. Southam Inc.*, [1997] 1 S.C.R. 748; *Baker v. Canada (Minister of Citizenship and Immigration)*, [1999] 2 S.C.R. 817; *Rizzo & Rizzo Shoes Ltd. (Re)*, [1998] 1 S.C.R. 27; *Hornblower v. Boulton* (1799), 8 T.R. 95, 101 E.R. 1285; *Micro Chemicals Ltd. v. Smith Kline & French Inter-American Corp.*, [1972] S.C.R. 506; *Bell ExpressVu Limited Partnership v. Rex*, [2002] 2 S.C.R. 559, 2002 SCC 42; *Tremblay v. Daigle*, [1989] 2 S.C.R. 530; *Winnipeg Child and Family Services (Northwest Area) v. G. (D.F.)*, [1997] 3 S.C.R. 925; *Free World Trust v. Électro Santé Inc.*, [2000] 2 S.C.R. 1024, 2000 SCC 66; *In re Bergy, Coats, and Malik*, 195 U.S.P.Q. 344 (1977).

By Binnie J. (dissenting)

*Théberge v. Galerie d'Art du Petit Champlain inc.*, [2002] 2 S.C.R. 336, 2002 SCC 34; *Continental Soya Co. v. J. R. Short Milling Co. (Canada) Ltd.*, [1942] S.C.R. 187; *Laboratoire Pentagone Ltée v. Parke, Davis & Co.*, [1968] S.C.R. 307; *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623, aff'g [1987] 3 F.C. 8; *Re Application of Abitibi Co.* (1982), 62 C.P.R. (2d) 81; *General Electric Co.'s Application (Patent)*, [1961] 2 R.P.C. 21; *Re Application for Patent of Connaught Laboratories* (1982), 82 C.P.R. (2d) 32; *Diamond v. Chakrabarty*, 447 U.S. 303 (1980); *Monsanto Canada Inc. v. Schmeiser*, [2003] 2 F.C. 165, 2002 FCA 309; *Somerset v. Stewart* (1772), Lofft 1, 98 E.R. 499; *Bishop v. Stevens*, [1990] 2 S.C.R. 467; *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504; *Hinks & Son v. Safety Lighting Co.* (1876), 4 Ch. D. 607; *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred*

*International, Inc.*, 122 S. Ct. 593 (2001); *Commissioner of Patents v. Winthrop Chemical Co.*, [1948] S.C.R. 46; *Tennessee Eastman Co. v. Commissioner of Patents*, [1974] S.C.R. 111; *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153, 2002 SCC 77; *Grant of European patent No. 0 169 672 (Onco-mouse/Harvard)* (1992), OJ EPO 1992, 588.

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*Act respecting Patents of Invention*, S.C. 1869, c. 11, s. 6.

*Agreement on Trade-Related Aspects of Intellectual Property Rights*, 1869 U.N.T.S. 299 (being Annex 1C of the *Marrakesh Agreement Establishing the World Trade Organization*, 1867 U.N.T.S. 3), art. 27(2).

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*Canadian Charter of Rights and Freedoms*, ss. 1, 7, 15.

*Canadian Environmental Protection Act*, R.S.C. 1985, c. 16 (4th Supp.).

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*Convention on the Grant of European Patents*, October 5, 1973, art. 53(a).

*Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions*, art. 5(1), (2), 6.

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APPEAL from a judgment of the Federal Court of Appeal, [2000] 4 F.C. 528, 189 D.L.R. (4th) 385, 7 C.P.R. (4th) 1, [2000] F.C.J. No. 1213 (QL), reversing a decision of the Trial Division, [1998] 3 F.C. 510, 146 F.T.R. 279, 79 C.P.R. (3d) 98, [1998] F.C.J. No. 500 (QL). Appeal allowed, McLachlin C.J. and Major, Binnie and Arbour JJ. dissenting.

*Graham R. Garton, Q.C., and Frederick B. Woyiwada, for the appellant.*

*A. David Morrow, Steven B. Garland, and Colin B. Ingram, for the respondent.*

*William J. Sammon*, for the interveners Canadian Council of Churches and Evangelical Fellowship of Canada.

*Michelle Swenarchuk, Theresa McClenaghan, and Paul Muldoon*, for the interveners Canadian Environmental Law Association, Greenpeace Canada, Canadian Association of Physicians for the Environment, Action Group on Erosion, Technology and Concentration, and Canadian Institute for Environmental Law and Policy.

Written submissions only by *Jerry V. DeMarco* for the intervener Sierra Club of Canada.

Written submissions only by *Clayton C. Ruby* and *Lesli Bisgould* for the interveners Animal Alliance of Canada, International Fund for Animal Welfare Inc. and Zoocheck Canada Inc.

The reasons of McLachlin C.J. and Major, Binnie and Arbour JJ. were delivered by

1           BINNIE J. (dissenting) — The biotechnology revolution in the 50 years since discovery of the structure of DNA has been fuelled by extraordinary human ingenuity and financed in significant part by private investment. Like most revolutions, it has wide ramifications, and presents potential and serious dangers as well as past and future benefits. In this appeal, however, we are only dealing with a small corner of the biotechnology controversy. We are asked to determine whether the oncomouse, a genetically modified rodent with heightened genetic susceptibility to cancer, is an invention. The legal issue is a narrow one and does not provide a proper platform on

which to engage in a debate over animal rights, or religion, or the arrogance of the human race.

2           The oncomouse has been held patentable, and is now patented in jurisdictions that cover Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, the United Kingdom and the United States. A similar patent has been issued in Japan. New Zealand has issued a patent for a transgenic mouse that has been genetically modified to be susceptible to HIV infection. Indeed, we were not told of any country with a patent system comparable to Canada's (or otherwise) in which a patent on the oncomouse had been applied for and been refused.

3           If Canada is to stand apart from jurisdictions with which we usually invite comparison on an issue so fundamental to intellectual property law as what constitutes an "invention", the respondent, successful everywhere but in Canada, might expect to see something unique in our legislation. However, one looks in vain for a difference in definition to fuel the Commissioner's contention that, *as a matter of statutory interpretation*, the oncomouse is not an invention. The truth is that our legislation is not unique. The Canadian definition of what constitutes an invention, initially adopted in pre-Confederation statutes, was essentially taken from the United States *Patent Act* of 1793, a definition generally attributed to Thomas Jefferson. The United States patent on the oncomouse was issued 14 years ago. My colleague, Bastarache J., acknowledges that the fertilized, genetically altered oncomouse *egg* is an invention under our *Patent Act*, R.S.C. 1985, c. P-4 (para. 162). Thereafter, we part company, because my colleague goes on to conclude that the resulting *oncomouse*, that grows from the patented egg, is not itself patentable because it is not an invention. Subject matter patentability, on this

view, is lost between two successive stages of a transgenic mouse's genetically pre-programmed growth. In my opinion, with respect, such a "disappearing subject-matter" exception finds no support in the statutory language.

4           A patent, of course, does not give its holder a licence to practise the invention free of regulatory control (any more than an *unpatented* invention enjoys such immunity). On the contrary, the grant of a patent simply reflects the public interest in promoting the disclosure of advancements in learning by rewarding human ingenuity. Innovation is said to be the lifeblood of a modern economy. We neglect rewarding it at our peril. Having disclosed to the public the secrets of how to make or use the invention, the inventor can prevent *unauthorized* people for a limited time from taking a "free ride" in exploiting the information thus disclosed. At the same time, persons skilled in the art of the patent are helped to further advance the frontiers of knowledge by standing on the shoulders of those who have gone before.

5           The issues being thus identified, I think the majority decision of the Federal Court of Appeal was correct. The appeal should be dismissed.

A. Statutory Interpretation

6           The issue, in the words of s. 2 of the *Patent Act*, is whether the oncomouse that has been produced by a combination of genetic engineering and natural gestation is a "composition of matter" that is new, unobvious and useful. If it is, then the President and Fellows of Harvard University, who funded the research, are entitled to a patent. My colleague, Bastarache J., writes of the oncomouse as follows (at para. 163):

The fact that it has this predisposition to cancer that makes it valuable to humans does not mean that the mouse, along with other animal life forms, can be defined solely with reference to the genetic matter of which it is composed. [Emphasis added.]

7           While acknowledging, therefore, that the oncomouse is a “composition of [genetic] matter”, my colleague’s contention is that the oncomouse is a “composition of [genetic] matter” *plus* something else, undefined. The respondent, however, does not claim to have invented the “plus”. Its sole claim is to have modified what my colleague describes as the “genetic matter of which [the oncomouse] is composed”, as described in the disclosure portion of the patent application:

- (i)           the desired oncogene is obtained from the genetic code of a non-mammal source, such as a virus;
- (ii)          a vehicle for transporting the oncogene into the mammal’s chromosomes is constructed using a small piece of circular bacterial DNA referred to as a plasmid; the plasmid is chemically cut and the oncogene is chemically “spliced” into the plasmid;
- (iii)         the plasmid containing the oncogene is then mechanically injected into fertilized eggs at a site called the male pronucleus;
- (iv)         the eggs are then implanted in a host mammal or “foster mother”;
- (v)         the eggs are permitted to develop and the offspring are delivered by the foster mother;

- (vi) after delivery, the offspring are tested for the presence of the oncogene; the offspring that contain the oncogene are called “founder” animals;
- (vii) founder animals are subsequently mated with ordinary animals and the offspring are again tested for the presence of the oncogene before the offspring are used in research.

8           As will be explained more fully below, I believe that the extraordinary scientific achievement of altering every single cell in the body of an animal which does not in this altered form exist in nature, by human modification of “the genetic material of which it is composed”, is an inventive “composition of matter” within the meaning of s. 2 of the *Patent Act*.

9           The position taken by the Commissioner of Patents is, I think, curious. While expressly acknowledging that the oncomouse is new, useful and non-obvious, and therefore meets the usual statutory criteria, the Commissioner of Patents denies that “higher life forms” fall within the *subject matter* contemplated by Parliament as patentable. He says, at para. 51 of his factum:

In 1869, when Parliament first made provision for the patenting of “any new and useful . . . manufacture, or composition of matter”, genetic engineering was unheard of. Thus, Parliament could not at the time of enactment have *intended* that higher life forms would come within the meaning of those words. [Emphasis added.]

10           It is true, of course, that in 1869, when the post-Confederation patent act was passed, Parliament did not contemplate genetically engineered “higher life forms” (*Act respecting Patents of Invention*, S.C. 1869, c. 11). Parliament in 1869 did not

contemplate genetically engineered “*lower life forms*” either, although in recent years Canadian patents have regularly been issued for such inventions. (My colleague, Bastarache J., at para. 201, affirms that “*lower life*” forms will continue to be patentable.) Nor did Parliament in 1869 contemplate moon rockets, antibiotics, telephones, e-mail or hand-held computers. The proper question is not whether Parliament intended to include “*oncomice*” or “*higher life forms*” or biotechnology generally in patent legislation, but whether Parliament intended to protect “*inventions*” that were not anticipated at the time of enactment of the *Patent Act*, or indeed, at any time before the claimed invention.

- 11           I accept, as does my colleague, that the proper approach to interpretation of this statute is to read the words “in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament”: E. A. Driedger, *Construction of Statutes* (2nd ed. 1983), at p. 87. In my opinion, with respect, the context and scheme of the *Patent Act* reinforce the expansive sense of the words “composition of matter” to render the oncomouse patentable. The intent that can properly be attributed to Parliament, based on the language it used and the context of patent legislation generally, is that it considered it to be in the public interest to encourage new and useful inventions without knowing what such inventions would turn out to be and to that end inventors who disclosed their work should be rewarded for their ingenuity. A further indication of Parliament’s intent is that the Commissioner of Patents was given *no* discretion to refuse a patent on the grounds of morality, public interest, public order, or any other ground if the statutory criteria are met: *Patent Act*, s. 40. In my view, the respondent has fulfilled the statutory criteria and “by law” is entitled to the patent.

B. International Scope of Intellectual Property Law

12 Intellectual property has global mobility, and states have worked diligently to harmonize their patent, copyright and trademark regimes. In this context, the Commissioner's approach to this case sounds a highly discordant note. Intellectual property was the subject matter of such influential agreements as the *International Convention for the Protection of Industrial Property (Paris Convention)* as early as 1883. International rules governing patents were strengthened by the *European Patent Convention* in 1973, and, more recently, the *World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)* in 1994 (1869 U.N.T.S. 299). Copyright was the subject of the *Berne Convention for the Protection of Literary and Artistic Works* in 1886, revised by the *Berlin Convention* of 1908 and the *Rome Convention* of 1928. The *Universal Copyright Convention* was concluded in 1952. Legislation varies of course, from state to state, but broadly speaking Canada has sought to harmonize its concepts of intellectual property with other like-minded jurisdictions.

13 The mobility of capital and technology makes it desirable that comparable jurisdictions with comparable intellectual property legislation arrive (to the extent permitted by the specifics of their own laws) at similar legal results: *Théberge v. Galerie d'Art du Petit Champlain inc.*, [2002] 2 S.C.R. 336, 2002 SCC 34, at para. 6.

14 The appellant Commissioner's definition of *unpatentable* "higher life forms" includes not only animals but also plants and seeds. Genetically modified foods are controversial, but these are not controversies that should be dealt with by judicial exclusion of "higher life forms" from the definition of an "invention". Parliament itself has clearly signalled its limited view of the role and function of the *Patent Act*. In 1993,



it repealed the prohibition in the former s. 27(3) of the *Patent Act* against patenting an “invention that has an illicit object in view”. It thereby made it clear that granting a patent is not an expression of approval or disapproval. At that time, Parliament did *not* add a provision, present in the *European Patent Convention* and in many civil law systems and international agreements, that patents will not be granted for inventions whose use or exploitation would be inconsistent with *ordre public*, public morality, or environmental or health protection. That type of provision would open the door to value judgments in assessing patentability. Parliament did not endorse such an approach, even though the 1993 amendments were introduced to bring Canadian patent law into compliance with various international agreements. Parliament thereby signalled, however passively, that these important aspects of public policy would continue to be dealt with by regulatory regimes outside the *Patent Act*.

- 15           A more recent indication of the government’s approach is the *Assisted Human Reproduction Act*. A discussion paper was placed before the Canadian public in 2000 and a bill placed before Parliament by the Minister of Health as Bill C-56 on May 9, 2002 (re-introduced in the same form as Bill C-13 on October 9, 2002). The bill would prohibit the cloning of human beings, modifying the germ line identity of human beings and the use of human embryos for industrial or commercial purposes. At the same time, Bill C-13 would *not* prevent inventions in that regard from being patented in Canada. This illustrates, again, the fundamental distinction made by Parliament between patentability of an invention and regulation of activity associated with an invention.

C. The Commercial and Scientific Context

16               Biotechnology is global in scope. Worldwide demand is expected to more than double from \$20 billion in 1995 to \$50 billion by 2005. Canada is a significant player. Statistics Canada reports that Canada's biotechnology sector in 1999 generated almost \$2 billion in revenues, including \$718 million in exports. These revenues are expected to exceed \$5 billion in 2002. The Canadian Biotechnology Advisory Committee (CBAC), formed in 1999 to advise the federal government on these matters, recently reported that Canada has more biotechnology companies *per capita* than any other country: *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee*, June 2002, p. 2. It was calculated by Ernst & Young in its *Seventh Annual European Life Sciences Report 2000*, that Canada is second behind the U.S. in terms of number of companies, third behind the U.S. and U.K. in revenues, and first in R & D *per employee*.

17               Genetic tests and "engineered" products hold out the possibility of modifying genetic mutations that either cause a disorder (e.g., Tay-Sachs disease, cystic fibrosis, Huntington's disease) or are responsible for increasing an individual's risk to develop, at some point during his or her lifetime, a particular disease (e.g., breast cancer). In addition, some research indicates a genetic element in some "behavioural illnesses" such as schizophrenia, Alzheimer's, autism, attention-deficit hyperactivity disorder, and Tourette's syndrome: P. S. Florencio, "Genetics, Parenting, and Children's Rights in the Twenty-First Century" (2000), 45 *McGill L.J.* 527, at p. 535.

18               This is not to suggest that because something is beneficial it is necessarily patentable. As stated, such value judgments have been excluded from the administration of the *Patent Act*. It is to say, however, that the massive investment of the private sector

in biotechnical research is exactly the sort of research and innovation that the *Patent Act* was intended to promote.

D. Financing Research and Development

19               As this case demonstrates, even university research has to be paid for, and intellectual property rights are an important contributor.

20               We are told that in the United States (comparable statistics do not seem to be available in Canada), a health-related biotechnology product on average costs between 200 and 350 million dollars (U.S.) to develop, and takes 7 to 10 years from the research and development stage to bring it to market (Statistics Canada, *Biotechnology Use and Development — 1999* (March 2001), at p. 25). One would think it in the public interest to shorten the time and reduce the cost of research designed to minimize human suffering, and to reward those who develop research tools (such as the oncomouse) that might make this possible, provided the inventors disclose their work for others to build on.

21               Transgenic mice, including the oncomouse, have a role of potential importance. The evidence is that use of transgenic mice improves the effectiveness of the research that can be done, and shortens the time required to produce results. As Dr. Philip Leder, the co-inventor of the oncomouse, told a U.S. Congressional hearing in 1989:

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.

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

(Quoted in T. Schrecker et al., *Ethical Issues Associated with the Patenting of Higher Life Forms* (1997), at pp. 25-26.)

22 Dr. Leder's view is widely shared:

Transgenic mice produced by DNA injection have been employed in a vast range of studies. For instance the method allows evaluation of the effects of gene mutations thought to be implicated in the inception of cancer. It has also contributed greatly to our understanding of the immune defence system. Indeed there are few areas of biology which have not been illuminated by the study of transgenic mice.

(Extract from J. Bishop, *Transgenic Mammals* (1999), at p. 7)

23 The CBAC report of June 2002 observed that healthcare is the major beneficiary of biotechnology. "More than 90 per cent of the advanced biotechnology products on the world market are related to health. It is expected that about three-quarters of global biotechnology demand will continue to be in this area" (*supra*, p. 2). Medical research inevitably relates to life, and its products will often impinge, directly or indirectly, on "higher life forms".

24 The practical *application* of biotechnology is in large measure the preoccupation of enterprises that need to profit from their successes to finance continued research on a broader front. These successes are few and far between (Statistics Canada, *supra*, at pp. 13-14). It seems Du Pont spent about US\$15 million to fund the oncomouse research: C. Arthur, "The onco-mouse that didn't roar" (1993), 138 *New Scientist* 4. Leder, the afore-mentioned co-inventor of the Harvard mouse, made the point to Congress as follows:

[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.

(Quoted in Schrecker, *supra*, at p. 25.)

25           There are those who question the level of incentive required to induce sufficient research in the biomedical field. Professor Gold of McGill University argues:

The argument for greater patent protection should be understood for what it is: an attempt to maximize profit, not to maximize levels of innovation. Clearly, a company would prefer to have as large a monopoly as possible. . . . But patent law is not about individual profit maximization; it is about maximizing the overall level of innovation in society. The two do not necessarily go together.

(E. R. Gold, “Biomedical Patents and Ethics: A Canadian Solution” (2000), 45 *McGill L.J.* 413, at p. 423)

Nevertheless it is indisputable that vast amounts of money must be found to finance biomedical research. It is necessary to feed the goose if it is to continue to lay the golden eggs. The *Patent Act* embodies the public policy that those who directly benefit from an invention should be asked, through the patent system, to pay for it, at least in part.

#### E. Patenting Life Forms in Canada

26           My colleague, Bastarache J., comments that “[t]he patentability of lower life forms is not at issue before this Court, and was in fact never litigated in Canada” (para. 198). However, certain enzyme products (which are living matter) were held to be patentable by this Court 60 years ago in *Continental Soya Co. v. J. R. Short Milling*

*Co. (Canada) Ltd.*, [1942] S.C.R. 187, as were engineered micro-organisms used as an antibiotic in *Laboratoire Pentagone Ltée v. Parke, Davis & Co.*, [1968] S.C.R. 307.

27           The attempt to patent life forms last came before this Court in *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623. In that case, a patent was sought for a new soybean variety developed from artificial crossbreeding and selection, but cultivated naturally. The applicant’s “disclosure” consisted of depositing seed samples with the Patent Office. This Court upheld the rejection of the patent application on the basis that filing a seed sample did not meet the disclosure requirements of s. 36(1) of the *Patent Act*, R.S.C. 1970, c. P-4, which then (as now (s. 27(3))) required the inventor to set forth clearly the various steps required to make the “composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it appertains, or with which it is most closely connected, to make . . . it”. In light of the deficient disclosure, the Court expressly declined to go on to consider whether the new soybean variety could be regarded as an invention within the meaning of s. 2.

28           In the course of his reasons for the Court, however, Lamer J. (as he then was) pointed out an important distinction between two approaches to “genetic engineering”. The first method (employed by Pioneer Hi-Bred) was hybridization and selection. In this method, “[t]here is thus human intervention . . . which does not alter the actual rules of reproduction, which continues to obey the laws of nature” (pp. 1632-33).

29           The second method (which was used here to develop the oncomouse) 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 [crossbreeding] 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. [p. 1633]

30 I do not think Lamer J. expressed any doubt that an “alteration of the genetic code affecting all the hereditary material” produced “an invention” (although he did not decide the point). His doubts seemed rather to be related to whether crossbreeding *without* altering the genetic code using modern variants of techniques that are almost as old as agriculture itself was inventive within the scope of the Act (at p. 1634):

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.

The Harvard researchers did not merely “uncover” a naturally occurring oncomouse. The complexity of the genetic splicing did not “follow” the laws of nature, but was a human intervention of a high order. They engineered that part of its genetic code that appears to be responsible for its commercial value.

31 Reference should also be made to *Re Application of Abitibi Co.* (1982), 62 C.P.R. (2d) 81 (Pat. App. Bd.), in which the applicant sought to patent a living organism, namely a “mixed fungal yeast culture system” (p. 83) useful in digesting effluent from wood pulp mills. In holding the subject matter to be patentable, the Patent Appeal Board rejected the Patent Office’s somewhat narrow view “derived from a time when the many gradations of living forms were not as fully apprehended as is now possible” (*General*

*Electric Co.'s Application (Patent)*, [1961] 2 R.P.C. 21, at p. 25, cited in *Abitibi* at p. 85). Somewhat in advance of its time, the Patent Appeal Board in *Abitibi* then commented at p. 90 that “[i]f an inventor creates a new and unobvious insect [i.e., a “higher life form”] which did not exist before (and thus is not a product of nature), and can recreate it uniformly and at will, and it is useful (for example to destroy the spruce bud worm), then it is every bit as much a new tool of man as a micro-organism” and thus, subject to certain conditions as to reproducibility, patentable. In relation to the *Abitibi* micro-organism at hand, the Patent Appeal Board ruled (at p. 91):

The organism, to be claimed, should not of course have existed previously in nature, for in that event the “inventor” did not create it, and his “invention” is old. It must also be useful, in the sense that it carries out some useful known objective, such as separating oil from sand, producing antibiotics or the like. It cannot be a mere laboratory curiosity whose only possible claim to utility is as a starting material for further research. And it must be sufficiently different from known species that it can be said that its creation involved the necessary element of inventive ingenuity. In the present case we believe the product claims meets these tests, and the [Patent Office] objection should be withdrawn.

32                    In *Re Application for Patent of Connaught Laboratories* (1982), 82 C.P.R. (2d) 32, the Patent Appeal Board allowed that cell lines derived from “higher life forms” were patentable, thus removing another possible dividing line. Not all aspects of “higher life forms” were unpatentable. The Patent Office (now the Canadian Intellectual Property Office) regularly allows patents on human genes, proteins, cells and DNA sequences. Under Canadian law, it is not “life” *per se* which is unpatentable. The issues are, rather, the view taken by the Commissioner to narrow the range of living matter to be considered patentable, and where in the *Patent Act* is there statutory authority for the line the Commissioner wants to draw?



F. Patenting of “Higher Life Forms” in Comparable Jurisdictions

33                   In 1873, Louis Pasteur was granted a patent in the United States on a certain yeast, which is a living organism.

34                   A patent for the Harvard oncomouse was issued by the United States Patent Office on April 12, 1988 and by the European Patent Office on May 13, 1992, despite the explicit power under the *European Patent Convention* to refuse a patent based on “morality” or “*ordre public*”. As mentioned earlier, a similar patent has been issued in Japan, and New Zealand has issued a patent for a transgenic mouse.

35                   The appellant Commissioner’s principal argument is that to allow the oncomouse patent would be to “expand” the scope of the *Patent Act* (i.e., his factum, paras. 2, 3, 35 and 73), but the opposite conclusion reached in so many countries with comparable legislation suggests the contrary. In those jurisdictions, patents for the oncomouse have been issued without any need for legislative amendment, including the United States where the language of our definition of “invention” originated. The Commissioner seeks to *restrict* the legislative definition of invention, and he does so (in my view) for policy reasons unrelated to the *Patent Act* or to its legitimate role and function.

36                   The majority of the Federal Court of Appeal in this case found persuasive the interpretative principles applied by the United States Supreme Court in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). In that case the inventor, Al Chakrabarty, had genetically engineered bacteria capable of breaking down crude oil spills. The invention was environmentally useful but the bacteria, necessarily, were alive. One of the

arguments made by the U.S. Commissioner of Patents and Trademarks, echoed in this appeal before us 22 years later, was that

micro-organisms cannot qualify as patentable subject matter until Congress expressly authorizes such protection. [The Commissioner's] position rests on the fact that genetic technology was unforeseen when Congress enacted § 101. From this it is argued that resolution of the patentability of inventions such as respondent's should be left to Congress. The legislative process, the [Commissioner] argues, is best equipped to weigh the competing economic, social, and scientific considerations involved, and to determine whether living organisms produced by genetic engineering should receive patent protection. [p. 314]

37           Burger C.J.'s answer (at p. 315), also applicable here, was that "[i]t is, of course, correct that Congress, not the courts, must define the limits of patentability; but it is equally true that once Congress has spoken it is 'the province and duty of the judicial department to say what the law is'". The 5-4 majority held at pp. 309-10 that the inventor's micro-organism

plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter — a product of human ingenuity "having a distinctive name, character [and] use". [Emphasis added.]

The proper distinction was not living *versus* inanimate but between the *discovery* of a product of nature (whether living or not) *versus* a human-made *invention*. Burger C.J. did not subscribe to the notion that patents could be obtained for "anything under the sun that is made by man", quoted as part of his narrative in footnote 6. In fact, at p. 309, he specifically states that "[t]his is not to suggest that [the Act] has no limits or that it embraces every discovery". On the contrary, the patent issued because its subject matter was held to be a "manufacture" or "composition of matter" within the statutory test laid down by Congress. "A rule that unanticipated inventions are without protection would

conflict with the core concept of the patent law that anticipation undermines patentability” (*Chakrabarty*, at p. 316).

38           The appellant Commissioner argues that *Chakrabarty* should be rejected because of differences he perceives in the legislative history in Canada and the United States, an allegedly different common understanding of what “composition of matter” meant when the *Patent Act* was passed in 1869, and subsequent legislative action in Canada in 1990 with respect to plant breeders (factum, at paras. 60 and 61). In my view, for reasons given below, these distinctions are not well founded but, in any event, the only interest we have in *Chakrabarty* is the extent to which its reasoning adds persuasive force to the respondent’s argument and confirms harmony, broadly speaking, in intellectual property matters among like-minded jurisdictions.

G.   The Interpretation of Section 2 of the *Patent Act*

39           The appellant Commissioner denies that a patent can be obtained in Canada for “anything under the sun that is made by man” and I agree. He says that this expression, used in Congressional hearings in 1952, distinguishes the U.S. legislative history from ours, but this is not so, strictly speaking. A 1952 expression of opinion by a Congressional Committee almost 150 years after the definition was inserted into the U.S. *Patent Act* of 1793 is scarcely *contemporanea expositio*.

40           The check on the indiscriminate grant of patents lies in the established criteria of utility, novelty and non-obviousness. Those are the criteria judged by Parliament to be relevant to its statutory purpose, which is to encourage ingenuity by rewarding its disclosure. The expression “composition of matter” was included in our

patent laws prior to Confederation. It appears in 1824 in the Lower Canada statute entitled *An Act to promote the progress of useful Arts in this Province*, 4 Geo. 4, c. 25, and in Upper Canada two years later in *An Act to Encourage the Progress of Useful Arts within this Province*, 7 Geo. 4, c. 5. The 1826 Act included the terms “manufacture” and “composition of matter” in the preamble setting out its object:

WHEREAS it is expedient for the encouragement of Genius and of Arts in this Province to secure an exclusive right to the Inventor of any New and Useful Art, Machine, Manufacture, or Composition of Matter . . . .

41                   Section 91(22) of the *Constitution Act, 1867*, assigned legislative competence in respect of “Patents of Invention and Discovery” to Parliament which two years later defined patentable subject matter as follows:

Any person . . . having invented or discovered any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement on any art, machine, manufacture or composition of matter, not known or used by others before his invention or discovery thereof, or not being at the time of his application for a patent in public use or on sale in any of the Provinces of the Dominion with the consent or allowance of the inventor or discoverer thereof . . . . [Emphasis added.]

(*Act respecting Patents of Invention*, S.C. 1869, c. 11, s. 6)

The wording has not changed much in the intervening years, apart from dropping the reference to “discovery”. Section 2 of the present *Patent Act* now provides as follows:

“invention” means 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;

« invention » Toute réalisation, tout procédé, toute machine, fabrication ou composition de matières, ainsi que tout perfectionnement de l’un d’eux, présentant le caractère de la nouveauté et de l’utilité.

42                   It is common ground that to meet the subject matter criteria of the *Patent Act* the oncomouse must qualify as a “composition of matter” or a “manufacture”.

(i) “*Composition of Matter*”

43                   “Composition of matter” (*composition de matières*) is an open-ended expression. Statutory subject matter must be framed broadly because by definition the *Patent Act* must contemplate the unforeseeable. The definition is not expressly confined to inanimate matter, and the appellant Commissioner agrees that composition of organic and certain living matter can be patented. In the case of the oncomouse, the modified genetic material is a physical substance and therefore “matter”. The fertilized mouse egg is a form of biological “matter”. The combination of these two forms of matter by the process described in the disclosure is thus, as pointed out by Rothstein J.A. ([2000] 4 F.C. 528, at para. 120), a “composition of matter”.

44                   What, then, is the justification under the *Patent Act* for drawing a line between certain compositions of living matter (*lower* life forms) and other compositions of living matter (*higher* life forms)?

45                   My colleague, Bastarache J., quotes from the *Oxford English Dictionary* (2nd ed. 1989), vol. IX, at p. 480, the entry that “matter” is a “[p]hysical or corporeal substance in general . . . , contradistinguished from immaterial or incorporeal substance (spirit, soul, mind), and from qualities, actions, or conditions”, but this, of course, depends on context. “Matter” is a most chameleon-like word. The expression “grey matter” refers in everyday use to “intelligence” — which is about as incorporeal as “spirit” or “mind”. Indeed, the same Oxford editors define “grey matter” as

“intelligence, brains” (*New Shorter Oxford English Dictionary* (1993), vol. 1, at p. 1143). The *primary* definition of matter, according to the *Oxford English Dictionary*, is “[t]he substance, or the substances collectively, out of which a physical object is made or of which it consists; constituent material” (p. 479). The definition of “*matière*” in *Le Grand Robert de la langue française* (2nd ed. 2001), vol. 4, quoted by my colleague, is to the same effect. The question, then, is what, in the Commissioner’s view, is the “constituent material” of the oncomouse as a physical entity? If the oncomouse is not composed of matter, what, one might ask, are such things as oncomouse “minds” composed of? The Court’s mandate is to approach this issue as a matter (that slippery word in yet another context!) of law, not murine metaphysics. In the absence of any evidence or expert assistance, the Commissioner now asks the Court to take judicial notice of the oncomouse, if I may use Arthur Koestler’s phrase, as a “ghost in a machine” but this pushes the scope of judicial notice too far. With respect, this sort of literary metaphor (or its dictionary equivalent) is an inadequate basis on which to narrow the scope of the *Patent Act*, and thus to narrow the patentability of scientific invention at the dawn of the third Millennium.

(ii) *Defining the Exception for “Higher Life Forms”*

46           The appellant Commissioner says the Federal Court of Appeal erred by allowing a patent on a “higher intelligent life form”, but he himself offers no definition of an “intelligent” life form, much less does he identify a dividing line between a “higher” intelligent life form and a “lower” intelligent life form.

47           The *Patent Act* does not distinguish, in its definition of invention, between subject matter that is less complex (“lower life forms”) and subject matter that is more

complex (“higher life forms”). The degree of complexity is not a criterion found in the Act or in the jurisprudence in determining patentability. The distinction between “lower life forms” and “higher life forms” in its application to s. 2 is the invention of the Patent Office.

48                   While refusing to issue a patent for a higher animal life form in this case, the Commissioner has issued patents under the *Patent Act* for higher plant life forms: see, e.g., Canadian Patent 1,313,830 issued February 23, 1993 for “Roundup Ready Canola”, a genetically modified plant, recently before the courts in *Monsanto Canada Inc. v. Schmeiser*, [2003] 2 F.C. 165, 2002 FCA 309.

49                   The CBAC report says, at p. 6:

*The term “higher life form” is not defined in law. In common usage, it includes plants and non-human animals other than single-celled organisms.*  
[Emphasis added.]

The line, on this view, is not drawn between sentient beings and non-sentient beings or intelligent beings and unintelligent beings, but between simple one-cell organisms (such as bacteria) and their more complicated cousins, perhaps as rudimentary as moulds or other fungi.

50                   Other approaches abound. In a paper prepared for the Intellectual Property Policy Directorate of Industry Canada, *A Study of Issues Relating to the Patentability of Biotechnological Subject Matter* (1996), J. R. Rudolph offered the following explanation, at pp. 11-12:

Microorganisms are a large and diverse group of organisms consisting of only one cell or cell clusters of prokaryotic or eucaryotic cells. Examples of eukaryotic organisms are algae, fungi, molds and yeasts. An example of prokaryotes is bacteria. An important distinction between single cells or cell clusters which are microorganisms, and single cells or cell clusters which are not microorganisms, is that microbial cells are able to live alone in nature: single animal or plant cells or cell clusters are unable to exist by themselves in nature and can only be successful in either a specialized environment such as a culture system (typically created by man in the laboratory) or as part of a multicellular organism such as a plant or animal. The so-called “higher life forms” are complex multicellular organisms such as simple plants or oysters, for example, which contain thousands or hundreds of thousands of cells. The human, which is a complex multicellular organism, has been estimated to contain at least  $10^{14}$  cells. [Emphasis added.]

51           My colleague, Bastarache J., takes the view that a key factor is “the unique ability of higher life forms to self-replicate” (para. 170), but in fact self-reproduction is also a fundamental characteristic of “lower life forms”. Indeed, one of the most widely held objections to the genetically engineered bacteria in the *Chakrabarty* case was the potential for such unnatural bacteria to escape and reproduce in the wild with unknown consequences for the environment.

52           The various distinctions attempted to be made between “patentable” lower life composition of matter and “unpatentable” higher life composition of matter, shows, I think, the arbitrariness of the Commissioner’s approach. My colleague writes at para. 199:

The distinction between lower and higher life forms, though not explicit in the Act, is nonetheless defensible on the basis of common sense differences between the two.

With respect, there seems to be as many versions of “common sense” as there are commentators:



(1) Some would say all living organisms are excluded (e.g., Brennan J. for the dissenters in *Chakrabarty*);

(2) Some would allow micro-organisms but only those that can be produced en masse with identical features, like bacteria. In *Re Abitibi, supra*, the Patent Appeal Board recommended that patents extend “to all new life forms which are produced *en masse* as chemical compounds are prepared, and are formed in such large numbers that any measurable quantity will possess uniform properties and characteristics” (p. 89). “Mass” live organisms have a long history of patentability, including food products such as beer and yogurt.

(3) Then there are the proponents of “higher life” organisms versus “lower life” organisms, the latter being defined by the CBAC as having only a single cell.

(4) Others divide the universe between *prokaryotic* cells (e.g., bacteria and certain forms of algae) and *eukaryotic* cells (more complex life forms) and consider “higher” life forms to start only with more “complex” multicellular organisms.

(5) The Patent Appeal Board allowed multi-celled organisms such as moulds and fungi in *Connaught Laboratories, supra*.

(6) Some argue that “complex life forms” are unpatentable. Nadon J. took this position at trial in this case, [1998] 3 F.C. 510, at para. 35.

(7) The Commissioner issues patents for genetically modified complex plants (*Monsanto, supra*) but refuses to issue a patent for a genetically modified complex mouse.

(8) Others draw the line at sentient beings.

(9) Still others draw the line at “intelligent” beings.

(10) The Commissioner opened his argument in this case by asking whether “a complex, intelligent, living being could be considered an invention”.

53            In my view, none of these proposed dividing lines arise out of the present text of the *Patent Act*. All of them are policy driven and, if they are to be introduced at all, should be introduced by Parliament.

54            The Federal Court of Appeal and CBAC drew the line at human bodies in their entirety at any stage of development, as discussed below. The true basis for the exclusion is not extraneous to the *Patent Act* but lies in an explicit limitation in s. 40 which provides that:

**40.** Whenever the Commissioner is satisfied that an applicant is not by law entitled to be granted a patent, he shall refuse the application . . . .  
[Emphasis added.]

**40.** Chaque fois que le commissaire s’est assuré que le demandeur n’est pas fondé en droit à obtenir la concession d’un brevet, il rejette la demande . . . [Emphasis added.]

The reference to “by law” is not limited to the *Patent Act* itself (as the French version “*fondé en droit*” makes clear). It has been established for over 200 years that people cannot, at common law, own people: *Somerset v. Stewart* (1772), Lofft 1, 98 E.R. 499 (K.B.). The issue of whether a human being is a “composition of matter” does not, therefore, arise under the *Patent Act*. If further reinforcement is required, ss. 7 and 15 of the *Canadian Charter of Rights and Freedoms* would clearly prohibit an individual from being reduced to a chattel of another individual.

55           The situation here bears some resemblance to *Bishop v. Stevens*, [1990] 2 S.C.R. 467, a copyright case, where this Court refused to read an “implied exception to the literal meaning” (p. 480) of the broad rights given to copyright holders in s. 3(1)(d) of the *Copyright Act*, R.S.C. 1985, c. C-42. McLachlin J. (as she then was) stated that “policy considerations suggest that if such a change is to be made to the Act it should be made by the legislature, and not by a forced interpretation” (p. 485). And so it is in this case too.

56           The difference between the Commissioner and the CBAC is that the Commissioner wants the judges to read down the word “matter” to include only a subdivision of “matter” whereas the CBAC is making its proposal to the government, and through the government to Parliament, which is the proper forum in which such restrictions or regulatory structures should be debated and resolved.

(iii) “*Manufacture*”

57           The inventors argued that the oncomouse falls within the *extended* definition of “manufacture” in s. 2. I do not accept that view, but the submission is of significance

in terms of the correct approach to the interpretation of the *Patent Act*. The English law of patents finds its root in the *Statute of Monopolies* (1623), which defined the permissible subject matter for a patent in a rather limited way as the “sole working or making of any manner of new Manufactures” (s. 6). The definitional approach adopted by my colleague, Bastarache J., leads him to define “manufacture” in the context of the present s. 2 of the Act as “a non-living mechanistic product or process” (para. 159). However, the tradition of patent jurisprudence has been expansive, not restrictive. By 1851 the learned text *Godson on Patents* (2nd ed.) noted that the word “manufactures” had received from the English courts “very extended signification. It has not, as yet, been accurately defined; for the objects which may possibly come within the spirit and meaning of that act, are *almost infinite*” (p. 35 (emphasis added)).

58               Of course the word “manufacture” in our statute appears in conjunction with the words “art, . . . machine . . . or composition of matter” and must be read in context. Nevertheless, it is, I think, worth pointing out the contrast between the expansionist view that has characterized patent jurisprudence to date and the limiting view of the words “manufacture” and “composition of matter” now proposed by my colleague.

59               We should not encourage the Commissioner to try to circle each of the five definitional words with tight language that creates arbitrary gaps between, for example, “manufacture” and “composition of matter” through which useful inventions can fall out of the realm of patentability. To do so would conflict with this Court’s earlier expression of a “judicial anxiety to support a really useful invention”: *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504, *per* Dickson J. (as he then was), at p. 521, citing *Hinks & Son v. Safety Lighting Co.* (1876), 4 Ch. D. 607. The definition

of invention should be read as a whole and expansively with a view to giving protection to what is novel and useful and unobvious.

H. Negative Inference from the *Plant Breeders' Rights Act*

60           The Commissioner argues that we should take from the passage in 1990 of the *Plant Breeders' Rights Act*, S.C. 1990, c. 20, the negative inference that plants were not intended by Parliament to be patentable under the *Patent Act*. (I leave aside, for present purposes, the Commissioner's inconsistency in issuing a patent for Roundup Ready Canola in 1993, three years after the *Plant Breeders' Rights Act* was enacted — see *Monsanto, supra.*) From this questionable premise, the Commissioner reasons that, if plants are not patentable subject matter, the exclusion must also apply to other “higher life forms” such as seeds and animals, all of which are able to reproduce themselves. When *Pioneer Hi-Bred* was before the Federal Court of Appeal, Marceau J.A. expressed the view that, if Parliament had intended to include plants in the *Patent Act*, he would have expected that in the definition of invention in s. 2 “words such as ‘strain’, ‘variety’ or ‘hybrid’ would have appeared” ([1987] 3 F.C. 8, at p. 14).

61           I do not accept this argument. Firstly, there is nothing in the *Plant Breeders' Rights Act* that expressly bars an application under the *Patent Act*, which confers much more exclusive and valuable rights. The *Plant Breeders' Rights Act* grants protection for 18 years on the sale and propagation for sale of enumerated new plant varieties — cultivars, clones, breeding lines, or hybrids that can be cultivated. The plant breeder pays “annual maintenance fees and [must] provide propagating material throughout the term of [protection]. The right does not prevent the development of different varieties from protected plants or the use of seeds taken from protected varieties”: D. Vaver,

*Intellectual Property Law: Copyright, Patents, Trade-marks* (1997), at p. 126. As to the legislative purpose of the *Plant Breeders' Rights Act*, I agree with my colleague, Bastarache J., when he writes, at para. 192:

[I]t may well be that the *Plant Breeders' Rights Act* was passed not out of recognition that higher life forms are not a patentable subject matter under the *Patent Act*, but rather out of recognition that plant varieties deserve some form of intellectual property protection despite the fact that they often do not meet the technical criteria of the *Patent Act*.

The rights available under the *Plant Breeders' Rights Act* fall well short of those conferred by patent, both in comprehensiveness and in duration.

62                Secondly, to address the comment of Marceau J.A., use of specific terms such as “strain” or “hybrid” would undermine the generality that s. 2 seeks to achieve by use of the term “composition of matter”.

63                Thirdly, the *Patent Act* language reaches back (as stated) prior to Confederation. This particular argument suggests that a “negative inference”, arising when the plant legislation was enacted in 1990, should somehow be read back to narrow a definition that had at that time been in effect more than a century. This would amount to a repeal by implication, and would necessarily require an inconsistency between the two pieces of legislation. There is no such inconsistency. Rights acquired under both Acts can live together. Similar arguments were rightly rejected by the United States Supreme Court in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 122 S. Ct. 593 (2001).

I. Nature of Rights Granted by a Patent

64           A patent does not exempt the owner from any relevant regulation or prohibition. While s. 44 (now s. 42) of the *Patent Act* gives the owner, as against the rest of the world, “the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used” (emphasis added), and in that respect is framed as a positive right, its effect is essentially to prevent others from practising an invention that, but for the patent monopoly, they would be permitted to practise. In exchange for disclosure to the public, the patent protects the disclosed information from unauthorized use for a limited time.

65           The limited nature of the rights conferred by a patent was fully appreciated by CBAC in its Interim Report, *Biotechnology and Intellectual Property: Patenting of Higher Life Forms and Related Issues* (November 2001), at p. vi:

It is crucial for rational debate on questions related to what should or should not be patentable to recognize that patents confer only prohibitive rights. The Canadian patent system is not designed to decide about what uses of technology are permissible nor is the *Patent Act* designed to prevent dangerous or ethically questionable inventions from being made, used, sold or imported. The responsibility and tools for dealing with such matters resides elsewhere (e.g., through regulatory approval or product safety processes). [Emphasis added.]

I agree with this observation. This is not to say that patents are “neutral”, or have no link to the ethical and social issues raised by the interveners. It is to say that those issues transcend the narrow question of patentability circumscribed by ss. 2 and 40 of the *Patent Act*.

J. A Working Definition of “Life”

66           The subtext of much of the argument for the appellant Commissioner and his supporters invokes Dolly the cloned sheep and the potential of eugenics and “designer” human beings. However, the scientific notion of life begins at a much lower level. There is a good deal of debate about what constitutes “life” but some consensus about a few of its characteristics. These include the capacity to grow and develop (including reproduction), i.e., a metabolism, the ability of an organism to draw energy from its environment for this purpose, and the ability to respond to stimuli. Other characteristics are sometimes added. For example, the Massachusetts Institute of Technology, in designing its probe for extraterrestrial “life”, suggests that the definition of live organisms includes their tendency to ensure self-preservation, and that they be significantly differentiated from their surrounding environment.

67           Life is no less wondrous at the microscopic level, and to think of “life” primarily in terms of dolphins, chimpanzees and blue whales (examples urged by the appellant Commissioner in the oral hearing) is something of an oversimplification.

68           Some of the interveners objected to Harvard claiming credit for inventing a form of life. The Canadian Council of Churches and Evangelical Fellowship of Canada protested that the analysis of Rothstein J.A. “is built on a false premise that this [oncomouse] was a new form of life. It is not”. That is true, of course. Harvard did not construct the mouse from scratch, nor did it create “life”. What it did was to modify the genome of the oncomouse so that every cell in its body contained a modified gene. It is not like adding a new and useful propeller to a ship. The oncogene is everywhere in the genetically modified oncomouse, and it is this important modification that is said to give the oncomouse its commercial value, which is what interests the *Patent Act*.



69           The point is that Harvard is not being credited with inventing life. It claims to have modified every cell of a living creature in a new and useful way, and to the extent that modification is a valuable addition to the advancement of learning, Harvard claims only whatever rewards the *Patent Act* entitles it to for its disclosure.

K. The Ongoing Parliamentary Process in Canada

70           The appellant Commissioner of Patents invites the Court to intervene in the debate about a proper legal framework for genetic research (or hasten its conclusion prematurely) that is already underway in the government and in Parliament. None of the parties suggested that the *Patent Act* was an adequate vehicle to deal with biotechnology in general or the ethical issues arising from research into “higher life forms” (however defined) in particular. Patent rights are such a limited aspect of the debate that one would not expect to find such comprehensive regulation jammed into the *Patent Act*.

71           Parliament seems to be of that view. On May 9, 2002, as mentioned, the Minister of Health introduced into Parliament the *Assisted Human Reproduction Act* based in part on the work of CBAC. In its recent report dated June 2002, the CBAC accepted that life forms come within the definition of “invention” of the present patent legislation, and recommended that life forms *continue* to be patentable, but proposed an express exception in the case of *human life* as follows (at p. x):

*No patent shall be granted on human bodies at any stage of development.*

This, as earlier stated, is consistent with both the common law and the *Charter*. Such an amendment, the CBAC reasoned, at p. 9, would

apply only to entire human bodies from the zygote to an adult body; DNA sequences, gametes, stem and other cells, or organs will remain patentable. [Emphasis added.]

72           The CBAC emphasized that its proposed exemption related to the “whole human body and not . . . its parts” (for example, artificially created human organs), and intended the proposed exception to be “read narrowly” (p. 9). “It is important” opines the CBAC, “not to discourage research on stem cells and the creation of artificial organs” (p. 9). The CBAC recommended *against* extending non-patentability to non-human animals (which again presumes that under the current *Patent Act* non-human animals are patentable). The *Patent Act* is “not a sufficiently subtle instrument” for those evaluations, and the “dignity of and respect for animals can be better protected through animal welfare and habitat protection measures” (p. 10).

73           The majority of the CBAC also concluded that the “overall public good is best attained by providing patent rights over higher life forms, provided that these rights are no greater in substance than those granted over other inventions, taking into account the particularities of biologically based inventions” (p. 11). Given that one of those particularities is the ability to reproduce, among other characteristics, the CBAC states that this recommendation must be read together with several other recommendations, including the farmers’ privilege, protection for innocent bystanders, research and experimental use exception, guidelines for biological inventions, and establishment of an opposition procedure.

74           It is not our job to comment on the CBAC proposals one way or the other except to say that they are directed to the proper destination — the legislators.

L. Policy Arguments Against Granting a Patent for the Oncomouse

75           The appellant Commissioner contends that the Federal Court of Appeal showed no understanding that this case is a “harbinger of a new era”. The majority judgment, he says, looked narrowly at the case but failed to consider the broader context. What may have appeared as a small step for the oncomouse was, so to speak, a very large policy leap for patentability. Nevertheless, we must deal with the *Patent Act* as it is. Change ought to come through statutory amendment, not by the Court reading down the *Patent Act* to exclude non-human “higher life forms” from patentability by creative statutory interpretation.

76           The Court heard from a coalition of advocates opposed to the granting of a patent, including religious, environmentalist, agricultural, and non-profit research groups in addition to the concerns voiced by the Commissioner himself.

(i) *The Religious Objection*

77           Some opponents object to scientists “playing God”. A hint, perhaps, of their objection is reflected in the reasons of my colleague, Bastarache J., at para. 163:

Although some in society may hold the view that higher life forms are mere “composition[s] of matter”, the phrase does not fit well with common understandings of human and animal life.

78           I do not think that a court is a forum that can properly debate the mystery of mouse life. What we know, in this case, is that the inventors were able to modify a particular gene in the oncomouse genome, and produce a new, useful and unobvious

result. That is all we know about the mysteries of oncomouse life and, in my view, it is all we need to know for the purposes of this appeal.

(ii) *The “Lack of Regulatory Framework” Objection*

79           As already mentioned, much of the Commissioner’s argument turned on the lack of the regulatory framework that is necessary, he says, to address the ethical and scientific issues raised by genetic research. The argument is that because in his view genetic patents should be regulated, and because the *Patent Act* fails to do the job, Parliament cannot in 1869 have intended to grant patents for genetically engineered “higher” life forms. My colleague, Bastarache J., accepts this argument at para. 167, where he writes:

. . . the fact that the *Patent Act* in its current state is ill-equipped to deal appropriately with higher life forms as patentable subject matter is an indication that Parliament never intended the definition of “invention” to extend to this type of subject matter.

With respect, I do not agree.

80           First, we all probably have strong views that certain activities or things should be regulated. Some say contraceptive devices should not be patented because their use is immoral and unregulated. Others might wish to deny patents to environmentally risky chemical compositions for which, in their view, there is no adequate regulation. On the other hand, others feel that the use of potentially dangerous inventions like explosives and firearms should *not* be regulated. I do not think patents should be denied as a protest against perceived shortcomings in regulatory structures. The opponents of such patents should address themselves to Parliament, not the courts.

As Rand J. commented in *Commissioner of Patents v. Winthrop Chemical Co.*, [1948] S.C.R. 46, at p. 57:

. . . 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. [Emphasis added.]

This passage was quoted with approval in a patent context by Pigeon J. in *Tennessee Eastman Co. v. Commissioner of Patents*, [1974] S.C.R. 111, at p. 121, and again by Lamer J. in *Pioneer Hi-Bred, supra*, at p. 1643. What I consider to be the Commissioner's misinterpretation of s. 2 of the *Patent Act* proceeds, with respect, from "general considerations" of what he considers to be "reasonable or equitable" regulation of a controversial area of biotechnology. His views may or may not reflect desirable public policy but they have nothing to do with "the language" used by Parliament in s. 2 of the *Patent Act*.

81                This is not to deny the importance of context as an aid to statutory construction. It is simply to say that a court has no mandate to deny patentability because of the novelty or the potential social, economic or cultural impact of an invention, whether it be nuclear technology in the 1950s, biotechnology in the 1990s, or reproductive technology in the year 2002.

82                Second, regulation necessarily follows, rather than precedes, the invention. No doubt most people would agree that nuclear technology requires regulation; yet the regulation could hardly have been anticipated in 1869, decades before Ernest Rutherford, while at McGill University, with Frederick Soddy, first formulated the theory of atomic

disintegration. Prescription drugs are regulated, but the regulatory structure for new drug approval is not in the *Patent Act*. The grant of a patent does not allow the drug to be marketed. Nor should it. Health and safety are not, and never have been, the preoccupation of intellectual property legislation.

83           It is evident that there are as many areas of potential regulation as there are areas of invention. I think it is also evident that all of these regulatory regimes cannot and should not be put under the inadequate umbrella of the *Patent Act*. Parliament has shown a preference for using more specific statutes altogether outside the framework of patent law. This allows Parliament to tailor the statutory scheme and relevant incentives more precisely to the subject matters involved. Such collateral legislative activity, however, does not justify “reading down” the definition of “invention” in the *Patent Act*, in my opinion.

(iii) *The “Laws of Nature” Objection*

84           The appellant Commissioner rejected the oncomouse patent in part because the inventors exercised no control over the genetic characteristics of the mouse (hair colour, length of whiskers, etc.) except for the presence of the oncogene. Further, the Commissioner argued, the oncomouse is not reproducible *en masse* like bacteria. The trial judge upheld these objections. The animal resulting from the patented gene insertion process, he said, is “completely unknown and unknowable” because the mouse’s “inherent genetic makeup” controls many characteristics and the whole mouse, *with the exception of the oncogene*, is completely independent of human intervention. This is true but not, in my opinion, relevant. The utility of the invention has nothing to

do with the length of the mouse's whiskers. Its value, in terms of the patent, appears to reside wholly in the oncogene.

85           My colleague, Bastarache J., as stated, acknowledges that the fertilized genetically modified egg is patentable (para. 162) but accepts the Commissioner's argument that the oncomouse itself is unpatentable because it develops through the natural process of gestation (which everyone agrees was not invented by Harvard) without further "human intervention" (para. 162). Rothstein J.A. rejected this argument (at para. 121):

Although the natural gestation process is required to allow the fertilized mouse egg to develop, this does not mean the organism ceases to become a "composition of matter" as it develops from the single-cell stage into an oncomouse. The founder oncomouse is therefore itself a composition of matter.

86           Counsel for the Commissioner says there is a world of difference between a fertilized single cell and the animal it becomes, but if the one is allowed, where is the cut-off point? At what point in the process of gestation does the fertilized single cell *cease* to be a "composition of matter"?

87           Counsel for the Commissioner says that growth from a single fertilized cell to the complete mouse has nothing to do with the inventors and everything to do with the "laws of nature". This is true (although each cell of the live mouse contains the genetic modification), but this is scarcely a fatal objection. The "laws of nature" are an essential part of the working of many and probably most patented inventions. Patents on biotechnical processes such as fermentation, wholly dependent on the "laws of nature", were first issued in the early 1800s. Pharmaceutical drugs utilize the normal bodily

processes and functions of animals and humans and are not on that account regarded as less patentable. The anti HIV-AIDS drug AZT ingested orally would achieve nothing were it not circulated and processed through the body by the “laws of nature”. Indeed, the AZT pill, like the oncomouse, could not be brought into existence without reliance on “the laws of nature” in general and the processes of biochemistry in particular. In *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153, 2002 SCC 77, released concurrently, we uphold as valid the AZT patent despite the fact that AZT would lack utility (a statutory prerequisite to the issuance of a patent) unless the “laws of nature” arranged for it to “be absorbed into the human blood stream, make its way to the T-cells infected with HIV, enter the T-cells and inhibit the reproduction of the HIV infection without proving toxic to other cells, and demonstrate clinical improvement in the patient” (para. 20). Such natural processes, before, during and after the construction of the pill, are no more the creation of the AZT inventor than the gestation of an oncomouse (essential to *its* utility) is the creation of the Harvard inventors. An inventor whose invention harnesses the forces of nature is no less an inventor.

(iv) *The “De Minimis” Objection*

88           The Commissioner rather downplays the inventor’s achievement. The implicit objection seems to be, “What’s 1 gene in 30,000?” My colleague writes, at para. 163:

A person whose genetic make-up is modified by radiation does not cease to be him or herself. Likewise, the same mouse would exist absent the injection of the oncogene into the fertilized egg cell; it simply would not be predisposed to cancer.



89               Such an argument, it seems to me, significantly understates the scientific achievement. The “modification” of the gene is not an add-on. Modification of even a single gene does not, with respect, leave the creature like “him or herself” or “the same mouse”. Genetic modification is not like a haircut or a tonsillectomy. Modification or mutation of even a single gene can have colossal consequences. It is instructive, for example, to note the description of Tay-Sachs disease, mentioned earlier, which results in infantile deaths from the mutation of but a *single* gene:

... a familial disease of infancy in which there is a progressive degeneration of nerve cells throughout the whole nervous system and in the retina. It is characterized clinically by progressive muscular weakness and paralysis, mental deterioration and blindness, usually leading to death in coma or convulsions towards the end of the second year.

(*Butterworths Medical Dictionary* (2nd ed. 1978), at p. 1496)

Any suggestion that a child with or without the mutant Tay-Sachs gene is “the same person” would seriously underestimate the power of the science that we are being asked to consider.

(v) *Ordre Public or Morality*

90               NAFTA and TRIPS each provide that contracting states may *exclude* from patentability inventions the exploitation of which would be contrary to *ordre public* (which seemingly equates to the protection of public security, the physical integrity of individuals as members of society, and the protection of the environment) or morality: *North American Free Trade Agreement Between the Government of Canada, the Government of the United Mexican States and the Government of the United States of America* (1992), Can T.S. 1994 No. 2 (entered into force January 1, 1994), art. 1709(2);

*Agreement on Trade-Related Aspects of Intellectual Property Rights* (April 15, 1994), 1869 U.N.T.S. 299, art. 27(2). The exclusion presupposes a general rule of patentability. Parliament has amended the *Patent Act* to take account of each of these agreements, but has chosen not to include such an exclusion from patentability in the *Patent Act*.

91           The *European Patent Convention* contains an *ordre public* exclusion from patentability, and the corresponding European “oncomouse” patent application was examined having specific regard to this exclusion. In its decision of April 3, 1992, the Examining Division of the European Patent Office stated the issue as follows:

In the case at hand three different interests are involved and require balancing: there is a 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, moreover, cruelty to animals has to be avoided. The latter two aspects may well justify regarding an invention as immoral and therefore unacceptable unless the advantages, i.e. the benefit to mankind, outweigh the negative aspects.

(*Grant of European patent No. 0 169 762 (Onco-mouse/Harvard)* (1992), OJ EPO 1992, 588, at pp. 591-92)

We do not possess such a “balancing” test in our *Patent Act*, though some thought must have been given to it when Parliament “opened up” the *Patent Act* for NAFTA and TRIPS-related amendments in 1994.

92           The Examining Division of the European Patent Office concluded that issuance of the oncomouse patent was not contrary to *ordre public* or public morality and further that “[i]f the legislator is of the opinion that certain technical knowledge should be used under limited conditions only it is up to him to enact appropriate legislation” (*id.*, p. 591).

93           The European Community Directive on biotechnology (*Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological invention*) names specific inventions (human cloning, modifying germ line, commercial use of human embryos, and causing suffering to animals without substantial medical benefit to humans or animals) as contrary to *ordre public* or morality. If Parliament thinks it wise to spell out such a policy in the *Patent Act*, it will pass appropriate amendments. More likely, as the government has already signalled, such measures will be put into special legislation equivalent to the proposed *Assisted Human Reproduction Act*.

(vi) *Unjust Enrichment*

94           Other critics take the view that the rewards given by a patent, whether they reflect innovation or not, are unjust. Why, it is asked, should Harvard be rewarded for “inventing” a creature that occurs in its original form in nature? In a scientific laboratory, the wild mouse becomes a research platform. Harvard researchers made an “improvement” by genetic modification, but the remaining unmodified genes contribute to producing the mouse, and shaping its reaction to the laboratory experiments. Why, then, should the whole mouse be considered “patentable”? Why should Harvard appropriate to itself the whole value attributable to the “platform” when all it contributed is an improvement to that platform?

95           Such an argument relates to remedies rather than patentability. A view that the *Patent Act* rewards a patent owner too richly is not a sound basis on which to deny

a patent. The inventor of the frisbee (patented in 1967) would also, no doubt, be thought by some critics to have been excessively rewarded.

96           The scientific accomplishment manifested in the oncomouse is profound and far-reaching, and a numerical count of the genes modified and the genes not modified misses the point. Every cell in the animal's body has been altered in a way that is profoundly important to scientific research. If researchers were to discover that cancers were entirely attributable to one gene and then modified individuals so that they were cancer-free, no one would deny that such a modification would be of enormous importance regardless of the fact that only one gene was changed.

97           Researchers who wish to use a wild mouse can catch one in the parking lot. Harvard would have no complaint. It is only if they wish to take advantage of the advances in learning disclosed in the oncomouse patent that they would require authorization from the inventor who made the disclosure they now seek to exploit.

98           If the patent were refused on the oncomouse itself, it would be easy for "free riders" to circumvent the protection sought to be given to the inventor by the *Patent Act* simply by acquiring an oncomouse and breeding it to as many wild mice as desired and selling the offspring (probably half of which will be oncomice) to the public. The weakness of this protection would undermine the incentives intended by the *Patent Act*. I agree with William Hayhurst when he writes:

Some patents for processes may be of little practical value. To discover that a competitor is carrying out the process may be difficult. If a process produces a living organism that reproduces itself, the process may have to be carried out only once: competitors who are able to get their hands on the organism need not repeat the process of producing it. What is needed is a patent for the organism . . . .

(W. L. Hayhurst, "Exclusive Rights in Relation to Living Things" (1991), 6 *I.P.J.* 171, at p. 177)

99           On the other hand, if the oncomouse is patented, and Harvard obtains a judgment for the infringer's profits, the infringer could always contend that the profits should be apportioned between profits attributable to the invention and those profits not attributable to the invention. Harvard will contend that the whole of the laboratory value of the oncomouse is due to its genetic make-up. Others may disagree. Such questions remain, at this stage, entirely premature.

(vii) *Animal Rights*

100           Animal rights supporters object to the fact that the oncomouse is deliberately designed to cause sentient beings to grow painful malignant tumours. Of course, whatever position is adopted under *patent* law, animals have been and will continue to be used in laboratories for scientific research. Pets are property. Mice are already commodified. Parliament may wish to address animal rights as a distinct subject matter. If the claim for the patent on the oncomouse itself is refused, the result will *not* be that Harvard is denied the opportunity to make, construct, use and sell the oncomouse. On the contrary, the result will be that *anyone* will be able to make, construct, use and sell the oncomouse. The only difference will be that Harvard will be denied the *quid pro quo* for the disclosure of its invention.

(viii) *The Commodification of Human Life*

101           Some critics argue that life and property rights are incompatible. Patents, they say, treat “life” as a commodity that can be bought and sold, and therefore diminish the respect with which life ought to be regarded. Living entities become “objects”.

102           The major concern is that human beings constitute a line that cannot be crossed. The CBAC agrees. But others argue that patenting *any* form of life puts us on a slippery slope. Today the oncomouse; tomorrow Frankenstein’s creature. I do not agree. There is a qualitative divide between rodents and human beings. The broadest claim here specifically excepts humans from the scope of transgenic mammals. Moreover, for the reasons already expressed, I do not believe that the issue of patentability of a human being even arises under the *Patent Act*.

(ix) *Environmental Protection*

103           Environmental concerns include the diversity of the gene pool and potential escape of genetically modified organisms into the environment. These are serious concerns which serious people would expect Parliament to address. The concerns, however, have little to do with the patent system. Patents or no patents, genetically engineered organisms have arrived in our midst. The genie is out of the bottle. As Rothstein J.A. observed, “even if the oncomouse were found not to be patentable, such a decision would not prevent inventors from developing the product or indeed, other genetically engineered living organisms” (para. 197). Patentability addresses only the issue of rewarding the inventors for their *disclosure* of what they have done. Larger questions are answered elsewhere.

(x) *Globalization*

104           Anti-globalization groups object to the impact of broad patentability on developing countries, noting that research dollars and the beneficial effects of patented products are concentrated in developed countries. This criticism is, of course, first a broad attack on intellectual property rights generally and, second, a vote of no confidence in multilateral agreements such as TRIPS. The concerns of developing countries have received wide attention, and rightly so. A countervailing consideration is that the developing world may lose as much benefit as the economically developed world if excessive emphasis is placed on granting equitable access to inventions already made as opposed to continuing to offer adequate incentives for inventions to come. This too is an issue that does not arise for consideration on this appeal.

(xi) *Contrary Considerations*

105           If a certain subject matter is unpatentable as a matter of law, inventors who do carry on inventing will gravitate toward alternative sources of protection. The most obvious would be trade secrets protection. The problem with this alternative, in terms of the public interest, is that the public would lose the *quid pro quo* of public disclosure that they receive under patent law.

106           Lacking legal protection against unauthorized appropriation of ideas, ingenious people may tend to hide and hoard the products of their ingenuity rather than disclose them for others to build on that knowledge. The “hide and hoard” mentality was the very mischief the *Patent Act* was aimed at.

107           There are, in other words, many policy implications of *excluding* patent protection as well as the policy implications of inclusion relied upon by the appellant Commissioner. The balance between the competing interests is for Parliament to strike.

(xii) *Policy Options*

108           Parliament may wish to regulate *outside* the framework of the *Patent Act* the creation and use of “higher life forms” (however Parliament chooses to define “higher” life forms) in many ways: ethics boards could be set up to consider “higher life form” patentability on a case-by-case basis, including any patent applications on human genetic material; animal rights legislation might require that all transgenic animal varieties be “engineered” to alleviate or mitigate pain from experimentation; a policy of balancing the potential alleviation of human suffering against animal suffering might be added. Patents on human genetic material, including stem cell research and cloning, might include a provision to exempt all research from patent infringement, or specify compulsory licences for such research.

109           Even a partial listing of the possibilities demonstrates why it should occasion no surprise that such regulatory structures are not crammed into the *Patent Act*, which has always had the more modest and focussed objective of simply encouraging the disclosure of the fruit of human inventiveness in exchange for the statutory rewards.

M. Alleged Deficiencies in the Patent Regime

110           There is much scholarly controversy in Canada over the role of intellectual property in biotechnology: E. R. Gold, *Body Parts: Property Rights and the Ownership*



*of Human Biological Materials* (1996); E. R. Gold, “Making Room: Reintegrating Basic Research, Health Policy, and Ethics Into Patent Law” in T. A. Caulfield and B. Williams-Jones, eds., *The Commercialization of Genetic Research: Ethical, Legal, and Policy Issues* (1999), 63; T. A. Caulfield, “Underwhelmed: Hyperbole, Regulatory Policy, and the Genetic Revolution” (2000), 45 *McGill L.J.* 437; B. M. Knoppers, “Reflections: The Challenge of Biotechnology and Public Policy” (2000), 45 *McGill L.J.* 559; P. R. Mooney, *The Impetus for and Potential of Alternative Mechanisms for the Protection of Biotechnological Innovations* (March 2001), at p. 13.

111           Some thoughtful critics suggest that patents in this field may in fact deter rather than promote innovation: M. A. Heller and R. S. Eisenberg, “Can Patents Deter Innovation? The Anticommons in Biomedical Research” (1998), 280 *Science* 698; Gold, “Biomedical Patents and Ethics: A Canadian Solution”, *supra*.

112           On a more technical level, it is pointed out that a 20-year patent is a very long time in the life cycle of biotechnology. A shorter patent life, with conditions more tailored to the industry, would, it is said, provide sufficient incentive. Then there are those who advocate the “farmers’ privilege” to avoid farmers being subject to patent enforcement in the case of the progeny of patented plants and animals. Others advocate protection for “innocent bystanders” who inadvertently make use of a genetically engineered plant or animal, unaware of its being patented.

113           My colleague, Bastarache J., suggests that the *absence* of such provisions supports his conclusion that the oncomouse is unpatentable, but this approach, with respect, simply substitutes the Court’s notion of good public policy for the judgment of Parliament, whose members are well aware of these and similar proposals. Parliament

has had the *National Biotechnology Strategy* since 1983, renewed as the *Canadian Biotechnology Strategy: An Ongoing Renewal Process* 15 years later in 1998, the work of the CBAC and *Proceed with Care: Final Report of the Royal Commission on New Reproductive Technologies* (1993).

114           Parliament may find merit in some of the CBAC proposals for legislative reform enumerated by my colleague, Bastarache J., in his judgment at paras. 169 to 175, and 183, but Parliament has not done so to date, and neither the Commissioner of Patents nor the courts have the authority to declare, in effect, a moratorium on life (or “higher” life) patents until Parliament chooses to act. The respondent is entitled to have the benefit of the *Patent Act* as it stands.

N. Conclusion

115           In my view, the oncomouse is patentable subject matter. This does not mean that claims 1 to 12 therefore must be allowed. They ought to be considered by the Commissioner in accordance with the usual patent principles (note, for example, that the European Patent Office ultimately modified claim no. 1 to include only “transgenic rodents” rather than, as claimed, “transgenic non-human mammals”: *European Patent Office Press Release*, November 7, 2001).

116           I would therefore have remitted the patent application to the Commissioner to have the specific claims 1 to 12 considered and dealt with.

117           I would dismiss the appeal.

The judgment of L'Heureux-Dubé, Gonthier, Iacobucci, Bastarache, and LeBel JJ. was delivered by

BASTARACHE J. —

I. Introduction

118           This appeal raises the issue of the patentability of higher life forms within the context of the *Patent Act*, R.S.C. 1985, c. P-4. The respondent, the President and Fellows of Harvard College, seeks to patent a mouse that has been genetically altered to increase its susceptibility to cancer, which makes it useful for cancer research. The patent claims also extend to all non-human mammals which have been similarly altered.

119           The Commissioner of Patents upheld the Patent Examiner's refusal to grant the patent. This decision was in turn upheld by the Federal Court, Trial Division, but was overturned by a majority of the Federal Court of Appeal. A preliminary issue is the standard of review applicable to the Commissioner's decision to refuse the patent. I agree with the majority of the Federal Court of Appeal that the standard applicable to the Commissioner's decision in this case is correctness. While the decision to refuse to grant a patent may in some cases be accorded deference, the nature of the question is in this case determinative. In my view, the courts are as well placed as the Commissioner to decide whether the definition of invention in s. 2 of the *Patent Act* encompasses higher life forms, since this question approaches a pure determination of law that has significant precedential value. Nor do I agree with the minority of the Federal Court of Appeal's position that the Commissioner's decision is owed deference for the reason that he has a discretion to refuse a patent on public policy grounds. To refuse a patent, the

Commissioner must be satisfied that the applicant is not “by law” entitled to the patent, wording which indicates that the Commissioner has no discretion independent of the *Patent Act* to consider the public interest when granting or denying a patent.

120           Given that there is no discretion on the part of the Commissioner to deny a patent on a particular subject matter of invention, the sole question is whether Parliament intended the definition of “invention”, and more particularly the words “manufacture” or “composition of matter”, within the context of the *Patent Act*, to encompass higher life forms such as the oncomouse. In my opinion, Parliament did not intend higher life forms to be patentable. Had Parliament intended every conceivable subject matter to be patentable, it would not have chosen to adopt an exhaustive definition that limits invention to any “art, process, machine, manufacture or composition of matter”. In addition, the phrases “manufacture” and “composition of matter” do not correspond to common understandings of animal and plant life. Even accepting that the words of the definition can support a broad interpretation, they must be interpreted in light of the scheme of the Act and the relevant context. The Act in its current form fails to address many of the unique concerns that are raised by the patenting of higher life forms, a factor which indicates that Parliament never intended the definition of “invention” to extend to this type of subject matter. Given the unique concerns associated with the grant of a monopoly right over higher life forms, it is my view that Parliament would not likely choose the *Patent Act* as it currently exists as the appropriate vehicle to protect the rights of inventors of this type of subject matter.

## II. Factual Background

121               On June 21, 1985, the respondent, the President and Fellows of Harvard College (“Harvard”), applied for a patent on an invention entitled “transgenic animals”. The invention aims to produce animals with a susceptibility to cancer for purposes of animal carcinogenic studies. The animals can be used to test a material suspected of being a carcinogen by exposing them to the material and seeing if tumours develop. Because the animals are already susceptible to tumour development, the amount of material used can be smaller, thereby more closely approximating the amounts to which humans are actually exposed. In addition, the animals will be expected to develop tumours in a shorter time period. The animals can also be used to test materials thought to confer protection against the development of cancer.

122               The technology by which a cancer-prone mouse (“oncomouse”) is produced is described in the patent application disclosure. The oncogene (the cancer-promoting gene) is obtained from the genetic code of a non-mammal source, such as a virus. A vehicle for transporting the oncogene into the mouse’s chromosomes is constructed using a small piece of bacterial DNA referred to as a plasmid. The plasmid, into which the oncogene has been “spliced”, is injected into fertilized mouse eggs, preferably while they are at the one-cell stage. The eggs are then implanted into a female host mouse, or “foster mother”, and permitted to develop to term. After the offspring of the foster mother are delivered, they are tested for the presence of the oncogene; those that contain the oncogene are called “founder” mice. Founder mice are mated with mice that have not been genetically altered. In accordance with Mendelian inheritance principles, 50 percent of the offspring will have all of their cells affected by the oncogene, making them suitable for the uses described above.

123 In its patent application, the respondent seeks to protect both the process by which the oncomice are produced and the end product of the process, i.e. the founder mice and the offspring whose cells are affected by the oncogene. The process and product claims also extend to all non-human mammals. In March 1993, by Final Action, a Patent Examiner rejected the product claims (claims 1 to 12) as being outside the scope of the definition of “invention” in s. 2 of the *Patent Act*, but allowed the process claims (claims 13 to 26). In August 1995, after a review by the Commissioner of Patents and a hearing before the Patent Appeal Board, the Commissioner confirmed the refusal to grant a patent for claims 1 to 12. The Federal Court, Trial Division dismissed the respondent’s appeal from the decision of the Commissioner. The respondent’s further appeal to the Federal Court of Appeal was allowed by a majority of the court, Isaac J.A. dissenting. The Commissioner of Patents appeals from that decision.

### III. Relevant Statutory Provisions

124 *Patent Act*, R.S.C. 1985, c. P-4

2. In this Act, except as otherwise provided,

...

“invention” means 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;

2. Sauf disposition contraire, les définitions qui suivent s’appliquent à la présente loi.

...

« invention » Toute réalisation, tout procédé, toute machine, fabrication ou composition de matières, ainsi que tout perfectionnement de l’un d’eux, présentant le caractère de la nouveauté et de l’utilité.

**27.** (1) The Commissioner shall grant a patent for an invention to the inventor or the inventor's legal representative if an application for the patent in Canada is filed in accordance with this Act and all other requirements for the issuance of a patent under this Act are met.

**40.** Whenever the Commissioner is satisfied that an applicant is not by law entitled to be granted a patent, he shall refuse the application and, by registered letter addressed to the applicant or his registered agent, notify the applicant of the refusal and of the ground or reason therefor.

#### IV. Judicial History

##### A. *Decision of the Patent Examiner — Final Action* (March 24, 1993)

125               As noted above, the Patent Examiner refused claims 1 to 12, which pertain to the transgenic mice and mammals as products of the invention, but allowed claims 13 to 26 pertaining to the process.

126               The Patent Examiner's rejection of claims 1 to 12 was based on his conclusion that higher life forms fall outside the definition of "invention" as given in s. 2 of the *Patent Act*, and therefore are not patentable subject matter. He cited several cases for the proposition that the Commissioner has a right to interpret s. 2 as excluding certain subject matter from patentability on the basis that it is not in the public interest to grant a patent: *Commissioner of Patents v. Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning*, [1964] S.C.R. 49, at p. 56; *Lawson v. Commissioner of Patents* (1970), 62 C.P.R. 101 (Ex. Ct.), at p. 109; *Tennessee Eastman Co. v. Commissioner of Patents*, [1974] S.C.R. 111, at p. 119.

127           In addition, the Patent Examiner noted that neither the Patent Appeal Board nor the courts have expressly stated that higher life forms constitute patentable subject matter. In *Re Application of Abitibi Co.* (1982), 62 C.P.R. (2d) 81, the Patent Appeal Board held only that lower life forms were patentable. In *Re Application for Patent of Pioneer Hi-Bred Ltd.* (1986), 11 C.P.R. (3d) 311 (Pat. App. Bd.), the Commissioner rejected claims to a plant and its seed under s. 2 of the Act. While the Supreme Court of Canada did not make a ruling on the Commissioner's decision to reject the claims (see *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623), the majority of the Federal Court of Appeal upheld the Commissioner's rejection of these claims under s. 2 of the Act (*Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1987] 3 F.C. 8). The Patent Examiner concluded that he was bound by the Federal Court of Appeal decision in *Pioneer Hi-Bred, supra*, since if a plant is held to be non-patentable subject matter, then the same must be said for animals.

B. *Decision of the Commissioner of Patents* (August 4, 1995)

128           The Commissioner of Patents disagreed that he had a right or an obligation to decide that a particular invention can be found unpatentable as a matter of policy or discretion rather than as a result of an interpretation of the provisions of the *Patent Act*: *Monsanto Co. v. Commissioner of Patents*, [1979] 2 S.C.R. 1108; *Farbwerke Hoechst, supra*. The Commissioner stated that in order to reject an application, he must be satisfied that by law the applicant is not entitled to a patent and be able to give reasons based on an interpretation of the *Patent Act* and applicable jurisprudence.

129           The Commissioner went on to note that in *Pioneer Hi-Bred, supra*, this Court deliberately chose not to decide whether the soybean resulting from artificial



crossbreeding was a patentable invention under s. 2 of the Act. On this basis, the Commissioner concluded that neither he nor the examiner is bound by the decision of the Federal Court in that case: *R. v. Secretary of State for the Home Department, ex parte Al-Mehdawi*, [1989] 1 All E.R. 777 (C.A.). Nonetheless, he determined that the decision of the majority of the Federal Court of Appeal in *Pioneer Hi-Bred* could be of high persuasive influence.

130           Turning to the issue at hand, the Commissioner expressed the view that the words “manufacture” and “composition of matter” as found in s. 2 apply to something that has been made under the control of the inventor. At the same time, the resulting product must be reproducible in a consistent manner. Considering the invention in question, the Commissioner determines that there are two distinct phases. The first phase involves the preparation of the genetically engineered plasmid. The second involves the development of a genetically engineered mouse in the uterus of the host mouse. The Commissioner concluded that while the first phase is controlled by human intervention, in the second phase it is the laws of nature that take over to produce the mammalian end product. He was therefore unwilling to extend the meaning of “manufacture” or “composition of matter” to include a non-human mammal. In his view, the inventors do not have full control over all of the characteristics of the resulting mouse, and human intervention ensures that reproducibility extends only so far as the cancer-forming gene.

C.   *Federal Court, Trial Division*, [1998] 3 F.C. 510

131           Nadon J. conceded that there is no dispute that the oncomouse is new, useful and unobvious. The question is whether it is an “invention” to which the *Patent Act* applies. He reviewed the decision of the U.S. Supreme Court in *Diamond v.*

*Chakrabarty*, 447 U.S. 303 (1980), a decision cited by Harvard in support of the grant of the patent. In *Chakrabarty*, a majority of five judges held that the proper question in patenting a bacterium used to degrade crude oil was whether the subject of the patent application was “human-made” or was something occurring naturally. On that basis they allowed the claim. The minority of four referred to the existence of the 1930 *Plant Patent Act* and the 1970 *Plant Variety Protection Act* and concluded that Congress had provided separate intellectual property protection for living things within these statutes, thus signalling a lack of intention to include living things within the scope of the U.S. *Patent Act*. Nadon J. expressed his preference for the minority view.

132               Nadon J. turned next to examine what is meant by “manufacture” and “composition of matter” in the Canadian Act. He examined four issues which, in his view, serve as indicia of how s. 2 should be construed. First, he considered whether the degree of an inventor’s control over the creation is a relevant factor. In this respect, he noted that the process of insertion of the oncogene into the fertilized mouse egg is already patented. But a mouse is a complex life form with many features that are not under the control of the inventors. Though the inventors have created a method to inject eggs with an oncogene, they have not invented the mouse. Nadon J. further stated that even on the broadest interpretation he could not find that a mouse is “raw material” which was given new qualities by the inventor.

133               Second, he considered the distinction between human intervention and the laws of nature. In this regard, he observed that anything which is merely a discovery is not patentable subject matter. There must be some inventive step involved. He agreed with the respondent that the essential feature of the mouse is the presence of the transgene, since this is what makes it useful for testing carcinogens. In addition, he

agreed that the transgene would not be present without human intervention, rendering the oncomouse a “marriage between nature and human intervention” (para. 27). He noted, however, that not all the offspring mice have the gene. The presence of the gene only transfers with the natural rate of inheritance, the “Mendelian ratio”. After the gene has been introduced, the gene passes with a normal breeding process. This, Nadon J. stated, is akin to the crossbreeding process that was suggested to be unpatentable in *Pioneer Hi-Bred*, by reason that it is simply in line with the laws of nature. In a chemical process, the chemical reaction and its products are known and constant, whereas the parameters of the resulting mammal in this case are largely unknown and change every time.

134                Third, Nadon J. considered the relevance of the test of reproducibility. In his view, the question of reproducibility is related to the scope of the respondent’s invention. He concluded that because the respondent is not merely claiming the transgene but the entire mammal, and the respondent has not made any claims to even minor control over any aspect of the mammal except the presence of the transgene, the respondent can make no claim to being able to reproduce the mammal at will by doing anything other than ordinary breeding.

135                Finally, Nadon J. considered whether it is appropriate to make distinctions between higher and lower life forms. He noted that *Abitibi, supra*, only claimed lower life forms were patentable if they were reproducible *en masse*. Since the Federal Court of Appeal in *Pioneer Hi-Bred, supra*, disallowed a patent claim over the result of the crossbreeding of soybeans, Nadon J. was of the view that the same result ought to apply to the “cross-breeding of mice” (para. 33), which is essentially what occurs when a founder mouse is bred with an ordinary mouse. Although he did not directly consider

policy issues, Nadon J. remarked that it would be appropriate to make a distinction between higher and lower life forms on the grounds of policy. He further concluded that a complex life form does not fit within the current parameters of the *Patent Act* without stretching the meaning of the words to the breaking point. If Parliament so wishes, it clearly can alter the legislation so that mammals can be patented.

D. *Federal Court of Appeal*, [2000] 4 F.C. 528

(1) Rothstein J.A.

136 Speaking for the majority of the court, Rothstein J.A. reversed the decision of the court below and directed the Commissioner of Patents to grant a patent covering claims 1 to 12 of the Patent Application. At the outset, Rothstein J.A. remarked that s. 40 of the Act, which permits the Commissioner to refuse a patent, is not discretionary. In addition, he expressed the view that policy considerations were not relevant in the appeal since all that was at issue was the interpretation of the *Patent Act*.

137 Rothstein J.A. then stated his conclusion that the oncomouse is a “composition of matter”. In this regard, he accepted the expansive definition adopted by the majority of the U.S. Supreme Court in *Chakrabarty, supra*, and further noted that “[t]he language of patent law is broad and general and is to be given wide scope because inventions are, necessarily, unanticipated and unforeseeable” (para. 116). Rothstein J.A. explained that both the DNA and the fertilized mouse egg are forms of biological matter which, when combined, are a “composition of matter”. This composition of matter is transferred to a host mouse and allowed to develop to term, resulting in a founder mouse that is the product of the “composition of matter”. Similarly, offspring mice are the

product, since they are linked to the transgenic unicellular material which the Patent Commissioner found to be a composition of matter. In addition, nothing in the term “composition of matter” suggests that living things are excluded from the definition. Nor is the oncomouse a mere discovery or product of nature, since its genetic structure is different from what it would have been without intervention at the genetic level.

138 Rothstein J.A. then outlined why he differs with the reasoning and conclusions of the Patent Commissioner and the trial judge. He reiterated his view that the majority reasoning in *Chakrabarty, supra*, was convincing and further rejected the minority position that there is a “common understanding” that patents are not available to cover living organisms. He turned next to the issue of control. In his view, it is apparent that the control (and reproducibility) tests are not freestanding, but are rather implicit in the statutory requirement that an “invention” be “useful”. However, in this case, the Patent Commissioner and the trial judge applied a far broader control test, not implied by the usefulness requirement for an invention. He further concluded that control over the length of a tail, colour of eyes or texture of fur is irrelevant to the usefulness of the invention. All that is important for the usefulness of the product in this case is that a mouse is produced with all of its cells affected by the oncogene.

139 In respect to reproducibility, Rothstein J.A. reiterated his view that the fact that other characteristics of the oncomouse are not reproducible by will by the inventor or a person skilled in the science is irrelevant because they are not necessary for the usefulness of the oncomouse. Other than the requirement for sufficient disclosure of an invention in s. 27(3)(b), about which there is no dispute on this appeal, there is nothing in the *Patent Act* pertaining to reproducibility which the inventors can be said to have failed to meet. Rothstein J.A. also disagreed with the Commissioner’s approach of

dividing the invention into two phases on the basis that, once it is accepted that most inventions involve the laws of nature, “there can be no valid basis for splitting an invention between the portion that is the result of inventive ingenuity and the portion that is not” (para. 167). He further noted that full protection for the inventors would require a patent on both the process and the product, since without a patent on the product anyone could purchase a founder mouse or offspring having the oncogene in its cells and breed it.

140 Rothstein J.A. went on to conclude that the court below placed too much emphasis on the Federal Court of Appeal reasons in *Pioneer Hi-Bred, supra*. He distinguished *Pioneer Hi-Bred* on the basis that it dealt with the crossbreeding of plants, whereas in the current case there is intervention at the genetic level and a sharp and permanent alteration of a hereditary trait. In response to Isaac J.A.’s findings on the standard of review, Rothstein J.A. concluded that the decision of the Commissioner should be reviewed on a standard of correctness since the issue — whether higher life forms come within the definition of “invention” — is a fundamental one which will have significant precedential value. In addition, even if the standard were reasonableness *simpliciter*, Rothstein J.A. would have concluded that the Commissioner’s decision was clearly wrong.

141 A final question considered by Rothstein J.A. was whether the *Patent Act* could be extended to cover human beings. Rothstein J.A. answered this question in the negative on the basis that patenting is a form of ownership of property which would be prohibited pursuant to s. 7 of the *Canadian Charter of Rights and Freedoms*.

142 Isaac J.A. dissented primarily on the grounds that the decision of the Commissioner should be accorded deference. In his view, the standard of review applicable to the Commissioner's decision was reasonableness *simpliciter*. This view was based on the Commissioner's expertise, the fact that the nature of the question (the patentability of the oncomouse) is squarely within that expertise, and the purpose of the Act. In respect to purpose, Isaac J.A. expressed the view that the Commissioner is entitled to consider the public interest at stake when reviewing a patent application. Isaac J.A. concluded that the Commissioner's decision was reasonable because it took a cautious approach to the patenting of new life forms. Isaac J.A. also noted that the Commissioner is entitled to refuse a patent under s. 40 if, by law, the applicant is not entitled to it. In his view, though the Commissioner was not bound by the Federal Court of Appeal's decision in *Pioneer Hi-Bred, supra*, he was entitled to find it highly persuasive. Finally, Isaac J.A. noted that following the refusal of the Supreme Court of Canada in *Pioneer Hi-Bred* to accommodate crossbred soybean varieties within the definition of "invention", Parliament enacted the *Plant Breeders' Rights Act*, S.C. 1990, c. 20. He concluded, at para. 78:

In all the circumstances of this case, including the limited role that our jurisprudence has assigned to the courts in this area and the serious moral and ethical implications of this subject-matter, it seems to me that Parliament is the most appropriate forum for the resolution of the issues in dispute here.

## V. Analysis

### A. *The Commissioner's Power to Refuse a Patent under Section 40*

143 As noted above, the Patent Examiner concluded that the Commissioner of Patents has the right to deny a patent on the basis that it is not in the public interest to grant a patent on the subject matter in question. In his dissenting opinion, Isaac J.A. approved of this approach, stating that one of the purposes of the *Patent Act* is that the Commissioner must always be aware of, and take into account, the public interest in granting a patent. In a morally divisive case, the court should defer to the Commissioner's decision to refuse to grant a patent pursuant to s. 40 where this decision is informed by considerations of public policy.

144 I disagree that s. 40 of the *Patent Act* gives the Commissioner discretion to refuse a patent on the basis of public policy considerations independent of any express provision in the Act. The non-discretionary nature of the Commissioner's duty was explained in *Monsanto, supra*, a case cited by Rothstein J.A. At pages 1119-20, after citing s. 40 (then s. 42) of the *Patent Act*, Pigeon J., speaking for the majority, stated:

I have underlined by law [in s. 42] to stress that this is not a matter of discretion: the Commissioner has to justify any refusal. As Duff C.J. said in *Vanity Fair Silk Mills v. Commissioner of Patents* (at p. 246):

No doubt the Commissioner of Patents ought not to refuse an application for a patent unless it is clearly without substantial foundation. . . . [Emphasis in original.]

145 Some commentators remark that the Canadian courts have in the past excluded certain subject matter from patentability on moral, ethical or policy grounds (J. R. Rudolph, *A Study of Issues Relating to the Patentability of Biotechnological Subject Matter* (1996); S. Chong, "The Relevancy of Ethical Concerns in the Patenting of Life Forms" (1993), 10 *C.I.P.R.* 189). While it is true that certain categories of invention were excluded from patentability with these policy concerns in mind, these



exclusions were justified by reference to explicit provisions of the *Patent Act*. For example, patents on medical or surgical methods of treatment of animals, including humans, were disallowed, presumably so as not to impede physicians in the practice of their profession (see *Tennessee Eastman, supra*, at p. 113; Chong, *supra*, at p. 198). In *Tennessee Eastman*, however, the determination that a method for bonding incisions and wounds was not an “art” or a “process” was based primarily on the fact that the bonding material itself when prepared for medical purposes would not be patentable under what was then s. 41 of the *Patent Act*. Section 41, since removed from the Act, restricted the scope of patents on substances prepared or produced by chemical processes and intended for food or medicine. The Court stated, at p.119, in this respect:

. . . if a method of treatment consisting in the application of a new drug could be claimed as a process apart from the drug itself, then the inventor, by making such a process claim, would have an easy way out of the restriction in s. 41(1).

146           In the absence of any discretion on the part of the Commissioner to refuse a patent on policy grounds, the sole question in this appeal is whether the words “manufacture” or “composition of matter”, within the context of the *Patent Act*, are sufficiently broad to include higher life forms such as “inventions”. The Commissioner correctly identified this as the relevant question and concluded that he could not, by law, extend the meaning of “manufacture” or “composition of matter” to include a non-human mammal.

147           In dissent, Isaac J.A. held that the Commissioner’s decision in this regard should be accorded deference. This point was also argued before this Court by the interveners Sierra Club of Canada, Canadian Council of Churches and Evangelical Fellowship of Canada.

148 In my view, the decision of the Commissioner as to whether the definition of “invention” includes higher life forms is reviewable according to the correctness standard. The test to determine the appropriate standard of review was revisited by this Court in *Moreau-Bérubé v. New Brunswick (Judicial Council)*, [2002] 1 S.C.R. 249, 2002 SCC 11. As noted by Arbour J., at para. 37:

This Court’s jurisprudence has evolved to endorse a pragmatic and functional approach to determining the proper standard of review, which focuses on a critical question best expressed by Sopinka J. in *Pasiechnyk v. Saskatchewan (Workers’ Compensation Board)*, [1997] 2 S.C.R. 890, at para. 18:

[W]as the question which the provision raises one that was intended by the legislators to be left to the exclusive decision of the Board?

In *Pushpanathan v. Canada (Minister of Citizenship and Immigration)*, [1998] 1 S.C.R. 982, *Canada (Director of Investigation and Research) v. Southam Inc.*, [1997] 1 S.C.R. 748, and *Baker v. Canada (Minister of Citizenship and Immigration)*, [1999] 2 S.C.R. 817, this Court set out a number of factors that a court should consider when attempting to determine whether a question is one which Parliament intended to be left to the exclusive decision of the administrative tribunal. Upon considering these factors, it is my opinion that the courts are as well placed as the Commissioner to determine whether a higher life form fits within the definition of “invention”.

149 Though it will not be determinative, the fact that the *Patent Act* contains no privative clause and gives applicants a broad right of appeal from the decision of the Commissioner is relevant and suggests a more searching standard of review (*Pushpanathan, supra*, at para. 30).

150                Perhaps more important in this case is the nature of the problem under review, i.e. whether it constitutes a question of law, fact or mixed law and fact. In my view, the question of whether a higher life form can be considered a “manufacture” or “composition of matter” approaches a pure determination of law. There is no disagreement in this case regarding the nature of the specific invention: if it is determined that higher life forms are “manufacture[s]” or “composition[s] of matter”, then the oncomouse is an invention. The task is rather to determine whether Parliament intended the definition of “invention” to be interpreted broadly enough to encompass higher life forms, a question which the courts are as well suited to answer as the Commissioner. Since the determination of whether a higher life form is an invention within the meaning of the *Patent Act* is “a finding which will be of great, even determinative import for future decisions of lawyers and judges”, less deference is warranted (*Southam, supra*, at paras. 36-37; *Pushpanathan, supra*, at para. 37). In addition, though the Commissioner does possess considerable expertise in the areas of science, medicine and engineering, this expertise must be considered in the context of the problem under review. In my view, this specialized training does not leave the Commissioner in a better position than the courts to determine whether the creation in question is a “manufacture” or “composition of matter” since those are very broad phrases to which either a very narrow or very expansive meaning may be attached, depending on legislative intent.

151                The above in no way implies that decisions of the Commissioner will always be reviewed according to a correctness standard. If, for example, the question to be decided was whether or not a particular life form such as a fungus should be classified as a higher life form or as a lower life form, the Commissioner’s decision would likely be accorded deference. As noted, s. 40 of the Act states that it is the Commissioner who

must be “satisfied” that a patent should not be issued. In such an instance, the Commissioner’s scientific expertise suggests that the courts defer to his decision in respect to whether he is satisfied that the life form falls within a category of patentable subject matter.

152           As discussed earlier, I disagree that the purpose of the *Patent Act* counsels deference to the Commissioner on a question such as this. I do not accept Isaac J.A.’s suggestion that the Commissioner is in a position to weigh competing policy interests for and against the grant of a patent and that this counsels deference. Nor do I agree that the wording of s. 40, which states that the Commissioner shall refuse an application where he is “satisfied” that an applicant is not by law entitled to be granted a patent, implies a discretion to refuse a patent on policy grounds. As noted above, the Commissioner must be satisfied that an applicant is not “by law” entitled to be granted a patent (see *Monsanto, supra*, at p. 1119). Though Isaac J.A. cites *Farbwerke Hoechst, supra*, as support for the existence of a discretionary power on the part of the Commissioner to refuse a patent, the Court in that case pointed out that “[a]n inventor gets his patent according to the terms of the *Patent Act*, no more and no less” (p. 57 (emphasis added)).

B.   *The Definition of “Invention”: Whether a Higher Life Form Is a “Manufacture” or a “Composition of Matter”*

153           The sole question in this appeal is whether the words “manufacture” and “composition of matter”, in the context of the *Patent Act*, are sufficiently broad to include higher life forms. If these words are not sufficiently broad to include higher life forms, it is irrelevant whether this Court believes that higher life forms such as the oncomouse ought to be patentable. The grant of a patent reflects the interest of

Parliament to promote certain manifestations of human ingenuity. As Binnie J. indicates in his reasons, there are a number of reasons why Parliament might want to encourage the sort of biomedical research that resulted in the oncomouse. But there are also a number of reasons why Parliament might want to be cautious about encouraging the patenting of higher life forms. In my view, whether higher life forms such as the oncomouse ought to be patentable is a matter for Parliament to determine. This Court's views as to the utility or propriety of patenting non-human higher life forms such as the oncomouse are wholly irrelevant.

154           This Court has on many occasions expressed the view that statutory interpretation cannot be based on the wording of the legislation alone (*Rizzo & Rizzo Shoes Ltd. (Re)*, [1998] 1 S.C.R. 27). Rather, the Court has adopted E. A. Driedger's statement in his text *Construction of Statutes* (2nd ed. 1983), at p. 87 : "[T]he words of an Act are to be read in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament" (*Rizzo, supra*, at para. 21).

155           Having considered the relevant factors, I conclude that Parliament did not intend to include higher life forms within the definition of "invention" found in the *Patent Act*. In their grammatical and ordinary sense alone, the words "manufacture" and "composition of matter" are somewhat imprecise and ambiguous. However, it is my view that the best reading of the words of the Act supports the conclusion that higher life forms are not patentable. As I discuss below, I do not believe that a higher life form such as the oncomouse is easily understood as either a "manufacture" or a "composition of matter". For this reason, I am not satisfied that the definition of "invention" in the *Patent Act* is sufficiently broad to include higher life forms. This conclusion is

supported by the fact that the patenting of higher life forms raises unique concerns which do not arise in respect of non-living inventions and which are not addressed by the scheme of the Act. Even if a higher life form could, scientifically, be regarded as a “composition of matter”, the scheme of the Act indicates that the patentability of higher life forms was not contemplated by Parliament. Owing to the fact that the patenting of higher life forms is a highly contentious and complex matter that raises serious practical, ethical and environmental concerns that the Act does not contemplate, I conclude that the Commissioner was correct to reject the patent application. This is a policy issue that raises questions of great significance and importance and that would appear to require a dramatic expansion of the traditional patent regime. Absent explicit legislative direction, the Court should not order the Commissioner to grant a patent on a higher life form.

(1) The Words of the Act

156           The definition of “invention” in s. 2 of the *Patent Act* lists five categories of invention: art (*réalisation*), process (*procédé*), machine (*machine*), manufacture (*fabrication*) or composition of matter (*composition de matières*). The first three, “art”, “process” and “machine”, are clearly inapplicable when considering claims directed toward a genetically engineered non-human mammal. If a higher life form is to fit within the definition of “invention”, it must therefore be considered to be either a “manufacture” or a “composition of matter”.

157           Rothstein J.A. concluded that the oncomouse was a “composition of matter”, and therefore did not find it necessary to consider whether it was also a “manufacture”. In coming to this conclusion, he relied, at para. 115, on the following definition of

“composition of matter” adopted by the majority of the U.S. Supreme Court in *Chakrabarty*, *supra*, at p. 308:

. . . all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids.

In *Chakrabarty*, the majority attributed the widest meaning possible to the phrases “composition of matter” and “manufacture” for the reason that inventions are, necessarily, unanticipated and unforeseeable. Burger C.J., at p. 308, also referred to the fact that the categories of invention are prefaced by the word “any” (“any new and useful process, machine, manufacture, or composition of matter”). Finally, the Court referred to extrinsic evidence of Congressional intent to adopt a broad concept of patentability, noting at p. 309 that: “The Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to ‘include anything under the sun that is made by man’”.

158 I agree that the definition of “invention” in the *Patent Act* is broad. Because the Act was designed in part to promote innovation, it is only reasonable to expect the definition of “invention” to be broad enough to encompass unforeseen and unanticipated technology. I cannot however agree with the suggestion that the definition is unlimited in the sense that it includes “anything under the sun that is made by man”. In drafting the *Patent Act*, Parliament chose to adopt an exhaustive definition that limits invention to any “art, process, machine, manufacture or composition of matter”. Parliament did not define “invention” as “anything new and useful made by man”. By choosing to define invention in this way, Parliament signalled a clear intention to include certain subject matter as patentable and to exclude other subject matter as being outside the confines of

the Act. This should be kept in mind when determining whether the words “manufacture” and “composition of matter” include higher life forms.

159 With respect to the meaning of the word “manufacture” (*fabrication*), although it may be attributed a very broad meaning, I am of the opinion that the word would commonly be understood to denote a non-living mechanistic product or process. For example, the *Oxford English Dictionary* (2nd ed. 1989), vol. IX, at p. 341, defines the noun “manufacture” as the following:

The action or process of making by hand . . . . The action or process of making articles or material (in modern use, on a large scale) by the application of physical labour or mechanical power.

The *Grand Robert de la langue française* (2nd ed. 2001), vol. 3, at p. 517, defines thus the word “*fabrication*”:

[TRANSLATION] Art or action or manufacturing. . . . The manufacture of a technical object (by someone). Manufacturing by artisans, by hand, by machine, industrially, by mass production . . . .

In *Chakrabarty, supra*, at p. 308, “manufacture” was defined as

the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery.

These definitions use the terminology of “article”, “material”, and “*objet technique*”. Is a mouse an “article”, “material”, or an “*objet technique*”? In my view, while a mouse may be analogized to a “manufacture” when it is produced in an industrial setting, the



word in its vernacular sense does not include a higher life form. The definition in *Hornblower v. Boulton* (1799), 8 T.R. 95, 101 E.R. 1285 (K.B.), cited by the respondent, is equally problematic when applied to higher life forms. In that case, the English courts defined “manufacture” as “something made by the hands of man” (p. 1288). In my opinion, a complex life form such as a mouse or a chimpanzee cannot easily be characterized as “something made by the hands of man”.

160           As regards the meaning of the words “composition of matter”, I believe that they must be defined more narrowly than was the case in *Chakrabarty, supra*, at p. 308 namely “all compositions of two or more substances and . . . all composite articles”. If the words “composition of matter” are understood this broadly, then the other listed categories of invention, including “machine” and “manufacture”, become redundant. This implies that “composition of matter” must be limited in some way. Although I do not express an opinion as to where the line should be drawn, I conclude that “composition of matter” does not include a higher life form such as the oncomouse.

161           The phrase “composition of matter” (*composition de matières*) is somewhat broader than the term “manufacture” (*fabrication*). It is a well-known principle of statutory interpretation that the meaning of questionable words or phrases in a statute may be ascertained by reference to the meaning of the words or phrases associated with them (P.-A. Côté, *The Interpretation of Legislation in Canada* (3rd ed. 2000), at pp. 313-14). Also, a collective term that completes an enumeration is often restricted to the same genus as those words, even though the collective term may ordinarily have a much broader meaning (p. 315). The words “machine” and “manufacture” do not imply a conscious, sentient living creature. This provides *prima facie* support for the conclusion that the phrase “composition of matter” is best read as not including such life forms.

This argument is bolstered by the fact that there are a number of factors that make it difficult to regard higher life forms as “composition[s] of matter”.

162 First, the *Oxford English Dictionary*, *supra*, vol. III, at p. 625, defines the word “composition” as “[a] substance or preparation formed by combination or mixture of various ingredients”, the *Grand Robert de la langue française*, *supra*, vol. 2, at p. 367, defines “*composition*” as [TRANSLATION] “[a]ction or manner of forming a whole, a set by assembling several parts, several elements”. Within the context of the definition of “invention”, it does not seem unreasonable to assume that it must be the inventor who has combined or mixed the various ingredients. Owing to the fact that the technology by which a mouse predisposed to cancer is produced involves injecting the oncogene into a fertilized egg, the genetically altered egg would appear to be cognizable as “[a] substance or preparation formed by combination or mixture of various ingredients” or as [TRANSLATION] “[a]ction or manner of forming a whole . . . by assembling several parts”. However, it does not thereby follow that the oncomouse itself can be understood in such terms. Injecting the oncogene into a fertilized egg is the but-for cause of a mouse predisposed to cancer, but the process by which a fertilized egg becomes an adult mouse is a complex process, elements of which require no human intervention. The body of a mouse is composed of various ingredients or substances, but it does not consist of ingredients or substances that have been combined or mixed together by a person. Thus, I am not satisfied that the phrase “composition of matter” includes a higher life form whose genetic code has been altered in this manner.

163 It also is significant that the word “matter” captures but one aspect of a higher life form. As defined by the *Oxford English Dictionary*, *supra*, vol. IX, at p. 480, “matter” is a “[p]hysical or corporeal substance in general . . . , contradistinguished from

immaterial or incorporeal substance (spirit, soul, mind), and from qualities, actions, or conditions”. “*Matière*” is defined by the *Grand Robert de la langue française, supra*, vol. 4, p. 1260, as [TRANSLATION] “corporeal substance ‘that is perceptible in space and has mechanical mass’”. Although some in society may hold the view that higher life forms are mere “composition[s] of matter”, the phrase does not fit well with common understandings of human and animal life. Higher life forms are generally regarded as possessing qualities and characteristics that transcend the particular genetic material of which they are composed. A person whose genetic make-up is modified by radiation does not cease to be him or herself. Likewise, the same mouse would exist absent the injection of the oncogene into the fertilized egg cell; it simply would not be predisposed to cancer. The fact that it has this predisposition to cancer that makes it valuable to humans does not mean that the mouse, along with other animal life forms, can be defined solely with reference to the genetic matter of which it is composed. The fact that animal life forms have numerous unique qualities that transcend the particular matter of which they are composed makes it difficult to conceptualize higher life forms as mere “composition[s] of matter”. It is a phrase that seems inadequate as a description of a higher life form.

164                Lastly, I wish also to address Rothstein J.A.’s assertion that “[t]he language of patent law is broad and general and is to be given wide scope because inventions are, necessarily, unanticipated and unforeseeable” (para. 116). In my view, it does not thereby follow that all proposed inventions are patentable. On the one hand, it might be argued that, in this instance, Parliament could foresee that patents might be sought in higher life forms. Although Parliament would not have foreseen the genetically altered mouse and the process of genetic engineering used to produce it, Parliament was well aware of animal husbandry or breeding. While the technologies used to produce a

crossbred animal and a genetically engineered animal differ substantially, the end result, an animal with a new or several new features, is the same. Yet Parliament chose to define the categories of invention using language that does not, in common usage, refer to higher life forms. One might thus infer that Parliament did not intend to include higher life forms in the definition of “invention”. Although he was referring specifically to crossbred plants and not to higher life forms in general, a similar point was made by Marceau J.A. in *Pioneer Hi-Bred* (F.C.A.), *supra*, at p. 14:

It is argued that the very nature of the patent system and the benefits that were expected therefrom should lead to the conclusion that Parliament intended the most open and favourable approach to its statute. Maybe so, but I do not think that such an approach would permit the interpreter to dispense with the necessity to respect the results suggested by a careful analysis of the terms used in the statute. Besides, speaking of the intention of Parliament, given that plant breeding was well established when the Act was passed, it seems to me that the inclusion of plants within the purview of the legislation would have led first to a definition of invention in which words such as “strain”, “variety” or “hybrid” would have appeared . . . .

165           On the other hand, it is important to recall that there is a qualitative difference between crossbreeding and genetic alteration. In *Pioneer Hi-Bred* (S.C.C.), Lamer J. (as he then was) articulated that difference in the following terms (at p. 1633):

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.

It is thus possible that Parliament did not regard crossbred plants and animals as patentable, not because they are higher life forms, but because they are better regarded as “discoveries”. Unable to anticipate genetic alteration, Parliament would not have foreseen that higher life forms could be created in a manner reasonably understood as an invention. If this is the case, we should be wary of applying too broad or literal an

interpretation of the phrase “composition of matter”. Even if higher life forms were more easily cognizable as “composition[s] of matter”, I still would find it difficult to conclude that the definition of “invention” was intended to be sufficiently broad to include higher life forms.

166            Patenting higher life forms would involve a radical departure from the traditional patent regime. Moreover, the patentability of such life forms is a highly contentious matter that raises a number of extremely complex issues. If higher life forms are to be patentable, it must be under the clear and unequivocal direction of Parliament. For the reasons discussed above, I conclude that the current Act does not clearly indicate that higher life forms are patentable. Far from it. Rather, I believe that the best reading of the words of the Act supports the opposite conclusion — that higher life forms such as the oncomouse are not currently patentable in Canada.

## (2) The Scheme of the Act

167            This interpretation of the words of the Act finds support in the fact that the patenting of higher life forms raises unique concerns which do not arise with respect to non-living inventions and which cannot be adequately addressed by the scheme of the Act. In *Pioneer Hi-Bred* (F.C.A.), Marceau J.A. discussed the intention of Parliament to include crossbred plants in the following terms (at p. 14):

. . . it seems to me that the inclusion of plants within the purview of the legislation would have led . . . to the enactment of special provisions capable of better adapting the whole scheme to a subject matter, the essential characteristic of which is that it reproduces itself as a necessary result of its growth and maturity. I do not dispute the appellant’s contention that those who develop new types of plants by cross-breeding should receive in this country, as they do elsewhere, some kind of protection and reward for their efforts but it seems to me that, to assure such result, the

legislator will have to adopt special legislation, as was done a long time ago in the United States and in many other industrialized countries.

Marceau J.A.'s observation in this regard is compelling. The patenting of higher life forms raises special concerns that do not arise in respect of non-living inventions. Unlike other inventions, biologically based inventions are living and self-replicating. In addition, the products of biotechnology are incredibly complex, incapable of full description, and can contain important characteristics that have nothing to do with the invention (see Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee*, June 2002, at p. 11; see also Rudolph, *supra*, at p. 5). In my view, the fact that the *Patent Act* in its current state is ill-equipped to deal appropriately with higher life forms as patentable subject matter is an indication that Parliament never intended the definition of "invention" to extend to this type of subject matter.

168           The respondent argues that the concerns arising out of higher life forms as patentable subject matter are "external to the *Patent Act* and its jurisprudence" and that there is therefore no statutory basis to reject the patentability of higher life forms on moral, ethical or environmental grounds. I agree with the respondent that some of the policy concerns raised by the interveners are more appropriately dealt with outside the patent system. For example, some interveners expressed concern for the environmental and animal welfare implications of biotechnology. These issues are only tenuously linked to the patentability of higher life forms and are more directly related to the development and use of the technology itself. With regard to research and experimentation involving animals, by the time a researcher is in a position to file for a patent, any harm to the animal resulting from research will already have been done.

Correspondingly, it is preferable to address this issue through existing or new regimes for protecting animal welfare. Similarly, if it is determined that additional measures are needed to protect the environment from the products of biotechnology, this may be effected through the *Canadian Environmental Protection Act*, R.S.C. 1985, c. 16 (4th Supp.), or other comparable regulatory mechanisms.

169           While the above-mentioned concerns are only indirectly related to the *Patent Act*, several of the issues raised by the interveners and in the literature are more directly related to patentability and to the scheme of the *Patent Act* itself. These issues, which pertain to the scope and content of the monopoly right accorded to the inventor by a patent, have been explored in depth by the Canadian Biotechnology Advisory Committee (CBAC), a body created in 1999 with a mandate to provide the government with advice on policy issues associated with biotechnology. In June 2002, the CBAC released its final report, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee*. The report recommends that higher life forms should be patentable. Nonetheless, it concludes, at p. 7, that given the importance of issues raised by the patenting of higher life forms and the significant “values” content of the issues raised, Parliament and not the courts should determine whether and to what degree patent rights ought to extend to plants and animals.

170           Two of the issues addressed by the CBAC (farmers’ privilege and innocent bystanders) arise out of the unique ability of higher life forms to self-replicate. Because higher life forms reproduce by themselves, the grant of a patent covers not only the particular plant, seed or animal sold, but also all of its progeny containing the patented invention. In the CBAC’s view, this represents a significant increase in the scope of

rights offered to patent holders that is not in line with the scope of patent rights provided in other fields (*Patenting of Higher Life Forms and Related Issues*, *supra*, at p. 12).

171           One significant concern arising out of the increased scope of patent protection is the impact that it will have on Canada's agricultural industry. The CBAC recommends that a farmers' privilege provision be included in the Act. The privilege would permit farmers to collect and reuse seeds harvested from patented plants and to breed patented animals for their own use, so long as these were not sold for commercial breeding purposes. Although the CBAC puts forward suggestions pertaining to the general nature of such a provision, it nonetheless recognizes that more work would need to be done to identify the extent of the privilege in relation to plants and animals.

172           Another concern identified by the CBAC in respect to self-replication pertains to infringement. The CBAC observes that since plants and animals are often capable of reproducing on their own, it must be recognized that they will not always do so under the control or with the knowledge of those who grow the plants or raise the animals. Patent law does not currently require a patent holder to prove that an alleged infringer knew or ought to have known about the reproduction of a patented invention. An "innocent bystander" may therefore be faced with high costs to defend a patent infringement suit and an award of damages for infringement without a countervailing remedy against the patent holder. The CBAC correspondingly recommends that the *Patent Act* contain a provision that would allow the so-called "innocent bystander" to rebut the usual presumption concerning knowledge of infringement in respect of inventions capable of reproducing, such as plants, seeds and animals.



173 In its recommendations, the CBAC also deals with a concern that was raised before this Court by the intervener Canadian Environmental Law Association. The intervener submitted that patents on life forms may actually deter further innovation in the biomedical field by foreclosing opportunities for research and product development to those that do not hold the patent. Arguably, this potential is inherent in the nature of a patent system. Yet the impact may be more significant with respect to the products of biotechnology. As noted by the CBAC, at p. 14: “Access to basic or platform technology such as DNA sequences, cell lines, plants and animals at reasonable cost is crucial to research”. High research costs can be expected to drive up the price of the end product, which in the case of biotechnology includes diagnostic tests and therapeutic agents important to the health of Canadians (see T. Schrecker et al., *Ethical Issues Associated with the Patenting of Higher Life Forms* (1997), at p. 44).

174 In response to the above-stated concerns, the CBAC recommends that the *Patent Act* be amended to include a research and experimental use exception. The CBAC recognizes that this Court established a common law experimental use exception in the context of research aimed at sustaining a compulsory licence: see *Micro Chemicals Ltd. v. Smith Kline & French Inter-American Corp.*, [1972] S.C.R. 506. Nonetheless, the scope and nature of this exception is uncertain, particularly since Canada has since eliminated its compulsory licence provisions. The CBAC reiterates that it is Parliament and not the courts which should create the exception (at p. 15):

First, the values content of the issues calls for a Parliamentary rather than a judicial approach. Second, the responses we received from the research community suggest that researchers do not feel that the current research exception is sufficiently clear. Third, studies have illustrated that the failure to have a clear research exception has curtailed important health research. Fourth, the member states of the European Union have included experimental use exceptions in their patent legislation without any apparent

negative effect . . . . Fifth, provincial governments have called for a clarification of the experimental use exception in Canada.

175           Perhaps the most significant issue addressed by the CBAC is the patentability of human life. The CBAC recommends that if Canada decides to permit patents over higher life forms, human bodies at all stages of development should be excluded. It observes in this regard that although humans are also animals, no country, including Canada, allows patents on the human body. According to the CBAC, this understanding derives from the universal principle of respect for human dignity, one element of which is that humans are not commodities (see CBAC, *supra*, at p. 8).

176           The potential for commodification of human life arises out of the fact that the granting of a patent is, in effect, a declaration that an invention based on living matter has the potential to be commercialized. The commodification of human beings is not only intrinsically undesirable; it may also engender a number of troubling consequences. Many of the consequentialist concerns (i.e., the creation of “designer human beings” or features) are directed at genetic engineering in general and not at patenting *per se*, and are perhaps better dealt with outside the confines of the *Patent Act* (see Schrecker, *supra*, at pp. 64-65). Nonetheless, there remains a concern that allowing patents on the human body will lead to human life being reconceptualized as genetic information. A related concern is the potential for objectification. As noted by Schrecker, *supra*, at p. 62: “[t]o 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”.

177            Whatever justification is used to support the assumption, there seems to be little debate that human life is not patentable. In response to the hypothetical question of whether patentability could be extended to human beings, Rothstein J.A. replied, at para. 207: “The answer is clearly that the *Patent Act* cannot be extended to cover human beings”. He based this conclusion on the fact that patenting is a form of ownership of property and that ownership concepts cannot be extended to human beings pursuant to s. 7 of the *Charter*. He concluded the topic by remarking that “[t]here is, therefore, no concern by including non-human mammals under the definition of ‘invention’ in the *Patent Act*, that there is any implication that a human being would be patentable in the way that the oncomouse is” (para. 207).

178            In my view, this general response to concerns over the implications for human beings of patenting higher life forms is an oversimplification. Reference to the *Charter* does not address the issue of whether the definition of “invention” in s. 2 applies to human subject matter as a matter of statutory interpretation. Should this Court determine that higher life forms are within the scope of s. 2, this must necessarily include human beings. There is no defensible basis within the definition of “invention” itself to conclude that a chimpanzee is a “composition of matter” while a human being is not. As noted by this Court in *Bell ExpressVu Limited Partnership v. Rex*, [2002] 2 S.C.R. 559, 2002 SCC 42, at para. 62, “*Charter* values” are to be used as an interpretative principle only in circumstances of genuine ambiguity, i.e. where a statutory provision is subject to differing but equally plausible interpretations. To read legislation in conformity with the *Charter* in cases where there is no real ambiguity is to deprive the government the opportunity to justify a provision that appears to conflict with the *Charter* under s. 1.

179 In addition, while it is likely that s. 7 of the *Charter* would have some impact on the patenting of human life, it is unlikely to resolve many of the more specific issues that may arise. Section 7 states that everyone has the right to “life, liberty and security of the person”. Because the section deals only with “person[s]”, it leaves the status of fetuses uncertain: see *Tremblay v. Daigle*, [1989] 2 S.C.R. 530, at p. 553; *Winnipeg Child and Family Services (Northwest Area) v. G. (D.F.)*, [1997] 3 S.C.R. 925. In its report to Parliament, the CBAC recommends that the *Patent Act* be amended to say that no patent shall be granted on human bodies “at any stage of development” (p. x). In its view, this wording would demonstrate an intention not only to include human bodies of infants, children and adults, but also all precursors to the human body from zygotes to fetuses. Recognition by the CBAC of the necessity of specifically addressing this issue supports the view that reference to s. 7 of the *Charter* alone cannot dispose of concerns associated with the patenting of human life.

180 Applicants may also seek to patent human tissues and organs rather than the entire person, in which case s. 7 may not apply. The patenting of body parts raises yet another issue: the increasingly blurred line between human beings and other higher life forms. In the new field of xenotransplantation, human genes are introduced into mammals such as pigs to make the animals’ organs more acceptable to the human body for the purposes of organ transplantation. As noted by the intervener Animal Alliance of Canada, at para. 68 of its submissions, this scientific development calls into question the once clear distinction between human and animal life:

The pig receives human genes. The human receives pig organs. Where does the pig end and the human begin? How much DNA does it take before one becomes the other? The answer to these questions, once ridiculous and offensive, may now just be a matter of degree.

181           The problem posed by the above technology with respect to locating the defining line which separates humans from animals is not insurmountable. It does, however, call into question Rothstein J.A.’s assumption that s. 7 of the *Charter* is capable of addressing the issues associated with the patenting of human life. In my view, it is not an appropriate judicial function for the courts to create an exception from patentability for human life given that such an exception requires one to consider both what is human and which aspects of human life should be excluded.

182           The scenarios above demonstrate that the issue of patenting of human life forms is a complex one that cannot be readily dismissed by reference to the *Charter*. Once again, it is an issue that demands a comprehensive Parliamentary response. Illustrative in this regard is *Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions*, which sets out several detailed exceptions to patentability pertaining to the human body. The first paragraph of article 5 of the Directive sets out the primary exception:

The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

The second paragraph allows for a patent on “[a]n element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene . . . even if the structure of that element is identical to that of a natural element”. Paragraph 1 of article 6 sets out a general exception to patentability for inventions where their commercial exploitation would be contrary “to *ordre public* or morality”. Paragraph 2 further specifies that processes for cloning human beings, processes for modifying the germ line genetic identity of human beings and uses of

human embryos for industrial or commercial purposes are all considered unpatentable as being contrary to “*ordre public* or morality”.

183           As noted earlier, the CBAC has recommended that higher life forms (i.e., plants, seeds and non-human animals) that meet the criteria of novelty, non-obviousness and utility be recognized as patentable. The concerns above therefore are not raised to justify a position that higher life forms should not be patentable, but rather serve to illustrate that the *Patent Act* in its current form is not well suited to address the unique characteristics possessed by higher life forms. The lack of direction currently in the *Patent Act* to deal with issues that might reasonably arise signals a legislative intention that higher life forms are currently not patentable. In addition, the discussion of the issues raised by the CBAC and other groups illustrates the complexity of the concerns. In my view, this Court does not possess the institutional competence to deal with issues of this complexity, which presumably will require Parliament to engage in public debate, a balancing of competing societal interests and intricate legislative drafting.

(3) The Object of the Act

184           The respondent submits that the object of the *Patent Act* is to encourage and reward the development of innovations and technology. In its view, this objective supports a broad reading of the definition of “invention” that does not exclude any area of technology save for the statutory exclusion in s. 27(3).

185           There is no doubt that two of the central objects of the Act are “to advance research and development and to encourage broader economic activity” (see *Free World Trust v. Électro Santé Inc.*, [2000] 2 S.C.R. 1024, 2000 SCC 66, at para. 42). As noted

earlier, this does not, however, imply that “anything under the sun that is made by man” is patentable. Parliament did not leave the definition of “invention” open, but rather chose to define it exhaustively. Regardless of the desirability of a certain activity, or the necessity of creating incentives to engage in that activity, a product of human ingenuity must fall within the terms of the Act in order for it to be patentable. The object of the Act must be taken into account, but the issue of whether a proposed invention ought to be patentable does not provide an answer to the question of whether that proposed invention is patentable. In addition, the manner in which Canada has administered its patent regime in the past reveals that the promotion of ingenuity has at times been balanced against other considerations. For example, under the former provisions of the *Patent Act*, a licence could be granted to manufacture a patented medicine seven years after the patent first appeared on the market. The existence of this compulsory licence scheme demonstrates that other objectives, including fairness and the promotion of Canada’s universal healthcare system, have at times existed as part of the patent regime (see Chong, *supra*; see also Rudolph, *supra*, at p. 35, note 74).

186                Given the above, the respondent’s argument that the object of the Act leads inexorably to the broadest reading of the definition of “invention” possible is problematic and is, in my view, based on an oversimplification of the patent regime. In the court below, Rothstein J.A. preferred the approach taken by the majority of the U.S. Supreme Court in *Chakrabarty*, *supra*. The majority read the language of the Act expansively on the basis that the Act embodied Thomas Jefferson’s philosophy that “ingenuity should receive a liberal encouragement” (p. 308). The minority of the court did not wholly accept this characterization, commenting in respect to the objective of the Act, at p. 319 of the reasons:

The patent laws attempt to reconcile this Nation's deep-seated antipathy to monopolies with the need to encourage progress. *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 530-531 (1972); *Graham v. John Deere Co.*, 383 U.S.1, 7-10 (1966). Given the complexity and legislative nature of this delicate task, we must be careful to extend patent protection no further than Congress has provided. In particular, were there an absence of legislative direction, the courts should leave to Congress the decisions whether and how far to extend the patent privilege into areas where the common understanding has been that patents are not available.

187               Based on the language and the scheme of the Act, both of which are not well accommodated to higher life forms, it is reasonable to assume that Parliament did not intend the monopoly right inherent in the grant of a patent to extend to inventions of this nature. It simply does not follow from the objective of promoting ingenuity that all inventions must be patentable, regardless of the fact that other indicators of legislative intention point to the contrary conclusion.

(4) Related Legislation: The *Plant Breeders' Rights Act*

188               It is a well-established principle of statutory interpretation that given ambiguity in the law, the substance and the form of subsequent legislation may be relevant (see *Côté, supra*, at pp. 343-44). Of significance to the interpretation of the *Patent Act* and the issue of its applicability to higher life forms is the *Plant Breeders' Rights Act*, passed in 1990 subsequent to this Court's decision in *Pioneer Hi-Bred, supra*, in which it was determined that a crossbred soybean variety did not meet the disclosure requirements of the *Patent Act*. As noted by one commentator, the Act "is much better tailored than the *Patent Act* to the particular characteristics of plants" (N. M. Derzko, "Plant Breeders' Rights in Canada and Abroad: What are These Rights and How Much Must Society Pay for Them?" (1994), 39 *McGill L.J.* 144, at p. 159). In



return for specifically tailored and less onerous requirements a narrower monopoly right is granted than that available under the *Patent Act*.

189           The existence of the *Plant Breeders' Rights Act* is relevant to the issue of whether Parliament intended higher life forms to be patentable under the *Patent Act* for several reasons. First, it is argued that had plants been patentable under the *Patent Act*, it would have been unnecessary for Canada to pass a *Plant Breeders' Rights Act* to begin with. A related argument was put forward by the appellant, who submits that although Parliament passed “special legislation” to provide protection for plant breeders, it made no move to amend the *Patent Act* or to adopt other special legislation to provide for the protection of forms of animal life. In addition, in the face of Marceau J.A.’s opinion in *Pioneer Hi-Bred* (speaking for a majority of the Federal Court of Appeal) that the *Patent Act* had never been intended or understood to include crossbred plants — one form of higher life — in patentable subject matter, Parliament did nothing to alter that intention or understanding. A final point is that the *Plant Breeders' Rights Act* was passed in recognition that the *Patent Act* was not tailored to plants due to their unique characteristics. Since other higher life forms share many of these characteristics, it is reasonable to assume that Parliament would choose to protect these life forms through legislation other than the *Patent Act* or through an amended *Patent Act* that is better suited to the subject matter.

190           In *Chakrabarty, supra*, a minority of four judges of the U.S. Supreme Court found that the passage of the 1930 *Plant Patent Act* and the 1970 *Plant Variety Protection Act* evidenced Congress’s understanding that the *Patent Act* does not include living organisms. As noted, at p. 320:

If newly developed living organisms not naturally occurring had been patentable under § 101 [the equivalent to the definition of “invention” in s. 2 of the Canadian *Patent Act*], the plants included in the scope of the 1930 and 1970 Acts could have been patented without new legislation. Those plants, like the bacteria involved in this case, were new varieties not naturally occurring.

The minority went on to note, at pp. 321-22:

... the Court’s decision does not follow the unavoidable implications of the statute. Rather, it extends the patent system to cover living material even though Congress plainly has legislated in the belief that § 101 does not encompass living organisms. It is the role of Congress, not this Court, to broaden or narrow the reach of the patent laws. This is especially true where, as here, the composition sought to be patented uniquely implicates matters of public concern.

191           The majority of the court in *Chakrabarty* rejected the above argument, asserting that factors other than congressional intent to exclude higher life forms from the definition of “invention” were responsible for the passage of the Acts. In particular, the majority notes that, prior to 1930, the belief existed that plants, even those artificially bred, were products of nature for the purposes of the patent law. The second obstacle to patent protection for plants was the fact that plants were thought not amenable to the “written description” requirement of the patent law. In enacting the *Plant Patent Act*, Congress addressed both of these concerns. The majority also addressed the passage of the 1970 *Plant Variety Protection Act* which, in its view, was passed to provide protection for sexually reproduced plants not covered by the 1930 Act.

192           Given that the *Plant Breeders’ Rights Act* was passed following this Court’s decision in *Pioneer Hi-Bred* that the soybean variety in question was unable to meet the written description requirement of the *Patent Act*, the point of view of the majority in *Chakrabarty* may have merit in the Canadian context. In other words, it may well be

that the *Plant Breeders' Rights Act* was passed not out of recognition that higher life forms are not a patentable subject matter under the *Patent Act*, but rather out of recognition that plant varieties deserve some form of intellectual property protection despite the fact that they often do not meet the technical criteria of the *Patent Act*.

193                Nonetheless, this does not diminish the weight of the appellant's argument that although Parliament responded to *Pioneer Hi-Bred* by enacting special legislation for the protection of plant breeders, it did not address other higher life forms. This is particularly significant given the majority of the Federal Court of Appeal's conclusion in that case that crossbred plants did not fall within the definition of "invention" in the *Patent Act*, and the fact that this Court did not broach the subject, effectively leaving open the issue of whether or not such plants and other higher life forms are patentable subject matter. Given that the *status quo* position of the Patent Commissioner is that higher life forms are not patentable, had Parliament intended to extend patentability to higher life forms other than crossbred plants, it would likely have done so at that time.

194                Though the arguments above are not absolutely indicative of parliamentary intent, they are of some significance. Far more significant, in my view, is that the passage of the *Plant Breeders' Rights Act* demonstrates that mechanisms other than the *Patent Act* may be used to encourage inventors to undertake innovative activity in the field of biotechnology. As discussed above, the *Plant Breeders' Rights Act* is better tailored than the *Patent Act* to the particular characteristics of plants, a factor which makes it easier to obtain protection. The *quid pro quo* is that a narrower monopoly right is granted. For example, the monopoly right relates only to the propagating material (the seed and the cuttings) and not to the actual plant. As explained by Derzko, *supra*, at p. 161, "[t]his is done because, unlike inert objects that are patentable, and unlike

unicellular organisms that replicate into exact copies of each other, higher organisms such as plants start off from a cell and then grow and differentiate into a complete plant". The following statement of the Honourable Donald Mazankowski (then Minister of Agriculture) demonstrates that the *Plant Breeders' Rights Act* was passed to accommodate the special characteristics of crossbred plants as self-reproducing higher life forms while at the same time striking an appropriate balance between the holder of the monopoly right and others:

. . . Bill C-15 is designed to allow Canadian producers access to the best possible plant varieties, whatever country they originate in. It provides for certain rights for plant breeders and outlines their application, and further details restrictions that will apply to these rights to better protect the public interest. The legislation is designed to deal with the complexities of the issue and that is why we have chosen this route rather than to amend the *Patent Act*.

(See House of Commons, *Minutes of Proceedings and Evidence of the Legislative Committee on Bill C-15: An Act Respecting Plant Breeders' Rights*, Issue No 1, October 11, 1989 at p. 1:15.)

195           Although legislation addressing the rights of plant breeders was introduced into the House of Commons as early as May 1980, the *Plant Breeders' Rights Act* was not passed and brought into force until August 1990, some 10 years later (see Canadian Food Inspection Agency, *10-Year Review of Canada's Plant Breeders' Rights Act* (2002)). The CBAC has only very recently issued its final report to the Government of Canada on the patenting of higher life forms. Given the opportunity to consider the recommendations therein and other sources of information on the topic, it is not clear that Parliament would choose to strike the balance between the inventor of a higher life form and the public in the same way that the *Patent Act* does.

196 Many of the issues that arose with respect to intellectual property protection for plant varieties also arise when considering the patentability of other higher life forms (e.g. impact on farmers and on research and development). If a special legislative scheme were needed to protect plant varieties, a subset of higher life forms, a similar scheme may also be necessary to deal with the patenting of higher life forms in general. As noted above, only Parliament is in the position to respond to the concerns associated with the patenting of all higher life forms, should it wish to do so, by creating a complex legislative scheme as in the case of crossbred plants or by amending the *Patent Act*. Conversely, it is beyond the competence of this Court to address in a comprehensive fashion the issues associated with the patentability of higher life forms.

C. *Drawing the Line: Is it Defensible to Allow Patents on Lower Life Forms While Denying Patents on Higher Life Forms?*

197 The respondent notes that the Commissioner of Patents has since 1982 accepted that lower life forms come within the definitions of “composition of matter” and “manufacture” and has granted patents on such life forms accordingly. It adds that the *Patent Act* does not distinguish, in its definition of “invention”, between subject matter that is less complex (lower life forms) and subject matter that is more complex (higher life forms). It submits that there is therefore no evidentiary or legal basis for the distinction the Patent Office has made between lower life forms such as bacteria, yeast and moulds, and higher life forms such as plants and animals.

198 The patentability of lower life forms is not at issue before this Court, and was in fact never litigated in Canada. In *Abitibi*, *supra*, the Patent Appeal Board, the Commissioner concurring, rejected the prior practice of the Patent Office and issued a patent on a microbial culture that was used to digest, and thereby purify, a certain waste

product that emanates from pulp mills. The decision, in this regard, was based largely on the U.S. Supreme Court's decision in *Chakrabarty, supra*, and on the practice in Australia, Germany and Japan. Having noted that judicial bodies in these countries altered their interpretation of patentable subject matter to include micro-organisms, the Board observed, at p. 88: "[o]bviously the answer to the question before us, which once had seemed so clear and definite has become clouded and uncertain". The Board was careful to limit the subject matter to which the decision would apply (at p. 89):

... this decision will extend to all micro-organisms, yeasts, moulds, fungi, bacteria, actinomycetes, unicellular algae, cell lines, viruses or protozoa; in fact to all new life forms which are produced *en masse* as chemical compounds are prepared, and are formed in such large numbers that any measurable quantity will possess uniform properties and characteristics.

199            Though this Court is not faced with the issue of the patentability of lower life forms, it must nonetheless address the respondent's argument that the line between higher and lower life forms is indefensible. As discussed above, I am of the opinion that the unique concerns and issues raised by the patentability of plants and animals necessitate a parliamentary response. Only Parliament has the institutional competence to extend patent rights or another form of intellectual property protection to plants and animals and to attach appropriate conditions to the right that is granted. In the interim, I see no reason to alter the line drawn by the Patent Office. The distinction between lower and higher life forms, though not explicit in the Act, is nonetheless defensible on the basis of common sense differences between the two. Perhaps more importantly, there appears to be a consensus that human life is not patentable; yet this distinction is also not explicit in the Act. If the line between lower and higher life forms is indefensible and arbitrary, so too is the line between human beings and other higher life forms.

200           The appellant submits that a fully developed non-human mammal is worlds apart from a yeast, a mould, or even the single-celled egg leading to its development. Whereas simple organisms are easily defined or identified by reference to a limited number of properties, complex life forms are not. In addition, simple organisms are often produced by processes similar to the manufacture of chemicals, while complex intelligent life forms are not.

201           As I stated above, the issue of whether a lower life form is a “composition of matter” or “manufacture” was never challenged in the courts in this country and it is difficult to say whether the Canadian courts would have followed the approach of the majority of the U.S. Supreme Court in *Chakrabarty, supra*, or whether the approach of the minority would have been preferred. Regardless of the wisdom of the decision, it is now accepted in Canada that lower life forms are patentable. Nonetheless, I agree with the appellant that this does not necessarily lead to the conclusion that higher life forms are patentable, at least in part for the reasons that it is easier to conceptualize a lower life form as a “composition of matter” or “manufacture” than it is to conceptualize a higher life form in these terms.

202           First, as noted in *Abitibi, supra*, at p. 89, micro-organisms are produced “*en masse* as chemical compounds are prepared, and are formed in such large numbers that any measurable quantity will possess uniform properties and characteristics”. The same cannot be said for plants and animals. In *re Bergy, Coats, and Malik*, 195 U.S.P.Q. 344 (1977), the U.S. Court of Customs and Patent Appeals explained the distinction in terms of process, at p. 350:

The nature and commercial uses of biologically pure cultures of microorganisms . . . are much more akin to inanimate chemical

compositions such as reactants, reagents, and catalysts than they are to horses and honeybees or raspberries and roses.

The difference in the end product was noted by Derzko, *supra*, at p. 161, in reference to the *Plant Breeders' Rights Act*:

The rights do not extend to the actual plant. This is done because, unlike inert objects that are patentable, and unlike unicellular organisms that replicate into exact copies of each other, higher organisms such as plants start off from a cell and then grow and differentiate into a complete plant. The difficulty lies in having to decide what should and should not be protected.

203           The above distinction was rejected by Rothstein J.A. on the rationale that so long as the mouse contains the desired feature (the oncogene), it does not matter whether the inventor is capable of controlling the other features of the mouse. I agree that Rothstein J.A.'s reasoning makes sense when approaching the issue of whether the invention meets the requirement of being new, useful and non-obvious. If the oncomouse contains the oncogene, it does not make any difference whether its fur is brown or grey. Nonetheless, the argument has some merit when considering the threshold issue of whether the mouse can be categorized as a "composition of matter" or "manufacture". For the reasons cited above, it is far easier to analogize a micro-organism to a chemical compound or other inanimate object than it is to analogize a plant or an animal to an inanimate object.

204           Second, this appeal deals specifically with the issue of whether an animal (in particular a mammal) can be considered to be a "composition of matter" or "manufacture". Several important features possessed by animals distinguish them from both micro-organisms and plants and remove them even further from being considered



a “composition of matter” or a “manufacture”. In particular, the capacity to display emotion and complexity of reaction and to direct behaviour in a manner that is not predictable as stimulus and response, is unique to animal forms of life. The interveners Animal Alliance of Canada, International Fund for Animal Welfare Inc. and Zoocheck Canada Inc. cast the distinction in the following terms: “[h]igher life forms are distinguishable from ‘lower life forms’ for which patents have already issued, in that, *inter alia*, they are sentient and conscious”. Of course, if sentience is the determining factor that renders a higher life form incapable of receiving patent protection, then the current line between higher and lower life forms is misplaced. As stated earlier, given the complexity of the issues involved, it is not the task of the Court to situate the line. It may well be that Parliament chooses to exclude plants from patentability for other reasons, such as their capability to self-propagate and the infringement issues that this raises.

205                Finally, the respondent refers to the World Trade Organization’s *Agreement on Trade Related Aspects of Intellectual Property Rights* (TRIPS), 1869 U.N.T.S. 299, and the *North American Free Trade Agreement* (NAFTA), Can. T.S. 1994 No. 2, which both contain an article whereby members may “exclude from patentability” certain subject matter, including plants and animals other than micro-organisms. The respondent argues that it is apparent from this provision that plants and animals are considered patentable, unless specifically excluded from patentability. I see little merit to this argument since the *status quo* position in Canada is that higher life forms are not a patentable subject matter, regardless of the fact that there is no explicit exclusion in the *Patent Act*. In my view, the fact that there is a specific exception in TRIPS and NAFTA for plants and animals does however demonstrate that the distinction between higher and lower life forms is widely accepted as valid.

206           As I remarked above, it is up to Parliament and not the courts to assess the validity of the distinction drawn by the Patent Office between higher life forms and lower life forms. Yet, even if this Court were to alter the *status quo* and find higher life forms patentable, it would be unable to avoid engaging in line-drawing. The majority of the Federal Court of Appeal, which found that the *Patent Act* did apply to higher life forms, was nonetheless compelled to draw a distinction between higher life forms and human beings. In doing so, it merely substituted one line, that between humans and animals, for the line preferred by the Patent Office, that between higher and lower life forms. In my opinion, the decision to move the line in this manner was ill-advised. As I stated earlier when considering the definition of “invention”, the patenting of all plants and animals, and not just human beings, raises several concerns that are not appropriately dealt with in the *Patent Act*. In addition, a judicially crafted exception from patentability for human beings does not adequately address issues such as what defines a human being and whether parts of the human body as opposed to the entire person would be patentable.

## VI. Conclusion

207           For the reasons given above, the appeal is allowed. No order as to costs will be given in light of the Commissioner’s oral submissions.

*Appeal allowed, McLACHLIN C.J. and MAJOR, BINNIE and ARBOUR JJ. dissenting.*

*Solicitor for the appellant: The Attorney General of Canada, Ottawa.*

*Solicitors for the respondent: Smart & Biggar, Ottawa.*

*Solicitors for the interveners Canadian Council of Churches and Evangelical Fellowship of Canada: Barnes, Sammon, Ottawa.*

*Solicitors for the interveners Canadian Environmental Law Association, Greenpeace Canada, Canadian Association of Physicians for the Environment, Action Group on Erosion, Technology and Concentration, and Canadian Institute for Environmental Law and Policy: The Canadian Environmental Law Association, Toronto.*

*Solicitors for the intervener Sierra Club of Canada: The Sierra Legal Defence Fund, Toronto.*

*Solicitors for the interveners Animal Alliance of Canada, International Fund for Animal Welfare Inc., and Zoocheck Canada Inc.: Ruby & Edwardh, Toronto.*