A-334-98

President and Fellows of Harvard College (*Appellant*)

v.

Commissioner of Patents (*Respondent*)

and

Canadian Environmental Law Association (*Intervener*)

Indexed as: President and Fellows of Harvard Collegev. Canada (Commissioner of Patents) (C.A.)

Court of Appeal, Linden, Isaac and Rothstein JJ.A.-- Ottawa, December 9, 1999 and August 3, 2000.

Patents -- Patentability of genetically altered non-human mammals for use in carcinogenicity studies -- Commissioner of Patents rejecting claims 1 to 12 in patent application as outside definition of "invention" in Patent Act, s. 2 but allowing claims 13 to 26 -- Appeal to F.C.T.D. dismissed -- Object of Patent Act to promote development of inventions for benefit of inventor, public -- Invention must be new, useful, unobvious -- As Act silent regarding biotechnological inventions, new life forms, claims in relation thereto decided according to traditional patent requirements -- Oncomouse unobvious, new, useful "composition of matter", therefore "invention" within meaning of Act, s. 2 -- Patent Act not excluding living organisms, e.g. non-human mammals, from definition of "invention" -- Product herein result of human ingenuity at genetic level, laws of nature, therefore patentable -- Complex life forms within parameters of Patent Act -- Provisions of Act cast in broad terms to fulfil Parliament's objective to promote invention -- Human beings not patentable but Parliament or courts will have to decide as to human genes, products at genetic level.

Animals -- Appellant seeking patent for production of animals with susceptibility to cancer for carcinogenicity studies -- Product of claims 1 to 12 in patent application referred to as transgenic non-human mammal or oncomouse -- Whether patentable in accordance with interpretation of Patent Act -- Oncomouse unobvious, new, useful composition of matter, therefore "invention" within Act, s. 2 -- Not merely product of laws of nature, rather result of both ingenuity, laws of nature, therefore patentable -- Test for usefulness of product mouse produced with all of cells affected by oncogene -- Control, reproducibility tests met -- No common understanding patent law not extending to living organisms -- Definition of "invention" not excluding from patentability higher life forms such as oncomouse.

Administrative law -- Judicial review -- Certiorari -- Commissioner of Patents denying patent with respect to claims 1 to 12 in patent application covering forms of transgenic non-human mammals -- Refusal upheld by F.C.T.D. -- F.C.A. holding decisions of Patent Commissioner warranting more deferential approach by reviewing courts when made within area of expertise -

- Even when reviewed on more deferential reasonableness simpliciter standard, Commissioner's decision could not stand -- Patent Commissioner, F.C.T.D. Judge committed numerous errors in reasoning, conclusions -- Commissioner applied overly broad control test, not implied by usefulness requirement -- Erred in splitting invention into phases, relying upon F.C.A. decision in Pioneer Hi-Bred Ltd. which was distinguishable.

This was an appeal from a Trial Division decision upholding the refusal by the Commissioner of Patents to grant a patent covering claims 1 to 12 in a patent application in relation to forms of transgenic non-human mammals. The objective of the appellant is to produce animals with a susceptibility to cancer for purposes of animal carcinogenicity studies by using an activated oncogene sequence. A plasmid containing the oncogene is injected into a fertilized mouse egg which is then transferred into a female "host" mouse and allowed to develop to term. If the resulting mouse is found to have all of its cells affected by the oncogene, it is called a "founder mouse". The founder mouse is then mated with an uninjected mouse. The Commissioner of Patents confirmed the decision by the Patent Examiner to reject claims 1 to 12 as being outside the definition of "invention" in section 2 of the *Patent Act*. The Trial Judge considered four *indicia* in interpreting section 2: (1) the inventor's degree of control over the creation of the invention; (2) the distinction between human intervention and the laws of nature in the creation of the oncomouse; (3) the relevance of the test of reproducibility and (4) the appropriateness of making distinctions between higher and lower life forms. On the basis of those *indicia*, the Trial Judge upheld the Commissioner of Patents' decision. On appeal, the issue was the patentability of genetically altered non-human mammals for use in carcinogenicity studies.

Held (Isaac J.A. dissenting), the appeal should be allowed.

Per Rothstein J.A.: A patent protects an invention. The object of the *Patent Act* is to promote the development of inventions in a manner that benefits both the inventor and the public. An invention may be any new and useful process or product or a new or useful improvement to a process or product. Under section 28.3 of the *Patent Act*, the subject-matter of a patent claim must not have been obvious to persons skilled in the art or science. The Commissioner's duty is not discretionary: when a process or a product satisfies the requirements of the Act, an application for a patent must be granted. To the extent that this appeal gives rise to policy questions, they are to be addressed by Parliament and not by the Court. Because the *Patent Act* contains no provision relating to biotechnological inventions and new forms of life in particular, the type of claims at issue will be patentable if they are within the scope of existing legislation and meet the traditional conditions and requirements for a patent.

The issue was whether claims 1 to 12 amount to an "invention" within the meaning of section 2 of the *Patent Act*. The oncomouse is both unobvious and a new and useful "composition of matter"; therefore it is an "invention" within the meaning of section 2 of the Act. The language of patent law is broad and general and is to be given wide scope because inventions are, necessarily, unanticipated and unforeseeable. The Court must respect Parliament's use of such language and not adopt a narrow approach that would conflict with its obvious intention. The *Patent Act* does not exclude living organisms, that is non-human mammals, from the definition of "invention". Patentability requires a non-naturally occurring "composition of matter" arising from the application of inventiveness or ingenuity. The oncomouse must be considered to be the result of

both ingenuity and the laws of nature: ingenuity in the initial genetic engineering involving the assembly of the oncogene, incorporating it into the plasmid and injecting the plasmid into the zygote; and the laws of nature, with the oncogene then affecting all the cells of the oncomouse in the course of gestation, the subsequent mating of an oncomouse and an uninjected mouse, and the reliance on Mendelian laws of inheritance to obtain offspring oncomice. The ingenuity in this case relates not only to the introduction of genetic material into the mouse by artificial means, but extends to the makeup of the critical oncogene itself. The oncomouse described in the patent claims would not exist in nature; rather, it is the result of both human ingenuity at the genetic level and the laws of nature. Having regard to section 40 of the *Patent Act*, on a straightforward interpretation of the term "composition of matter" and taking into account the roles of ingenuity and the laws of nature, there is no reason in law why the product, in this case the oncomouse, is not patentable.

The Commissioner of Patents and the Trial Judge made a number of errors in their reasonings and conclusions. First, the Trial Judge expressed his preference for the minority view in a decision of the Supreme Court of the United States, *Diamond v. Chakrabarty*, in which, by a 5-4 majority, a bacterium which could break down crude oil was found to be patentable. While American patent decisions are not binding on Canadian courts, where the statutory language which is being interpreted is similar in both countries and where the reasoning underlying the United States Court's interpretation of the language is persuasive, there is no reason why Canadian courts should ignore the American case law. Significant reliance should be placed on the majority opinion in *Chakrabarty* in concluding that the definition of "invention" does not exclude from patentability higher life forms such as the oncomouse. There is no "common understanding" that patent law does not extend to living organisms. Second, the Commissioner of Patents refused to grant a patent for claims 1 to 12 mainly because the inventors did not have full control over all characteristics of the resulting oncomouse. The Trial Judge agreed with that conclusion. Control is implied in the requirement that an invention be useful. If there is insufficient control over a product such that it would not be practically useful, the usefulness requirement of the definition of "invention" would not be met. The Commissioner of Patents and the Trial Judge applied a far broader control test, not implied by the usefulness requirement for an invention. They read into the definition of "invention" words not expressed by Parliament, or implied by the language used by Parliament, and in doing so, erred in law. Usefulness is necessary for patentability and implies control in the sense that the desired result will be achieved when the product is used or produced. The desired result herein is an oncomouse with susceptibility to cancer for use in carcinogenicity studies. Once that has been achieved, control over other characteristics of the mouse is irrelevant. If the product is a composition of matter that is new, useful and unobvious, it is a patentable "invention". Third, the Trial Judge found that "for an invention to be patentable, it must be reproducible". In his view, the oncomouse was not reproducible. By using the methods described in the specification of the patent application, an oncomouse is producible with all of its cells affected by the oncogene. Such a mouse is reproducible and is useful. The reproducibility requirement, in the context of usefulness, has been satisfied. Fourth, the Commissioner of Patents split the invention into two phases. Once it was conceded that most inventions involve the use of some of the laws of nature, there could be no valid basis for splitting an invention between the portion that is the result of inventive ingenuity and the portion that is not. Splitting the invention into phases was not legally justified. It denied to the inventors a patent on a product which was the result of a combination of

inventive ingenuity and the laws of nature both of which were central to the invention. Fifth, the Trial Judge erred in finding that complex life forms were not within the parameters of the *Patent Act*. There may be policy reasons against patentability of higher life forms. However, such arguments are for Parliament, not for courts. Sixth, the Trial Judge erred in concluding that the patentability of the oncomouse would provide the inventor with no additional protection beyond that provided by patenting claims 13 to 26. A patent provides legal protection against the world, that is others who might come into possession of an oncomouse and reproduce it. Finally, the Trial Judge and the Commissioner of Patents erred in putting too much emphasis on the Federal Court of Appeal's decision in *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*. The findings in that case with respect to cross-breeding of soybeans are not applicable to the case at bar which involves inventive ingenuity and intervention at the genetic level and the creation of a specific new life form.

As to the standard of review, the decision of the Trial Judge is reviewable on a correctness standard. On the other hand, the expertise of the Commissioner of Patents warrants a more deferential approach by reviewing courts on decisions made by him within his area of expertise. Even on the more deferential reasonableness *simpliciter* standard, the Commissioner's decision is properly reviewable by the Court. The Commissioner was wrong notably in applying control and reproducibility tests that are not expressed in or implied by the *Patent Act* and in splitting the invention into phases without legal justification.

A final issue raised was the obvious concern as to whether a finding that "invention" includes living organisms could be extended to human beings. The *Patent Act* cannot be extended to cover human beings. Patenting is a form of ownership of property which cannot be extended to human beings. A further ground for so concluding was Charter section 7, which protects the liberty of the person. Even so, as scientific research advances, Parliament or the courts will have to decide whether human genes or products at the genetic level are patentable.

Per Isaac J.A. (*dissenting*): The first question that a Court must ask, when hearing an appeal from an administrative tribunal, is what is the standard of review. The Trial Judge failed to do so. The Commissioner's decision was not protected by a privative clause. However, it is beyond doubt that the Commissioner of Patents has expertise on the issue of patentability of inventions; he is an expert tribunal. Since the nature of the question (the patentability of the oncomouse) is squarely within his area of expertise, his decision should be accorded deference on the reasonableness *simpliciter* standard. The purpose of the *Patent Act* also weighs in favour of greater deference to decisions of the Commissioner. The Act recognizes that the Commissioner must always be aware of, and take into account, the public interest in granting a patent. In a morally divisive case such as this, the Court should defer to the Commissioner's decisions where they are informed by considerations of public policy. The Commissioner's decision was reasonable because it took a cautious approach to patenting new life forms. The Trial Judge was right to dismiss the appeal even though he did not appreciate the need for a standard of review analysis. Under section 40 of the Act, the Commissioner must be satisfied that an applicant is legally entitled to a patent. It is not sufficient to conclude that a patent must be granted once the requirements of the Act have been met. The grant or refusal of a patent is not a matter of discretion but this does not mean that an applicant is not required to satisfy the Commissioner and his officials that he is by law entitled to the grant.

The issue was whether the decision of the Commissioner was reasonable. What was done in other jurisdictions is irrelevant to the resolution of that issue. The decision on this appeal should not be affected by the fact that the oncomouse has been patented in the United States of America and Europe. The Commissioner's decision was reasonable. Absent evidence to the contrary, the Court is bound to accord appropriate respect for his finding. In all the circumstances of this case, including the serious moral and ethical implications of this subject-matter, it seems that Parliament is the most appropriate forum for the resolution of the issues in dispute here.

statutes and regulations judicially considered

Canadian Charter of Rights and Freedoms, being Part I of the *Constitution Act, 1982*, Schedule B, *Canada Act 1982*, 1982, c. 11 (U.K.) [R.S.C., 1985, Appendix II, No. 44], s. 7.

Customs Tariff, S.C. 1997, c. 36.

Federal Court Act, R.S.C., 1985, c. F-7 , s. 24(1) (as am. by S.C. 1990, c. 8, s. 6).

Patent Act, R.S.C. 1970, c. P-4 , ss. 2, 36(1), 42, 44.

Patent Act, R.S.C., 1985, c. P-4 , ss. 2 "invention" (as am. by S.C. 1993, c. 2, s. 2), 10 (as am. by S.C. 1993, c. 15, s. 28), 17, 27 (as am. *idem*, s. 31), 28.3 (as enacted *idem*, s. 33), 35(1) (as am. by R.S.C., 1985 (3rd Supp.), c. 33, s. 12), 40, 41 (as am. *idem*, s. 16), 42 (as am. *idem*), 46 (as am. *idem*; S.C. 1993, c. 15, s. 43).

Patent Act, 35 U.S.C. § 101 (1988).

Patent Rules, SOR/96-423, RR. 30(6), 40, 45(2), 46, 47(2),(5).

Patents Act 1977 (U.K.), 1977, c. 37.

Plant Breeders' Rights Act, S.C. 1990, c. 20.

Plant Patent Act (The), 35 U.S.C. § 161 (1930).

Plant Variety Protection Act (The), 7 U.S.C. § 2402(a) (1970).

Trade-marks Act, R.S.C., 1985, c. T-13.

cases judicially considered

applied:

Monsanto Company v. Commissioner of Patents, [1979] 2 S.C.R. 1108; (1979), 100 D.L.R. (3d) 385; 42 C.P.R. (2d) 161; 28 N.R. 181; *Pushpanathan v. Canada (Minister of Citizenship and Immigration)*, [1998] 1 S.C.R. 982; (1998), 160 D.L.R. (4th) 193; 11 Admin. L.R. (3d) 1; 43 Imm. L.R. (2d) 117; 226 N.R. 201; amended reasons [1998] 1 S.C.R. 1222; (1998), 11 Admin. L.R. (3d) 130; *Canada (Director of Investigation and Research) v. Southam Inc.*, [1997] 1 S.C.R. 748; (1997), 144 D.L.R. (4th) 1; 50 Admin. L.R. (2d) 199; 71 C.P.R. (3d) 417; 209 N.R. 20; *Diamond v. Chakrabarty*, 447 U.S. 303 (1980); *Application No. 003,389 of N.V. Organon, Re* (1973), 15 C.P.R. (2d) 253 (Pat. App. Bd.).

distinguished:

Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents), [1987] 3 F.C. 8; (1987), 11 C.I.P.R. 158; 14 C.P.R. (3d) 491; 77 N.R. 137 (C.A.); *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623; (1989), 60 D.L.R. (4th) 223; 25 C.I.P.R. 3; 25 C.P.R. (3d) 257; 97 N.R. 185.

considered:

Cadbury Schweppes Inc. v. FBI Foods Ltd., [1999] 1 S.C.R. 142; (1999), 167 D.L.R. (4th) 577; [1999] 5 W.W.R. 751; 59 B.C.L.R. (3d) 1; 117 B.C.A.C. 161; 42 B.L.R. (2d) 159; 83 C.P.R. (3d) 289; *Commissioner of Patents v. Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning*, [1964] S.C.R. 49; (1963), 41 C.P.R. 9; 25 Fox Pat C. 99; *Electric Fireproofing Co. of Canada v. Electric Fireproofing Co.* (1910), 43 S.C.R. 182; affg (1909), 34 Que. S.C. 388; *Tennessee Eastman Co. et al. v. Commissioner of Patents*, [1974] S.C.R. 111; (1972), 33 D.L.R. (3d) 459; 8 C.P.R. (2d) 202; *Perka et al. v. The Queen*, [1984] 2 S.C.R. 232; (1984), 13 D.L.R. (4th) 1; [1984] 6 W.W.R. 289; 28 B.C.L.R. (2d) 205; 14 C.C.C. (3d) 385; 42 C.R. (3d) 113; 55 N.R. 1; *Molson Breweries, a Partnership v. John Labatt Ltd.* (2000), 5 C.P.R. (4th) 180; 252 N.R. 91 (F.C.A.); *X v. Commissioner of Patents* (1981), 59 C.P.R. (2d) 7; 46 N.R. 407 (F.C.A.); *British Columbia Telephone Co. v. Shaw Cable Systems (B.C.) Ltd.*, [1995] 2 S.C.R. 739; (1995), 125 D.L.R. (4th) 443; 31 Admin. L.R. (2d) 169; 183 N.R. 184; *International Longshoremen's and Warehousemen's Union, Ship and Dock Foremen, Local 514 v. Prince Rupert Grain Ltd.*, [1996] 2 S.C.R. 432; (1996), 135 D.L.R. (4th) 385; 40 Admin. L.R. (2d) 1; 96 CLLC 210-037; 198 N.R. 99; *Application of Abitibi Co., Re* (1982), 62 C.P.R. (2d) 81 (Pat. App. Bd.); *Rice v. Christiani*, [1931] A.C. 770 (P.C.).

referred to:

Diversified Products Corp. v. Tye-Sil Corp. (1991), 35 C.P.R. (3d) 350; 125 N.R. 218 (F.C.A.); *Vanity Fair Silk Mills v. Commissioner of Patents*, [1939] S.C.R. 245; [1938] 4 D.L.R. 657; *Lawson v. Canada (Commissioner of Patents)* (1970), 62 C.P.R. 101 (Ex. Ct.); *Consolboard Inc. v. MacMillan Bloedel (Sask.)*, [1981] 1 S.C.R. 504; (1981), 122 D.L.R. (3d) 203; 56 C.P.R. (2d) 145; 35 N.R. 390; *Pezim v. British Columbia (Superintendent of Brokers)*, [1994] 2 S.C.R. 557; (1994), 114 D.L.R. (4th) 385; [1994] 7 W.W.R. 1; 92 B.C.L.R. (2d) 145; 22 Admin. L.R. (2d) 1; 14 B.L.R. (2d) 217; 4 C.C.L.S. 117; *Ex parte Hibberd*, 227 U.S.P.Q. 443 (Bd. Pat. App. & Int. 1985); *Application No. 016,962 (Patent No. 947,179), Re* (1973), 17; C.P.R. (2d) 177 (Pat. App. Bd.); *Application No. 880,719 (Patent No. 944,693), Re* (1973), 18 C.P.R. (2d) 114 (Pat. App. Bd.); *Application for Patent Containing Claims that Read on Mental Steps Performed by a Human Operator in Deciding to Transmit a Signal, Re* (1972), 23 C.P.R. (2d) 93 (Comm. Pat.).

authors cited

Canada. Patent Office. *Manual of Patent Office Practice*. Ottawa: The Office, 1998.

Canada. Royal Commission on New Reproductive Technologies. *Proceed with Care: Final Report of the Royal Commission on New Reproductive Technologies.* Ottawa: Minister of Government Services, 1993.

Fox, Harold G. *The Canadian Law and Practice Relating to Letters Patent for Inventions*, 4th ed. Toronto: Carswell, 1969.

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

Hoffmaster, Barry. "The Ethics of Patenting Higher Life Forms" (1989), 4 *I.P.J.* I.

Kreuzer, Helen and Adrianne Massey. *Reconbinant DNA and Biotechnology: A Guide for Teachers*. Washington, D.C.: ASM Press, 1996.

New Oxford Dictionary of English. Oxford: Clarendon Press, 1998 "transgenic".

"United States Patent and Trademark Office, Animals-- Patentability", 1077 *Official Gazette U.S. Patent & Trademark Office* 8 (April 21, 1987).

Vaver, David. *Intellectual Property Law: Copyright, Patents, Trade-Marks*. Toronto: Irwin Law, 1997.

APPEAL from a Trial Division decision ([1998] 3 F.C. 510; (1998), 79 C.P.R. (3d) 98; 146 F.T.R. 279) dismissing an appeal from a refusal by the Commissioner of Patents to grant a patent of invention for claims 1 to 12 of the appellant's application regarding genetically altered non-human mammals for use in carcinogenicity studies. Appeal allowed.

appearances:

A. David Morrow and *Steven B. Garland* for appellant.

Frederick. B. Woyiwada for respondent.

Paul Muldoon, Theresa A. McClenaghan and *Michelle Swenarchuk* for intervener.

solicitors of record:

Smart & Biggar, Ottawa, for appellant.

Deputy Attorney General of Canada for respondent.

Canadian Environmental Law Association, Toronto, for intervener.

The following are the reasons for judgment rendered in English by

[1]Isaac J.A. (*dissenting*): I have had the privilege of reading, in draft, the reasons which Mr. Justice Rothstein proposes to deliver in this appeal. I am unable to subscribe to them or to his proposed disposition of the appeal. Since I have reached a different conclusion respecting the disposition of the appeal, I must state the reasons which impel me to do so.

[2]The appeal is from a judgment of the Trial Division which dismissed an appeal by the appellant, pursuant to section 41 of the *Patent Act*,[1] and subsection 24(1) of the *Federal Court Act*,[2] from a refusal by the Commissioner of Patents (hereinafter the Commissioner) to grant a patent of invention for claims 1 to 12 of the appellant's application. The reasons for judgment are reported in [1998] 3 F.C. 510.

[3]Section 41 of the Act reads:[3]

41. Every person who has failed to obtain a patent by reason of a refusal of the Commissioner to grant it may, at any time within six months after notice as provided for in section 40 has been mailed, appeal from the decision of the Commissioner to the Federal Court and that Court has exclusive jurisdiction to hear and determine the appeal.

[4]Subsection 24(1) of the *Federal Court Act* reads:

24. (1) Except as otherwise provided in this Act or any other Act of Parliament, the Trial Division has exclusive original jurisdiction to hear and determine all appeals that under any Act of Parliament may be taken to the Court.

[5]The Commissioner's authority to refuse to grant a patent of invention is found in section 40 of the Act. That section reads:[4]

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. [Emphasis added.]

THE FACTS

[6]The facts upon which the learned Judge proceeded are found in paragraphs 3 and 4 [pages 514-515] of the reported reasons. There is, therefore, no reason to repeat them here.

PROCEDURAL HISTORY

[7]It would be helpful to recite the procedural history of the appellant's application for the patent from the commencement of the process to the present proceeding, because, in my respectful view, that is the only way for this Court to assess the reasonableness of the Commissioner's conclusions and the reasons for them. As I will show later, this is the assessment that the Judge in the Trial Division should have made; but, did not make.

[8]On 21 June 1985, the appellant filed a petition for the grant of a patent of invention respecting transgenic animals described and claimed in the specifications.[5]

[9]On 9 April 1987, the Commissioner notified the appellant, pursuant to subsection 45(2) of the *Patent Rules*,[6] of an action by an Examiner in relation to the application. The action by the Examiner consisted of a request, pursuant to rule 40, for particulars of the prior art.[7]

[10]On 23 June 1987, the appellant replied.[8]

[11]On 21 February 1990, the Commissioner notified the appellant of a further action taken by the Examiner pursuant to Rule 46 of the *Patent Rules* in the public interest. The Examiner stated that the appellant's application had been examined and that of the 24 claims in the application, 18 had been rejected--claim 14 was rejected because the subject- matter lacked inventive ingenuity; claims 1 to 12 and 15 to 17 were rejected as being directed to non-statutory subject-matter and as being outside the definition of invention as given in section 2 [as am. by S.C. 1993, c. 2, s. 2] of the Act; and claims 18 and 19 were rejected as being directed to a method of medical treatment which is outside the definition of invention in section 2 of the Act. The Examiner stated that an amendment of the application was required in light of the action taken.[9]

[12]By letter dated 21 June 1990, the solicitors for the appellant asked for a two-month extension to reply to the "Office Action".[10]

[13]By letter dated 6 July 1990, the Commissioner granted the extension to 21 August 1990.[11]

[14]By letter dated 16 August 1990, the solicitors for the appellant replied in language that found favour with Mr. Justice Rothstein, as evidenced by his reasons, and asked for favourable reconsideration of the application.[12]

[15]By letters dated 11 September and 5 October 1990, respectively, the solicitors for the appellant submitted further material.[13]

[16]By letter dated 14 January 1992, Examiner S. Kemdirim notified the appellant of a further action that was taken pursuant to "Rule 46 of the *Patent Rules* in the public interest." The letter continued:

This application has been examined pursuant to applicant's correspondence dated August 16, 1990; September 11, 1990 and October 5, 1990.

The number of claims in this application is 24.

Applicant's arguments presented in his amendment of August 16, 1990 have been considered. However, it has been decided that these arguments do not overcome the objections set forth in the last Official Action. The objections to claims 1-12, 14 to 19 are maintained.[14]

[17]Reasons were given for the rejection of each claim. Particularly instructive, were the reasons given for the rejection of claims 1-12 and 15-17. They read:

Claims 1 to 12 and 15-17 are rejected as being directed to non-statutory subject matter. Subject matter directed to plants or animals is held to be outside the definition of invention as given in Section 2 of the Patent Act. Any further modification of said matter does not confer patentability thereto if it remains in a living or viable state.

Applicant made reference to Section 2 of the Patent Act and Section 12.03.01 of the Manual of Patent Office Practice and argued that Section 2 and Manual of Patent Office Practice Section 12.03.01(a) do not exclude all animals from patentability.

Section 2 of the Patent Act defines a patentable invention:

"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;

Section 2 sets forth the criteria for patentability of a manufacture or a composition of matter. It must possess novelty and utility. While Section 2 is silent with respect to patentability of animals per se, a limiting interpretation should be given to the language embodied in the definition of the word "invention". Thus, applicant's alleged invention of claims 1 to 12 and 15-17 do not qualify as a "manufacture" within the definition of invention as defined in Section 2 of the Patent Act.

Moreover, given that animals were in existence when the Patent Act was enacted, had it been the intention of Parliament to include animals as a patentable subject matter, then words such as "animals" or "higher life forms" would have appeared in the definition of "invention" as given in Section 2 of the Patent Act.

Contrary to applicant's statement, the Manual of Patent Office Practice (M.O.P.O.P.) Section 12.03.01(a) does exclude all animals from patentability:

"Plants and animals are not patentable subject matter" M.O.P.O.P. Section 12.03.01(a), as amended January 1990. For guidance only.

Applicant made reference to the Supreme Court decision in the Pioneer Hi-Bred case. Applicant argued that his instant alleged invention was essentially microbiological and involved human manipulation of genetic material. This, applicant stated, should be contrasted with the natural process of crossbreeding process described in Pioneer Hi-Bred. It must also be remarked that the crossbreeding process described in Pioneer Hi-Bred was not reproducible.

Although the process of claims 15-17 involves human manipulation of genetic material, the process is not reproducible, as was the case with the Pioneer Hi-Bred crossbreeding process. This is because the injected activated oncogene is randomly incorporated into the chromosome of the embryo. One can not predict with any certainty the locus in which it will be integrated. Consequently, different scientists following the teachings of instant specification will not obtain the same results, in that different genetically distinct lines of transgenic mice will be obtained.

In view of the foregoing, claims 1 to 12 and 15-17 are rejected.[15]

[18]By letter dated 13 April 1992, the solicitors for the appellant wrote to the Commissioner requesting an extension of time to reply to the official action.[16]

[19]By letter dated 27 April 1992, the Commissioner replied, extending the time for reply to the Examiner's action.[17]

[20]By letter dated 14 July 1992, the solicitors for the appellant replied to the official action of 14 January 1992. The reply, consisting of some ten pages with a five-page attachment, reads, in part:

This letter is filed in response to the official action of January 14th, 1992.

Please replace the claim pages on file with new claim pages containing claims 1 to 26 submitted herewith in duplicate.

Please replace disclosure pages 1 and 2 with new disclosure pages submitted herewith.

R E M A R K S

Claim 1 has been amended by restricting the subject matter to a mammal. Similar amendments have been made in claims 2 to 15. Claim 14 has been restricted similarly and steps in the method included. Claims 18 and 19 have been amended to be in "use" format. Claims 25 and 26 have been added to this application. Claim 25 finds support on pages 5 and 6 and 17 of the disclosure and claim 26 finds support on page 5 of the disclosure.

In view of the amendments to the claims, various minor amendments have been made to pages 1 and 2. The amendments to page 1 have been made to improve support for claim 1 and the amendments to page 2 have been made to improve support for claims 15, 14 and 3, respectively.[18] [Emphasis added.]

[21]What emerges from this response, clearly, in my view, is the vigorous debate between the solicitors for the appellant and the Examiner, respecting the patentability of the subject-matter of the application. One should notice, too, that in the give and take of this debate, each party accepts or rejects the positions taken by the other. The excerpts quoted in paragraphs 22 and 23, *infra*, demonstrate the nature and quality of the debate.

[22]I excerpt below from the solicitors reply at pages 122-123:

The balance of the official action relates to an objection to claims 1 to 12 and 15 to 17 as being directed to non-statutory subject matter. As the Examiner correctly observes Section 2 is silent with respect to patentability of animals per se. However, the Examiner interprets the silence of this section of the Patent Act as indicating that a limiting interpretation should be put on the language embodied in the definition of the word "invention". Applicant respectfully disagrees. Applicant understands that in a common law jurisdiction such as Canada, if there is no express prohibition of an activity, such as patenting a new, useful and unobvious animal, then applicant is free to obtain such protection. Applicant also respectfully disagrees with the Examiner's statement that the subject matter of claims 1 to 12 does not qualify as a "manufacture". New genetic material, new arrangements of old genetic material combinations of new and old genetic material are commonly accepted as patentable. Vectors containing such genetic material are patentable. Cells containing such material are patentable. However, the Patent Office appears to draw a line between cells and differentiated aggregations of cells in the form of a mammal. Whether or not the cells are differentiated, the subject matter of the claims has required human intervention and, it is respectfully submitted, does quality as "manufacture".[19] [Emphasis added.]

[23]The Examiner's final action is dated 24 March 1993. Examiner, M. Gillen, informed the appellant that the refusal of claims 1 to 12 was maintained but that claims 13 to 26 were allowable. I reproduce, in part, the reasons given for maintaining the refusal of claims 1 to 12:

Claims 1-12 are directed to a transgenic non-human mammal. Said claims are rejected as being directed to non-statutory subject matter. It is held that a higher life form, like an animal, is outside the definition of invention as given in Section 2 of the Patent Act.

Applicant has argued "that in a common law jurisdiction such as Canada, if there is no express prohibition of an activity, such as patenting a new, useful and unobvious animal, then applicant is free to obtain such protection". The implication of this statement is that if something is not

expressly prohibited by the Patent Act, and provided it is new, useful and unobvious, then it is patentable. This is clearly not the case in Canada and the Commissioner's right to both interpret Section 2 of the Patent Act and to reject certain subject matter and activities as being directed to non-patentable subject matter has been confirmed by the Courts.

In *Commissioner of Patents v Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning* (1964) S.C.R. at 56 Judson J. said, ". . . in Canada the Patent Office, supervised by the Court, does examine as to inventiveness, and an applicant may appeal to the highest court. Moreover, in the particular class of case with which we are here concerned dealing with drugs and medicines, there is considerable public interest at stake, and the Commissioner should most carefully scrutinize the application to see if it merits the grant of monopoly privileges and to determine the scope of the monopoly available." Judson J. affirmed the Commissioner's right to consider the public interest in interpreting Section 2 of the Act. [Emphasis added.]

In *Lawson v Commissioner of Patents* (1970) 62 C.P.R. 101, at 109 Cattanach J. states "I take it as well settled that all new and useful arts and manufactures are not necessarily included in s. 2(d) of the Patent Act." In *Lawson v Commissioner of Patents* the Exchequer Court upheld the Commissioner's refusal to grant a patent for subdivided land in the shape of a champagne glass.

In *Tennessee Eastman v Commissioner of Patents* (1974) S.C.R. 111, at 119 Pigeon J. said, "Having come to the conclusion that methods of medical treatment are not contemplated in the definition of `invention' as a kind of `process', the same must, on the same basis, be true of a method of surgical treatment." In this case the Court upheld the Commissioner's interpretation of "invention" to exclude methods of medical or surgical treatment.

In *Pioneer Hi-Bred Ltd. v Commissioner of Patents* (1987), 3 F.C. 8, 77 N.R. 137, the Federal Court of Appeal upheld the refusal of the Commissioner of Patents to grant a patent for a new plant variety, where claims to the plant and its seed were rejected as being directed to non-statutory subject matter. The Commissioner based his objection on an interpretation of the definition of "invention" as given in Section 2 of the Patent Act.

The foregoing clearly demonstrates that not everything which is new, useful and inventive is *a priori* patentable subject matter. The Commissioner of Patents has both a right and an obligation to consider the public interest in the granting of a patent. [Emphasis added.]

Applicant has argued that "patenting of higher life forms (plants and animals) is clearly comtemplated [*sic*] in decisions of the Patent Appeal Board and the Courts". However, on the question of the patentability of higher life forms, neither the Patent Appeal Board nor the Courts have expressly stated that these life forms constitute patentable subject matter.

In the *Abitibi* case (*Re application of Abitibi Co. (1982), 62 C.P.R. (2d) 81*) the Commissioner concurred with the recommendation of the Patent Appeal Board that microorganisms be considered as patentable subject matter. The Commissioner's decision made a distinction between lower life forms like animals. The *Abitibi* decision established the patentability of lower life forms "produced en masse as chemical compounds are prepared" and "formed in such large numbers that any measurable quantity will possess uniform properties and characteristics." As

for higher life forms, like plants and animals, the Commissioner's decision concluded, regarding the question of patentable subject matter, "Whether it reaches up to higher life forms--plants (in the popular sense) or animals--is more debatable". [Emphasis in original.]

The issue of higher life forms as patentable subject matter was dealt with subsequent to the *Abitibi* decision in an application for patent protection for a plant and its seed, submitted by *Pioneer Hi-Bred Ltd.* A Commissioner's decision upheld by the Federal Court of Appeal (referenced above) rejected claims to a soybean plant and its seed. Marceau J. in his summary stated: "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, and second to the enactment of special provisions capable of better adapting the whole scheme to a subject matter, the essential characteristics of which is that it reproduces itself as a necessary result of its growth and maturity."

While the issue of the patentability of higher life forms was "more debatable" in the *Abitibi* decision, the Commissioner concluded in the *Pioneer Hi-Bred* case that one type of higher life form, i.e. plants, was outside the definition of invention as given in Section 2 of the Patent Act. While the Supreme Court did not make a ruling on the Commissioner's rejection of claims to a plant and its seed under Section 2 of the Act, the Federal Court of Appeal upheld the Commissioner's rejection of these claims under this section of the Act.

If one accepts that an animal, in this case a mammal, is a more complex and higher life form than a plant, it seems logical to conclude that if a plant is held to be non-patentable subject matter, then the same must be said for animals.

In rejecting claims 1-12, directed to a transgenic non-human mammal, the examiner is guided by the Commissioner's decision in the *Abitibi* case and bound by the Federal Court of Appeal decision in the *Pioneer Hi-Bred* case. Claims 1-12 are rejected as being directed to a form of living matter which is outside the definition of invention as given in Section 2 of the Patent Act.[20]

[24]By letter dated 24 September 1993, the appellant's solicitors responded to the Examiner's final action. Their position, summarized at page 9 of the letter was that:

1) There is no statutory basis for excluding higher life forms from patent protection;

2) There is no legal precedent that prohibits patenting of higher life forms created by significant technical intervention of man; and

3) It is in the interest of the Canadian public to allow patents for higher life forms.

In view of the foregoing, we respectfully request that the Commissioner of Patents allow claims 1-12 of the present application.[21]

[25]In the letter, the solicitors also asked the Commissioner to review the Examiner's final action and for an oral hearing before the Patent Appeal Board as provided in subsections 47(2) and (5), respectively, of the *Patent Rules*.

[26]By letter dated 22 June 1994, the Chairman of the Patent Appeal Board informed the appellant's solicitors, *inter alia*, that an oral hearing had been fixed for 28 July 1994.[22]

[27]The oral hearing was held on 28 July 1994. On 14 August 1995, the Chairman of the Patent Appeal Board informed the appellant's solicitors of the Commissioner's decision refusing to grant a patent containing claims 1-12 of the application and informing them of their client's statutory right of appeal.[23]

[28]On 2 February 1996, the appellant filed, in the Trial Division, a notice of appeal from the decision of the Commissioner rejecting claims 1-12 of the application.[24] No particular grounds of error are alleged in the notice.

[29]On 21 April 1998, the Trial Division issued judgment dismissing the appeal. It is from that judgment that this appeal is taken.

DECISION OF THE COMMISSIONER

[30]Although Mr. Justice Rothstein has dealt with the Commissioner's decision in his reasons, I find it necessary to highlight certain portions of it for purposes of these reasons.

[31]I note, first, the final statement in the first paragraph of the Commissioner's reasons:

. . . I have subsequently reviewed the prosecution of the application and discussed the rejection with the Board before rendering my decision.[25] [Emphasis added.]

[32]Secondly, the Commissioner's description of the subject-matter of the application should be noticed here:

The application is directed to a transgenic mammal, in particular a transgenic mouse which can be used as a test vehicle for substances suspected of being carcinogenic or for substances thought to confer protection against the development of neoplasms.[26]

[33]Thirdly, he noticed that this Court, in *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*[27] unanimously refused to accept the definition of "manufacture" and "composition of matter" that the Supreme Court of the United States had relied upon in *Diamond v. Chakrabarty*,[28] the decision that Mr. Justice Rothstein urges us to accept guidance from.

[34]Fourthly, he agreed with counsel for the appellant that, because the Supreme Court of Canada, did not decide *Pioneer Hi-Bred* on the merits, the Examiner was wrong to say in the final action that he was bound by the decision of this Court in *Pioneer Hi-Bred*. He did allow, however, that the decision of this Court in *Pioneer Hi-Bred* was of high persuasive value.[29]

[35]Fifthly, he observed that in *Application of Abitibi Co., Re*,[30] a decision of the Patent Appeal Board, on whose recommendation the Commissioner's decision was based, was reluctant to consider claims to higher life forms to be patentable.

[36]Sixthly, after rejecting the argument by counsel for the appellant that he should interpret the words "manufacture" and "composition of matter" found in section 2 of Act, according to U.S. practice, he stated:

. . . I do not however consider that much weight can be given to United States practice in interpreting Canadian legislation.

In my view the words "manufacture" and "composition of matter" as found in Section 2 apply to something that has been made under the control of the inventor. In the case of "manufacture" it is the production of articles for use from starting materials, prepared by giving these materials new forms, qualities, properties or combinations whether by hand labour or machinery. As to the term "composition of matter" I would construe the term broadly to include not only the result of chemical union or mechanical admixture but also microbiological, or genetic engineering techniques so long as they are performed and controlled by the human hand. At the same time the resulting product must be reproducible in a consistent manner.[31] [Emphasis added.]

[37]Finally, he concluded his analysis as follows:

Since the plasmids and the transgenic unicellular material are produced under the full control of the inventor and are reproducible, I am satisfied that they are a "manufacture" or a "composition of matter" under Section 2 of the Act. I note that no objections, based on Section 2, were raised against such claims in the instant application.

However I cannot extend the meaning of "manufacture" or "composition of matter" to include a non-human mammal. On the plain and ordinary meaning of the words, and here I am strongly influenced by the Federal Court of Appeal decision in *Pioneer Hi-Bred*, I do not find that a non-human mammal like a mouse falls within the definition of "invention". The inventors do not have full control over all the characteristics of the resulting mouse since the intervention of man ensures that reproducibility extends only as far as the cancer forming gene.[32]

[38]He, therefore, refused to grant a patent concerning claims 1-12.[33]

REASONS OF THE TRIAL DIVISION

[39]The Judge of the Trial Division treated the appeal as one that came to him to be heard as an appeal *de plano*. No doubt, rising to the submissions made to him by counsel, he accepted that [at page 516] "this is the first time the Court has been faced with the question of whether a higher life form, a mammal, is patentable." In my respectful view, the Judge was misled by counsel into believing that he was doing something more than sitting to review the decision of a specialized tribunal. It is true that the appellant was given a right of appeal by statute. However, since *Pezim v. British Columbia (Superintendent of Brokers)*,[34] the first question that a Court must ask, when hearing an appeal from an administrative tribunal, like the present one, is what is the standard of

review. This is so, notwithstanding the existence of a statutory right of appeal and the fact that the constitutive statute of the tribunal does not contain a privative clause.

[40]This approach was affirmed to *Pushpanathan v. Canada (Minister of Citizenship and Immigration)*,[35] where Bastarache J., for the majority stated:

One of the elements necessary for the disposition of an application for judicial review is the standard of review of the decision of the administrative tribunal whose decision is being reviewed, and that question is clearly in issue in this case. Reluctant as this Court is to decide issues not fully argued before it, determining the standard of review is a prerequisite to the disposition of this case. [Emphasis added.]

[41]The principle laid down in that case respecting the need to decide what the standard of review in judicial review proceedings apply with equal force, in my respectful view, to statutory appeals since the judgment of the Supreme Court in *Pezim*.

[42]As I have already said, that is the first question the Court below should have asked. It did not. It is a question that I must now ask and answer because, in my respectful view, the answer is "a prerequisite to the disposition of this case."[36] With great respect to those who are of a contrary opinion, it is my view that the failure of counsel for the parties to raise the issue of standard of review does not relieve reviewing courts of their obligation to do a standard of review analysis.

STANDARD OF REVIEW

[43]In a number of recent decisions, the Court has addressed the standard of review of the decisions of the Registrar of Trade Marks, a tribunal established under the *Trade-marks Act*,[37] a statute in *pari materia*. The latest decision is *Molson Breweries, a Partnership v. John Labatt Ltd.*[38] There, Mr. Justice Rothstein writing for a majority of the Court, stated the standard as follows at paragraph 29 [page 196]:

I think the approach in *Benson & Hedges v. St. Regis* and in *McDonald v. Silcorp* are consistent with the modern approach to standard of review. Even though there is an express appeal provision in the *Trade-marks Act* to the Federal Court, expertise on the part of the Registrar has been recognized as requiring some deference. Having regard to the Registrar's expertise, in the absence of additional evidence adduced in the Trial Division, I am of the opinion that decisions of the Registrar, whether of fact, law or discretion, within this area of expertise, are to be reviewed on a standard of reasonableness *simpliciter*. [Emphasis added.]

[44]The Supreme Court in *Pushpanathan* enumerated four factors to consider in applying the pragmatic and functional test to determine the appropriate standard of review: the presence or absence of a privative clause; the expertise of the decision-maker; the purpose of the provision in particular and the Act as a whole; and the nature of the problem in question.

[45]There is no privative clause in this case; however, as the Supreme Court recognized in *Pezim*,[39] this does not end the inquiry. Tribunals whose decisions are reviewed by way of appeal may still warrant some deference when the other factors so indicate.

[46]In my respectful view, that the Commissioner has expertise on the issue of patentability of inventions is not open to doubt.

[47]*X v. Commissioner of Patents*[40] was an appeal under section 44 [R.S.C. 1970, c. P-4] (now section 40) of the Act from a decision of the Commissioner which had approved the recommendation of the Patent Appeal Board and refused the appellant's application for a patent for an alleged invention. The appellant alleged that the Commissioner erred in finding that the patent was inoperable. Thurlow C.J., for an unanimous court, concluded that the Commissioner was an expert tribunal and that "the Court would be bound to accord appropriate respect" to his decision. This is how he expressed it at page 10 of his reasons:

On the material in the record, consisting of the specification and the communications between the appellant and the Patent Office, and in the absence of evidence on the point, it does not appear to me that the Court is in any position to form an opinion that differs from that of the Board as to whether or not a device of the kind described in the specification could be constructed and made to work. Even if the Court were inclined to take a view differing from that of the Commissioner and his advisers, the Court would be bound to accord appropriate respect for their finding on the same material, having regard to the technical expertise such officials are presumed to have and exercise. [Emphasis added.]

[48]Thurlow C.J. wrote those reasons, more than a decade before the Supreme Court of Canada decided *British Columbia Telephone Co. v. Shaw Cable Systems (B.C.) Ltd.* where L'Heureux-Dubé J., writing for the Court that was unanimous on this point, stated at paragraph 30:

The case at hand concerns a specialized administrative tribunal, the CRTC, which possesses considerable expertise over the subject matter of its jurisdiction. However, despite the expertise of the CRTC, its decision in the case at hand is not protected by a privative clause and is, in fact, subject to an express statutory right of appeal. Nonetheless, it was clearly established in both *Pezim*, *supra*, and *Bell Canada v. Canada (Canadian Radio-television and Telecommunications Commission)*, [1989] 1 S.C.R. 1722, that a specialized tribunal such as the CRTC, acting within its area of expertise and jurisdiction, is entitled to curial deference, even in the absence of a privative clause and the presence of a statutory right of appeal.[41]

Curiously the approaches to the review of decisions of expert tribunals, which these two decisions contain, do not differ in any significant respect from that which Mr. Justice Rothstein stated in *John Labatt Ltd.*

[49]It is clear from my statement of the points raised by the various examiners in my recitation of the procedural history of this case that they are persons with technical expertise.[42] Furthermore, at the request of the applicant, the Examiner's final action was referred to the Patent Appeal Board--another body with patent expertise--to hold hearings pursuant to subsection 30(6) of the *Patent Rules*.[43] It should be noticed that, in his decision, the Commissioner indicated that he had discussed the Examiner's refusal with the members of the Patent Appeal Board before rendering his decision.[44] For these reasons, it is my respectful view that the Commissioner is an expert tribunal.

[50]Since the nature of the question (the patentability of the oncomouse) is squarely within the Commissioner's area of expertise, it is my opinion that his decision should be accorded deference on the reasonableness *simpliciter* standard, as stated by Mr. Justice Rothstein in *John Labatt Ltd.*

[51]The purpose of the Act also weighs in favour of greater deference for the Commissioner. Judson J., for a unanimous Court in *Commissioner of Patents v. Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning*, stated that "there is considerable public interest at stake" in patents relating to drugs and medicines, and therefore "the Commissioner should most carefully scrutinize the application to see if it merits the grant of monopoly privileges, and to determine the scope of the monopoly available."[45] There is no question in my mind that the public interest is engaged in applications of the kind in issue here.

[52]That the public interest is paramount in patent cases is also exemplified by section 10 [as am. by S.C. 1993, c. 15, s. 28] of the Act which, subject to certain safeguards for patent applicants,[46] allows the general public to inspect all patents and documents filed in connection with patents. If patent applications resulted merely in bilateral disputes between the patent examiners and the applicant, there would be no need for the public to have access to patent documents. The Act thus recognizes that the Commissioner must be aware of and consult the public interest in all patent cases.

[53]Finally, as Binnie J. stated in *Cadbury Schweppes Inc. v. FBI Foods Ltd.*:

. . . at least one of the policy objectives underlying the statutory remedies available to a patent owner is to make disclosure more attractive, and thus hasten the availability of useful knowledge in the public sphere in the public interest.[47]

[54]It is, thus, clear to me that one of the purposes of the 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 such as this,[48] this Court should defer to the Commissioner's decisions where they are informed by considerations of public policy.

[55]I therefore conclude that the Commissioner's decision should have been reviewed on the standard of reasonableness *simpliciter*, i.e., in the words of Iacobucci J. in *Canada (Director of Investigation and Research) v. Southam Inc.*[49] at paragraph 56:

An unreasonable decision is one that, in the main, is not supported by any reasons that can stand up to a somewhat probing examination. Accordingly, a court reviewing a conclusion on the reasonableness standard must look to see whether any reasons support it. The defect, if there is one, could presumably be in the evidentiary foundation itself or in the logical process by which conclusions are sought to be drawn from it. An example of the former kind of defect would be an assumption that had no basis in the evidence, or that was contrary to the overwhelming weight of the evidence. An example of the latter kind of defect would be a contradiction in the premises or an invalid inference.

[56]In my respectful view, if the Judge below had adopted this approach, he would certainly have reached the conclusion that he should have given deference to the Commissioner's decision,

since the issue within his jurisdiction and his decision was reasonable. In his erudite exposition, the learned Judge concluded that it was correct. In the absence of any contrary evidence on the point, I must infer that it was also reasonable in the sense in which Iacobucci J. defined it in *Southam*.

[57]The Commissioner's decision was also reasonable because it took a cautious approach to patenting new life forms. As William L. Hayhurst, Q.C. has stated: "if Canada's past performance in intellectual property matters is any indication, one thing is clear: Canada will move cautiously."[50] The need for this cautious approach to new technologies was emphasized in the *Final Report* of the *Royal Commission on New Reproductive Technologies*, which reported that:

. . . although public attitudes of 40 years ago--captured in the phrase "better living through modern technology"--are still prevalent, there are also increasing concerns about scientists "playing God" and technologies "tampering with nature." There is a growing unease on the part of some that the "genie has been let out of the bottle," and technology will never be "contained" again.[51]

[58]Applying the foregoing approach to this case, it is my respectful view that the Judge below was right to dismiss the appellant's appeal even though, as I have said, he did not appreciate the need for a standard of review analysis.

[59]This conclusion is sufficient to enable me to dismiss this appeal. However, in view of the way in which the appeal was argued before us and in deference to counsel, I consider it helpful to address some of the issues raised and dealt with by Mr. Justice Rothstein in his reasons.

[60]I deal, first, with the twin issues of whether the Commissioner has any discretion to issue or to refuse the patent and whether policy considerations are relevant. This leads to a discussion of section 40 of the Act.

[61]I repeat that section here for ease of reference:

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. [Emphasis added.]

[62]Mr. Justice Rothstein's conclusion based on a quotation taken from *Monsanto Company v. Commissioner of Patents*[52] is that [*infra*, paragraph 109] "[i]t is apparent that when a process or a product satisfies the requirements of the *Patent Act*, an application for a patent must be granted." This statement, in my respectful view, overlooks the clear provision in section 40 that it is the Commissioner who must be satisfied that an applicant is legally entitled to a patent. It is not sufficient, in my view, to conclude that a patent must be granted once the requirements of the Act have been met. I agree that discretion is not involved in the grant or refusal of a patent. However, that is not to say that an applicant must not satisfy the Commissioner and his officials that, by law, he or she is entitled to a patent.

[63]Furthermore, in my respectful view, the quotation in *Monsanto* does not support Mr. Justice Rothstein's conclusion. In that case, Pigeon J. made the statement in response to a complaint made in the following circumstances: the applicant for a patent had tendered affidavit evidence based on scientific principles. The Commissioner and his officials did not take issue with those principles, but simply said "[w]e are not satisfied that this is adequate." Pigeon J., writing for the Court stated that this response was insufficient because "if accepted, it makes the right of appeal illusory."[53] He then went on to quote section 42 (now section 40) of the Act and indicated as Mr. Justice Rothstein has said that the grant or refusal of a patent is not a matter of discretion. I am in respectful agreement with Pigeon J. that the grant or refusal of a patent is not a matter of discretion, but, as I have already said, this does not mean that an applicant is not required to satisfy the Commissioner and his officials that he is by law entitled to the grant.

PIONEER HI-BRED AND *CHAKRABARTY*

[64]In *Pioneer Hi-Bred*, this Court was concerned with the patentability of varieties of cross-bred soybean. One of the issues in the appeal was whether the cross-bred soybean varieties were "manufacture" or a "composition of matter" within the meaning of section 2 of the Act. As happened in this case, the Commissioner refused to issue the patent and the appellant in that case contended that the Commissioner erred in determining that a strain of naturally born plant derived by artificial cross-breeding was not an invention within the meaning of section 2 of the Act.

[65]Counsel for the appellant, citing the decision of the United States Supreme Court in *Chakrabarty* and the decision of the United States Board of Appeals and Patent Interferences in *Ex parte Hibberd*[54] urged the Court to conclude, on the basis of these decisions, that the subject-matter of their application was a "manufacture" or a "composition of matter". The decision of the (Canadian) Patent Appeal Board in *Abitibi* was also cited. In *Pioneer Hi-Bred*, Marceau J.A. wrote reasons in which Pratte and Lacombe JJ.A. concurred. After reviewing the arguments based on these decisions, he rejected the definitions of "manufacture" and "composition of matter" relied upon by the United States Supreme Court in *Chakrabarty*, stating:

Even if those definitions were held to be applicable to a micro-organism obtained as a result of a laboratory process, I am unable to go further and accept that they can also adapt to a plant variety produced by cross-breeding. Such a plant cannot really be said, other than on the most metaphorical level, to have been produced from raw materials or to be a combination of two or more substances united by chemical or mechanical means. It seems to me that the common ordinary meaning of the words "manufacture" and "composition of matter" would be distorted if a unique but simple variety of soybean were to be included within their scope.[55]

[66]Pratte J.A., in separate reasons, added, as a further ground for dismissing the appeal, the fact that the applicant had not complied with the disclosure requirements of subsection 36(1) of the Act.

[67]The appellant appealed the judgment of this Court to the Supreme Court of Canada. That Court dismissed the appeal for the additional reason given by Pratte J.A., and without expressing any opinion on the views expressed by Marceau J.A.

[68]Given the reliance placed on *Chakrabarty* in this Court, it is not unreasonable to assume that the appellant in that case did rely upon it in the Supreme Court of Canada. The decision is not mentioned in the reasons of Lamer J. [as he then was] who wrote for the Court; but, it is reasonable to assume that by implication at least, that Court refused to adopt the definitions of "manufacture" and "composition of matter" which the United States Supreme Court accepted in that case.

[69]What then is the precedential value of the reasons of this Court in *Pioneer Hi-Bred* as expressed by Marceau J.A. in light of the decision of the Supreme Court of Canada? Based on decisions of the Court of Appeal of England, the Commissioner concluded that it was not binding on him, but was of high persuasive value only. I agree. Although we are not bound by it, it is my respectful view that judicial comity requires us to pay considerable deference to it. For that reason alone, I would reject the reasoning of the majority of the Supreme Court in *Chakrabarty* and the United States Board of Appeals and Patent Interferences in *Ex parte Hibberd*.

[70]It is plain, from his reasons, that Mr. Justice Rothstein has placed great reliance on the decision of the United States Supreme Court in *Chakrabarty*. Indeed, at paragraph 147 of his reasons, he states that he places "significant reliance" on *Chakrabarty* without any acknowledgement whatsoever that the arguments advanced in *Pioneer Hi-Bred* based on *Chakrabarty* had been considered by this Court and unanimously rejected by it and probably by a unanimous Supreme Court of Canada.

WHETHER OUR DECISION SHOULD BE INFLUENCED BY THE FACT THAT THE ONCOMOUSE HAS BEEN PATENTED IN THE UNITED STATES AND EUROPE

[71]At paragraph 110 of Mr. Justice Rothstein's reasons, he stated that "[i]t is arguable on policy grounds that there is merit to uniformity" between Canada and the United States and Europe. In my respectful view, to take this into account is clearly to introduce policy consideration into our decision-making. In my respectful view, if Mr. Justice Rothstein is right that we are faced here with a simple problem of statutory interpretation, then we should construe the words "manufacture" and "composition of matter" in their ordinary meaning and in their total legislative context. The practice in other countries is certainly not part of the legislative context of the definition of those terms in the Act. Where Parliament decides that such matters are relevant, it says so.[56]

[72]Furthermore, there is no evidence before us of the nature of the material that was presented to the authorities in those jurisdictions to persuade them to grant the patent, what their legislative regimes were, or what criteria they used. These are all facts that the appellant would have had to prove to the requisite degree before they could have been admitted and considered, if relevant. They were not.

[73]The issue for us in this case is whether the decision of the Commissioner was reasonable. What was done in other jurisdictions is quite irrelevant to a resolution of that issue.

[74]I conclude then that our decision on this appeal should not be affected in any way by the fact that the oncomouse has been patented in the United States of America and Europe.

[75]The Commissioner, the authority in which Parliament has confided the responsibility to decide such matters, is of the view that it cannot be patented here for the reasons that he gave. His decision was reasonable. Like Thurlow C.J. in *X v. Commissioner of Patents, supra*, it is my respectful view that, absent evidence to the contrary, and there was none in the record presented to us, "this Court is bound to accord appropriate respect for their finding".

[76]I wish to emphasize why, in my view, it is necessary to pay deference to the findings of the Commissioner by referring to some observations that Cory J., for a unanimous Court, made in *International Longshoremen's and Warehousemen's Union, Ship and Dock Foremen, Local 514 v. Prince Rubert Grain Ltd.*[57] There the Court reversed a decision of this Court that the Canada Labour Relations Board did not have jurisdiction to determine the composition of a bargaining unit for collective bargaining purposes and for certification under the Canada Labour Code. In giving his reasons for doing so, Cory J. took the opportunity to warn of the approach courts should take in assessing the decisions of administrative tribunals generally and of labour relations boards in particular. He made the following observations at paragraph 20 [page 445]:

At the outset it should be stated, once again, that it would be all too easy for courts to find that empowering provisions of statutes creating administrative tribunals are jurisdictional in nature, thereby increasing the likelihood that their jurisdiction will be unnecessarily limited. The result of adopting such an approach would be that a great many decisions of the tribunals would be required to be correct in the eyes of the courts. There have been very salutary warnings sounded against the courts taking such a position.

After citing from three authorities, he continued at paragraphs 23-24 (pages 446 and 447), as follows:

If these warnings are not heeded, the operation and indeed the whole concept of administrative tribunals may be jeopardized. These tribunals are often set up to operate in areas where specific expertise, experience, and sensitivity to the particular problems involved are essential to their resolution. Administrative tribunals are designed to function expeditiously, inexpensively, and with less formality than courts. There is little doubt either of the need for these tribunals or of the very important role they fulfil in Canadian society.

It has often been very properly recognized that labour relations boards exemplify a highly specialized type of administrative tribunal. Their members are experts in administrating comprehensive labour statutes which regulate the difficult and often volatile field of labour relations. Through their constant work in this sensitive area, labour boards develop the special experience, skill and understanding needed to resolve the complex problems of labour relations. There were very sound reasons for the establishment of labour boards and the protection of their decisions by broad privative clauses. Parliament and provincial legislatures have clearly indicated that decisions of these boards on matters within their jurisdiction should be final and binding. The courts could all too easily usurp the role of these boards by characterizing the empowering legislation according them authority as jurisdiction limiting provisions which would

require their decisions to be correct in the opinion of the court. Quite simply, courts should exercise deferential caution in their assessment of the jurisdiction of labour boards and be slow to find an absence or excess of jurisdiction.

[77]Although those observations were made in relation to the approach to decisions on jurisdiction, nevertheless they appear to be equally applicable to the decisions of expert tribunals such as the Commissioner whose decisions call for the exercise of experience, skill, and expertise in resolving complex problems with which courts are not equipped to deal. It is not sufficient, in my respectful view, to assess the decision on the standard of correctness and then, as an after thought, to lay it on a procrustean bed and charaterize it as unreasonable.

[78]Following the refusal of the Supreme Court in *Pioneer Hi-Bred* to accommodate cross-bred soya bean varieties within the definition of "invention" in section 2 of the Act, Parliament enacted the *Plant Breeders' Rights Act*,[58] within eleven months after the Supreme Court had dismissed the appeal. 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.

[79]I do not find it necessary to deal with the other points which Mr. Justice Rothstein raised in his reasons.

CONCLUSION

[80]For all these reasons, then, I am of the view that the appeal should be dismissed with costs to the respondent. There will be no costs to the intervener.

* * *

The following are the reasons for judgment rendered in English by

Rothstein J.A.:

OVERVIEW

[81]The issue in this appeal is the patentability of genetically altered non-human mammals for use in carcinogenicity studies. Claims 1 to 12 in patent application 484723 (the 723 patent) (set out in Appendix A) cover forms of transgenic non-human mammals. The Commissioner of Patents found that the appellant was not entitled to be granted a patent covering these claims.[59] Claims 13 to 26 in the patent application (set out in Appendix B) are for methods for the production of transgenic non-human mammals or transgenic cell cultures, for using transgenic non-human mammals, methods of testing materials suspected of being carcinogens using transgenic non-human mammals, and various plasmids and somatic cell cultures. Claims 13 to 26 were found to be patentable.[60]

[82]An appeal to the Federal Court Trial Division from the Patent Commissioner's refusal to grant a patent in respect of claims 1 to 12 was dismissed.[61] This is an appeal from the decision of the Federal Court Trial Division.

OBJECTIVES OF PATENT CLAIMS 1 TO 12

[83]The "Summary of the Invention" in the patent application provides a description of what is intended by the inventors. The objective of the appellant is to produce animals with a susceptibility to cancer for purposes of animal carcinogenicity studies. The animals can be used to test a material suspected of being a carcinogen by exposing the animals to the material and seeing if cancerous tumours develop. Because of the propensity of the animals to develop tumours, amounts of materials tested can be smaller, more closely approximating the amounts to which humans are exposed. The animals will be expected to develop tumours much sooner because they already have that propensity. The animals can also be used to test materials thought to confer protection against the development of cancer. The result is that carcinogenicity studies can be carried out more effectively and with closer comparability to the effect of test materials on humans than would be possible without the transgenic mammals.

[84]The technology by which a cancer-prone mouse is produced is described in the Commissioner's decision. An activated oncogene sequence (oncogene) is a gene which makes a mouse more susceptible to cancer.[62] A plasmid (a carrier) is constructed containing the oncogene. The plasmid is injected into a fertilized mouse egg (preferably while it is at the one-cell (zygote) stage and generally not later than the eight-cell stage). The injected egg is then transferred into a female "host" mouse and allowed to develop to term. The reason for injecting the oncogene preferably into the zygote is to ensure, to the extent the oncogene is taken up, that it will affect all the cells of the mouse which develops from the zygote. If the resulting mouse is found to have all of its cells[63] affected by the oncogene, it is called a "founder mouse".[64] The founder mouse is then mated with an uninjected mouse. In accordance with Mendelian inheritance of single loci, 50% of the offspring will be found to have all their cells affected by the oncogene.

[85]The appellant seeks to protect the product of this process, that is, the founder mammal and the offspring whose cells are affected by the oncogene. In this decision, for ease of reference, the product of claims 1 to 12 will be referred to as a transgenic non-human mammal or an oncomouse.

JUDICIAL HISTORY

[86]The 723 patent application was filed on June 21, 1985 for an invention entitled "Transgenic Animals". The invention had been assigned by the inventors, Leder and Stewart, to the appellant, President and Fellows of Harvard College.

[87]On March 24, 1993, by Examiner's final action, the Examiner rejected claims 1 to 12 as being outside the definition of "invention" in section 2 of the *Patent Act* but allowed claims 13 to 26.

[88]On August 4, 1995, after review by the Commissioner of Patents and a hearing before the Patent Appeal Board, the refusal to grant a patent for claims 1 to 12 was confirmed by the Commissioner.

1. Decision of the Patent Commissioner

[89]In his decision, having regard to section 40 of the *Patent Act*,[65] the Commissioner determined that to reject an application as unpatentable subject-matter, he must be satisfied that, by law, the appellant is not entitled to a patent and must give reasons based on an interpretation of the *Patent Act* and any applicable jurisprudence.

[90]The Commissioner reviewed decisions of the Patent Commissioner, Federal Court of Appeal and Supreme Court of Canada. He then observed that on April 12, 1988, a patent had been granted in the United States for transgenic non-human mammals. Although the definitions of the term "invention" in the United States and Canadian legislation are similar, the Commissioner was of the view that in interpreting Canadian legislation, not much weight could be given to the U.S. practice. In considering the words "manufacture" and "composition of matter" in the definition of "invention" in section 2 of the *Patent Act*, the Commissioner found that they required something to be made under the control of the inventor and that the resulting product be reproducible in a consistent manner.

[91]With respect to the application in this case, the Commissioner found there were two distinct phases involved: "firstly, the preparation of the genetically engineered plasmid and secondly the development of a genetically engineered mouse in the uterus of the host mouse".[66] In the first phase human intervention is involved. The Commissioner was satisfied that the plasmids and the transgenic unicellular material were produced under the full control of the inventor and were reproducible and were therefore a "manufacture" or a "composition of matter" under the definition of "invention" in section 2 of the *Patent Act*. In the second phase, he found that the laws of nature take over. Being "strongly influenced" by the Federal Court of Appeal's decision in *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*,[67] he would not include a non-human mammal as being patentable. His reason was that "[t]he inventors do not have full control over all the characteristics of the resulting mouse since the intervention of man ensures that reproducibility extends only as far as the cancer forming gene".[68]

[92]In distinguishing *Application of Abitibi Co., Re*[69] (*Abitibi*) in which the Commissioner's predecessor had been satisfied that micro-organisms such as yeast, mould, fungi, bacteria, actinomycetes, unicellular algae, virus or protozoa could be the subject of patent protection, the Commissioner found that "different considerations" (which he did not identify) applied as between claims to lower life forms as in *Abitibi* and higher life forms as in this case.

[93]Accordingly, he refused to grant a patent covering claims 1 to 12.

2. Decision of the Federal Court Trial Division

[94]The appellant appealed to the Federal Court Trial Division. The Trial Division Judge first determined that as there were no special provisions in the *Patent Act* regarding biotechnology, it

was necessary to apply the ordinary tests of patentability. To be patentable, the subject-matter must be an "invention" according to the definition in section 2 of the *Patent Act* and must be new, useful and unobvious. In his opinion:[70]

There is no dispute here that the oncomouse is new, useful and unobvious. The question is whether this is an "invention" to which the *Patent Act* . . . applies.

[95]He then considered a decision of the Supreme Court of the United States, *Diamond v. Chakrabarty*,[71] in which, by a 5-4 majority, a bacterium which could break down crude oil was found to be patentable. The five member majority found that the proper question to be addressed was not whether the subject-matter of the patent application was animate or inanimate, but rather, whether it was made by a person as opposed to being something naturally occurring. They found it was the product of human ingenuity and was patentable. The four member dissenting minority held that the United States patent system did not encompass living organisms. The learned Trial Division Judge expressed his preference for the minority view.

[96]He then turned to the Canadian legislation and concluded that the issue was whether claims 1 to 12 related to patentable subject-matter according to the definition of "invention" in section 2 of the *Patent Act*. He considered four *indicia* in interpreting section 2.

[97]The first was the inventor's degree of control over the creation of the invention. He found that a mouse was a complex life form, in which none of the features except the presence of the oncogene were under the control of the inventor. Although in his view it was not necessary for the inventor to control all aspects of the natural process leading to the creation of the end product, in this case, he found the end product was completely unknown and unknowable. He concluded that once the oncogene was introduced, everything else about the oncomouse was independent of human intervention and that the inventors lacked sufficient control over the oncomouse to meet the control requirement.

[98]The second issue was the distinction between human intervention and the laws of nature in the creation of the oncomouse. The learned Judge found that the creation of the oncomouse is a marriage between nature and human intervention. While he found that oncomice do not occur naturally, "[w]hat will result from the gestation process is infinitely variable and, in its detail, unknown".[72]

[99]The third issue was reproducibility. The learned Judge found that for an invention to be patentable, it must be reproducible. He found that "although the gene will be present in some mice, at some place, with some characteristics, the precise mouse, the precise location, and the precise quality of the gene are unreproducible".[73] He added that "[t]he variations of the gene are created and controlled completely by the laws of nature and are infinite".[74] Because the oncomouse cannot be reproduced at will, except for the oncogene, the test for reproducibility had not been met.

[100]The fourth issue was whether a distinction was to be made for patentability purposes between higher and lower life forms. In his view, a complex life form was not patentable.

A complex life form does not fit within the current parameters . . . without stretching the meaning of the words to the breaking point, which I am not prepared to do.[75]

[101]As a final point, he expressed the view that to stretch the definition of invention to include the oncomouse would not enhance the protection already accorded the appellant by the patenting of claims 13 to 26.

[102]For all these reasons he dismissed the appeal.

[103]The learned Judge, in his reasons, did not address the issue of the standard of review of the decision of the Patent Commissioner. It appears that it was either not argued before him or perhaps he thought it unnecessary to deal with the issue in view of his conclusion to uphold the decision of the Patent Commissioner.

ANALYSIS

1. The *Patent Act*

   (a) Object and purpose of the *Patent Act*

[104]Some insight into the appropriate approach to interpreting the *Patent Act* may be derived from a consideration of the object and purpose of the legislation.

[105]A patent protects an invention. When a patent for an invention is granted, the patentee is given the "exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used"[76] for a period specified in the *Patent Act*: 17 years from the date on which the patent is issued for patent applications filed before October 1, 1989, as in this case, or 20 years from the date of the filing of a patent application filed on or after October 1, 1989.[77] The 17 or 20 year terms are intended to enable the inventor to exploit the invention free from competition for that period. The purpose is to permit the recovery of research and development investment necessary to produce the invention and a return on that investment to the inventor, commensurate with the value purchasers place on the invention. The intention is to provide an incentive for the creation of processes or products which are new, useful and unobvious. Without patent protection, as soon as a product implementing a new idea is marketed, others could copy it and compete with the original inventor without having to have made the initial research and development investment. Competitors who did not have to cover such costs could drive prices down to such a level that the original inventor could not recoup the research and development investment made, let alone a return on that investment, thereby discouraging the creation of inventions.[78]

[106]In return for the 17- or 20-year period of protection from competition, the patentee is required to make full disclosure of the invention. In its recent decision in *Cadbury Schweppes Inc. v. FBI Foods Ltd.*,[79] the Supreme Court of Canada described the "bargain that lies at the heart of patent protection":

A patent is a statutory monopoly which is given in exchange for a full and complete disclosure by the patentee of his or her invention . . . . Accordingly, at least one of the policy objectives

underlying the statutory remedies available to a patent owner is to make disclosure more attractive, and thus hasten the availability of useful knowledge in the public sphere in the public interest.

Thus, the object of the *Patent Act* is to promote the development of inventions in a manner that benefits both the inventor and the public.

(b) The requirement that an invention be new, useful and unobvious

[107]An invention may be any new and useful process or product or a new or useful improvement to a process or product. "Invention" is defined in section 2 of the *Patent Act*:

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.

[108]Under section 28.3 of the *Patent Act* the subject-matter of a patent claim must not have been obvious to persons skilled in the art or science. Section 28.3[80] provides:

28.3 The subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to

(*a*) information disclosed more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant in such a manner that the information became available to the public in Canada or elsewhere; and

(*b*) information disclosed before the claim date by a person not mentioned in paragraph (*a*) in such a manner that the information became available to the public in Canada or elsewhere.

The requirement that to be patentable, the subject-matter would not have been obvious, was a common law principle affirmed by the Supreme Court of Canada[81] and applied in patent jurisprudence of this Court[82] before the enactment of section 28.3 in 1993. It was said that inventiveness or ingenuity, without which an advance was considered to be obvious and therefore unpatentable, was implied in the term "invention" in section 2.[83]

(c) Non-discretionary nature of patentability decision

[109]By reason of section 40 of the *Patent Act*, an application for a patent is to be refused where it is determined that an applicant is not, by law, entitled to be granted a patent. Section 40 states:

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.

The non-discretionary nature of the Commissioner's duty is highlighted in *Monsanto Company v. Commissioner of Patents*.[84] At pages 1119-1120, after citing section 40 (then section 42) of the *Patent Act*, the majority judgment of Pigeon J. stated:

I have underlined by law [in section 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*,[85] (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 . . . .

It is apparent that when a process or a product satisfies the requirements of the *Patent Act*, an application for a patent must be granted.

(d) Policy considerations

[110]There was considerable fanfare in this appeal that significant policy questions are at stake. The evidence is that the oncomouse has been patented in the United States and Europe. It is arguable on policy grounds that there is merit to uniformity and that Canada should follow suit. On the other side, there were arguments made against patenting the oncomouse based on human health, environmental and other concerns. However, all that is at issue in this appeal is the interpretation of the *Patent Act* and the determination of whether, on the basis of the evidence, the appellant's product is patentable in accordance with that interpretation. It is the duty of the Court to take the statute as it finds it, neither expanding its interpretation beyond Parliament's intention as expressed by the language in the statute, nor limiting that interpretation by reading words of limitation into the statute not placed there by Parliament. To the extent that the appeal gives rise to policy questions, they are to be addressed by Parliament and not the Court.

(e) Supreme Court observations on patentability of life forms

[111]The Supreme Court of Canada has instructed that because the *Patent Act* contains no provision relating to biotechnological inventions and new forms of life in particular, the type of claims at issue here will only be patentable if they are within the scope of existing legislation and if they meet the traditional conditions and requirements for a patent. At page 1642 of *Pioneer Hi-Bred, supra*, Lamer J. (as he then was), referring to the cross-breeding of soybean varieties, stated:

It is true that most countries give the producers of new plant varieties special protection; even in Canada, several legislative proposals for this purpose have appeared over the years. Though this kind of legislation might act as a catalyst in the development of scientific research in Canada, I consider that this Court does not have the right to stretch the scope of patent protection beyond the limits of existing legislation. Accordingly, since the *Patent Act* contains no provisions relating directly to biotechnological inventions and new forms of life in particular, this new soybean variety will only be patentable if it meets the traditional conditions and requirements for a patent. [Emphasis added.]

[112]The Supreme Court also has instructed that where the issue is the patentability of a form of life involving new technology, a cautious approach to the scope of pronouncements by the courts must be adopted. At page 1632 of *Pioneer Hi-Bred* Lamer J. stated:

The real issue in this appeal is the patentability of a form of life. This is in fact a claim for a new product developed in the field of biotechnology, an area of activity taking in all types of techniques having a common purpose, "the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services" . . . . This is regarded by many as the latest technological system to be developed in the 20th century and the harbinger of a new era, and we must therefore be very cautious regarding the scope of our pronouncements. [Emphasis added.]

I do not take the words of Lamer J. to mean that the courts must adopt a restrictive approach to interpreting the *Patent Act* whenever a living organism is at issue. Rather, when called upon to make a legal determination in respect of living matter under the *Patent Act*, the courts must be particularly careful and mindful of the need for precision in their pronouncements.

2. Patentability of the oncomouse

[113]The issue is whether claims 1 to 12 amount to an "invention" within the meaning of that term in section 2 of the *Patent Act*. The learned Trial Division Judge found that the oncomouse was new, useful and unobvious. There is no dispute on this appeal with respect to these findings. Because the oncomouse is not "art" or a "process" or a "machine", the controversy is only whether it may be considered to be a "manufacture" or "composition of matter".

[114]I conclude that the oncomouse is both unobvious and a new and useful "composition of matter". Therefore it is an "invention" within the meaning of that term in section 2 of the *Patent Act*. As I conclude that the oncomouse is a "composition of matter", it is not necessary for me to consider whether it is also a "manufacture".

[115]In *Chakrabarty, supra*, in dealing with the term "composition of matter" Chief Justice Burger, speaking for the five member majority, stated at page 308:

. . . "composition of matter" has been construed consistent with its common usage to include "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."

[116]Burger C.J. noted that the terms "manufacture" and "composition of matter", as modified by the comprehensive "any" in the definition of "invention" in the United States patent statute, were expansive, and "Congress plainly contemplated that the patent laws would be given wide scope".[86] At page 316, the Chief Justice observed that Congress employed broad general language because inventions are often unforeseeable.

This is especially true in the field of patent law. A rule that unanticipated inventions are without protection would conflict with the core concept of the patent law that anticipation undermines

patentability . . . . Mr. Justice Douglas reminded that the inventions most benefiting mankind are those that "push back the frontiers of chemistry, physics, and the like." . . . Congress employed broad general language in drafting § 101 precisely because such inventions are often unforeseeable. [Citations omitted.]

The majority's approach is clear. The language of patent law is broad and general and is to be given wide scope because inventions are, necessarily, unanticipated and unforeseeable.

[117]I find this reasoning persuasive. I see no reason why it would not be applicable in interpreting the definition of "invention" in section 2 of the *Patent Act*. Parliament has used the same broad and general language as the United States Congress. The Court must respect Parliament's use of such language and not adopt a narrow approach that would conflict with Parliament's obvious intention.

[118]In this case, the question is whether the oncomouse is a "composition of matter". What is an "oncomouse" for the purposes of the analysis is to be understood by reference to patent claim 1. It includes both the founder oncomouse, which has had the oncogene introduced at its zygote stage, and subsequent generations of offspring oncomice which will have inherited the oncogene from a parent.

[119]Using the definition applied in *Chakrabarty*, I am of the view that the oncomouse is a "composition of matter".

[120]The process here involves injecting a plasmid containing the oncogene into a fertilized mouse egg. The oncogene is comprised of DNA. Kreuzer and Massey[87] define DNA as:

. . . **(deoxyribonucleic acid)** The chemical molecule that is the basic genetic material found in all cells . . . DNA belongs to a class of biological molecules called nucleic acids.

DNA is a physical substance and is 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 specification is thus a "composition of matter". This conclusion is consistent with the Patent Commissioner's finding that the "transgenic unicellular material" (the oncogene injected fertilized mouse egg) was a "manufacture" or a "composition of matter".[88]

[121]What the Commissioner described as "transgenic unicellular material" is transferred to a host mouse and is allowed to develop to term. The resulting founder oncomouse is the product of that "composition of matter". The genetic alteration which has been performed at the single cell stage is permanent and is reproduced in all cells of the oncomouse. 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.

[122]Similarly, offspring oncomice are the product, in accordance with the Mendelian inheritance ratio of single loci, of the mating of a male mouse and a female mouse, one of which is an oncomouse. One might argue this simply involves the natural processes of mouse

reproduction. However, such a view ignores the fact that an offspring oncomouse has the artificial oncogene sequence by virtue of its introduction into the genome of the initial founder oncomouse. The offspring oncomouse has a particular genetic trait which would not occur in nature. Offspring oncomice are therefore linked to the transgenic unicellular material which was found to be a composition of matter by the Patent Commissioner. Once that is recognized, it follows that an offspring oncomouse is a "composition of matter", notwithstanding the fact it possesses the oncogene through genetic inheritance, as opposed to through the initial injection process.

[123]While what is at issue are living organisms and in particular higher life forms, i.e. non-human mammals, nothing in the term "composition of matter" suggests that living things are excluded from the definition. Indeed, in the Federal Court of Appeal decision in *Pioneer Hi-Bred*, *supra*, Marceau J.A. stated at page 12:

I am prepared to accept that the Canadian patent legislation does not support the assumption that life forms are definitely not patentable.

At the Supreme Court of Canada in *Pioneer Hi-Bred*, Lamer J., at page 1627 noted that Marceau J.A. was of the opinion that Canadian patent legislation did not expressly exclude living organisms from patentability and did not take exception with this view. In fact, at page 1643, Lamer J. observed that the *Patent Act* contains no provision relating to new forms of life and therefore a new soybean variety in that case would only be patentable if it met the traditional conditions and requirements for a patent. It is apparent that Lamer J. was not excluding life forms from patentability. In *Abitibi*, *supra*, the Patent Commissioner found that microbial cultures and other lower life forms could constitute inventions for purposes of the *Patent Act*. *Abitibi* was cited before the Supreme Court of Canada in *Pioneer Hi-Bred* and there was no disapproval expressed of that finding. For these reasons, I am satisfied that the *Patent Act* does not exclude living organisms, i.e. non-human mammals, from the definition of "invention".

[124]That is not to say that the term "composition of matter" has no limits. In both Canada and the United States, natural phenomena, scientific principles and abstract theorems are not patentable. In Canada, subsection 27(8) [as am. by S.C. 1993, c. 15, s. 31] of the *Patent Act* excludes scientific principles and abstract theorems from patentability.

27. . . .

(8) No patent shall be granted for any mere scientific principle or abstract theorem.

[125]In *Chakrabarty*, Burger C.J. stated at pages 303-304:

This is not to suggest that § 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena and abstract ideas have been held not patentable . . . . Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are "manifestations of . . . nature, free to all men and reserved exclusively to none . . . ."

Judged in this light, respondent'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. [Citations omitted; underlining added.]

In *Pioneer Hi-Bred*, Lamer J. expressed a similar view in the following words at page 1634:

The intervention made by Hi-Bred does not in any way appear to alter the soybean reproductive process, which occurs in accordance with the laws of nature. Earlier decisions have never allowed such a method to be the basis for a patent. The courts have regarded creations following the laws of nature as being mere discoveries the existence of which man has simply uncovered without thereby being able to claim he has invented them. [Emphasis added.]

[126]The definition of "invention" in the *Patent Act* does not expressly exclude discoveries that follow the laws of nature. It would thus appear that the reason creations or discoveries that only follow the laws of nature do not meet the requirements of patentability is because they are not considered new and unobvious. Rather, such creations or discoveries are considered to have existed and only to have been uncovered by man. Something more is required for patentability, namely, a non-naturally occurring "composition of matter" arising from the application of inventiveness or ingenuity.

[127]The question then is whether the oncomouse is merely a discovery of a natural phenomenon or involves the application of inventive ingenuity. What is sought to be patented is a mouse with a genetic structure different from what it would have been without human intervention at the genetic level. The learned Trial Division Judge found that the oncomouse was new and accepted that "Oncomice do not occur naturally".[89] Such findings, which are not in dispute on this appeal and which I accept, are sufficient to satisfy the test that the oncomouse is not merely the product of the laws of nature and is therefore patentable.

[128]Further support for this view is found in the decision of the Patent Examiner which determined that claims 13 to 26 were patentable. The oncomouse is the creation of the process described in claims 14 and 15. Claims 14 and 15 provide:

14. A method of producing a transgenic cell culture comprising:

a) introducing an activated oncogene sequence into pluripotent cells of a mammalian embryo;

b) allowing said embryo to develop into an adult animal; and,

c) culturing somatic cells of said animal.[90]

15. A method of producing a transgenic mammal having an increased probability of developing neoplasms, said method comprising introducing into a mammal embryo an activated oncogene sequence.

If the process for producing the product is patentable, it is because it must be considered to involve ingenuity and not merely the discovery of the operation of a law of nature or the existence of a naturally occurring phenomenon. It must logically follow that the product of that process must also be considered to involve that same ingenuity and be patentable.

[129]In my opinion, the oncomouse must be considered to be the result of both ingenuity and the laws of nature--ingenuity in the initial genetic engineering involving the assembly of the oncogene, incorporating it into the plasmid and injecting the plasmid into the zygote; and the laws of nature, with the oncogene then affecting all the cells of the oncomouse in the course of gestation, the subsequent mating of an oncomouse and an uninjected mouse, and the reliance on Mendelian laws of inheritance to obtain offspring oncomice. However, the use of the laws of nature by inventors does not disqualify a product from being an invention, provided inventiveness or ingenuity is also involved. As Professor Vaver has explained:

Patents can, of course, be granted for a new practical application of the theory of gravity--for example, on an improved gravity pump.[91]

[130]Indeed, substantially more is involved here than merely the operation of the laws of nature. By definition, transgenic organisms come into being through human manipulation at the genetic or molecular level. The *New Oxford Dictionary of English* defines "transgenic" as:

. . . of, relating to, or denoting an organism that contains genetic material into which DNA from an unrelated organism has been artificially introduced.

In this case, we are dealing with a transgenic mouse, all of whose cells contain a foreign oncogene which was assembled and artificially incorporated into the genome of the mouse as a result of human intervention. The genetic material which has been introduced is itself an artificial composition. Thus, the ingenuity in this case relates not only to the introduction of genetic material into the mouse by artificial means, but extends to the makeup of the critical oncogene itself.

[131]While one might argue that nature already produces some mice with a genetic predisposition to develop cancer, it would be wrong to say that the appellant has simply "discovered" or merely "recreated" something which naturally occurs (or might naturally occur). When trying to objectively determine whether the creation of the oncomouse involves human ingenuity or only the laws of nature, this Court ought not equate the reason why the oncomouse is useful, i.e. its predisposition to develop cancer, with what has actually been produced. The question is not whether cancer prone mice exist in nature. Rather, the question is whether the oncomouse described in the patent claims would exist in nature. Clearly it would not.

[132]It is true that the laws of nature must be employed in the gestation of the oncogene injected zygote in the uterus of the host mouse and the resulting production of a founder mouse and the subsequent mating of the founder mouse to produce offspring mice affected with the oncogene. If only the laws of nature were involved, the oncomouse would not be patentable. However, here, the product is the result of both human ingenuity at the genetic level and the laws of nature.

[133]Having regard to section 40 of the *Patent Act*, *supra*, on a straightforward interpretation of the term "composition of matter" and taking into account the roles of ingenuity and the laws of nature, there is no reason in law why the product, in this case the oncomouse, is not patentable.

3. Errors in the reasoning in the decisions below

[134]I now explain, with reference to their reasons, why I differ with the reasoning and conclusions of the Patent Commissioner and the learned Trial Division Judge.

(a) Reliance on the majority decision in *Chakrabarty*

[135]There is no authoritative Canadian jurisprudential interpretation of the term "composition of matter" as it appears in the definition of "invention" in the *Patent Act*. In the Supreme Court decision in *Electric Fireproofing Co. of Canada v. Electric Fireproofing Co.*,[92] Idington J. adopted the position of the Court below[93] in stating that "the composition need not be a chemical, but may be a mechanical one". However, a statement to the effect that a "composition of matter" may be either the result of a chemical reaction which produces a new chemical compound, or a mere mechanical mixture of substances, does not advance the analysis very far in determining the scope of the term "composition of matter".

[136]In coming to my conclusion, I have placed considerable reliance on the majority opinion of the United States Supreme Court in *Chakrabarty* and, in doing so, differ from the approach of both the Patent Commissioner and the learned Trial Division Judge. The Commissioner was of the view that not much weight should be accorded to the practice of the United States Patent and Trademark Office to not refuse to grant patents for non-human multicellular living organisms, including animals.[94] As the Patent and Trademark Office granted a patent for transgenic non-human mammals on April 12, 1988 on the authority of *Chakrabarty*, inferentially the Patent Commissioner was not according much weight to the interpretation of the definition of "invention" by the Supreme Court of the United States in that case. The Commissioner did not cite authority for this view. However, there would seem to be some support for it in the older jurisprudence. In *Rice v. Christiani*,[95] Lord Tomlin stated:

It may be true that the framers of the earlier Canadian statutes relating to patents looked for a model towards the American law rather than towards the English law, but there are marked differences between the American and Canadian statutes, and an examination of the development of American patent law is not of assistance in construing the language of the statute now under consideration.

At page 6 of his text,[96] Mr. Fox observes that the origin of patent law is grounded in the common law of England and specifically the royal prerogative to grant monopolies for new inventions that dates back hundreds of years. Accordingly, the law of the United Kingdom is often accepted as authoritative in interpreting Canadian patent law.

[137]However, it is doubtful that UK decisions are helpful for the specific purpose of construing the definition of "invention" in the Canadian *Patent Act*. The view had been expressed[97] that the terms in the definition of "invention" in the Canadian statute should be interpreted co-extensively

with the terminology ("any manner of manufacture") used in the British *Patents Act*.[98] After canvassing a number of English cases, Professor Fox stated at pages 19-20 of his text:

An examination of these decisions will demonstrate that included within the word "manufacture" [in the context of the U.K. *Patents Act*] are arts, machines, manufactures, compositions of matter, and processes, and that, as early as 1835, the word "manufacture" was taken to be almost synonymous with invention. It may, therefore, be accepted in principle that the requirements with regard to subject-matter are co-extensive under the British and Canadian statutes, and that the jurisprudence established on this point by the courts of the United Kingdom is authoritative in this country. [Citations omitted.]

[138]This approach has been questioned by the Supreme Court of Canada. In *Tennessee Eastman Co. et al. v. Commissioner of Patents*,[99] Pigeon J. stated for the Court that:

. . . I would first observe that I doubt whether decisions dealing with the patentability of inventions under the U.K. Act are entitled in Canada to the weight which authors such as Fox (Canadian Patent Law and Practice, 4th ed. p. 19) seem to think they should have. There are substantial differences between the British and Canadian statutes which need not be enumerated.

[139]However, the Canadian *Patent Act*, first enacted in 1869, was modelled on the United States patent statute of 1836. In their material aspects, the respective definitions of "invention" continue to be almost identical. For comparison purposes, I repeat section 2 of the Canadian *Patent Act*:

2. In this Act, except as otherwise provided,

"invention" means <u>any</u> new and useful art, <u>process, machine, manufacture or composition of matter</u>, or any new and useful improvement in any art, process, machine, manufacture or composition of matter. [Emphasis added.]

The United States patent statute[100] provides:

Whoever invents or discovers <u>any new and useful process, machine, manufacture, or composition of matter</u>, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title. [Emphasis added.]

Where Canadian and U.S. statutory provisions are similar, Mr. Fox indicates that United States decisions are "treated with respect" but do not operate as *stare decisis*.[101]

. . . that United States decisions are accepted only on very particular points where the relevant statutes make similar provision. They are treated with respect, as is proper, but they do not operate as *stare decisis* or constitute an estoppel. [Citations omitted.]

[140]I agree with Mr. Fox that while United States patent decisions are obviously not binding on Canadian courts, where the statutory language which is being interpreted is similar in both countries and where the reasoning underlying the United States Court's interpretation of the

language is persuasive, there is no reason why Canadian courts should ignore the U.S. jurisprudence.

[141]In *Chakrabarty, supra*, the issue was whether human-made micro-organisms were patentable. The inventors had discovered a process by which four different plasmids capable of degrading four different oil components could be transferred and maintained stably in a single pseudomonas bacterium which itself had no capacity for degrading oil. The majority of the Court:

(1) approached the matter bearing in mind the principle that the Court should not read into patent laws, limitations and conditions which the legislature has not expressed;

(2) construed the terms "manufacture" and "composition of matter" broadly in view of the expansiveness of these terms particularly as modified by the comprehensive "any"; and

(3) recognized that laws of nature, physical phenomena and abstract ideas had been held to be nonpatentable.

Having regard to these principles, the majority found that the inventors had produced a new bacterium which, with markedly different characteristics from any found in nature and having significant utility, was patentable.

[142]I see no reason why the analysis of the United States Supreme Court does not provide useful guidance for the purposes of construing the same words in Canadian *Patent Act*. Canadian courts must not read into legislation conditions and limitations not expressed by Parliament. The broad language of the definition reflects the fact that inventions are unforeseeable. As Burger C.J. pointed out, in the field of patent law, the statute cannot be confined to the particular applications contemplated when the legislation was enacted.[102]

A rule that unanticipated inventions are without protection would conflict with the core concept of the patent law that anticipation undermines patentability.

The same principle is applicable to Canadian patent law.

[143]In Canada, the products of the operation of the laws of nature are not patentable and it will only be creations that also involve ingenuity that will be.

[144]For these reasons, I disagree with the Patent Commissioner's inference that the *Chakrabarty* case deserves not much weight. I agree with the learned Trial Division Judge that the case is relevant and helpful. However, with respect to the learned Trial Division Judge, for the reasons that follow, I think that the majority view in *Chakrabarty* is to be preferred over that of the minority to which he subscribed.

[145]In coming to the conclusion that United States patent law did not cover living organisms, the minority observed that where there is an absence of legislative direction [at page 319]:

. . . 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 [i.e. to cover living organisms].[103]

On this fundamental issue of whether there is a "common understanding" that patent legislation does not extend to living organisms, I do not find the minority view compelling. I have difficulty reconciling the proposition that there is a "common understanding" that patents are not available to cover living organisms with the object and purpose of patent legislation--to promote inventions. The "common understanding" cannot mean that there are limitations on the areas of research and innovation that may result in patentable inventions. Here, I think the logic of the majority is more persuasive, that the distinction as to what is and is not patentable is not between animate and inanimate things, but between discoveries resulting from the laws of nature, whether living or not, and human made inventions.[104]

[146]In Canada, there is no "common understanding" that patent law does not extend to living organisms. As I have already noted, the decision of the Patent Commissioner to grant a patent to cover yeast, moulds and other lower life forms in the *Abitibi* patent application in 1982 suggests the opposite.[105] And in *Pioneer Hi-Bred*, the Supreme Court of Canada has accepted that the Canadian *Patent Act* does not necessarily exclude living things from patent protection.[106]

[147]I am, therefore, of the view that the majority opinion of the United States Supreme Court in *Chakrabarty* provides useful guidance in interpreting the definition of "invention" in the Canadian *Patent Act*, and in the preceding analysis (paragraphs 113 to 125), I have placed significant reliance on it in concluding that the definition of "invention" does not exclude from patentability, higher life forms such as the oncomouse.

(b) Control

[148]A major reason why the Commissioner of Patents refused to grant a patent for claims 1 to 12 was that the inventors did not have full control over all characteristics of the resulting oncomouse. At page 7 of his decision, he stated:

The inventors do not have full control over all the characteristics of the resulting mouse since the intervention of man ensures that reproducibility extends only as far as the cancer forming gene.

The learned Trial Division Judge agreed with this conclusion. While he allowed that not all characteristics need be under the direct control of the inventor, he was of the view that an element of control was essential and that, apart from the presence of the transgene:

. . . everything else about the mouse is present completely independently of human intervention.[107]

[149]Counsel before us did not indicate the source of the control test as a requirement for patentability. No prior Federal Court or Supreme Court of Canada jurisprudence was cited on this point.

[150]However, there is reference in the Canadian Patent Office *Manual of Patent Office Practice* to a control test.

In assessing whether subject matter falls within the meaning of the definition of a patentable invention under Section 2 of the Patent Act, the prerequisites established by Canadian jurisprudence and legislation that must be satisfied are, inter alia:

. . .

(b) whether the subject matter is operable, controllable and reproducible by the means described by the inventor so that the desired result inevitably follows whenever it is worked.

The reference in the Manual appears to be based upon a line of Patent Appeal Board decisions[108] which applied "control" and "reproducibility" tests to establish whether something claimed as an "art or process" was "useful" as required by the definition of "invention" in section 2 of the *Patent Act*. The words in the Patent Office Manual appear to be taken from the Patent Appeal Board decision in *Organon*, at pages 257-258:

The other factor to be decided is whether the "art" in terms of the present process satisfies the prerequisites of being a "useful" art or process within the meaning of s. 2(*d*), which may be conveniently stated, *inter alia*, as to: whether the subject-matter is useful in a "manual or productive art" (as distinct from a fine art such as that in which novelty is solely the exercise of professional skills, or that having intellectual meaning or aesthetic appeal alone), whether the subject-matter is controllable and reproducible by the means disclosed so that the desired result inevitably follows whenever it is worked, and whether the subject-matter has utility in practical affairs (as that in relation to trade, commerce or industry) which is beneficial to the public. [Emphasis added.]

[151]From the *Organon* decision it is apparent that the control (and reproducibility) test is considered to be implicit in the statutory requirement that an "invention" be "useful". In *Organon*, the Patent Appeal Board spoke of an art or process being "useful" as distinct from a "fine art" having "intellectual meaning or aesthetic appeal alone".

[152]I agree with the Patent Appeal Board in *Organon* that control is implied in the requirement that an invention be useful. However, the words in the *Organon* decision apply only to art or a process and not a product. I am prepared to accept, without deciding, that the control test set out in *Organon* is also applicable to products. It follows that if there is insufficient control over a product such that it would not be practically useful, the usefulness requirement of the definition of "invention" would not be met.

[153]However, in this case, the Patent Commissioner and the learned Trial Division Judge applied a far broader control test, not implied by the usefulness requirement for an invention. In doing so, I am of the respectful view that they read into the definition of "invention" words not expressed by Parliament, or implied by the language used by Parliament, and in doing so, clearly erred in law.

[154]The learned Trial Division Judge accepted that the presence of the oncogene in the oncomouse was under the control of the inventors. His concern was that the "myriad" of other characteristics of the mouse were not under their control. As he pointed out:

. . . it may be that there is a logical place at which one can draw a line and say definitively that a certain percentage of characteristics must be controlled before one can claim the entire life form as an invention. However, that line was not shown to me in the present case and the complexities of the issue make it unlikely that the Court is the forum in which to decide where the line should be drawn.[109]

I think his comments demonstrate that once a control test is extended beyond what is necessarily implied by the statutory language, i.e. control in the context of usefulness, trying to decide how much and what type of control is sufficient introduces virtually imponderable considerations. There is no doubt that the inventors do not have, or claim to have, control over the length of the oncomouse's tail, the colour of its eyes or the texture of its fur. The difficulty with a broad control test is that nothing in the *Patent Act* or in the common law jurisprudence provides any guideline or methodology that might provide any clue as to what degree or type of control would be "sufficient".

[155]The point is that control over the length of a tail, colour of eyes or texture of fur is irrelevant to the usefulness of the invention. No reason has been disclosed which would explain why, in the abstract, some degree or type of control of features not necessary for usefulness is a requirement for patentability. I do not see it as relevant that the myriad of other characteristics which are influenced by the genetic makeup of the oncomouse are not under the control of the inventors. All that is important for the usefulness of the product (the use of the oncomouse in carcinogenicity studies) is that, using the methods described by the inventors, a mouse is produced with all of its cells affected by the oncogene. That the other genes of the mouse are not under the control of the inventors does not detract from the usefulness of the invention.

[156]The learned Trial Division Judge recognized that the genetic makeup of the oncomouse, except for the presence of the oncogene, was irrelevant for purposes of the invention. However, he concluded that everything except the presence of the oncogene was independent of human intervention, and the control test was, therefore, not met. With respect, I am of the opinion that the learned Judge erred in imposing a control test in respect of characteristics of the oncomouse that were irrelevant to establishing that it was useful.

[157]As indicated in note 64, in the "Production of Transgenic Mice" section of the patent application, the inventors disclosed that of 28 mice analyzed, 2 males (7%) were found to have retained the oncogene and both subsequently transmitted the oncogene sequence through the germ line in a ratio consistent with the Mendelian inheritance of single loci, i.e. 50%. The Patent Commissioner and the learned Trial Division Judge did not base their lack of sufficient control conclusion on the relatively low percentage of founder mice derived from the process described by the inventors. In my view, they were correct in not doing so for two reasons. The first is that the process was found to be patentable by the Patent Examiner and this finding was not challenged. The second is that a low rate of founder oncomice production is not evidence that the inventors do not have control over the process or the product. The reason for the low percentage

is not explained, although the record indicates that after the filing of the patent application, "many transgenic animals within the claims have successfully been made".[110] As long as the process produces some founder oncomice and offspring oncomice in accordance with Mendelian inheritance, a useful product has been created. The relevant control test is therefore satisfied.

[158]In sum, usefulness is necessary for patentability and implies control in the sense that the desired result will be achieved when the product is used or produced. That desired result in this case is an oncomouse with susceptibility to cancer for use in carcinogenicity studies. Once that has been achieved, control over other characteristics of the mouse is not necessary or relevant. Such "additional" control has nothing to do with the desired result. If the product is a composition of matter that is new, useful and unobvious, it is a patentable "invention". These conditions have been met in this case.

(c) Reproducibility

[159]In his reasons, the learned Trial Division Judge found that "for an invention to be patentable, it must be reproducible".[111] In his view (and in the view of the Patent Commissioner) the oncomouse was not reproducible. The Patent Commissioner did not cite authority for his reference to reproducibility. The learned Trial Division Judge referred to paragraph 27(3)(*b*) [as am. by S.C. 1993, c. 15, s. 31] of the *Patent Act* as authority for the reproducibility requirement.

[160]Paragraph 27(3)(*b*) provides:

27. . . .

(3) The specification of an invention must

. . .

(*b*) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it;

[161]As I read paragraph 27(3)(*b*), it requires the specification of an invention to set out clearly the steps of the process or the method of compounding or using a composition of matter in such terms as to enable a person skilled in the science to compound or use it.

[162]Compliance with paragraph 27(3)(*b*) is not a condition precedent to an invention. The provision is only concerned with sufficiency of disclosure by the inventor. Provided disclosure is sufficient to enable another person skilled in the science to make and use the product, its requirements have been met.[112]

[163]There is no dispute here that the specification contained sufficient disclosure to comply with paragraph 27(3)(*b*). Indeed, claims 13 to 26 were found to be patentable and it is therefore implicit that there has been compliance with paragraph 27(3)(*b*). If the process claims are not

disqualified by reason of paragraph 27(3)(*b*), it follows that neither should the product claims that derive from the patentable process claims.

[164]The discussion of reproducibility in the reasons of the learned Trial Division Judge appear to relate closely to the issue of control which I have already addressed. Indeed, the reproducibility test also appears to originate from the *Organon* decision which asserts both control and reproducibility tests in the context of the usefulness requirement for an art or process (and arguably a product) to be an invention. By using the methods described in the specification of the patent application, an oncomouse is producible with all of its cells affected by the oncogene. Such a mouse is reproducible and is useful. The fact that other characteristics of the oncomouse are not reproducible at will by the inventor or person skilled in the science is irrelevant because they are not necessary for the usefulness of the oncomouse.

[165]Other than the requirement for sufficient disclosure of an invention in paragraph 27(3)(*b*), about which there is no dispute on this appeal, I see nothing in the *Patent Act* pertaining to a reproducibility requirement which the inventors can be said to have failed to meet. The reproducibility requirement derived from *Organon*, *supra*, in the context of usefulness, has been satisfied in this case.

(d) Splitting the process in phases

[166]The Patent Commissioner split what the inventors did into two phases. Phase one, engineering the plasmid and the transgenic unicellular material, involved human intervention and was found to be patentable. Phase two, developing a genetically engineered oncomouse in the uterus of a host mouse was found not to be patentable. The learned Trial Division Judge accepted that distinction.

[167]With respect, I am unable to agree with the Commissioner's distinction. The Trial Division Judge correctly accepted that most inventions involve the use of some of the laws of nature. It seems to me that once this is conceded, 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. I agree that one could view the creation of the oncomouse as involving two phases (or perhaps more). However, this does not justify splitting them. The oncomouse is the product of both. If the laws of nature may be employed together with human ingenuity in developing an invention, it should not matter whether the laws of nature are employed at the beginning, during or at the end of the process or whether the steps of the process can or cannot easily be separated into phases.

[168]Splitting what the inventors did into phases also results in a curious inconsistency in this case. Claim 25 provides:

A somatic cell culture derived from a transgenic mammal wherein the cells of said cell culture contain an activated oncogene sequence integrated into a chromosome.

Claim 25 was found to be patentable. However, the somatic cell culture is only derived once a transgenic mammal has been brought into existence. It has not been explained why the somatic cell culture would be considered patentable when the transgenic mammal from which it is

derived is not. What we are left with from the phasing approach is the patentability of the somatic cell culture derived from a non-patentable transgenic mammal which in turn is derived from patentable transgenic unicellular material. I think the discontinuity that has occurred here points out the incongruous results from an approach which provides for the splitting into phases of what the inventors have done.

[169]In my respectful view, splitting the invention into phases was not legally justified. It denied to the inventors a patent on a product which was the result of a combination of inventive ingenuity and the laws of nature both of which were central to the invention.

(e) Lower and higher life forms

[170]The learned Trial Division Judge found that a complex life form such as the oncomouse does not fit within the current parameters of the *Patent Act*. Contrary to the decision of the Patent Appeal Board in *Abitibi*, the learned Judge was of the view that a distinction between the patentability of lower and higher life forms was appropriate on the grounds of policy. In coming to this conclusion, he also relied on the minority opinion in *Chakrabarty* that life forms were not patentable at all.

[171]As has already been pointed out, the majority of the United States Supreme Court had found that there was no limitation in the United States patent statute against patenting living organisms. Having so found, Burger C.J. for the majority observed at page 317 that policy concerns that might justify a limitation on patenting life forms were not matters for the courts.

What is more important is that we are without competence to entertain these arguments--either to brush them aside as fantasies generated by fear of the unknown, or to act on them. The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot. That process involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives. Whatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.

[172]I agree. It is not up to the Court, for policy reasons, to place limits on the scope of legislation not supported by the words. That is the role of the legislative branch of Government. In *Abitibi*, lower living organisms such as yeast, were found to be patentable. There may be policy reasons against the patentability of higher life forms (or lower life forms for that matter). However, such arguments are for Parliament and not the courts. For the reasons already given, the words of the definition of "invention" in the *Patent Act* do not exclude living organisms and the Court may not impose such a limitation on policy grounds. I must conclude that the learned Trial Division Judge erred in finding that complex life forms were not within the parameters of the *Patent Act*.

(f) Protection afforded by patenting the oncomouse

[173]The learned Trial Division Judge concluded that to patent the oncomouse would provide the inventor with no additional protection beyond that provided by patenting claims 13 to 26. Again, I must respectfully disagree. If patent protection ends there, the inventors have no practical patent protection over the product of their ingenuity. As was stated by William L. Hayhurst, Q.C.:[113]

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 on the organism . . . .

Anyone can purchase a founder mouse or offspring having the oncogene in its cells, and breed it. While the inventors or their assignees or licensees might impose a condition on the sale of an oncomouse that it not be bred, such a contractual condition is only effective against the purchaser. A patent provides legal protection against the world, that is, others who might come into possession of an oncomouse and reproduce it. In contrast to the protection afforded by a patent, Professor Vaver has pointed out weaknesses in the common law alternatives:

. . . common law protection is volatile. It can disappear despite the owner's best efforts. Someone may learn of the secret independently or may reverse-engineer it or the product that contains it; innocent buyers from an industrial spy may profit from their purchase and can end up destroying its value as a trade secret by publicizing it. Departing employees can also use information that has become part of their general skills and knowledge.[114]

In my opinion, the patentability of the oncomouse does provide protection not provided by the patenting of claims 13 to 26, or by non-statutory alternatives such as the law of contract.

(g) *Pioneer Hi-Bred*

[174]Certain comments of Marceau J.A. in *Pioneer Hi-Bred* appear to have had significant influence on the findings of the Patent Commissioner and the Trial Division Judge. These comments are found at pages 13-14 [*supra*, note 67] of the Federal Court of Appeal judgment in *Pioneer Hi-Bred*:

I have not been convinced. Even if those definitions [definitions of "manufacture" and "composition of matter" taken from *Chakrabarty*] were held to be applicable to a micro-organism obtained as a result of a laboratory process, I am unable to go further and accept that they can also adapt to a plant variety produced by cross-breeding. Such a plant cannot really be said, other than on the most metaphorical level, to have been produced from raw materials or to be a combination of two or more substances united by chemical or mechanical means. It seems to me that the common ordinary meaning of the words "manufacture" and "composition of matter" would be distorted if a unique but simple variety of soybean were to be included within their scope.

. . .

In sum, relying both on the common meaning of the words of the definition for "invention" as it appears in the Act and on the legislative context in which they are found, insofar as the intention of Parliament may be derived therefrom, I am satisfied that the soybean variety developed by the appellant cannot be the subject matter of a patent of invention.

[175]What was at issue in *Pioneer Hi-Bred* was the cross-breeding of soybeans. There was no human intervention at the molecular or genetic level as in the case at bar.

[176]In the present case, there has been a sophisticated genetic alteration performed. This is quite different from cross-breeding plants as in *Pioneer Hi-Bred* and constitutes what Lamer J. noted in the Supreme Court decision was the "second type" of genetic engineering. At page 1633 he stated:

This procedure [cross-breeding of plants] differs from the second type of genetic engineering, which requires a change in the genetic material--an alteration of the genetic code affecting all the hereditary material--since in the latter case the intervention occurs inside the gene itself. The change made is thus a molecular one and the "new" gene is thus ultimately the result of a chemical reaction, which will in due course lead to a change in the trait controlled by the gene. While the first method implies an evolution based strictly on heredity and Mendelian principles, the second also employs a sharp and permanent alteration of hereditary traits by a change in the quality of the genes.

In this second type of genetic engineering that is involved in the case at bar, there is intervention at the genetic level and a sharp and permanent alteration of an hereditary trait by insertion of a non-naturally occurring activated oncogene sequence into the fertilized mouse egg and its presence in all the cells of the oncomouse. A mouse zygote is altered in this case by implanting a specific non-naturally occurring activated oncogene sequence with a known function into it, thus producing a specific life form that did not exist in nature.

[177]Indeed, the Patent Examiner, in allowing a patent for claims 14 and 15, found that the process for the production of the oncomouse was patentable and no objection was taken to this determination on the basis of the comments of Marceau J.A. in *Pioneer Hi-Bred* by the Patent Commissioner or the learned Trial Division Judge. If the process for the production of the oncomouse was not disqualified from patentability on this ground, it follows that the oncomouse itself cannot be disqualified.

[178]The findings of Marceau J.A. in *Pioneer Hi-Bred* with respect to cross-breeding of soybeans are not applicable to the case at bar which involves inventive ingenuity and intervention at the genetic level and the creation of a specific new life form.

STANDARD OF REVIEW

[179]The dissenting reasons of Isaac J.A. appear to be largely based on deferring to the decision of the Patent Commissioner by application of the reasonableness *simpliciter* standard of review.

[180]There is no question that the decision of the Trial Division Judge, which was the subject of this appeal, is reviewable on a correctness standard. None of the *indicia*, e.g. expertise, privative clauses, which would suggest a more deferential standard of review is applicable.

[181]On the other hand, the decision of the Patent Commissioner may be entitled to some deference. I say "may" because the issue of standard of review was not dealt with by the Trial Division Judge, nor was it raised by the respondent on this appeal and we have not had the benefit of prior consideration or argument on it.

[182]There is no privative clause in respect of decisions of the Patent Commissioner. Rather, there is a statutory right of appeal from the decision of the Patent Commissioner to the Federal Court Trial Division.[115] The issue involves the interpretation of the *Patent Act*. The issue is a fundamental one and in respect of which a decision will have important precedential value--whether higher life forms come within the definition of "invention" in the *Patent Act*. In *Pioneer Hi-Bred, supra,* the Supreme Court of Canada did not suggest there was any deference owed to the Patent Commissioner on the interpretation of the definition of "invention" in the *Patent Act*. These considerations suggest a higher standard of scrutiny of the Patent Commissioner's decision in this case.

[183]On the other hand, there is no doubt that the expertise of the Patent Commissioner warrants a more deferential approach by reviewing courts on decisions made by the Commissioner within his area of expertise.[116] However, the broader the proposition and the further the implications of a decision stray from the core expertise of the Commissioner as in this case, less deference is warranted.

[184]Having regard to the functional and pragmatic approach to determining the standard of review reiterated and further explained by Bastarache J. in *Pushpanathan v. Canada (Minister of Citizenship and Immigration)*, [1998] 1 S.C.R. 982, the generality of the proposition at issue here suggests that the question in this case is one that Parliament intended be left to the courts. At paragraph 38 [pages 1011-1012] of *Pushpanathan*, Bastarache J. stated:

Keeping in mind that all the factors discussed here must be taken together to come to a view of the proper standard of review, the generality of the proposition decided will be a factor in favour of the imposition of a correctness standard. This factor necessarily intersects with the criteria described above, which may contradict such a presumption, as the majority of this Court found to be the case in *Pasiechnyk, supra*. In the usual case, however, the broader the propositions asserted, and the further the implications of such decisions stray from the core expertise of the tribunal, the less likelihood that deference will be shown. Without an implied or express legislative intent to the contrary as manifested in the criteria above, legislatures should be assumed to have left highly generalized propositions of law to courts.

[185]While I am of the view, on a functional and pragmatic basis, that the Patent Commissioner's decision in this case is likely reviewable on the less deferential standard of correctness, I am also satisfied that even on the more deferential reasonableness *simpliciter* standard, the decision is properly reviewable by the Court.

[186]The seminal case which established the reasonableness *simpliciter* standard is *Canada (Director of Investigation and Research) v. Southam Inc.*, [1997] 1 S.C.R. 748. Iacobucci J. stated at page 776 [paragraph 56]:

An unreasonable decision is one that, in the main, is not supported by any reasons that can stand up to a somewhat probing examination. Accordingly, a court reviewing a conclusion on the reasonableness standard must look to see whether any reasons support it.

At page 778 [paragraphs 59-60], he stated:

The standard of reasonable *simpliciter* is also closely akin to the standard that this Court has said should be applied in reviewing findings of fact by trial judges. In *Stein v. "Kathy Kay" (The Ship)*, [1976] 2 S.C.R. 802, at p. 806, Ritchie J. described the standard in the following terms:

. . . the accepted approach of a court of appeal is to test the findings (of fact) made at trial on the basis of whether or not they were clearly wrong rather than whether they accorded with that court's view of the balance of probability. (Emphasis in original.)

Even as a matter of semantics, the closeness of the "clearly wrong" test to the standard of reasonableness *simpliciter* is obvious. It is true that many things are wrong that are not unreasonable; but when "clearly" is added to "wrong", the meaning is brought much nearer to that of "unreasonable".

Applying the approach of Iacobucci J. in *Southam, supra*, to the appeal at bar, I am satisfied that the decision of the Patent Commissioner is clearly wrong. The Commissioner applied control and reproducibility tests that are not expressed in or implied by the *Patent Act*. He split the invention into phases without legal justification. He relied on the decision of the Federal Court of Appeal in *Pioneer Hi-Bred* in arriving at his conclusion when that decision is clearly distinguishable. And there are significant and unexplained inconsistencies between what was found to be patentable and what was not. In short, the reasons of the Patent Commissioner do not support his conclusion. Even on a reasonableness *simpliciter* standard, the decision of the Patent Commissioner is properly the subject of review by the Trial Division and this Court.

THE INTERVENER'S SUBMISSIONS

[187]The Canadian Environmental Law Association was granted intervener status in this appeal. The intervener supports the respondent's position. The intervener makes submissions in relation to the interpretation of the *Patent Act* and public interest considerations.

[188]In so far as statutory interpretation is concerned, the intervener raised two arguments not put forward by the respondent. The first is the doctrine of *contemporanea expositio*--that the meaning of words in an enactment will be understood in the sense which they bore when the enactment was passed. The intervener argued that the definition of "invention" in the *Patent Act* is in all material respects unchanged from the way in which it appeared when the first *Patent Act* was enacted in 1869. The intervener says that at that time it could not have been contemplated

that higher life forms were included within the definition of "invention" when such inclusion would give rise to serious ethical issues.

[189]The doctrine of *contemporanea expositio* does not apply to the definition of "invention" in the *Patent Act*. As I have already noted, this argument was addressed by the majority of the Supreme Court of the United States in *Chakrabarty* when it found that a rule that would deny patent protection because an invention was unknown when the Act was passed would conflict with the core concept of patent law, that anticipation undermines patentability, and that broad general language was employed because inventions are often unforeseeable.

[190]In Canada, it has been recognized that the doctrine of *contemporanea expositio* does not apply to all statutes. In *Perka et al. v. The Queen*,[117] Dickson J. (as he then was) stated:

This does not mean, of course, that all terms in all statutes must always be confined to their original meanings. Broad statutory categories are often held to include things unknown when the statute was enacted. In *Gambart v. Ball* (1863), 32 L.J.C.P. 166, for example, it was held that the *Engraving Copyright Act* of 1735, which prohibited unauthorized engraving or "in any other manner" copying prints and engravings, applied to photographic reproduction--a process invented more than one hundred years after the Act was passed. (See also Maxwell, *supra*, at pp. 102 and 243-44.) This kind of interpretive approach is most likely to be taken, however, with legislative language that is broad or "open textured". It is appropriate, as the judgments of Viscount Sankey in *Edwards v. Attorney-General for Canada*, [1930] A.C. 124, and Viscount Jowitt in *Attorney-General for Ontario v. Attorney-General for Canada* (the *Privy Council Appeals Reference*), [1947] A.C. 127, indicate, to the interpretation of the words in constitutional documents, whose meaning must be capable of growth and development to meet changing circumstances. [Emphasis added.]

[191]The inclusion of things unknown must be applicable to the definition of "invention" in the *Patent Act*. The words of the definition are broad and open-textured. Inventions are, by definition, "new". With respect to the definition of "invention" in the *Patent Act*, this argument of the intervener is misplaced.

[192]The intervener then relies on the enactment of the *Plant Breeders' Rights Act*[118] which provides a form of property protection for plant breeders. The intervener says that this enactment demonstrates that the products of plant breeding were not protected under the *Patent Act* and by implication, that other life forms which are the product of genetic engineering are similarly not patentable under the *Patent Act*.

[193]The type of protection offered by the *Plant Breeders' Rights Act* is broader than under the *Patent Act* because it covers the product of cross-breeding resulting solely from the application of the laws of nature. However, there is no necessary implication from this enactment that the definition of "invention" in the *Patent Act* excludes living organisms resulting from application of human ingenuity. The same argument was made before the Supreme Court of the United States in *Chakrabarty* respecting plant breeders legislation in that country and was rejected. Similarly, there is nothing in the Canadian *Plant Breeders' Rights Act* that implies that living

things are excluded from the definition of "invention" in the *Patent Act* provided they are the result of human ingenuity and are not solely a product of the laws of nature.

[194]The intervener then makes a number of public interest arguments which are summarized in its factum as follows:

The public interest implications include issues of equitable access to the benefits of biodiversity; the environmental and human health hazards arising from products of this technology; and issues relating to animal welfare; and commodification and objectification of life; and the public interest in rapid dissemination of scientific research results.

[195]These considerations are not appropriate for the Court to take into account for two reasons.

[196]The first is that, as the appellant points out, they raise factual questions on which evidence could be lead on both sides of the issues. There is no opportunity on appeal to do so. In the absence of evidence, the Court cannot entertain arguments on these issues.

[197]The second and more fundamental point is that as already explained, such arguments are properly addressed to Parliament and not the Court. In this type of case, the Court is not the forum for a public policy debate. Moreover, what is at issue here is not whether the oncomouse or any other living organisms should be created. A patent does not give a positive right to develop or use an invention, but rather only a right to exclude others from using or reproducing the invention for a limited period of time. Thus, 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.

[198]I have already indicated that, in my respectful view, the words of the *Patent Act* do not exclude living things. It is Parliament and not the Court that defines the limits of patentability. The provisions of the *Patent Act* have been cast in broad terms to fulfil Parliament's objective--to promote invention. If anyone is of the opinion that the scope of patentability should be narrowed, it is open to that person to ask Parliament to do so.

SCOPE OF CLAIMS

[199]The appellant has applied its technology to produce mice with a genetic predisposition to develop cancerous tumours using the c-myc oncogene, but claims that the process can be applied to non-human mammalian life forms generally and that the technology is identical for all oncogenes. The appellant's claim covers <u>all</u> transgenic non-human mammals and all oncogenes. The rationale for claiming all non-human mammals and all oncogenes is that if the claims were restricted to mice or to the c-myc gene, the appellant's technology could be easily appropriated by a competitor by following the methods in the patent claims using other mammals such as rats or sheep or other oncogenes.[119]

[200]On appeal before this Court, there was no argument to limit the patentability of the claims to mice or to the c-myc gene. However, these restrictions had been raised by the Patent Examiner in respect of claims 1 and 15.[120] Although claim 1 had been rejected by the Patent Examiner,

claim 15 was found to be patentable. The appellant appears to have satisfied the Patent Examiner that claim 15 should not be restricted to mice or to the c-myc oncogene. Indeed, the Patent Examiner allowed claim 17 which explicitly provided for a method of producing a transgenic mammal with an activated oncogene sequence comprised of a DNA sequence from one of 33 oncogene sequences that were identified. This is a sufficient basis for this Court to accept the claims as drawn, that is, covering all non-human mammals and all oncogenes.

[201]The legal principles on the issue of overbreadth of patent claims relevant to this case are discussed in *Monsanto*.[121] In *Monsanto*, the Commissioner of Patents rejected patent claims of the applicant in respect of 126 chemical compounds as being too broad on the basis that the applicant disclosed details of the preparation of only three of them. At page 1117, Pigeon J. held that there could be:

. . . just two possible reasons for rejecting claims such as those in issue.

1. There is evidence of lack of utility in respect of some of the area covered;
2. It is not a sound prediction.

[202]If the Patent Commissioner decides to reject patent claims as being overbroad for either of these reasons, section 42 (now section 40) of the Act places an onus upon him to justify any such refusal. In ruling that the Patent Appeal Board improperly rejected Monsanto's claims on the basis of overbreadth, Pigeon J. held at page 1121:

In the instant case, the Board, in spite of a complete absence of any evidence of unsoundness of the prediction, deny [*sic*] the claims and would in the end limit them to the area of *proved utility* instead of allowing them to the extent of *predicted utility*. In my view this is contrary to s. 42 [now section 40] of the *Patent Act*.

[203]A patent specification is addressed to a person skilled in the art or science. Although the various steps are disclosed only for a mouse and the c-myc gene, the same steps are involved for other non-human mammals and other oncogenes and any person skilled in the science would know that similar results should be expected.

[204]The only basis for rejecting the claims as overbroad would be if there was evidence of lack of utility in respect of some of the area covered or if what is disclosed in the specification is not a sound prediction. There was no finding by the Patent Examiner that any of the claims did not have utility or that the specification did not contain sound predictions. There is therefore no basis for this Court to restrict the claims.

THE IMPLICATION FOR HUMAN BEINGS

[205]A final question is whether the *Patent Act* could be extended to cover human beings. In other words, could a finding that "invention" includes living organisms extend to human beings? For example, on a theoretical level, could a person whose genome has been modified by the addition of an engineered gene in order to eliminate or suppress a genetic predisposition to a disease be the subject-matter of a patent?

[206]Strictly, the question does not arise here, because the patent claims are restricted to non-human mammals. However, the potential extension to human beings is an obvious concern.

[207]The answer is clearly that the *Patent Act* cannot be extended to cover human beings. Patenting is a form of ownership of property. Ownership concepts cannot be extended to human beings. There are undoubtedly other bases for so concluding, but one is surely section 7 of the *Canadian Charter of Rights and Freedoms* [being Part I of the *Constitution Act, 1982*, Schedule B, *Canada Act 1982*, 1982, c. 11 (U.K.) [R.S.C., 1985, Appendix II, No. 44]] which protects liberty. There 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.

[208]In saying this, I make no finding or observation on the patentability of human genes or products or processes at the genetic level. As scientific research advances, these and other related matters will require determination by the courts or by Parliament.

CONCLUSION

[209]The appeal will be allowed with costs in this Court and in the Trial Division. The decisions of the learned Trial Division Judge and the Commissioner of Patents are quashed and the matter will be remitted to the Commissioner of Patents with the direction to grant a patent covering claims 1 to 12 of the patent application.

Linden J.A.: I agree.

[1] R.S.C., 1985, c. P-4 [as am. by R.S.C., 1985 (3rd Supp.), c. 33, s. 16] (hereinafter the Act).

[2] R.S.C., 1985, c. F-7 [as am. by S.C. 1990, c. 8, s. 6].

[3] *Supra*, note 1, s. 41.

[4] *Supra*, note 1, s. 40.

[5] Appeal Book, at pp. 39-64.

[6] SOR/96-423.

[7] *Supra*, note 5, at p. 65.

[8] *Ibid.*, at pp. 66-69.

[9] *Ibid.*, at pp. 70-71.

[10] *Ibid.*, at pp. 72-74.

[11] *Ibid.*, at p. 75.

[12] *Ibid.*, at pp. 76-83.

[13] *Ibid.*, at pp. 84-111.

[14] *Ibid.*, at p. 112.

[15] *Ibid.*, at pp. 113-114.

[16] *Ibid.*, at pp. 115-116.

[17] *Ibid.*, at p. 117.

[18] *Ibid.*, at pp. 118-133.

[19] *Ibid.*, at pp. 122-123.

[20] *Ibid.*, at pp. 134-136.

[21] *Ibid.*, at p. 146.

[22] *Ibid.*, at p. 137.

[23] *Ibid.*, at p. 158.

[24] *Ibid.*, at pp. 36-38.

[25] *Ibid.*, at p. 160.

[26] *Ibid.*

[27] [1987] 3 F.C. 8 (C.A.); affd [1989] 1 S.C.R. 1623 (hereinafter *Pioneer Hi-Bred*).

[28] 447 U.S. 303 (1980) (hereinafter *Chakrabarty*).

[29] Appeal Book, at p. 164.

[30] (1982), 62 C.P.R. (2d) 81 (Pat. App. Bd.) (hereinafter *Abitibi*).

[31] Appeal Book, at p. 165.

[32] *Ibid.*, at p. 166.

[33] *Ibid.*, at pp. 159-166.

[34] [1994] 2 S.C.R. 557 (hereinafter *Pezim*).

[35] [1998] 1 S.C.R 982, at p. 1004 (hereinafter *Pushpanathan*).

[36] *Ibid*. See also, Lamer J., as he then was, in *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623, at p. 1635.

[37] R.S.C., 1985, c. T-13.

[38] (2000), 5 C.P.R. (4th) 180 (F.C.A.) (hereinafter *John Labatt Ltd.*).

[39] *Supra*, note 34.

[40] (1981), 59 C.P.R. (2d) 7 (F.C.A.).

[41] [1995] 2 S.C.R. 739, at p. 757.

[42] They are also required by statute to be "competent" which is further evidence of their expertise. See s. 35 (1) [as am. by R.S.C., 1985 (3rd Supp.), c. 33, s. 12] of the Act, which reads as follows:

35. (1) The Commissioner shall, on the request of any person made in such manner as may be prescribed and on payment of a prescribed fee, cause an application for a patent to be examined by competent examiners to be employed in the Patent Office for that purpose. [Emphasis added.]

[43] R. 30(6) reads: "Where the rejection is not withdrawn pursuant to subsection (5), the rejection shall be reviewed by the Commissioner and the applicant shall be given an opportunity to be heard." The Patent Appeal Board is a non-statutory body created pursuant to the Canadian Patent Office *Manual of Patent Office Practice* (March 1998), which reads: "the Patent Appeal Board (PAB) consists of one or more senior members of the CPO who have not participated in the examination of the application under review. The Board reviews the grounds for rejection in final actions and hold hearings under s. 30(6) of the Patent Rules when requested by applications and advises the Commissioner on these matters." [Emphasis added.]

[44] *Supra*, note 25.

[45] [1964] S.C.R. 49, at p. 56.

[46] The safeguards are an 18 month confidentiality provision and no examination for patents withdrawn within 18 months of filing the application.

[47] [1999] 1 S.C.R. 142, at para. 46 [p. 172].

[48] See, for ex., Barry Hoffmaster, "The Ethics of Patenting Higher Life Forms" (1989), 4 *I.P.J.* 1, at p. 2. Professor Hoffmaster describes how an announcement by the U.S. Patent and Trademark Office that non-human multicellular living organisms are a patentable subject matter "provoked a moral maelstrom."

[49] [1997] 1 S.C.R. 748, at pp. 776-777 (hereinafter *Southam*).

[50] W. L. Hayhurst, "Exclusive Rights in Relation to Living Things" (1991), 6 *I.P.J.* 171, at p. 196.

[51] Canada. *Proceed with Care: Final Report of the Royal Commission on New Reproductive Technologies* (Ottawa: Minister of Government Services, 1993), at p. 24.

[52] [1979] 2 S.C.R. 1108 (hereinafter *Monsanto*).

[53] *Ibid*., at p. 1119.

[54] 227 U.S.P.Q. 443 (Bd. Pat. App. & Int. 1985).

[55] *Supra*, note 27, at pp. 13-14.

[56] See for ex., the *Customs Tariff*, S.C. 1997, c. 36, where Parliament has said clearly that in interpreting the customs tariff, the ordinary rules of statutory interpretation are superseded by interpretative tools written by an international organization.

[57] [1996] 2 S.C.R. 432, at p. 445.

[58] S.C. 1990, c. 20, Royal Assent was given on 19 June 1990.

[59] Decision of Commissioner of Patents, dated August 4, 1995.

[60] Decision of the Patent Examiner, dated March 24, 1993.

[61] [1998] 3 F.C. 510 (T.D.).

[62] The inventors have constructed an "activated oncogene sequence" which contains DNA from an oncogene which harbours the genetic code, or blueprint, for the production of protein specific to that oncogene in cells of the non-human mammal. This protein plays a role in the growth and division of cells. Elevated levels of the protein in cells cause the predisposition in the mammal to develop cancerous tumours. In order to "activate" the oncogene to direct the increased levels of protein, the inventors have fused a "promoter sequence" of DNA from a different source to the oncogene. The combined effect of the oncogene code and the promoter sequence is to produce a mammal which is susceptible to cancerous tumour growth.

[63] Patent claim 1 provides:

1. A transgenic non-human mammal whose germ cells and somatic cells contain an activated oncogene sequence introduced into said mammal, or an ancestor of said mammal, at an embryonic stage.

"Germ cells" are reproductive cells, and "somatic cells" are all other cells of the organism other than reproductive cells. It is understood that the transgenic non-human mammals which are sought to be patented will have the oncogene present in all reproductive and somatic cells.

[64] Of 28 mice analyzed by the inventors, 2 males or about 7% were found to have retained the oncogene.

[65] R.S.C., 1985, c. P-4.

[66] Decision of Commissioner of Patents, *supra*, note 59, at p. 6.

[67] [1987] 3 F.C. 8 (T.D.); affd by [1989] 1 S.C.R. 1623.

[68] Decision of Commissioner of Patents, *supra*, note 59, at p. 7.

[69] (1982), 62 C.P.R. (2d) 81 (Pat. App. Bd.).

[70] *Supra*, note 61, at para. 12 [p. 521].

[71] 447 U.S. 303 (1980).

[72] *Supra*, note 61, at para. 30 [p. 530].

[73] *Ibid.*, at para 32 [p. 531].

[74] *Ibid.*

[75] *Ibid.*, at para 35 [p. 532].

[76] S. 42 [as am. by R.S.C., 1985 (3rd Supp.), c. 33, s. 16] of the *Patent Act* provides:

42. Every patent granted under this Act shall contain the title or name of the invention, with a reference to the specification, and shall, subject to this Act, grant to the patentee and the patentee's legal representatives for the term of the patent, from the granting of the patent, the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used, subject to adjudication in respect thereof before any court of competent jurisdiction.

[77] R.S.C., 1985, c. P-4 , s. 46 (as am. *idem*; S.C. 1993, c. 15. s. 43).

[78] See the introduction to chapter three, "Patents" in David Vaver, *Intellectual Property Law: Copyright, Patents, Trade-Marks*, (Toronto: Irwin Law, 1997), at pp. 113-114.

[79] [1999] 1 S.C.R. 142, at pp. 171-172 [para. 46]. Although it was not a patent case, the Court described the essence of patent law in order to distinguish it from the law of breach of confidence in the context of trade secrets.

[80] As enacted by S.C. 1993, c. 15, s. 33.

[81] Inventiveness was affirmed as "an essential attribute of patentability" by the Supreme Court of Canada in *Commissioner of Patents v. Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning*, [1964] S.C.R. 49, at p. 56.

[82] See for ex., *Diversified Products Corp. v. Tye-Sil Corp.* (1991), 35 C.P.R. (3d) 350 (F.C.A.). At p. 365 Décary J.A. stated: "There is no specific section in the *Patent Act* relating to the requirement for inventiveness or inventive ingenuity, but it has been held and is no longer questioned that by use of the words `invention' and `inventor' throughout the Act, inventiveness or inventive ingenuity is required to obtain a valid patent."

[83] Vaver, *supra*, note 78, at p. 126.

[84] [1979] 2 S.C.R. 1108.

[85] [1939] S.C.R. 245.

[86] At p. 308.

[87] Helen Kreuzer and Adrianne Massey. *Recombinant DNA and Biotechnology: A Guide for Teachers*, (Washington, D.C.: ASM Press, 1996), at p. 537.

[88] *Supra*, note 59, at p. 7.

[89] *Supra*, note 61, at para. 29 [p. 530].

[90] Although claim 14 is for a transgenic cell culture, the cell culture requires the prior development of the oncomouse.

[91] *Supra*, note 78, at p. 128.

[92] (1910), 43 S.C.R. 182, at p. 186.

[93] (1909), 34 Que. S.C. 388, at p. 401 (*per* Archibald J.).

[94] "United States Patent and Trademark Office, Animals--Patentability", 1077 *Official Gazette U.S. Patent & Trademark Office* 8 (April 21, 1987)

[95] [1931] A.C. 770 (P.C.), at p. 779.

[96] Fox, H. G. *The Canadian Law and Practice Relating to Letters Patent for Invention*, 4th ed. Toronto: Carswell, 1969.

[97] As stated by Fox, *supra*, note 96, at p. 19. One example of this approach being applied in Canada is the judgment of Cattanach J. in *Lawson v. Canada (Commissioner of Patents)* (1970),

62 C.P.R. 101 (Ex. Ct.) where he stated at page 111: "Therefore, it is accepted in principle that the requirements with regard to subject-matter of a patent are co-extensive under the British and Canadian statutes and that the jurisprudence established by the Courts of the United Kingdom is authoritative in Canada."

[98] *Patents Act* 1977 (U.K.), 1977, c. 37.

[99] [1974] S.C.R. 111, at p. 120. Similar doubts have previously been expressed by the Supreme Court. In *Electric Fireproofing Co. of Canada v. Electric Fireproofing Co., supra*, note 92, at pp. 185-186, Idington J. stated: "Our statute defines what is patentable. I am not clear that the ground it covers is identical with that portion of the Royal Prerogative reserved and preserved by statute as the foundation in England for grants of the like kind of rights."

[100] 35 U.S.C. § 101 (1988).

[101] *Supra*, note 96, at p. 6.

[102] *Chakrabarty, supra*, note 71, at p. 316.

[103] The minority went even further and found there was no absence of legislative direction in the *Chakrabarty* case. They found that Congress had passed legislation extending patent or patent-like protection to new plant varieties (*The Plant Patent Act*, 35 U.S.C. § 161 (1930), and *The Plant Variety Protection Act*, 7 U.S.C. § 2402(a) (1970)). In these circumstances, the minority held that the United States patent statute must have been enacted by Congress in the belief that the definition of "invention" in the statute did not cover living organisms. It is neither necessary nor appropriate for this Court to be concerned with the implications of other United States legislation on the scope of the United States patent statute.

[104] *Chakrabarty, supra*, note 71, at p. 315.

[105] In *Abitibi, supra*, note 69, at pp. 84-88, the Patent Commissioner traces English, American and Canadian decisions on the issue of whether life forms are subject to patentability. The modern view in all countries and in Canada in particular since *Abitibi* in 1982, is that the "common understanding" is that patent law does extend to living organisms.

[106] See paragraph 123 above.

[107] *Supra*, note 61, at para. 24 [p. 527].

[108] *Application No. 003,389 of N.V. Organon, Re* (1973), 15 C.P.R. (2d) 253 (Pat. App. Bd.); *Application No. 016,962 (Patent No. 947,179), Re* (1973), 17 C.P.R. (2d) (Pat. App. Bd.); *Application No. 880,719 (Patent No. 944,693), Re* (1973), 18 C.P.R. (2d) 114 (Pat. App. Bd.); *Application for Patent Containing Claims that Read on Mental Steps Performed by a Human Operator in Deciding to Transmit a Signal, Re* (1972), 23 C.P.R. (2d) 93 (Comm. of Pat.).

[109] *Supra*, note 61, at para. 23 [pp. 526-527].

[110] In correspondence from the appellant to the Commissioner of Patents, dated July 14, 1992, at p. 4.

[111] *Supra*, note 61, at para. 31 [p. 530].

[112] See *Consolboard Inc. v. MacMillan Bloedel (Sask.)*, [1981] 1 S.C.R. 504, at p. 527, *per* Dickson J. [as he then was].

[113] "Exclusive Rights in Relation to Living Things" (1991), 6 *I.P.J.* 171, at p. 177.

[114] *Supra*, note 78, at p. 114.

[115] As per ss. 41 and 17 of the *Patent Act*.

[116] See by analogy to the Commissioner of Trade-marks *Molson Breweries v. John Labatt Ltd.* (2000), 5 C.P.R. (4th) 180 (F.C.A.), at paras. 45-51 [pp. 202-204].

[117] [1984] 2 S.C.R. 232, at p. 265.

[118] S.C. 1990, c. 20.

[119] *Supra*, note 110, at p. 2.

[120] In the "Notice of Official Action" from the Patent Examiner, dated January 14, 1992.

[121] *Supra*, note 84, at pp. 1114-1119.

Appendix "A"

Claims found to be non-patentable

1. A transgenic non-human mammal whose germ cells and somatic cells contain an activated oncogene sequence introduced into said mammal, or an ancestor of said mammal, at an embryonic stage.

2. The mammal of claim 1, a chromosome of said mammal including an endogenous coding sequence substantially the same as a coding sequence of said oncogene sequence.

3. The mammal of claim 2, said oncogene sequence being integrated into a chromosome of said mammal at a site different from the location of said endogenous coding sequence.

4. The mammal of claim 2 wherein transcription of said oncogene sequence is under the control of a promoter sequence different from the promoter sequence controlling the transcription of said endogenous coding sequence.

5. The mammal of claim 4 wherein said promoter sequence controlling transcription of said oncogene sequence is inducible.

6. The mammal of claim 1 wherein said oncogene sequence comprises a coding sequence of a

c-myc gene.

7. The mammal of claim 1 wherein transcription of said oncogene sequence is under the control of a viral promoter sequence.

8. The mammal of claim 7 wherein said viral promoter sequence comprises a sequence of an MMTV promoter.

9. The mammal of claim 7 wherein said viral promoter sequence comprises a sequence of an RSV promoter.

10. The mammal of claim 1 wherein transcription of said oncogene sequence is under the control of a synthetic promoter sequence.

11. The mammal of claim 1, said mammal being a rodent.

12. The mammal of claim 11, said mammal being a mouse.

Appendix "B"

Claims Found to be Patentable

13. A method of testing a material suspected of being a carcinogen comprising exposing the mammal of claim 1 to said material and detecting neoplasms as an indication of carcinogenicity.

14. A method of producing a transgenic cell culture comprising:

a) introducing an activated oncogene sequence into pluripotent cells of a mammalian embryo;

b) allowing said embryo to develop into an adult animal; and,

c) culturing somatic cells of said animal.

15. A method of producing a transgenic mammal having an increased probability of developing neoplasms, said method comprising introducing into a mammal embryo an activated oncogene sequence.

16. The method of claim 15 wherein an activated oncogene sequence comprises a fused gene comprising an oncogene sequence fused to an activating viral or synthetic promoter sequence.

17. The method of claim 15 wherein said activated oncogene sequence comprises a DNA sequence from one of the oncogene sequences src, yes, fps, abl, ros, fgr, erbB, fms, mos, raf, Ha-ras-1, Ki-ras 2, Ki-ras 1, myc, myb, fos, ski, rel, sis, N-myc, N-ras, Blym, mam, neu, erbA1, ra-ras, mht-myc, myc, myb-ets, raf-2, raf-1, Ha-ras-2, erB.

18. Use of the transgenic mammal of claim 1 in a method of testing a material suspected of altering neoplastic development, said method comprising treating said mammal with said material and detecting a reduced or increased incidence of development of neoplasms, compared to an untreated mammal of claim 1, as an indication of said alteration.

19. The use of claim 18, further comprising exposing said treated and untreated mammals to a carcinogen prior to, after, or simultaneously with treating said mammal with said material.

20. Plasmid having ATCC Accession No. 39745.

21. Plasmid having ATCC Accession No. 39746.

22. Plasmid having ATCC Accession No. 39747.

23. Plasmid having ATCC Accession No. 39748.

24. Plasmid having ATCC Accession No. 39749.

25. A somatic cell culture derived from a transgenic mammal wherein the cells of said cell culture contain an activated oncogene sequence integrated into a chromosome.

26. Use of a transgenic mammal according to any one of claims 1 to 12 to test a material suspected of altering neoplastic development in a mammal.