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Canadian Appeals Court Permits Harvard Mouse Patent: Is the Intellectual Property Provision in the North American Free Trade Agreement Superfluous

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Canadian Appeals Court Permits 'Harvard Mouse' Patent: Is the Intellectual Property Provision in the North American Free Trade Agreement Superfluous?

*Nicola M. Shiels**

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I. Introduction

A. PURPOSE OF THIS ARTICLE

On August 3, 2000, Canada permitted a patent on the infamous "Harvard mouse." The issue has been in the Canadian courts for about fifteen years, and even now the government has appealed the case to the Supreme Court of Canada. Canada has typically been reluctant to issue patents on "living organisms," but as this article will demonstrate, Canada is slowly following the steps of other major countries around the world. This article questions whether Canada's latest decision in the "Harvard mouse" case makes the provision about biological processes for the production of plants or animals in the NAFTA superfluous.

B. NAFTA PROVISIONS REGARDING INTELLECTUAL PROPERTY

Two international agreements dealing with the protection of plants and animals are the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),¹ part of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), and the North American Free Trade Agreement (NAFTA).² The TRIPS was the first international agreement to be passed. NAFTA came a little later and essentially adopted the same language as the TRIPS with regard to intellectual property rights on biological processes. These two agreements represent major accomplishments in efforts to harmonize patent laws throughout the world.

NAFTA provides that the United States, Canada, and Mexico may exclude from patentability: "(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than microorganisms; and (c) essentially biological processes for the production of plants or animals, other than non-biological and microbiological processes for such production."³ This language, which was modeled after article 27 of TRIPS, contains almost identical language regarding the exclusion of plants from patentable subject matter.⁴

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1. See General Agreement on Tariffs and Trade: Multilateral Trade Negotiations Final Act Embodying the Results of the Uruguay Round of Trade Negotiations, Apr. 15, 1994, 33 I.L.M. [hereinafter TRIPS].
 2. See North American Free Trade Agreement, Dec. 17, 1992, 32 I.L.M. 605, 673 (1993) (entered into force Jan. 1, 1994) [hereinafter NAFTA].
 3. *Id.*
 4. See TRIPS, *supra* note 1, at 1208.
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NAFTA does permit the member countries to patent products of nature.⁵ However, a member country *may* make exceptions "to protect human, animal or plant life or health or to avoid serious prejudice to nature or the environment."⁶ In addition, a member country can block the patenting of multi-cellular plants and animals, but it must allow the patenting of microorganisms and microbiological processes.⁷ Furthermore, Canada, Mexico, and the United States must extend reciprocal patent rights on "pharmaceutical or agricultural chemicals," including natural microbiological products and processes.⁸ Reciprocity demands uniform, least common denominator enforcement of intellectual property rights.⁹

Since the passage of NAFTA, there has been concern that the permitted exclusions in NAFTA might allow large areas of technology to be declared unpatentable.¹⁰ People have argued that because NAFTA may exclude patentability on the basis of public order or morality,¹¹ commercial interests are subject to the present or future whim of the general public.¹² It has been argued that because these exceptions allow Canada and Mexico to exclude transgenic plants and animals from patentable subject matter, it diminishes the incentive for investment and research.¹³

C. BACKGROUND ON BIOTECHNOLOGY

In order to better understand the controversial issues surrounding patenting of higher life forms it is best to begin with a discussion of the science of biotechnology. Biotechnology is made up of the activities of science as they are applied to living organisms.¹⁴ There are a number of subdisciplines that make up biotechnology. The most noteworthy of the subdisciplines, for purposes of this article, is genetic engineering.¹⁵ "Genetic engineering involves altering the genetic make-up of cells by deliberately inserting, removing or altering individual genes."¹⁶

5. See Henry Robertson, *Patenting Products of Nature*, SYNTHESIS/REGENERATION 17 (1998), available at <http://www.greens.org/s-r/17/17-22.html>.

6. *Id.*

7. *Id.*

8. *Id.*

9. *Id.*

10. See Eileen McMahon, *Symposium Issue, Intellectual Property and the FDA: Article: NAFTA and the Biotechnology Industry*, 33 CAL. W. L. REV. 31, 34 (1996).

11. NAFTA, *supra* note 2, at 673.

12. McMahon, *supra* note 10, at 34.

13. Scott J. Fields, *NAFTA Would Extend Protection of Rights; Historic Changes Expected if Pact is Ratified*, THE LEGAL INTELLIGENCER, Sept. 29, 1993, at 9.

14. See Paul Ratanaseangsuang, *Trend and Development: Patent Pending: Are Higher Life Forms Patentable?* 4 APPEAL 14 (1998) (citing CANADIAN DICTIONARY OF THE ENGLISH LANGUAGE 139 (1997)) [hereinafter Ratanaseangsuang].

15. *Id.*

16. *Id.* (citing S. Chong, *The Relevancy of Ethical Concerns in the Patenting of Life Forms*, 10 CANADIAN INTELLECTUAL PROPERTY REPORTER 190 (1993)).

Numerous techniques are utilized in order to genetically alter animals. The methods include microinjections, cell fusion, electroporation, and retroviral transformation.¹⁷ There are many advantages to using genetic engineering instead of traditional breeding.

Genetic engineering has a greater capacity to produce a specific outcome than traditional breeding.¹⁸ With genetic engineering, a specific gene can be isolated and transferred to another species. Almost any organism can donate or receive the gene, and the length of the process is reduced from generations to months.¹⁹

In recent years, the development of genetic engineering techniques has resulted in an extraordinary interest in using living organisms.²⁰ Some examples are: human tissue and by-products, uses for new drugs, foods, chemicals, and agricultural products.²¹ Due to the increased interest in genetic engineering, there has been a substantial amount of money involved in this area of science.

"Within the biotechnology industry, a battle is being waged to secure the massive profits these products will potentially generate."²² However, this interest is not limited to private commerce. "Increases in government funding of genetic research have attracted intense political attention also."²³

D. TRANSGENIC TECHNOLOGY

The form of genetic engineering that this article will focus on is transgenic technology. Transgenic technology is now widespread in academic laboratories and biotechnology firms.²⁴ This science involves creating plants and animals that are genetically engineered either to contain unfamiliar genes or to exclude existing ones.²⁵

Transgenically-created animals function as living test tubes. They allow scientists to reproduce human diseases, attempt better treatments, and produce larger amounts of beneficial proteins more cheaply than ever before.²⁶ Furthermore, transgenic animals make researching causes and possible treatments of disease easier.²⁷

17. Eileen Morin, *Of Mice and Men: The Ethics of Patenting Animals*, 5 HEALTH L.J. 147, 149 (1997) (citing Michael E. Sellers, *Patenting Non-Natural Occurring, Man-Made Life: A Practical Look at the Economic, Environmental and Ethical Challenges Facing "Animal Patents,"* 47 ARK. L. REV. 269, 271 (1994)) [hereinafter Morin].

18. *Id.* at 151.

19. *Id.* (citing David Manspeizer, *The Cheshire Cat, the March Hare, and the Harvard Mouse: Animal Patents Open Up a New, Genetically-Engineered Wonderland*, 43 RUTGERS L. REV. 417, 424 (1991)).

20. Stevan M. Pepa, *International Trade and Emerging Genetic Regulatory Regimes*, 29 LAW & POL'Y INT'L BUS. 415 (1998).

21. *Id.*

22. *Id.*

23. *Id.*

24. *Id.*

25. *See id.*

26. *Supra* note 20.

27. *See* Carrie F. Walter, *Beyond the Harvard Mouse: Current Patent Practice and the Necessity of Clear Guidelines in Biotechnology Patent Law*, 73 IND. L.J. 1025, 1030 (1998) [hereinafter Walter].

Scientists often use mice as living laboratories. This removes a significant amount of guesswork from the toxicological studies.²⁸ In addition, transgenic animals permit the study on both the first generation animal, as well as its subsequent generations, thereby making it possible for researchers to observe the effects of the genetic mutations in the animal's offspring.²⁹ In the end, the results of using transgenic animals are quicker, less expensive, and more realistic than other methods.³⁰

E. MOVEMENT TO PROCURE PATENT PROTECTION FOR LIVING ORGANISMS

The movement to procure patent protection for living organisms has not been easy. The progress has been met with considerable opposition.³¹ It seems as though individuals who oppose the patenting of higher life forms are those who are opposed to genetic engineering and genetic research in general.³²

In contrast to how opponents view patent protection for living organisms, supporters find that the object of the Patent Act is actually in accordance with their views. The purpose of the Patent Act is to encourage research and the sharing of information.³³ It strives to achieve these goals by providing an inventor financial incentive for the efforts of his or her ingenuity, scientific know-how, and subsequent disclosure of the technology.³⁴

The opportunities that the Patent Act gives to inventors are significant. The incentives can take the form of an exclusive right to make, use, or sell a particular invention.³⁵ License agreements usually provide the patent owner with some type of compensation in exchange for the licensee being free to profit from the use, manufacture, or sale of the product.³⁶ The licenses can be exclusive or nonexclusive, and in addition they can cover part or all of the patent period.³⁷

F. CONTROVERSY OVER PATENTABILITY OF ANIMALS

The most recent controversy surrounding issues addressed in this provision is the patentability of animals. The controversy over patenting animals has been stirring since the U.S. Supreme Court's 1980 decision that allowed the patenting of microorganisms.³⁸ In 1987, the Board of Patent Appeals and Interferences reversed a long-standing

28. See *id.* (citing Manspeizer, *supra* note 19, at 426).

29. *Id.* (citing Malcolm Gladwell, *Building a Better Mouse to Minimize Lab Guesswork*, WASH. POST, Oct. 30, 1989, at A3).

30. *Id.* at 1031 (citing *Advances in Genetic Research and Technologies: Challenges for Public Policy: Hearings Before the Senate Comm. on Labor and Human Resources*, 104th Cong., 47-48 (1996)).

31. See Ratanaseangsuang, *supra* note 14, at 20.

32. See *id.*

33. See *id.*

34. See *id.*

35. See *id.*

36. Morin, *supra* note 17, at 154.

37. *Id.*

38. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 U.S.P.Q. (BNA) 193 (U.S. 1980). The patent application related to Chakrabarty's invention of a bacterium from the genus *Pseudomonas*

Patent and Trademark Office (PTO) policy that multicellular animals did not constitute patentable subject matter.³⁹ From this point forward, the United States has had a liberal interpretation of patentable subject matter.

In 1988, the PTO granted the first U.S. animal patent. This patent covered a genetically engineered cancer-prone mouse.⁴⁰ Just four days after that decision, the Commissioner of the Patent and Trademark Office, Donald J. Quigg, announced the PTO's intention to issue patents on non-naturally occurring, non-human multi-cellular living organisms.⁴¹

1. *Animal Patents in the United States*

a. *The Three Patents Granted*

Despite the fact that patenting higher life forms seems controversial, no clear policy has ever been articulated regarding animal patents.⁴² The PTO accepted transgenic animals as patentable subject matter essentially without any controversy.⁴³ In recent years, the PTO has issued mouse patents to Ohio University, GenPharm International, and Harvard University.

The Ohio University patent (5,175,385) is for a mouse strain that continuously produces a low level of beta interferon. The significance is that beta interferon attacks viruses and helps prevent infection.⁴⁴ Therefore, the purpose behind this patent is that the mouse can be used to study the immune system's response to cancer.⁴⁵

Injecting a human gene that promotes interferon secretions into mouse embryos created the strain.⁴⁶ Ohio University holds the patent on this injection technique. This patent was received on December 29, 1992.⁴⁷

containing at least two stable energy-generating plasmids, each providing a separate hydrocarbon degradative pathway. *See id.* at 195. Chakrabarty's patent claims were of three types: first, the process for the method of producing the bacteria; second, claims for an inoculum comprised of a carrier material floating on water and the new bacteria, and third, claims to the bacteria themselves. *See id.* at 195-96. The Court held that a live, human-made microorganism is patentable subject matter. *Id.* at 201.

39. *PTO Issues Three Patents for Genetically Engineered Mice*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), Jan. 12, 1993.

40. *See id.*

41. *See House Panel Hears Testimony on Animal Patenting Issues*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), Sept. 28, 1989.

42. Walter, *supra* note 27, at 1025.

43. *See id.* at 1026 ("[T]he PTO accepted transgenic animals as patentable subject matter, essentially, by default").

44. *See Patent and Trademark Office: PTO Issues Three Patents for Genetically Engineered Mice*, 45 PTCJ 158 (1993) [hereinafter *PTO Issues Three Patents for Genetically Engineered Mice*].

45. *Id.*

46. *See id.*

47. *Ohio University Gets Patent for Mouse*, WASH. POST, Dec. 24, 1992, at A2.

The GenPharm mouse (5,175,384) has been engineered so that it cannot develop mature T-cells. The importance is that T-cells are vital to a functional immune system.⁴⁸ The strain will be used in research on immune system diseases and autoimmune disorders.⁴⁹

GenPharm has two goals that it wishes to achieve with this patent. According to Jonathan MacQuitty, GenPharm's chief executive, the mouse mimics human immune deficiency conditions, such as AIDS. In addition, the mouse can be used to study organ transplantation.⁵⁰

The Harvard patent was developed in the laboratory at Harvard Medical School. The new mouse is engineered to develop benign prostatic hypertrophy, or enlargement of the prostate gland.⁵¹ The mouse will provide a system for testing potential drug treatments for prostate enlargement, as well as suspected carcinogens.⁵²

There has been controversy regarding the patenting of these mice. Plaintiffs in the suit filed against Patent Commissioner Donald J. Quigg argued that the office was "trying to shoehorn a conscious, sentient, thinking creature into the category 'composition of matter,'" said one of the animal rights attorneys, Steven M. Wise of Boston's Fraser and Wise P.C.⁵³ He also said, "They have gone far beyond what Congress intended. They've gone beyond common sense, beyond logic and have trespassed into the category of very complex philosophical and religious issues."⁵⁴

b. Controversy Over the Three Patents

As stated previously, these patents resulted in substantial debate in the United States. The greatest cause of concern seems to have been that if the PTO permits patents on animals, they may eventually allow patents on human beings also. At the government level, there were House Panel hearings and proposed moratoriums on this issue.

House Report 1556 was introduced to create awareness of the PTO's determination that genetically-altered animals are patentable. In addition, it was to clarify that human beings are not patentable, explained Representative Robert Kastenmeir (D-Wis.) in his opening statement.⁵⁵ This concern about the issue can also be seen in the several proposed moratoriums on this issue.

House Report 1556 did not receive overwhelming support. The co-inventor of the "Harvard mouse," Dr. Philip Leder, stated that further technological advances are needed to predict or direct where a new gene will "land" among the collection of genes.⁵⁶ In addition, Leder stated that he could not support HR 1556 because it would restrict

48. See *PTO Issues Three Patents for Genetically Engineered Mice*, *supra* note 44.

49. *Id.*

50. See Richard Saltus, *Harvard Wins 3 Patents on Gene-Altered Rodents*, J. COM., Dec. 31, 1992, at 7A.

51. See *PTO Issues Three Patents for Genetically Engineered Mice*, *supra* note 44.

52. *Id.*

53. Marianne Lavelle, *Just Whose Life Is It, Anyway?* NAT'L L.J., Aug. 15, 1988, at 3.

54. *Id.*

55. See *House Panel Hears Testimony Addressing Animal Patenting Issues*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), Sept. 25, 1989.

56. *Id.*

patent protection for the invention of any transgenic farm animal and create major uncertainties for research and development.⁵⁷

Beginning in 1987, Senator Mark Hatfield (R-Ore.) introduced legislation to place a moratorium on animal and gene patenting. Hatfield urged that a permanent advisory panel be set up to make policy recommendations to Congress on the social, ecological, and ethical implications of human genetic research.⁵⁸ His proposed moratorium was only marginally effective.

Bernadine Healy, NIH Director, stated her opposition to patenting entire animals or human beings, but pointed out that a moratorium on gene patenting would turn current discoveries into "spent arrows" that could never be protected by patents after they are published.⁵⁹ Surprisingly, the PTO did agree to a voluntary eight-month moratorium on animal patenting.⁶⁰ Of course, following the moratorium, the PTO issued the "Harvard mouse" patent.⁶¹

The proposed moratorium bills did not end. On September 12, 1989, Representative Benjamin L. Cardin (D-Md.) introduced HR 3247 to impose a two-year moratorium on the issuance of animal patents.⁶² Representative Cardin felt that a moratorium was necessary to allow for the establishment of a proper regulatory review and approval process that would take into consideration environmental, health, safety, and biomedical ethical standards on the commercialization of an animal.⁶³

Cardin explained that HR 3247 would provide for a moratorium on the patenting of animal life until the proper regulatory review and approval process was in place,⁶⁴ but this proposal was not successful.

Cardin again introduced a bill, HR 4989, to impose a moratorium.⁶⁵ This bill proposed a five-year moratorium on the patenting of genetically engineered animals.⁶⁶ Identical to the bill offered earlier by Senator Hatfield, the bill would have stopped the "patenting and commercialization of genetically engineered animals pending establishment of a federal review process was to impose 'environmental, health and safety, economic and ethical standards.'" ⁶⁷ This proposal also died.

c. Current State of Patentability of Animals

The current situation with patenting animals is precarious. By granting patent protection to the Harvard mouse, the PTO lifted the last obstacle in the fight for animal

57. *Id.*

58. *See Intellectual Property: IP Laws Attempt to Adapt to Changes of New Technologies*, 45 PTCJ 249 (1993).

59. *Id.*

60. *See Legislation: House Panel Hears Testimony Addressing Animal Patenting Issues*, 38 PTCJ 555 (1989) [hereinafter *Panel Hears Testimony Addressing Animal Patenting Issues*].

61. *See id.*

62. *See id.*

63. *See id.*

64. *Id.*

65. *See PTO Issues Three Patents for Genetically Engineered Mice*, *supra* note 44.

66. *Id.*

67. *Id.*

patents.⁶⁸ However, sensitivity to political pressures has affected the number of patents and the willingness of the PTO to actually grant animal patents.⁶⁹ Furthermore, although the number of animal patents has increased, the problem remains that there are still few guidelines and many unanswered questions.⁷⁰

Scientists wish to patent human gene sequences and human embryos. Due to this overwhelming interest, it is important that there be a solid foundation in the law on animal patents.⁷¹ No court has yet to decide whether the PTO exceeded its authority by issuing its statement that they would grant animal patents.⁷²

The same criteria are required for an animal patent as for other kinds of patents. Biomedical advances that satisfy the requirements of novelty, utility, and nonobviousness may receive patent protection.⁷³ Some argue that it is impossible for living matter to be novel because animals and gene sequences exist naturally.⁷⁴

That argument does not recognize the way biotechnology works. Biotechnology changes naturally existing organisms so that they differ dramatically from other naturally occurring organisms.⁷⁵ In addition, the Supreme Court's decision in *Chakrabarty* makes apparent that non-naturally occurring organisms that have been man-made or man-altered satisfy the novelty requirement.⁷⁶

Proponents of the patentability of animals point out that when a transgenic animal is created, it is a product of human ingenuity. As such, it qualifies as patentable under the standard of novelty.⁷⁷ Furthermore, by issuing its ruling that an animal is patentable subject matter the PTO has strengthened its position stated in *Chakrabarty*.⁷⁸

2. Animal Patents in Europe

a. Rejection of Animal Patent

The issue of patenting animals did not go without controversy in Europe either. In July 1989, European examiners rejected Harvard's application. The basis for the rejection was that the mouse was an 'animal variety,' which cannot be patented under European law.⁷⁹

68. Walter, *supra* note 27, at 1036.

69. *Id.* at 1036-37 (citing *Disclosure Duty and Cost Concerns Dominate "PTO Day" Discussions*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), Jan. 10, 1992, available in WESTLAW, 1/10/92 PTD).

70. *Id.* at 1037.

71. *Id.*

72. *Id.* (citing Terri A. Jones, *Note, Patenting Transgenic Animals: When the Cat's Away, the Mice Will Play*, 17 VT. L. REV. 875, 888 (1993); *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920 (Fed. Cir. 1991)).

73. Walter, *supra* note 27, at 1037.

74. *See id.*

75. *See id.*

76. *Id.*

77. *See id.*

78. *Id.*

79. Edmund L. Andrews, *Europe Still Uncertain About Harvard's Mouse*, N.Y. TIMES, Oct. 13, 1990, at 34.

The President and Fellows of Harvard College had applied to the European Patent Office (EPO) for a patent, and the Examining Division 023 of the EPO refused to issue a patent on the ground that the application did not meet the requirements of Articles 53(b) and 83 of the European Patent Convention (EPC).⁸⁰ The Examining Division found Harvard's claims unrealistically broad and not reproducible.⁸¹ As a result of this adverse decision, Harvard appealed.

b. Approval of Animal Patent

The "Harvard mouse" was granted patent protection in Europe in 1992.⁸² The Examining Division of the European Patent Office in Munich granted the application of the President and Fellows of Harvard College for a transgenic mouse, which will be used in cancer research.⁸³ The Board of Appeal pointed out that the fact that a claim is broad is not in itself a ground for rejection.

The Board of Appeal was not aware of any such facts that cast serious doubt on the possibility that a skilled person could carry out Harvard's invention as claimed.⁸⁴ Furthermore, the Division determined that the genetic mouse is not an 'animal variety,' which is excluded from patentability by article 53(b) of the European Patent Convention (EPC). As such, the grant of the patent would not violate public order or morality under article 53(a).⁸⁵

The Division explained their rationale in the following way. Rodents or even mammals constitute a taxonomic classification unit much higher than species. An 'animal variety' or 'race animal' is 'a subunit of a species' and therefore of even lower ranking than a species.⁸⁶ Accordingly, article 53(b) is not considered to cover the subject matter of the claims to animals per se.⁸⁷

c. Morality

Morality was a factor that the Division took into consideration. Regarding the morality question, the Division said that in the case of genetic manipulation of animals involving, as in this case, the insertion of an activated oncogene, there are compelling reasons for granting the patent. One such reason is its use in fighting cancer, which may outweigh concerns over the suffering of animals or the possible risks to the environment.⁸⁸

The Division also noted that it had to balance three different interests. The first interest was the "basic interest of mankind to remedy widespread and dangerous diseases."⁸⁹

80. *See Genetically Engineered Mouse May Be Patentable in Europe*, 40 PAT. TRADEMARK & COPYRIGHT J. (BNA) 535 (Oct. 25, 1990).

81. *Id.*

82. *See Examining Division Allows Patent for Genetically-altered Mouse*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), Jan. 8, 1992.

83. *See id.*

84. *Genetically Engineered Mouse May Be Patentable in Europe*, *supra* note 80.

85. *Examining Division Allows Patent for Genetically-altered Mouse*, *supra* note 82.

86. *Id.*

87. *Id.*

88. *Id.*

89. *Id.*

The second interest was the protection of the environment against "the uncontrolled dissemination of unwanted genes."⁹⁰ And the third interest was the issue of cruelty to test animals.⁹¹

d. Public Policy Considerations

The Division decided that any contribution to the development of new and improved human anti-cancer treatments "is therefore a benefit to mankind and must be regarded as valuable and highly welcome by everybody."⁹² "[T]he Division explained that current legislation in EPC Contracting States 'allows animal testing under certain restrictions and subject to administrative approval' and that this invention would require fewer test animals than conventional testing."⁹³ "[T]he examining division was careful to emphasize that for each individual invention the question of morality has to be examined and possible detrimental effects and risks have to be weighed and balanced against the merits and advantages aimed at."⁹⁴

3. Canada's Decision to Permit an Animal Patent

Canada has been criticized for its somewhat backward attitude toward the patenting of higher life forms. Many considered the patenting of higher life forms a necessary ingredient for future progress.⁹⁵ However, Canada currently only allows the patenting of microorganisms.

Even though microorganisms may be patented, plants, seeds, and animals may not be patented,⁹⁶ and methods of medical treatment may not be patented.⁹⁷ This is an administrative and judicial decision.⁹⁸ It is important to note that this is not, or at least to this point has not been, a political decision.

In 1985, Harvard applied for a Canadian patent for the process used to develop the oncogene mouse.⁹⁹ In 1993, the Canadian patents commissioner allowed the process, but not the animals to be patented.¹⁰⁰ The Canadian practice had been to allow simple organisms, such as bacteria, to be patented, not animals.¹⁰¹

The definitions of "invention" in the United States' legislation and in Canada's Patent Act are similar. Despite the similarities, the Board refused to give weight to U.S. practice

90. *Id.*

91. *See supra* note 82.

92. *Id.*

93. *Id.*

94. Thomas W. Bailey, *Attempts to Patent Transgenic Animals Stir Public Controversy*, LAW. WKLY., July 7, 1995.

95. Peter Winter, *Landmark Biotech Patent Ruling Allows Higher Life Form Claims*, BIOWORLD TODAY, Aug. 23, 2000.

96. *See McMahon, supra* note 10, at 33.

97. *See id.* at 33-34.

98. *Id.* at 34.

99. *See Campbell Clark, Court Approves 'Frankenmouse': Ruling Orders Canada's First Patent on Animal Developed by Harvard*, GLOBE AND MAIL, Aug. 4, 2000.

100. *Id.*

101. *Id.*

in interpreting Canada's Patent Act.¹⁰² The Commissioner refused to extend the meaning of 'manufacture' or 'composition of matter' to include a nonhuman mammal.

In addition, the Commissioner was strongly influenced by the Federal Court of Appeal decision finding that a nonhuman mammal, like a mouse, does not fall within the definition of invention in section 2 of the Patent Act.¹⁰³ The Commissioner was also persuaded by the fact that the inventors could not fully control the reproducibility of the organism. In this case, the characteristics of the resulting mouse could not be controlled, since the intervention of man only ensured that reproducibility extended as far as the cancer-forming gene.¹⁰⁴

In 1995, the trial division of the Federal Court rejected Harvard's first appeal. The court ruled that Harvard did not 'manufacture' the mice because the forces of nature played a key role in developing most of the characteristics in the animal.¹⁰⁵ However, on August 3, 2000, in a 2-1 split decision, the Federal Court of Appeal overruled that decision, saying there is nothing in the Patent Act that outlaws the patenting of animals.¹⁰⁶

Writing for the majority, Justice Marshall Rothstein concluded that the issue is whether organisms are man-made, not whether they are living.¹⁰⁷ He wrote that even though one could argue that natural processes determine much of the mouse's characteristics, that interpretation would ignore the new man-made traits.¹⁰⁸

'The point is that control over the length of a tail, color of eyes or texture of fur is irrelevant to the usefulness of the invention,' he wrote.¹⁰⁹ '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 [cancer gene].'¹¹⁰

In essence, the court reasoned the following: the mouse does not exist in nature, since it was only created by hard work by the U.S. researchers,¹¹¹ and if the researchers are not granted a patent they won't be able to recoup any money spent on the mouse.¹¹²

The court held that the mouse is sufficiently invention-like to be included under the general spirit of the Patent Act.¹¹³ Under the rationale of the Patent Act, as well as Judge Rothstein's reasoning, the oncomouse is certainly the kind of useful, important, progressive step that people want to encourage to come into being.¹¹⁴ In an editorial

102. McMahon, *supra* note 10, at 34.

103. See generally Brian W. Gray, *Canada: Appeal Filed Against Rejection of 'Harvard Mouse' Application*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), Mar. 26, 1996; Pioneer Hi-Bred Ltd. v. Canada, 25 C.P.R.3d 257 (1989).

104. See *id.*

105. Clark, *supra* note 99.

106. *Id.*

107. *Id.*

108. See *id.*

109. *Id.*

110. *Id.*

111. *A Man-Made Mouse*, GLOBE AND MAIL, Aug. 8, 2000, at A14.

112. *Id.*

113. *Id.*

114. *Id.*

of *The Globe and Mail*, the editor said, "If an antibiotechnological interpretation of the Patent Act discourages that, we are betraying the roots of modern life."¹¹⁵

Judge Rothstein said there might be reasons why so-called 'higher life forms' should not be patented, but they have not been written into the law.¹¹⁶ Such arguments, he said, are for Parliament, and not the courts.¹¹⁷ This reasoning is like that used in the United States. However, the attempts made in the United States to suspend animal patenting have not been very effective.

The federal government is opposed to doing away with its 131-year-old Patent Act.¹¹⁸ The Federal Court of Appeal declared that there is nothing in the Patent Act of 1869 to prevent ownership rights of all animals except humans. The only requirement is that they satisfy the definition of "invention" set out in the legislation.¹¹⁹

The judges based their decision on a strict interpretation of the Patent Act. Despite the rather fierce moral debate surrounding the issue of patenting animals, they felt that it was not their place to make a moral judgment. This court repeatedly insisted that the morality issue is a matter for Parliament, rather than the courts.¹²⁰

The court went on to note that section 40 of the Patent Act stipulates that the Patent Commissioner's decision on patentability is nondiscretionary. This means, an application for a patent is to be refused "where the Commissioner determines that the applicant is not, by law, entitled to be granted a patent."¹²¹ Furthermore, the majority noted that the issue of patentability was to be determined without regard to the conflicting policy arguments made in the case.¹²² "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," Justice Rothstein said.¹²³

There was another interesting facet about this case—the court relied heavily on U.S. law to a greater extent than in any other important patent case.¹²⁴ Justice Rothstein took note that the definition of "invention" in the U.S. patent statute and Canada's Patent Act are similar. As a result, he cited extensively from the leading U.S. case on the patentability of life forms, *Chakrabarty*.¹²⁵ Obviously, he strongly disagreed with the Commissioner's view that U.S. case law had little weight in Canada.¹²⁶

The ruling has ignited a fire, calling for Ottawa to amend its legislation. People want to prevent the patenting of higher life forms and protect animal welfare, among other

115. *Id.*

116. Clark, *supra* note 99.

117. *Id.*

118. Janice Tibbetts, *Ruling Sparks Calls for Overhaul to Federal Patent Act: Harvard Mouse Case*, NAT'L POST, Aug. 8, 2000, at A6.

119. *Id.*

120. *Id.*

121. Cristin Schmitz, *Non-Human Animals are Patentable as 'Inventions': Federal Court of Appeal*, LAW. WKLY., Aug. 25, 2000.

122. *Id.*

123. *Id.*

124. Ed Hore, *Focus on Intellectual Property and Continuing Legal Education: Mouse Case May Signal Shift to U.S. Law*, LAW. WKLY., Sept. 8, 2000.

125. *Id.*

126. *Id.*

things.¹²⁷ Of course, it was not until this recent decision that people in Canada even debated the issue of patenting higher life forms.

The measure that opponents in Canada are calling for are much more grave than the proposed moratoriums in the United States in the 1980s. Opponents to the patenting of animals immediately called for the government not only to appeal, but also to consider new legislation to outlaw such patenting.¹²⁸ "If Canada is going to make it possible to patent all life forms, if we're going to make that decision, let's make it after a broad public debate and with the proper safeguards in place," said Michelle Swenarchuk of the Canadian Environmental Law Association (CELA), which intervened in the court case.¹²⁹

Swenarchuk is not the only person who spoke out. Paul Muldoon of CELA stated, "There has to be a debate and there has to be legislation. What are the limits and what are the lines?"¹³⁰ Unfortunately, for Swenarchuk and Muldoon, any decision to amend the law would ultimately rest with John Manley, the Industry Minister. A spokesman in his office said changes are not being considered.¹³¹

In contrast to Europe and the United States, the "Harvard mouse" has generated relatively little public debate in Canada.¹³² The Canadian government has begun to study the issue. The Intellectual Property Policy Directorate of Industry Canada commissioned studies on the economic, ethical, and legal issues raised by patenting higher life. In addition, the Standing Committee on Environment and Sustainable Development issued a report in November 1996 on biotechnology regulation in Canada.¹³³ During the pending mouse ruling, the Canadian Intellectual Property Office has about 250 applications dealing with animal patents.¹³⁴

The government made the decision to appeal to the Supreme Court of Canada on the last day it could, which was sixty days following the appellate court ruling.¹³⁵ In its application, the government said it considers it necessary to refer the matter to the Supreme Court of Canada in order to obtain a definitive judgment on the scope of the current patent law.¹³⁶ Furthermore, the government said it intends to make a motion to stay the effect of the Court of Appeal's order, pending the application to the Supreme Court.¹³⁷

127. Tibbetts, *supra* note 118.

128. Clark, *supra* note 99.

129. *Id.*

130. Tibbetts, *supra* note 118.

131. *Id.*

132. See Morin, *supra* note 17, at 148 (referring to Telephone Interview with Brian Botting, Political Analyst, Intellectual Property Policy Directorate of Industry Canada (Dec. 16, 1996)).

133. *Id.*

134. See Tibbetts, *supra* note 118.

135. *Federal Government is Appealing Potential Patent of Cancer Mouse*, CANADIAN PRESS, Oct. 2, 2000.

136. *Canada Government Appeals Harvard Mouse Case to Supreme Court*, DOW JONES NEWS SERVICE, Oct. 4, 2000.

137. *Id.*

4. International Law

On an international level, there has been a movement to harmonize and strengthen intellectual property rights worldwide. The movement has addressed the concerns of international exporters who fear piracy of their inventions, especially in less developed countries where technology receives little, if any, patent protection.¹³⁸ It is due to this concern that the TRIPs was enacted by the signatory countries of GATT.¹³⁹ Whereas technologically sophisticated countries are concerned about theft of technological know-how, less developed countries object to the use of their genetic resources without compensation.¹⁴⁰

G. THE "HARVARD MOUSE"

Since it is specifically the "Harvard mouse" that has generated so much controversy, what exactly it is should be explained. The Harvard mouse is a genetically engineered mouse designed for cancer research. It was created through a genetic-engineering technique known as microinjection.¹⁴¹

First, purified copies of genes are injected directly into a fertilized animal egg.¹⁴² The egg is then surgically implanted into the mother so that she may bring it to term.¹⁴³ Very few of the injections result in the live birth of a transgenic animal.

Successful injections result in offspring that display traits attributable to the genes inserted in the mouse.¹⁴⁴ To create the "Harvard mouse," a laboratory mouse was injected with a gene known to cause cancer. As a result, transgenic mice were extremely prone to breast cancer.¹⁴⁵

Some of the resulting mice are found to have the preferred modified genes. Then some of these mice pass them on to their offspring.¹⁴⁶ These mice are referred to as "founder mice."¹⁴⁷ The demand for the offspring of the founder mice in cancer research is great, and so the economic incentive to obtain patent protection is equally great.¹⁴⁸

The "Harvard mouse" serves as a valuable research tool. Since these mice are so sensitive to carcinogens, they act as detectors. Scientists can monitor both the sources of the disease and the causes.¹⁴⁹

138. Morin, *supra* note 17, at 166.

139. *Id.* (citing J. Stackhouse, *Rich North, Poor South Divided Over Labour Practices*, *GLOBE AND MAIL*, Dec. 9, 1992, at A12).

140. *Id.* at 167.

141. See Walter, *supra* note 27, at 1029.

142. *Id.*

143. *Id.*

144. *Id.*; see also Sellers, *supra* note 17.

145. *Id.* (citing Michael B. Landau, *Multicellular Vertebrate Mammals as "Patentable Subject Matter" Under 35 U.S.C. 101: Promotion of Science and the Useful Arts or an Open Invitation for Abuse?* 97 *DICK. L. REV.* 203, 214 (1993)).

146. See Gord Jepson, *Is an Animal Patentable? Federal Court Must Decide Legal and Ethical Issues in the 'Harvard Mouse' Case*, *LAW. WKLY.*, June 28, 1996.

147. *Id.*

148. *Id.*

149. See Walter, *supra* note 27, at 1029.

Scientists insert human genes into the mice. The human gene then mutates when it is exposed to carcinogens.¹⁵⁰ "When testing a carcinogenic substance, the gene mutates indicating the carcinogenic nature of the substance."¹⁵¹

There is another useful purpose for conducting this technique on the mice. "With the mice more prone to cancers, a known time frame for developing cancer is present."¹⁵² If the mouse develops cancer significantly sooner than the known time frame with the introduction of the carcinogen, the carcinogen may be implicated in the cause of human breast cancer.¹⁵³

Licensing rights for the patent are held by DuPont Co., which financed the Harvard research.¹⁵⁴ These licensing rights could have wide commercial possibilities in cancer laboratories. And with the recent decision in Canada, it could open up a large new market for genetically-altered animals used in drug research and development.¹⁵⁵

DuPont has claimed patent protection on any anticancer product ever derived from the mice.¹⁵⁶ The corporate excitement around the oncomouse reached its pinnacle in 1988, when a major financial magazine labeled the mouse the product of the year.¹⁵⁷ As part of the license agreement, DuPont pays the massive legal bills that have been generated by years of litigation.¹⁵⁸

Though Harvard will not reveal the license fee paid by DuPont, it is small in corporate terms. The University takes in a total of \$15 million per year from all technology licensing, a small fraction of its budget.¹⁵⁹ The mice typically sell for about \$50 to \$60 each.¹⁶⁰ Industry officials said that the impact of the ruling would not be large, since Canada is a small market. Even in the United States the demand for the oncomouse is limited.¹⁶¹

On April 12, 1988, the PTO granted co-inventors, Philip Leder (of Harvard University) and Timothy A. Stewart (of Genentech) a patent for a genetically-altered mouse,¹⁶² which covers a process of injecting genes into mice embryos to make the mice susceptible to cancer, as well as the affected mice and their offspring.¹⁶³ The mice develop tumors quickly if exposed to cancer-causing chemicals, thereby serving as a valuable

150. *Id.*

151. *Id.*

152. *Id.*

153. *Id.* (citing Gladwell, *supra* note 29).

154. See Malcolm Gladwell, *Harvard Scientists Win Patent for Genetically-altered Mouse; Award is First to be Issued for an Animal*, WASH. POST, Apr. 12, 1988, at A1.

155. See Malcolm Gladwell, *Mouse Patent May Bolster Research Efforts; New Genetic Techniques Could Reduce Drug Costs*, WASH. POST, Apr. 13, 1988, at F1.

156. See RAFI, *Canadian Court Rules Mammals Can Be a Patented Invention*, FIN. EXPRESS, Aug. 14, 2000.

157. *Id.*

158. See Joshua E. Gewolb, *Harvard U.: Harvard Wins Genetic Patent in Canada*, U-WIRE, Aug. 14, 2000.

159. *Id.*

160. *Id.*

161. *Id.*

162. See Morin, *supra* note 17, at 157 (citing to U.S. Patent No. 4,736,866; Filed 22 June, 1984; Date of Patent: 12 April, 1988).

163. See Winter, *supra* note 95.

'cancer detective' in testing the effects of those chemicals on humans.¹⁶⁴ "The patent owners possess a legal right to prevent other inventors from making, using, or selling any genetically-altered mammal with human breast cancer DNA."¹⁶⁵

In addition, the patent covers all non-human mammals created by the process.¹⁶⁶ The patent application seeks protection for "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."¹⁶⁷ The Harvard applicants argued that, without such broad protection, someone could breach their patent by using their invention on some mammal other than a mouse.¹⁶⁸

II. U.S. Case Law on Patentability of Living Organisms

Patenting living organisms goes as far back as 1873, when Louis Pasteur obtained a U.S. patent for yeast.¹⁶⁹ The landmark decision on the issue that higher animal life forms are patentable is the 1980 U.S. Supreme Court case *Diamond v. Chakrabarty*.¹⁷⁰ In this case, the PTO had rejected two claims for patents on unicellular microorganisms, and the case involved a genetically engineered bacterium designed to break down crude oil.¹⁷¹

About the same time, *In re Bergy, Coats and Malik* was being considered on the issue of whether an invention, otherwise patentable, is excluded from the categories of patentable subject matter because it is alive.¹⁷² The Patent Appeals Court held:

the purposes underlying the patent system require us to include microorganisms and cultures within the terms 'manufacture' and 'composition of matter' in section 101 and concluded that the fact that microorganisms are alive is a distinction without legal significance and that they should be treated under 101 no differently from chemical compounds.¹⁷³

A few years later, the decision in *Ex parte Allen* extended patents to higher life forms.¹⁷⁴ The patent application was for genetically modified oysters. These oysters grew bigger than natural oysters and could be harvested year-round, unlike natural oysters, which were inedible during the reproductive system.¹⁷⁵

The "Harvard mouse" patent applies not only to the original transgenic mouse, but also to any of its progeny and any mammal bearing the inserted oncogene sequence. The

164. *Genetically Engineered Mouse May Be Patentable in Europe*, *supra* note 80.

165. Ratanaseangsuang, *supra* note 14, at 14.

166. Jeffrey Miller, *Off the Record: Who'll Play Pied Piper to Harvard Mouse?* LAW. WKLY., Aug. 25, 2000.

167. *Id.*

168. *Id.*

169. See Morin, *supra* note 17, at 154 (referring to U.S. Patent 141, 072).

170. See *Chakrabarty*, 447 U.S. 303.

171. See *id.*

172. *In re Bergy, Coats and Malik*, 201 U.S.P.Q. 352, 357 (C.C.P.A. 1979).

173. *Id.* at 373.

174. See *Ex parte Allen*, 2 U.S.P.Q.2d 1425, 1426 (Bd. Pat. App. & Inter. 1987).

175. See Morin, *supra* note 17, at 156.

claims include the animals containing the oncogene because the oncogene is expressed in the phenotype of the animal.¹⁷⁶ "Therefore, the unauthorized creation or use of other similarly-altered animals, such as rats or cats, would constitute infringement of the patent."¹⁷⁷

III. Canadian Patent Protection Generally

A big issue that needs to be addressed in Canada is the scope of its Patent Act. The Canadian courts and the general public need to be aware that the Patent Act does not regulate, nor does it attempt to regulate, the subject matter it considers patentable.¹⁷⁸ The object of the Patent Act is to encourage research and the sharing of information.¹⁷⁹ The Patent Act attempts to do so by providing the opportunity for an inventor to gain financial reward from the efforts of his or her ingenuity, scientific know-how, and subsequent disclosure of the technology.¹⁸⁰ This opportunity takes the form of exclusive right to make, use, or sell a particular invention.¹⁸¹ Essentially, the inventor is granted a limited form of property right over a particular manufacture or composition of matter.¹⁸²

A. STATUTORY PROTECTION

The Commissioner of Patents, pursuant to the Patent Act, ultimately governs the granting of patents.¹⁸³ The Act provides that a patent will only be granted for an "invention." Section 2 defines invention as: "any new and useful improvement in any art, process, machine, manufacture or composition of matter."¹⁸⁴

Section 2 indicates that there are two requirements for receiving a patent. First, the item for which the patent is needed must be an "invention."¹⁸⁵ Second, the invention must be both "new" and "useful."¹⁸⁶

The debate over whether the Patent Act permits patents of higher life forms is limited in scope. It is the interpretation of the general term "invention" that has given rise to the debate over whether a life form is patentable. In particular, there is considerable debate as to what constitutes a "manufacture" or a "composition of matter."

176. *See id.* at 157.

177. *Id.*

178. Ratanaseangsuang, *supra* note 14, at 20.

179. *Id.*

180. *Id.*

181. *Id.*

182. *Id.*

183. *See id.* at 15 (citing Chong, *supra* note 16).

184. Ratanaseangsuang, *supra* note 14, at 16.

185. *Id.*

186. *Id.*

B. CASE LAW ON PATENTABILITY OF ANIMALS

In Canada, the patentability of non-naturally occurring higher life forms, such as genetically-altered plants and animals, is uncertain.¹⁸⁷ The central legal issue is whether such life forms come within the definition of "invention" as set forth in section 2 of the Canadian Patent Act.¹⁸⁸ Unfortunately, Canadian case law is not informative as to this crucial legal issue.

Canadian patent practitioners had hoped that this issue would be resolved by the Supreme Court of Canada in *Pioneer Hi-Bred Ltd. v. Commissioner of Patents*, which dealt with the patentability of a new variety of soybean.¹⁸⁹ However, the Supreme Court sidestepped the opportunity to squarely address this issue, and instead held the patent application invalid based on insufficient disclosure of the invention.¹⁹⁰

"Prior to *Pioneer*, the Patent Appeal Board had granted patents for fungi and certain living micro-organisms."¹⁹¹ In fact, some believed that this trend would be to extend to higher life forms.¹⁹² Despite the promising language in *Re Application of Abitibi*, the likelihood of higher life forms being patented was diminished by the decision in *Pioneer*.¹⁹³

As noticed with the "Harvard mouse," Canada has taken smaller steps towards the same end as the United States. In 1982, the Patent Appeal Board held that living matter could constitute a patentable subject matter.¹⁹⁴ It could very well end that Canada allows patents on animals. The Patent Appeal Board noted that patent offices in the United States, Australia, the United Kingdom, Germany, and Japan have adapted their interpretation of patentable subject matter in light of current technologies and industries to grant patents for microorganisms.¹⁹⁵

"In *Re Application for Patent of Pioneer Hi-Bred Ltd.*, the patentability of higher life forms was raised, but the Supreme Court declined to decide the issue."¹⁹⁶ "Both the Patent Appeal Board and the Federal Court of Appeal narrowly construed the definition

187. Bailey, *supra* note 94.

188. *Id.*

189. *Id.*; see *supra* note 103.

190. Bailey, *supra* note 94.

191. Ratanaseangsuang, *supra* note 14, at 16.

192. See *id.* Ratanaseangsuang uses the example of *Re Application of Abitibi*, where the Patent Appeal Board suggested that it saw no reason why the patentability of living organisms should not be extended to higher life forms, such as plants and animals, provided they meet the requirements of the Patent Act. *Id.*

193. See *id.* In *Pioneer*, the applicant wanted to patent a new variety of soybean plant that was produced by traditional cross-breeding techniques, but still required direct human intervention, which was the breeding process. See *id.* Despite this element of scientific intervention, the Federal Court of Appeal rejected the soybean patent application on the ground that a plant variety produced by cross-breeding did not fall within the definition of "invention" as set out in section 2 of the Patent Act. *Id.*

194. Morin, *supra* note 17, at 163; see also *Re Application of Abitibi Co.*, 62 C.P.R.2d 81 (Pat. App. Bd. 1982).

195. Morin, *supra* note 17, at 163.

196. *Id.* (referring to *Re Application for Patent of Pioneer Hi-Bred Ltd.*, 11 C.F.R.3d 311 (Pat. App. Bd. 1986)).

of invention, holding that a plant produced by cross-breeding could not fall within the categories 'manufacture' and 'composition of matter.'¹⁹⁷ The Supreme Court of Canada unanimously disposed of the appeal solely on the grounds of inadequate disclosure.¹⁹⁸

The Canadian Manual of Patent Office Practice provides that: plants and animals are not patentable subject matter [but that] plant varieties that are distinct, uniform and stable may be protected under the *Plant Breeders' Rights Act*. [Whereas] lower life forms which are new, useful and inventive are patentable...higher life forms are not patentable subject matter. However, a process for producing a higher life form may be patentable provided the process requires a significant technical intervention by man and is not essentially a natural biological process which occurs according to the laws of nature (e.g. traditional plant cross-breeding).¹⁹⁹

The decision in *Pioneer* represented both the first and last time that the issue of higher life form patentability came before the Canadian federal court.²⁰⁰ Although the Commissioner of Patents has referred to the case as a means by which to interpret Section 2 of the Patent Act, it is in fact, of limited guidance due to the Court's reluctance to directly address the patentability issue.²⁰¹

It was not surprising that the CIPO refused the patent application for the "Harvard mouse" in Canada.²⁰² The application was filed on June 21, 1985, and was rejected by the Patent Office and then by the Patent Appeals Board on August 4, 1995.²⁰³ The Federal Court of Canada (Trial Division) heard the appeal brought by the President and Fellows of Harvard College on November 17, 1997.²⁰⁴ A. David Morrow, the Ottawa attorney who argued the case for Harvard, predicts that the case will be heard in the Court's 2001 session.²⁰⁵

IV. Canada's Approach Becoming More Like the United States

The Canadian approach to the patentability of higher life forms stands in direct contrast to that of the United States, which has been calling for the patenting of "everything under the sun made by man." Despite the Canadian courts' often reluctance to use U.S. precedent when interpreting Canadian statutes, in this specific instance there is a close factual tie between the two jurisdictions that renders the U.S. jurisprudence particularly relevant.²⁰⁶ The Canadian courts may not want to acknowledge the marked similarity between the Canadian and U.S. statutes, but the fact remains that the two jurisdictions are quite comparable.

197. See Morin, *supra* note 17, at 164.

198. *Id.* (referring to *Pioneer Hi-Bred Ltd. v. Commissioner of Patents*, 25 C.P.R.3d 257, 265 (S.C.C. 1989)).

199. *Id.* at 165 (citing Section 16.04(a) of the Canadian Patent Office, *Manual of Patent Office Practice* (Ottawa-Hull: Industry Canada, Canadian Intellectual Property Office, 1996)).

200. Ratanaseangsuang, *supra* note 14, at 17.

201. *Id.*

202. See Morin, *supra* note 17, at 165.

203. *Id.*

204. See *id.* at 166.

205. Gewolb, *supra* note 158.

206. Ratanaseangsuang, *supra* note 14, at 19.

Section 2 of the Canadian Patent Act is parallel to 35 U.S.C. 101. That provision aims to protect "anyone who invents or discovers, a process, machine, manufacture, composition of matter, or improvement thereof."²⁰⁷ In addition, it is a well-known fact that "the statutory provisions of Canadian law have borrowed extensively from the U.S. system."²⁰⁸

Many Canadian patents are issued for foreign technology that is developed in the United States.²⁰⁹ The fact that biotechnology is moving towards a trend of international globalization constitutes a reason why the Canadian court may have looked beyond the Canadian jurisprudence and patenting tradition when it decided the issue of patenting higher life forms.²¹⁰ Despite these legitimate reasons, this recent decision has not gone without controversy.²¹¹

David Conn, patent agent with an Ottawa law firm, told *BioWorld Today* that the decision is surprising in view of the Patent Office's longtime refusal of claims to higher life forms and the federal court's reluctance to tackle politically-charged issues such as this one.²¹² He also noted that it should provide an additional incentive for biotechnological research and development to be carried out in Canada.²¹³ Also, according to Joyce Groote, President of BIOTECCanada, this decision means that innovators of new, multi-cell plant and animal products obtained using biotechnology now have patent protection for their innovations.²¹⁴

Many feel that Canada's biotechnology is in danger of losing ground. Some people feel that Canada is losing ground because of Ottawa's reluctance to confront the controversial issue of animal patenting.²¹⁵ Dr. Jack Wearing, chairman of the Industrial Biotechnology Association of Canada, said that the decision to deny a patent in Canada to Harvard University for a genetically engineered mouse was "a setback for the advance of the biotechnology sector."²¹⁶

In addition, Wearing also noted that this is the sort of issue that countries that want to lead in biotechnology need to address.²¹⁷ The United States, Europe, Japan, Australia, and France have all made positive decisions in the area of animal patents.²¹⁸

207. *Id.* at 19-20.

208. *Id.* (citing I. GOLDSMITH, *PATENTS OF INVENTION* (Toronto: Carswell, 1981)).

209. *Id.*

210. *Id.*

211. See Stephanie Boyd, *Campus Mice Scampering North Work for DuPont*, *TORONTO STAR*, Aug. 18, 2000 ("Rather than helping find a cure for cancer, the new Canadian patent will increase research costs since buyers and breeders of the mouse will have to pay royalties to DuPont.").

212. Winter, *supra* note 95.

213. *Id.*

214. *Id.*

215. Alan Toulin, *The Mouse that Roared: Ottawa Under Fire From Research Community for Refusing to Permit Patents on Genetically Engineered Animals, Led by a Mouse from Harvard*, *FIN. POST*, Mar. 14, 1996, at 3.

216. *Id.*

217. *Id.*

218. *Id.*

"Unfortunately, the Canadian approach has been to commission endless studies to, in effect, postpone addressing the issue," stated Wearing.²¹⁹

Opponents to the patentability of higher life forms suggest that it won't end with mice. Pat Mooney, executive director of the Ottawa-based Rural Advancement Foundation International, said, "It's not just a mouse, of course. It's a mammal. And if the patent is granted on this mouse just for experimental purposes, then it could be granted on cows, chickens, pigs or us."²²⁰ "It would be hard for the Canadian government to stop any of that once this patent was granted."²²¹

The court rulings on this matter have twice agreed that the issue of life patenting is more appropriately decided by Parliament. Curiously, the government continues to avoid the democratic process. Many see this inaction as hiding beneath the judge's robes.²²² Through other official documents, such as the Canadian Biotechnology Strategy, the present government has made it clear that they support the biotechnology industry's desire for patenting anything that moves.²²³

V. Canada's Reaction to the Federal Appeals Court Decision

The federal appeals court announcement marks the first time that patent law will protect a genetic change in a higher life form.²²⁴ Not everyone is happy about this latest decision. "We're outraged," said Jeremy Rifkin, president of the Foundation on Economic Trends, an anti-biotechnology group based in Washington.²²⁵

On the other hand, some see this latest decision as no great surprise. Geoffrey Karny, a Washington patent attorney, felt that this was "not a radical departure from existing policy. Granting a patent on animals is an entirely logical application of existing patent law principles, and in many respects is nothing different from what society has been doing with regard to the commercial ownership of animals for thousands of years."²²⁶

Industry experts said that with the guarantee of patent protection for the fruits of research and development, the number of companies doing research could increase. In addition, the amount of money spent on its research and development could skyrocket in the next few years.²²⁷ The result could be dramatically lower costs for producing drugs.²²⁸

"Patent protection is the lifeblood of the pharmaceutical and biotechnology industries," said Steven Holtzman, chief operating officer of the Ohio-based Embryogen Corp., one of a handful of companies nationwide that have been developing genetically-altered

219. *Id.*

220. Marty Logan, *Canada Refuses Patent for Research Rodent*, CANADIAN PRESS NEWSWIRE, Mar. 4, 1996.

221. *Id.*

222. RAFI, *supra* note 156.

223. *Id.*

224. Gladwell, *supra* note 154.

225. *Id.*

226. *Id.*

227. Gladwell, *supra* note 155.

228. *Id.*

animals for laboratory and commercial use.²²⁹ Don Hudson, president of the Worcester, Massachusetts-based Transgenic Sciences Inc., said, "[t]his patent decision gives everyone much more incentive to enter this field."²³⁰ Companies involved in "transgenic" animals say patent protection is crucial, because otherwise they have no way to prevent customers from simply buying one animal and breeding as many others as they like.²³¹

Some have noted that the court ruling could help Ottawa's biotech sector attract venture capital.²³² The ruling makes it more commercially practical for Canadian biotech firms, including those in Ottawa's own growing industry, to develop groundbreaking advancements.²³³ Many biotech firms just need capital from companies in order to put their ideas into use.

"It will make it easier to get commercial interest and attract venture capital here," said Peter Morand, chair of the Ottawa Life Sciences Council.²³⁴ That's because investors prefer to sink money into companies whose innovations are patented.²³⁵ "Canada is lagging behind in its acceptance of allowing these patents," Morand said.²³⁶ "This (ruling) puts Canada on a more even playing field in terms of commercializing these technologies."²³⁷

While many are excited at the prospects for the future, some are a little more cautious in what this ruling really means. Joyce Groote, president of Ottawa-based industry group BIOTECCanada, said, "You must still go through an extensive regulatory approval process that is also subject to research ethical boards. This judgment does not change one iota of that."²³⁸

Lobbyists for the biotechnology industry argue that Canada should get on board.²³⁹ What some find most worrisome about all of this is that there has been virtually no public discussion in Canada about either the risks or ethics of genetic engineering.²⁴⁰ The federal government has so far chosen to duck all of the hard questions.²⁴¹

In 1996, a Commons committee called on the government to implement new legislation and regulations to control genetic engineering.²⁴² The government has not done

229. *Id.*

230. *Id.*

231. Edmund L. Andrews, *U.S. Resumes Granting Patents on Genetically-altered Animals*, N.Y. TIMES, Feb. 3, 1993, at A1.

232. Christine Wong, *Mouse Means Money Ruling on Cancer Test Patent Helps Local Biotech Sector*, OTTAWA SUN, Aug. 5, 2000, at 44.

233. *Id.*

234. *Id.*

235. *Id.*

236. *Id.*

237. *Id.*

238. Wong, *supra* note 232.

239. Thomas Walkom, *Federal Court to Rule on Patenting Higher Life Forms*, TORONTO STAR, Nov. 18, 1997, at A2.

240. *Id.*

241. *Id.*

242. *Id.*

so.²⁴³ Instead, the government appears content to take its lead from industry, market forces, and the courts.²⁴⁴

The Canadian Environmental Law Association (CELA) complains that even in the 'Harvard mouse' case the Canadian government is arguing its case too narrowly.²⁴⁵ In private, government officials agree that is exactly what they are doing.²⁴⁶ A lawyer who works for the biotechnology industry said, "If the court says that, yes, animals are patentable, then the government might well change its patent policy."²⁴⁷

Regardless of how good the fruits of this decision may seem to many, there are many other people who do not see this decision as a good outcome. Critics claim that the ruling commercializes the blueprint for life itself.²⁴⁸ "This is saying that if you tweak one mammal in a certain way, you can own the patent to the whole mammal," said Paul Muldoon of the CELA.²⁴⁹ Muldoon called the decision "the commodification of life."²⁵⁰

Richard Gold, a law professor at the University of Western Ontario, said Canada probably should not refuse to grant such patents since many of its biggest trading partners already do.²⁵¹ But, said Gold, "subjecting higher life forms to the same type of patent protection as you give to the mouse trap or a light bulb or a chemical is probably not completely appropriate either."²⁵² Gold believes the government needs something in between.²⁵³

VI. Policy Reasons for the Uses of Transgenic Animals

A. REASONS AGAINST PATENTABILITY OF TRANSGENIC ANIMALS

Developing countries are not importers of technologies and patented products and for the most part are opposed to the patenting of life.²⁵⁴ Many of them have been following the 'Harvard mouse' case in Canada, hoping it would strengthen their opposition to the life patenting provisions of the TRIPs agreement.²⁵⁵

Another strong argument against patenting animals is concern over cruelty to animals. Opponents say that the availability of patent protection for these new animals will lead to an increase in the number of animals born with crippling and painful defects. Opponents argue that as a result, "new forms of cruelty" to animals will ensue.²⁵⁶

Meanwhile, proponents of transgenic animal uses say that "a lawsuit of this kind does not serve any kind of public interest," said George A. Frank, a senior attorney for

243. *Id.*

244. Walkom, *supra* note 239.

245. *Id.*

246. *Id.*

247. *Id.*

248. Valerie Lawton, *Altered Mouse Can Be Patented, Court Says*, *TORONTO STAR*, Aug. 4, 2000.

249. *Id.*

250. *Id.*

251. *Id.*

252. *Id.*

253. *Id.*

254. RAFI, *supra* note 156.

255. *Id.*

256. Lavelle, *supra* note 53 (referring to Quigg, *supra* note 72).

the medical products department of I. E. DuPont De Nemours & Co.²⁵⁷ Others also said that the patent system is a "morally and politically neutral" system for judging whether an individual is entitled to a property right for his or her invention.²⁵⁸

Opponents also point out that many of these transgenic animals are used for profit. Ursula Franklin, an experimental physicist and professor emeritus at the University of Toronto, sees "science moving away from the common good, toward profit...with patenting being one of the means to that profit."²⁵⁹ "When Canadian researchers Frederick Banting and Charles Best discovered insulin in 1922, they decided not to take out a patent and profit themselves, but scientists are now and tend to view their findings as private property," says Franklin.²⁶⁰ In many disciplines, this is acceptable, says Franklin, but in biotechnology, the issues can often deal with fundamental questions about the essence of life itself.²⁶¹

Others disagree with the patenting of animals because they feel that it is actually counter-productive. Some groups believe that in some situations, proliferating patents can actually inhibit the progress of research. The argument is that they give patent holders a license to charge whatever the market will bear from the resulting products.²⁶²

There is also concern that this type of holding is not advantageous to all countries. Developing countries may have little to gain, and much to lose, from a system of intellectual property protection that is organized around the priorities of large corporations.²⁶³ Further complications arise because commitments under NAFTA and the WTO create obstacles for any country that wishes to craft a distinctive approach that balances commercial and other imperatives.²⁶⁴

B. REASONS FOR PATENTABILITY OF TRANSGENIC ANIMALS

There is always the concern for investment and development. Opponents argue that the biotechnology industry is lobbying the Canadian government to follow the lead of the European Union, Japan, Australia, and other countries that allow patenting of higher life.²⁶⁵ However, proponents say that patent rights are critical if Canadian biotechnology companies are to "attract and hold the investment necessary to develop their inventions in Canada."²⁶⁶

Some authors have taken notice that transgenic animals and human gene sequences have enormous commercial value in agriculture, biomedical research, medicine, and

257. *Id.*

258. *Id.* (statement made by biotechnology lawyer Geoffrey M. Karney of Dickstein, Shapiro & Morin).

259. Patricia Orwen, *The Invasion of the Genesnatchers*, *TORONTO STAR*, May 8, 1994, at F1.

260. *Id.*

261. *Id.*

262. Ted Schrecker, *Harvard Mouse: Sound Law, Thoughtless Policy*, *GLOBE AND MAIL*, Aug. 15, 2000, at A13.

263. *Id.*

264. *Id.*

265. Orwen, *supra* note 259.

266. *Id.*

the pharmaceutical industry.²⁶⁷ Furthermore, transgenic animals, or genetically-altered animals, can serve as models to study human diseases and test drugs. Also, they are being developed to donate organs for transplantation in humans.²⁶⁸

In addition to the social reasons, a number of commentators have noted that there are economic incentives resulting from animal patenting.²⁶⁹ The most dramatic evidence of the economic incentive resulting from animal patenting has been the significant increase in the stock values of corporations engaged in biotechnology research.²⁷⁰ There are many examples of companies that have gained significant amounts of money from being involved in the biotech industry.

Just four months after the U.S. Supreme Court decision in *Chakrabarty*, Genentech raised \$36 billion in one day by its public stock offering.²⁷¹ A 1984 National Academy of Sciences study estimated that the biotechnology industry could yield a yearly business of between \$40 billion and \$100 billion.²⁷² With evidence like this, there is no doubt that patents stimulate the growth of industry and, therefore, the industry of biotechnology welcomes any patent protection it receives.²⁷³

Jason Flint, general manager of the Industrial Biotechnology Association of Canada, estimates that the core industry is capitalized at about one billion dollars already and is growing by about 26 percent a year.²⁷⁴ As well, most of the powerful multinational drug firms, with all their political clout, are involved.²⁷⁵ In addition, governments are anxious for any good news on the job front, which regularly laud biotechnology as the wave of the future.²⁷⁶

Various people have noted that it is one of the two technologies in America that will define the next century's economic progress and the well being of society.²⁷⁷ The field encompasses the whole range of life sciences.²⁷⁸

There is further evidence that the biotechnology industry has had positive effects on the economy. "Having barely existed a generation ago, the biotechnology industry in recent years has mushroomed, roughly doubling in size between 1993 and 1999,

267. Walter, *supra* note 27, at 1029 (citing Jones, *supra* note 72, at 880-81).

268. See Morin, *supra* note 17, at 148.

269. See Sellers, *supra* note 17, at 284.

270. *Id.*

271. *Id.* (citing Jeremy Rifkin, *ALGENY 7*, at 11 (Viking Press 1983)).

272. *Id.* (citing *Coordinated Framework for Regulation of Biotechnology: Hearing Before the Subcommittee on Investigations and Oversight and the Subcommittee on Natural Resources, Agriculture Research and Environment and the Subcommittee on Science, Research and Technology of the House Committee on Science and Technology*, 99th Cong., 2nd Sess. 6 (1986)).

273. See Walter, *supra* note 27, at 1025.

274. Walkom, *supra* note 239, at A2.

275. *Id.*

276. *Id.*

277. Julius A. Karash, *KC Seeks to Fly Banner in Biotech Revolution; Explosion of Biological Science Kindles Hope for New Cures, Forges Dreams for Area Economy*, KAN. CITY STAR, Oct. 15, 2000, at A1 (statement was made by Richard J. Mahoney, former head of Monsanto Co. and now an executive in residence at the Center for the Study of American Business at Washington University in St. Louis).

278. *Id.*

to employ more than 153,000 people in high-wage jobs.”²⁷⁹ “More than 1,200 biotech companies now operate in the United States.”²⁸⁰

It is an expensive business.²⁸¹ Flint notes that biotechnology firms want to market their products worldwide to spread the costs of research.²⁸² More particularly, they want worldwide monopolies on the genetically-altered plants or animals they create.²⁸³

An animal with cancer genes would allow for more sophisticated and effective testing of carcinogens. Moreover, it could prove to be useful in testing potential drug therapies. This permits scientists to study breast cancer in a living system and test drugs without involving human patients.²⁸⁴

“To a young growing company, intellectual property is essential for attracting and maintaining investments through the years it takes to develop important, innovative products, products that benefit consumers.”²⁸⁵ Patents also make knowledge publicly available.²⁸⁶ This new information becomes accessible to the scientific community and stimulates further innovation.²⁸⁷

The fact that the Patent Office refuses applications made upon a particular subject matter simply means that subject matter is unregulated by patent legislation.²⁸⁸ It does not amount to a prohibition upon the use of that technology, nor does it mean that there will be a reduction in the use of products that utilize that technology.²⁸⁹ The current practice of refusing to patent higher life forms merely encourages companies to conduct research of this type outside Canada, the products of which are not prevented from being used in Canadian industry.²⁹⁰ Further, it forces researchers to seek other methods, such as keeping the information secret, in order to protect their inventions.²⁹¹ Arguably, a situation where genetic research activities go undisclosed is not a desirable one for the overall good of society.²⁹²

While it is possible that revising current policy in order to allow the patenting of higher life forms might conceivably encourage more research in this area (which is the objective of the Patent Act), it does not follow that it will then become more difficult to regulate genetic engineering practices.²⁹³ In fact, by allowing a more liberal interpretation of section 2, the courts arguably make room for Parliament to enact specific legislation

279. *Id.*

280. *Id.*

281. Walkom, *supra* note 239.

282. *Id.*

283. *Id.*

284. Gladwell, *supra* note 155.

285. News Release, Harvard Mouse Decision: BIOTEC Canada Applauds Recent Federal Court of Appeal Decision on Patenting of Higher Life Forms (Aug. 3, 2000), *available at* <http://www.biotech.ca/EN/nrAug3.html>.

286. *Id.*

287. *Id.*

288. Ratanaseangsuang, *supra* note 14, at 21.

289. *Id.*

290. *Id.*

291. *Id.*

292. *Id.*

293. *Id.*

regulating the fruits of biotechnology.²⁹⁴ This is the more appropriate and measured approach to take if they are to achieve a satisfactory resolution to the issue of genetic engineering.²⁹⁵

A 1994 survey indicates that about 60 percent of Canadians were undecided in their attitudes toward genetic engineering, while an almost equal percentage of Canadians described themselves as true believers and avid opponents of the technology.²⁹⁶ Thus, a greater awareness of the nature of genetic engineering is needed in order to raise consumer confidence in the field.²⁹⁷ In addition, the development of the laws relating specifically to biotechnology would help fill the gaps in legislation that arise as science outpaces the law.²⁹⁸ However, the law will not be able to respond immediately to every new development as it arises, and the laws will not necessarily prevent the unethical uses of genetic engineering.²⁹⁹

C. INTERNATIONAL CONSIDERATIONS

Even if a country tried to resist the trend towards patenting higher forms of life, it would confront two realities.³⁰⁰ First, the biotech industry is international.³⁰¹ Companies can easily move from one country to another in order to take advantage of favorable regulatory climates.³⁰² Therefore, efforts by any one country to aggressively enforce ethical standards may well encourage companies to move elsewhere.³⁰³

Second, regulating countries face a set of international conventions relating to patents and international trade.³⁰⁴ A country wanting to exclude animal patents would be subject to trade sanctions under the World Trade Organization agreements unless it could prove that the sale of that material would violate moral standards.³⁰⁵

VII. Conclusion

This article set out to determine whether the latest Canadian decision in the "Harvard mouse" case has essentially made the intellectual property provision in NAFTA superfluous. There does not seem to be a clear answer. What is clear is that Canada, and

294. Ratanaseangsuang, *supra* note 14, at 21.

295. *Id.*

296. Morin, *supra* note 17, at 197 (citing Survey by Optima as analyzed by Ekos Research Associates, Inc., Industry Canada, Office of Consumer Affairs, *Biotechnology: What is it All About?* (1996), available at <http://info.ic.gc.ca/>).

297. *Id.*

298. *See id.*

299. *Id.*

300. Timothy A. Caulfield & E. Richard Gold, *Whistling in the Wind*, 15 F. FOR APPLIED RES. & PUB. POL'Y 75 (2000).

301. *Id.*

302. *Id.*

303. *Id.*

304. *Id.*

305. *Id.*

the United States for that matter, needs to articulate a clear policy on the patentability of higher life forms.

The ability to patent animals allows many good outcomes to having the ability to patent animals. Scientists can find cures for diseases. In addition, the field of biotechnology creates many jobs and helps the economy in numerous ways. However, the ability to patent animals can also present a dark side.

Neither the court systems in the United States nor Canada have addressed this specific issue. However, it appears that in both jurisdictions the courts want to interpret the patent statutes in such a way as to permit the patenting of animals. The statutes the courts use for guidance do not expressly prohibit this act.

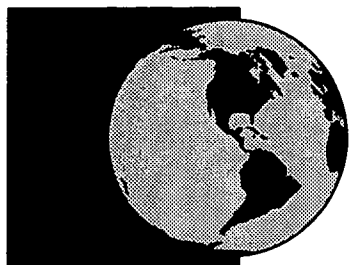
Both countries have essentially determined that the patentability of animals falls under the definitions in their respective statutes. What both jurisdictions seem to be looking for is guidance from the government. In the United States, there were several proposed moratoriums, and only one was even minimally successful. Canada has not taken any such action.

We live in an ever-changing world and it seems that the only proper solution is to draw a compromise. Both governments probably would agree that there are many far-reaching benefits to patenting animals. However, both governments would also probably acknowledge a great potential for disaster if there were not proper regulations and guidelines by which the biotech industry must abide.

It is important for there to be clear guidelines in this area, as to avoid animal cruelty, not exploit underdeveloped nations, and not implicate what seems to be the inevitable—patenting humans. These concerns can be balanced against the desire to learn more about diseases, create more jobs, and boost the economy. However, it will be up to the governments to take action, since that is simply beyond the function of the courts.

Furthermore, if the governments do choose to take affirmative steps to regulate patents on higher life forms, it would create greater awareness about the biotechnology field. So many people do not understand genetic engineering and transgenic animals. Government regulations would be beneficial to everyone, because maybe some people that have traditionally opposed biotechnology might then attain a better understanding of the field.

In the end, I believe that as the years go by, the current state of the intellectual property provision of NAFTA regarding the patentability of plants and animals will be superfluous, if it is not already. In an age where the biotech industry is booming and employing numerous people, and scientists are able to discover cures for what once were considered incurable diseases, it is difficult to imagine that Canada will choose not to be a part of that market.



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