

**IN THE FEDERAL COURT OF APPEAL**

**B E T W E E N:**

PRESIDENT AND FELLOWS OF HARVARD COLLEGE

Appellant

- and -

COMMISSIONER OF PATENTS

Respondent

- and -

CANADIAN ENVIRONMENTAL LAW ASSOCIATION

Intervenor

**INTERVENOR'S MEMORANDUM OF FACT AND LAW**

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## **INTERVENOR'S MEMORANDUM OF FACT AND LAW**

1. This appeal concerns an important legal issue of whether higher life forms are patentable in Canada. It also raises important public policy questions regarding the social and ethical considerations implicit in this decision. In interpreting the term “invention”, both basic patent law principles and the rules of statutory interpretation demonstrate that higher life forms are not patentable. The public policy implications flowing from this issue, however, are so profound that they must be resolved ultimately by Parliament as to if, and how, such patents should be granted.

### **PART I: FACTS**

2. The Canadian Environmental Law Association, a legal aid clinic in the province of Ontario with a mandate to represent low income and disadvantaged communities and to seek to improve the law and policy to protect human health and the environment, sought intervention status in this appeal. On February 12, 1999, Chief Justice Isaac granted the Canadian Environmental Law Association intervenor status in this hearing.

3. The Intervenor takes no issue with the account of factual matters set out in paragraphs 1 to 15 and 18 of the Appellant's Memorandum of Fact and Law, and in paragraphs 2 to 6 of the Respondent's Memorandum of Fact and Law.

### **PART II: ISSUES**

4. Whether the Respondent erred in law in denying patents for claims 1 through 12 of the application on the grounds that a transgenic non-human mammal is not an invention within the meaning of s.2 of the *Patent Act*.

## **PART III: ARGUMENT**

### **A. The Interpretation of the Term “Invention”**

#### **(i) Introduction**

5. The essence of this appeal relates to the definition of the term in the *Patent Act*. The first Canadian statute granting rights of patents for inventions was *An Act Respecting Patents of Invention*, R.S. 1869, c.11. Its description of the right to patent was essentially identical to the wording of the definition of "invention" in the current statute, with the exception of the omission of patentability of "process," as it provided in Section 6:

*An Act Respecting Patents of Invention*, R.S. 1869, c.11, s.6, Tab 1

6. The definition of "invention" in the current *Patent Act* is only slightly changed from the definition as it first appeared in 1869, and in all respects material to this Appeal, is unchanged.

*The Patent Act*, R.S.C. 1985, Chap. P-4, as amended , Tab 2.

7. It is respectfully submitted that the term “invention” as currently understood in Canadian patent law was not intended to include and does not include the higher life forms. This argument is based on the understanding of the terms “reproducibility”, “manufacture” and “composition or matter” and the rules of statutory interpretation.

#### **(ii) Law of Statutory Interpretation**

8. The primary rule of modern statutory interpretation is that:

“...courts are obliged to determine the meaning of legislation in its total context, having regard to the purpose of the legislation, the consequences of proposed interpretations, the presumptions and special rules of interpretation, as well as

admissible external aids....”

Sullivan, Ruth, *Driedger on the Construction of Statutes*, (3d) (Toronto: Butterworths Canada, 1994) at p. 131, Tab 3

9. The relevant special rule of statutory construction in the present context is the "Original Meaning Rule. It is generally presumed that the meaning of words used in legislation is stable.

A... Canadian courts draw a sharp distinction between ordinary legislation and constitutional texts. With respect to ordinary legislation, the original meaning rule prevails. It assumes that the meaning of legislation is fixed when the legislation is first enacted and, once fixed, nothing short of amendment or repeal can change it. With respect to the Charter and other constitutional documents, the courts adopt a dynamic approach. (emphasis added)

Sullivan, Ruth, *Driedger on the Construction of Statutes*, (3d) (Toronto: Butterworths Canada, 1994) at p. 137, Tab 3

10. The rule was expressed by Dickson, J. as:

AThe doctrine of contemporanea expositio is well established in our law. AThe words of a statute must be construed as they would have been the day after the statute was passed...Sharpe v. Wakefield. See also Driedger, Construction of Statutes: A Since a statute must be considered in the light of all circumstances existing at the time of its enactment it follows logically that words must be given the meanings they had at the time of enactment. and the courts have so held; Maxwell on the Interpretation of Statutes..."The words of an Act will generally be understood in the sense which they bore when it was passed."

*Perka v. R.* (1984), 13 D.L.R. (4th) 1 at 26. (S.C.C.), Tab 4

11. In order to reconcile this rule with the expectation that readers be able to rely on conventional meanings of words, and to adapt law appropriately to social change, the courts do adapt dynamic interpretations, but to a limited extent, in order not to exceed their institutional role.

An examination of the cases in which the problem of original meaning has arisen suggests that in applying the original meaning rule the courts in fact have regard to both concerns. Law reform initiatives involving political choice are left to the legislature, but simple

adaptation, in which the original purposes and policies of the legislature are applied to new facts, is regularly undertaken by the courts.

Sullivan, Ruth, *Driedger on the Construction of Statutes*, (3d) (Toronto: Butterworths Canada, 1994) at p. 140, Tab 3

12. It is submitted that the "Original Meaning Rule" clearly applies to this case, given the history of the *Patent Act*, and the date of enactment of the definition of "invention." To interpret the terms "manufacture" and "composition" from a statute dating from 1869 to include genetically modified living animals is not a mere adaptation of words but a clear departure from what was intended and was the plain meaning of the words at the time. It would constitute a significant law reform which should only be undertaken by the legislature.

Driedger, *supra*, page 140. Tab. 3

13. It is unreasonable to consider that the legislators of the definition of "invention" in *An Act Respecting Patents of Invention* in 1869, and in as essentially unchanged today, intended patenting to be exercised in a manner that gives rise to serious ethical issues. Parliament is the appropriate authority to consider, with full attention to these issues, whether the statute should be amended to provide for the extension of patenting to mammals.

Driedger, *supra*, p. 140. Tab. 3

### **(iii) Reproducibility**

14. The Intervenor adopts the arguments of the Respondent regarding reproducibility.

### **(iv) "Manufacture" and "Composition of Matter"**

15. It is submitted that a living mouse or other mammal is not an article or thing made by hand, and was not within the concept of "manufacture" of the original writers of the *Patent Act*. Nor could transgenic mice or other mammals possibly have been within their contemplation. The plain meaning of the words at that time did not include animals, and certainly did not include genetically-modified ones.

*Hornblower and Maberley v. Boulton and Watt* (1799), 8T.R. 95; Dav.P.C.221  
*R. v. Wheeler* (1812), 2B & Ald. 345 at 350.

16. The Appellant relies on definitions of manufacture in *The New Shorter Oxford English Dictionary on Historical Principles* and in two English authorities from 1799 and 1812. All three authorities emphasize that "manufacture" is

An article made by hand; a person's physical handiwork (*The Shorter Oxford English Dictionary on Historical Principles*) (Oxford:Clarendon) 1993, at 1691.

...something made by the hands of man... (*Hornblower and Maberley v. Boulton and Watt*)

(*infra*)

something of a corporeal and substantial nature, something that can be made by man from the matters subjected to his art and skill... (*R. v. Wheeler*) (*infra*)

17. In rejecting a patent for a unique soybean variety, produced through traditional breeding techniques, Marceau, J. of the Federal Court of Appeal, found that the words of the definition of "invention" did not include the subject matter of that application:

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...

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 characteristic of which is that it reproduces itself as a necessary result of its growth and maturity. I do not dispute that appellant's contention that those who develop new types of plants by cross-breeding should receive in this country, as they do elsewhere, some kind of protection and reward for their efforts but it seems to me that, to assure such result, the legislator will have to adopt special legislation...

*Pioneer Hi-Bred Ltd. v. Commissioner of Patents* (1987), 14 C.P.R. (3d) 491 (F.C.A) at page 7 (QL version), Tab 5; (aff'd. on other grounds, (1989), 60 DLR (4th) 223 (S.C.C.)

18. The opinion of the Court, that the words of the statute could apply to a plant variety only "on the most metaphorical level" and that "special legislation" would be required to include such life forms in patentability, apply even more strongly to animals. These life forms are even more removed from the "common and ordinary meaning of either or both the term "manufacture" and "composition of matter." It is even less appropriate to consider that the intention of Parliament was to include animals within the meaning of the definition.

*Pioneer Hi-Bred*, supra, at p. 7 Tab 5

19. Subsequent to the decision of the Federal Court of Appeal in the *Pioneer Hi-Bred* case, the government of Canada enacted the *Plant Breeders Rights Act*, S.C. 1990, c.20, providing a form of intellectual property protection for plant breeders, a form of "special legislation" consistent with the words of Marceau, J. The passage of the *Plant Breeders Act* is a confirmation that Parliament did not intend plant breeders to obtain intellectual property protection under the Patent Act. Again, it is even less appropriate to consider that the intention of Parliament was to include animals within the ambit of the Patent Act.

*Plant Breeder's Rights Act*, S.C. 1990, c.20, ss. 1-4, Tab 6

## **B. The Public Interest Implications of the Interpretation of the Term “Invention”**

### **(i) Introduction**

20. While statutory interpretation of the term “invention” is pivotal issue in this case, there are unequivocal public interest implications arising from that interpretation. 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.

21. The Supreme Court of Canada, in upholding the constitutionality of the *Canadian Environmental Protection Act*, R.S.C 1985, c. 16 (4th Supp.), underscored the importance of environmental protection and of Canada’s international obligations:

...the protection of the environment is a major challenge of our time. It is an international problem, one that requires action by governments at all levels. And, as is stated in the preamble to the Act under review, "Canada must be able to fulfil its international obligations in respect of the environment"...the stewardship of the environment is a fundamental value of our society ...

*R v. Hydro-Québec*, 24 C.E.L.R. (N.S.) p.167, at p. 303

22. The importance of biodiversity is demonstrated by the international consensus which led to the Convention on Biological Diversity. In June 1992, at Rio de Janeiro, at the United Nations Conference on Environment and Development, many countries including Canada signed the United Nations *Convention on Biological Diversity*. Canada ratified the Convention on December 4, 1992.

*Convention on Biological Diversity*, June 5, 1992, Tab 8

Canadian Instrument of Ratification, December 4, 1992, Tab 9

23. Conservation of biological diversity has consistently been identified as one of the most pressing global environmental issues. In the preamble to the *Convention on Biological Diversity*, countries

expressed concern that biological diversity is being significantly reduced by certain human activities. The *Convention on Biological Diversity* included in its objectives the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources. Biological diversity includes the variability among living organisms from all sources; and includes diversity within species, between species and of ecosystems. "Biological resources" includes genetic resources.

*Convention on Biological Diversity*, Preamble, Articles 1 and 2, Tab 8

24. Two issues related to the goals of the *Convention* are raised from the patenting of life forms: equitable access to the benefits of biodiversity, and environmental and health hazards associated with genetically-modified living organisms.

### **(ii) Equitable Access to Benefits of Biodiversity**

25. The Convention provides for sharing of resources while recognizing intellectual property rights where they exist, but establishes, by international consensus, the importance of equitable sharing of the economic returns of commercial utilization of genetic resources. This international consensus is relevant to the Court's consideration of potential patent rights which grant monopoly ownership to the genetically modified animals that are the subject of this application. The issue of distribution of benefits from biodiversity is related to patenting of life forms, particularly in regard to agriculture. Patents on genetic makeup of crops and livestock may further concentrate economic power in large agricultural businesses, and facilitate appropriation by them of genetic resources and knowledge about them developed over millennia by indigenous and local communities in the Third World. The

monopoly ownership and appropriation of economic benefits of biodiversity through patenting contradicts the goal of equitable sharing of benefits of genetic resources of biodiversity. The approach of the *Convention*, regarding the utilization of genetic resources, is to foster a balance between intellectual property rights, and the global value of equitable sharing of economic benefits from genetic resources. A grant of the mouse patent and the multi-species patent claims in this application, providing monopoly ownership and resulting economic benefits, would reflect a lack of such a balance.

*Convention on Biological Diversity*, Article 1. Book of Authorities, Tab 8.

Nijar, Gurdial Singh and Chee, Yoke Ling, "The Implications of the Intellectual Property Rights Regime of the Convention on Biological Diversity and GATT on Biodiversity Conservation: A Third World Perspective", in *Widening Perspectives on Biodiversity*, 1994, Sci. Med. pp 277 - 286, at pages 277, 281, 283 and 285, Tab 10.

### **(iii) Environmental Hazards and Their Relation to conservation of biodiversity**

26. The Appellant argued at the trial level that patenting provides an important incentive to the biotechnology industry to continue research in this field.

Appellant's Record, (Trial Division) Tab 23, page 8.

27. To the extent that patenting of life forms contributes to further biotechnological experimentation, it also contributes to greater likelihood of environmental and health hazards associated with production or release of genetically-modified organisms. The scientific literature demonstrates that these potential hazards are of sufficient concern to warrant current and future investigation. These hazards include:

- # the possible interbreeding of the genetically-modified organisms with other species, and the transfer of the modified trait to other species:

Mikkelsen, T.R. , Andersen, B. and Jergensen, R.B., “The risk of crop transgene spread.” *Nature*, Vol. 380, p.31, 1996, Tab 11.

Boening, Dean. W. “Biotechnology and Environmental Pollution: Scientific and Ethical Reflections”, in Environmental Ethics, Vol. 21, No.1, pp.111-112, Tab 12.

Bergelson,J., Purrington, C., Wichmann, G., “Promiscuity in transgenic plants”, *Nature*, Vol 395, p.25, 1998, Tab 12.

Doyle, J.D., Stotzky, G., McClung, G, Hendricks, C., “Effects of Genetically Engineered Microorganisms of Microbial Populations and Processes in Natural Habitats”, *Advances in Applied Microbiology*, Vol. 40, pp.237-287, Tab 14.

# in particular, the production of new weed species:

Mikkelsen, T.R., Andersen, B., Jorgensen, R.B. “The risk of crop transgene spread”, *Nature*, Vol. 380, p.31, 1996, Tab 11.

# the proliferation in transgenic plants of the important biological insecticide, *Bacillus thuringiensis*, and its accumulation and persistence in soil, causing a hazard to non-target insects and potentially enhancing the selection of toxin-resistant target insects.

Crecchi, C. and Stotzky, “Insecticidal Activity and biodegradation of the Toxin from *Bacillus Thuringiensis* subsp. *Kurstaki* Bound to Humic Acids from Soil”, in *Soil Biol.Biochem.* Vol. 30, No.4, pp.463-470, 1998, Tab 15.

# the transfer of allergenic properties from one plant to another, causing risks to human health

Nordley, Julie A.; Taylor, Steve L; Townsend, Jeffrey A.; et al, “Identification of a Brazil-Nut Allergen in Transgenic Soybeans,” *The New England Journal of Medicine*, Vol. 334, No. 11, 688-692, Tab 16.

# the possible extinction of diverse indigenous species to be replaced by a reduced number of strains of genetically superior ones

Beoning, Dean W. “Biotechnology and Environmental Pollution: Scientific and Ethical Reflections” in Environmental Ethics, Vol. 21, No. 1, p.111, Tab 12.

Westminster Institute for Ethics and Human Values and McGill Centre for Medicine,

Ethics and Law, *Ethical Issues Associated with the Patenting of Higher Life Forms*

(London: Westminster Institute, 1994) at p.64, Tab 17.

28. The governments of Canada, Mexico, and the United States, agreed to Article 1709 of NAFTA, which provides for exclusion from patentability of inventions including "to avoid serious prejudice to nature or the environment," thereby recognizing that patentability may contribute to such risks.

*The North American Free Trade Agreement*, Article 1709, Subsection 2, Tab 18.

29. Hazards associated with living modified organisms resulting from biotechnology are of sufficient concern internationally that Parties to the *Convention on Biological Diversity* agreed to two risk-management commitments. Parties committed to, "as far as possible," establish domestic regulatory regimes to manage risks associated with use and release of living modified organisms.

*Convention on Biological Diversity*, Article 8(g), Tab 8.

30. They further agreed to develop a biosafety protocol of procedures, including advance informed agreement, for the transboundary movement of living modified organisms.

*Convention on Biological Diversity*, Article 19(3), Tab 8.

31. To the extent that life-form patents provide an impetus to biotechnological research and development, they increase the possibility of such hazards. Whether the presumed benefits of the industry will balance these risks has not been thoroughly examined in Canadian public policy, and is beyond the scope of this Appeal. However, the possibility of these negative effects provides support for the argument that the current practice of refusing patents for multicellular life forms should not be changed without a thorough review of these issues through a Parliamentary process.

#### **(iv) Animal Welfare**

32. Genetic engineering may be harmful to animals in various ways, including introduction of developmental abnormalities, and designed-in vulnerability to human diseases (as in the case of the animals which are the subject of this application). Laboratory controls to regulate practices which

cause suffering in animals may be ineffective if the introduced trait in itself leads to increased suffering. Whether the possible benefits of increased biotechnological research, spurred by patenting, will balance these impacts has not been thoroughly examined in Canadian public policy nor can it be in this Appeal. However, the possibility of these impacts on animal welfare indicates that the current practice of refusing patents for multicellular life forms should not be changed without a thorough review of these issues in a Parliamentary process.

Westminster Institute for Ethics and Human Values and McGill Centre for Medicine, Ethics and Law, *Ethical Issues Associated with the Patenting of Higher Life Forms* (London: Westminster Institute, 1994) at p.71-75, Tab 17

#### **(v) Commodification and Objectification**

33. Scholars have expressed concern that both genetic engineering and patenting may contribute to reduced moral respect for life and living organisms. This may lead to increased acceptance of suffering of laboratory and farm animals and spiritual impoverishment of humans as life processes are reduced to physical and chemical processes capable of utilitarian manipulation. If we commodify living things (consider them as objects for commercial transactions), we raise the ethical concern in treating a subject, a “moral agent” merely as an instrument for the desires of others. These concerns are directly related to patenting if distinctions are not made between living and non-living things, as patenting has the potential for the commercialization of living organisms in new and unprecedented ways. If no distinction is made between living and non-living things, living things are reduced to the level of things to which no respect is due.

Westminster Institute for Ethics and Human Values and McGill Centre for Medicine, Ethics and Law, *Ethical Issues Associated with the Patenting of Higher Life Forms* (London: Westminster Institute, 1994) at pp.84 -85, Tab 19

Nijar, Gudial Singh and Chee Yoke Ling, “The Implications of the Intellectual Property Rights Regime of the Convention on Biological Diversity and GATT on Biodiversity Conservation: A Third World Perspective” in Widening Perspectives

on Biodiversity, 1994, Sc. Med. Pp.277-286, at p.281, Tab 10.

34. It is difficult to evaluate whether patenting higher life forms leads to commodification and/or objectification since empirical evidence would be required for such an evaluation, and predictions would be uncertain. However, such an examination is important since new technologies may have subtle effects on how we view the world and other creatures. Close attention to ethical and social implications is warranted where uncertainty exists regarding the potential impact of technologies on attitudes, values and behaviour.

Westminster Institute for Ethics and Human Values and McGill Centre for Medicine, Ethics and Law, *Ethical Issues Associated with the Patenting of Higher Life Forms* (London: Westminster Institute, 1994) at p.94, Tab 17

35. Parliament is the appropriate authority to consider, with close attention to ethical and social implications, whether the statute should be amended to provide for the extension of patenting to such animals.

36. In the landmark U.S. Supreme Court decision, *Diamond, Commissioner of Patents and Trademarks v. Chakrabarty*, four of the nine justices dissented from the majority decision that the bacterium in question was patentable. Mr. Justice Brennan, writing for the dissenters, found that the legislative history of the relevant Act did not indicate an intention of Congress that the bacterium be patentable. Further, he found that

It is the role of Congress, not this Court, to broaden or narrow the reach of the patent laws. This is especially true where, as here, the composition sought to be patented uniquely implicates matters of public concern.

*Diamond, Commissioner of Patents and Trademarks v. Chakrabarty* 2206 U.S.P.Q. at p.202, Tab 19

**(vi) The Public Interest in Open and Timely Exchange of Scientific Knowledge and Research Results**

37. Society and science benefit from the quick disclosure of the fruits of research. However, concern has been expressed that the increased commercialization of research, non-disclosure agreements, and the treatment of research results as “proprietary” may lead to suppression of research results, delays in publication of data, and other restrictions on information and research tools so that individuals or corporations can obtain competitive advantages.

Nadis, Steve, “US concern grows over secrecy clauses” in *Nature*, 398, at p. 359, 1999, Tab 20

Harris, Noel, “It’s time to ‘out’ the selfish researchers”, in *Nature*, Vol. 398, p.102, 1999, Tab 21

38. Patenting is precisely such an assertion of a proprietary right, and protection of information to protect patentable advances may lead to these results. To that extent, patenting may impede rather than stimulate innovation.

**PART IV: CONCLUSION AND ORDER SOUGHT**

39. The Appellant's claims 13 to 25, which include methods of testing, methods of production, and plasmids or cell cultures, have been allowed. Therefore, the Appellant's inventiveness will result in economic benefits to it. Its efforts in this matter, therefore, will not go unrewarded if the Commissioner's decision is upheld.

40. A full examination of the public interest concern related to patenting of higher life forms, such as could be conducted by Parliament, could consider whether or not these plants and animals should be patented, and if so, under what conditions. Parliament might consider various strategies to

respond to related ethical and environmental concerns, such as:

- # a mechanism for ethical review in the patenting decision-making process;
- # environmental assessment of potential impacts of genetically modified life forms as an element of ethical review;
- # provisions to protect the rights of farmers in the use of genetically-modified plants or animals;
- # provisions to facilitate the rapid dissemination of scientific research results;
- # the possibility of mandatory licensing requirements for patented products deemed to be in the public interest.

It is appropriate that the public interest in these questions be fully explored through a public review prior to any decision to modify the current Canadian practice regarding patentability of life forms.

41. We therefore conclude that the Learned Trial Judge did not err in finding the subject matter of this Application non-patentable within the definition of "invention" in the *Patent Act*, given that:

- a. The definition dates from an era when such subject matter was not within the contemplation or intention of Parliament;
- b. A living animal is not within the meaning of "manufacture" or "composition of matter," in the *Patent Act*;
- c. The relevant rule of statutory interpretation, the "Original Meaning Rule" should be applied to this matter, leading to a conclusion that a decision to extend the definition of "invention" to the subject matter of the Appeal, would constitute a significant law reform, which should be done, if at all, by the legislature, rather than by the Court;
- d. That the question of life-form patenting involves serious matters of public policy, impacts, and controversy, including questions of ethics and environmental impacts, which cannot be fully considered in this proceeding. These policy issues should be fully considered by Parliament prior to a decision on whether multicellular-life forms should be subject to patenting.

42. The Intervenor therefore requests that the appeal be dismissed.

Respectfully submitted by:

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Michelle Swenarchuk

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Paul Muldoon