Court File No. 28155

**IN THE SUPREME COURT OF CANADA**
(ON APPEAL FROM THE FEDERAL COURT OF APPEAL)

B E T W E E N:

THE COMMISSIONER OF PATENTS

Appellant
(Respondent)

- and -

THE PRESIDENT AND FELLOWS OF HARVARD COLLEGE

Respondent
(Appellant)

- and -

THE CANADIAN COUNCIL OF CHURCHES AND THE EVANGELICAL FELLOWSHIP OF CANADA, CANADIAN ENVIRONMENTAL LAW ASSOCIATION, GREENPEACE CANADA, CANADIAN ASSOCIATION OF PHYSICIANS FOR THE ENVIRONMENT, ACTION GROUP ON EROSION, TECHNOLOGY AND CONCENTRATION AND THE CANADIAN INSTITUTE FOR ENVIRONMENTAL LAW AND POLICY, SIERRA CLUB OF CANADA, ANIMAL ALLIANCE OF CANADA, INTERNATIONAL FUND FOR ANIMAL WELFARE INC. AND ZOOCHECK CANADA INC.

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# FACTUM OF THE INTERVENERS, CANADIAN ENVIRONMENTAL LAW ASSOCIATION, GREENPEACE CANADA, CANADIAN ASSOCIATION OF PHYSICIANS FOR THE ENVIRONMENT, ACTION GROUP ON EROSION, TECHNOLOGY AND CONCENTRATION AND THE CANADIAN INSTITUTE FOR ENVIRONMENTAL LAW AND POLICY

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## INTERVENER'S MEMORANDUM OF FACT AND LAW

1. This appeal concerns the important legal issue of whether higher life forms are patentable in Canada. It also raises important public policy questions regarding the social, scientific, environmental 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 related to this issue are profound and complex, and since full information about these implications is not available to this Court, Parliament is the appropriate body to decide, after full examination of all the implications, whether to change Canadian law to permit such patents, and if so, with what conditions and safeguards.

### PART I: FACTS

#### These Interveners

2. The Canadian Environmental Law Association (CELA) was the only intervener in this matter before the Federal Court of Appeal. CELA, Greenpeace Canada, the Canadian Institute for Environmental Law and Policy, the Action Group on Erosion, Technology and Concentration and the Canadian Association of Physicians for the Environment have all been variously active in research, policy or advocacy with respect to human health and the environmental issues of biosafety, biodiversity, genetically modified organisms and life form patenting, as more particularly described in their Motion to intervene before this Court. On October 25, 2001, Madam Justice Arbour granted these Interveners leave to intervene in this hearing and to file a joint factum.

3. The Interveners take no issue with the account of factual matters set out in paragraphs 1 to 30 of the Appellant's Memorandum of Fact and Law.

## PART II: POINTS IN ISSUE

4. These Interveners agree with the statement of the Points in Issue as outlined by the Appellant, namely "whether higher life forms, like the complex and intelligent life forms in this case, constitute patentable subject matter under the *Patent Act*."

5. These Interveners will adopt and agree with the submissions of the Appellant regarding the issues addressed in paragraph 32a) and 32b) of the Appellant's factum and will focus their submissions on the issues raised in paragraph 32c) of the Appellant's factum, namely whether the policy decision as to whether higher life forms should be included in patentable subject matter should be left to Parliament.

## PART III: ARGUMENT

### A. The Interpretation of the Term "Invention"

6. These Interveners agree with and adopt the argument of the Appellant at paragraphs 36 to 48 of the Appellant's factum.

### B. Whether Parliament intended that higher life forms should be patentable subject matter

7. These Interveners agree with and adopt the argument of the Appellant at paragraphs 49 to 61 of the Appellant's factum.

### C. Whether the policy decision as to whether higher life forms should be included in patentable subject matter should be left to Parliament.

#### (i) Introduction

8. While statutory interpretation of the term "invention" is pivotal issue in this case, there are important public interest implications related to that interpretation. The public interest implications include whether patenting higher life forms affects the public interest in innovation and in scientists unfettered exchange of scientific knowledge, research tools, and research

results; whether it affects equitable access to the benefits of biodiversity; and whether it affects or exacerbates the environmental and human health hazards arising from products of this technology. These Interveners will make submissions on these three public interest issues.

9. Because a full consideration of these questions requires extensive information that is not available to this Court, Parliament is the appropriate authority to decide, with full consideration of ethical, scientific, environmental and social implications and a process for public consultation and debate, whether the statute should be amended to provide for the extension of patenting to such animals.

> 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, l994) at 101 and 102 **[Tab 9]**

**(ii) The Public Interest in the Advancements of Science through Scientists' Unfettered Exchange of Scientific Knowledge, Research Tools, and Research Results.**

10. Impacts from biomedical patents and from patenting life forms are already being experienced and discussed in academic and policy literature. A review of these impacts demonstrates the kinds of issues that Parliament ought to consider as part of its decision as to whether to extend patent options to life forms. These include issues of dissemination of research, cost and accessibility of research tools, cost and accessibility of diagnostic tests, and disclosure of commercial interests.

11. While patents are intended to spur and reward innovation, patents on life forms may actually deter further innovation in the biomedical field by foreclosing opportunities for research and product development to those who do not hold the patent. This is particularly harmful to the public since the field of biomedical research has the potential to provide life-saving medical discoveries and treatments. The proliferation of patenting has

> changed the conduct of biomedical research in some ways that are not always consistent with the best interests of science. It has promoted the creation of sometimes aggressive and usually expensive offices at many academic institutions to protect intellectual

> property and to regulate the exchange of biological materials that would at one time have been freely shared among academic colleagues. It has encouraged some companies to make protected materials and methods available to investigators under terms that seem unduly onerous. In a few well-publicized cases, and likely in many more undocumented ones, it has fostered policies that have inhibited the use of new scientific findings, even in the not-for-profit sectors, and has reduced open exchange of ideas and materials among academic scientists.
>
> Varmus, Dr. Harold, "Testimony Harold Varmus, Hearing on Gene Patents and Other Genomic Inventions" (The House Judiciary Subcommittee on Courts and Intellectual Property), 13 July 2000, online: <http://www.house.gov/judiciary/varm0713.htm> (date accessed: 15 March 2002). **[Tab 45]**
>
> Heller M. A. & Eisenberg R. S., "Can Patents Deter Innovation? The Anticommons in Biomedical Research" (1998) 280 Science 698 at 698-701. **[Tab 29]**

12. Patenting of life forms has resulted in inaccessibility and high cost of research tools, including transgenic mice. Mice are the most frequently used animals in scientific research; it is estimated that in 2000, twenty five million mice were used worldwide in research, constituting 90% of all animals used in research. Scores have been patented in the US subsequent to the US patenting of the mammals that are the subject of this appeal.

> Malakoff, D., "Suppliers: The Rise of the Mouse, Biomedicine's Model Mammal" (2000) 288 Science 248. **[Tab 32]**
>
> Marshall, E., "Property Claims: A Deluge of Patents Creates Legal Hassles for Research" (2000) 288 Science 255 at 255 and 257. **[Tab 33]**

13. Following the granting to Harvard University of US Patent 4,736,866 for the mammals that are the subject of this appeal, Harvard granted E.I. DuPont de Nemours and Company (hereinafter, DuPont) an exclusive license to distribute the mice. Some scientists objected to the terms of DuPont's licences which included a "reach through" clause requiring anyone who developed a product through the use of the mouse, or any derivative strain, to pay royalties to DuPont. Dupont also placed limits on breeding or redistributing these patented animals. Dr.

Harold Varmus, then Director of the National Institutes of Health, initiated a four year process of negotiation with DuPont to make the mice broadly available to non-profit researchers. The resulting Memorandum of Understanding between DuPont and the Public Health Service of January 18, 2000, provides that the Public Health Service and its grantees (non-profit academic researchers) may use the patented transgenic non-human mammals without cost for biomedical research purposes. A similar agreement had been negotiated previously between The National Institutes of Health and DuPont regarding the use of the "cre-lox' mouse, and the NIH has subsequently contributed funding to a mouse breeding facility to make unpatented mice available to academic researchers. In effect, senior research scientists have been impelled to reverse the impact of the patents on transgenic mice in order to spur innovation in non-profit medical research.

Marshall, E., *Ibid*. **[Tab 33]**

Anderson, C., "Researchers Win Decision on Knockout Mouse Pricing" (1993) 260 Science 23 at 23-24. **[Tab 12]**

Smaglik, P., "NIH cancer researchers to get free access to 'OncoMouse'" (2000) 403 Nature 350. **[Tab 43]**

Memorandum of Understanding between E.I.DuPont de Nemours and Company and Public Health Service US Department of Health and Human Services, 18 January 2000, online: Office of Technology Transfer Search <http://ott.od.nih.gov/_vti_script/ newpages_Search.htm0.idq> (date accessed: 15 March 2002). **[Tab 37]**

Marshall, E., "Sharing Reagents: NIH, DuPont Declare Truce in Mouse War" (1998) 281 Science 1261. **[Tab 34]**

14. Providing access to the mammals which are the subject of this application to non-profit researchers at nominal cost, subsequent to the grant of the corresponding U.S. patent, required the intervention of the senior scientist at the National Institutes of Health, and an extended negotiation process. Such a solution would not necessarily be available in Canada regarding these mammals or with regard to other patented research materials.

15. Patents may cause interference with downstream research through patents on mice, genes or partial genes early in the process. A transgenic mouse used for research into Alzheimer's disease was the subject of patent litigation between the non-profit Mayo Foundation, which provides its mice to academic institutions at nominal costs, and for-profit Elan Pharmaceuticals. At issue was Mayo's distribution of the mice to academic institutions at nominal cost. Judgment for Mayo was described as giving "researchers at the Mayo Foundation, other academic institutions and biotechnology companies the opportunity to continue research."

> Dalton, R., "Patent suit on Alzheimer's mouse rejected" (2000) 405 Nature 989. **[Tab 25]**

16. Whether higher life forms can be patented, the issue of this appeal, has implications for many issues in the field of biotechnology, including patenting of genetic materials, which was commenced in Canada without scrutiny by the courts.

> Vaver, D., *Intellectual Property Law: Copyright, Patents, Trade-marks* (Concord: Irwin Law, 1997). at 124. **[Tab 8]**

17. As the fields of biotechnology expand and become more diverse, the problems related to genetic patenting are likely to occur increasingly in relation to higher life forms, if those are patented. It is therefore relevant for this Court to consider examples of the impacts of patents on genetic materials in this matter as examples of the kinds of issues that must be considered in making the decision as to whether to allow patenting of higher life forms.

18. The patenting of a protein, CCR5, required for efficient HIV replication, by Human Genome Sciences Inc. has caused concerns as scientists who wish to use it for development of pharmaceuticals will have to pay a license fee to the company. Other possible complimentary patents could mean that drug researchers will be required to "cross-license" or pay two fees to work on the drug. As there is an acute public interest in development of treatments for HIV/AIDs, patents and the attendant costs of license fees which may retard research, are contrary to the public interest.

Smaglik, P., "Could AIDS treatments slip through patents loophole?" (2000) 404 Nature 322. **[Tab 44]**
Marshall, E., "Gene patents: Patent on HIV Receptor Provokes an Outcry" (2000) Vol 287, No. 5457 Science 1375 at 1375-1377. **[Tab 35]**

19. Other biomedical patents have been criticized for interfering in the availability of diagnostic tools and tests. Myriad Genetics of Utah has patented two genes, BRCA 1 and BRCA2, implicated in possibly 10% of breast cancer cases and has exclusive rights to a diagnostic test for mutations on these genes. Scientists in France, the Netherlands and Britain object to Myriad's claims that only its test can be used for these genes as "an unwarranted and novel restriction on medical practice." French scientists object that the requirement that all samples be sent to Utah for testing will deny French scientists data and expertise and hamper development of new tests and that the breadth of the patent prevents marketing tests developed elsewhere using techniques differing from Myriad's.

Butler, D. & Goodman S., "French researchers take a stand against cancer gene patent" (2001) 413 Nature 95. **[Tab 21]**
Balter, M., "Cancer Research: Transatlantic War Over BRCA1 Patent" (2001) Vol. 292, No. 5523 Science 1818. **[Tab 13]**
Wadman, M., "Testing time for gene patent as Europe rebels" (2001) 413 Nature 443. **[Tab 46]**
Marshall E., "Biotechnology Patents: The Battle Over BRCA1 Goes to Court; BRCA2 May be Next" (1997) Vol. 278, No. 5345 Science 1874. **[Tab 36]**

20. Obtaining public benefits from genomic discoveries can also be inhibited by patents on genetic testing methods. Some US laboratories have refrained from offering genetic testing services for haematochromatosis, a progressive iron-overload disease, because of patents granted on tests for the disease. Laboratories had begun genetic testing before the patents were awarded, but 30% of those surveyed reported discontinuing or not developing genetic testing after the grant of the exclusive licence on the patents. Limited clinical testing may inhibit further discoveries regarding the gene which causes the disease."…the patents inhibited adoption (of HFE testing) , perhaps by creating a financial risk for laboratories, and a disincentive to develop and validate a clinical assay that could be stopped by patent enforcement." The study showed a

delay in publication of data regarding cloning the HFE of a year after the patent application was filed and that gene patents may affect the cost and availability of clinical-diagnostic testing.

Merz J. F. *et al*., "Diagnostic testing fails the test"(2002) 415 Nature 577 at 579. **[Tab 38]**

21. In summary, patents on life forms may cause numerous problems for researchers and for provision of medical diagnosis and treatment including:

- inappropriate rewards given by patenting partial and uncharacterized cDNA sequences;
- impediments to development of diagnostics and therapeutics due to costs of patented research data;
- patent stacking (several different ways of patenting a genomic sequence) which discourages product development due to high royalty costs payable to all patent owners;
- secrecy of patent applications resulting in scientists finding, late, that patents have already been granted related to work they are doing, leading to unexpected licensing costs and patent infringement penalties;
- private biotechnology patent holders can monopolize certain gene test markets;
- patent holders are being allowed to patent a part of nature, a basic constituent of life;
- and patent filings are replacing journal articles as places for public disclosure, reducing the body of knowledge in the literature.

Human Genome Project Information, online: ORNL <www.ornl.gov/hgmis/elsi/patents.html> (last modified: 27 September 2001). **[Tab 30]**

22. Patenting in the biomedical field has contributed to delay in the publication of scientific results. A survey of life scientists found that 19.8% of those questioned said their publication results had been delayed by more than 6 months at least once (considerably longer than the 60 days considered acceptable by the National Institutes of Health). Of those, 46% reported delays to allow time for patent applications; 33% to protect the proprietary value of research results by means other than patent applications…26% to allow time to negotiate licence agreements; and 17% to resolve disputes over intellectual property. Further, "The fact that 34% of faculty have been denied access to research results suggests that data withholding has affected many life-

science faculty.

> Blumenthal *et al*., "Withholding Research Results in Academic Life Science, Evidence From a national survey of Faculty" (1997) 277:15 Journal of American Medical Association 1224 at 1224-1228. **[Tab 17]**

23. Unfettered and timely sharing of research results is a fundamental requirement for scientific advance.

> Openness in the sharing of research results is a powerful ideal in modern science ….communalism, the shared ownership and free exchange of research results and approaches, is a fundamental norm underlying the social structure of science. Such sharing is critical to the advancement of science, for without it researchers unknowingly build on something less than the total accumulation of scientific knowledge, and scientific work is slowed by problems for which solutions already exist but are unavailable. …External pressures (for breaching the ideal of openness) include…processes and procedures related to the commercialization of university research." (p1)…Recent studies have shown that 58% of life-science companies that sponsor academic research typically require investigators to refrain from publishing research results for more than 6 months, and that nearly 20% of life-science faculty admitted to withholding data from publication for more than 6 months to protect the commercial value of the results.
>
> Blumenthal *et al*., *Ibid*. **[Tab 17]**
>
> Blumenthal *et al*., "Participation of Life-Science Faculty in Research Relationships with Industry" (1996) 335 N. Eng. J. Med.1734 at 1734, 1737 and 1738. **[Tab 18]**

24. In addition to contributing to delay in the publication of scientific results, the commercialization of science, including through patenting of results, may be undermining the integrity of scientific publications, in the opinion of the editors of leading journals including Nature and Nature Neuroscience, "Commercial considerations may also lead to a culture of secrecy, including delays in publication while patents are filed…The most serious concern, however…is that conflicts of interest may affect what gets published." The editors cited studies showing that studies of drugs and cancer treatments supported by manufacturers have been found more likely to find results favourable to the companies' products than studies not funded by commercial interests.

> "Financial conflicts in biomedical research" (Editorial) (2000) vol.3 No.4 Nature

Neuroscience 299. **[Tab 28]**

25. Nature instituted a new policy in August 2001, applicable to those wishing to publish in the journal due to "suggestive evidence" that publication practices in biomedical research have been influenced by the commercial interests of writers and general concern among researchers and others about the possible undermining of the integrity of scientific research by increasing commercial links and consequent influences. Authors "will be invited" to disclose competing financial interests including funding, employment, personal financial interests and "patents or patent applications whose value may be affected by publication." Those authors who decline to provide the information may still publish, but their refusal to provide disclosure will be reported.

Campbell, P., "Declaration of Financial Interests" (2001) 412:6849 Nature 751. **[Tab 23]**

26. This Court has recognized that biotechnology is "the harbinger of a new era" and that the Court "must therefore be very cautious regarding the scope of our pronouncements." The widespread and diverse potential impacts of life form patents on crucial fields of scientific research are factors which demonstrate the need for this caution.

*Pioneer Hi-Bred Ltd. v. Canada*, [1989] 1 S.C.R. 1623 at 1632. **[Appellant's book of Authorities, Tab 7]**

27. Given the plethora of negative impacts on science resulting from biomedical patents, including the patenting in the United States of the transgenic mammals that are the subject of this application, Canada should not simply follow the U.S. lead in patenting these multicellular life forms which are also important scientific tools. Rather, Canada should consider the full range of impacts from patents to determine how to best protect the public interest in scientists' unfettered exchange of scientific knowledge, research tools, and research results. The extensive information necessary to study crucial impacts from patenting life forms and to devise solutions is not available to this Court. We submit that Parliament is the appropriate forum to conduct a broad study, debate, and public consultation on these questions and then determine whether to patent multicellular life forms, and if so, under what conditions to ensure that the public interest

in the advancement of science is protected and promoted.

**(iii) Equitable Access to Benefits of Biodiversity**

28. Concerns regarding conservation of biological diversity led to the conclusion of the *Convention on Biological Diversity* at the United Nations Conference on Environment and Development, in Rio de Janeiro in 1992. Canada ratified the Convention on December 4, l992. Countries expressed concern that biological diversity (the variability among living organisms from all sources, including diversity within species, between species and ecosystems) is being significantly reduced by certain human activities.. Equitable access to genetic resources for people in developing countries is also an issue of international concern. The *Convention* 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.

> *Convention on Biological Diversity*, June 5, 1992, Na. 927807 (UNEP) **[Tab 1]**
> Canadian Instrument of Ratification, December 4, 1992. **[Tab 2]**

29. The patenting of life forms may interfere with equitable access to the benefits of biodiversity as patents result in exclusive rights over the life forms that are the subjects of the patents. 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 developing countries. The approach of the *Convention on Biological Diversity* 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 exclusive rights and resulting economic benefits, would reflect a lack of such a balance.

> *Convention on Biological Diversity*, *Supra*. Article 1. **[Tab 1]**

> Nijar, G. S. & Chee, Y. L., "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. 277 at 278, 281, 283 and 285. **[Tab 40]**

Africa-Europe Faith and Justice Network, "Equitable Protection for Intellectual Property in Africa: The African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders and for the Regulation of Access to Biological Resources - Action Plan 2002" at 11-12, online: Africa-Europe Faith and Justice Network <http://www.aefjn.org> (last accessed: 15 March 2002). **[Tab 11]**

30. A growing global concern regarding the patenting of life forms is the possible inappropriate exploitation of indigenous peoples' knowledge to the benefit of the patent holder. Applicants for patents need not identify the geographic origin of genetic materials claimed, nor whether the purported invention was developed using the knowledge of indigenous peoples. This results in a risk of misappropriation of indigenous knowledge, through patenting, without the consent of the peoples whose knowledge has been used and/or without appropriate compensation to them. Allowing patents on life forms, including mammals, without a system for testing novelty related to indigenous knowledge, considering equitable access issues and ensuring compliance with the *Convention* will only exacerbate these problems since the *Patent Act* was never intended to apply to life forms when it was enacted and accordingly was not designed to deal with such issues.

Bystrom, M., Einarsson, P. & Nycander, G. A., "Fair and Equitable: Sharing the benefits from use of genetic resources and traditional knowledge" (1999) Swedish Scientific Council on Biological Diversity at 48. **[Tab 22]**

Africa-Europe Faith and Justice Network, *Supra*. at pages 11-12. **[Tab 11]**

Khor, M., "A worldwide fight against biopiracy and patents on life" (2002) online: Third World Network <http://www.twnside.org.sg/title/pat-ch.htm> at 2 (date accessed 18 February 2002). **[Tab 31]**

European Patent Office "Neem tree oil" case: Abstract of Patent #EP0436257 revoked, online: European Patent Office Press <http://european-patent-office.org/news/pressrel/2000_05_11_e.htm> (date accessed: 15 March 2002) **[Tab 27]**

31. "Farmer's Rights" mean "rights arising from the past, present and future contributions of farmers in conserving, improving, and making available plant genetic resources, particularly

those in the centres of origin/diversity." The UN Food and Agriculture Organization (FAO) Commission on Plant Genetic Resources introduced this principle of Farmers' Rights in Resolution 5/89 which was unanimously adopted by all member countries as an Annex to the International Undertaking on Plant Genetic Resources for Food and Agriculture. The Undertaking, originally adopted by the FAO Conference in 1982 has 113 adherents. Canada expressed a reservation to the 1983 Undertaking, but the Resolution 5/89 included all members, both signatory and non-signatory. Patenting seeds or other agricultural resources thus developed over millennia may contradict the Farmers' Rights recognized by Resolution 5/89. This is a concern to farmers in both developed and developing countries as well as to indigenous farmers. The *Patent Act* does not recognize and protect farmers' rights in life forms, whether animal or plant, again since it was never originally intended to apply to life forms. In considering whether to patent higher life forms in Canada, the existence of Farmers Rights should also be considered with appropriate legislative protection for these rights. Parliament is the body which could enact such protections.

> *International Undertaking on Plant Genetic Resources*, UN Food and Agriculture Organization, 29 November 1989. **[Tab 3]**
>
> *International Treaty on Plant Genetic Resources for Food and Agriculture*, UN Food and Agriculture Organization, 3 November 2001. **[Tab 4]**
>
> International Undertaking on Plant Genetic Resources (background material), online: FAO Website: <http://www.fao.org/ag/cgrfa/IU.htm> (date accessed: 15 March 2002). **[Tab 5]**

**(iv) Environmental and Human Health Hazards**

32. To the extent that patents play a role in fostering the research and development of biotechnology and in encouraging financial investment and commercial application of biotechnology, patents on life forms may indirectly contribute to the risks associated with the products of biotechnology. The consequences may be unexpected and widespread, given the capacity of living modified organisms to replicate themselves and the potential for gene flow from modified organisms to other organisms. The *Patent Act* does not contain safeguards

regarding these risks as it was not intended to apply to higher life forms.

33. A report by the Royal Society of Canada, released in 2001, provides a thorough review of the environmental and human health risks associated with biotechnology and food. This report and other scientific literature demonstrate that the potential environmental and health hazards are of sufficient concern to warrant continuing investigation and a precautionary approach.

> *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology of Food Biotechnology in Canada*, An Expert Panel Report on the Future of Food Biotechnology prepared by the Royal Society of Canada, (Ottawa: January, 2001). **[Tab 7]** [Hereinafter referred to as the "Royal Society of Canada Report"]

34. In November of 2001, the Government of Canada released an Action Plan to respond to the Royal Society Report. The Government of Canada does not contest the findings of risks identified by the Royal Society.

> Action Plan of the Government of Canada in response to the Royal Society of Canada Expert Panel Report, *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology of Food Biotechnology in Canada*, (Ottawa: 23 November 2001). **[Tab 10]**

35. This Court has recognized the value of a precautionary approach to issues involving environmental risk.

> *114957 Canada Ltée (Spraytech, Société d'arrosage) and Services des espaces verts Ltée/Chemlawn v. Town of Hudson*, 2001 SCC 40 at paras. 31 and 32 **[Tab 6]**

36. Examples that indicate the types of hazards that patenting life forms promotes include risks from genetically-modified foods, and diverse ecological interactions of genetically-modified organisms.

**Risks to Human Health**

37. There are two sources of concern regarding potential harm to human health from foods that have been genetically modified, toxicity and allergenicity.

38. There is the potential for increased exposure to toxicologically active components of genetically modified food in our diets but the dangers are unclear since, as the authors of the Royal Society of Canada report noted, they were "unaware of any validated study protocols currently available to assess the safety of GM foods in their entirety (as opposed to food constituents) in a biologically and statistically meaningful manner."

Royal Society of Canada Report, *Supra.* at 46, 47 and 48 **[Tab 7]**

39. Genetically modified food may increase the potential risk for causing allergic reactions, especially as advances are made in the scope and range of genetic modifications, consumption of such foods increases, and more innovative transgenic combinations are introduced. Risks may arise from the type of genes inserted into foods (i.e. A Brazil nut gene in soybeans) , and increases in a consumers' total dietary exposure to the allergen. A person who is allergic to a genetically modified food will have difficulties in identifying allergenic triggers if the genetically modified protein that promotes the allergy is present in several types of food.

Royal Society of Canada Report, *Supra.* at 55, 56 and 58 **[Tab 7]**

Nordlee, J. A., Taylor, S. L. Townsend, J. A. *et al*, "A Identification of a Brazil-Nut Allergen in Transgenic Soybeans," (1996) Vol. 334, No. 11 The New England Journal of Medicine 688 AT 691. **[Tab 41]**

**Environmental Risks**

40. It is difficult to predict the environmental risks associated with genetically-modified crops because there are "diverse ecological interactions that can potentially occur in agricultural and natural plant communities" and rare events that could result in serious ecological impacts are extremely difficult to predict given the limits of conventional ecological experiments.

Royal Society of Canada Report, *Supra.* at 131. **[Tab 7]**

41. However, scientists have identified numerous potential environmental risks pertaining to plants and crops including whether genetically modified plants can become invasive and whether genes can be transferred between genetically modified crops and wild plants. The essential concern is that, because many GM crops have been modified to be resistant to

pesticides, the invasion or gene transfer would lead to the development of "superweeds" resulting in reduced crop yields, disruptions to the ecosystems and losses in biodiversity.

> Mikkelsen, T.R., Andersen, B. & Jergensen, R.B., "The risk of crop transgene spread." (1996) 380 Nature 31. **[Tab 39]**
>
> Boening, D. W. "Biotechnology and Environmental Pollution: Scientific and Ethical Reflections," (1999) Vol. 21, No.1 Environmental Ethics 110. **[Tab 20]**
>
> Bergelson, J., Purrington, C. & Wichmann, G., "Promiscuity in transgenic plants", (1998) 395 Nature 25. **[Tab 16]**
>
> Doyle, J.D., Stotzky, G., McClung, G. *et al.*, "Effects of Genetically Engineered Microorganisms of Microbial Populations and Processes in Natural Habitats," (1995) 40 Advances in Applied Microbiology 237 AT 267. **[Tab 26]**

42. Large quantities of seeds can enter the soil after cropping and emerge in subsequent years essentially as "volunteer" or non-intended crops. However, many of these seeds are herbicide resistant. As noted in the Royal Society of Canada report:

> Unfortunately, herbicide-resistant volunteer canola plants are beginning to develop into a major weed problem in some parts of the Prairie Provinces of Canada. Indeed, some weed scientists predict that volunteer canola could become one of Canada's most serious weed problems because of the large areas of the Prairie Provinces that are devoted to this crop. Of particular concern is the occurrence of gene exchange via pollen among canola cultivars resistant to *different* herbicides …..Such "gene stacking" represents a serious development because, to control multiple herbicide-resistant volunteer canola plants, farmers are forced to used older herbicides, some of which are less environmentally benign than new products. [Emphasis in Original]
>
> Royal Society of Canada Report, *Supra.* at 122-123. **[Tab 7]**

43. Further, there is evidence that where genetically modified crops and wild plants co-exist, there will be a likelihood for gene transfer to take place over time. The ecological importance of this will depend on whether the wild plants with the new transgenes have sufficiently enhanced fitness to increase in numbers.

> Royal Society of Canada Report, *Supra.* at 126. **[Tab 7]**

44. One of the most significant concerns regarding genetically modified organisms relates to potential loss of biodiversity. Concerns over the loss of biodiversity include:

(a) With the increase in use of herbicide resistant crops, weeds will evolve that are genetically resistant to herbicides and thus cause loss of biodiversity by invading natural plant communities;

(b) Wild gene pools of the major crop plants may become contaminated in those regions of the world where the crop originated;

Quist, D. & Chapela I. H. "Transgenic DNA introgressed ino traditional maize landraces in Oaxaca, Mexico" (2001) 414 Nature 541 **[Tab 42]**

(c) Herbicide resistant plants may have impacts on wildlife – the use of genetically modified herbicide tolerant crops could result in severe reductions in weed populations with subsequent negative effects on seed-eating birds, and

Watkinson A. R., *et al*., "Predictions of Biodiversity Response to Genetically Modified Herbicide-Tolerant Crops" (2000) 289:5484 *Science* 1554. **[Tab 47]**

(d) The possibility of engineering crops to grow in marginal lands (wetlands, rainforests, deserts) could lead to the extensive loss of wildlands and their constituent biodiversity

Royal Society of Canada Report, *Supra.* at 126. **[Tab 7]**

Beoning, Dean W. *Supra* at 111. **[Tab 20]**

Watkinson A. R., *et al*., *Supra* **[Tab 47]**

45. Many species of plants have been modified to include genes, such as *Bacillus thuringiensis* (Bt), for the purpose of increasing their resistance to major insect pests. The proliferation in transgenic plants of Bt and its accumulation and persistence in soil, is 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"

(1997) Vol. 30, No.4, Soil Biol. Biochem. 463. **[Tab 24]**

46. There is clear evidence that insects have evolved to resist biological insecticides such as Bt. The appearance of Bt-resistant pest populations could have other negative impacts. First, Bt may no longer be available to organic farmers, threatening their economic viability and the expansion of these types of more sustainable farming practices. Second, Bt resistance may make it less effective as a pesticide ingredient, and cause conventional farmers to use more chemical insecticides.

Royal Society of Canada Report, *Supra.* at 139. **[Tab 7]**

47. Fish farming (aquaculture) is rapidly expanding in Canada and has been accompanied by large numbers of escapes of cultured fish and natural spawning by escaped cultured fish in British Columbia rivers. Potential risks arise from the interaction of cultured and wild fish when farmed fish escape. These risks include predation, competition for food, space and mates, and the transmission of disease and parasites between cultured and wild fish. These risks, in part, lead to a recommendation outlined in Royal Society of Canada report to place a moratorium on the rearing of genetically modified fish in aquatic netpens.

Royal Society of Canada Report, *Supra.* at 151 and 170. **[Tab 7]**

48. There is a growing body of literature that suggests that modification in transgenic animals may induce undesirable changes in an animal's physiology and behaviour.

49. As the Royal Society of Canada report notes, "these results inevitably trigger major animal welfare concerns and require full consideration prior to the release of the technology."

Royal Society of Canada Report, *Supra.* at 91-92 and 101. **[Tab 7]**

50. To the extent that life-form patents provide an impetus to biotechnological research and development, they increase the possibility of the environmental and human health hazards identified by scientists. 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. Since the Patent Act was not intended to apply to life forms, it does not include safeguards regarding possible impacts of life patents. Therefore, 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 which could include adoption of precautionary protections.

**D. Conclusion**

51. 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.

52. 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:

- Whether such patents are a spur or a deterrence to innovation in medical fields;
- What the thresholds should be for novelty, inventiveness and utility;
- What the duties of patent holders should be regarding licensing their patented inventions, particularly regarding licensing in the public sector;
- Whether the results of research in the public sector, or funded by public monies, should be placed in the public domain rather than being patented;
- Whether an exemption to patent rights should be made available to researchers;
- What legal remedies should be made available to developing countries to ensure equitable access to genetic resources and products of medical research;
- Mechanisms for ethical review in the patenting decision-making process;
- Provisions to protect the rights of farmers in the use of plants or animals;

- Provisions to facilitate the rapid dissemination of scientific research results;

- Assessment of environmental and human health risks as an element of decision-making regarding patenting of plants and animals and consideration of potential safeguards.

> Bobrow, M. & Thomas S., "Patents in a genetic age: The present patent system risks becoming a barrier to medical progress" (2001) 409 Nature 763 at 763-764. **[Tab 19]**
>
> Barton J. H. & Strauss J., "How can the developing world protect itself from biotech patent-holders" (2000) 406 Nature 455. **[Tab 14]**
>
> Barton J. H., "Intellectual Property Rights: Reforming the Patent System" (2000) Vol. 287, No. 5460 Science 1933. **[Tab 15]**

53. 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 question of life-form patenting involves serious matters of public policy, and controversy, including questions of scientific, ethical, social 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.

## PART IV: ORDER SOUGHT

54. These Interveners therefore request that the appeal be allowed and the judgement of the Federal Court, Trial Division be restored.

Respectfully submitted by

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