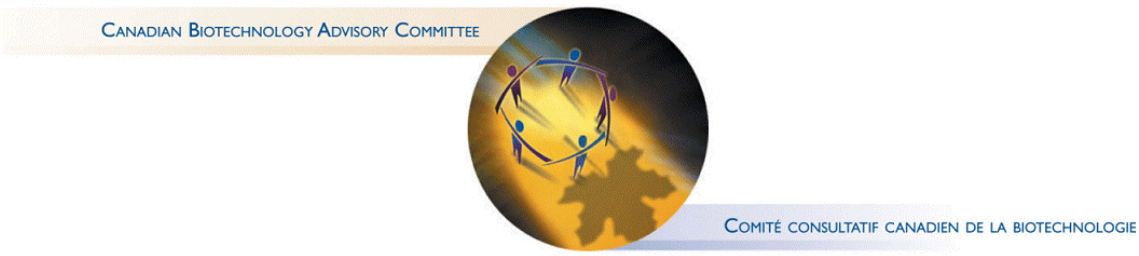

February 24, 2003

Canadian Biotechnology Advisory Committee
Advisory Memorandum

Higher Life Forms and The *Patent Act*

Background

In early 2000, the Canadian Biotechnology Advisory Committee (CBAC) initiated a research and consultation project on the patenting of higher life forms and related issues.

In August 2000, the Federal Court of Appeal found in favour of Harvard, which had appealed the decision of Canada's Commissioner of Patents to refuse to grant a patent on its onco-mouse, a genetically modified strain used in medical research. Shortly thereafter, CBAC issued an Advisory Memorandum addressing the issues raised by the appeal court's ruling.

In October 2000, government lawyers representing the Commissioner of Patents filed an application seeking leave to appeal the decision to the Supreme Court of Canada (SCC). Leave was granted, and in May of 2002, the Supreme Court heard the case.

In the meantime, CBAC proceeded with its project on the patenting of higher life forms and related issues. It commissioned background research, held workshops with scientists, industry members, and non-governmental organizations, developed a consultation document to guide national consultations, held roundtable meetings in five regional centres, invited comments from the public by email, telephone and letter, and issued an interim report in November 2001. After taking account of all the earlier input and the responses to the interim report, CBAC issued its recommendations in its report of June 2002.

On December 5, 2002, the Supreme Court of Canada issued its decision in the case of *Harvard* v. *The Commissioner of Patents*, concerning the patentability of the Onco-mouse.

The CBAC Report

CBAC's report, *Patenting of Higher Life Forms*, addressed and made recommendations on three categories of issues:

- matters pertaining to the patenting of higher life forms,
- other matters of principle related to biotechnological intellectual property, and
- operational issues in the current patent system.

The majority of CBAC members recommended that non-human higher life forms (defined as seeds, plants and animals) be patentable, *subject to* the incorporation of certain provisions in the patent regime. Annex A contains an overview of the final report and the complete List of Recommendations.

The Supreme Court Decision

The only question before the Supreme Court of Canada was whether Harvard's onco-mouse was a "composition of matter" and therefore fit within the definition of "invention" in section 2 of the *Patent Act*. In a 5-4 decision, the Court ruled that the mouse was not a composition of matter and, therefore, was not an invention.

The majority pointed out that it was not up to the courts to decide whether higher life forms *should* be patentable. Justice Bastarache wrote that, due to the controversial nature of patenting of higher life forms and the complex issues raised, higher life forms should only be considered to be patentable under the clear and unequivocal direction of Parliament.

The Court also noted that the *Patent Act* is currently ill-equipped to deal with the complex issues that arise in relation to higher life forms; the Court considered this an indication that it was not Parliament's original intent to patent higher life forms. The fact that genetically modified higher life forms are living and self-replicating raises concerns and issues that other types of inventions do not.

Some of the matters mentioned by the majority in their decision related to recommendations in CBAC's final report on the patenting of higher life forms, namely:

- farmers' privilege
- innocent bystander protection
- a research and experimental use exception from claims of infringement
- non-patentability of humans at all stages of development.

The minority of the Court concluded that Harvard's onco-mouse was a composition of matter and therefore patentable. Despite this conclusion, the justices were not prepared to rule that the patents should be granted; rather, they would have sent the patent application back to the Commissioner to re-examine the patent claims related to the entire mouse.

The majority decision quotes fairly extensively from the CBAC report and the minority refers to it, noting that its recommendations were properly directed to Parliament. Both use the report in support of their arguments.

Congruence between the SCC decision and CBAC's Conclusions and Recommendations

Both the majority and the minority opinions made a number of references to CBAC's report. Without endorsing specific recommendations, the Court cited the CBAC report a number of times, as providing useful information for discussions about patenting of higher life forms.

The Supreme Court of Canada was in agreement with the issues CBAC identified as being within the purview of the *Patent Act.*

> …several of the issues raised by the intervenes and the literature are more directly related to the patentability and to the scheme of the *Patent Act* itself. These issues which pertain to the scope and content of the monopoly right accorded to the inventor by a patent, have been explored in depth by CBAC, …the report recommends that higher life forms should be patentable. Nonetheless, it concludes, at p.7, that given the importance of issues raised by the patenting of higher life forms and the significant "values" content of the issues raised, Parliament and not the courts should determine whether and to what degree patent rights ought to extend to plants and animals.
>
> Para. 169

Furthermore,

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

In both opinions, the justices made it clear that human beings are not patentable, although they differed on whether it would be necessary to spell this out in the *Patent Act*.

The majority also acknowledge that the judicially created research exemption may no longer provide suitable guidance because the legislation being considered in the court case which established it has since been changed. The Court identified many of the same points raised by CBAC about the need to clarify what researchers may and may not do without requiring a licence from the patent-holder. Such a clarification would benefit both researchers and patent-holders.

The Supreme Court also concurred with CBAC's approach to dealing with many of the wide range of peripheral issues that various groups sought to use as justification for changes to the *Patent Act*. The SCC argued, for example, as had CBAC, that:

> These issues are only tenuously linked to the patentability of higher life forms and more related to the development and use of the technology itself… It is preferable to address this issue through existing or new regimes for protecting animal welfare. Similarly, if it is determined that additional measures are needed to protect the environment from the products of biotechnology, this may be effected through the *Canadian Environmental Protection Act*, R.S.C. 1985,c. 16 (4th Supp.), or other comparable regulatory mechanisms.
>
> Para. 168

Implications of the SCC decision

Several inventors and developers expressed disappointment in the Supreme Court decision. BIOTECanada, in a news release issued the day of the decision, went so far as to say that it "stops our pursuit of knowledge and innovation dead in our tracks. It is a great loss to Canada at both the social and economic level." Yet, at a certain level, nothing has changed. Canada's Patent Office still does not grant patents on higher life forms while those of most other OECD countries do. Inventors and developers are still free to apply for these patents outside Canada. Even within Canada, they can still apply for patents on modified DNA sequences in higher life forms or the processes used to create them. The full impact of the Supreme Court's decision requires further in-depth analysis and will be on CBAC's agenda in the coming months. Nonetheless, there is immediate concern that inventors and developers who were anticipating that the Federal Court of Appeal ruling would be upheld may view the Supreme Court of Canada ruling as an indication that Canada is not sufficiently supportive of biotechnology.

If the availability of patents on higher life forms is seen by the biotechnology industry in Canada as crucial to their ability to continue growing, one implication of the Supreme Court's decision will be pressure on the government to bring Canada's patent regime into line with those of its main trading partners. CBAC saw this as an important argument in favour of higher life forms being patentable. However, as noted in our report, higher life forms are different from other types of inventions. Simply amending the *Patent Act* to declare them patentable, without addressing their special characteristics, was not seen by CBAC as an appropriate way to achieve that end.

The patent regime is not the only way in which governments in Canada, both federal and provincial, support biotechnology. It should be remembered that, although other countries have allowed patents on higher life forms for many years, the biotechnology industry/sector has flourished in Canada, to where this country is now second in the world in the number of biotechnology companies. Other mechanisms may be available

for encouraging research and development in Canada, such as the legislated research exception proposed in our report.

Sorting out the implications of the special characteristics of higher life forms for the patent regime will not be accomplished overnight. Taking the time to do so carefully and thoroughly, however, is, in CBAC's view, a worthwhile endeavour. Working through the questions raised by CBAC and mentioned in the Supreme Court decision does not mean that researchers, inventors, and industry are unprotected in the meantime. Most patent applications contain many claims. For example, although Monsanto was not granted a patent on Round-Up Ready canola, its patent on the particular modified gene sequence which conferred the "readiness" enables it to exercise its patent rights over the plants in which that modified gene sequence appears.

Conclusions

If the Government of Canada wishes higher life forms to be patentable, it must propose amendments to the *Patent Act* and gain Parliament's agreement. Patentability can no longer be extended, as it has been in other countries, and was in Canada with regard to single-celled organisms, through administrative or judicial action. This gives Canada the unprecedented opportunity to ensure that the special characteristics of biological inventions are taken into account throughout the *Patent Act* and not only in the definition of "invention".

We encourage the Minister of Industry to introduce, as soon as is practicable, amendments to the *Patent Act* based on our Recommendations 1-5 (making non-human higher life forms patentable with certain safeguards), 10 (guidelines for biotechnological inventions) and 13 (opposition procedure).

CBAC further encourages the Government of Canada to identify responsible departments and/or mechanisms for addressing

- the non-*Patent Act* issues identified in Recommendations 6-9 (liability, access to genetic resources, benefit-sharing, and handling of traditional and local knowledge), and
- other issues raised by biotechnology, such as the impact of biotechnological inventions on regulatory systems, the impact of gene patents on access to health care and sustainability of the health care system, and the availability of highly qualified personnel.

Annex A

Following is an overview of CBAC's June 2002 report together with the complete List of Recommendations.

Patenting of Higher Life Forms is a report to the Biotechnology Ministerial Co-ordinating Committee of the Government of Canada that arose from a project undertaken by the Canadian Biotechnology Advisory Committee (CBAC). The key issue addressed in the report is whether Canada should permit the patenting of plants, seeds and animals. The report identifies a number of factors bearing on that question. In the course of the project, it became clear that the patenting of biological material generally (whether DNA sequences, breast cancer genes, microbes, or Harvard mice) raised a number of additional issues worthy of consideration.

In arriving at our recommendations, we have commissioned research, consulted with stakeholders and the public, and considered comments received in response to an Interim Report. The present document follows the general structure of the Interim Report, except that some of the descriptive material presented there now appears in annexes to this document in order to keep the focus on our recommendations. In formulating our recommendations (reduced to 13 from 16), we took into account a Statement of Principles and Values we adopted to guide our activities.

The report is divided into four major topic areas:

Social and Ethical Concerns Raised by Biotechnology: This section of the report, describes a number of social and ethical concerns arising from or linked with the development of biotechnology. It summarizes three possible approaches to addressing these considerations.

Patentability of Higher Life Forms: After addressing the issue of the patentability of human beings, this section of the report describes the main arguments supporting or opposing the patenting of plants, seeds and animals. Four of the five recommendations in this section are linked and should be considered as a group.

Other Issues Related to Biotechnology and Intellectual Property: This section deals with other issues of a social or ethical nature that are clearly linked to the patent regime. It contains recommendations about liability for damage caused by the unwanted spread of products of biotechnology, access to genetic resources, benefit-sharing, and protection of traditional knowledge. This section also draws attention to recent developments concerning the impact of biotechnology patents on the health care system.

Improving the Administration of the Patent System: This section contains a series of comments and recommendations concerning both the operation and the policy orientation of the Canadian patent system. The advice provided to the Government of Canada in this section is intended to ensure that Canada's patent policies and procedures keep pace with developments in the Canadian biotechnology industry, while ensuring that the appropriate balance between inventors and citizens is maintained. The focus of this section is to identify a series of measures to strengthen the patent system.

List of Recommendations

Human Beings Not Patentable

1. We recommend that the *Patent Act* be amended to include the following statement: *No patent shall be granted on human bodies at any stage of development.*

Patentability of Higher Life Forms

2. We recommend that higher life forms (i.e., plants, seeds and non-human animals) that meet the criteria of novelty, non-obviousness and utility be recognized as patentable. The scope of the patent rights in respect of these higher life forms is to be determined in accordance with Recommendations 3, 4 and 5.

Farmers' Privilege

3. We recommend that a farmers' privilege provision be included in the *Patent Act*. It should specify that farmers are permitted to save and sow seeds from patented plants or to breed patented animals, as long as these progeny are not sold as commercial propagating material or in a manner that undermines the commercial value to its creator of a genetically engineered animal, respectively. The drafting of this provision must be sensitive to the differences that exist both in the nature and use of plants and non-human animals.

Innocent Bystanders

4. We recommend that the *Patent Act* include provisions that protect innocent bystanders from claims of patent infringement with respect to adventitious spreading of patented seed or patented genetic material, or the insemination of an animal by a patented animal.

Research and Experimental Use

5. We recommend that the *Patent Act* be amended to include a research and experimental use exception that includes the following statement:

   It is not an infringement of a patent to use a patented process or product either:
   (a) privately and for non-commercial purposes, or
   (b) *to study the subject-matter of the patented invention to investigate its properties, improve upon it, or create a new product or process.*

Liability for Damages

6. We recommend that Canada actively participate in international negotiations to address issues of liability and redress for adventitious spreading of patented seed, genetic material, or the insemination of an animal by a patented animal.

Access to Genetic Resources and Benefit-Sharing

7. We recommend that the federal government, in consultation with other levels of government and other stakeholders, develop policies and practices that encourage the sharing of the benefits of research involving genetic material. In particular, we recommend that:

   (a) the benefits of medical and pharmaceutical research based on human genetic material (including its commercial exploitation) be shared with the groups or communities who provided the material. All bodies (public, private, and corporate) involved in funding research and/or establishing guidelines or codes of conduct for the ethical conduct of research should ensure that benefit-sharing is addressed. Health Canada should lead an initiative to engage all stakeholders in developing best practices in regard to benefit-sharing for research involving human subjects.

   (b) with respect to research based on plant and animal genetic material, Canada :
   - continue to participate in the ongoing processes of the Convention on Biological Diversity to address outstanding issues with respect to the voluntary Bonn *Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization* (such as user country obligations and consideration by the Working Group on Article 8(j) of the *Guidelines by Indigenous and Local Communities)*;
   - encourage and facilitate compliance with the Bonn *Guidelines* within Canada as well as internationally;
   - sign and ratify as soon as possible *the International Treaty on Plant Genetic Resources for Food and Agriculture,* participate in the development of the standard material transfer agreement, including provisions requiring benefit-sharing, and encourage and facilitate their use within Canada; and
   - generally encourage and facilitate benefit-sharing arrangements between the users of genetic resources and traditional and local communities within Canada.

Traditional Knowledge and Intellectual Property

8. We recommend that Canada support the efforts being undertaken in the World Intellectual Property Organization working group on Genetic Resources, Traditional Knowledge and Folklore to determine whether a form of intellectual property could be developed with respect to traditional knowledge.

9. We recommend that the Canadian Intellectual Property Office provide guidance to patent examiners on assessing as “prior art” traditional knowledge that has been made public through oral as well as written or published transmission.

Guidelines for Biotechnological Patents and Processes

10. We recommend that the Canadian Intellectual Property Office develop and publish interpretative guidelines concerning biological inventions. The guidelines should be updated on a regular basis and should provide direction to applicants and examiners, notably on:
    a) the interpretation of the criteria for issuing a patent (i.e., novelty, non-obviousness, utility and breadth of claims) as they relate to biological inventions, and
    b) the process to be followed by patent applicants and the benchmark time frames for each step, to the extent (if any) that these may differ from other patent applications.

Service Standards and Performance Reporting

11. We recommend that the Canadian Intellectual Property Office :
    (a) regularly update its service standards, based on best international practice, for processing patent applications, and
    (b) report regularly on its performance with respect to those standards and the steps being taken (such as increasing capacity and/or expertise) to meet them.

International Harmonization

12. We recommend that Canada pursue further harmonization of patent policies and procedures at the international level by:
    a) continuing to participate in international initiatives to harmonize patent law policy, such as reform of the *Patent Cooperation Treaty*, the work of the Substantive Patent Law Committee, and work under the Agenda for Development of the International Patent System (the Patent Law Agenda), and
    b) ratifying, as soon as possible, the *Patent Law Treaty*, which addresses the formal requirements for filing patent applications and maintaining patents.

Opposition Procedure

We recommend that the government introduce an opposition procedure into the *Patent Act* to permit a patent to be opposed on the grounds that it is invalid or void. As it is essential that this process be faster, less cumbersome and less expensive than the procedures currently available, we recommend that the time limit for filing oppositions be six months from the date the patent was granted and that procedures be established and resources provided to ensure that proceedings are concluded within 18 months from the date the patent was granted.