

Canadian Biotechnology  
Advisory Committee

# BIOTECHNOLOGY AND INTELLECTUAL PROPERTY: Patenting of Higher Life Forms and Related Issues

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Interim Report to the Government of  
Canada Biotechnology Ministerial  
Coordinating Committee

## EXECUTIVE SUMMARY



BIOTECHNOLOGY AND  
INTELLECTUAL PROPERTY:  
Patenting of Higher Life  
Forms and Related Issues

Interim Report to the Government of Canada  
Biotechnology Ministerial Coordinating Committee

Canadian Biotechnology Advisory Committee

November 2001

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Biotechnology and Intellectual Property: Patenting of Higher Life Forms  
and Related Issues

Canadian Biotechnology Advisory Committee

240 Sparks Street, Room 570E

Ottawa ON K1A 0H5

Comments on the Interim Report should be submitted by March 15, 2002.

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# Executive Summary

This summary is intended to present not only the array of draft recommendations proposed by CBAC, but also the background and context against which the major facts and arguments considered in arriving at those recommendations must be understood. As a result, this summary is rather longer than is usual in most interim reports of this nature. Because of its length, this summary contains the same section headings as does the main body of the interim report.

## Introduction

### *Background*

The Government of Canada has consistently expressed its support for biotechnology as one of the key sectors in the knowledge-based economy. An important element of the 1998 renewal of the Canadian Biotechnology Strategy (which began in 1983 under a different name) was the creation of an expert, arm's-length committee to advise the government on biotechnology issues, raise public awareness and engage Canadians in discussions on biotechnology matters.

The Canadian Biotechnology Advisory Committee (CBAC) was established to provide the government with advice on crucial policy issues associated with the ethical, social regulatory, economic, scientific, environmental and health aspects of biotechnology from a group of independent members (see Annex A for list of members). It provides its advice to the Biotechnology Ministerial Coordinating Committee (BMCC), which includes the federal Ministers of Industry, Agriculture and Agri-Food, Health, Environment, Fisheries and Oceans, Natural Resources, and International Trade. More information on CBAC and its activities, including other consultation topics, as well as information on biotechnology in general, is available on the committee's Web site: [www.cbac-cccb.ca](http://www.cbac-cccb.ca).

In early 2000, CBAC initiated a policy research and consultation program (see Annexes B and C for details) on the patenting of higher life forms and related issues. It chose this topic as a priority issue for consultation, as government officials had identified intellectual property issues relating to biotechnology in general and the patenting of higher life forms in particular as areas of immediate concern. Most OECD members, including the United States and the members of the European Union, permit plants and animals to be patented. Many developing countries, on the other hand, have concerns about the impacts of biotechnology patenting in the absence of recognition of traditional knowledge. In addition, some hold the view that patents should not be permitted, not only on plants and animals, but on any biological material (DNA sequences, genes, cells) at all. Currently, Canada does not permit patenting of higher life forms, Canada has not addressed either concerns about innovation and investment or about the effects of and implications of biotechnology. Even among countries that do consider higher life forms to be patentable, there is no consensus on how associated social and ethical considerations should be addressed.

The World Trade Organization (WTO) Agreement on the Trade-Related Aspects of Intellectual Property (TRIPs) addresses the patentability of higher life forms in Article 27.3(b), which allows member countries to exclude plants and animals from patentability. When the mandated review of this section takes place, some countries (mostly developing nations) can be expected to support expanding this section, while other countries (most notably the United States) will likely want to either narrow or eliminate this exception. Canada will be better able to contribute to this debate by developing a domestic policy prior to the commencement of these negotiations.

In order to address all of these issues, CBAC commissioned a number of research studies, organized three stakeholder roundtables (with non-governmental organizations, university scientists and industry) and reviewed public opinion research. Next, CBAC released a Consultation Paper to seek input from Canadians both directly and through a series of multi-stakeholder roundtable discussions held across the country in the spring of 2001. This variety of activities is part of CBAC's continuing effort to ensure that all Canadians have opportunities to participate in these important public discussions about biotechnology in Canada.

### ***Structuring the Debate***

During the consultation phase of the project, it became clear that the patenting of higher life forms and other issues concerning the patenting of biological material is too broad and complex a subject to be discussed productively without some organization of the issues and opinions. In order to prepare this report, we synthesized the discussions and comments heard to date to bring into focus various aspects of this complex subject and the divergent views surrounding it (see Annex D). The organizing principle for the synthesis was the extent to which the granting of intellectual property rights should be conditioned by social and ethical considerations.

Such a broad spectrum of views of the role of the patent system in society generates an equally broad range of preferred solutions to specific questions. In consequence, CBAC acknowledges that consensus on all issues is unlikely, even among its own membership, which itself reflects this diversity. Nevertheless, we have tried, in developing the draft recommendations presented here, to do justice to the major arguments put forward and to provide clear explanations for the tentative positions we have taken in this interim report.

### ***Ethical Context***

A nation's laws, institutions and policies should reflect the predominant values of its citizens. As values or circumstances change over time, the laws and institutions and policies should also evolve to reflect the new reality. CBAC believes that public policy recommendations are, or ought to be, formulated in a way that explicitly recognizes the socio-ethical context in which they are to be imbedded. Ethical judgments about complex issues are not "stand-alone" judgments. Rather, they tend to be "all things considered" judgments that take into account economic, political, legal, scientific, social, environmental and other factors (see Annex E).

Recent advances in biotechnology raise a host of complex issues with significant social and ethical dimensions. There are two general approaches, not mutually exclusive, by which social controls have been imposed on the applications of these advances. One is through interpretation of existing laws and regulations in the courts or other tribunals. The second is through the modification of existing laws and regulations or the creation of new ones. CBAC is of the view that, on questions such as the patentability of higher life forms, the social and ethical considerations are significant enough to warrant the social controls to be developed through the second approach, since the legislative process involves open, public debate and deliberation.

This is not to say that legislation is necessarily the best tool for dealing with all issues that arise in a rapidly changing field such as biotechnology. Moreover, even if legislation is the best option, a single legislated tool such as the *Patent Act* is unlikely to be sufficient to address the several areas where social controls may be necessary or desirable. This is certainly true in dealing with the questions that arise concerning the social controls that should be applied to the array of applications that may be derived from biotechnological intellectual property.

|   |  |   |   |
|---|--|---|---|
| Economic only, social/ethical elsewhere | Economic, with limited capacity for social/ethical | Economic and social/ethical of equal weight | Social and ethical values outweigh economic |
|---|--|---|---|

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## **Key Issues**

The key issues addressed in this interim report concern:

- approaches for addressing social and ethical concerns related to biotechnology
- whether higher life forms (i.e., plants, seeds and animals) should be patentable in Canada
- whether particular uses of patented higher life forms should be exempt from claims of patent infringement
- other issues concerning biotechnology and intellectual property.

CBAC will formulate its final recommendations only after considering the responses to this interim report and further discussion among its members. CBAC welcomes comments on the report and the issues addressed in it from interested parties. These should be received by CBAC before March 15, 2002 in order to be taken into account in the formulation of the final report to the Government of Canada.

## **Organization of the Report**

This interim report synthesizes and organizes CBAC's policy research, the input received in response to the Consultation Paper and through stakeholder and regional public roundtable consultations, and its internal deliberations, and presents draft recommendations on how the Government of Canada might proceed. Following the Introduction, the interim report, including recommendations on the key issues, is divided into six additional sections:

- Biotechnology, Intellectual Property and the Patent System
- Possible Approaches for Addressing Social and Ethical Concerns
- Patentability of Higher Life Forms (Plants, Seeds and Animals)

- Other Issues Related to Biotechnology and Intellectual Property
- Improving the Administration of the Patent System
- Next Steps.

## **Biotechnology, Intellectual Property and the Patent System**

Intellectual property can be defined as non-tangible property that is the result of creativity. It covers a wide range of human activity from literature to invention. Intellectual property rights include copyright, patents, confidentiality or non-disclosure agreements ("trade secrets"), industrial designs and trade-marks. These mechanisms, well established by the 18th century, allow creative persons to protect their innovations from unauthorized use by others. In the field of biotechnology, the primary method of intellectual property protection in the industrialized world is the patent.

A patent gives its holder the right to prevent others from making, using or selling the invention during the life of the patent. In exchange, the patent holder is required to disclose all information about the invention, thus making useful knowledge quickly available to society. To obtain a patent, the applicant must demonstrate that the product or process is new, not obvious and useful. It is crucial for rational debate on questions related to what should or should not be patentable to recognize that patents confer only prohibitive rights. The Canadian patent system is not designed to decide about what uses of technology are permissible nor is the *Patent Act* designed to prevent dangerous or ethically questionable inventions from being made, used, sold or imported. The responsibility and tools for dealing with such matters resides elsewhere (e.g., through regulatory approval or product safety processes).

In Canada, patents have been granted on biotechnological processes, on products made with those processes, on plant, animal and human DNA sequences, genes and cells and on so-called lower-life forms or micro-organisms (single-celled living organisms such as bacteria or yeast). To date, the Canadian Intellectual Property Office (CIPO) has not considered higher life forms to be patentable in Canada (see Annex F for an international comparison), although this view has been challenged through two levels of court and will now be decided by the Supreme Court of Canada.

## Possible Approaches for Addressing Social and Ethical Concerns

Following are some of the most frequently raised social and ethical concerns about the granting of intellectual property rights with respect to living beings:

- *Commodification of Life:* The granting of a patent (that is, the right to prevent others from making, using or selling the invention) is, in effect, a declaration that an invention based on living matter has the potential to be commercialized. The greater the number of patents on biological material, the greater the potential for the purchase, sale or trading of living things or products derived from them, the more likely to be treated as commodities.
- *Benefit Sharing:* Studies of specific populations or groups of people (such as extended families) may lead to patentable inventions; however, there is no requirement that any benefits arising be shared with those whose participation enabled the invention.

- *Traditional Knowledge:* The traditional knowledge of indigenous or local cultures is often used by industry to help identify plants and non-human animals that may have properties of medical or industrial value, thus saving the companies significant effort. Yet, the traditional knowledge of people(s) or communities on which a patented invention was based does not entitle them, under current patent regimes, to receive any benefit from the patent or the invention.
- *Animal Welfare:* Animals may be used in developing or applying patented biotechnological inventions in ways which may lead to impairment of the health and welfare of animals that may not be justified by the degree of human, animal or environmental benefit to be obtained.
- *Abuse of Economic Power:* Patents may have the undesirable effect of providing a means through which multinational corporations create and abuse a dominant position in the production and distribution of food products or health-related products, tests and services.

There is general agreement that social and ethical concerns such as these are important and must be addressed. Where people differ is on whether the *Patent Act* is the most appropriate mechanism for doing so, since it is almost always the commercialization of the invention or the use to which it may be put which raises the social and ethical concerns. Neither use nor sale is governed by the *Patent Act*.



The international Agreement on Trade-Related Aspects of Intellectual Property (TRIPs) allows countries to declare types of inventions unpatentable only if their *commercialization* would lead to a breakdown of public order or otherwise offend the moral values of the society (an “*ordre public* or morality” provision).<sup>1</sup> Among developed countries, the governments of the European Union members, Japan and Korea have decided that inventions with such effects should not be patentable. The governments of Australia and the United States, on the other hand, have generally taken the view that moral concerns should be addressed in specific laws or regulations and not in patent law.

This report categorizes the broad options for addressing social and ethical concerns as follows.

### ***Outside the Patent System***

- *The Status Quo Approach (No Role for the Patent System):* Address concerns about the sale and/or use of inventions through regulatory and other control mechanisms (e.g., *Criminal Code*, regulatory approval processes for new products, etc.).

### ***Within the Patent System***

- *The Alignment Approach (Limited Role for the Patent System):* Allow the Patent Office to suspend the enforceability of a patent if the sale or use of the invention has already been made illegal by other means on the grounds that it would offend “*ordre public* or morality.”
- *The Open-ended Approach (Broad Role for the Patent System):* Allow or require the Patent Office itself to consider whether the commercial exploitation of the invention would offend public order or morality and to deny, suspend or impose conditions on the patent to address matters of “*ordre public* or morality.”

Each of these approaches could be implemented in a variety of ways. Whichever is chosen, it will have to be developed in a manner that is consistent with Canada’s international obligations under TRIPs and other agreements.

CBAC is now requesting further input from all interested parties before we develop specific recommendations for addressing social and ethical concerns related to biotechnology and the patent system. In particular, CBAC would like to know, first, whether this categorization scheme is useful for discussing how to take social and ethical considerations into account. Second, CBAC would like to hear from as many people as possible which of these approaches they view as most likely to be able to effectively address the particular issues that most concern them.

People’s views of the appropriate role of the patent system with respect to biotechnology will depend on the approach chosen to address social and ethical considerations. CBAC is putting forward draft recommendations on other issues now so that it will have feedback both on the possible approaches and on specific issues (recognizing that people’s views of the latter will depend on their views of the former) before final recommendations are formulated.

## **Patentability of Higher Life Forms (Plants, Seeds and Animals)**

Higher life forms are all those living organisms that have more than one cell. Multicellular organisms include all members of the plant and animal kingdoms as well as human beings.

<sup>1</sup> Article 27.2 reads: Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect “*ordre public* or morality,” including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

The patentability of higher life forms is a matter currently before the courts in Canada. The Supreme Court has agreed to hear an appeal against the Federal Court of Appeal decision in favour of Harvard College in respect of the patenting in Canada of the “Harvard mouse.” In the United States and Europe, the patentability of higher life forms has been established through judicial interpretation of existing laws. Europe has incorporated these changes into the laws governing patenting of biological material. In an Advisory Memorandum to the federal government, CBAC urged that, in Canada, this matter be taken up and resolved through a parliamentary process.

### ***Patentability of Human Beings***

Since human beings cannot be owned or enslaved, it has generally been considered that humans cannot be patented. Regardless of the views expressed about patenting of other higher life forms, there is unanimous agreement that human beings *ought* not be patentable. In some countries, such as Australia and Europe, this principle has been explicitly stated in patent legislation. CBAC believes such a statement should also be included in Canada’s *Patent Act*.

#### ***Draft Recommendation: Human Beings Not Patentable***

- 1. CBAC recommends that the Patent Act include a statement that human beings, at all stages of development, are not patentable.***

This recommendation is framed in lay, rather than legal or scientific, language. CBAC is aware that developing appropriate wording to give effect to the intent of the recommendation may be difficult. For example, if the term “human beings” is used, does this mean that parts of humans (e.g., tissues or organs) would become patentable? and would that be acceptable if so? If the term “human body” is used instead, at what point in human development

from or after conception is there a “body”? Even the phrase “at all stages of development” is not straightforward, as it has been defined in European legislation to include sperm and unfertilized eggs. Canada currently permits patents to be granted with respect to human DNA sequences, genes, proteins and cells.

Questions also arise about biotechnological processes that may be applied to humans, whether described as beings or bodies. The recently adopted European Directive on the Protection of Biotechnology Inventions also specifies that inventions which involve cloning of human beings, modifying the germ line identity of human beings and the use of human embryos for industrial or commercial purposes are not patentable because they offend against “*ordre public* or morality.” In Canada, the draft *Assisted Human Reproduction Act* (currently being reviewed by the House of Commons Standing Committee on Health), as currently written, would also prohibit these activities, but would not prevent them from being patented in Canada.

### ***Patentability of Higher Life Forms (Plants, Seeds and Non-human Animals)***

Whether Canada should permit plants, seeds and non-human animals to be patented is not a simple question to answer. Persuasive arguments can and have been made both in favour of and against permitting the patenting of higher life forms. In fact, the TRIPs Agreement specifically allows member countries to exclude plants and animals from patentability on the grounds that their commercial exploitation would offend public order or morality. Such exclusions are specifically permitted to protect human, animal or plant life or health or to avoid serious prejudice to the environment.

Arguments in favour of patenting of higher life forms include:

- The availability of patent protection fosters openness and innovation, which in turn brings scientific knowledge and benefits to Canadian society.
- Patents are necessary to attract investment for R&D and commercialization.
- Since Canada's major trading partners (United States, European Union countries and Japan) permit patents on higher life forms, Canada must do the same in order to remain competitive.
- Patenting of whole plants and animals would allow issues pertaining to such patents to be addressed directly as opposed to the situation in which patents on DNA sequences and genes allow the patent holder to exercise control over the whole organism without such control having been explicitly considered in the patenting process.

Arguments opposed to patenting of higher life forms include:

- Patenting plants and animals gives rise to serious moral and ethical questions that involve issues such as animal rights, biodiversity, economic and environmental concerns, and the commodification or objectification of life.
- The notion that a part or a species of complex animal life should be viewed as an invention of a person or corporation objectifies the natural world.
- Patents on higher life forms are unnecessary, since other patents related to the invention (e.g., on DNA sequences or genes or on the processes necessary to generate an invented plant or animal) sufficiently protect the inventor's rights.

CBAC has not reached a consensus on whether higher life forms should be patentable. The majority of CBAC members who have reached a conclusion are persuaded by the arguments favouring the patenting of higher life forms. One member has found most persuasive the argument that, as life forms have intrinsic value as a part of nature, they should not be patentable.

### ***Draft Recommendation: Patentability of Higher Life Forms***

2. ***CBAC recommends 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, subject to the limits on patent holders' rights contained in draft recommendations 3, 4 and 5.<sup>2</sup>***

### ***Limits on Patent Holders' Rights***

#### ***Farmer's Privilege***

Many farmers have traditionally saved some of the seed from crops for planting the following year. This practice would be an infringement of a patent holder's rights. Farmer's privilege would allow this practice, so long as the next generation of plant or animal was sold as produce and not sold for further replanting or breeding.

#### ***Draft Recommendation: Farmer's Privilege***

3. ***CBAC recommends that a farmer's privilege provision be included in the Patent Act that specifies that farmers are permitted to save and sow seeds from patented plants or to reproduce patented animals, as long as these offspring are not sold as commercial propagating material, in the case of plants, or commercial breeding stock, in the case of animals.***

<sup>2</sup> With respect to plants, Canada has existing obligations with respect to the International Convention on the Protection of Plant Varieties (UPOV) and the Canadian *Plant Breeders' Rights Act*, which would have to be respected in the implementation of this recommendation, were it accepted.

## ***Innocent Bystanders***

Since patented plants and animals may be capable of reproducing on their own, it must be recognized that they will not always do so under the control of the patent holder or subsequent owner or licensee of a patented plant or animal.

### ***Draft Recommendation: Protection from Patent Infringement Claims***

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

### ***Draft Recommendation: Liability for Damages***

5. ***CBAC recommends that Canada actively participate in international negotiations to address issues of liability (such as those currently in progress under the Biosafety Protocol) for undesired natural/accidental spreading of patented seed, patented genetic material, or the insemination of an animal by a patented animal.***

## ***Research and Experimental Use***

Without authorization, research or experimentation using a patented invention to develop new inventions infringes on the patent holders' rights. An experimental use exemption, included in the regime of many countries, attempts to balance the interests of patent holders to commercialize their inventions with those of society to foster further research. In Canada, this aspect of patent law was established by the courts, rather than Parliament. CBAC is of the view that it should be included in the *Patent Act*.

## ***Draft Recommendation: Experimental Use Exception***

6. ***CBAC recommends that the Patent Act be amended to include a research and experimental use exception which states that it is not an infringement of a patent to use a patented process or product for either (a) private or non-commercial study, or (b) to conduct research on the subject-matter of the patented invention to investigate its properties, improve upon it, or create a new product or process. In developing the specific provision, care should be taken to ensure that differential impacts among technologies or economic sectors are avoided.***

## **Other Issues Related to Biotechnology and Intellectual Property**

### ***Addressing Certain Social and Ethical Considerations***

Earlier in this report, CBAC described three general approaches for addressing social and ethical considerations raised with respect to biotechnology, and asked Canadians for their views of those approaches (see p. vii). Here, we present draft recommendations concerning traditional knowledge and benefit sharing that could be implemented no matter which approach may ultimately be favoured.

### ***Draft Recommendation: Benefit Sharing***

7. ***CBAC recommends that the federal research granting councils, the National Committee on Ethics in Human Research and other relevant bodies explore options for sharing the benefits of research (including its commercial exploitation) with the communities or populations involved in the research.***

### **Draft Recommendations: Traditional Knowledge**

8. **CBAC recommends that Canada support the efforts being undertaken in the World Intellectual Property Organization (WIPO) working group on Genetic Resources, Traditional Knowledge and Folklore to determine whether and how intellectual property can be used to protect traditional knowledge.**
9. **CBAC recommends that the Canadian Intellectual Property Office clarify that the description of the existing state of knowledge (“prior art”) in patent applications must include, so far as is practicable, traditional knowledge that has been made public through oral, as well as written or published, transmission.**

### **Effects of Biotechnology Patenting on the Health Care System**

Patented biotechnological inventions are anticipated to have major impacts on Canadian society by virtue of their effects on individual consumers and users of products or processes. In addition, they may impact on Canadians in a collective sense because of their effects on publicly funded services such as those provided through the universal health care system. While such considerations are not confined to health care, recent events have led us to the view that it is particularly timely for a systematic inquiry to see whether the current balance between the rights of patent holders and those seeking access to the benefits of biotechnological innovations in health care is working.

CBAC is also interested in learning whether and to what extent similar issues arise in other sectors and whether similar inquiries should be undertaken in those areas.

### **Draft Recommendation: Research on Impact of Biotechnology on Health Care**

10. **CBAC recommends that a systematic program of research be undertaken on the impact of biotechnology patents on health services, including on:**
  - **the incentive or disincentive effects of patents on biotechnological inventions on the conduct of basic and applied research on preventive, diagnostic, therapeutic, epidemiological and service delivery aspects of health care.**
  - **the effect of patents on the incentives and ability of patent holders or companies to commercialize their inventions, thus making them available to the health care system.**
  - **the effect of patenting of biological inventions on the net cost of health care, including comparative risk-benefit analyses of biotechnological and alternative methods.**
  - **the effect of patenting of biological inventions on factors, other than cost, affecting accessibility to important preventive, diagnostic and therapeutic innovations.**
  - **methods to address concerns about the impact of the cost of new inventions for the health care system (for example, licences, mandatory access, large buyer groups, assessments of medical/health value to support provincial formularies or analogous systems used for other kinds of medical technology).**
  - **the effect of Canada’s international obligations on the various options for addressing the impact of biotechnological patents on the health care system.**
  - **whether there are features of biotechnological or biological patents that suggest they should be treated differently from other patented inventions used in health care.**

# Improving the Administration of the Patent System

## ***Guidelines for Biotechnological Patents and Processes***

Information contained in the Manual of Patent Office Practice concerning biotechnology does not address many of the issues discussed in this paper. It would be beneficial if CIPO were to issue detailed guidelines on the current patentability of biological material and how it evaluates applications. Should higher life forms also be patentable, the guidelines should be expanded. This would be particularly useful for smaller biotechnology companies not experienced in the patent process. These guidelines could be developed with the assistance of an expert advisory panel.

If an “*ordre public* or morality” provision were to be included in Canadian patent law, either under the Alignment Approach or the Open-ended Approach to taking social and ethical considerations into account (see p. vii), guidelines should also be developed concerning the requirements and procedure for applying this provision.

### ***Draft Recommendation: Guidelines for Patents on Biological Material***

11. ***CBAC recommends that the Canadian Intellectual Property Office develop and publish interpretative guidelines concerning biological material. The guidelines should be updated on a regular basis and should provide reasonable direction to applicants and examiners, including on:***
  - ***the interpretation of the criteria for issuing a patent (i.e., novelty, non-obviousness, utility and breadth of claims) as they relate to biological material and/or inventions.***

- ***how traditional knowledge made public through oral transmission is to be described as part of the prior art (see also Recommendation 9).***
- ***the process to be followed by patent applicants and the benchmark time frames for each step.***

## ***Performance Reporting***

Statistical evidence appears to show that CIPO takes longer to issue biotechnology patents than does the United States. While recognizing that these differences may be more apparent than real as a result of differences in data definition and collection, it is imperative that CIPO be able to properly evaluate its performance in relation to other countries, identify its relative strengths and weaknesses and take appropriate steps to maximize the strengths and reduce the weaknesses.

### ***Draft Recommendation: Standards***

12. ***CBAC recommends that the Canadian Intellectual Property Office develop, publish and regularly update service standards, based on best international practice, for processing patent applications.***

### ***Draft Recommendation: Performance Reporting***

13. ***CBAC recommends that the Canadian Intellectual Property Office report regularly on its performance with respect to its service standards and on the steps being taken (such as increasing capacity and/or expertise) to meet them.***

## ***International Harmonization of Patent Law and Procedures***

Due to the relatively large size of their markets, the patenting policies of the United States, Japan and the European Union have more impact on the biotechnology industry in Canada than does Canada's own patenting policy. As a result, the more

aligned Canadian patent procedure and administration is with the laws of its trading partners, the more successful Canada will be in attracting and maintaining investment and in promoting a thriving research community.

### ***Draft Recommendations: International Harmonization***

14. ***CBAC recommends that Canada pursue further harmonization of patent policies at the international level.***
15. ***CBAC recommends that Canada ratify the Patent Law Treaty, which addresses the formal requirements for filing patent applications and maintaining patents, as soon as possible.***

### ***Simplified System for Challenging Patents***

Several participants in our consultation process, especially from the research community, called for easier ways to challenge issued patents, which must now be done through a lengthy court proceeding. Some of Canada's major trading partners have simpler procedures, which allow third parties to oppose the granting of a patent.

### ***Draft Recommendation: Opposition Procedure***

16. ***CBAC recommends that the Canadian Intellectual Property Office establish an opposition procedure to permit a patent to be opposed on the grounds that it is invalid or void (i.e., fails to meet the requirements for patentability, is too broad, was obtained through failure to disclose material information, or intentionally provided information intended to mislead). To be effective, it is essential that this process be faster, less cumbersome and less expensive than the procedures currently available.***

## **Next Steps**

With the release of this report, CBAC enters Phase 3 of its work on intellectual property and the patenting of higher life forms. Phase 3 entails collecting additional input from stakeholders and other interested Canadians on the recommendations presented here, and on the ethical principles and values that CBAC has identified as being central to its work (see Annex E).

CBAC will then analyze the additional input and take it into account in preparing its final report to the Government of Canada. As with all of CBAC's reports, it also will be made available to the public.

As biotechnology as a whole, and the patenting of biotechnology products including higher life forms, is a highly dynamic field, CBAC will continue to monitor developments and may, at a future date, revisit this subject in other consultations. CBAC also continues to monitor and consult with Canadians on other biotechnology areas such as genetically modified foods and a broad framework for addressing overall ethical issues.

Anyone wishing to comment on this report should do so by March 15, 2002. Comments may be submitted either through the Web site at [www.cbac-cccb.ca](http://www.cbac-cccb.ca), by fax at (613) 946-2847, or by mail to CBAC, 240 Sparks Street, Room 570E, Ottawa, Ontario K1A 0H5. Further information on this and other CBAC activities may be obtained through the CBAC Web site or by calling CBAC's toll-free number at 1-866-748-2222.