BIOTECHNOLOGY AND INTELLECTUAL PROPERTY:

Patenting of Higher Life Forms and Related Issues

Interim Report to the Government of Canada Biotechnology Ministerial Coordinating Committee

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Canadian Biotechnology Advisory Committee

November 2001

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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.

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

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).[1] 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.

[1] 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.[2]

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.***

[2] 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 licencee 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, 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.

Patenting of Higher Life Forms and Related Issues

Introduction

Background

This document is an interim report of the Canadian Biotechnology Advisory Committee (CBAC) to the Government of Canada on the patenting of higher life forms and other intellectual property issues related to biotechnology. The purpose of this report is twofold:

- to present to the Biotechnology Ministerial Co-ordinating Committee CBAC's draft recommendations regarding the patenting of higher life forms and related issues
- to invite Canadians to express their views on the issues and draft recommendations.

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.

CBAC was created to provide the government with independent, impartial advice on crucial policy issues associated with the ethical, social regulatory, economic, scientific, environmental and health aspects of biotechnology (see Annex A for a 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.

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In order to address all 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 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 views. 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. The organizing principle for the synthesis is the extent to which the granting of intellectual property rights should be conditioned by social and ethical considerations.

At one end of the spectrum is the view that patents are a purely economic instrument and that social and ethical values have no role to play in determining what is patentable or the scope of patent holders' rights. The extreme version of this view would allow patenting of all invented biological material, up to and including human beings (although it does not appear that anyone has suggested doing so). In the middle of the spectrum are two views: one that there should be a limited role for social and ethical values in the patent system, the other that social and ethical values should have equal weight with the economic values the patent regime promotes. At the other end of the spectrum is the view that social and ethical values should always take precedence over purely economic ones. The extreme version of this view would prohibit patenting of any biological material. In order to facilitate a better understanding of the nature of these positions, Annex D, *Structuring the Debate*, provides a fuller description.

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. CBAC acknowledges that consensus is therefore unlikely. Nevertheless, CBAC has tried in developing the draft recommendations presented here to do justice to all of the arguments put forward and to provide clear explanations for the tentative positions we have taken in this interim report.

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

Ethical Context

A nation's laws, institutions and policies should reflect the values of its citizens. As values and/or circumstances change over time, the laws and institutions and polices should also evolve to reflect the new reality.

Recent advances in biotechnology can have profound economic and social effects. Many predict that this new knowledge and its related applications will have increasingly important impacts throughout the world. These impacts, both positive and negative, will continue to cause many members of our society to raise new issues and to revisit existing values and underlying ethical premises. In some cases, this deliberation may lead to a call for reassessment of a range of existing laws and regulations or the institution of specialized courts. Patent policy as well as the laws and regulations that embody it constitute one of the key areas requiring re-evaluation in the light of the rapid pace of developments in biotechnology and its applications.

Patent systems serve to protect an inventor's creation from unauthorized use by others. They provide an incentive for innovative activity in society by granting the creators, developers and distributors of inventions the potential for an economic reward and by ensuring that information about inventions is publicly available. They reflect the view that there is social value in individuals having a right to benefit from their creativity and innovations. They also reflect the view that the patent system, by making new knowledge publicly available, allows others to build on that knowledge. Patents are thus superior to the main alternative form of intellectual property protection – trade secrets – on which biotechnology inventors are likely to rely.

The public interest is the most important consideration in developing government policies and programs. Public interest embraces, for instance, people's health and quality of life, the health of the environment, a strong national economy and a peaceful global community. It calls for good governance, which in turn requires integrity and transparency of operations, independence from inappropriate influence, openness to the views of Canadians, responsiveness to citizen concerns and the integration of the diversity of Canadians' interests and priorities.

Public policy recommendations are, or ought to be, formulated in this ethical context. Ethical judgments are not "stand alone" judgments; rather, they are "all things considered" judgments that take into account economic, political, legal, scientific and other factors. In developing recommendations on biotechnology, CBAC attempts to integrate these various factors and to develop recommendations that best serve the greater good and overall public interest.

CBAC has identified a set of ethical principles and values (shown in the box on p. 4) for its consultations and discussions with stakeholders and Canadians. These principles represent the ethical lens through which CBAC will conduct its work and make its recommendations. Given the importance of the principles, the committee presented them to roundtable participants to solicit their views on them. Specifically, its members wanted to know if the principles were appropriate and/or if additional ones should be considered. Participants' reactions are presented in Annex E. Public comment is also welcome.

Statement of Principles and Values Guiding CBAC	
Justice	A commitment to ensure a fair distribution of benefits and burdens. A commitment to ensure that policies and practices do not contribute to the oppression of vulnerable groups.
Accountability	A commitment to be transparent and answerable.
Autonomy	A commitment to promote informed choice. A commitment to promote the conditions necessary to allow Canadians to pursue their fundamental values and interests.
Beneficence	A commitment to pursue benefits for Canadians and others throughout the world.
Respect for diversity	A commitment to ensure respect for diverse ways and forms of life.
Knowledge	A commitment to value both scientific and traditional knowledge.
Caution	A commitment to adopt a precautionary approach when knowledge is incomplete.

This statement of principles and values was also presented to roundtable participants in CBAC's other current work, recently published in the interim report titled *Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada.* Suggestions received concerning this statement in the comment periods for both interim reports will assist CBAC in its work toward a global framework for addressing social and ethical considerations associated with biotechnology.

Key Issues

After considering the range of social and ethical issues raised during the consultations on the patenting of higher life forms and proposals for changes to the *Patent Act*, CBAC sought to address a number of interrelated questions:

- Could legitimate views be accommodated without severely limiting the effectiveness of the *Patent Act* in the achievement of its primary goals?
- Would the proposed amendments to the *Patent Act* achieve the goals sought by the proponents. or would other tools be more effective?
- Is the administration of the *Patent Act* the appropriate focus of a dialogue on fundamental values of Canadian society and, if not, what should be the focus?
- Who should decide on the values that should be embedded in Canadian laws and regulations – public service administrators, the courts or the political system?

With regard to the last question, CBAC has concluded that the political system is the appropriate locus for taking decisions on the fundamental social and ethical issues that should be addressed through legislation and/or regulation. For such issues, neither the Canadian Intellectual Property Office (CIPO) nor the courts should play the role of ethical filter, since neither is empowered nor structured to do so. The imposition of ethical and value-based standards on society, whether through legislation or regulation, should be the responsibility of Parliament and the government.

Once the standards of conduct are agreed and imbedded in policy or legislation by the government, then a range of tools – including, in some cases, the *Patent Act* – could be used to attain the agreed values.

CBAC believes that the recommendations made to the government concerning biotechnological intellectual property, the patenting of higher life forms and other matters must be based on what really matters to Canadians. Its current and continuing work on this and other projects will endeavour to ensure that this goal is achieved.

The key issues to be addressed in this paper are as follows:

- approaches for addressing social and ethical concerns related to biotechnology
- whether higher life forms (i.e., plants, seeds and animals) should be patentable and, if so under what conditions
- whether particular uses of patented higher life forms should be exempt from claims of patent infringement.

Organization of the Report

This report synthesizes and organizes CBAC's policy research, input received in response to the Consultation Paper and through stakeholder and regional public roundtable consultations, and its internal deliberations and outlines draft recommendations on how the Government of Canada might proceed concerning the patenting of higher life forms and other relevant patent-related issues. In addition to this Introduction, this interim report is divided into six additional sections, with recommendations on the key issues:

- 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

Charting a sound policy course for the use of biotechnology is challenging in that biotechnology touches on many areas of public interest. The challenge is amplified by the ever-accelerating pace of scientific discovery.

Biotechnology is defined in various ways depending on the context in which the term is used. CBAC defines biotechnology as a body of technical knowledge about living organisms or their constituent parts, and applied biotechnology as those aspects of biotechnology that are used to make products and drive processes that serve social, scientific or economic purposes. The *Canadian Environmental Protection Act* defines biotechnology as "the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms."

Many biotechnology applications may provide significant economic and social benefits in areas such as health, agriculture, the environment and industry. Some applications, however, may involve risks to health or the environment, or challenge the capacity of current approaches to the protection of health and the environment and/or other serious social and ethical questions.

Biotechnology is one of the world's fastest-growing industries, with global demand expected to more than double from $20 billion in 1995 to $50 billion by 2005.[3] Canada is emerging as a significant contributor to this growth.

[3] National Biotechnology Advisory Committee, *Leading in the Next Millennium*, 6th report (Ottawa: Industry Canada, 1998).

Biotechnology's greatest impact, both in Canada and worldwide, is in health care. More than 90 percent of the advanced biotechnology products on the world market are health-related. It is expected that about three quarters of global biotechnology demand will continue to be in this area.

When biotechnological research leads to the invention of a new product or process, the inventors and/or sponsors of the work may seek intellectual property rights to protect those inventions. While other forms of intellectual property (such as trade secrets and plant breeders' rights) do exist, a patent is often the form of intellectual property protection sought for biotechnology innovations. Accordingly, CBAC's work has focussed on this method of intellectual property protection.

A patent gives its holder the right to prevent others from making, constructing, using and selling an invention for 20 years from the date the application for the patent was filed. A person or entity may hold a patent but still be prevented from using the invention due to conflicting property rights or specific laws or regulations. The patent also allows the holder to assign a whole or partial interest in the invention to another. Some inventors have obtained patents and then declared their intention not to enforce their patent rights in order to ensure that their invention and the related new knowledge stays in the public domain and is available to anyone who wishes to use it. Patents are granted on a country-by-country basis.[4] Persons or companies applying for a patent in Canada may also apply for patents for the same invention in other countries. Canadian patents are issued by CIPO under the *Patent Act.*

A patent may be granted on an invention if the invention meets the *Patent Act's* definition of novelty, non-obviousness and utility. For the purposes of patent law (whose definitions are not always in accord with popular usage), a product or process is novel if it has not been disclosed before the filing date of its patent application (subject to a grace period in some countries[5]). The invention is non-obvious if it is not apparent (without the disclosure contained in the patent application) to a person skilled in the art or science to which it relates. It is useful if it has a realistic and substantial industrial application and is operational.

While intellectual property rights were originally designed to reward innovation or creativity, today they are recognized primarily as economic tools. The main purpose of patent systems is to maximize innovative activity in society by granting the creators, developers and distributors of inventions sufficient economic reward. The economic reward comes in the form of a market monopoly. While the monopoly itself does not guarantee financial returns, it does provide the opportunity – market and other forces willing – to earn such returns. This monopoly has limitations. The main one is a time limit – 20 years in most countries.[6] Others include certain exclusions from the scope of the patent monopoly (for example, use of the invention for experimental purposes) and the exclusion of certain inventions if the monopoly would prevent socially useful activities such as medical treatments. A number of these limits are discussed further in later sections of this report.

Although each country applies these general rules slightly differently, the fundamental nature of patent protection is fairly consistent in developed countries. A successful application must include, among other things, information concerning the nature and use of the invention. In Canada, this information becomes

[4] Until recently, a patent application would have to be made in each country. Under the Patent Co-operation Treaty, of which Canada is a signatory, an applicant can file in one country and list the other countries in which a patent is desired. Although the other countries will apply their own patentability criteria, they will treat the application in the original country as an application in their own.

[5] While national laws differ on the nature and extent of the grace period, Canada's *Patent Act* provides a one-year grace period for disclosures made by the inventor or by someone through the inventor.

[6] Canada, as a member of the World Trade Organization and bound by the Agreement on Trade-Related Aspects of Intellectual Property (TRIPs), changed its rules so that patents filed on or after October 1, 1989, receive a 20-year term of patent protection starting from the filing date. Previously, Canada granted patent protection for 17 years from the date the patent was actually granted.

public 18 months from the filing date so that the public (including other researchers) may use some of the information disclosed in the patent application to conduct more research and discovery.

Despite the wide range of inventions that can be patented, there are certain statutory exclusions such as scientific principles and abstract theorems. Courts have also established other exclusions to patentability, some of which are discussed later in this document.

With respect to biotechnology, Canada grants patents on genetic material (DNA, RNA and genes), whether of plant, animal or human origin, provided that they meet the *Patent Act* requirements of novelty, non-obviousness and utility. Biotechnology processes – the means by which new biotechnology products are made – are also patentable. Canada also grants patents on single-celled organisms (also referred to as lower life forms) such as bacteria, fungi, algae, cell lines and hybridomas.[7]

While a primary purpose of patents is to stimulate economic activity by encouraging inventors to commercialize their inventions, the patent holders' ability to actually do so depends on a variety of other legislative and regulatory constraints. For example, before the holder of a patent on a pharmaceutical product can sell that drug in the marketplace, approval must be obtained from Health Canada to ensure that the product is safe and effective. In carrying out the studies that are required to demonstrate safety and effectiveness, the patent holder will have to comply with rules or regulations governing the laboratories in which research is done, the treatment of animals used in early stages of research, and university or hospital rules governing research on human subjects. The approval itself may impose limitations: the product may be sold only by prescription; labelling and warning requirements must be met; and, if too many adverse reactions occur, the drug may have to be withdrawn. Other kinds of limits on patent holders' ability to exploit their inventions may be found in competition law, criminal law and specific statutes such as the draft *Assisted Human Reproduction Act.*

Possible Approaches for Addressing Social and Ethical Concerns

Social and Ethical Concerns Raised by Biotechnology

Biotechnology and its uses raise a number of social and ethical concerns in their own right. How these issues may best be addressed is discussed later in this report. In order to provide a social and ethical context for subsequent sections of this report, some of these issues are described briefly below.

Commodification of Life

The commodification of life (including genetic material) is one of the relatively few ethical concerns identified as arising directly from patenting itself. The granting of a patent, a right, in itself declares that an invention based on living matter has the potential to be commercialized. However, our society distinguishes between different life forms. It allows the buying or selling of plants and animals as property (hence "commodification"), but outlaws slavery (i.e., the buying or selling of humans). If social mores were to change in this regard, the impacts would be far-reaching and should be addressed on a broad societal basis, rather than within the limited purview of the *Patent Act.* In addition, Parliament has no jurisdiction within the *Patent Act* to regulate matters solely pertaining to human life and genetic material, animal ownership and animal welfare that do not involve the patent scheme *per se*. Legislation governing property and

[7] A cell line is a culture of a particular type of cell that can reproduce indefinitely, thus making it "immortal." A hybridoma is a new cell resulting from the fusion of a particular type of immortal tumour cell line, such as a myeloma, with an antibody-producing B lymphocyte. Cultures of such cells can grow continuously and can secrete antibodies against the antigen of interest. While both of these substances originate in cells, once the cell line or hybridoma is created, it is very different from the original cells (for example, those found in the human body). Neither cell lines nor hybridomas exist in nature.

contract rights between individuals, including the ownership of non-human animals and plants, falls under provincial rather than federal jurisdiction.

Benefit Sharing

Canada does not have a formal policy or laws on the sharing of financial benefits of a patented invention with those groups or populations who have contributed to it in some way. During the consultation, some participants identified several situations in which benefit sharing arrangements ought to be considered. Two examples are where the invention depends on access to traditional knowledge (see related discussion below) and where it depends on access to a population or sub-population in the search for the cause of a genetic disease. The diversity of circumstances in which benefit sharing might be applicable implies that a variety of arrangements may be appropriate.

Traditional Knowledge

Some roundtable participants raised concerns about the unequal distribution of the benefits of patents and their possible impingement on cultural norms. They described patents as protecting developed economies but perhaps disadvantaging other cultures in less developed countries.

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 peoples on whose traditional knowledge a patented invention was based are not entitled under current patent regimes to obtain the benefits of the patent or the invention. Many participants believe there is also a moral obligation to share profits resulting from the use of traditional knowledge, and that compensation or royalties must be provided if traditional knowledge is used in research leading to a patentable invention.

Participants also noted that if a patent is granted on a chemical or gene sequence found in a wild plant, that plant acquires a monetary value it did not previously have. This creates an incentive to harvest it, which may result in over-harvesting to the point where the plant becomes an endangered species. If particular communities are using this same plant, its scarcity could affect their culture.

Animal Welfare

Animal Welfare provides another example of a class of social issues raised in the consultations where some of the new applications of biotechnology have the potential to compromise a societal value, the protection of animals from unnecessary suffering.

Abuse of Economic Power

A number of participants in the consultations raised questions about whether patents were having 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. Their recommendations generally included removing patents from inventions altogether or, in the extreme, denying patents on biotechnological inventions. This position raises several issues, including standards that ought to be used to determine whether an unacceptable degree of market power has been developed; if it has developed, whether this power is being abused; the agency within the government most capable of rendering these decisions; and appropriate remedies to be applied to reduce or end the abuse.

Three Possible Approaches

Although patents are primarily concerned with economic incentives, they are not socially and ethically neutral instruments. By providing economic incentives to conduct certain biotechnology research, the patent system encourages activities that have both significant potential for positive and negative ethical, environmental, health and/or social consequences. Most commentators are familiar with

the importance of patents – creating incentives for products such as new medicines, improvements to economic productivity, and contributions to improved human health and welfare. However, some commentators also see a range of potentially negative consequences – commodification of life, inequitable distribution of benefits arising from patents, potential abuse of corporate ownership of genetic resources, among others – being reinforced or precipitated by patents on biological material, including higher life forms.

Patent law has been designed primarily as a tool to protect the rights of inventors, to provide incentives for commercialization of inventions and the dissemination of new patented knowledge. It does not have many of the design or implementation attributes of a general tool designed to regulate social and ethical conduct. In consequence, CBAC has concluded that, in its current form, it provides only a limited means by which to address social and ethical matters, with the primary responsibility resting elsewhere.

As noted, CBAC is of the view that social and ethical considerations are essential underpinnings of effective public policy, and that the full range of legal, regulatory and institutional means needs to be considered when developing policy related to fundamental values.

In its deliberations, CBAC has also sought to identify potential trade-offs among the societal goals and values expressed in the consultations. Because the patent system and society interact in subtle and changing ways, rules and procedures are required that are both robust and flexible so that inventions can be evaluated in the particular context in which they will be used. At the same time, the ethical and social consequences of *not* encouraging certain innovations must be taken into account, in that doing nothing can sometimes be more socially and ethically damaging than encouraging innovation.

In its examination of all these issues, CBAC has sought to identify mechanisms and potential responsibility centres that are empowered to address the matters raised and that are or could be encouraged to examine the incentives and potential limits to be imposed on patents or patent holders. A number of the mechanisms noted fall outside the *Patent Act*, while others are or could be within the patent system. These options are described in the next sections.

Addressing Social and Ethical Considerations Outside the Patent System

The social and ethical issues raised during the consultations on the patenting of higher life forms generally fall into two groups: those related to the commodification of life and those related to the use of biotechnology inventions. The fact that a patent gives its holder the right to prevent anyone else from using, making or (especially) selling the invention by definition turns the invention into a commodity, even if it is not commercialized. As discussed earlier, plants and animals have long been bought and sold. While some people would prefer that animals (and perhaps plants) not be treated this way, commodification does not depend on whether or not patents are permitted.

With respect to controlling or prohibiting the use (or particularly uses) of biotechnology inventions in general and biological inventions in particular, the patent system may not be an effective tool. In general terms, this is because:

- Most activity with ethical implications takes place either upstream or downstream of the reach of the *Patent Act*. Social policy objectives may most effectively be inserted in legislation or regulation at steps that occur before an innovation can be patented or, probably more importantly, when a new invention is brought to the market. Specific legislation (for instance, the proposed federal act to address assisted human reproduction that will prohibit human reproductive cloning) or voluntary mechanisms directed to controlling the particular offensive activity will be more effective than the *Patent Act* at deterring undesirable activity.

- Even if patenting were not allowed, that would not prevent someone from using, selling, reproducing or importing or exporting an invention that some consider morally repugnant. This is because the *Patent Act* grants an exclusive right over a biotechnological invention. Without a patent, anyone who is aware of it – not just the inventor – is free to make, use or sell the invention. Thus, preventing undesirable activity in most cases appears to require specific tailored controls.
- Even if Canada decides not to grant patents over plants and non-human animals, many of its trading partners do. Again, this means that Canada would require a properly constructed regulatory system in order to prevent undesirable products from being imported and used in Canada.

Animal Welfare

With regard to research and experimentation involving animals, by the time a researcher is in a position to file for a patent, any inappropriate harm to the animal resulting from the research will have already been done. Hence, the *Patent Act* can have little, if any, effect in such situations.

The *Criminal Code* prohibits cruelty to animals; provincial and municipal authorities may also have laws or regulations governing the treatment of animals or the operation of facilities where animals are kept.

Voluntary mechanisms such as the non-profit Canadian Council on Animal Care (CCAC) are in place to address animal welfare. CCAC's ethical review system is designed to integrate the needs of scientists, animals and the community at the local level, and to set standards for the care and use of animals in science at the national level. Researchers who receive federal funds (most university and hospital researchers) are required, as a condition of funding, to comply with CCAC standards. While many private companies no doubt adhere to them, they are not obligated to do so.

If new rules and regulations are required to prevent animal suffering, it may be preferable to address them through special mechanisms that build on existing regimes for protecting animal welfare, rather than through the *Patent Act*.

Abuse of Economic Power

Canada and other developed nations all have laws and agencies dedicated to ensuring that corporations are not able to accumulate inappropriate market power or to abuse power they have acquired. The design and administration of these laws is a complex matter requiring considerable expertise and resources. These laws and the related enforcement institutions are applicable to companies in all sectors of the economy, all regions within a country and all technologies in use within the economy. They also establish relationships and agreements with their counterparts in other countries to facilitate enforcement of competition laws where national borders are crossed. In Canada, the Competition Bureau monitors for potential abuses and prosecutes offenders before the Competition Tribunal.

The system of a single set of laws and a single agency responsible for enforcing competition laws has generally proven to be more effective than fragmented competition laws and enforcement agencies for each sector of the economy, for each region within a country or for each new technology. The potential for an agency such as CIPO to be effective at monitoring and enforcement activities that are related to preventing abuse of dominant corporate power is very limited. In part, this is because it does not have the expertise needed and, in part, because the tools that it has available to apply sanctions or order remedies are limited to patents and would exclude the wide range of potential abuses arising from other sources. This does not mean that competition agencies can be complacent as new technologies and new markets develop and as new corporate strategies are established. Rather, it means that they must be particularly vigilant when a new transformative body

of knowledge and technology develops. This vigilance can and should include re-examination of policies, guidelines, enforcement practices, remedies and legislation in the light of new developments.

Other Existing Mechanisms

In addition to these specific examples, Canada has a variety of regulatory mechanisms which address some of the social and ethical concerns raised. For example, the *Canadian Environmental Protection Act* requires that substances to be released into the environment (including products of biotechnology such as invented plants or animals) must be assessed to determine whether they are or could be harmful to human or environmental health (including biodiversity). Whether invented plants or animals were patented would not change this requirement or the criteria which must be met to permit release into the environment.

New Mechanisms

In other jurisdictions, vehicles such as the National Biotechnology Advisory Committee in the United States have been mandated to discuss a wide range of social and ethical issues related to biotechnology (not just intellectual property) and advise the government. Other organizations concern themselves with ethical and social issues related to a particular technology or field of interest, such as the international Human Genome Organisation Ethics Committee.

As part of its long-term program, CBAC's project Incorporating Social and Ethical Considerations into Biotechnology will include examining an array of issues with regard to the identification of Canadian values and how they can be effectively implemented in public policy. As part of its methodology, it is examining the pragmatic requirements of both determining Canadian values and developing effective instruments for giving expression to those values. In each of its other projects, as in this one, CBAC also seeks input on its proposed Ethical Framework (see Annex E). CBAC will synthesize its research and experience from these projects on these matters and will report its findings to the government in the next two to three years.

Addressing Social and Ethical Considerations Within the Patent System

All countries agree that social and ethical considerations are important; they differ only on whether these concerns should be addressed within patent law or through specific laws and regulations outside the patent regime. While many would argue that the *Patent Act* should not be used as a tool to implement social and ethical policies, many countries do use their patent systems in this way by including an "*ordre public* or morality" provision. Such a provision prohibits patents over inventions whose commercialization would offend society's fundamental and shared moral standards. European and Asian patent legislation includes such provisions; Canadian and U.S. law does not.

The Agreement on Trade-Related Aspects of Intellectual Property (TRIPs) permits members to refuse to grant patents on inventions if their *commercialization* would threaten "*ordre public* or morality," including human and animal health and the environment.[8] Adding this concept to Canadian patent law would involve several considerations, some of which are very complex. One concerns the scope of the exclusion – that is, should the provision list the specific products and/or processes considered socially or ethically unacceptable, or should it be more general in nature? Second, given that the commercial use of the invention may change over time, how would the patent system deal with a new use, developed after the patent had been granted, whose commercialization would contravene "*ordre public* or morality"? Conversely, what would happen if a new beneficial use were found after the patent had been refused? Third, since

[8] Article 27.2: 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.

a patent does not entitle its holder to exploit the invention,[9] commercial exploitation can be, and frequently is, regulated by other legislation governing the field in question. Fourth, even if a patent is refused, it would still be possible for the invention to be commercially exploited (by the patent applicant or anyone else), despite the breach of "*ordre public* or morality." Finally, who would decide what inventions or uses of inventions would contravene the provision, what criteria would they apply and how would the criteria or guidelines be established?

When discussing "*ordre public*," many people refer to the provision contained in the European Community's *Directive on the Legal Protection of Biotechnological Inventions*. This provision deems that certain inventions – human cloning, modifying human germ-line identity, using human embryos for commercial purposes and causing suffering to animals without substantial medical benefit to humans or animals – are specifically contrary to "*ordre public* or morality."[10] This model has been criticized as both over- and under-inclusive, not sufficiently flexible to adapt as new developments occur or ethical norms change and, by addressing the inventions rather than their uses, is unlikely to actually stop objectionable conduct. A more general provision, for example using part or all of the language in Article 27.2 of TRIPs (see footnote 8 for text), would avoid the problems identified in the European Community *Directive*.

If the decision is made to include an "*ordre public* or morality" provision in the *Patent Act*, it could be made part of the patentability requirements (new, non-obvious, useful *and* not contrary to *ordre public* or morality) or only as a basis for opposing the grant of a patent. In the latter case, if the invention was new, non-obvious and useful, a patent could be granted, but then be opposed on the basis it was contrary to *ordre public* or morality in addition to the usual grounds of not meeting the patentability requirements.

Wherever the provision was placed, guidance would have to be provided to the decision maker to determine whether a particular invention or use was in fact contrary to the provision. The criteria developed to make these determinations could be fairly narrow or quite broad.

Use of "*Ordre Public*" or Morality Provisions

Country	*Ordre Public*	Morality	Human Health
Canada			
United States			
Japan			
Europe			
Australia			
Hungary			
Korea			

Source: Gold, Richard (2001), *Patenting Life Forms: An International Comparison* (Ottawa: Canadian Biotechnology Advisory Committee), p. 9.

[9] That is, a patent merely prevents others from exploiting the invention without the patent holder's permission; it does not necessarily mean that the patent holder can commercialize or otherwise exploit it.

[10] Only two known cases have occurred where this clause has been used to withhold patents: one over a hairless mouse used to test hair growth products, and the other an invention involving the cloning of a fused human and pig cell. The clause was also raised in respect of the Harvard onco-mouse. Although the European Examination Division originally found that the mouse patent did not violate *ordre public* or morality, Greenpeace and other organizations commenced opposition proceedings against the patent. The patent was upheld in November 2001.

Limited Role for the Patent System. A narrow approach would address only the commercialization of activities already prohibited in Canada. While TRIPs states that the mere fact that something is illegal is not sufficient to establish that something contravenes *ordre public* or morality, the reason a certain activity has been prohibited may very well be. For example, it may be clear in the debates leading up to a new law that the reason a certain activity was made illegal was precisely because it was found to offend against moral values (for example, selling blood is not allowed in Canada because this offends our beliefs that the human body and its parts should not be commodified; drugs cannot be sold in Canada until they have received Health Canada regulatory approval). This approach could be referred to as one of alignment – bringing the patent system in line with pre-existing societal decisions on social and ethical issues.

Open-Ended Role for the Patent System. In a broader approach, the *ordre public* or morality provision would also be able to address inventions or uses of inventions the *commercialization* of which raises ethical and social concerns which have not (yet) been addressed through law, regulation or other means of social control. This approach could be called open-ended. Article 27.2 of the TRIPs agreement allows countries to exclude from patentability (that is, declare them ineligible to be patented) certain categories of inventions if their commercialization would be offensive to that society.

As previously mentioned, a single invention may have a number of uses, only some (or even only one) of which are objectionable and others which have clear benefits. If the baby is not to be thrown out with the bathwater, there is a need for flexibility, which could be addressed by allowing the decision maker to suspend the patent, rather than refuse it. In legal terms, this would mean the patent holder could not stop anyone else from exploiting the invention. In practical terms, without this ability to exclude others, it would be very difficult for the patent holder to raise the funds needed to commercialize the invention. A further option would be to grant the patent, suspend it and also deny the patent holder the right to exploit the patent. If circumstances changed (new uses which did not offend, a shift in public sensibilities, etc.), the suspension could be lifted.

The question of who makes the determination would also have to be addressed. In the European system, it is the patent examiners and technical experts hearing oppositions who make the decisions concerning ethical determinations, a situation that has been criticized on the basis that patent examiners are not specially trained in social or ethical policy. This criticism suggests either the need for new expertise within the Patent Office or creation of a system for referring patent claims which raise ethical considerations to a specialized body (either to provide advice or actually to make the determination).

Whether for a limited role or a broader one, the definition of the concept of *ordre public* or morality, the procedures and deadlines for invoking it, the criteria for determining whether a patent should be denied or restricted, the identification and qualifications of the decision maker, the necessary administrative support system, etc., should be laid out in regulations under the *Patent Act*.

If "*ordre public* or morality" is to be included in the Canadian patent system, the objective should be to establish a system that has public trust, reflects the collective values of the diversity of the Canadian people, is open, transparent, effective and efficient, and does not unnecessarily impede what is already an expensive, cumbersome process.

Summary of Three Approaches for Addressing Social and Ethical Concerns

Status Quo: No Role for the Patent System

Ethical and social issues continue to be addressed through existing mechanisms, including the proposed *Assisted Human Reproduction Act*, criminal and

competition law, regulations under the *Food and Drugs Act*, requirements of funders or professional organizations for the ethical treatment of human and animal research subjects, etc. Newly identified issues would continue to be addressed by appropriate bodies such as Parliament, granting councils, hospital research ethics bodies, etc., resulting in new laws or regulations or other appropriate responses.

This option does not require any changes to either the *Patent Act* or its administration and thus has the advantages of continuity, stability and predictability, which are highly valued in the business community. A disadvantage of this option is that inventions which raise similar social and ethical considerations, but arise in different fields of endeavour, may not be treated similarly.

Alignment: Limited Role for the Patent System

Where ethical and social issues have already been addressed in law, regulation or other means, a patent can be denied, suspended or restricted to align with those decisions. The patent system would continue to be predictable (as in the *status quo* option) in that the existing social and ethical decisions would be known to potential patent holders in advance. Consistency of treatment between the patent system and decisions made in other legal or regulatory venues can also be seen as an advantage. The major disadvantage of this option is its reactive nature.

Open-Ended: Broad Role for the Patent System

This option provides the greatest scope for taking social and ethical considerations into account within the patent system.[11] A particular advantage of this approach is that issues which have only recently been identified and have not yet become the subject of other mechanisms of social control could be addressed by denying or restricting patents. This ability to adapt to new developments, however, also introduces uncertainty and unpredictability into the patent system, which may deter innovation and investment in Canada.

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.

[11] Although referred to as "open-ended," it is not wide open. Rather, it is bound by the scope of the "*ordre public* or morality" provision itself.

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

The term "higher life form" is not defined in law. In common usage, it includes plants and non-human animals[12] other than single-celled organisms.[13] In Canada, the Patent Office describes higher life forms as "multi-cellular differentiated organisms (plants, seeds and animals)" and does not consider them to be patentable.[14] This interpretation of Canadian patent law is currently being challenged in the courts in the "Harvard mouse" case.[15] In arguing this case at the Supreme Court of Canada, the government will be supporting the position that the *Patent Act* does not allow for the patenting of whole animals.[16]

Even though the government is currently arguing in the courts that higher life forms are not patentable, Canada could decide, through the parliamentary process, that patenting of higher life forms should be allowed, either generally or subject to certain exclusions or limitations on the rights normally provided by the patent.[17] In designing any exclusions or limitations, Canada must take into account the international trade agreements to which it is party. These agreements, such as TRIPs and the North American Free Trade Agreement (NAFTA), specify that countries may not discriminate between one technology and another. This likely means, in the context of these agreements, that countries can create separate rules for a certain technology based only on the nature of the invention itself and not on its ethical implications.[18]

A number of roundtable participants voiced deep concern over extending patent law to plants and animals at all. There were a variety of reasons for this concern. For example, some felt that the regulatory regimes designed to protect health and the environment were currently inadequate and that patenting should not be available as an incentive to invent until proper regulatory systems are in place. Some people had spiritual concerns about the sanctity of life and the place of humankind in the natural universe. Inherent in patenting is an unjustifiable commodification. To allow patents over biotechnological inventions is in itself an ethical decision, signifying a Parliamentary stamp of approval on inventive activity that leads to the marketing of life forms in whole or in part. While the reasons may vary, the proponents of this option are united in their opposition to patenting higher life forms.

Patentability of Human Beings

If Canada decides to permit patents over higher life forms, human beings, at all stages of development, should be excluded. This restriction would not, however, prevent the grant of patents over DNA sequences, cell lines or stem cells of human origin. It is generally believed unlikely that a holder of a

[12] Even though human beings are animals, most lawyers maintain that a whole human being is not patentable, or else that patents over whole humans would not be enforceable.

[13] In the Consultation Paper, CBAC defined "higher life forms" as including not only whole plants or animals, but also parts, such as DNA sequences and cells. Even though these are not generally included in the definition of higher life forms and are already patentable, we included them because it is difficult to draw a firm line between the effect of a patent on whole plants and animals on the one hand and a patent on genetic information and cells on the other.

[14] Manual of Patent Office Practice, Ch. 16, section 16.05 Living Matter and section 16.04 Examples of Non-Statutory Subject-Matter.

[15] The Commissioner of Patents denied the patent application and Harvard appealed to the Federal Court, which upheld the Commissioner's decision. The Federal Court of Appeal agreed with Harvard. The Supreme Court of Canada will now consider whether animals can be patented under Canadian law.

[16] Whatever the Supreme Court decides, the *Patent Act* could be amended to state explicitly whether higher life forms are or are not patentable.

[17] If the Supreme Court decides that higher life forms are patentable, Canada could amend the *Patent Act* to make this explicit.

[18] For example, countries can and have created separate rules providing that patent applicants can deposit biological materials in a recognized facility instead of making the patent applicant follow written description rules that are impossible to satisfy in the case of biotechnology. On the other hand, it is unlikely that the trade agreements would allow the creation of separate rules dealing with the ethical implications of biotechnological inventions.

patent over a human DNA sequence or cells (including stem cells) would be able to exercise control over a human being containing that sequence or cell. Nevertheless, the law has never explicitly addressed this issue.

Although humans are also animals, no country, including Canada, allows patents on the human body. It is generally understood that an entire human being could not be patented. This understanding derives from the universal principle of respect for human dignity, the foundation and source of all human rights, a principle recognized in the United Nationals Declaration on Human Rights. One element of the concept of human dignity is that humans are not commodities. Even if the act of granting a patent on an invented human were not, in itself, a violation of basic human rights, exercising the patent's exclusive right to make, use or sell an invented human would almost certainly violate the *Canadian Charter of Rights and Freedoms* and the *Canadian Human Rights 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 in 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? 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)

While Canada does not currently grant patents over plants and non-human animals, many of its trading partners do (see Annex F for an international comparison). Two trains of thought exist concerning the economic pros and cons of this situation. Some people believe that this situation is beneficial to Canada. If companies find that the patent laws of other nations overly restrict their activity, they may choose to locate in Canada, increasing investment here. As noted above, it is not necessary to hold a patent to commercialize an invention. On the other hand, the present situation of not allowing patents on plants and non-human animals may create the impression that Canada is unfriendly toward biotechnology, thus impeding international investment in Canada's biotechnology industry. While this latter concern relates more to Canada's reputation than to patent law, it is a relevant consideration in determining Canada's patent policy.

In addition, if Canada does not provide patent protection over plants and non-human animals, inventors will likely rely on trade secret protection. This would have a negative impact on the Canadian scientific community as trade secret protection

prevents the free flow of basic knowledge in the research community. By requiring disclosure of the invention, patents facilitate the dissemination of knowledge once the patent application is laid open to the public 18 months following the priority date.[19]

In Canada, plant varieties are already protected by a specialized legal system outside patent law called plant breeders' rights. Internationally, plant breeders' rights were first recognized in 1961 by the International Convention for the Protection of New Varieties of Plants (UPOV). The 1978 revision did not permit a country to provide both plant variety protection and patent protection. In 1991, UPOV was amended again and now permits countries to provide both patent and plant variety protection to plants. Coverage under the treaty was also extended to "essentially derived varieties and to harvested materials." This means that the breeder has rights to prevent others, not only from breeding the same plant as the one protected, but also from breeding plants that are significant derivatives of the original plant.

Canada has ratified the 1978 version of UPOV, although it has indicated its intention to ratify the 1991 version. If Canada decides to permit patents on plants, it would either have to carve out a patent exclusion so that a genus or species subject to plant breeders' rights cannot be patented, or it must ratify the 1991 UPOV Convention. A number of roundtable participants suggested that Canada do so. On the other hand, CBAC also received comments that suggest Canada should stay with the 1978 UPOV Convention.

The concern about trade secrets also arises with respect to patents over animal varieties. The European Community has determined that animal varieties, like plant varieties, are excluded from patent protection. The United States does not exclude animal varieties from protection. The problem with excluding animal varieties is in defining what constitutes an animal variety. The European Community did not attempt to do so, nor does any good international standard exist as to what the term means. Should Canada want to exclude animal varieties from patent protection, it would need to create a workable definition of the term.

A stronger rationale for granting patents over plants, seeds and non-human animals is the consequence of not doing so. There is no bright line between the patent claims that can be made with respect to DNA sequences and cell lines, which are patentable, and those relating to whole plants, seeds and non-human animals, which are not. This is because a person holding a patent in a plant, seed or animal gene can significantly control how that plant, seed or animal is used. This matter was recently addressed in the case of *Monsanto Canada Inc. v. Schmeiser* in the Federal Court of Canada. The effect of this case is that the holder of a patent over an artificially constructed gene and cells containing that gene can prevent others from growing plants containing that gene or cells, even though the patent does not cover the entire plant.

If Canada decides that it will grant patents over whole plants and non-human animals, it should also determine whether there should be any additional exclusions to patentability. Whether or not species other than humans should be excluded is a difficult question. Whereas current laws can make the decision not to patent humans essentially one of practicality if not ethics, the question becomes more difficult when the exclusion of animals of various species is considered. If certain non-human animals are to be excluded, should it be those that are quantifiably similar to humans (for example, a certain percentage of genetic variance from humans), or animals that are qualitatively similar to humans (for example, their ability to think and reason)?

[19] Usually, the date of priority is the first date on which a patent application was filed (although, in some cases, the priority date may precede the date of first filing). If, as is often the case, the first application was in another country, the date of publication in Canada would be less than 18 months.

A distinction on a quantitative basis appears to be unworkable and could lead to the undesirable result that an organism derived from essentially human genes, as long as it crossed the threshold for genetic variance from the "human genetic norm," could qualify for patentability. Moreover, setting the threshold could be considered arbitrary, and the attempt to differentiate great apes, which are genetically very similar to humans, unworkable. For this reason, however, it may be justifiable merely to exclude great apes from the patentable mix, along with humans.

Alternatively, qualitative distinctions (for example, level of perceived cognition, ability to communicate in languages) may provide a more workable mechanism. This, however, may be an ethically dangerous approach in that humans would be forced to decide which animals are worthy of safeguarding and which are not, and this decision could possibly be based on opinion rather than research and information.

Canada must also determine if placing such distinctions in the *Patent Ac*t would be in the public interest and, further, if this would be in line with Canada's international obligations.[20]

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.[21]

Limits on Patent Holders' Rights

Farmer's Privilege

Many participants felt that if patenting is to be allowed over whole plants and animals and varieties thereof, an exemption from infringement would be essential to the maintenance of food security and the robustness of Canadian agriculture. A farmer's privilege would allow farmers to collect and reuse seeds harvested from patented plants and to reproduce patented animals for their own use. While farmers would be entitled to sell the plants and animals so grown, they would not be entitled to sell them as breeding stock.

Farmers in Canada currently benefit from a farmer's privilege concerning plants under Canada's *Plant Breeders' Rights Act* (although this exemption from infringement is not legislated). The European Community's patent laws contain a farmer's privilege that allows a farmer to reproduce non-human animals and certain plants (the latter for a relatively small fee) for his or her own use, without the consent of the patent holder.

Plant or non-human animal patent holders would still be able to license, rather than sell, the patented non-human animal or plant if they so chose. Under a licence, patentees can impose whatever contractual obligations they wish, including an obligation on the farmer not to reuse the seeds or breed the non-human animals. As long as such activity is not determined to be anti-competitive, current law does not restrict this practice.

[20] Efforts are currently being made to develop a United Nations Declaration on the Rights of Great Apes, which would guarantee great apes some of the same rights currently extended to humans: the rights to life, liberty and freedom from torture. In the event that such a Declaration were adopted by the UN and ratified by Canada, it would then be logical to amend the statement referred to in Draft Recommendation 1 accordingly.

[21] 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.

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.***

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 licencee 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 Exemption

As noted earlier, patent holders gain the exclusive right to make, use and sell their inventions in exchange for making the information about the invention public in order to foster further innovation. Subsequent inventions can usually only be made after further research or experimentation using the patented invention. However, without authorization, these activities infringe on the patent holders' rights. Consequently, patent legislation in many countries states that research using and experimentation on a patented invention is not an infringement of the patent holders' rights. This experimental use exemption attempts to balance the interests of patent holders to commercialize their inventions with those of society to foster further research.

In the United States, the experimental use defence is very narrow. It applies only to research having the purpose of "philosophical enquiry." While this concept is unclear, it likely applies only to research that has no reasonable possibility of being commercially applied. The European Patent Convention's experimental use exemption is wider, permitting commercial research on the invention itself, as opposed to research merely using the invention.

In Canada, the exemption has been developed by the courts. Generally speaking, this exemption permits persons other than the patent holder to use a patented invention for a non-commercial purpose, usually research, or to determine if the invention works as described in the patent. However, the full scope of the experimental use defence has been difficult to determine.

Most people practising patent law agree that the current general experimental use exemption is unclear, especially with regard to biotechnological inventions. There is less agreement on how this lack of clarity should be addressed. Many roundtable participants preferred a wider experimental use exemption, arguing that a narrow one reduces innovative activity by preventing access to basic

technology or at least making access more difficult. Some theoretical and empirical research (including a CBAC-sponsored survey of biotechnology researchers) suggests that patents do prevent some research from occurring. Other industry representatives believe that a wide experimental use exemption is not required as industry would never bother to bring suit against a non-commercial researcher. These individuals also point out that instituting a wide exception could make it more difficult or impossible to enforce patents.

Given that biotechnology research often aims to eventually develop a commercially viable product, the use of this exemption with regard to biotechnology is uncertain. The scope of this defence is particularly important with regard to the patenting of whole plants and animals, given that genetically engineered crops and breeding animals often become the platform for new research. It is therefore important for scientists to know what research they can and cannot conduct without violating a patent.

Access to basic or platform technology at reasonable cost is crucial to research. The lack of clarity that currently exists in Canadian patent law can only cast a pall on university and independent researchers afraid of even the possibility of facing a patent infringement lawsuit. This chilling effect could lead to under-investment in basic research. Canada should address this concern by amending the *Patent Act* to include an explicit experimental use exception to clarify the case law on this subject.

Biotechnology researchers require access to many platform technologies including DNA sequences, cell lines, and plants and animals. While it would be inappropriate for these scientists to use patented inventions as mere tools to conduct further research without paying a licence fee, it is important to provide them with the ability to study, experiment on and improve biotechnological inventions without charge. This is particularly so in agricultural biotechnology, where inventions often build on each other. Given that even basic research often leads to commercial products, it is inadvisable to distinguish between scientists conducting research for merely private purposes and those with a commercial interest.

If Canada decides to include an experimental use exception in its *Patent Act*, its patent laws in this area would accord with those of European countries and with the European Community Patent Convention. It is therefore unlikely that it would put Canada out of line with its international trade obligations. However, to address the concerns of some industry representatives, particularly those in the pharmaceutical field, it may be necessary for Canada to review other regulations to ensure that the combination of current rules and an open experimental use exemption do not affect the ability of companies to enforce their patents when someone is using the patented invention to compete with them.

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. Here, we present draft recommendations concerning traditional knowledge and benefit sharing (see p. 8) which can be implemented no matter which approach may ultimately be favoured.

Benefit Sharing

In April 2000, the Human Genome Organization (HUGO) Ethics Committee released a Statement on Benefit Sharing concerning whether and how to distribute profits that may accrue to commercial enterprises, governments and academic institutions on the basis of the participation of particular communities or populations.

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.

Traditional Knowledge

Some countries (for example, Kenya) are establishing procedures to protect indigenous knowledge and/or share the benefits that may arise from research based on that knowledge. Some research centres (for instance, the Danforth Centre, St. Louis, U.S.A.) make their patents available to developing countries without charge. Some participants proposed addressing the issue of protecting traditional knowledge within the patent system. Others propose developing a new intellectual property scheme that specifically addresses this community-based knowledge. The World Intellectual Property Organization (WIPO), of which Canada is a member, has convened a Working Group on Genetic Resources, Traditional Knowledge and Folklore to address these issues.

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

Biotechnological inventions are anticipated to have major impacts on medicine, medical treatment and on the health care system. Since many of these innovations will be patented, the effects on the system of patenting such inventions warrant study. If detrimental effects are found that outweigh the beneficial effects of patents, appropriate safeguards could be established.

In the past, the balance between the benefits of patents and the unique situation arising for health care led to the creation of the Patented Medicine Prices Review Board (PMPRB). The PMPRB is a quasi-judicial body empowered to ensure that the selling prices of patented medicines by the patentee are not excessive. It also plays a role in monitoring the research and development activity of the pharmaceutical industry in Canada. More recently, in the developing world, special arrangements have been negotiated in South Africa and Brazil ensuring that these countries can have access to patented medicines at lower cost for the treatment of AIDS.[22]

Looking to the future, it may be worth inquiring into whether the current balance between the rights of patent holders and those of citizens seeking improved health is appropriate in a world filled with new biotechnological health inventions. While CBAC considers all of these concerns important, most are beyond the scope of its current work program and consultations.

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.***

[22] Most patent legislation, including Canada's, allows the government to override patent rights in a national emergency or if the patent-holder is abusing their rights. South Africa intended to import lower-cost generic versions of the drugs, while Brazil threatened to issue a compulsory licence to have them manufactured in Brazil if prices were not lowered.

Improving the Administration of the Patent System

Guidelines for Biotechnological Patents and Processes

It would be beneficial if CIPO were to issue detailed guidelines on the patentability of biological material and how applications are assessed. Information contained in the Manual of Patent Office Practice concerning biotechnology does not address many of the issues discussed in this paper.

The United States Patent and Trademark Office (USPTO) currently issues guidelines. 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.

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 do regimes in other developed countries. More investigation is required to determine why this is so. If it is found that the delays are due to a shortage of qualified examiners, this needs to be addressed quickly. Some participants suggested that CIPO hire more examiners and pay higher salaries to keep the ones it has. Others suggested that Canada accept the patent decisions made in the United States or Europe. A related issue raised by some industry participants at the special hearings was the possibility of Canada adopting a patent restoration policy similar to those that exist in the United States, Europe and Japan. This would compensate patent holders the period of exclusivity lost while CIPO makes its decision. Further research will be required on this subject.

To accommodate the increasing number of biotechnology and other patents, CIPO must have not only sufficient numbers of personnel, but also sufficient expertise. It may be valuable to undertake a capacity audit of CIPO to determine how many applications could be handled within a reasonable time, whether or not additional examiners are required and what skills and/or expertise are missing. The government must provide incentives to retain these individuals and their expertise so that they are not lost to more lucrative private sector positions in Canada or the United States.

Performance reporting that includes clear targets for performance and regular reporting against those targets can be a valuable tool for ensuring transparency and accountability. While it may be technically demanding to develop meaningful standards and a related reporting mechanism, this remains a valuable instrument for ensuring that the interested public are able to monitor performance.

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

As noted earlier, as a WTO member, Canada is subject to the provisions of TRIPs. The purpose of TRIPs is to establish consistency among WTO members on the protection of intellectual property rights, including patents. Canada is also a member of the World Intellectual Property Organization (WIPO), which promotes the protection of intellectual property and encourages administrative cooperation in this regard among member states. In June 2000, WIPO concluded a Patent Law Treaty to harmonize the formality requirements for filing patent applications and maintaining patents. It will take several years for the treaty to come into force. Canada signed the treaty in May 2001, which is the first step toward ratification.

Some industry representatives have stated that the patenting policies of other nations such as the United States, Japan and Europe have more impact on Canadian industry than does Canada's own patenting policy, given the relatively large size of those markets. The more aligned Canada is with the patent systems of its trading partners, the more successful Canada will be in attracting and maintaining investment and in promoting a thriving research community. This suggests that Canada should work to harmonize patent law and patent procedures internationally so as to enable Canadian industry to take advantage of patents world wide. Implementing the Patent Law Treaty is a step in this direction. However, Canada should, at the same time, continue to advocate for a transparent, fast, uniform patent system at the international level.

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, especially those from the research community, called for easier ways to challenge issued patents. Currently, Canada has a re-examination process with respect to undisclosed prior art (that is, previously existing and publicly available information) and can challenge patents through the Federal Court. Some participants in CBAC's special hearings suggested that Canada institute an opposition procedure. Some of Canada's major trading partners have opposition procedures allowing third parties to challenge a patent either before (e.g., Japan, Australia) or after it has been granted (e.g., European Union).

Given that any opposition procedure would affect all patents, not just those on higher life forms or other biological inventions, proposing that Canada in fact provide such a procedure may be seen as beyond the mandate given to CBAC. Nevertheless, we think there is much to commend the idea of a speedy mechanism to resolve disputes about whether it is proper that a particular patent be granted.

In 1998, the National Biotechnology Advisory Committee[23] recommended that CIPO introduce "an effective opposition procedure with a time limit of six months after grant, similar to procedures in Europe" (*Leading in the Next Millennium*).[24] Among the points made by NBAC were that patents can affect third-party rights and that it is in the public interest to ensure that patents are granted with the proper scope and that they do not have unduly broad claims. Broad patents, especially when broader than those granted by trading partners, can hamper the commercial activities of companies.

NBAC also stated that there would be an advantage to creating a system in CIPO that allows third parties to challenge the validity of a patent short of a full-blown court case. Such a system would allow for a more thorough examination of patents thought to have strong commercial significance and allow CIPO to reconsider its decision in light of third-party arguments. NBAC also noted the importance of ensuring that opposition procedures do not cause significant delays – hence the six-month recommended time period.

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.

Over the next three months, CBAC will garner this additional input using three broad approaches. The first is to make this report as widely available as possible so that Canadians can review the material and submit comments on the committee's recommendations. CBAC will then analyse the additional input and take it into consideration in refining the draft recommendations presented here. It will submit its final report of recommendations to the Government of Canada by April 30, 2002. The report will also 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.

[23] The National Biotechnology Advisory Committee was formed in 1983 to advise the Minister of Industry on issues related to industry growth and competitiveness in biotechnology and, later, on a regulatory framework for biotechnology. In 1998, it released its sixth report titled *Leading in the Next Millennium.*

[24] Other countries, such as Japan and Australia, have pre-grant opposition procedures.

CBAC would appreciate receiving comments on its recommendations to assist in determining both their likely effectiveness and the impact of its recommendations on the Act's traditional roles of protecting inventors, providing stimulus for innovation and economic development and ensuring that information is publicly available about new inventions.

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, 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.

Annex A: Members of the Canadian Biotechnology Advisory Committee

Dr. Arnold Naimark
Chair, Canadian Biotechnology Advisory Committee
Director, Centre for the Advancement of Medicine, University of Manitoba, Winnipeg, Manitoba

Dr. Mary Alton Mackey
President, Alton Mackey and Associates
Portugal Cove, Newfoundland

Dr. Lorne Babiuk
Director, Veterinary Infectious Disease Organization, Saskatoon, Saskatchewan

Dr. Françoise Baylis (to June 30, 2001)
Associate Professor of Medicine and Philosophy
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Ms. Gloria Bishop
Vice-President, Public Affairs and Communications, University Health Network, Toronto, Ontario

Prof. Timothy Caulfield
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Dr. Bartha Maria Knoppers
Law Professor and Senior Researcher
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Dr. Murray McLaughlin
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Ms. Anne Mitchell
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Dr. Peter W.B. Phillips
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Dr. Douglas Powell
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University of Guelph, Guelph, Ontario

Dr. René Simard
Former Rector, Université de Montréal
Montréal, Quebec

Mr. Jonathan Bjorn Syms
Medical Student
Queen's University
Kingston, Ontario

Mrs. Denny Warner
Manager, Vanderhoof Chamber of Commerce, Vanderhoof, British Columbia

Annex B: CBAC Publications and Commissioned Research

Consultation Documents

Biotechnological Intellectual Property and the Patenting of Higher Life Forms: Consultation Document 2001.

A Summary of Principal Ideas Arising from Research Papers Not Addressed in the Biotechnological Intellectual Property and Patenting of Higher Life Forms Consultation Document 2001.

Consultations 2000/2001

Summary of Consultations on Biotechnological Intellectual Property and the Patenting of Higher Life Forms.

Summary Report of the Non-Governmental Organization (NGO) Hearing to CBAC, November 22, 2000, rapporteur Dr. Richard Gold, Assistant Professor, Faculty of Law, University of Western Ontario, London, Ontario; Assistant Professor, Senior Fellow, Einstein Institute for Science, Health & the Courts; Research Associate, Health Law Institute, University of Alberta.

Summary Report of the President/CEO Industry Hearing to CBAC, September 29, 2000, rapporteur Dr. Richard Gold, Assistant Professor, Faculty of Law, University of Western Ontario, London, Ontario; Assistant Professor, Senior Fellow, Einstein Institute for Science, Health & the Courts; Research Associate, Health Law Institute, University of Alberta.

Summary Report of the Scientific Researcher On-line E-forum, February 5-9, 2001, rapporteur Dr. Richard Gold, Assistant Professor, Faculty of Law, University of Western Ontario, London, Ontario; Assistant Professor, Senior Fellow, Einstein Institute for Science, Health & the Courts; Research Associate, Health Law Institute, University of Alberta.

Commissioned Research

Alternatives to the Use of Animals for Research, Testing and as Sources of Bioengineered Products, by Dr. Gilly Griffin and Dr. Clément Gauthier, Canadian Council on Animal Care, Ottawa, Ontario.

Biotechnology, Ethics and Government: A Synthesis, by Dr. Michael McDonald, Director, Centre for Applied Ethics, University of British Columbia, Vancouver, British Columbia.

A Brief History of the Canadian Patent System, by Vic Duy, Consultant, Ottawa, Ontario.

Economic Profile of the Biotechnology Sector, by Kenneth White, Acton, White and Associates, Manotick, Ontario.

EU Directive and the Legal Protection of Biotechnological Inventions, by Dr. Richard Gold, Assistant Professor, Faculty of Law, University of Western Ontario, London, Ontario; Assistant Professor, Senior Fellow, Einstein Institute for Science, Health & the Courts; Research Associate, Health Law Institute, University of Alberta; and Alain Gallochat, Advisor, French Ministry of Research, France.

Human Rights Issues in Patenting of Higher Life Forms — The Role of the Canadian Charter of Rights and Freedoms, by Barbara von Tigerstrom, Professor of Law, Health Law Institute, University of Alberta, Edmonton, Alberta.

Human Rights Issues Related to the Patenting of Human Biological Materials, by Barbara von Tigerstrom, Professor of Law, Health Law Institute, University of Alberta, Edmonton, Alberta.

Impact of Canada's Patent System on the Ability of Publicly Funded Organizations to Transfer, and Private Sector Firms to Commercialize Biotechnological Inventions, by Tom Clarke, Stargate Consultants Ltd, Nanaimo, British Columbia.

Innovation in the Livestock Industry, by Dr. Robert Kemp, RAK Consulting Ltd, Lethbridge, Alberta.

Intellectual Property Protection for Biotechnological Innovations, by Mona Frendo, Legal Analyst, Corporate Governance Branch, Industry Canada, Ottawa, Ontario.

Intellectual Property Rights in Biotechnology: The Economic Argument, by Dr. Ron Hirshhorn, Hirshhorn Consulting Inc., Nepean, Ontario; and Jock Langford, Economist, Corporate Governance Branch, Industry Canada, Ottawa, Ontario. (Pending)

The Interface of Biotechnology Patents and Competition Law, by Warren Grover, Q.C., Barrister and Solicitor, Blake, Cassels and Graydon, Toronto, Ontario.

New Enclosures: The Impetus for and Potential of Alternative Mechanisms for the Protection of Biotechnological Innovations, by Patrick Mooney, Rural Advancement Foundation International (RAFI), Winnipeg, Manitoba.

Patenting of Biotechnological Innovations Concerning Animals and Human Beings, by Ted Schrecker, Consultant, Ted Schrecker-Research and Consulting, Montreal, Quebec; and Alex Wellington, Department of Philosophy, Ryerson Polytechnic University, Toronto, Ontario.

Patenting of Higher Life Forms and Human Biological Materials, by Ted Schrecker, Consultant, Ted Schrecker-Research and Consulting, Montreal, Quebec; and Alex Wellington, Department of Philosophy, Ryerson Polytechnic University, Toronto, Ontario.

Patenting Life Forms: An International Comparison, by Dr. Richard Gold, Assistant Professor, Faculty of Law, University of Western Ontario, London, Ontario; Assistant Professor, Senior Fellow, Einstein Institute for Science, Health & the Courts; Research Associate, Health Law Institute, University of Alberta.

Patents in Genes, by Dr. Richard Gold, Assistant Professor, Faculty of Law, University of Western Ontario, London, Ontario; Assistant Professor, Senior Fellow, Einstein Institute for Science, Health & the Courts; Research Associate, Health Law Institute, University of Alberta.

Towards an Adequate Ethical Framework for Setting Biotechnology Policy, by Dr. Susan Sherwin, Munro Chair in Philosophy, Department of Philosophy, Dalhousie University, Halifax, Nova Scotia.

The Use of Animals in Scientific Research and as Sources of Bioengineered Products, by Dr. Clément Gauthier and Dr. Gilly Griffin, Canadian Council on Animal Care, Ottawa, Ontario.

Annex C: CBAC's Research and Consultation Process on the Patenting of Higher Life Forms

CBAC began its research and consultation program on biotechnological intellectual property and the patenting of higher life forms in early 2000. The work has taken place in four phases, two of which are now complete and the third of which is just starting.

Phase 1: The first phase consisted of collecting and analysing information on various aspects of the topic. This included the preparation of research papers and technical reports by experts in pertinent fields, and a review of existing studies and documentation. The committee also held preliminary hearings with biotechnology representatives in industry, non-governmental organizations and the research community in fall 2000 and early 2001 to target the areas of interest for the Multi-stakeholder National Roundtables in April and May 2001.

Phase 2: In March 2001, CBAC began Phase 2 of the project. This consisted of two tasks, both designed to garner the views of Canadians concerning the patenting of higher life forms. The first task was the release of a Consultation Document focussing on four broad issues, and inviting interested Canadians to comment on them.[25] The four themes were: What should and should not be patented? What are the mechanisms of governance available for change? How should social and ethical issues be addressed? The fourth theme dealt with international obligations and competitiveness.

To reach as many people as possible, the Consultation Document was posted on CBAC's Web site, and a media release was issued to tell Canadians about the report and how to contribute their opinions. Several organizations representing producers, environmental and citizen interests, consumers, health professionals and industry also helped to disseminate it. People were invited to send comments, from March to May 14, 2001, via the committee's toll-free telephone number or Web site, or by fax or regular mail. A wide range of organizations and many individual Canadians took the time to provide CBAC with their thoughtful responses.

The second task of Phase 2 consisted of Multi-stakeholder National Roundtables in April and May 2001 in five cities across Canada. The purpose of the roundtable discussions was to garner the views of people involved in, or with a particular interest in, patents and biotechnology. The roundtables focussed on how to enhance the ability of Canadians to use intellectual property rights pertaining to biotechnology in a socially responsible way, and whether or not Canada should patent plants and non-human animals and/or related processes. Reports summarizing the individual roundtable discussions are available on CBAC's Web site, as is an omnibus report synthesizing the views expressed at all five roundtables. In concluding Phase 2, CBAC prepared this interim report to serve as the basis for Phase 3.

Phase 3: Phase 3 involves soliciting the views of Canadians and stakeholders on these draft recommendations and preparing the final report and recommendations. In order to do this, CBAC is making this document available as widely as possible

[25] This report was accompanied by a companion piece entitled *Summary Document*: *A Summary of Principal Ideas Arising from Research Papers Not Addressed in the Biotechnological Intellectual Property and the Patenting of Higher Life Forms Consultation Document 2001.*

so all interested Canadians can review the draft recommendations and submit comments. In order to ensure that Canadians have sufficient time and opportunity to consider the material and to prepare and submit comments if they wish to do so, this interim report is open for comments until March 15, 2002. Submissions may be made by phone, fax, mail or e-mail to the contact points listed below.

In addition, as in Phase 1, CBAC will be consulting with specialized audiences, such as presidents and chief executive officers of industry, non-governmental organizations and the scientific community.

CBAC will reconsider and refine the draft recommendations proposed, taking into account all the input received by March 15. A follow-up report outlining CBAC's final recommendations will be released in the spring of 2002.

Annex D: Structuring the Debate

The views expressed during the course of our research and consultations range along a spectrum according to the extent to which it is held that biological inventions involving higher life forms should be treated as intellectual property and the extent to which intellectual property rights should be conditioned by social and ethical considerations.

To simplify the discussion of this complex subject, we have identified four "Positions" (shown below) along this spectrum that cover the main thrust of the range of views expressed to us.

A The patent system is only about economic forces and, while ethical and social concerns are important, they could be better addressed using other tools (for example, regulation, *Criminal Code*, etc.).

B While the patent system is largely about economic forces, it has some ability – albeit limited – to address certain ethical and social concerns. Other tools should be used to address the remaining ethical and social concerns.

C Concerns about ethical and social matters should be given as much weight as economic concerns in awarding patents – after all, patent law aims to achieve the social good and should be crafted to attain that good.

D It is inappropriate to apply economic considerations to higher life forms, and therefore patents over higher life forms should be prohibited.

There are a number of options for changes in government policy and practice flowing from each position that emerged during the course of our studies and consultations. There are also issues of implementation that would have to be addressed if particular options were to be adopted. Options and their practical implications are referred to in this document as "Implementation Options."

Position A: Patents as Purely Economic Tools

The following observations and conclusions are consistent with the view that patents are purely economic tools and that, as long as an invention (including the invention of a plant or non-human animal) is new, useful and non-obvious, it should be patentable.

In consequence, Canada's *Patent Act* should be amended to allow the patenting of plants and non-human animals in addition to the current patentability of genetic material and cells. Among the reasons advanced for allowing patenting of plants and non-human animals are the following:

- The *Patent Act*'s key purpose is to encourage inventive activity and reward innovators.
- Mechanisms outside the *Patent Act* can more effectively address ethical and social concerns.
- Canada's major trading partners grant such patents.
- Not granting patents on plants and animals may not, in fact, prevent plants and non-human animals from being subject to rights flowing from patents awarded on genetic materials and cells (see, for example, the recent Federal Court of Appeal of Canada decision in the *Monsanto Canada Inc. v. Schmeiser* case).

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

- Without patents, inventors will likely rely more on trade secret protection, which would impede the free flow of knowledge.
- CIPO is neither qualified nor empowered to make social and ethical decisions.

While the *Patent Act* should be amended to prohibit the human body, at all stages of development, from being patented, this restriction should not prohibit patents over DNA sequences, cell lines or stem cells of human origin.

What should be excluded from patentability or exempted from patent infringement? If Canada decides to grant patents over whole plants and non-human animals, it should also determine what exclusions and exemptions ought to be provided for and what matters require clearer codification.

Methods of medical treatment: Canada does not issue patents for methods of medical treatment. Such methods have traditionally been considered unpatentable because they fail to meet the utility criterion of industrial applicability and reproducibility.[26] The prevailing view is that how well such treatments work depends on the skill of the physician or veterinarian administering them. However, pharmaceuticals and diagnostic tools, tests and devices are patentable in Canada. While there may have been reasons for this distinction (e.g., avoidance of health care costs including those incurred in patent infringement litigation), it has been argued that the distinction is of questionable validity, especially in the light of modern biotechnology. It has therefore been suggested that Canada should amend the *Patent Act* to permit patenting of methods of medical treatment with the proviso that neither medical activities performed by medical practitioners, nor the institutions in which they work, can be subject to action for patent infringement. Control of other costs would have to be achieved through other means.

Plant varieties: In Canada, plant varieties are protected outside the patent system; namely, through the *Plant Breeders' Rights Act* (PBRA). Internationally, plant breeders' rights were encompassed by the International Convention for the Protection of New Varieties of Plants (UPOV). In 1991, UPOV was amended to permit countries to extend both patent protection and plant variety protection, of the PBRA type, to plants and to extend coverage to "essentially derived varieties and to harvested materials." In 1999, a bill died on the House of Commons Order Paper that would have permitted Canada to ratify the 1991 version of UPOV. Several nations, including Canada's major trading partners, have modified their regulations to conform to the 1991 version. Most of the comments received during our roundtable consultations favoured the suggestion that Canada introduce a bill leading to ratification of the 1991 UPOV Convention. Others, however, were opposed, in that conflicts might arise between rights of patent holders and those of breeders operating under the PBRA.

Experimental use exemption: Canada allows persons other than the patent holder to use a patented invention for a non-commercial purpose (usually for research) or to determine if the invention works as described in the patent. Most people practising patent law agree that the current general experimental use exemption is unclear, especially with regard to biotechnological inventions. It has been proposed that Canada address this concern by amending the *Patent Act* to include an explicit experimental use exemption. However, to address some industry concerns, it was suggested that Canada review related recommendations (such as those concerning pharmaceutical patents) to ensure that the combination of current rules and an open experimental use exemption do not hinder companies from enforcing their patents when someone is using the patented invention to compete with them.

[26] That is, the results cannot be consistently reproduced as the interaction between physician and patient depends on many factors.

Scope of Patent Protection: Two matters related to the scope of patent protection were identified.

- Due to concerns that it is not sufficiently evident that a clearly inventive step is required to move an invention from the realm of "creation of nature" to the realm of "created by human ingenuity" as required for a patent, it was suggested that patent protection not be extended to mere products of reproduction without practical human intervention.
- Given that courts could interpret patent claims over DNA sequences and cells as extending to whole plants and non-human animals, it is necessary to define the relationship between patents for DNA sequences and cells (including stem cells) on the one hand, and patents over whole plant and non-human animals on the other. There is also concern that excessively broad patents can inhibit research and commerce without justification. It was therefore proposed that holders of patents over DNA sequences, or cells containing a particular DNA sequence should not be allowed to prevent others from using, making or selling either whole plants or non-human animals or their parts that contain the patented sequence or cells. At a minimum, the legislation should make clear that the holder of a patent over a DNA sequence (or cells containing the sequence) that occurs in humans has no rights over a human body containing that sequence.

Patent System (CIPO): Two matters were raised in connection with the patent system itself, as represented by CIPO; namely, the need for CIPO to issue **guidelines** on the patentability of biological material and the way it will approach such applications; and the need for CIPO to reduce the **amount of time** it takes to issue a patent.

International Harmonization: While recognizing the need for a balance between a "made in Canada" approach and harmonization with other countries so that Canada is seen as a responsible trading partner, there were calls for the government to encourage the further **harmonization of patent policies and procedures** at the international level, including the ratification of the Patent Law Treaty, which Canada signed in May 2001.

Position B: Patents as Economic Tools Reflecting Limited Social and Ethical Concerns

Those whose views are aligned with Position B consider patent law to be primarily concerned with economic incentives but with some ability – albeit limited – to address certain social and ethical issues. Three such additional initiatives reflecting social and ethical concerns were identified: one within patent law, one outside patent law and one in the international arena.

- *Ordre public* or morality: Within patent law, one could consider instituting an "*ordre public* or morality" clause that would prohibit patents over inventions whose commercialization would threaten public safety or offend society's moral standards, as well as guidelines for applying these ethical considerations.
- *National Review Board*: Position B also accommodates the view that neither CIPO nor the courts should play the role of ethical filter and that such a function should instead be served by a separate publicly accountable body or structure, enabled by legislation to address ethical issues. This system should have public trust; reflect Canada's diversity; be open, transparent, effective and efficient; and not hinder the patent process. Such a review board would have expertise in ethics and social policy concerns, including competition. It would review patent applications referred to it by a patent examiner or third party. It would not have the power to grant or revoke patents, but would be able to suspend them (temporarily or permanently). Its decisions would be open to judicial review by, but not appeal to, the Federal Court, Trial Division. It would be encouraged to issue guidelines as to how it would apply its discretion.

- *International Advisory Board:* Given that unethical activity occurring elsewhere can affect Canada, only an international approach to ethics – even if no firm international standards are possible or desirable – will assure Canadians that their concerns are properly addressed. To this end, it was felt that the government should encourage the creation of an international body that would provide advice to nations concerning the application of *ordre public* or morality.

Public support for research: One ethical concern is that expanded patentability would lead both to further concentration of control of biological information in the hands of industry and to a primary focus on commercialization to the exclusion of research and development in areas not deemed to be commercially attractive. While an *ordre public* or morality clause would partially address this concern, it alone is insufficient. In fact, the patent system appears to have no way to address this issue satisfactorily. An additional measure put forward is for governments to maintain and strengthen support for research in areas that are important but which may not lead to commercial products. This would help to ensure that research would continue in areas that industry may not consider financially viable.

Farmers' Privilege: While Canada currently has an unlegislated farmers' privilege concerning plants under the *Plant Breeders' Rights Act*, no such privilege exists regarding animals. Amending the *Patent Act* to include the right of farmers to collect and reuse seeds harvested from patented plants and to reproduce patented animals for their own personal use would codify the current farmer's privilege with regard to plants and extend it to animals. This would also protect individuals who have accidentally had their crops or animals fertilized or inseminated by a patented plant or animal (for example, if a patented seed blows onto a neighbour's land producing a crop). Canada could amend the *Patent Act* to provide that farmers may use the offspring of a purchased patented non-human animal for domestic use (for example, a dairy farmer could use the offspring of a cow to produce milk or to sell as meat but could not sell the cow or its offspring as breeding stock). Patentees could still license, rather than sell, the patented animal or plant, which would allow them to impose any contractual obligations they wish, including an obligation on the farmer not to reuse the seeds or breed the non-human animals.

Traditional Knowledge: Industry often uses the traditional knowledge of indigenous peoples and some developing nations to help identify plants and non-human animals that could lead to valuable products, but the companies are not required to share the benefits of these products. The government is seen as having a responsibility to support the efforts of these groups to create an internationally recognized form of intellectual property protection for their traditional practices and knowledge.

Position C: Social and Ethical Concerns Equal to Economic Concerns

Those whose views are aligned with Position C would support the suggested changes and initiatives described under Positions A and B but would go further in that they would accord social and ethical concerns the same level of consideration in the patenting system as economic concerns through the creation of a mixed regime involving patents and other mechanisms.

In addition to introducing an "*ordre public* or morality" clause into the *Patent Act*, regulations would be established under the Act to set a clear guidance for interpreting the criteria of novelty, non-obviousness and utility with respect to biological products (this would require amending the *Patent Act* to create the power to set these regulations); and, implementing a new legislative regime (*Biological Product Protection Act* – BPPA) that could replace the *Plant Breeders' Rights Act* in protecting biological products. The BPPA, which would need to be established through new federal legislation, would describe a process to apply for biological product protection, the scope and duration of that protection and its enforcement.

Proponents of Position C also addressed international matters, by calling on the government to consider the possibility of renegotiating NAFTA and TRIPs to allow countries to treat biotechnological inventions differently from other inventions so that their ethical and social implications can be addressed. It further calls for Canada to argue for the creation of international standards regarding compliance with ethical and social norms, even if NAFTA and TRIPs are not renegotiated.

Position D: No Patenting of Human Genetic Material, Plants or Animals

Proponents of Position D believe it is wrong to patent any biological product derived from higher life forms and that the *Patent Act* should be amended to reflect this. Their concerns include:

- spiritual considerations (sanctity of life and the effects of its commodification)
- philosophical precepts (humans should adapt to nature rather than vice versa)
- pragmatic concerns (the regulatory system cannot effectively protect human health and the environment)
- economic impacts (health care costs and other social costs could rise)
- social impacts (potential threat to genetic privacy)
- environmental impacts (new life forms could harm ecosystems)
- other matters such as the lack of benefits sharing and animal welfare.

Specifically, proponents of Position D propose that the *Patent Act* be amended to exclude biological products (DNA sequences, cells, cell lines, stem cells, tissues, organs and whole plants and animals) from patent protection and that consideration be given to excluding processes using biological materials. The proponents of Position D would, however, support efforts to create an internationally recognized form of intellectual property protection for traditional practices and knowledge.

Areas Requiring Special Examination

Three important areas were identified as requiring special examination by the government that are not readily ascribed to a particular position. They are:

- the feasibility of instituting an **opposition procedure** that would allow third parties to challenge the validity of a patent without having to undertake a full-blown Federal Court action, as is currently the case
- the extent to which allowing patents over plant and non-human animals does in fact constitute an **incentive to innovation** relative to other forms of intellectual property protection
- the interaction between the **regulatory regime** for biotechnology and the patenting system in determining the degree of incentive for research and development in Canada.

Annex E: Ethical Framework: Reactions of Roundtable Participants and Next Steps

At Multi-Stakeholder Roundtables, which took place in April and May 2001, CBAC presented participants with its proposed ethical principles and requested their reactions to the principles. Specifically, it wanted to know if the proposed principles were appropriate and if others should be added.

Are the Proposed Principles Appropriate?

There was strong support among roundtable participants for CBAC's proposed principles. It was felt that the broad terms in which the principles are stated is appropriate given that the principles are intended to be overarching and directional.

However, some individuals suggested that the principles represent a framework that is too outcome oriented. They proposed that, before assuming a particular outcome, CBAC should determine which goals Canada should pursue in the field of biotechnology. This determination should be done in a way that probes the underlying moral and philosophical concerns raised by biotechnology in general and by intellectual property and the patenting of higher life forms in particular. It should also include Canada's position on matters such as the nature and ownership of life and whether or not humanity should have the right to manipulate life.

It was evident from CBAC's consultations that while the proposed principles provide a reasonable framework for determining policy in the area of biotechnology patenting, the real challenge lies in interpreting and applying those principles. Many participants felt that CBAC needed to continue to identify, understand and describe Canadian values and to ensure that these values are reflected in the principles. They also felt that the principles must be more clearly defined since, as currently described, some are open to varying interpretations (see box, "*Specific Suggestions for Wording of CBAC's Proposed Principles*"). Some participants urged CBAC to go further and clarify how the principles can be incorporated into specific decisions in the real world of innovation, patenting and marketing.

Many participants felt that Canada, with its links to both the United States and Europe, is in a position to exercise moral leadership in establishing an international consensus on values and principles and their implementation in the patenting of higher life forms. However, they felt that before entering the international arena Canada should develop a national position through inclusive, open, transparent processes that reflect Canada's diversity. They suggested that the development of Canada's position probably should not be driven purely by altruism; Canada needs to look after its own interests at the same time it considers the longer-term consequences of a new international patenting regime.

Should Other Principles Be Added?

Participants suggested that the following principles should be considered.

- *Biodiversity:* The ability of nations to control their biological resources.
- *Environmental Protection:* The maintenance of genetic diversity and promotion of sustainable development.
- *Responsible Stewardship of Life:* Define humanity's obligations to other forms of life.
- *Non-malfeasance:* Do no harm; ensure that biotechnology will not be misused.
- *Freedom to Explore, Investigate and Expand Knowledge:* Encourage learning and human curiosity.
- *Respect for Human Rights and Dignity:* Recognition and protection of human rights, and the dignity of humanity and of all life.

Specific Suggestions for Wording of CBAC's Proposed Principles

Justice

- Some participants suggested that this principle, as written, is a political statement because it deals with the distribution of benefits and burdens but does not address whether these benefits and burdens should be allowed to occur.
- In addition to oppression, add a reference to avoiding **exploitation** of vulnerable groups.
- Justice should also be considered in the context of developing countries. At present, the distribution of benefits of biotechnology is unfairly weighted in favour of developed countries. The emphasis of benefits should be shifted to developing countries.
- A definition of Justice is required – what is meant by "fair," who are the vulnerable groups, who determines this?

Accountability

- Definition of accountability must describe who is answerable should something go wrong.
- Add the concept of enduring liability.
- Consider combining accountability and autonomy so they can be balanced against each other.

Autonomy

- The reference to informed choice may require elaboration. The principle should define how to properly engage people who may lack the knowledge or understanding of what is proposed in a way that ensures an "informed" decision.
- Consider breaking this principle into two parts
  - –being informed
  - –ability to act independently
  - and define both.
- Include a reference to non-coercion; ensure the ability to make independent choice and decisions.

Beneficence

- Define as a commitment to pursue **all** benefits.
- Include in the definition the concept of the benefits of investment.

Respect for Diversity

- Definition should specify "bio-diversity in its broadest sense."
- Extend the concept to specifically include plants, non-human animals and the environment.

Knowledge

- As currently written, the principle is not clear – define what is meant by knowledge.

Caution

- It was proposed that this principle should simply be "a commitment to adopt a precautionary approach" and that the phrase "when knowledge is incomplete" is unnecessary. Where there is uncertainty, the "safest choice" should be made. The document must clearly define this principle.
- It was suggested that the intent of this principle should be to avoid rushing into things without serious prior consideration, but should also be concerned with being so cautious that any progress is not possible – must be balanced.
- It was noted that biotechnology requires "a lot of caution" because even experts are unclear about potential risks.
- The precautionary principle, upon which the caution principle is based, is controversial, and there are several interpretations. Does CBAC mean "if you don't know, don't do it" or does it mean "anticipate, go slowly and ensure you have an escape strategy"? This needs to be clarified.
- Is the concept of "substantial equivalence" used in regulation development consistent with this principle?

Next Steps for CBAC's Proposed Principles:

CBAC views the process of developing and refining its proposed principles as one of its highest priorities. It also understands that, as new technology becomes available, there will be a continuing need to update these principles. To this end, it will continue to solicit the views of Canadians on how to better define the principles.

Annex F: Patentability in Canada and Selected Other Countries of Plant, Animal and Human Material and of Processes Using Higher Life Forms

There are different approaches to patenting of higher life forms and related processes around the world. This chart compares Canada with other major biotechnology exporting countries (United States, Japan and the members of the European Union) and selected other countries (Australia, Hungary and Korea). The shaded areas show what is permitted to be patented in these countries.

	Canada	United States	Japan	European Union	Australia	Hungary	Korea
Proteins (plant, animal, human)							
Genes (plant, animal, human)				**			
Cells (plant, animal, human)				**			
Plants							***
Plant varieties							
Plant breeders' rights							
Animal organs							
Animals							
Animal varieties							
Human organs							
Processes without substantial human intervention							
Animal diagnostics*							
Animal therapies							
Gene therapy for animals*							
Human diagnostics*							
Human therapies							
Gene therapies for humans*							

* "Animal diagnostics" and "Human diagnostics" apply only to diagnostic procedures used on animals or humans directly (that is, not diagnostic methods performed outside the body). Similarly, "Gene therapy for animals" and "Gene therapy for humans" apply only to gene therapy procedures performed on animal or human bodies and include neither the materials used in gene therapy nor processes that occur outside the body.

** Although the European Patent Office has issued patents over human genes and cells that are applicable in France, the French Minister of Justice stated in June 2000 that these patents may be invalid if challenged in France.

*** Asexually reproduced plants only.

Source: Gold, Richard (2001), *Patenting Life Forms: An International Comparison* (Ottawa: Canadian Biotechnology Advisory Committee), p.7.