BIOTECHNOLOGICAL INTELLECTUAL PROPERTY AND THE PATENTING OF HIGHER LIFE FORMS

Consultation Document 2001

This publication is also available electronically on the Canadian Biotechnology Advisory Committee (CBAC) Web site at the following address: *www.cbac-cccb.ca*

This publication can be made available in alternative formats upon request.

Biotechnological Intellectual Property and Patenting of Higher Life Forms Consultations
Canadian Biotechnology Advisory Committee
5th Floor, Room 570E
240 Sparks Street
Ottawa ON K1A 0H5

CBAC Web site: *www.cbac-cccb.ca/IPConsult_eng.htm*
CBAC toll-free number: 1 866 748-CBAC (2222)
CBAC toll-free TTY/ATS: 1 866 835-5380

Your comments on the issues raised in this Consultation Document or a completed questionnaire may be submitted in hard copy to the address above. Copies may also be submitted by facsimile to (613) 946-2847.

In order for your views to be considered in a timely fashion, please return your completed questionnaire to CBAC by **Monday May 14, 2001.**

Cat. No. C21-32/1-2001
ISBN 0-662-65549-4
53337B

15% recycled material

CONTENTS

To obtain additional copies of this Consultation Document or to learn more about CBAC and its various activities, please consult or contact CBAC at:

CBAC Web site:	*www.cbac-cccb.ca/IPConsult_eng.htm*
CBAC Toll-free Number:	1 866 748-CBAC (2222)
CBAC Toll-free TTY/ATS:	1 866 835-5380

In order for your views to be considered in a timely fashion, please return your completed questionnaire to CBAC by **Monday May 14, 2001**.

INTRODUCTION AND PURPOSE

The Canadian Biotechnology Advisory Committee (CBAC) is an independent expert advisory committee created to assist the Government of Canada in the formulation of public policy on a broad range of biotechnology subjects. Its advice is provided to the Biotechnology Ministerial Coordinating Committee (BMCC), which comprises the federal Ministers of Industry, Agriculture and Agri-Food, Health, Environment, Fisheries and Oceans, Natural Resources, and International Trade.

CBAC's members bring expertise in diverse fields such as science, business, nutrition, law, environment, philosophy, ethics and public advocacy, and serve on a part-time, volunteer basis. CBAC's Program Plan 2000, released in February 2000, describes in detail the committee's organization, operating procedures and program of activities. CBAC's first Annual Report, released in February 2001, offers further information on the origin and activities of CBAC, its ongoing monitoring and advisory role, advice it has delivered to government to date, and broader perspectives on developments in biotechnology. These documents may be viewed and obtained through the CBAC Web site: *www.cbac-cccb.ca*. They may also be obtained by calling CBAC's toll-free telephone number (1-866-748-CBAC (2222)).

CBAC is currently preparing advice for government on *Biotechnological Intellectual Property and the Patenting of Higher Life Forms*. CBAC wishes to solicit the views of Canadians on this topic and take these into consideration in developing its advice. This Consultation Document is an important instrument through which CBAC is seeking this input. This document describes four key issues and poses specific questions that seek the perspectives of respondents. These questions as well as an area for general comments are compiled in Annex 4.

To assist in the dissemination of this Consultation Document, CBAC is seeking the assistance of a network of organizations representing producers, environmental interests, consumers, health professionals, industry and various citizen groups. This Consultation Document is directed primarily to groups and individuals with a particular knowledge of and interest in biotechnological intellectual property and the patenting of higher life forms and related processes in Canada. All Canadians interested in providing views to CBAC are invited to respond. You may respond to one, some, or all of the questions contained in this report, and you may develop and submit comments individually, in small groups, or on behalf of an organization.

Comments can be submitted electronically, using an on-line document and questionnaire at *www.cbac-cccb.ca/IPConsult_eng.htm*, or in paper form by completing and returning the *questionnaire in Annex 4 of this document*. For this latter purpose, the questionnaire can be sent by facsimile to (613) 946-2847 or by mail to:

Biotechnological Intellectual Property and Patenting of Higher Life Forms Consultations
Canadian Biotechnology Advisory Committee
5th Floor, Room 570E
240 Sparks Street
Ottawa ON K1A 0H5

In order for your views to be considered in a timely fashion, please return your completed questionnaire to CBAC by **Monday May 14, 2001**.

The process leading up to a final report to government is as follows:

- In addition to the comments received via this document by mail and through its toll-free number and Web site, CBAC is also collecting the views of Canadians through multistakeholder roundtables. Summary reports of the results of each multistakeholder roundtable, as well as an overall summary report of all input collected, will be available on the CBAC Web site for public comment.

- Based on the information in the above reports, as well as on research papers, commissioned studies and recent public-opinion polls, CBAC will then prepare a report to government clarifying issues, options and consequences, and setting out its recommendations. The report will be published in Summer 2001 and will also be available through CBAC's toll-free telephone number and on its Web site. CBAC will welcome comments on this report for three months following its release. After the end of this period CBAC will review these comments to determine whether it ought to refine its advice.

Please note that CBAC is also, at this time, initiating consultations on the Regulation of Genetically Modified Food. Please contact CBAC or consult the CBAC Web site for details and documentation. As well, in Fall 2001, CBAC is planning a citizen engagement initiative which will address a number of topics including biotechnological intellectual property.

Information on all CBAC activities will continue to be available on the CBAC Web site and can also be obtained through the CBAC toll-free number.

ETHICAL CONTEXT

Ethical judgments are not "stand-alone" judgments. Rather, they are "all things considered" judgments. They are integrative judgments that take into account economic, political, legal, environmental, scientific and other factors. In this respect, ethical considerations are not one set of factors among many, but rather take into account all relevant factors.[1] CBAC's task in developing recommendations on biotechnology is to integrate these various factors and develop a set of recommendations that best serve the greater good and overall public interest.

CBAC views the public interest as the primary criterion for the development of sound government policies and programs. It comprises, for instance, the health of Canadian citizens, the quality of life of Canadians, the health of the environment, the prosperity of the Canadian economy, fair distribution of the benefits and burdens, and a sustainable, peaceful global community. The primacy of the public interest 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 their concerns and effective balancing of the diversity of interests and priorities of the people of Canada.

CBAC has identified the principles contained in Box 1 as setting out the ethical context for its consultation and discussion with Canadians. CBAC welcomes your comments on the applicability of these principles to the discussion of public policy issues related to biotechnological intellectual property and the patenting of higher life forms and related processes.

Box 1

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.

As the articulation of the ethical context is further developed and refined, it should serve as a useful framework for assessing proposals for public policy related to biotechnology.

[1] cf. Annex 2 reference to Dr. Michael McDonald.

OVERVIEW

Any discussion of intellectual property and the patenting of higher life forms and related processes is necessarily complex. This is due, in part, not only to the technical nature of modern biotechnology, but to the many different ways that people think about intellectual property and higher life forms. From a patent law perspective, for example, there is no fundamental difference between patenting a life form and any other thing. Provided that the life form is an invention (as that term is understood within patent law) and is disclosed, it is patentable. From the perspective of someone involved with human rights, a central question might be the status of the life form. If it is deserving of rights, then we must act in certain ways. To an environmentalist, however, the question of patenting a life form might be tied to the implications of the patenting process and of that patent on the environment. While each of these different perspectives is legitimate, they make discussion of the issues addressed in the Consultation Document difficult. To the extent possible, CBAC has attempted, in this document, to describe the different ways of viewing the issues.

DEFINITIONS

For the purposes of this Consultation Document, the following words have the following meanings:

Biotechnology: 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."

Patent: A patent is the right to exclude all others from making, constructing, using and selling an invention for a period of 20 years from the date an application for the patent was first filed.[2] Simply having a patent does not permit the patent holder to use the invention; he or she may only do so if there are no conflicting property rights or any laws or regulations preventing use of the invention. The patent also allows the holder to assign a whole or partial interest in the invention to another. Patents are granted on a country-by-country basis. Canadian patents are provided under the *Patent Act*.

Higher life form: The term "higher life form" has no technical meaning within the law. In common parlance it includes plants and animals[3] other than single-celled organisms. In its deliberations on biotechnological intellectual property, CBAC uses the term "higher life form" to encompass whole plants and animals (including non-human primates), and parts of an animal or plant, such as an organ, tissue, cell and genetic material.[4] The broad scope of this definition of higher life forms means that one must almost always specify which of the many higher life forms one is referring to in discussing particular issues.

BIOTECHNOLOGY

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.

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

[2] More precisely, patents filed on or after October 1, 1989, receive a 20-year term of patent protection starting from the first filing date.

[3] Even though human beings are animals, most lawyers do not generally believe that a whole human being is patentable.

[4] Although not included in the definition of "higher life forms," processes that make use of higher life forms to manufacture something or to provide a service are also potentially patentable. It is important to note that some processes using plants and animals involve nothing more than allowing nature to do its work while others involve substantial human intervention.

approaches to the protection of health and the environment. Several uses of biotechnology raise serious social and ethical questions.

Box 2

Canada's Biotechnology Industry

Canada's biotechnology industry consists of about 360 firms, one quarter of which are publicly traded. It employs almost 10,000 people (with another 2,000 jobs unfilled) and generates $1.9 billion in sales, 40 percent of which is exported. Most of the companies are either small or medium-sized, with 72 percent having fewer than 50 employees, 15 percent having 51–150 employees, and 13 percent having more than 150 workers. Québec has the most biotechnology companies, followed by Ontario and British Columbia.

Almost 95 percent of the industry's firms conduct biotechnology research. Overall R&D expenditures are in the $800-million range, 90 percent of which are in the health sector. More than half of the companies use state-of-the-art tools such as DNA-based technologies, bio-informatics, genomics and molecular modelling. About 10 percent of the federal government's research budget goes to biotechnology. In 1997–98, the federal government spent $314 million on biotechnology R&D.

Source: BioteCanada's Report on the Road to Success, 2000.

The biotechnology industry 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.[5] Canada is emerging as a significant contributor to this growth.

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.

Biotechnology is a highly dynamic field, with new developments emerging at an ever-accelerating pace. As the number of applications for biotechnological innovations multiplies, patents will become increasingly important in realizing biotechnology's benefits.

PATENTS

When biotechnological research leads to the invention of a new product or process, the inventors and/or the sponsors of the work may seek intellectual property rights to protect those inventions. Although it depends on the type of invention involved, a patent is often the form of intellectual property protection sought for biotechnology innovations. However, other forms of intellectual property protection such as copyright, trademark, trade secrets and plant breeders' rights, do exist. The patent gives the inventor and/or the sponsors of the work the right to prevent anyone else from making, using or commercially exploiting the invention in Canada for a period of 20 years. By international agreement, the person or company applying for a patent in Canada may also apply for patents for the same invention in other countries.

Canada and its major trading partners abide by international agreements on the issuance of patents. Although each country applies these rules slightly differently, the fundamental nature of patent protection remains relatively constant throughout the developed world. Canada grants patents on inventions in exchange for public disclosure of the research and data on those inventions. For the purposes of patent law (which contains its own definitions that may or may not accord with popular usage), an invention is a product or process that is new, non-obvious and useful. An invention is new if it has not been disclosed prior to the filing date of its patent application (subject to a grace period in some countries[6]). An 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. An invention is useful if it has a realistic and substantial industrial application.

The traditional justification for granting patents over inventions is that patents act as an incentive to those conducting research and development. Patents provide inventors with the chance to commercially

[5] *Leading in the next millennium*, National Biotechnology Advisory Committee, Sixth Report. Industry Canada. 1998.

[6] 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 someone through the inventor.°

exploit their invention for 20 years following the date on which they submit the patent application. This allows creators and innovators an opportunity to reap the rewards of their endeavours, recover their investment, and make a profit. It is also thought that talented researchers, knowing of this reward, will be more likely to invest time and money in creating new inventions. A successful application must include, among other things, information concerning the nature and use of the invention. This information becomes public in Canada 18 months from the filing date. Even before the end of the 20-year period, the public (including other researchers) may use the information disclosed in the patent application to conduct more research and discovery.

The tests of novelty, non-obviousness and utility apply to an invention whether it is a new mousetrap, a piece of DNA or the newest electronic device. Despite the wide range of things that can potentially be patented, there are certain statutory exclusions such as scientific principles and abstract theorems. Courts have also found other exclusions to patentability, some of which will be discussed later in this document.

One of the exclusions that is relevant for biotechnological inventions relates to "things as they exist in nature." For example, it is not possible to patent a gene, a protein, a cell or any other biological material *as it exists in nature*. This, however, does not prevent the patenting of the products of biotechnological innovation. This is because biotechnology does not limit itself simply to explaining how things work in nature; it seeks to harness the power of biological materials to do something new. Therefore, researchers take biological materials out of their natural settings to make them do something of commercial use. As soon as the researcher removes the materials from the natural setting, the materials potentially become subject to patents if they are new, non-obvious and useful.

In Canada, the question of whether whole animals are excluded from patent protection is currently before the courts. Currently, the courts are considering whether animals are included in the definition of a patentable invention. The Federal Court of Appeal determined in August 2000 that a mouse that has been genetically engineered by Harvard University (the so-called "Onco-mouse") was patentable in Canada. The government has sought leave to appeal that decision to the Supreme Court of Canada. If and when the Supreme Court of Canada decides this case, it may provide guidance on the question of the extent to which higher life forms generally are patentable in Canada. The government holds that the current *Patent Act* does not allow for the patenting of whole animals.

The biotechnology industry is currently exploring a number of mechanisms to either supplement or replace patents as the "vehicle of choice" for establishing technological lead in specific markets. These options include technological devices that prevent reproduction, the use of monitoring technologies, and the entry into contractual agreements through which the industry can control the use being made of technology. As with patenting, each of these alternatives raises significant socio-economic and ethical issues that require examination.

[6] 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 someone through the inventor.º

CONSULTATION ISSUES

INTRODUCTION

Several factors joined forces in recent years to prompt CBAC to select biotechnological intellectual property and the patenting of higher life forms and related processes as a priority issue for consultation. A key factor is that no broad international consensus exists on the patenting of higher life forms and related processes.[7] Countries continue to review the scope and nature of higher-life-form patenting within the framework of the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) to which Canada is a signatory. To help facilitate that review, Canada requires a coherent, thought-out position that takes into account the views of Canadians.

The purpose of the present CBAC consultations is to garner the views of stakeholders and the public concerning patents and biotechnology, and to use these opinions as a key element in CBAC's advice to the Government of Canada. This advice will focus on two main areas:

- initiatives to enhance the ability of Canadians to protect and use intellectual property rights pertaining to biotechnology in a manner that continues to be socially responsible; and
- whether or not the patenting of some or all higher life forms or related processes should be permitted in Canada.

The issues surrounding the patenting of biological material in general and higher life forms and related processes in particular are complex. To bring some structure to the discussions, CBAC commissioned a series of studies (see Annex 2) on a variety of topics relating to intellectual property rights in biological material. It also held preliminary discussions 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 broader consultations to take place in Spring 2001.

The broader consultations will consist of two general categories. One concerns a series of roundtable discussions with stakeholders in Halifax, Montréal, Toronto, Vancouver and Saskatoon from late April to May 2001. The other part of the consultations involves public input. From March to May 14, 2001, the public is invited to submit views on the issues outlined below or other relevant matters. Submissions may be made by phone, fax, mail or e-mail to the contact points listed at the front of this document.

CBAC has divided the issues into four themes, covering a range of topics and policy choices relating to biotechnology patenting. The four themes are: What should and should not be patented? What are the mechanisms of governance available for change? How should social and ethical issues be addressed? International obligations and competitiveness. These items set out a framework for discussion about the fundamental value choices at stake in biotechnology and intellectual property rights, in examining the relative advantages and risks of various policy instruments, in formulating particular recommendations within the context of these choices and instruments, and in proposing Canada's approach to its international obligations and the need to remain internationally competitive.

[7] All of Canada's major trading partners currently grant patents over whole animals (other than human beings) and plants and on many parts of animals and plants. All of these countries also grant patents on certain processes using plants and animals, although there are differences in approach. Canada and all of its major trading partners currently grant patents on genetic material whether of animal, plant, or human origin.

1. WHAT SHOULD AND SHOULD NOT BE PATENTED?

Discussion Points concerning Specific and General *Patent Act* Exclusions

In developing its policy on the patentability of higher life forms and related processes, Canada must determine both the types of higher life forms and related processes, if any, that ought to be subject to patent protection and the extent to which a patent holder over these higher life forms or related processes can prevent others from using the invention. The first set of issues relates to whether or not higher life forms and/or related processes ought to be patentable and, if so, if there should be any exclusions to this rule. The second question relates to the use that can be made of a patent by individuals other than the patent holder without violating the patent. This question is discussed below under the heading "Experimental Use."

The first decision Canada must make is which higher life forms and related processes, if any, may be patented and which will be excluded from the *Patent Act*. It must also decide whether to choose specific exclusions (that is, exclusions targeted at specific materials such as, for example, human tissues and organs, and specific processes such as those used for modifying the genetic identity of animals that would likely cause them harm without substantial medical benefit) or more general exclusions that are interpreted on a case-by-case basis. General exclusions could include, for example, a general "ordre public or morality"[8] provision or a narrower exclusion of inventions that threaten the environment or human, animal or plant health. Whichever way Canada deals with patenting of higher life forms, it is generally understood that an entire human being could not or would not be patented. This is so because human beings are not thought to satisfy the tests for patentability and because of the concern that exercising patent rights over an entire human being would likely violate human rights.

Specific exclusions could provide greater certainty, although they must be carefully designed to minimize questions of interpretation.[9] A general exclusion based on "ordre public" or morality is more flexible but therefore more uncertain. It leaves greater discretion to the patent office and the courts to decide when the exclusion should apply, and some people question if patent officials should be making such decisions. Depending on its interpretation, an "ordre public" exception might be adequate but would need to be carefully worded to ensure that all relevant concerns are addressed. Perhaps such a determination should not be spelled out but be determined on a case-by-case basis. General exclusions on the basis of morality without further elaboration provide, however, little clarity or certainty. The issue also remains of whether the interpretation of this exclusion should rest with a body other than the patent office.

Canada may wish to exclude patents over certain higher life forms or related processes because of the fear that the proliferation of patent rights may actually reduce, rather than enhance, inventive activity. Authors have dubbed this phenomenon the "anti-commons" effect. One sector that may be particularly and negatively affected by the proliferation of patents is the Canadian livestock breeding industry. This industry is relatively small and cooperative. One CBAC study concluded that this put the industry at a distinct disadvantage in gaining access to innovation protected by intellectual property rights. The result of this may be that Canadian industry will lose ground against the larger multinational corporations which have the resources necessary to purchase access to this innovation.

In the design of any exclusions, relevant international trade law must be taken into account. Canada is a member of NAFTA and as a WTO member is subject

[8] The European Directive on the Legal Protection of Biotechnological Inventions, for example, contains an "ordre public" or morality provision that allows patents to be withheld on the grounds that the invention's commercial use could cause significant public unrest or disorder or that it violates fundamental and shared European norms. "Ordre public" may include, but not necessarily be limited to, the need to protect fundamental values, or human, animal or plant life, health, or to avoid serious prejudice to the environment. An "ordre public" or morality type of exclusion is discussed in more detail under the heading, How should Social and Ethical issues be addressed?

[9] For example, where a "human being" is excluded, it must first be determined what the definition of human being should include. In making this determination, we need to ask whether human embryos or animals containing a substantial number of human genes are considered "human beings."

to the provisions of TRIPs. These agreements require member states to provide patent protection to all new, useful and non-obvious inventions without discrimination as to the place of invention, field of technology and whether the products were imported or locally produced. As TRIPs prohibits member states from imposing additional substantiative conditions for patentability apart from newness, non-obviousness and utility (called industrial applicability in TRIPs), Canada cannot do so without being in violation of its international obligations. And, as TRIPs requires all fields of technology to be treated equally under the law, any exceptions to Canada's patent law cannot discriminate against biotechnology as a whole. However, NAFTA and TRIPs do permit member states to exclude certain inventions from patentability (for example, inventions can be denied patent protection in order to protect "ordre public" or morality). Member states may also exclude medical procedures, and plants and animals other than micro-organisms and essentially biological processes for the production of plants and animals as long as they provide some form of intellectual property protection for plant varieties. Canada's current Plant Breeders' Rights legislation provides a *sui generis* system of protection for plant varieties in accordance with this requirement.

Also, given that Canada is highly trade-dependent and that intellectual property policy and trade policy are increasingly interconnected, Canada may wish to look to the options selected by its major trading partners that export and import biotechnology, in determining *Patent Act* exclusions.

Suggested Questions for Discussion

1. *Should Canada allow the patenting of higher life forms and related processes? If so, are there types of higher life forms and/or related processes that should not be patentable and on what grounds?*

* *Do you have any other comments on this issue?*

Discussion Points concerning Exclusions and Defences: Methods of Medical Treatment and Research/Experimental Use

Methods of Medical Treatment: Canada does not issue patents for surgical or medical methods of treatment of conditions such as disease. It does allow patents for diagnostic methods dealing with a human or animal condition such as aging. The Supreme Court has determined that surgical and therapeutic methods of medical treatment cannot be patented because these types of treatments do not have industrial applicability and consequently do not satisfy the traditional standard for utility for an invention. However, diagnostic methods and any process that does not involve actual treatment of the human body or an animal are not "methods of medical treatment" in the strictest sense and therefore may be patented. Also patentable are new therapeutic uses of existing compounds even though these new uses can be seen as essentially new "methods of medical treatment," and articles or apparatus for treating humans or animals.

The application of the traditional medical treatment exclusion to biotechnological innovation is complicated. Some recent inventions, such as gene therapy, have characteristics that fall both within the exclusion and outside it. Thus, some parts of gene therapy may be patentable (for example, those parts practised outside the body) while others may fall within the exclusion (for instance, the injection of the modified gene into the body). It may make sense to redefine or clarify the medical treatment exclusion. Another consideration regarding this exclusion is whether it should be explicitly set out in legislation, as in the European Patent Convention, or left to judicial interpretation as is currently the case in Canada.

Experimental Use: Canada must determine under which circumstances, if any, someone may use a patented higher life form or related process without infringing upon the patent. The experimental use defence or exemption was first developed by Canadian courts in an attempt to answer this question. It balances the interests of patent holders to commercialize their inventions with those of society to foster further research. Generally speaking, this defence permits persons other than the patent holder to use a patented invention for a non-commercial purpose, usually research or to determine if an invention works as described in the patent, without infringing the patent. However, the full scope of the experimental use defence has been difficult to determine. It has been used successfully as a defence to a claim of patent infringement

in a few cases but is unavailable when the research is motivated by a commercial purpose. Given that biotechnology research often aims to eventually develop a product capable of commercial use, the applicability of the experimental use defence to biotechnology is uncertain. The scope of this defence is particularly important to the patenting of whole plants and animals. Since genetically engineered crops and breeding animals often become the platform from which new research is conducted, it is important for researchers in these industries to understand which research they may carry out without violating a patent.

In the United States, the experimental use defence is even narrower than in Canada. It applies only to research having the purpose of "philosophical enquiry." While this concept is unclear, it likely applies only to research with no reasonably possible commercial application. Under the laws of the Member States of the European Union, the experimental use defence is wider as it permits not only "philosophical enquiry" but also research on the subject matter of the patent. Therefore, even commercial research on the invention itself (as opposed to research merely using the invention) does not violate the patent on that invention.

Canada may wish to consider whether a broad experimental use defence is warranted or whether a narrower defence best balances the interests of inventors and researchers in the area of biotechnology. It must also consider if creating an experimental use defence for biotechnology alone would discriminate against biotechnology and thus violate international obligations. If so, Canada may opt to create a general experimental use defence rather than one targeted at higher life forms and related processes. If Canada creates an experimental use defence for biotechnological inventions, it may want to determine whether the scope of that defence should vary depending on whether it is being applied, for example, to human therapeutics or plants.

Suggested Questions for Discussion

2. *Should we codify the experimental use defence and/or the method of medical treatment exclusion with respect to biotechnological patents by including it in the* Patent Act*? Is the scope of each sufficient or should it be narrowed or broadened?*

* *Do you have any other comments on this issue?*

Discussion Points concerning Farmers' Privilege and Plant and Animal Varieties Exclusions

Plants: Canada's Plant Breeders' Rights legislation is a form of intellectual property protection that is specific to plant varieties. The *Plant Breeders' Rights Act* (PBRA) gives a breeder the right to exclude others from selling and producing a specific plant variety for the purpose of selling the propagating material (for example, seeds and cuttings). It contains two exemptions. The first, farmers' privilege, is an implied exemption. It allows farmers to save and reuse the seeds obtained from their cultivation of protected plant varieties for farming purposes. For example, a farmer could replant seeds from a wheat crop for the purpose of selling the resulting wheat as food but could not sell the wheat as a means of reselling the seeds themselves. However, if the genetic material contained in a protected variety is patented, the farmer might be liable for patent infringement under the *Patent Act*, notwithstanding farmers' privilege under the PBRA. The second exemption in the PBRA concerns research. It allows others to use protected varieties not only for research purposes, as in the *Patent Act*, but also for breeding and developing new varieties for commercial purposes.

Some people consider the protection granted to plant breeders under the PBRA to be limited in that they do not extend to the underlying genetic material or restrict the commercialization of the plant variety's parts such as its fruit, root or leaves. While some observers suggest that the patent system be expanded to include plants and animals per se, others contend that this would create a conflict between the rights of patent holders and those of breeders under the PBRA.

Providing for a plant varieties exemption under the patent system may be one solution. However, whether or not this represents an acceptable solution depends on how patent offices and courts interpret the scope of the exemption. It may also be unacceptable to those who support the right of innovators to choose the type of protection appropriate to their innovations. An alternative solution would be to add a farmers' privilege provision within the *Patent Act*.

Canada's plant breeders' rights system provides a *sui generis* system of intellectual property protection for plant varieties in accordance with its international obligations.

Internationally, plant breeders' rights were first recognized in 1961 by the International Convention for the Protection of New Varieties of Plants (UPOV). Canada ratified the 1978 version of the UPOV Convention. UPOV was amended in 1991 to permit countries to provide both patent and plant variety protection to plants and to extend coverage under the treaty to "essentially derived varieties and to harvested materials," both of which represent significant changes from the previous UPOV. Several nations have modified their legislation to conform with the 1991 Convention although few countries (including Canada's major trading partners) have ratified it. Bill C-80,[10] tabled in the House of Commons in 1999, contained amendments which would have allowed Canada to ratify the 1991 UPOV Convention but the bill died on the Order Paper. Currently, Canada follows the 1978 UPOV Convention.

Some organizations concerned about the environment believe that plant variety protection is preferable to patent protection over plants. They argue that patents encourage the holding of basic plant technologies in the hands of a few companies. Since these companies sell a limited stock of plant seed, fewer different kinds of plants will be grown. These organizations fear that this will reduce the amount of genetic diversity among crops grown around the world, lessening the inherent resistance of our food crops to infestation by pests. They believe that plant variety protection is preferable to patents since they have a lesser effect in concentrating basic technology in the hands of a few.

Canada may wish to consider reviewing and revisiting current PBRA legislation to accord with co-extensive patent legislation, today's scientific and technological environment and current Canadian socio-economic concerns about biotechnology. Canada may wish to consider synchronizing the *Patent Act* with the PBRA so that a similar farmers' privilege exemption applies to each. It may also wish to consider creating a legal obligation between exercising certain patent rights and exercising PBRs, as in Europe. (This would require, for example, a researcher who incorporates patented genetic material into a protected plant variety to pay a royalty for the commercialization of the resulting modified variety and/or its seeds.) Canada may also wish to consider re-introducing relevant portions of former Bill C-80.

Animals: The question of animal variety protection is more difficult than that of plant variety protection because of the absence of international agreements or consensus on the subject. There are scientific reasons behind this lack of consensus. Animals tend to have much higher genetic variation than do plants. Livestock species rely exclusively on sexual reproduction and have a significant range of genetic variation, making stable incorporation of any genetic sequence in offspring much more unpredictable. In assessing an animal varieties exemption, Canada may wish to consider how "animal variety" would be defined.

Healthy animal populations require an ongoing exchange of genes and a diverse choice of genetic combinations from which to draw to maintain genetic diversity and avoid inbreeding. Concerns have been raised that some domestic livestock populations lack this diversity. Patenting of animals would give the right to exclude certain animals and their offspring from use unless royalties are paid. Canada may wish to consider the implications of splitting of breeding populations (those for which breeders are willing to pay royalties and those for which they are not), including the amount of genetic variation remaining and future scientific progress.

Breed associations under the *Animal Pedigree Act* currently invest heavily in the testing of young animals. Since genetic improvement is cumulative, investments on behalf of the entire breed make sense. However, financial considerations could result in several top tested bulls or boars being picked up by biotechnology firms seeking to establish their own exclusive foundations. Canada may wish to consider what the interface should be between the *Patent Act* (in a context where patents on animals are allowed) and the *Animal Pedigree Act*.

Suggested Questions for Discussion

3. Should the Patent Act *include a farmers' privilege and/or a plant and animals varieties exemption?*

** Do you have any other comments on this issue?*

---

[10] An Act to revise and consolidate certain Acts respecting food, agricultural commodities, aquatic commodities and agricultural inputs, to amend the *Canadian Food Inspection Agency Act*, the *Agriculture and Agri-Food Administrative Monetary Penalties Act*, the *Health of Animals Act*, the *Plant Protection Act* and the *Plant Breeders' Rights Act*, and to repeal and amend other Acts in Consequence.

2. WHAT ARE THE MECHANISMS OF GOVERNANCE AVAILABLE FOR CHANGE?

Discussion Points concerning Legislative versus Policy versus Jurisprudential Approaches

The *Patent Act* establishes the general rules that apply to patenting, and the Canadian Intellectual Property Office (CIPO) interprets and administers the Act. In the case of a dispute as to the meaning of the Act or its application to a particular invention, the Federal Court of Canada and, ultimately, the Supreme Court of Canada, settles the dispute. Given the very general and open-ended nature of the *Patent Act*, the courts currently play an important role in defining the boundaries of patent law and the scope of rights that exist within it. In its Harvard Onco-mouse decision in Summer 2000, the Federal Court of Appeal stated that it was ultimately Parliament's responsibility to set the boundaries of patent law in the area of biotechnology.

Patent law emerges both through judicial interpretation and legislative amendment. Each approach has advantages and disadvantages. For example, the judicial approach would require affected individuals to take on the burden of bringing and arguing a case; deciding each case on its own merits causes uncertainty; and the judicial approach would involve more substantial delays than if the government proactively legislated changes. However, the flexibility of the judicial approach is an advantage over the legislative approach in that it may be difficult to design a legislative amendment which achieves the desired result and anticipates all potential problems, especially with respect to a quickly emerging and extremely variable domain as biotechnology.

Box 3

On August 3, 2000, the Federal Court of Appeal concluded that a patent ought to be granted to Harvard University for the creation of the Onco-mouse. It ruled that the wording of the Patent Act, *as it currently stands, permits the patentability of genetically altered, non-human mammals for use in carcinogenicity studies.*

In September 2000, CBAC issued an advisory memorandum to BMCC stating that it concurs with the Federal Court of Appeal's finding that Parliament, not the courts, should determine Canada's policy regarding the patenting of higher life forms (and the distinction between "lower" and "higher" life forms). CBAC observed that Canada's laws ought to reflect social values and that Canadians have not yet had an opportunity to debate the full range of moral, ethical and social issues at stake in this case. The memorandum noted CBAC's intention to facilitate such a debate in Spring 2001.

CBAC encouraged the Government of Canada to take "all reasonable and feasible steps" to facilitate a Parliamentary review of the issue. In this regard, a majority of CBAC members urged the government to prompt Parliament to amend the Patent Act *to explicitly forbid, on an interim basis and pending the completion of a Parliamentary review, the patenting of particular classes of higher life forms such as primates, the human body and certain plant species. Others favoured advising the government to appeal the Federal Court of Appeal's decision to the Supreme Court of Canada. On October 2, 2000, government lawyers representing the Commissioner of Patents filed an application seeking leave to appeal the decision to the Supreme Court of Canada.*

The courts have expressed an unwillingness to engage in an ethical review of patent applications within the current legislative scheme. Therefore, to the extent that certain subject matter ought to be excluded from patent protection or whether an "ordre public" or morality clause ought to be included in the *Patent Act*, recourse to the courts will be of little help. Thus, if it is decided that exclusions should extend to these, legislative action would be necessary.

Overall, then, Canada has a choice among a constellation of instruments through which to achieve its policy goals. These instruments can conveniently be described as follows, although a combination of the instruments is not only possible, but likely:

Patent office policy: CIPO could consider preparing guidelines as to the patentability of higher life forms and related processes and the application of an "ordre public" or morality clause should one be enacted. The United States Patent and Trademark Office issues non-binding examination guidelines to assist patent applicants in understanding the Office's interpretation of its governing legislation.

Legislative modification of the Patent Act *and Regulations (see Issue 1, What Should and Should Not be Patented?):* By legislation, Canada could introduce either specific exclusions to patentability or create a general "ordre public" or morality provision within the *Patent Act*. To the extent that such a provision is created, legislation could also set out the procedure under which inventions will be assessed for breach of the provision.

New legislative instruments: Canada could create a separate legislative scheme under which it deals with ethical and other non-economic concerns related to biotechnology patents. This legislation could, for example, create a new administrative body to review such claims.

Judicial: having the court system enforce Canadian values with existing tools: The courts could continue to elucidate patent law through court challenges over the coming years. Through this process, we can hope that a coherent and flexible set of rules with respect to the patentability of higher life forms and related processes will emerge.

Suggested Questions for Discussion

4. *Should Canada continue with the current division of responsibilities among Parliament, the Canadian Intellectual Property Office and the courts, or would a new approach better serve Canadians? If so, what should that approach be?*
5. *What is the best approach for dealing with the values and issues touching on biotechnology patenting – legislation and regulation, policy guidelines and codes of conduct, or judicial interpretation?*

* *Do you have any other comments on this issue?*

3. HOW SHOULD SOCIAL AND ETHICAL ISSUES BE ADDRESSED?

Discussion Points concerning Social and Ethical Issues

Society has values that underpin its ethical and social perspectives. These values are often expressed in legal, regulatory and policy instruments. Canada already has specific examples of ethical guidelines and related tools that have implications for biotechnology.[11] However, certain aspects of biotechnology, such as cloning, may raise new social and ethical issues. The question arises: should the patent office be ethically neutral or should it have a role in determining what is and is not patentable based on ethical concerns?

Some people suggest adding an "ordre public" or morality provision to Canada's *Patent Act*.[12] This involves several considerations. One concerns the scope of the exception. Depending on the wording used, the provision could prevent the patentability of either a broader or more circumscribed set of inventions. Second, the commercial use of the invention may change over time. How would the patent system deal with a new use that contravenes "ordre public" or morality that is only developed after the patent has been granted? Similarly, how would the patent system deal with the finding of a new non-violating use of an invention with respect to which a patent was originally refused under the provision? Third, since a patent does not entitle its holder to exploit the invention, commercial exploitation can be, and frequently is, regulated by other legislation governing the field in question. Fourth, even if a patent is refused, the invention may still be in the public domain for anyone to commercially exploit despite the breach of "ordre public" or morality.

[11] For instance, codes of ethics are in place dealing with the delivery of medical practices and research involving humans and animals; various laws and policies covering privacy and confidentiality of personal information; and professional and industrial codes of conduct.

[12] European and Asian patent offices have this power; Canadian, U.S. and Australian offices do not. All countries agree that "ordre public" and morality are important; they differ only as to whether these concerns should be addressed within patent law or through specific laws and regulations.

A second consideration involves determining which societal values ought to be incorporated in an "ordre public" or morality provision. As the case law of the European Patent Office demonstrates, this is a complicated issue which varies with each case and for which there is no clear solution.

A third issue involves determining which administrative entity(ies) should administer the "ordre public" or morality provision and handle appeals from decisions to withhold patents on the basis of this provision. If a patent application is to be rejected because it is contrary to "ordre public" or morality, the patent examiner may be the first person to assess the applicability of this provision. Consideration would have to be given as to whether or not a separate administrative entity should be empowered to make these decisions. This entity could, for example, examine the ethical concerns related to a patent prior to or concurrently with the technical examination of the patent by CIPO. Under this scenario, CIPO would only issue the patent if the invention passed both the technical and the ethical examinations. Alternatively, it may make sense to introduce questions of "ordre public" and morality only in an opposition procedure (a procedure under which someone challenges an issued patent). If this route is selected, Canada would have to design an opposition process.

A related question involves determining which body should address appeals in patent matters. In the European Patent Office, a decision by the Examining Division to refuse a patent lies with the Technical Board of Appeal. In Canada, a decision on a patent application can be appealed to the Patent Appeal Board and then further to the Federal Court. However, given that litigation is generally lengthy, consideration might be given to alternative mechanisms to resolve disputes.

In developing its policy on this issue, Canada may wish to consider methods to ensure the appropriate sharing of both the risks and benefits arising from technology. This might involve developing industry standards on benefit sharing or imposing legislative obligation to share benefits, and ensuring that those who participate or provide the material for technology derive equitable benefit from it. 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. Among its recommendations were that all humans have access to the benefits of genetic research; that researchers engage in prior discussion with communities or populations concerning benefit sharing; that researchers ought to ensure that community health needs are provided even in the absence of profits; and that profit-making entities dedicate 1–3 percent of annual net profits to health or humanitarian efforts.

The issue of benefit sharing was raised by certain developing nations in discussions leading up to the adoption of the *Convention on Biological Diversity* in 1992. These nations argued that since industry extracts plants and animals from these countries in order to develop medications or genetically engineered crops and breeding stock, that industry should provide some return to these countries. They also said that industry should provide some return for the use of the traditional knowledge of those living in these countries. Industry uses the knowledge built up over the years by those living in these countries to help identify plants or animals with medicinal qualities or plants that are particularly resistant to certain pests. This allows industry to focus its research on plants and animals that are likely to result in a useful product. Industry thus saves a significant amount of time and money in its research. Some developing countries believe that industry ought to share some of these savings with them.

Some have raised the concern that the granting of patents over plants and animals may undermine our respect for nature and the environment. Since patents encourage industry to make commercial use of their inventions, the fear is that industry will treat plants, animals and human beings as nothing more than the subject of a commercial relationship or a commercial potential. The fear is that, instead of valuing plants, animals and human beings as inherently deserving of respect, we may come to see them as simply another resource available for human consumption.

Suggested Questions for Discussion

6. *Is the* Patent Act *the best place to address the social or ethical issues flowing from biotechnology innovations? If not, how and/or where might these issues be better addressed?*
7. *Should Canada's* Patent Act *include an "ordre public" or morality exclusion? If so, what should be the scope of the provision? Which administrative entity should apply it? Should this exclusion be evaluated during examination or only in a later opposition procedure?*

** Do you have any other comments on this issue?*

4. INTERNATIONAL OBLIGATIONS AND COMPETITIVENESS

Discussion Points concerning International Obligations and Canada's Reputation re Patenting

Canada is party to international conventions relating to biotechnology, intellectual property, international trade, biological diversity and human rights. Each convention was created to meet a perceived need. Because biotechnology covers so many different aspects of life, several of these conventions have an impact upon its regulation.

While negotiators are careful to try to avoid inconsistencies between the obligations set out in these conventions, there may be some tension between the objectives pursued by different conventions. For example, the *Convention on Biological Diversity* sets up a framework to protect the biological diversity of the planet by giving the right to each country to control access to its biological resources. While nothing in the *Convention* precludes patent rights in biological resources, some feel that there is an inherent tension between the *Convention* and intellectual property rights. On the other hand, some conventions complement each other, such as those dealing with intellectual property and those dealing with international trade. Since the coming into force of TRIPs, a violation of certain intellectual property rules may lead to trade sanctions.

In formulating its position with respect to the patenting of higher life forms and related processes, Canada must take into account the constraints imposed on it by all of its international obligations. Where it is perceived that a conflict exists between the spirit of two conventions, how ought Canada resolve this conflict within its law?

The interaction of Canada's many international obligations may not, in the view of some, provide it with sufficient room to properly address the issues of patenting of higher life forms and related processes. In such a case, Canada may need to renegotiate certain of its international obligations. For example, if Canada concludes that the best solution to the question of patenting higher life forms and related processes is to create specific rights unique to biotechnology, it may have to (depending on the nature of those rights) first negotiate an exemption within TRIPs to permit countries to discriminate against biotechnology for certain reasons.

CBAC has heard different opinions on the degree to which Canada is living up to its present international commitments. The Government of Canada's view is that Canada is consistently meeting these commitments. Some industry representatives say, however, that Canada has an international reputation for being unwilling to live up to its international obligations with respect to patent protection;[13] that companies find it difficult to convince head offices to invest in research and development in Canada because patent polices appear to be unfair; and that Canada may be sending an indirect message to foreign investors and affiliates that biotechnology, and therefore investments, are not well protected in this country. Some representatives of non-governmental organizations, on the other hand, state concerns including those to the effect that expanding intellectual property regimes on higher life forms and related processes could accelerate consolidation among seedstock suppliers and further reduce access to genetic resources, and that Canada is viewed among developing countries and indigenous peoples as being overly friendly to the biotechnology industry.

[13] In particular, some industry representatives said that Canada had not fully implemented the 20-year patent term. In addition, even though a WTO trade dispute panel had found against Canada on this issue, Canada was slow in revising its laws.

Box 4

During CBAC's discussions with industry representatives in preparing for the public consultations, some representatives raised the issue that it takes longer to obtain a patent in Canada than in other countries, even where patent claims are co-extensive with patents granted by major trading partners. Patents remain unexamined in Canada for an average of 22 months following a formal request for examination. This is in addition to the delay following filing of the Patent Cooperation Treaty (PCT) priority application. Thus, the total delay from innovation to examination in Canada can be approximately four years. According to these representatives, a more timely examination would make it easier to attract investors. The longer the time between filing and grant, the longer prospective patentees have to wait before approaching investors, and the less valuable and attractive the invention becomes as the period of exclusivity expires. Representatives also noted that no explicit guidelines exist on some of the criteria for obtaining patents.

Discussion Points concerning Inconsistencies among Industrialized Countries and Impacts of Inconsistencies

Research commissioned by CBAC pertaining to patents and biotechnology revealed several inconsistencies among industrialized countries, and between Canada and other industrialized nations with respect to the patentability of higher life forms and related processes. These include the following:

- Unlike the situation in Canada where the general issue of whether higher life forms are patentable inventions is before the courts, both the United States and Europe grant patents over higher life forms. The United States did so through judicial interpretation, while in Europe legislation was required to clarify the patentability of higher life forms.
- Canada's major trading partners all have a form of patent restoration term to compensate industry for loss of marketing time while products are being reviewed for safety. Canada does not have such a system.
- Canada has not issued any guidelines addressing the standard of utility and description with respect to DNA sequences. The United States has explicitly done so through the United States Patent and Trademark Office. Because of the lack of guidelines and of the emerging nature of biotechnology, it is uncertain whether the concepts of utility and description are the same throughout industrial nations.
- Unlike its major trading partners, Canada has not acceded to the 1991 UPOV Convention.
- Unlike Europe but similar to the United States, Canada has no clear rules as to the scope and application of an experimental use defence or exemption.
- Like Europe, the scope of Canada's medical treatment exclusion is unclear. This problem does not arise in the United States as this exclusion does not exist there.

While Canada may gain some advantage by choosing a different intellectual property approach than its major trading partners, some of the research commissioned by CBAC suggested that the above inconsistencies could also disadvantage Canada. These include a possible decrease in foreign investment and, consequently, biotechnological development. Nevertheless, some industry representatives noted that Canada is a good place to conduct research because of its health care system and high level of education and expertise. In addition, the fear of economic effects of failing to match the intellectual property regimes of Canada's major trading partners may be exaggerated due to the fact that the Canadian market for biotechnology products is in general not significant enough to affect investment decisions in research and development.

Suggested Questions for Discussion

8. *To what extent, if any, is the spirit of each of Canada's international obligations in conflict regarding the patenting of higher life forms and related processes? How should Canada resolve such a conflict?*

9. *Is Canada restrained from implementing the optimal policy with respect to the patenting of higher life forms and related processes because of its international commitments? If so, how should Canada address this difficulty?*
10. *To what extent does the fact that Canada is the only G7 country that does not allow patenting of higher life forms affect Canada's competitiveness as a location for biotechnology research and development?*
11. *Should Canada change aspects of its intellectual property system to help make its biotechnology industry more competitive? If so, what changes should be implemented?*

** Do you have any other comments on this issue?*

ANNEX 1 — GLOSSARY

CIPO: Canadian Intellectual Property Office.

DNA: deoxyribonucleic acid, the genetic "blueprint" for most living organisms that codes for proteins.

DNA Sequence: a sequence of nucleic acids that may or may not code for a protein.

E.U. Directive: the European Union's Directive on the legal protection of biotechnological inventions.

Experimental Use Defence: a limited right of researchers to use or copy a patented invention without violation.

Farmers' Privilege: a limited right of farmers to use seeds and/or the offspring of breeding animals without violation of patent or plant breeders' rights.

Invention: a thing or a way of doing something that is new, non-obvious and useful.

Methods of Medical Treatment: methods for treating medical or pathological conditions such as a disease.

NAFTA: North American Free Trade Agreement

Non-obviousness: in respect of an invention, an invention that would not be apparent to a person skilled in the art or science to which it relates.

Novelty: in respect of an invention, an invention that has never before been disclosed in the relevant literature (subject to a grace period).

"Ordre Public" or Morality Clause: a provision that excludes patents over inventions the commercialization of which would cause public unrest or would violate fundamental and shared moral standards.

Patent: a right granted under the federal *Patent Act* to prevent anyone else from making, using or commercially exploiting an invention in Canada for a period of 20 years from the date an application for the patent was first filed.

PBRA: *Plant Breeders' Rights Act*.

Plant Breeders' Rights: the exclusive right to commercialize and breed a plant variety.

sui generis: in respect of Plant Breeders' Rights, a specialized and unique legal system outside of patent law.

TRIPs: Agreement on Trade Related Aspects of Intellectual Property Rights made under WTO.

Utility: in respect of an invention, the existence of a realistic, substantial and reproducible industrial application.

UPOV: The International Convention for the Protection of New Varieties of Plants.

WTO: World Trade Organization.

ANNEX 2 — RESEARCH STUDIES

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, by the Canadian Biotechnology Advisory Committee.

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.

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

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

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.

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.

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.

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.

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.

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

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

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

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.

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.

International Obligations for Intellectual Property and Biotechnology, by Sanjay Venugopal, Legal Analyst, Corporate Governance Branch, Industry Canada, Ottawa, Ontario. (Pending)

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.

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

CBAC Hearings 2000/2001:

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 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 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.

ANNEX 3 — OVERVIEW OF CBAC'S SPECIAL PROJECT ON BIOTECHNOLOGICAL INTELLECTUAL PROPERTY AND THE PATENTING OF HIGHER LIFE FORMS

In establishing CBAC, the Government of Canada recognized the need for Canada to be internationally competitive while ensuring the incorporation of ethical and social considerations into Canada's approach to biotechnology. CBAC recognized that these two fundamental concerns came together in the area of intellectual property protection for biotechnological inventions, particularly regarding questions surrounding the patenting of higher life forms. CBAC therefore created a special project to examine intellectual property and the patenting of higher life forms. The committee then identified five areas of study as follows:

- How does the Canadian system of intellectual property protection for higher life forms compare with the systems in other leading industrialized nations?
- To the extent that Canadian intellectual property protection for higher life forms differs from those of other countries, what implications does this have for Canada?
- How does the current Canadian system of intellectual property protection for higher life forms affect industries that develop, use and research these higher life forms?
- What changes in the system of intellectual property protection of higher life forms, if any, are desirable from a scientific, economic or ethical perspective?
- Which social and ethical considerations, if any, should be integrated (and how) into the design and implementation of a Canadian system of intellectual property protection over higher life forms?

Two events led CBAC to focus on the question of whether higher life forms ought to be patentable and, if so, how. The first of these was the 1998 decision by the Federal Court — Trial Division that a genetically engineered mouse was not patentable under Canada's *Patent Act*. (This has since been appealed to the Federal Court of Appeal which concluded, in 2000, that the mouse was patentable. The Government of Canada has since sought leave to appeal this decision to the Supreme Court of Canada.) The second was the beginning of the automatic review in 1999 of the Agreement on Trade Related Aspects of Intellectual Property Rights (the World Trade Organization agreement dealing with intellectual property rights) provisions dealing with the patenting of plants and animals. (This review is ongoing.)

Information Collection: Since 1999, CBAC has commissioned a series of research studies to examine the above questions in depth. It also organized three stakeholder hearings — with industry, non-governmental organizations and scientists — in which it collected the views of those most directly connected with and affected by biotechnological patenting. The committee also reviewed relevant public-opinion surveys.

Issues Analysis: Having considered the studies it commissioned, the stakeholder comments and the public-opinion surveys, the committee identified four questions that it wanted to pursue in greater depth. These are as follows:

- What should be included in the term higher life form? This definition could include not only the types of organism included (non-human animals, plants, organs and other body parts) but material derived from these organisms.
- What are the relative advantages and disadvantages of proceeding by legislative amendment rather than by judicial interpretation of the *Patent Act* or by Canadian Intellectual Property Office policy guidelines?

- Should ethical and social concerns be addressed in relation to the grant of intellectual property rights over higher life forms? If so, what approach should Canada take to addressing ethical and social concerns within its intellectual property laws? Should these issues be addressed by the Canadian Intellectual Property Office or by a separate body?
- What position should Canada take internationally on the patenting of higher life forms? What position should Canada advocate with respect to reconciling the policy objectives of various international treaties on intellectual property, the environment, and social and economic rights?

Consultations: CBAC has determined that, in order to assist it in providing advice to the Government of Canada on these issues, it would first consult with Canadians through various mechanisms. The primary method of beginning these consultations is through the present Consultation Document. CBAC will also hold multistakeholder roundtable discussions in April and May 2001, and is inviting the public to submit comments by mail and through CBAC's toll-free number and Web site on the issues raised in the Consultation Document before May 14, 2001. CBAC has also prepared a summary of principal ideas arising from research papers not addressed in its Consultation Document 2001, to facilitate public discussions about issues that, although not at the heart of the current consultations, are important in understanding intellectual property issues touching on biotechnology and the patenting of higher life forms.

Government Report: Once CBAC has completed its stakeholder roundtable discussions and has received comments from the public, it will prepare a report to the Government of Canada on intellectual property rights and the patenting of higher life forms. This report will be available through CBAC's toll-free number and on the CBAC Web site. After CBAC delivers this report to government in Summer 2001, it will invite comments from the public on it for a three-month period. CBAC will then review these comments to determine if the committee needs to refine its advice.

ANNEX 4 — QUESTIONNAIRE

Please use this questionnaire to provide your responses to the questions in this consultation document.

To begin — please help improve our analysis by completing the following table

Please indicate the perspective from which you are responding (please check one of the following)

- ☐ interested Canadian citizen(s)
- ☐ industry representative(s) involved in biotechnology
- ☐ representative(s) of non-governmental not-for-profit organization
- ☐ student(s)
- ☐ legal professional
- ☐ academic(s) or research scientist(s)
- ☐ other interest in Biotechnological Intellectual Property and/or the Patenting of Higher Life Forms

Please indicate your level of knowledge regarding Biotechnological Intellectual Property and the Patenting of Higher Life Forms in Canada:

- ☐ low
- ☐ medium
- ☐ high

Are you submitting one questionnaire on behalf of a group or organization? _____

If so, on behalf of how many people are you submitting? _____

Please indicate your age:

- ☐ under 25 years
- ☐ 26–45 years
- ☐ 46–65 years
- ☐ over 65 years

Part 1 — Specific Questions

What Should and Should Not be Patented?

1. Should Canada allow the patenting of higher life forms and related processes? If so, are there types of higher life forms and/or related processes that should not be patentable and on what grounds?

_____

_____

2. Should we codify the experimental use defence and/or the method of medical treatment exclusion with respect to biotechnological patents by including it in the *Patent Act*? Is the scope of each sufficient or should it be narrowed or broadened?

_____

_____

3. Should the *Patent Act* include a farmers' privilege and/or a plant and animals varieties exemption?

_____

_____

**Do you have any other comments on this issue?*

_____

_____

What are the Mechanisms of Governance Available for Change?

4. Should Canada continue with the current division of responsibilities among Parliament, the Canadian Intellectual Property Office and the courts, or would a new approach better serve Canadians? If so, what should that approach be?

_____

_____

5. What is the best approach for dealing with the values and issues touching on biotechnology patenting — legislation and regulation, policy guidelines and codes of conduct, or judicial interpretation?

_____

_____

** Do you have any other comments on this issue?*

_____

_____

How Should Social and Ethical Issues be Addressed?

6. Is the *Patent Act* the best place to address the social or ethical issues flowing from biotechnology innovations? If not, how and/or where might these issues be better addressed?

_____

_____

7. Should Canada's *Patent Act* include an "ordre public" or morality exclusion? If so, what should be the scope of the provision? Which administrative entity should apply it? Should this exclusion be evaluated during examination or only in a later opposition procedure?

_____

_____

** Do you have any other comments on this issue?*

_____

_____

International Obligations and Competitiveness

8. To what extent, if any, is the spirit of each of Canada's international obligations in conflict regarding the patenting of higher life forms and related processes? How should Canada resolve such a conflict?

_____

_____

9. Is Canada restrained from implementing the optimal policy with respect to the patenting of higher life forms and related processes because of its international commitments? If so, how should Canada address this difficulty?

_____

_____

10. To what extent does the fact that Canada is the only G7 country that does not allow patenting of higher life forms affect Canada's competitiveness as a location for biotechnology research and development?

_____

_____

11. Should Canada change aspects of its intellectual property system to help make its biotechnology industry more competitive? If so, what changes should be implemented?

_____

_____

** Do you have any other comments on this issue?*

_____

_____

Part 2 — Other Comments

Please use the space provided here for additional comments or feedback