Canadian Biotechnology Advisory Committee

Patenting of Higher Life Forms

June 2002

Patenting of Higher Life Forms and Related Issues

Report to the Government of Canada
Biotechnology Ministerial Coordinating Committee

Canadian Biotechnology Advisory Committee

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Patenting of Higher Life Forms and Related Issues
Canadian Biotechnology Advisory Committee
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June 2002

The Honourable Allan Rock
Minister of Industry
235 Queen Street, 11th Floor
Ottawa, Ontario
K1A 0H5

Dear Minister Rock:

On behalf of the Canadian Biotechnology Advisory Committee (CBAC), I am pleased to present to you, in your capacity as Convenor of the Biotechnology Ministerial Coordinating Committee, our report titled *Patenting of Higher Life Forms*.

We undertook this project in an attempt to identify and examine issues that should be taken into consideration in deciding whether higher life forms should be patentable in Canada and, if so, under what conditions. We have concluded that plants and animals should be patentable, *provided* that the special nature of biological inventions is taken into account.

Our recommendations were guided by research work, consultations with and feedback from key stakeholder groups and individual members of the public, as well as by the deliberations of the Intellectual Property Project Steering Committee and other CBAC members. The recommendations presented here reflect the importance of addressing social and ethical concerns related to biotechnology and the balance to be maintained between the rights of patent holders and those seeking access to the benefits of biotechnological inventions. In addition, a number of recommendations suggest improvements to the administration of the patent system.

On behalf of CBAC members, I would like to recognize the tremendous contribution of the Intellectual Property Project Steering Committee members and, in particular, the committee's Chair, Prof. Bartha Maria Knoppers, who spent many hours preparing this report and recommendations. We would also like to acknowledge Roy Atkinson, Executive Director of the Canadian Biotechnology Secretariat, and the CBAC staff, notably project manager Marnie McCall, for their efforts in producing this report.

I hope you will find this report and our recommendations of interest, and I and the other members of CBAC look forward to continuing to work with you and your colleagues on the Biotechnology Ministerial Coordinating Committee.

Yours sincerely,

Dr. Arnold Naimark
Chair
Canadian Biotechnology Advisory Committee

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As Chair of the Canadian Biotechnology Advisory Committee (CBAC), I wish to gratefully acknowledge all those who provided their expertise, time and wisdom in the development and completion of this report. One of CBAC's missions is to engage Canadians in a public dialogue about biotechnology issues. It is gratifying that so many Canadians took the time and effort to contribute to this project.

Firstly, thanks to all those Canadians who participated in this project and whose invaluable feedback and commentary guided our work, especially the following:

- Those who provided a context for our work by helping us understand, on a very practical level, the issues that arise when biotechnology meets intellectual property.
- Representatives of a wide range of non-governmental organizations, presidents and CEOs of biotechnology companies and scientific researchers from universities, research institutes and government provided CBAC with many angles from which to view this topic.
- Individuals and organizations who took part in the cross-country roundtable sessions or sent responses to the questions posed in our Consultation Document and who contributed tremendously to the development of the draft recommendations in our Interim Report.
- Those who examined the draft recommendations and gave us the benefit of their experience to let us know what the implications of these recommendations would be in real life. Their contributions greatly improved this report and helped us refine the recommendations contained in it.

Secondly, thanks are due to those affiliated with CBAC for their contributions to this report. Special mention must be made of the exemplary work and dedication of Dr. Bartha Maria Knoppers, Chair of the Intellectual Property Project Steering Committee and of the members of that committee as well as the Editorial Committee. Thanks are also due to the many consultants who carried out the background research for their contributions to the project, especially Dr. E. Richard Gold for his legal expertise and assistance in the drafting of this report. I would also like to acknowledge the contribution of Mr. Roy Atkinson, Executive Director, Canadian Biotechnology Secretariat, and all the CBAC staff who have worked on this project over the past two years, notably the project manager, Marnie McCall.

Finally, I want to thank The Honourable Allan Rock, Convenor, and the members of the Biotechnology Ministerial Coordinating Committee for their ongoing support for the work of CBAC.

Dr. Arnold Naimark
Chair
Canadian Biotechnology Advisory Committee

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EXECUTIVE SUMMARY

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

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

The report is divided into four major topic areas:

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

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

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

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

Conclusion: Once the decision of the Supreme Court of Canada in the Harvard mouse case is known, no matter the ruling, the federal government will have its own decisions to make. This report is intended to provide advice and suggest directions for the government in reaching those decisions.

LIST OF RECOMMENDATIONS

HUMAN BEINGS NOT PATENTABLE

1. We recommend that the *Patent Act* be amended to include the following statement:

   No patent shall be granted on human bodies at any stage of development.

PATENTABILITY OF HIGHER LIFE FORMS

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

FARMERS' PRIVILEGE

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

INNOCENT BYSTANDERS

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

RESEARCH AND EXPERIMENTAL USE

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

   It is not an infringement of a patent to use a patented process or product either:

   (a) privately and for non-commercial purposes, or

   (b) to study the subject-matter of the patented invention to investigate its properties, improve upon it, or create a new product or process.

LIABILITY FOR DAMAGES

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

ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING

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

   (a) the benefits of medical and pharmaceutical research based on human genetic material (including its commercial exploitation) be shared with the groups or communities who provided the material. All bodies (public, private and corporate) involved in funding research and/or establishing guidelines or codes of conduct for the ethical conduct of research should ensure that benefit-sharing is addressed. Health

Canada should lead an initiative to engage all stakeholders in developing best practices in regard to benefit-sharing for research involving human subjects.

(b) with respect to research based on plant and animal genetic material, Canada:

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

TRADITIONAL KNOWLEDGE AND INTELLECTUAL PROPERTY

8. We recommend that Canada support the efforts being undertaken in the World Intellectual Property Organization working group on Genetic Resources, Traditional Knowledge and Folklore to determine whether a form of intellectual property could be developed with respect to traditional knowledge.
9. We recommend that the Canadian Intellectual Property Office provide guidance to patent examiners on assessing as "prior art" traditional knowledge that has been made public through oral as well as written or published transmission.

GUIDELINES FOR BIOTECHNOLOGICAL PATENTS AND PROCESSES

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

SERVICE STANDARDS AND PERFORMANCE REPORTING

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

INTERNATIONAL HARMONIZATION

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

OPPOSITION PROCEDURE

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

INTRODUCTION

BACKGROUND

The Government of Canada, through the publication in 1983 of the Canadian Biotechnology Strategy and in other ways, has identified biotechnology as one of the key sectors in a knowledge-based economy. An important element of the 1998 renewal of the Strategy was the decision to create a body of external experts to advise the government on biotechnology issues, raise public awareness and engage Canadians in discussions on biotechnology matters. Accordingly, the Canadian Biotechnology Advisory Committee (CBAC) was created in 1999 with a mandate to provide the government with advice on crucial policy issues associated with the ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology. It provides its advice to the Biotechnology Ministerial Coordinating Committee (BMCC), which consists of 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, as well as information on biotechnology generally, is available on the committee's web site: www.cbac-cccb.ca.

In early 2000, we initiated a research and consultation program (see Annexes A and B for details) on the patenting of higher life forms and related issues. We chose this topic for study because the Harvard mouse case was before the courts in Canada and because both government officials and CBAC members had identified intellectual property issues relating to biotechnology generally and to the patenting of higher life forms in particular as areas of growing concern. Most member countries of the Organisation for Economic Co-operation and Development (OECD), including the United States and the European Union but not Canada, permit plants and animals to be patented. Many developing countries, on the other hand, have concerns about the impact of patenting biological inventions derived from plants and animals in the absence of recognition of traditional knowledge. There is also a segment of public opinion that holds that patents on plants and animals or any biological material (DNA sequences, genes, cells) whatsoever should not be permitted on moral grounds. The current situation in Canada, which does not permit patenting of higher life forms, means that a number of concerns about innovation and investment and about the effects and implications of biotechnology are not being addressed. Even among countries that currently consider higher life forms to be patentable, there is no consensus on how associated social and ethical considerations should be addressed. Annex C, *Structuring the Debate*, groups this wide variety of opinions into four approaches to determining the appropriate relationship between social and ethical concerns and the patent system.

The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property (TRIPs), in Article 27.3(b), 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 maintaining or 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 position on this matter prior to the commencement of these negotiations.

In order to address the foregoing issues, we commissioned a number of research studies, organized three stakeholder meetings (with non-governmental organizations, scientists and industry) and reviewed public opinion research. Next, we 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. Finally, an Interim Report on Biotechnology and Intellectual Property was issued in the fall of 2001. Comments were requested from interested Canadians by March 2002 and a summary of

responses can be found on the CBAC web site. Since then, a number of reports have been published in Canada and elsewhere, and several international meetings have taken place with relevance to this.

The present report represents our views on the patenting of higher life forms after having taken into account the results of our research studies, sector roundtables, review of public opinion research, multi-stakeholder consultations and responses to our Interim Report.

BIOTECHNOLOGY, INTELLECTUAL PROPERTY AND THE PATENT SYSTEM

CBAC defines "biotechnology" as a body of technical knowledge about living organisms or their constituent parts. It defines "applied biotechnology" as those aspects of biotechnology that are used to make products and drive processes that serve social, scientific or economic purposes. 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.[1] Canada is emerging as a significant contributor to this growth. According to Statistics Canada figures, Canada's biotechnology sector[2] in 1999 generated almost $2 billion in revenues, including $718 million in exports. These revenues are expected to exceed $5 billion in 2002. Canada has more biotechnology companies per capita than any other country. It is second behind the U.S. in terms of number of companies, third behind the U.S. and U.K. in revenues, and first in R&D per employee.[3] Biotechnology's greatest impact, both in Canada and worldwide, is in health care. More than 90 per cent of the advanced biotechnology products on the world market are related to health. 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 the most common form of intellectual property protection sought for biotechnology innovations.

A patent may be granted on an invention if the invention meets the *Patent Act*'s definitions of "novelty," "non-obviousness" and "utility." A patent gives its holder the right to prevent others from making, using, importing or selling an invention for 20 years from the date the application for the patent was filed.[4] Canada grants patents on genetic material (DNA, RNA and genes), whether of plant, animal or human origin, as well as on single-celled organisms such as bacteria, some fungi and algae, cell lines and hybridomas.[5] Biotechnology processes — the means by which new biotechnology products are made — are also patentable.

Many biotechnology applications may provide significant economic and social benefits in areas such as health, agriculture, the environment and industry. A patent does not, however, grant its holder the right to

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

2 "Biotechnology sector" is a short-hand way of referring to all those industries and firms within industries that use biotechnology in their business. Not all firms in an industry and not even all business activity of a firm may involve biotechnology; conversely, almost every industry uses biotechnology to some extent.

3 Ernst & Young, *European Life Sciences Report*, 2000.

4 Until recently, a patent application would have to be made in each country. Under the *Patent Cooperation 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. 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.

5 A cell line is a culture of a particular type of cell that can reproduce indefinitely. 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.

market or even use the invention. This is because some applications of the technology may pose risks to human or animal health or to the environment, challenge the capacity of current approaches to protecting health and the environment, and/or raise other serious social and ethical questions that must be addressed. Limits on patent holders' ability to exploit their inventions may be found in competition law, criminal law, specific statutes such as the *Assisted Human Reproduction Bill*, and in regulations governing research practices or facilities, product safety, labelling requirements and many other matters. The public expects government to provide the benefits and offer protection from the risks. It is our hope that this report will assist the federal government in achieving this dual responsibility.

KEY ISSUES AND ORGANIZATION OF THE REPORT

After considering the range of social and ethical issues concerning the patenting of higher life forms and related proposals for changes to the *Patent Act* that were identified in the research papers and during the consultations, we seek to address a number of interrelated questions:

- Ought higher life forms be subject to patent rights?
- If so, what measures are needed to protect the dignity of and maintain respect for human beings?
- If patent rights are extended to plants and animals, what ought to be the scope of those rights, taking into account their particular nature?
- How can the patent system be made more effective with respect to higher life forms?
- Does the intersection of biological inventions and patent law raise other issues that need to be addressed, whether in the patent system or elsewhere?

This report synthesizes and organizes CBAC's policy research as well as input received in response to the Consultation Paper, through sector and regional roundtable consultations, from responses to the Interim Report, and through our internal deliberations. It sets out recommendations on how the Government of Canada might proceed concerning the patenting of higher life forms and other relevant patent-related issues. Most of the recommendations are presented in lay language and are therefore not intended to be in a form suitable for direct transposition into legislation. Where we are recommending specific language, this is noted in the recommendation.

In addition to this Introduction, this report contains 13 recommendations and consists of four main sections:

- Social and Ethical Concerns Raised by Biotechnology
- Patentability of Higher Life Forms
- Other Issues Related to Biotechnology and Intellectual Property
- Improving the Administration of the Patent System

SOCIAL AND ETHICAL CONCERNS RAISED BY BIOTECHNOLOGY

We considered a number of social and ethical concerns raised by developments in biotechnology, and we described three possible approaches for addressing them. The issues included concerns about the commodification of life, equitable sharing of the benefits that come from biological inventions, the preservation and use of traditional and local knowledge, animal welfare, concentration of ownership and resulting lack of competition, possible abuses of economic power and access to genetic resources.

We identified three possible approaches for addressing social and ethical considerations related to the patenting of higher life forms. These approaches represent different views on both the adequacy and advisability of integrating social and ethical considerations directly in patent legislation. The three approaches are summarized below.

- **Status Quo: No Role for the Patent System —** Most social and ethical concerns arise either in the research stage leading up to a patent application or in the commercialization stage following the grant of a patent. A variety of mechanisms other than the patent system exist for addressing such concerns.
- **Alignment: Limited Role for Patent System —** Under this approach, patent rights would be withheld or suspended only if the invention is related to an activity the commercialization of which had already been prohibited in Canada.
- **Open-ended: Broad Role for Patent System —** Patents would be granted as in the other approaches. However, in cases of a serious and compelling ethical or social concern arising from the commercialization of the invention, a separate body would have the power to suspend the operation of the patent until the cause of the concern is addressed.

A discussion of the foregoing issues and approaches to addressing them was presented in our Interim Report and is reproduced in its entirety in Annex D. Readers of the Interim Report were invited to comment on whether this categorization of approaches was useful for discussing how to take these concerns into account. In addition, we asked to hear from as many people as possible which of these approaches seemed the most appropriate given the issues that concerned them most.

Comments received were, in the main, consistent with the view that the practices of greatest social and ethical concern arise in the stages leading up to a patent application or during the process of commercialization. They said existing mechanisms other than the patent system can address these practices, although they may need to be regularly updated to ensure that they keep pace with the challenges posed by new developments in biotechnology.

Comments from industry were consistently in favour of the status quo, but almost all recognized the validity of social and ethical concerns associated with biotechnology. In fact, BIOTECanada (a biotechnology industry association) adopted a Statement of Ethical Principles to guide its members in March 2002. Most argued that those concerns warranting a response by government could and should be addressed outside the patent system. It was felt that this approach would be both more effective and less disruptive of the operation of the patent regime and its goals. These alternate mechanisms could include a wide range of current or new policies, guidelines, regulations or legal prohibitions.

In our examination of all these issues, we sought to identify mechanisms and potential responsibility centres that are empowered to address the matters raised and that are examining, or could be encouraged to examine, the incentives and potential limits to be imposed on patents or patent holders (see Annex D for details). Laws such as the *Competition Act*, the *Criminal Code*, or the proposed *Assisted Human Reproduction Act* prohibit certain types of behaviour such as unfair economic practices, cruelty to animals, or the cloning of human beings. Furthermore, before many products can be sold in Canada, they must comply with regulations designed to protect human and environmental health, to ensure product

safety and to meet other requirements. Compliance with voluntary standards, such as Good Laboratory Practices or those of the Canadian Council on Animal Care, is necessary to maintain public confidence in the product and its maker.

We conclude that the status quo should be maintained; that is, social and ethical considerations raised specifically by biotechnology should continue to be addressed primarily outside the *Patent Act*. While some proposals have been made to modify the *Patent Act* (see Annex D), the existing range of mechanisms available to restrict or prevent activities determined to be socially or morally undesirable is quite extensive. If new limits are required, it will be more effective at present to modify or expand current regulations than to introduce a completely new mechanism into the *Patent Act*.

One advantage of maintaining the current approach is that it provides us with the opportunity to evaluate developments in relation both to technological development and to industry practices to determine whether a new approach might be warranted in the future. The European Union has adopted a similar approach; its Directive on the Legal Protection of Biotechnological Inventions calls for the publication on a regular basis of ethics reports in relation to biological patenting. We note, moreover, that in its May 2002 opinion on the ethical aspects of patenting inventions involving human stem cells, the body charged by the European Directive to prepare these reports — the European Group on Ethics in Science and New Technologies — recommended that an ethical review by an independent body should be incorporated into the patent examination process. Therefore, while CBAC concludes that it is premature to implement a new mechanism in the *Patent Act*, the idea deserves further study.

Having concluded that social and ethical concerns should be addressed primarily by mechanisms outside the *Patent Act*, there are nonetheless certain steps that can and should be taken within the parameters of the *Patent Act*. These steps are discussed in the following sections.

PATENTABILITY OF HIGHER LIFE FORMS

The term "higher life form" is not defined in law. In common usage, it includes plants and non-human animals[6] other than single-celled organisms. 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.[7] This interpretation of Canadian patent law is currently being challenged in the courts in the "Harvard mouse" case. 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, and the commissioner appealed. The Supreme Court of Canada is now considering, after a hearing on May 21, 2002, whether animals can be patented under Canadian law. Part of the federal government's argument before the Court was that deciding whether higher life forms should or should not be patentable is a complex question that Parliament, with its ability to balance many interests, is better suited than the courts to answer.

Even though the federal government has argued in the courts that higher life forms are not patentable [8] and even if the Supreme Court rules that they are not, 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. If limitations on patent rights were to be imposed, the government would have to ensure that they are consistent with Canada's international obligations. 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 general social implications.[9]

APPLICATION OF STATEMENT OF PRINCIPLES TO THE PATENTING DEBATE

Public policy recommendations are, or ought to be, formulated in an 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. With this in mind, we have formulated a Statement of Principles and Values to guide our consultations and discussions with Canadians (see box).

This statement represents the ethical framework within which we have been conducting our work and developing our recommendations. We have also used the statement to stimulate discussion about these principles and their application in the development of public policy related to biotechnology (see Annex E for more information).

We referred to these principles and values in resolving the central issues underlying the debate about whether to permit the patenting of higher life forms in Canada. We caution the reader to recognize the interconnected nature of these principles and values and therefore to consider our recommendations

6 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.

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

8 Canada's current position is consistent with its international obligations, as Article 27.3(b) of the TRIPs agreement permits countries to exclude plants and animals from patentability.

9 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 general social implications of biotechnological inventions.

in their entirety, since each recommendation captures a different aspect of these principles and values.

The first question confronting us was the determination of which institution ought to determine whether there should be changes to Canada's patent laws: the courts or Parliament. The principles of accountability and autonomy argue strongly in favour of adopting an open process to resolve issues relating to the patenting of higher life forms. That is, given the importance of these issues to Canadian society generally and to health care and agriculture in particular, as well as the significant "values" content of the issues raised, we believe that Parliament and not the courts should determine whether and to what degree patent rights ought to extend to plants and animals.

In taking this position, we acknowledge that the courts would likely formulate positions similar to those proposed here, in particular with respect to the non-patentability of the human body. Nevertheless, as we argued in our September 8, 2000, Advisory Memorandum on the Federal Court of Appeal's ruling overturning the decision of the Commissioner of Patents on the Harvard onco-mouse, it is Parliament's responsibility to establish policy in respect to the patenting of higher life forms. Even if the courts could technically develop answers to what can and cannot be patented and could formulate the necessary rules to implement that decision, the principles of accountability and autonomy call for a parliamentary solution. As noted in the Advisory Memorandum, even the Federal Court of Appeal in the Harvard onco-mouse case pointed to the need for Parliament to speak.

A second question we considered was how to conceive of patent rights. Through the processes of sector meetings, multi-stakeholder consultations and requests for responses to our Interim Report, we have heard patents characterized as everything from a natural right of inventors to a form of expropriation ("piracy") of common resources. Both of these extremes ignore the real purpose of patent rights. It has long been recognized that these rights are nothing more than tools to achieve the public good. As described by Mr. Justice Jackson of the United States Supreme Court in 1945:

> *The primary purpose of our patent system is not reward of the individual but the advancement of the arts and sciences. Its inducement is directed to disclosure of advances of knowledge which will be beneficial to society; it is not a certificate of merit, but an incentive to disclosure.*[10]

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 promote the conditions necessary to allow Canadians to pursue their fundamental values and interests. A commitment to be transparent and answerable.
Autonomy	A commitment to promote informed choice.
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.

10 Sinclair & Carroll Co., Inc., v. Interchemical Corporation 325 US 327 (1945) at 330–31.

Civil law jurisdictions, such as France, also frame their patent laws to achieve this same end.[11]

The patent system thus aims at attaining the public good. This matches the principle of justice, which we define in part as "a commitment to ensure a fair distribution of benefits and burdens." The patent system attains this goal by providing inventors with a sufficient incentive — but not more than sufficient — to disclose their inventions and to make their inventions available to the public. Therefore, except where their grant indicates a lack of appropriate respect for the subject-matter of the patent right — as in the case of the human body — patent rights ought not be judged in and of themselves but in terms of their effects on society as a whole. This involves a balancing of interests of the various stakeholders in any given field of endeavour such as biotechnology. In other words, the formulation of patent policy with respect to higher life forms calls for a commitment to justice.

PATENTABILITY OF HUMAN BEINGS

If Canada decides to permit patents over higher life forms, human bodies at all stages of development should be excluded. This restriction would not, however, prevent patent claims from being granted with respect to DNA sequences, cell lines or stem cells of human origin. It is generally believed unlikely that a holder of a patent over a human DNA sequence or cells (including stem cells) would be able to exercise control over a human body 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 body could not be patented. This understanding derives from the universal principle of respect for human dignity, which is the foundation and source of all human rights, a principle recognized in the *United Nations 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*.

Recommendation: Human Beings Not Patentable

1. We recommend that the *Patent Act* be amended to include the following statement:

   No patent shall be granted on human bodies at any stage of development.

The language one could use to express the principle of the non-patentability of humans can vary greatly in detail. For example, while Australia has expressed this principle in brief and very general language, the European Union Directive on the Legal Protection of Biotechnological Inventions describes the same principle in several recitals and in great detail. These provisions are reproduced in Annex F.

In choosing between a detailed and a general formulation of the concept of non-patentability of the human body, several principles of patent law ought to be kept in mind. First, patent law deals, by definition, with inventions that we cannot today contemplate. This means that whatever language is used to express the concept must be sufficiently flexible and clear so as to apply to future technology. Thus, any attempt to provide a complete list of unpatentable inventions or even narrow groupings of inventions is doomed to failure. Second, given that patent law already excludes the patentability of naturally occurring substances in their natural state, there is no need to attempt to make detailed distinctions between "discoveries" and "inventions." Third, the determination of what is patentable in principle is different from the determination of whether a particular invention qualifies as being novel, non-obvious or useful. Thus, it would be confusing to state that a human body part is unpatentable unless it were shown to have a specific utility: it would be unclear whether this statement was intended to alter the "utility" criterion or was making a general exclusion

11 Yves Jeanclos, « Les brevets d'invention en France à l'époque revolutionnaire : recherches sur l'objet brevetable » in Mélanges offerts à Jean-Jacques Burst, éditions Litec, 1997, Paris, pp. 19–37 at 20–21.

of the subject-matter from patent law. Some of the difficulty encountered in Europe with respect to its Directive is a result of this latter confusion.

Taking these patent law principles into account, we conclude that it is better to define the principle of non-patentability of the human body generally rather than in a detailed manner. Experience with the European Directive supports this suggestion. Despite the detailed recitals and provisions of the Directive, there is still confusion in Europe about which elements of the human body are patentable. France, for example, has asked the European Commission to clarify the meaning of the Directive in respect of genes of human origin. The detailed provisions contained in the Directive also led to confusing results. For example, Article 5(3) of the Directive requires that the patent application demonstrate the function of a human gene but does not require a similar demonstration in respect of non-human genes. Given, however, that the same gene may exist in both animals and in humans, it is unclear which requirement applies.

The use of the term "human beings" in our Interim Report and in the Australian *Patent Act* is, as noted in several of the responses we received, confusing. A human being is a metaphysical concept, not a biological one. The substitution of the word "body" for "being" eliminates this awkwardness and we have therefore replaced the word "beings" with the word "bodies" in Recommendation 1. We chose the plural to more clearly indicate that only entire human bodies are encompassed by the exclusion. That is, by using the plural, emphasis is placed on the whole human body and not on its parts (for example, artificially created human organs). Thus, the phrase "human bodies at all stages of development" is more likely to be read narrowly — as we intend. It is important not to discourage research on stem cells and the creation of artificial organs.

We use the phrase "all stages of development" to demonstrate our intent not only to include human bodies of infants, children and adults within the exclusion, but also all precursors to the human body from zygotes to fetuses. Although there is no judicial interpretation of the phrase "all stages of development," we believe it will not be interpreted to include ova or sperm cells, since these do not of themselves constitute a human body at any stage of development. Nor does the phrase include stem cells or other cells, since these are removed from a multi-cellular precursor of the human body (except for the zygote) and thus do not comprise a human body at any stage of development.

Thus, the statement that "no patent shall be granted on human bodies at any stage of development" will apply only to entire human bodies from the zygote to an adult body; DNA sequences, gametes, stem and other cells, or organs will remain patentable. We note that this recommendation is consistent with the proposed *Assisted Human Reproduction Act*, introduced in Parliament May 9, 2002, by the Minister of Health. That act would permit research on human DNA sequences, on gametes and cells (including stem cells) and on embryos under certain conditions, but prohibit the creation or use of human clones.

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)?

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, any threshold selected could be considered arbitrary and the attempt to differentiate great apes from other animals unworkable.[12]

12 Efforts are currently being made to develop a *United Nations Declaration on the Rights of Great Apes*, which would guarantee the rest of the great apes (chimpanzees, bonobos, gorillas, orangutans and humans) 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 Recommendation 1 accordingly.

Qualitative distinctions (for example, level of perceived cognition, ability to communicate in languages) may appear on the surface to provide a more workable mechanism. This, however, may be an ethically dangerous approach, because humans would be forced to decide which animals are worthy of being excluded from patentability and which are not, and this decision could be based on opinion rather than research and information.[13]

Canada must also determine if placing such distinctions in the *Patent Act* would be in the public interest. In addition, it would be necessary to consider if such distinctions would be in line with Canada's international obligations. All in all, it is our view that the *Patent Act* is not a sufficiently subtle instrument through which to make the evaluations that would be necessary were the exclusion of patent rights over human bodies to be extended to other animals. The dignity of and respect for animals can be better protected through animal welfare and habitat protection measures.

PATENTABILITY OF HIGHER LIFE FORMS (PLANTS, SEEDS AND NON-HUMAN ANIMALS)

Through its various consultations and responses to the Interim Report, we have heard many arguments in favour of and opposed to extending patent coverage to plants and non-human animals. A more detailed description of the views and arguments encountered can be found in Annex C. The following points represent the principal arguments advanced.

Those advocating the extension of patents to higher life forms make four principal arguments.

- Patents provide the necessary financial incentive to industry to invent, disclose and make available new technology to the Canadian public by helping industry attract investment and recoup its costs of research and development. That is, patents serve the public good by ensuring that industry obtains a sufficient financial reward from investing in the research and development necessary to put new products and services related to health care, agriculture and other industries on the market. Without this financial reward, industry will not invest in this work for fear that a competitor will copy their inventions without having to pay for the often high costs of research and development.
- The availability of patent protection fosters openness and innovation in the scientific community by providing an alternative to trade secrecy protection. Trade secrecy protection has a negative impact on the scientific community, because it prevents the free flow of basic knowledge within the research community. By requiring public 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.[14]
- Canada may suffer economically if it does not follow its major trading partners (United States, European Union countries and Japan) in permitting patents on higher life forms (see Annex G). This difference with its major trading partners 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 business reputation than to patent law, it is a relevant consideration in determining Canada's patent policy.
- At present, patents on DNA sequences can be used to claim control over a whole plant or animal. By explicitly allowing patents on whole plants and animals, provisions could be introduced that explicitly differentiate between specific patent rights that pertain to whole plants and animals and those that pertain to molecular sequences only. This differentiation provides an opportunity to better balance interests among

13 Apart from the issue of the values humans place on various animals, a qualitative approach may be ethically unacceptable on the grounds that it might be taken as support for the view that some human individuals (i.e., those whose cognitive or communicative capacities are less than the "norm") are less valuable than others.

14 Usually, the date of priority is the first date on which a patent application was filed anywhere in the world. If, as is often the case, the first application was in another country, the date of publication in Canada would be 18 months from that first application date.

stakeholders and to ensure that those patent rights remain within reasonable bounds.

We also heard arguments against the patenting of plants and non-human animals as follows:

- Patenting plants and animals gives rise to serious moral and ethical questions touching on animal rights, biodiversity, economic and environmental sustainability, and the commodification of life. The notion that a plant or a species of complex animal life should be viewed as an invention of a person or a corporation objectifies the natural world. Animals play a particular role in society and they ought not be treated as mere objects. These views often get lost in the usual cost-benefit analysis applied in considering patent policy. We as a society ought not contemplate extending patent law to higher life forms until we have determined the full effects of doing so.
- Patents on higher life forms are unnecessary, since other patents (e.g., on DNA sequences or genes or on the processes necessary to generate an invented plant or animal) and other intellectual property rights such as trade secrets and plant breeders' rights sufficiently protect the inventor's interests.
- Patents over plants and animals threaten to undermine the economic viability of industries that rely on plants and animals. Many of these industries are economically more important to Canada than is the biotechnology industry. For example, respondents noted that Canada has multi-billion-dollar cattle and pig export industries that could suffer if patents are extended to non-human animals. Many of the characteristics that make an animal valuable for breeding purposes have nothing to do with any genetic modification and, in any event, animal genetics is such that the inserted genetic trait will not be uniformly transferred to offspring.

In conformity with our commitment to the Statement of Principles and Values, we caution against an absolutist approach to the question of patenting higher life forms. We propose that the question of whether to grant patents over plants and non-human animals should be viewed in terms of attaining the overall public good. This means that the patent system should seek not only to encourage the accumulation of knowledge and the making of that knowledge available to Canadians and others, but also to maintain the integrity of Canada's health, agricultural, and educational sectors and to respect the values and knowledge of Canada's aboriginal and minority populations.

The majority of CBAC members has concluded that the overall public good is best attained by providing patent rights over higher life forms, provided that these rights are no greater in substance than those granted over other inventions, taking into account the particularities of biologically based inventions.[15]

Recommendation: Patentability of Higher Life Forms

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

Unlike other inventions, biologically based inventions can reproduce, can contain important characteristics that have nothing to do with the invention, and can, in the case of DNA sequences, cell lines, tissues and organs, contain basic personal

15 The dissenting member, Anne Mitchell, agrees with the position of the Commissioner of Patents that higher life forms are not patentable under Canadian law and, further, is of the view they should not become patentable. Nevertheless, if the law is to be changed, she argues that it should not be through a decision of the courts, but only after a full and public debate in Parliament on the whole range of issues related to patenting life. Ms Mitchell does agree with the limits proposed here in the event that plants and animals do become patentable in Canada.

information. If patent rights were simply extended to higher life forms, the patent holder not only would be given rights that inhibit other useful activity, but would also gain rights disproportionate to the scope of patent protection granted over other inventions that do not possess these characteristics. The latter point is especially important, given international trade agreements under which Canada has agreed to make patents available for any invention without discrimination as to the field of technology. In effect, by simply extending patent coverage to higher life forms, Canada would be discriminating in favour of some patent holders in the biotechnology field and against those in other fields.[16]

It is therefore imperative that, in extending the coverage of patent rights to higher life forms, Parliament not extend those rights too far. We propose a series of recommendations designed, on the one hand, to extend patent coverage to higher life forms and, on the other, to ensure that the scope of the patent rights granted is no greater than the patent rights granted over other, non-biological, inventions. **In order to achieve this goal, it is essential that Recommendation 2 be read together with Recommendations 3, 4, 5, 10 and 13** (farmers' privilege, protection for innocent bystanders, research and experimental use exception, guidelines for biological inventions, and establishment of an opposition procedure). In addition, given the particular importance of biological and other biotechnology inventions to health care and agriculture, it is appropriate to ensure that patent rights do not unreasonably prejudice other industries and institutions.[17] Therefore, we reiterate the importance of reading **all** recommendations in this report in their entirety.

16 If Canada wishes to permit patents on plants, it will likely have to sign and ratify the 1991 version of the International Convention on the Protection of Plant Varieties (UPOV) in order to remain in compliance with its international agreements. Further information about UPOV can be found in Annex C.

17 This is in conformity with Article 30 of TRIPs, which states: *Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.*

SCOPE OF PATENT HOLDERS' RIGHTS

Because higher life forms can reproduce by themselves, the grant of a patent over a plant, seed or non-human animal covers not only the particular plant, seed or animal sold, but also all its progeny containing the patented invention for all generations until the expiry of the patent term (20 years from the priority date). In addition, much of the value of the higher life form, particularly with respect to animals, derives from the natural characteristics of the original organism and has nothing to do with the invention. In light of these unique characteristics of biological inventions, granting the patent holder exclusive rights that extend not only to the particular organism embodying the invention but also to all subsequent progeny of that organism represents a significant increase in the scope of rights offered to patent holders. It also represents a greater transfer of economic interests from the agricultural community to the biotechnology industry than exists in other fields of science. The European Union recognizes this in its Directive by ensuring that certain uses of the progeny of a patented plant or non-human animal fall outside the scope of the patent holder's exclusive rights. We agree with this approach and propose two recommendations to provide a reasonable patent scope.

Farmers' Privilege

We heard from many individuals, organizations and industry groups who were of the view that, if patenting is to be allowed over whole plants and animals and varieties thereof, the scope of those rights ought to be rationally connected to the invention and not extend to all offspring produced during the life of the patent. As noted above, we agree that the scope of the patent rights granted should be not only proportionate to the discovery, but also in line with the scope of patent rights provided in other fields. By ensuring an appropriate scope to patents granted, Canada can both encourage its biotechnology industry while maintaining food security and the robustness of Canadian agriculture. One component of this strategy is the introduction of a farmers' privilege into patent law. A farmers' privilege would

allow farmers to collect and reuse seeds harvested from patented plants and to breed 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 for commercial breeding purposes.[18]

Recommendation: Farmers' Privilege

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

Farmers in Canada currently benefit from farmers' privilege under Canada's *Plant Breeders' Rights Act* (although this exemption from what would otherwise be patent infringement is not in the Act, but was declared to exist in a court ruling). The European Community's patent laws contain a farmers' 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. Because neither plants nor animals were previously subject to patent rights, no farmers' privilege had been needed in Canadian patent law. This situation will change if Recommendation 2 is adopted.

In both the consultations and in the responses to the Interim Report, CBAC was informed of the very different practices that exist with respect to plant and animal offspring. We recognize that, in proposing the inclusion of a farmers' privilege provision in the *Patent Act*, more work needs to be done to identify the extent of the privilege in relation to plants and for animals. For example, it is important to investigate the relationship among the *Patent Act*, the *Plant Breeders' Rights Act* and the *Animal Pedigree Act*. While the *Plant Breeders' Rights Act* provides protection over certain varieties of plants to the creator of that variety, the *Animal Pedigree Act* provides protection for the marketing of particular breeds of animals, which could include transgenic animals. It may therefore be appropriate, given the differences in relevant legislation, agricultural uses and the degree to which the plant or animal can "breed true," to formulate separate regimes. We note, for example, that it may be possible to define a farmers' privilege with respect to plants similar to that in Europe, while a farmers' privilege with respect to animals would have a somewhat greater scope. Such a differential response is justified given both the differential genetics of plants and animals and the different economics underlying plant and animal farming. Given the particular difficulties faced in the animal context, we have amended the wording of the draft recommendation to acknowledge the importance of clearly determining the appropriate scope of the farmers' privilege in respect of animals.

Innocent Bystanders

Since plants and animals are often capable of reproducing on their own, it must be recognized that they will not always do so under the control or with the knowledge of those who grow the plants or raise the animals. It is therefore foreseeable that adventitious[19] reproduction of patented seeds, genetic material and animals will occur. Reproduction of patented inventions without the permission of the patent holder is an infringement on the patent holder's rights; the patent holder can sue for damages or to stop further infringement or both.

18 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 contrary to other laws or regulations (such as amounting to anti-competitive behaviour), current law does not restrict this practice.

19 The Canadian Oxford Dictionary defines "adventitious" as accidental, not planned, or extrinsic.

Currently, patent law does not require a patent holder to prove that an alleged infringer knew or even ought to have known about the reproduction of a patented invention. This situation places individuals without knowledge of the reproduction of a patented plant, seed, or animal on their property or in their care in a difficult situation. That individual (the "innocent bystander") may face a patent infringement suit — one of the most difficult and expensive legal actions against which to defend — and damages for infringement without a countervailing remedy against the patent holder. While in theory such an individual may be able to sue for negligence for the adventitious spread of the plant or seed or the reproduction of the animal, the practical difficulties of doing so — proving a duty of care and a breach of that duty — may make this remedy illusory. At the same time, it would not be wise to deviate too far from the general principle of patent law that intention to reproduce the invention is irrelevant. After all, it would be difficult for a patent holder to demonstrate this level of intention.

In balancing the interests of patent holder and "innocent-but-technical" infringer, we believe the latter ought to receive protection within the body of the *Patent Act*. Nevertheless, we believe that such innocent bystanders ought to be made to show evidence to support his or her innocence. Thus, we propose that the *Patent Act* contain a provision that the usual presumption concerning infringement can be rebutted in respect of inventions capable of reproducing, such as plants, seeds and animals.

Recommendation: Protection from Patent Infringement Claims

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

The question of obtaining compensation for any damage caused to innocent bystanders as a result of adventitious introduction of patented organisms will be discussed later in the report.

Research and Experimental Use Exception

As noted earlier, patent holders gain the exclusive right to make, use, import and sell their inventions in exchange for making the information about the invention public in order to foster further innovation. Subsequent inventions can usually be made only 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/or experimentation on a patented invention is not an infringement of the patent holders' rights. This experimental use exception attempts to balance the interests of patent holders in commercializing their inventions with those of society in fostering further research.

The current Canadian experimental use exception is vague and dates from a 1971 decision of the Supreme Court of Canada decided in the context of research aimed at sustaining a compulsory licence. [20] Later cases do little to amplify the meaning of the exception. Since the Supreme Court decision, Canada has eliminated its compulsory licensing provisions, thus putting into question the scope and nature of the research exception in Canada. This situation was not remedied through the introduction of section 55.2 into the *Patent Act*. That section sets out a specific experimental use exception applicable only to regulated inventions such as pharmaceuticals. While section 55.2(6) explicitly preserves the common law exception as identified in the Supreme Court of Canada decision, it does nothing to clarify either its nature or extent.

Access to basic or platform technology such as DNA sequences, cell lines, plants and animals 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 and the

20 Micro Chemicals Ltd. v. Smith Kline & French Inter-American Corp. (1971) 2 C.P.R. (2d) 193 (SCC).

withholding of experimental results for fear that the disclosure of those results will draw the negative attention of the patent holder. We believe that Canada should address this concern by amending the *Patent Act* to include an explicit experimental use exception.

In the various consultations on this topic, the research community and the majority of people in the seed industry expressed support for an amendment to the *Patent Act* to clearly set out the scope and nature of the experimental use exception. Those who oppose introducing such an exception do so on the basis of a preference for a judicially crafted exception rather than one appearing in the *Patent Act* itself. There are several reasons why we believe that an exception crafted by Parliament is preferable to one created by the courts. First, the values content of the issues calls for a Parliamentary rather than a judicial approach. Second, the responses we received from the research community suggest that researchers do not feel that the current research exception is sufficiently clear. Third, studies have illustrated that the failure to have a clear research exception has curtailed important health research.[21] Fourth, the member states of the European Union have included experimental use exceptions in their patent legislation without any apparent negative effect, and an expert workshop of the OECD held in January 2002 recognized the need to clarify "the scope and function of different countries' research exemptions."[22] In fact, at that expert workshop, the recommendation contained in our Interim Report met with favourable review. Fifth, provincial governments have called for a clarification of the experimental use exception in Canada.[23]

We have formulated an experimental use exception starting with the language used in Europe in the Community Patent Convention,[24] but modified to address certain particular concerns.

Recommendation: Experimental Use Exception

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

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

The first modification we made is designed to clarify an area of uncertainty that exists in the convention's experimental use provision.[25] Under the convention, it is unclear whether a researcher can rely on the experimental use provision to use a DNA sequence, for example, to find molecules that bind to it or act upon it. The addition of the words "to investigate its properties, improve upon it, or create a new product or process" is designed to eliminate this uncertainty. Given the presence of the central requirement that the use be related to the "subject-matter" of the invention, only study related to the nature of the invention itself would fall within the exception. Thus, if a research tool were to be consumed in an experiment, the researcher would be required to purchase the right to use that tool in the experiment. This ensures that scientists who use patented inventions as mere tools to conduct further research will need to pay a licence fee.

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21 See, for example, Jon F. Merz, Antigone G. Kriss, Debra G.B. Leonard, & Mildred K. Cho, "Diagnostic testing fails the test: The pitfalls of patents are illustrated by the case of haemochromatosis" (2002) 415 Nature 577.

22 Conclusions of the OECD Expert Workshop on Genetic Inventions, IPRs and Licensing Practices held in Berlin 24–25 January 2002, available on-line at: http://www.oecd.org/EN/document/0,,EN-d...27-nodirectorate-no-20-25140-27,FF.htm (accessed 18 March 2002).

23 See, for example, Government of Ontario, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare* (Toronto: Government of Ontario, 2002), available on-line at: http://www.gov.on.ca:80/MOH/english/pub/ministry/geneticsrep02/report_e.pdf (accessed 18 March 2002).

24 It should be noted that this convention is not binding and that different Member States have used different language to express its principles.

25 See E. Richard Gold & Alain Gallochat, "The European *Biotech Directive*: Past As Prologue" (2001) 7 European Law Journal 328.

The second modification is the use of the verb "to study" instead of the adjective "experimental" used in the convention and the phrase "conduct research" used in the Interim Report. Responses to the Interim Report indicate a need to clarify that classroom use of an invention to study its subject-matter ought to be excluded from patent infringement. Thus, the use of a DNA sequence, cell, plant or animal in a laboratory course to investigate the properties of that sequence, cell, plant or animal ought to be exempt from patent infringement. We have thus used the more general term "to study" rather than the narrower terms "research" or "experimental."[26]

The resulting experimental use provision acknowledges two circumstances that fall outside of the patentee's exclusive rights. The first is an exception designed to protect individuals conducting private experiments without commercial motivation. The language used to express this exception is similar to that in the Community Patent Convention and is similar to the exception as it exists in the United States. The second exception is designed to ensure that future generations of researchers have access to the fundamental knowledge on which to build more knowledge and construct new and better inventions. Given that even basic research often leads to commercial products, we have not attempted to distinguish between research conducted for purely academic purposes and research with a commercial interest.

26 The Oxford English Dictionary defines "to study" as follows: "To apply the mind to the acquisition of learning, whether by means of books, observation, or experiment."

OTHER ISSUES RELATED TO BIOTECHNOLOGY AND INTELLECTUAL PROPERTY

LIABILITY FOR DAMAGES

The draft recommendation in the Interim Report urges Canada to take an active role in the development of an international approach to addressing liability issues related to the transboundary movement of patented higher life forms. A number of respondents pointed out that damage could be caused, and therefore liability and compensation issues raised, in Canada as well as in the international arena. They urged CBAC to expand the recommendation to address the domestic as well as the international situation.

In our view, Canadian law already adequately addresses issues of liability and compensation for damages through the common law of negligence and the civil law of obligations, which are based on principles of accountability and responsibility. Specific provisions for damages caused by products of biotechnology, patented or not, are not required. It should also be noted that, while the issue of liability and compensation was raised in the context of damage being caused by patented species, non-patented domestic species or invasive species might equally cause damage.

At the international level, governments are beginning to address liability and redress issues concerning both living modified organisms (such as plants or microbes) and invasive species, under the Convention on Biological Diversity. The Intergovernment Committee on the Cartagena Protocol on Biosafety is focussing on the former, while the Conference of the Parties has just adopted 15 Guiding Principles for developing effective strategies to minimize the spread and impact of invasive alien species. The results of these efforts may provide guidance to courts or legislatures in Canada in addressing claims for damage caused by products of biotechnology, whether or not they have been patented.

Recommendation: Liability for Damages

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

ADDRESSING CERTAIN SOCIAL AND ETHICAL CONSIDERATIONS

We have previously noted that most social and ethical concerns about biotechnology arise either during the research and development stage (e.g., animal welfare issues) or in the uses to which a new biotechnology application is put (e.g., crop technology). We have also noted that, since these concerns would exist whether or not the invention was patented, reliance for responding to these concerns ought to be placed primarily on mechanisms other than the patent system. There are, however, some concerns that are clearly closely connected with the patent system, even if indirectly. We take up several of these concerns in this section.

Access to Genetic Resources and Benefit-sharing

Advances in many areas of biological research, particularly medical and agricultural, are increasingly based on techniques for identifying, isolating and analyzing genes and for studying the functions and interactions of genes, proteins and the biochemical processes they regulate. These techniques involve obtaining genetic material from humans, plants or animals.

Medical researchers are interested in identifying genetic causes of certain diseases. Of equal interest is understanding why some people seem to be protected from developing certain diseases. The mechanisms involved may be identified by studying groups of people. Once the genetic component, if any, is known, it may be possible to develop diagnostic tests or pursue treatments or cures.

In agricultural biotechnology, the genetic basis for desirable traits such as disease resistance can be identified and used to transfer those traits to other species or varieties. The source of many of these discoveries is genetic material from plants and animals found in the developing world, where the majority of the world's biological diversity is found. Scientists have often relied on the traditional knowledge of local communities to select the plants and animals to be studied, but have not generally offered any compensation for the use of that knowledge. Opposing views on this issue are clearly reflected in the language: companies refer to their activities in biodiversity-rich countries as "bio-prospecting"; farmers and others object to what they refer to as "bio-piracy."

Much of the knowledge gained from studying these genetic resources can be patented and commercialized. Unfortunately, in some cases, the very people who made the discovery possible by contributing their own genetic material or sharing their traditional knowledge of local plant and animal resources are unable to afford the new drugs, treatments or seeds.

Recommendation: Benefit-sharing

7. We recommend that the federal government, in consultation with other levels of government and other stakeholders, develop policies and practices that encourage the sharing of the benefits of research involving genetic material. In particular, we recommend that:
   (a) the benefits of medical and pharmaceutical research based on human genetic material (including its commercial exploitation) be shared with the groups or communities who provided the material. All bodies (public, private and corporate) involved in funding research and/or establishing guidelines or codes of conduct for the ethical conduct of research should ensure that benefit-sharing is addressed. Health Canada should lead an initiative to engage all stakeholders in developing best practices in regard to benefit-sharing for research involving human subjects.
   (b) with respect to research based on plant and animal genetic material, Canada:
   - continue to participate in the ongoing processes of the Convention on Biological Diversity to address outstanding issues with respect to the voluntary Bonn *Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization* (such as user country obligations and consideration by the Working Group on Article 8(j) of the *Guidelines by Indigenous and Local Communities*);
   - encourage and facilitate compliance with the Bonn *Guidelines* within Canada as well as internationally;
   - sign and ratify as soon as possible the *International Treaty on Plant Genetic Resources for Food and Agriculture*, participate in the development of the standard material transfer agreement, including provisions requiring benefit-sharing, and encourage and facilitate their use within Canada; and
   - generally encourage and facilitate benefit-sharing arrangements between the users of genetic resources and traditional and local communities within Canada.

The principle of justice requires a commitment to ensuring that the benefits and burdens of biotechnology are equitably distributed and that policies and practices do not disadvantage vulnerable groups. These values are reflected in a variety of declarations and international agreements concerning the use of human, animal and plant genetic material.

The Human Genome Organization (HUGO) Ethics Committee in April 2000 released a Statement on Benefit Sharing. The statement is founded on the premise that since the human genome is part of the common heritage of all humanity, the Human Genome Project and subsequent work based on it should benefit all of humanity. Commercial enterprises, governments and academic institutions should determine benefits appropriate to the needs, values, priorities and cultural expectations of the group or community that provided the necessary human

genetic material. Benefits could be provided in the form of medical care, technology transfer, or infrastructure development or improvement. Where net profits are made as a result, the Ethics Committee recommends that a small percentage be dedicated to, for example, improving health care infrastructure.

The Convention on Biological Diversity (CBD), to which Canada has been a party since 1992, has as its three objectives conservation, sustainable use and equitable sharing of the benefits of biodiversity. The Convention reaffirms that states have sovereign rights over their biological resources. Article 15 recognizes that countries have the right to control their genetic resources and to decide who will have access to them and under what conditions. Parties to the Convention agree to facilitate access to the genetic resources in their territory to other parties, obtain prior informed consent (PIC) when accessing those resources, and take measures to achieve a fair and equitable sharing of the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the member country that provided the resources. The Convention anticipates that benefit-sharing could take the form, among other possibilities, of scientific co-operation and training, research infrastructure development, or exchange of information or technology, including indigenous and traditional technologies.

The Bonn *Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization* were adopted at the April 2002 Conference of the Parties to the CBD. These voluntary international guidelines provide guidance to parties in the development of access and benefit-sharing regimes (e.g., processes to obtain prior informed consent) and inform the practices of stakeholders in access and benefit-sharing arrangements regimes. Under the Bonn *Guidelines*, parties should take legal, administrative and policy measures, as appropriate, to support compliance with prior informed consent processes of countries where access to resources was obtained. These include measures to encourage the disclosure of the country of origin of the genetic resources and the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for patent or other intellectual property protection.[27]

In November 2001, the Food and Agriculture Organization of the United Nations adopted a binding *International Treaty on Plant Genetic Resources for Food and Agriculture*. This treaty is the outcome of a process to revise the 1983 International Undertaking on Plant Genetic Resources to bring it into harmony with the requirements of the CBD, including provisions addressing farmers' rights and access to plant genetic collections held privately. The aim of the treaty is to ensure plant genetic resources that are key to agriculture and world food sufficiency are conserved and are made available for plant breeding. Under the treaty, members are to establish a multilateral system to facilitate access to genetic resources and to share the resulting benefits.

Traditional Knowledge and Intellectual Property

Traditional knowledge is the knowledge, innovations and practices of indigenous and other local populations, embodying traditional lifestyles and practices adapted to the local environment. This knowledge has historically been transmitted orally from generation to generation in the manner of an apprenticeship; it may be handed down publicly or secretly as either practical (e.g., for farming or medicinal purposes) or religious knowledge. As noted in the previous section, traditional knowledge may be used by researchers to narrow their search for sources for new drugs or other patentable material.

Article 8(j) of the Convention on Biological Diversity (CBD) requires parties to "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities . . . relevant for the conservation and sustainable use of biological diversity." The provision also obligates members to promote the dissemination of these practices, with the

27 It remains to be determined, however, whether this suggestion conforms with TRIPs. In particular, there is some doubt whether this suggestion is in conformity with Article 27(1), that countries may not impose, in assessing a patent application, any criteria other than novelty, inventive step (non-obviousness), and industrial application (utility).

approval and consent of the holders of that knowledge, while ensuring the equitable sharing of the benefits from the utilization of the traditional knowledge, innovations and practices. Many countries with national access regimes for genetic resources also require a prior informed consent process to be followed when scientists and biotechnology companies access traditional knowledge of indigenous and local communities. To support these national access laws, the aforementioned Bonn *Guidelines* encourage governments to adopt measures to ensure disclosure of the sources of traditional knowledge in applications for patent rights.

The commercialization of products derived from genetic resources revealed to researchers by holders of traditional knowledge has made it clear that traditional knowledge is an asset that could be of significant economic value to the community of which the knowledge holders are a part. This is now being recognized in the efforts described in the previous section to develop mechanisms for returning some of that value to the source community through benefit-sharing arrangements. In addition, the World Intellectual Property Organization (WIPO) has established an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, which is considering, among other issues, whether a new form of intellectual property could be developed that would provide similar kinds of protection to traditional knowledge as are now currently available to inventors through patents.

Also being explored are ways to bring traditional knowledge to the attention of patent authorities when they are assessing "prior art" to determine whether an invention is sufficiently novel as to be granted a patent. Prior art has generally been understood to consist of written or published descriptions of the invention being examined. Knowledge that has become "publicly available" because it has been transmitted orally would not be taken into account in deciding whether the invention was new. A number of databases or registries of traditional knowledge have been created with respect to knowledge that is in the public domain (i.e., not including traditional knowledge which is transmitted under conditions of secrecy). A number of the issues related to recording or codification of traditional knowledge are described in the WIPO secretariat's December 2001 *Progress Report on the Status of Traditional Knowledge as Prior Art*; this report is now being considered by the intergovernmental committee.

Recommendations: Traditional Knowledge

8. We recommend that Canada support the efforts being undertaken in the World Intellectual Property Organization working group on Genetic Resources, Traditional Knowledge and Folklore to determine whether a form of intellectual property could be developed with respect to traditional knowledge.
9. We recommend that the Canadian Intellectual Property Office provide guidance to patent examiners on assessing as "prior art" traditional knowledge that has been made public through oral as well as written or published transmission.

Effects of Biotechnology Patents on the Health Care System

Biotechnological inventions are anticipated to have a major impact on medicine, medical treatment and the health care system. In its recent report, titled *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare*, the Government of Ontario outlines particular ways in which human gene patents may threaten Canada's publicly funded health care system. In that report, which was endorsed in principle by the premiers of all provinces at their January 25, 2002, meeting, Ontario calls for both further study of certain effects of human gene patents on the health care system and for the provinces to work with the federal government to address the provinces' concerns. We note that the Ontario report approved of several of the recommendations we made in our Interim Report.

We believe Ontario's suggestion that the provinces and the federal government work together to identify and then respond to negative effects of the patenting system on the public health care system is the appropriate mechanism to address such issues. As noted in the Interim Report, while these issues are very important, they are not central to our particular project on biotechnological intellectual property.

IMPROVING THE ADMINISTRATION OF THE PATENT SYSTEM

Whatever decision Canada adopts with respect to the patenting of non-human animals and plants, the Canadian patent system ought to handle all patent applications in as efficient a manner as possible. This does not mean that the Canadian Intellectual Property Office (CIPO) ought simply to award patents without adequate investigation, but that CIPO ought to have the resources necessary to conduct effective and efficient reviews of patent applications. Potential patent applicants should be able to obtain, prior to filing, sufficient information to make their applications as precise and complete as possible. In what follows, we recommend a series of measures designed to improve the operation of the patent system in Canada.

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 report.

The United States Patent and Trademark Office (USPTO) currently issues guidelines on how it applies patent criteria to different types of invention. These guidelines focus on some of the subtle distinctions that the USPTO is called upon to make. The guidelines are generally in a form that is more comprehensible to inventors and small companies than are the more formal patent manuals. These guidelines are particularly useful for smaller biotechnology companies not experienced in the patent process. Similar guidelines could be developed in Canada with the assistance of an expert advisory panel.

Recommendation: Guidelines for Patents on Biological Material

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

As its views on how patent law applies to biological inventions are formulated, we encourage CIPO to expand on the way it applies the criteria of novelty, non-obviousness and utility to higher life forms and on the level of description required to support a patent claim involving a higher life form. To take one example, guidelines should clearly delineate the extent to which CIPO considers the factors of uniformity and stability in their examination of patent applications relating to plants and animals. As a second example, CIPO should clarify whether a patent can be obtained on higher life forms created through the laborious application of natural selection and testing but without genetic engineering. A recent decision of the United States Supreme Court would grant a patent on such an invention.[28]

We further encourage CIPO to develop guidelines as to the appropriate scope of biological patents, including under what circumstances the holder of a

28 J. E. M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc. 122 S.Ct. 593 (2001).

DNA sequence patent has the right to prevent someone from growing a plant or animal that contains that sequence. CIPO should carefully consider the view expressed in a recent report from the Government of Ontario on gene patenting that there should be a distinction made between the chemical structure and the information contained in a DNA sequence in order to remedy some of the problems related to gene patents.[29] In addition, CIPO should play a role in the proposed joint federal-provincial-territorial study on the effects of gene patents on health care.

Another issue raised by some participants at our industry sector meeting is 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 for the period of exclusivity lost while CIPO makes its decision. Before accepting this position, we believe further insight and research by CIPO and Industry Canada is required on this subject.

To the extent that CIPO does not have the jurisdiction to elucidate itself these aspects of patent law, we encourage CIPO to bring these questions and options for their resolution to federal government policy makers.

As we noted earlier, if higher life forms are to be patentable in Canada, care must be taken to ensure that patent holders enjoy the same, but not greater, rights with respect to their biological inventions as holders of patents on non-biological inventions. Achieving this goal may require biological patents or the holders of them to be treated differently than other patents or patent holders.

29 Government of Ontario, *supra* note 23, at p. 49: *To remedy this problem the scope of patents over genetic material may need to be more rigorously defined to separate the chemical or structural nature of genetic material from its informational content. Patents should prevent the making, using, selling and importation of genetic material only when that material is used as a chemical, but should not unduly limit access and use of the particular information content of a naturally occurring sequence regardless of whether the sequence is being used in a natural or artificial form.*

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.

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 interested members of the public are able to monitor performance.

Recommendation: Service Standards and Performance Reporting

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

INTERNATIONAL HARMONIZATION 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 co-operation 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 worldwide. Implementing the *Patent Law Treaty* is a step in this direction. In addition, Canada should continue to advocate for a transparent, efficient, and uniform patent system at the international level. Opportunities to do so are available through the work of the WIPO Standing Committee on the Law of Patents, which is working toward a *Substantive Patent Law Treaty*, and work to be undertaken on the recently adopted Agenda for Development of the International Patent System.

Recommendation: International Harmonization

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

SIMPLIFIED SYSTEM FOR CHALLENGING PATENTS

Several respondents called for easier ways to challenge issued patents. Currently, Canada has a re-examination process whereby a patent claim may be challenged by filing undisclosed prior art (that is, previously existing and publicly available information). The prior art is reviewed and, if seen to have merit, the patentee is notified and given an opportunity to respond. The patent claim may be cancelled or confirmed; in addition, amended or new claims may be incorporated into the patent. The person challenging the patent is not involved in the process and there is no opportunity for others to intervene. Challenging a patent on any other basis after it has been granted requires a lawsuit; court proceedings in patent cases tend to be both very slow and very costly.

We believe Canada ought to follow many of its major trading partners by introducing an opposition procedure allowing third parties to challenge a patent after the patent has been granted. Given that any opposition procedure would affect all patents, not just those on higher life forms or other biological inventions, it may seem beyond our mandate to propose that Canada provide such a procedure. Nevertheless, we believe that there is much to commend the idea of a speedy mechanism to resolve disputes about whether a particular patent was properly granted, particularly over subject-matter such as plants and animals that are critical in Canadian health care and agriculture.

In 1998, the National Biotechnology Advisory Committee[30] recommended that CIPO introduce "an effective opposition procedure with a time limit of six months after grant, similar to procedures in Europe." 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 recommended six-month time limit.

Recommendation: Opposition Procedure

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

The draft recommendation in the Interim Report was generally supported, except by a few industry respondents. Several respondents noted that, in order to function effectively, the opposition procedure must be designed with care. Thus, in proposing this recommendation, we call upon the government to set out clear rules covering the following issues:

- Who can commence an opposition proceeding? We generally support the European position that any person may commence an opposition proceeding, even if that person has no economic interest in the outcome.
- Would the patent be suspended until the opposition is finally determined? While this is the rule in Europe, a mechanism is needed to ensure that patentees do not suffer from the unavailability of their patent rights because of frivolous oppositions. Thus, a screening process may be required before the patent is suspended.
- What evidence and procedures will be used to determine whether the opposition should be accepted?
- What timeline is appropriate in order to ensure that the opposition is quickly but appropriately decided? A schedule will need to be established, with completion dates for steps such as notification of the patentee, publication of the opposition, filing of interventions by interested parties, hearings on temporarily suspending the effect of the patent, filing of the positions of the various parties, holding the hearing and issuing a decision.

30 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*.

CONCLUSION

This project began, in part, because the question of whether a patent should be granted to Harvard for its onco-mouse had reached the courts and would almost certainly go all the way to the Supreme Court. Canada's patent office, unlike those of the United States, European Union, Japan, Australia and other countries, took the position that plants and animals are not patentable under Canadian law.

The case has now reached the Supreme Court. No matter what the Court decides, government will have to consider whether further action is required. If the Supreme Court rules that higher life forms are patentable, policies and practices of the Canadian Intellectual Property Office, which examines patent applications, would have to be revised. Amendments to the *Patent Act* or regulations might also be required. If the Supreme Court agrees with the Commissioner of Patents, the question would not necessarily be resolved. The more similar Canadian laws and regulations are to those of our major trading partners, the better the prospects for the biotechnology sector in the Canadian economy are believed to be. The government might therefore decide that higher life forms should be patentable in the future.

We undertook this project in an attempt to identify and examine issues which should be taken into consideration in deciding whether higher life forms should be patentable in Canada and, if so, under what conditions. We conclude that they should be, *provided* that the special nature of biological inventions is taken into account — *and only then*. Recommendation 2 should not be accepted or implemented unless accompanied by Recommendations 3, 4, 5, 10 and 13. We also point out the need for careful consideration to be given to the practical implications of deciding to permit patents on higher life forms. We identify a number of questions that will need to be answered if plants and animals are patentable. We urge the government to work with the interested parties to answer these questions as soon as possible.

As this report is released, the Harvard mouse case has just been argued in the Supreme Court. A decision is not expected for several months. Once the ruling is known, the government will have its own decisions to make. We hope the advice we provide in this report will assist the government in preparing to make those choices.

ANNEX A: 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) Meeting with 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 Meeting with 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.*

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.*

The Economic Argument, *by Dr. Ron Hirshhorn, Hirshhorn Consulting Inc., Nepean, Ontario; and Jock Langford, Economist, Corporate Governance Branch, Industry Canada, Ottawa, Ontario.*

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, Montréal, Québec; 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, Montréal, Québec; 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 B: 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, all of which, with this report, are now complete

Phase 1: The first phase consisted of collecting and analyzing information on various aspects of the topic. This included the preparation of research papers and technical reports by experts and meetings with biotechnology representatives in industry, non-governmental organizations and the research community to target the areas of interest for the Multi-stakeholder National Roundtables in April and May 2001.

Phase 2: In March 2001, we 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.[31]

To reach as many people as possible, the Consultation Document was posted on the CBAC 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 us 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 the CBAC web site, as is an omnibus report synthesizing the views expressed at all five roundtables. In concluding Phase 2, we prepared an Interim Report, released November 29, 2001 to serve as the basis for the next phase.

Phase 3: This phase involved soliciting the views of Canadians and stakeholders on the draft recommendations contained in the Interim Report and preparing the final report and recommendations. In order to ensure that Canadians had sufficient time and opportunity to consider the material and to prepare and submit comments if they wished to do so, the Interim Report was open for comments until March 15, 2002.

Phase 4: The final phase of this project involved analyzing the submissions made by phone, fax, mail and e-mail in response to the Interim Report and consulting again with specialized audiences. A number of organizations issued reports or held meetings or conferences since the Interim Report appeared. All of these inputs were considered by CBAC as we reviewed the draft recommendations and developed this report. While this report represents the formal end of this project of work, we will continue to monitor developments in the field.

31 This document 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.

ANNEX C: STRUCTURING THE DEBATE

The views expressed during the course of CBAC's research and consultations range along a spectrum according to the extent to which respondents believed 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.

CBAC noted, during its various consultations leading up to the Interim Report, that the subject of patenting higher life forms was complex, making it difficult for ordinary Canadians to participate actively in the consultation process. CBAC thus attempted to clarify this subject by identifying four "Positions" along a spectrum that cover the main thrust of the range of views expressed to it. These four views are as follows:

A The patent system ought only to take account of economic considerations. While ethical and social concerns are important, they are better addressed using other means, such as regulation, criminal law, or industry best practices.

B While the patent system is largely about economic forces, it has some ability — albeit limited — to address certain ethical and social concerns. In respect of these concerns, the patent system is the appropriate means to balance economic and other factors. In addition, Canada ought to use other means, such as those described in view A, to address the remaining ethical and social concerns.

C Concerns about ethical and social matters should be given as much weight as economic concerns within the patent system. Since patents are designed to attain the overall social good, the patent system represents an appropriate mechanism to address these concerns in a balanced manner.

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." We discuss each of these below, noting that while some elements of each position are compatible with those of other positions, many others are inconsistent with the other positions. The reader is thus cautioned to read each position as a different set of options flowing from the particular position adopted. In reading these positions, it is important to remember that CBAC is presenting them merely to assist Canadians in understanding both the general policy options as well as the practical implications of selecting one position rather than another.

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.

According to this position, 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 by rewarding innovators, while making information about those inventions public.

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

- 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 2001 decision of the Federal Court of Canada decision in *Monsanto Canada Inc. v. Schmeiser*).
- 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.

If Canada decides to grant patents over whole plants and non-human animals, it should also determine whether and which 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.[32]

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.

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 encountering the current general experimental use exemption find it 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.

32 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.

Patent System: The need for Canada to be internationally competitive leads to the conclusion that CIPO must have the resources and must meet international standards with respect to the amount of time needed to issue a patent in Canada.

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 is a need for the government to continue to harmonize its 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 positions were put forward for reflecting social and ethical concerns: 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, 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 might 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 use would codify the current farmers' 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). 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 has the 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 that could replace the *Plant Breeders' Rights Act* to protect all biological products. This regime 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 impact (health care costs and other social costs could rise)
- social impact (potential threat to genetic privacy)
- environmental impact (new life forms could harm ecosystems)
- other matters such as the lack of benefit-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 plants 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 D: POSSIBLE APPROACHES TO 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. These concerns became an important component of CBAC's consultations and informed CBAC's analysis of whether Canada ought to grant patents over higher life forms. Because of the importance of these concerns, CBAC has created this annex to both provide the reader with CBAC's understanding of these issues as well as to serve as a basis for further discussion among Canadians. In the first part of this annex, we set out some of the principal concerns raised while in the second part, we examine three methods to address them.

The concerns that CBAC identified through its consultations and its commissioned reports are as follows:

Commodification of Life

The commodification of life (including genetic material) is an ethical concern that most clearly arises directly from the application of patent law to higher life forms. The granting of a patent right in itself declares that an invention based on living matter has the potential to be commercialized. This gives rise to a concern that, by emphasizing the commercial value of animals and plants, Canadians will increasingly view animal and plant forms merely as commodities.

Current general law permits the buying or selling of plants and animals as property (hence "commodification"), but outlaws slavery (i.e., the buying or selling of humans). While the *Patent Act* further enforces this view of plants and animals as commodities, it clearly is not the source of this view. If the government wished to alter the ways that Canadians view animals and plants, this would require a significant public debate that far exceeds 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 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 consultations, 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 indigenous populations worldwide and local 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 generally perceived to deal 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 arguments in favour of patents — that they are believed to create incentives to create products and processes such as new medicines, improvements to economic productivity, and contributions to improved human health and welfare. However, as discussed in the first part of this annex, commentators also noted a range of potentially negative consequences — commodification of life, inequitable distribution of benefits arising from patented inventions, potential abuse of corporate ownership of genetic resources, among others — being reinforced or precipitated by patents on biological material, including higher life forms.

As noted in the report, 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

This option is premised on the belief that the patent system is not an effective tool with which to regulate social and ethical concerns linked to the commercialization of biotechnology. Those supporting this view raised arguments such as the following:

- 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.

Maintain the Status Quo

The analysis presented above leads those holding this point of view to argue against changing the *Patent Act* to address social and ethical issues.

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.[33] 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,

33 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.

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 a patent does not entitle its holder to exploit the invention,[34] 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."[35] 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 33 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 to apply to the patentability of an invention *ab initio* 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.

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.

34 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.

35 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 oncomouse. 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, although it was modified to apply only to rodents and not to all mammals.

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.

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 support the conclusion that it is immoral. 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; contrast this with the facts that even where there is no threat to our moral beliefs 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 inventions from patentability (that is, declare them ineligible to be patented) 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 change 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.[36] 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. Given the great speed at which advances occur in biotechnology, this approach provides the only realistic means to addressing social and ethical issues early on in the life of a new technology. 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.

36 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.

ANNEX E: ETHICAL FRAMEWORK: REACTIONS OF ROUNDTABLE PARTICIPANTS AND NEXT STEPS

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 policies 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 agencies or courts.

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 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.

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 promote the conditions necessary to allow Canadians to pursue their fundamental values and interests. A commitment to be transparent and answerable.
Autonomy	A commitment to promote informed choice.
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.

The statement was presented to participants in multi-stakeholder roundtables held in April and May 2001, as part of CBAC's projects on Regulating Genetically Modified Foods and Patenting of Higher Life Forms. Specifically, CBAC 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 are 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 "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.

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 — (a) being informed, (b) ability to act independently

— 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. Suggestions received during the consultations leading up to and the comment period following the interim reports *Improving the Regulation of Genetically Modified and Other Novel Foods* and *Patenting of Higher Life Forms and related issues* concerning this statement will assist CBAC in its work toward a global framework for addressing social and ethical considerations associated with biotechnology.

ANNEX F: NON-PATENTABILITY OF HUMANS — EXAMPLES OF WORDING

AUSTRALIA, *PATENTS ACT 1990*, NO. 83 OF 1990

18(2) Human beings, and the biological processes for their generation, are not patentable inventions.

DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 6 JULY 1998 ON THE LEGAL PROTECTION OF BIOTECHNOLOGICAL INVENTIONS

Recitals

(16) Whereas patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person; whereas it is important to assert the principle that the human body, at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its products, including the sequence or partial sequence of a human gene, cannot be patented; whereas these principles are in line with the criteria of patentability proper to patent law, whereby a mere discovery cannot be patented;

(17) Whereas significant progress in the treatment of diseases has already been made thanks to the existence of medicinal products derived from elements isolated from the human body and/or otherwise produced, such medicinal products resulting from technical processes aimed at obtaining elements similar in structure to those existing naturally in the human body and whereas, consequently, research aimed at obtaining and isolating such elements valuable to medicinal production should be encouraged by means of the patent system;

(20) Whereas, therefore, it should be made clear that an invention based on an element isolated from the human body or otherwise produced by means of a technical process, which is susceptible of industrial application, is not excluded from patentability, even where the structure of that element is identical to that of a natural element, given that the rights conferred by the patent do not extend to the human body and its elements in their natural environment;

(21) Whereas such an element isolated from the human body or otherwise produced is not excluded from patentability since it is, for example, the result of technical processes used to identify, purify and classify it and to reproduce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself;

Article 5

1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

Article 8

1. The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

2. The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation

or multiplication in an identical or divergent form and possessing those same characteristics.

Article 9

The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function.

Article 10

The protection referred to in Articles 8 and 9 shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market in the territory of a Member State by the holder of the patent or with his consent, where the multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation or multiplication.

Article 11

1. By way of derogation from Articles 8 and 9, the sale or other form of commercialisation of plant propagating material to a farmer by the holder of the patent or with his consent for agricultural use implies authorization for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm, the extent and conditions of this derogation corresponding to those under Article 14 of Regulation (EC) No 2100/94.

2. By way of derogation from Articles 8 and 9, the sale or any other form of commercialisation of breeding stock or other animal reproductive material to a farmer by the holder of the patent or with his consent implies authorization for the farmer to use the protected livestock for an agricultural purpose. This includes making the animal or other animal reproductive material available for the purposes of pursuing his agricultural activity but not sale within the framework or for the purpose of a commercial reproduction activity.

3. The extent and the conditions of the derogation provided for in paragraph 2 shall be determined by national laws, regulations and practices.

ANNEX G: PATENTABILITY OF PLANT, ANIMAL AND HUMAN MATERIAL AND OF PROCESSES USING HIGHER LIFE FORMS, CANADA AND OTHER COUNTRIES

There are different approaches to patenting of higher life forms and related processes around the world. This chart compares Canada to 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 in the table below 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*							

* Please note that the boxes "Animal Diagnostics" and "Human Diagnostics" apply only to diagnostic procedures used directly on animals or humans (that is, not diagnostic methods performed outside the body). Similarly, "Gene Therapy for Animals" and "Gene Therapies 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). This chart is an amalgamation of the three tables and supporting material in the box "Patentable Subject Matter" on page 7.