

## HIGHLIGHTS DOCUMENT

### CBAC ROUNDTABLE CONSULTATION ON BIOTECHNOLOGICAL INTELLECTUAL PROPERTY AND PATENTING OF HIGHER LIFE FORMS

**TORONTO SESSION  
APRIL 27, 2001**

**Prepared by:  
The Canadian Biotechnology Advisory Committee (CBAC)**

# Toronto Session

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## Consultation Participants

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### Stakeholders

Ainsworth, Peter J.	–	London Health Sciences Centre
Allore, Robert S. J.	–	Canadian Conference of Catholic Bishops
Baker, Mary Beth	–	Public
Brener, David	–	Canadian Institute of Health Research
Cherry, Glenn	–	Holstein Canada
Cotter, David A.	–	Head of Biology Department, University of Windsor
Crossman, Richard	–	Waterloo Lutheran Seminary
Dillon, John	–	Ecumenical Coalition for Economic Justice
Dobson, Bill	–	National Research Council
Donaghue, Terry	–	Director, Technology Transfer & Industrial Liaison Mount Sinai Hospital
Fish, Eleanor	–	University of Toronto – Faculty of Medicine
Galbraith, David	–	Canadian Botanical Conservation Network
Hamilton, Elizabeth	–	Consumers Association of Canada Hamilton & Associates Inc. Consulting Dietitians
Heller, David	–	Rideout & Maybee
Howe, Stuart	–	Hospital for Sick Children, Intellectual Property and Commercial Development Office
Hubbes, Martin	–	Faculty of Forestry, University of Toronto
Hunt, Murray	–	Canadian Livestock Genetics Association

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Hunter, Bruce	–	Syngenta Inc. (formerly Novartis Seeds Inc.)
Innis, Bert	–	Au Nature Farm, Organic Fruits and Vegetables
Inrig, Eileen	–	BIOTECanada
Keanye, Marilyn	–	Animal Care & Veterinary Service
Kemp, Kate	–	Mohawk McMaster Institute for Applied Health Sciences
Keougu, Ken	–	Health Canada/Genome Project
Leask, Bill	–	Canadian Seed Trade Association
McGuinness, Ursula	–	Sim & McBurney
McMain, Vanessa	–	Humane Society of Canada
McQuail, Tony	–	Ecological Farmers Association of Ontario
Mongeon, Marcel	–	Research Contracts & Intellectual Property Office – McMaster University
Nazarian, Vik	–	Life Sciences (Technology Transfer) University of Toronto
Owens, Richard	–	Centre of Innovation, Law and Policy, University of Toronto
Penner, Mark	–	Blake, Cassels & Graydon LLP
Poznansky, Mark J.	–	John P. Robarts Research Institute
Rowand, Melanie Sharon	–	Donahue, Ernst and Young
Rupprecht, Eleonore	–	Ontario Ministry of Energy, Science and Technology
Rutty, Andrea	–	Law Office of Cynthia Ledgley

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- Sheng, Grant – York Centre for Applied Sustainability, York University
- Singh, Ishwar – Chair, Chemical & Environmental Technology Department, Mohawk College
- Stirling, Art – Pioneer Hi-Bred – Dupont
- Van Donkersgoed, Elbert – Christian Farmers Association of Ontario

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## Roundtable Consultation Purpose and Objectives

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The Canadian Biotechnology Advisory Committee (CBAC) as part of its national consultation process held a roundtable in Toronto, Ontario, on April 27, 2001, to address matters concerning Biotechnological Intellectual Property and Patenting of Higher Life Forms.

### **Roundtable Purpose:**

To engage stakeholders in a dialogue to provide advice to CBAC on possible policy initiatives regarding Biotechnological Intellectual Property and the Patenting of Higher Life Forms.

### **Roundtable Objectives:**

- To obtain the views, opinions and advice of stakeholders on the key questions facing the Government of Canada in delivering a policy on IP and PHL.
- To initiate discussion among stakeholders to allow for a better understanding of the different perspectives regarding IP and PHL.

## Issues/Topics of Discussion

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The roundtable addressed three matters: identifying issues and guiding principles; the types of higher life forms, if any, that ought to be subject to patent protection; and determining Canada's international roles.

## Topic 1: Identifying Issues and Guiding Principles

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**Question A: What are the key issues that need to be understood and assessed in determining Canada's approach to developing a policy on IP and PHL?**

**The following issues were identified by participants:**

The starting point for the discussion by all three breakout groups was whether biological organisms are fundamentally different from other kinds of inventions with which the patent system has previously dealt. Biotechnology raises a host of new issues for society that the patent legislation has not anticipated. Questions and observations related to this point identified and made by participants include:

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- Should we develop and commercialize a technology just because we can? In some cases moral and ethical considerations need to be taken into account in assessing the merits of the technology.
- Should something that can reproduce without assistance be patentable?
- Do life forms have a special significance that requires a new decision-making process to determine patentability?
- We need to consider the ethics of manipulating natural life forms. Do humans have the right to modify life for our benefit?
- We need to assign responsibility, accountability and liability for unforeseen consequences caused by patenting biotechnology and higher life forms. Developers and implementers of life form based technology ought to be responsible for adverse effects on the life cycles of the patented animals and plants.
- Patenting of life forms increases the commodification of life.
- Patenting the products of biotechnology can adversely affect health care delivery if it makes diagnostic tools prohibitively expensive. In the United Kingdom, a publicly funded research foundation licensed its technology to industry on the condition that the technology be provided free of charge to the UK health care system.
- When we permit patents on gene sequences, we blur the distinction that we have traditionally maintained between living creatures and material objects. We do not yet understand the consequences of doing so.
- How can the spread of engineered genes be controlled and contained to that human health and the environment are not at risk? Can we permit biotechnological products to enter the market without appropriate safety guarantees?

### **Should the Patent system deal with social and ethical issues?**

Some participants maintained that while social and ethical issues pertaining to patenting biotechnology and higher life forms are important and must be addressed, patent law is not the best forum in which to do so. Ethical and social considerations should be dealt with first, to create a regulatory framework within which the patent system can operate. Patent office staff (CIPO) should not be making ethical decisions as to the patenting of plants and animals. A separate regulatory agency should deal with moral and ethical issues.

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Other participants were of the opinion that patenting is an implied stamp of approval on the patented technology so that the grant of patents constitutes ethical judgement. If society deems some things to not be patentable this would in itself be an ethical judgment.

### **A societal review of social and ethical considerations**

There is a need to provide for advance review of ethical concerns in the patent process as is now done with respect to research funding. There may be a role for an ethics review body to examine some aspect of patentability on moral grounds. Another approach would be a process that links an “ethical audit” to patenting. An independent body could look at ethical considerations and decide jointly with the patent office whether to grant a patent in particular circumstances.

As a counterpoint to this line of reasoning, some participants maintained that compulsory ethical review may not work because inventors may decide to avoid patenting their innovations, at least in Canada, and may opt for other mechanisms, including trade secret protection. This would prevent inventions from being publicized, as they would have been under the patent system.

There was broad agreement that a thorough review of the social and ethical aspects of biotechnology needs to be undertaken in the form of “ethical due diligence”. The result of this exercise would be a policy framework in which we could develop clear Canadian positions on IP and PHL. Having rules that anticipate risks and values would not work because risks change quickly. A more flexible mechanism is required.

Some additional comments about such a review process include the following:

- Finding the proper balance between economic and research benefits on the one hand and health and environmental concerns on the other.
- Defining “safe” and “equitable” is important and requires attention.
- Emphasis should be placed on accountability and enduring liability.
- The process must be open and transparent.
- Biotechnology encompasses many inventions, that have different effects on humans, animals and the environment and raise different issues from more traditional technology. The review should deal with each form of technology separately.
- Science has overtaken public understanding. Informed people must make the effort to communicate with the public and build awareness. This poses a real challenge

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## The benefits of the patent system

Some participants believed that the benefits of the patent system needed to be considered in determining Canada's policy pertaining to patenting the products of biotechnology including invented plants and animals. The purpose of the patent system is to encourage innovation. Innovation has several societal benefits including the following:

- Patenting may increase the amount of research undertaken in Canada.
- Patenting may provide those who invest in research and development with a way to recover their costs.
- By providing an incentive for research, patenting may help generate wealth in society.
- A patent requires disclosure, and disclosure aids research. The alternative to patents, namely, trade secrets, restricts the transfer of knowledge.
- If companies are forced to do research with no return for their efforts, Canada will lose its biotechnology industry to other, more receptive, countries.

While not calling into question the existence of the patent system, other participants raised some questions about these benefits:

- Financing may skew the research undertaken to commercial ends rather than what is best for society. The Eastman Commission<sup>1</sup> research funding recommendations propose a mechanism to address this problem.
- To whom do benefits of research go? Should they accrue only to those who can afford to pay for research? How is the public interest served?
- Patents can put restrictions on the use of enabling technologies, acting as a barrier to additional research.
- Biotechnology research on animals is currently being conducted, even without a clear position on the availability of patent protection for animals.

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<sup>1</sup> The Report of the Commission of Inquiry on the Pharmaceutical Industry, H.C. Eastman, Commissioner. Minister of Supply and Services Canada, 1985.



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- There may be no need to patent plants or animals. There are alternatives to patent protection, such as plant breeders' rights. Perhaps this is one area to pursue more vigorously.

## Competitiveness and harmonization

Some participants were of the view that the impact of Canada's approach to patenting on competitiveness needs serious assessment. It was suggested that the best solution for Canada would be to accept all decisions that come out the US patent system as to patentability of a particular invention.

While it was recognized that harmonization would bring benefits, it was also noted that Canada's social system was different than that of the US. Canadians has, for example, different concerns regarding the impact of patent law on Canada's publicly funded health care system.

From an investment perspective, a Canadian patent may not be important because the Canadian market is so small. If we want to attract industry, Canadian law needs to be more research-friendly than that of the U.S.

## Other Issues

A number of other issues relating to biotechnology and patenting were raised. These are as follows:

- A farmer's right to save and re-use seed should have precedence over the patent holder's rights over an invented seed (Farmer's privilege).
- Biotechnological products can contaminate organic farms or those farms that are free of genetically modified materials. One participant stated for example, that honey producers are losing the European market because the pollen carried by the bees is from genetically modified plants. Those producing and using genetically modified plants have a responsibility to control the spread and escape of modified biological materials into the environment.
- There is a concentration of power in the biotechnology industry. How can the industry be made accountable for the potential adverse effects of the technology it creates? How can we be certain that research on the impact of biotechnological products is truly independent?
- Global considerations require discussion. What are the effects, both economic and ethical of patenting plants and animals in Canada, on developing countries?

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## Principles

Participants were asked to comment on the principles on page 3 of the CBAC discussion paper as follows:

### **Justice:**

A commitment to ensure a fair distribution of benefits and burdens. A new commitment to ensure that policies and practices do not contribute to the oppression of vulnerable groups.

### **Accountability**

A commitment to be transparent and answerable.

### **Autonomy**

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

### **Beneficence**

A commitment to pursue benefits for Canadians and others throughout the world.

### **Respect for Diversity**

A commitment to ensure respect for diverse ways and forms of life.

### **Knowledge**

A commitment to value both scientific and traditional knowledge.

### **Caution**

A commitment to adopt a precautionary approach when knowledge is incomplete.

One breakout group felt that the principles were good but that the real challenge is in their implementation. How would this occur and who should be responsible for questions that remain to be answered? One participant suggested that what is most important is not any one particular principle, but the balancing of them all.

The following specific comments were provided:

### **Justice**

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There was a question as to what is meant by the words “burdens”, “costs”, “hazards”, “risks” and “vulnerable”. All of these terms need to be clearly defined.

This principle should include the developed-developing countries dimension of justice. At present the distribution of the benefits of biotechnology is unfairly weighted in favour of developed countries.

It was noted that, as written, the justice principle is a political statement because it deals with the distribution of benefits and burdens and does not address whether these benefits and burdens should even be occurring.

### **Knowledge**

This principle is not clear and needs elaboration. It was also proposed that “knowledge” should be described as “relevant and valuable”.

### **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 prevention or slowing of progress.

### **Respect for Diversity**

Ensure that biodiversity is considered in its broadest sense.

### **Beneficence**

The beneficence principle should also pertain to the investment that comes back into Canada from those who benefit from Canadian patents.

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## **Additional Principles to consider**

- A principle on “environmental protection” should be added.
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- All of the principles should not be solely written from an anthropocentric perspective. A principle that embraces an ecological perspective is warranted.
- There should be a principle on the “freedom to explore and investigate” or encouraging greater “knowledge”. Curiosity should not be stifled.
- We need a principle that allows for slowing down progress, which may be too fast, and beyond the ability of society to react.
- There should be a “do no harm” principle (or at least “do no avoidable harm”). How we would balance “do no harm” principle with other needs must be addressed.
- A “harmonization with trading partners” principle is required to ensure we maintain and enhance our research and development (i.e. support wealth generation).

## **Topic 2: What should be patentable?**

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Participants were charged with the task of discussing what plant and animal material should be patentable and under what conditions. The views were quite diverse and in stating their opinions, participants identified a range of concerns and issues that require more thought and analysis before resolution can be achieved.

Generally, there was greater support for the patenting of invented plants than patenting invented animals. The details of the discussions follow.

### **Plants**

Three major themes emerged from the discussion pertaining to patents over invented plants.

1. What is the specific subject matter being patented (e.g. is it a gene, a gene sequence or the whole plant?). Considerations may vary depending upon the nature of the subject matter of the patent.
2. How does patenting relate to existing legislation intended to support the agriculture industry?

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### 3. What are the benefits and disadvantages of patenting plants?

Many noted that patenting a specific gene to improve the output or quality of a plant may be the starting point. However, some inventors would seek to extend the scope of this protection to enhance the inventor's financial return.

#### **The Specifics of the Subject Matter Being Patented**

The differences in opinion varied most on the discussion of whether a whole plant could be patented or just a particular gene sequence. Many noted that patenting a specific gene to improve the output or quality of a plant may be the starting point. However, some inventors would seek to extend the scope of this protection to the entire plant and the industrial applications for which it would be useful. This broad patent protection would enhance the inventor's financial return. On the other hand, this broad patent protection could restrict access to technology and hinder further research and development.

The following opinions were expressed:

- Our major trading partners permit patenting of plants and given the global marketplace, Canada needs to keep pace.
- In addition, as a guideline, any biotechnological innovation not covered by plant breeders' rights, should be eligible to be patented.
- We need to preserve the ability to protect specific characteristics of patents by other means. Patents must not restrict access to important innovations.
- Guidelines for CIPO are required on the scope of the claims permissible.
- Pioneering patents (the first patent pertaining to a new invention) have larger scope of protection than patents that build on the invention. This may restrict future research and innovation on the same technology.
- It is acceptable to patent a gene sequence, a seed or a plant. However, multiple patents are often sought, for example, over genes, plants and related processes. This practice must be restricted.

The following questions were raised without resolution:

- If the plant itself is valuable should it be patentable? Who has the right, if any, to benefit?
- What is the scope of protection provided by patenting?
- If one enhances a gene in a plant and patents this gene, does one gain control, and in essence a patent on the entire plant? (e.g. *Schmeiser v. Monsanto*)

#### **How does Patenting Relate to Other Legislation?**

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Existing legislation, such as the *Plant Breeders' Rights Act* provides one way of ensuring the development and dissemination of new varieties. Many felt this is sufficient; rendering patenting unnecessary. With respect to the intellectual property protection of plants, the *Plant Breeders' Rights Act* and the *Patent Act* may be complementary. Different criteria apply for compliance with each act. The question was raised as to the extent to which one act affects the other.

There needs to be a thorough review of how the patenting process and *Patent Act* will interact with the *Plant Breeders' Rights Act*. Patenting should not diminish the rights and protection offered in the existing legislation .

The following points were also noted:

- Patenting of plants may inhibit innovation and prevent people from developing better varieties. The *Plant Breeders' Rights Act* may not be similarly restrictive.
- We do not want legislation that will in any way inhibit or interfere with traditional agricultural practices.
- Canada is not compliant with 1991 UPOV. We are compliant with the 1978 UPOV. We must get our legislation amended in order to catch up with our trading partners.

### **Benefits and Disadvantages of Patenting Plants**

The discussion focused on the economic potential and the generation of knowledge for broad social good, provided that economic concentration of resources into a few hands did not occur.

Patenting was seen by some participants as a way to encourage development of a greater number of plants varieties and it was argued that there now exists more diversity of plant varieties than 20 years ago. This means that the loss of biodiversity may not be a significant risk with increased intellectual property protection.

The following points were also noted:

- The alternative to patents is secrecy. Patents ensure disclosure which is preferable.
- Patenting provides economic protection for the patentee
- If a patented seed is to be re-used, a licensing fee could be paid. This might be cheaper than buying new seed
- We need mechanisms to examine the environmental and social effects of patenting plants
- We need to ensure variety and choice in the marketplace

### **Animals**

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Some participants stated that patenting of animals should absolutely not be allowed as this violated the sanctity of life. Others felt that there was no meaningful distinction between the patenting of plants and the patenting of animals so that patenting of animals ought to be permissible.

The central question appeared to be where the line should be drawn. Should all animals be subject to patenting or only some? Should primates and/or humans be excluded?

The following is a summary of the various positions taken and the key points made during the discussions:

## ***Animals ought not to be patentable***

- It is wrong to assume ownership over animals
- Animals have rights. Patenting allows humans to violate their rights
- Patenting of higher life forms does not serve the public interest
- Biological organisms are distinct from other inventions. They have evolved in concert with their surrounding environment and should not be altered by humans.
- Patenting is ownership over and interference in the genetic makeup of animals and we do not know the implications of our actions
- We have no faith in safeguards and decision-making processes to protect humans and the environment from the effects of patenting animals
- The *Patent Act* is not equipped for biotechnology. It was designed for industrial processes.
- If it is a high enough priority, society has other mechanisms to advance innovation and we need not rely on patenting as a driver
- Life forms that are able to feel pain and self-reproduce should not be patented

## ***If Patenting over whole animals is to be permitted, it is noted that:***

- Patents over animals are difficult to reconcile with breeders' rights
- Stewardship over animals is necessary. This requires control, monitoring the ability to trace the origin of the animal.
- Social values change over time

## ***Animals Ought to be Patentable***

- Canada should permit patenting of all plants and animals because we cannot draw a line in the sand between what is and what is not patentable
- It is inconsistent to allow patenting of animals and not humans. Societal acceptance is the only barrier.
- If someone does not like patents over animals then the person need not buy the resulting products (market will dictate policy)
- We already acknowledge property rights over animals (pets, livestock, etc.)

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- The *Patent Act* is not the place to deal with ethical concerns. Other regulations to act as safeguards are required

## **Safeguards and Conditions**

In addition to discussing the issue of patenting plants and animals, participants identified a range of safeguards and conditions that need to be addressed in conjunction with patenting activity as follows:

### ***Possible Exclusions:***

- A distinction must be made between breeding animals to improve productivity for our use and breeding animals as vectors for drugs
- There is no exclusion for all primates in international patent law but such an exclusion should be considered here

### ***Create unlimited liability legislation that would allow for:***

- Class action suits
- Claims for damages
- Collection for damages

### ***Create Legislation as Follows:***

- Patenting over animals ought to be subordinate to legislation on human rights and animal rights legislation (outside of the *Patent Act*)
- Legislation is needed to define the limit of how far patenting over animals should go
- We need legislation to ensure transparency and openness

### ***Accountability mechanisms***

- Ordre public clause
- Morality clause that deals with
  - Environmental harm
  - Harm to human health
  - Animal suffering
- Scientific safeguards to ensure that genetically modified species will not escape into the environment and replicate
- We need a “terminator” mechanism as a condition of all plant and animal patents so that genetically modified species will survive only under specific conditions
- We must provide for an opposition review of patent applications
- Institutional control that is independent of government, like CBAC, should be empowered to assess patentability on a case-by-case basis. Ethical review should be more than merely advisory
- Consider instituting a Biotechnology Ethical Review Body as an administrative tribunal



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- Issues of humane treatment and the reproductive process need to be regularly reviewed
- Government needs to bolster its credibility and to demonstrate that it can protect the public interests

### Topic 3: Determining Canadian International Role

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The third discussion topic was held in plenary session rather than individual breakout groups, and addressed Canada's international obligations and role concerning biotechnological intellectual property and the patenting of higher life forms.

The discussions centered on the following questions:

- a) Are there any inconsistencies in approach among Canada's various international obligations? What are they? Why are they significant?
- b) What actions, if any, should Canada take to address its international obligations regarding the patenting of higher life forms and related processes?
- c) Why are these actions necessary?

It was acknowledged by many participants that Canada needs to assess its approach to patenting in a way that best meets its needs in light of the patent systems in the United States, the European Union and other countries. While existing treaties and agreements place some requirements on Canada, there is sufficient flexibility to define a uniquely Canadian approach. It was further noted that even with the existing treaties and agreements, our major trading partners have taken somewhat different approaches. As a result, Canada need not adopt any one country's system or feel constrained by these agreements in developing its approach to patenting of plants and animals.

Some participants suggested that Canada should adopt the U.S. approach to intellectual property. The U.S. is Canada's largest trading partner and the economies of the two countries are highly integrated. From an investment and trade perspective, being consistent with the U.S. would maximize benefits for Canada by:

- allowing Canada to maintain its highly qualified research community
- providing a stimulus for research initiative
- establishing a favourable climate for increased capital investment in Canadian biotechnology
- supporting the country's growing biotechnology industry.

Others suggested that the approach of the European Union is preferred since the European Union places a greater emphasis on social policy considerations. This was viewed as being more consistent with Canadian social values.

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It was also proposed that Canada consider an approach that reflects the needs and values of other countries, especially less developed countries and not only its major trading partners.

No consensus was reached, other than that Canada needs to harmonize its patenting system with the world, in a way that makes sense for Canada. As a country we must define a policy framework for the protection of intellectual property and the patenting of plants and animals that is uniquely Canadian, reflecting our values and needs.

### **Defining a Future Role for Canada**

Many participants felt that Canada should assume a leadership role in all on-going and future international negotiations regarding biotechnological intellectual property and patenting of higher life forms. In particular Canada should assume a role that promotes human rights and environmental concerns as matters that are fully considered and addressed in any future treaties and agreements. Participants expressed a number of different views on which policies Canada should articulate including the following:

- recognition of indigenous people's rights and the significance of traditional knowledge
- strategies to ensure effective informed consent practices
- fair access by all to biotechnological research and innovations
- fair sharing of the benefits of biotechnological research and innovation for all
- full life cycle assessments of biotechnological innovations before patenting
- promotion of an ecosystem perspective rather than a human-centered perspective in assessing biotechnological innovations
- establishment of a right to biological commons
- promotion of safety laws (similar to that developed for Costa Rica) and laws governing genetic pollution

It was also proposed that Canada's role should extend beyond the negotiation table. Canada has an obligation to share biotechnological information and provide capacity development and institutional strengthening support and oversight systems, regarding intellectual property and patenting of higher life forms to countries in need. Canada should also develop policies and programs to facilitate the active involvement of the biotechnology industry and publicly funded researchers to participate in this information transfer and support role.

Finally it was proposed that alternative approaches to the transfer of biotechnological knowledge other than patenting should be considered. Regional food systems developed within an ecosystem context are an attractive alternative that Canada should promote.

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**Please note that similar reports from each of the 5 CBAC roundtable consultations on Biotechnology Intellectual Property and the Patenting of Higher Life Forms, conducted across Canada from April 23 to May 4, 2001, will be posted on the CBAC website. As well, results from all 5 roundtables will be integrated into a single roll-up report that will also be available on the CBAC website by the end of May 2001.**

**Please visit the CBAC website at [www.cbac-cccb.ca](http://www.cbac-cccb.ca) or call the CBAC toll-free number at 1-866-748-2222 for additional information or documents related to this or other CBAC projects.**