

## HIGHLIGHTS DOCUMENT

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

HALIFAX SESSION  
APRIL 23, 2001

Prepared by:  
The Canadian Biotechnology Advisory Committee (CBAC)

# Halifax Session

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## Consultation Participants

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### Stakeholders

John Argall – BioAtlantec

Jane Aucoin – Consumers Association of Canada (Newfoundland)

Robert Boyd – National Research Council/Genome Atlantic

Carl Breckenridge – Dalhousie University

Wendell Dawson – ARK Biomedical

Phil Ferraro – Institute for Bioregional Studies

Garth Fletcher – Aqua Bounty Canada Inc.

Ronald Fournier – Negentropy Farms

Kathleen Glover – Nova Scotia Agricultural College

Rejean Hall – Centre pour l'innovation scientifique et technologie dans l'industrie

Sarah Hill – Confederation of Mainland Micmacs

Marc Kielly – Department of Aquaculture, Memorial University

David King – Genesis Group

Helen Lee – Acadia University

Elizabeth Logan – Dietitians Network on Food Biotechnology

Chris MacDonald – Office of Bioethics Education and Research, Dalhousie University

William Mills – Innova Corp.

Gailene Murphy – PEI Development and Technology

Gordon Owen – Nova Universities Technologies Inc.

Rajaraman Rengaswami – Oncodynamics Inc.

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*Highlights of the Halifax Session*

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*The views presented in this report are those raised by participants in the session. These views do not reflect a consensus and should also not be construed to reflect the views of CBAC.*

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Bruce Squires – Newfoundland and Labrador Medical Association

Andy Tasker – Atlantic Veterinary College, University of PEI

Donna Viger – NRC Institute for Marine Biosciences

David Walker – NB Department of Agriculture, Fisheries and Aquaculture

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## **Technical Resources**

Holly Ferguson

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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 Halifax, Nova Scotia, on April 23, 2001, to address matters concerning Biotechnological Intellectual Property and Patenting of Higher Life Forms.

### **Roundtable Purpose:**

To engage stakeholders in a dialogue to provide their views 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:

#### **What are patents for, and who do they serve?**

Patents were developed more than a century ago to address perceived needs arising from the then dominant sciences of chemistry and physics. The same legislative principles are still being applied to biotechnological inventions. As living and reproducing matter, it was feared that there was a greater risk that biotechnological subject matter could escape into and affect other species and the environment. Questions were therefore raised as to whether biotechnology is appropriately protected by patent law which was originally intended for mechanical and chemical inventions.

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A number of questions were raised based on the premise that patents allow the protection of investments in new products, and deriving of profits.

- Do patents on living organisms serve only industry?
- Do patents serve the public or the interests of humanity?
- Do patents serve the development of science?
- Do patents contribute to the economic growth of individual nations or the world?
- Do patents offer appropriate or excessive rewards for innovation?
- How can the needs for altruistic development be made possible within a profit oriented patent system?
- Are the balances appropriately struck between competing interests in today's world?
- Are the benefits of patents appropriately shared and distributed to those who contributed to the invention's development and society at large?
- How are the interests of the public be defined and assessed, and by whom?

## **Patenting and the development of knowledge**

Patents are designed to protect the commercialization of inventions for a period of twenty years to allow the inventor to recover research and development expenditures and reap the benefits of exclusivity. Patents also are intended to place new knowledge into the public domain.

## **How does the patent process affect the development of science?**

Some participants raised concerns about the relative lack of publicly-funded-research and the fact that the private sector was now the main forum for research and development. The result is that ownership of patents is now more highly concentrated in the private sector. The benefits of free, non-commercial research which has a high value to society, should not be compromised by granting patent rights. Concerns were raised about the relationships between the advancement of knowledge through publicly funded research and the ownership of patent rights by companies.

## **Awareness and public information**

The issues around patenting are of great public significance. Some participants felt that much stronger efforts are needed to bring the issues before the public for broad debate and input into the development of policies. In addition, they decried the perceived lack of transparency in the patenting processes and sought openness, promotion of awareness and public access to knowledge. They believed the ability of society to make informed choice among policy options will be dependent on a well-informed public. It is equally important that policy-makers, and adjudicators, be aware of the views of the public and the relevant facts related to policy choices.

Huge gaps of understanding exist between the various players in determining public policy; scientists, policy makers, public advocacy groups, the media, the general public,

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all contain within each group as wide a range of opinions as there appear evident between groups. National debate is limited by expressions of the extreme positions, and by the processes of policy development that may tend to require organizational uniformity of view. As in almost any area of public policy, means of setting out the issues openly and transparently are essential.

## **Effects of patents on genetic diversity and the environment**

Concerns were expressed about increasing the concentration of corporate ownership of patents on the use of new organisms. The exclusivity that patents provide to companies in these circumstances could have the effect of decreasing genetic diversity.

The following questions were discussed without resolution: Will the holding of patents enhance the use of biotechnologically derived organisms to the detriment of the natural world, and loss of components of the global gene pool (loss of identity preservation)? Might such effects decrease the development and use of natural therapies? Is a global agreement needed on the environmental implications of biotechnological applications?

## **Question B: What are the principles that should be used to guide the development of a policy on IP and PHL?**

The Canadian Biotechnology Advisory Committee has identified principles to develop a useful framework for assessing proposals for public policy related to biotechnology. Comments were invited from participants on these principles.

### **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.

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## Caution

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

Specific comments on the principles were:

- The reference to vulnerable groups under “Justice” seems to lack definition. Humanity is vulnerable. Perhaps a non-exhaustive list with examples for policy and regulations would be helpful.
- The reference to informed choice under “Autonomy” may provide insufficient guidance. How does one engage people for whom this is not a priority?
- “Beneficence” should be defined as a commitment to pursue “ALL” benefits for Canadians and others throughout the world.

One breakout session suggested that the concept of respect and dignity should be extended to plants, animals and the environment.

The present proposals may be at too high a plane for general appreciation, not indicating to the majority of Canadians how the balances needed in any application of ethics and values can be achieved in the practical world when conflicts between principles or values must be resolved.

Some wished to place the highest priority on precaution. However, others pointed out that knowledge is never complete, and that science can never exclude all possibilities. The balance between the need for caution and the need for progress is complex. The desire to do good and do no harm was also expressed.

Openness, transparency, public awareness and access to knowledge to allow society to make informed choices were given high priority in the discussions.

The role of the patent system as promoter of social benefit needs further exploration. Wealth creation is a driving force behind innovation and use of the patent system. Although economic wealth is not without social value, the issue now may be to balance wealth creation through patenting with other values for society.

Human rights were a major concern, specifically the rights of people in less developed regions whose traditional practices could become the subject of intellectual property and exploited by industries in developed countries without appropriate compensation or benefits-sharing. Concern was expressed about the concentration of wealth in a few hands.

Exploitation also came up related to people/groups contributing tissue for gene identification and not sharing the benefits of the resulting research. The suggestion was made that under “justice” there should be a commitment to ensure that policies and practices do not contribute to the exploitation of vulnerable groups.



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Environmental considerations are of great importance, specifically the maintenance of genetic diversity, and promotion of sustainable development.

The principles in the CBAC discussion document were considered a welcome start. Enunciation of a coherent set of values and principles is very difficult. It was agreed that Canada first needed to determine the key objectives of its public policy, based on Canadian social and ethical values.

## **Implementation of Ethical values**

Citing ethical principles and values is not helpful if their applicability is not demonstrated. The following questions were posed without resolution: How should society regulate the moral aspects of biotechnology or ensure that they are appropriately addressed? Is a regulatory process needed to monitor patent applications? The existing regulatory framework is of limited assistance in that there is no legislation for many important issues. Further, legislation is slow to change. Courts may not be the appropriate forum in which to address ethical issues, as judges are bound by the interpretation of existing legislation and are not sufficiently responsive to rapidly changing ethical perceptions. However, voluntary approaches engender little public trust.

Participants tended to prefer a mechanism independent of the patent system for addressing social and ethical issues.

Accountability must be built into the legal system. Legislation is needed to address who is responsible for adverse effects of biotechnology, whether or not these are foreseen at the time of patenting, and how. For example, where a new life form is inadvertently spread to the detriment of a person or the environment, the responsible person must be identified and held accountable.

In an area as rapidly moving as biotechnology, since legislation is comparatively slow to respond, legislation should have a built-in review and renewal mechanism for patenting of biotechnology. For example, patents could be revoked for ethical reasons through the action of an independent body.

Many participants suggested that Canada should adopt an “ordre public” or morality provision in its legislation.

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

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This topic addressed the questions of whether there should be a policy to permit patenting of higher life forms for particular purposes and, if so, what factors must be considered and what safeguards and conditions are required?

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The range of innovations that can be patented caused concern to participants. A need was identified to make the definition of higher life forms that can be patented more precise. For example, it is not sufficient to draw the line between human and non-human life forms.

The ability to patent DNA sequences was questioned. Closely related to this question is the extent to which the utility of a DNA sequence must be disclosed in an application for patentability. What are the relevant criteria?

### **Question A: Is there a rationale for a policy allowing patenting for medical research and health care applications**

Generally, participants were favourable to a broad acceptability of patenting of higher life forms for medical use. However, participants were well aware that patenting of life forms may be offensive to some sectors of society on moral and cultural grounds.

Many participants expressed the view that the rationale for patenting for medical research and health care applications is no different than patenting for any other purpose. Participants also noted that patenting is one step, but other processes or mechanisms are also needed to monitor and regulate application and effects.

### **Factors to be Considered**

Participants identified a number of factors that needed to be considered and addressed in the context of patenting medical research and health care applications. These are:

- There must be safety for the public and the environment.
- Who is going to profit? Are there clear public benefits?
- Is there an urgent societal need?
- There needs to be clarity of definition of terms such as biodiversity.

### **Safeguards**

Participants listed a number of conditions and safeguards that should constrain or set guidelines and parameters. These are:

- an “ordre public” provision to provide a level of constraint and a moral filter.
- an ethics review board or a biotechnology advisory board which has an oversight responsibility within or over the Canadian Intellectual Property Office.
- employing a precautionary approach to assist government to deal with risk and the unknown.

### **Questions/Challenges**

Participants also identified a number of questions that must be answered and challenges to be addressed to arrive at a policy pertaining to patenting of higher life forms for these purposes.

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- Are there any boundaries? Where do we draw the line?
- What is the definition of a higher life form? Is it permissible to patent bacteria but not animals?
- How do we deal with the ownership of indigenous knowledge, traditional ecological knowledge, and Aboriginal knowledge?
- Public/societal awareness – we need to understand that patenting gives rise to legal rights over an invention, but does not equate to ownership of the product of that invention
- Canada must decide on its own domestic approach within the context of the positions of our major trading partners. For example, Canada should look to its trading partners to determine the appropriate scope of the experimental use exemption. Some participants argued that the boundary between research and commercial activity is eroding, making it increasingly difficult to determine what would fall within an experimental use exemption from patent infringement.

### **‘Question B: Is there a Rationale for a Policy Allowing for the Patenting of Animals and Plants for Agricultural Purposes?’**

Participants saw both benefits and disadvantages of patenting animals and plants for agricultural use.

The benefits identified were:

- Patenting will provide societal benefits such as increasing food production
- Patenting will provide protection of many wild plants and preserve diversity
- Patenting has the potential to enhance and change plants to meet needs of humans
- Patenting may have potential environmental benefits, i.e. reduce or avoid pesticide use

The disadvantages are:

- There is a system in place that works well for plants – Plant Breeders’ Rights – so that there may be no need to extend patent protection to plants
- The registered seed process now works, so changes are not needed
- Patenting may restrict research activity by others
- Patenting may concentrate the control of agriculture in the hands of a few

### **Factors**

A number of factors that should be considered when reviewing patent applications for agricultural purposes were identified. They are:

- Patenting must identify the unique characteristics of the sequence in a plant – they must be clearly defined.
- “Safeguards” must be implemented and assessed at the time the application is made.

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- The person who holds the patent must be responsible for the control of the material – if the patented material cannot be controlled or confined, the patent over the subject matter should not be issued.
- Patenting must not restrict access to the invention.
- Assessment of patent, length, exclusivity and allow for reasonable profit to innovate.
- Vegetation for use as food should not be controlled by patents.
- Farmers should be able to re-use seed, but not necessarily have the right to sell the seed.
- Question whether a patent owner be able to control the growing of a plant because of a patent on one gene inserted into that plant's genome (e.g. Schmeiser v. Monsanto)?
- Plants and animals are recognized in society to merit varying degrees of ethical treatment.

## Safeguards

The following safeguards were proposed:

- Legislative – need to address human rights in legislation.
- Genetic pollution law is required so that persons are held accountable for the dissemination of genetic material into the environment.
- The CBAC principles should be applied by an independent, multipurpose body for the review of patent applications.
- Developing good policy means “being cautious”.
- Establish an “ordre public” approach.
- Ethical safeguards are required to ensure human rights and possibly the rights of other primates.

## Questions/Challenges

Participants identified questions and challenges in patenting for agricultural purposes as follows:

- Should transgenic pollution by genetically modified plants causing farms to lose certification as organic producers be addressed in legislation?
- Participants had no objection to return on investment in research and development. However, the question was raised as to what the return should be and who should decide what is fair (motivation for patent)?
- Should patent and regulatory processes be kept separate?
- Should there be a moratorium on transgenic activity until ethical issues are resolved?
- Should we permit patenting for crops that are sold for purposes other than food?

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### **Question C: Is there a Rationale for the Patenting of Animals and Plants for Industrial Use?**

Two divergent points of view were clearly expressed.

The first view is that, the Patent Act is needed to provide protection of inventions and thereby encourage innovation. The social/environmental/moral issues need to be dealt with, but outside the patenting process.

The second view is that patenting should not be allowed because of unknown risk. We need to “stop the clock” while we undertake more research to have more knowledge of the benefits and risks and to have confidence to proceed. Technology may have outpaced society and social values.

There was also general concern with the potential for contaminating the gene pool as plant genomes mingle and through cross-breeding over time. Biological dissemination is very difficult to reverse.

#### **Factors**

Relevant factors include:

- The assessment of public good outweighing any risks.
- The real and documented benefits to the public or society as a whole.
- The contribution to enhancing or improving quality of life.

#### **Safeguards**

The only safeguards are those that exist through the approvals and regulatory processes. It may be necessary to establish mechanisms for monitoring and review to enhance safeguards.

#### **Questions/Challenges**

- How do we protect against contaminating gene pools?
- How do we rectify any errors in judgment?
- Who will determine what is the public good and make the judgments?

### **Topic 3: Determining Canada’s International Role**

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The third break-out discussion topic addressed Canada’s international obligations and role concerning biotechnological intellectual property and the patenting of higher life forms.

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Patenting systems vary considerably between countries. Canada is bound by treaties to specific actions in patenting, but also has some flexibility to take its own course. In addition to addressing its own sovereign interests, participants felt that Canada has an excellent opportunity to provide international moral leadership in a new order for patenting. Although it is economically relatively small, Canada has considerable international moral authority, which it could wield in introducing considerations of values and ethics into patenting regimes.

Canada needs to identify what is the right thing to do, and then consider how it can implement the identified actions within the existing limitations of treaties, obligations and national interests, rather than by starting from the present limitations and then considering what it can do.

The discussion focused on three themes:

**a) Are there any inconsistencies in approach among Canada's various international obligations? What are they? Why are they significant?**

Participants acknowledged that there were inconsistencies in the approach taken by trading partners with respect to patentability of biotechnology. Such inconsistencies included subject matter patentability, exemptions from infringement, and exclusions such as the "ordre public" and morality clauses. Most participants, however, favoured a "made-in-Canada" approach, with due regard to Canada's international obligations.

Inconsistencies among trading partners may be significant because Canada must compete in the international economy. Our own sovereignty and our ability to compete are influenced by many factors, including:

- Differences in legislation or regulations among trading partners.
- Treaty obligations restricting Canada's ability to develop its own processes and legislation.
- Differing interpretations between nations of those treaties.
- The time taken to issue patents in Canada as opposed to other countries, leading to gain or loss of commercial development.
- Competition between nations in patenting rights can affect retention of highly qualified personnel, and also the development and commercialization of new discoveries.

There appeared to be general agreement that Canada should develop positions on obligations presented by various treaties and agreements regarding patenting of higher life forms. These positions need not necessarily mean compliance and acceptance, but a clear articulation of a "made in Canada" policy.

**b) What actions, if any, should Canada take to address its international obligations regarding the patenting of higher life forms and related processes?**

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Participants suggested that to the extent possible, harmonization of legislation, regulation and processes should be pursued between Canada and its trading partners.

It was suggested that sufficient wiggle room exists within current international obligations for Canada. Many of the treaties and agreements provide for exemptions and exclusions; these should be assessed for application to Canada. A comprehensive biotechnology strategy that is uniquely Canadian is needed, that critically assesses what harmonization is in Canada's best interests and what exemptions should be made.

A preference emerged from the groups that an "ordre public" or morality clause should be developed that reflects the principles and values discussed in these consultations. Canada should also clearly state that human beings and other primates must not be patentable.

Many participants felt that Canada could and should assume a leadership role in any future international agreements concerning the patenting of higher life forms specifically, and biotechnology in general.

Some criticized the current treaties and agreements as biased in favour of trade and investment, with little regard for human rights and environmental matters. It was also noted that our major trading partners the US and the European Union take somewhat different approaches to the patenting of higher life forms. It was suggested that Canada assume a leadership role to ensure that future agreements fully consider and address human rights and environmental matters, as a balance to trade and investment. Specific actions could include:

- Mechanisms to ensure that indigenous peoples are fairly compensated for their contributions to biotechnology research and the patenting of higher life forms.
- An assessment of all patenting of higher life form proposals against the ethical context – the assessments should guide the development of Canada's position in future international trade negotiations.
- CBAC efforts should continue to seek the advice of Canadians respecting the patenting of higher life form issues – their advice should be reflected in future negotiations and international agreements.
- The consultations must be seen as an effective mechanism to inform policy makers of concerns of both the public and private sector research community and the Canadian public.

### **c) Why are these actions necessary?**

Several reasons were provided supporting compliance with current obligations:

- The time required to assess and approve an application for a patent takes too long in Canada when compared to the practices of our major trading partner, the United States. This was described as a constraint that not only slows but also discourages innovation in Canada. This results in a perception that Canada is not

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- receptive to research and innovation in the area of higher life forms and drives both research and investment out of the country.
- Canada's current position on patent restoration was also discussed as a further deterrent to research. By not providing for patent restoration rights biotechnological research is not as vibrant as it might otherwise be.
  - Canada's failure to make its approach to patenting of higher life forms clear and consistent with its trading partners provides an opportunity for them to challenge the Canadian patent system, resulting in patent policy for higher life forms being reactive and not proactive. As a result, Canada's policy is being developed in an ad hoc manner causing Canada's reputation in the international arena to suffer.
  - Canada's trade relations and economy is affected by the international perception that Canada adheres to its obligations and is a hospitable trade environment for foreign investment in biotechnology

Not all participants stated the view that Canada must harmonize its patent process for higher life forms with its trading partners:

- Patent restoration can result in negative societal impacts, especially in the health care area. By extending patent restoration rights the costs of medicine derived from the patenting of plants and animals may remain unnecessarily high for a longer period of time.
- Taking patenting of higher life forms positions consistent with Canada's trading partners may adversely affect the agricultural economy. The result may be additional costs to Canadian farmers or unfair restrictions to access of new food plants.
- Patenting of plants may not be necessary, other mechanisms like the Plant Breeders Rights and Seed Registration may be adequate.

This session concluded that Canada's present international stature should be the foundation for taking a leadership role in evolving to new international standards in the management of biotechnological innovation for the global good as well as in the interests of each nation, taking ethical and social values into full account.

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**Please note that similar reports from each of the 5 CBAC roundtable consultations on Biotechnological 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**



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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.