HIGHLIGHTS DOCUMENT

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

MONTREAL SESSION
APRIL 25, 2001

Prepared by:
The Canadian Biotechnology Advisory Committee (CBAC)

The views presented in this report are those raised by participants in the session. They should not be considered consensus views, and should also not be construed to reflect the views of CBAC.

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Montreal Session

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Montreal Session

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Roundtable Consultation Purpose and Objectives

The Canadian Biotechnology Advisory Committee (CBAC) as part of its national consultation process held a roundtable in Montreal, Quebec, on April 25, 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.
- To assess and consider the advice provided by stakeholders to assist CBAC in formulating recommendations to the Government of Canada.

Issues/Topics of Discussion

The roundtable addressed three topics: 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 role. The opinions presenting in this report should not be taken in any way as indicating a consensus among the participants.

Topic 1: Identifying Issues and Guiding Principles

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?

Social and Ethical Issues are Paramount

Participants in all groups stressed the importance of understanding and assessing the social and ethical issues related to biotechnology. The reasons for making social and ethical issues paramount is underscored when the following questions and statements are considered:

- The potential impacts of biotechnology are such that consideration of bioethics must be global.
- What should belong to all of society and therefore should patented?
- A process is needed to determine costs, risks and benefits. How do we deal with uncertainties with respect to the effect of biotechnology which may create new forms of risk? We need to build in safety criteria.
- How do we achieve transparency in the decision-making process?
- What is the risk to environment/society of releases that may affect the gene pool and biodiversity?

While participants had no specific answers to these questions, it was frequently mentioned that informed public debate was required to resolve them. These issues affect everybody, and should not be left to "the experts".

Some of the conditions identified for a constructive public debate on the ethics of biotechnology are as follows:

- Education to inform participants in the discussions
- Formulation of questions that the public and experts can discuss productively
- A clear understanding of what is important to Canadians, for example what are our values for a Canadian approach to health care versus American or European approaches?
- A means to capture the public consensus.
- A way to monitor the evolution of values and of technology.
- Different forms of biotechnology should be discussed separately. The issues and the public concerns with respect to food biotechnology are very different from those associated with medical or industrial applications. Treating these separately will make it easier to have a productive discussion.

Should social and ethical issues be a part of the patenting process?

There were three sets of views on the question as to whether social and ethical issues should be part of the patenting process. Some participants were of the view that as a property statute, the *Patent Act* is not the place to deal with social and ethical issues. A separate regulatory system should be in place. For example, a patent can be obtained for a new pharmaceutical, but it cannot be marketed without regulatory approval.

If a separate regulatory system were to be devised, participants wanted more clarity in the relationship between patenting and the assessment of social and ethical concerns. Some felt that the system should combine flexibility with security so as to respect ethical considerations without slowing down scientific development. The overall benefit to society should be the guiding criteria.

Other participants felt that moral considerations should take precedence over commercial ones in the patenting process. There was once a provision in the *Patent Act* that an illicit invention could not be patented. This kind of clause could be included in the *Patent Act* to deal with moral concerns.

A number of participants felt that it was difficult to discuss patenting issues without a moral and ethical framework. Their reasoning was that once we decide what ends we want to achieve as a society, it would be much easier to determine the appropriate role of patenting. They suggested that CBAC should undertake consultations on social and ethical issues as soon as possible.

The Pace of Change

Participants noted that the pace of change of biotechnology poses a particular challenge. Societal values also change. Whatever decisions are made will need to be reviewed and kept up to date as technology and values change.

Public Confidence

Participants stated that the public is suspicious of industry and lacks confidence in the safety of biotechnology, particularly with respect to food. In this context, industry should err on the side of caution and work to gain consumer confidence. In response to public concerns, industry should set standards that are higher than government standards. In this way, the marketplace could serve as a kind of regulatory mechanism.

On the other hand, the marketplace is also a driver of biotechnology, since biotechnological applications would not be developed if they could not be sold.

Other Issues

Other issues that were raised include:

- The need to conserve biodiversity by ensuring that the original organisms or strains of organisms are not lost due to the introduction of engineered organisms.
- The requirement to maintain confidentiality in research to preserve patent rights slows down the diffusion of knowledge, and thus scientific progress.

- Sources of traditional knowledge should obtain some compensation or royalties when traditional knowledge is used in research leading to a patentable invention.
- The purpose of the judicial system is to interpret the law. Parliament, not the courts, must consider the issues and make the laws.
- Should there be a right to patent higher life forms derived from ecosystems in other countries without the approval of that country?

Canada's patent protection policy will affect:
- The international perception of Canada.
- The investment climate for the biotechnology industry.
- The health of Canada's biotechnology industry.

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

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.

Participants had the following comments on the CBAC principles:

Accountability and autonomy

- Accountability and autonomy should be included in the same principle, so they can be balanced against each other.

Caution

- Participants supported this principle, but felt that it should be described more precisely.
- The principle could be simply stated as "do no harm"

Justice

Participants raised the following questions without resolution:

- Does this principle mean that we can block an invention we do not like? Who decides?
- Are plants or animals considered to be "vulnerable groups"?

Other Principles

The following were proposed as additional principles:

- Do not allow irreversible effects
- As law reflects the culture of each country it ought to be culturally sensitive
- Maintain biodiversity
- Ensure respect for the environment and higher life forms

Applying the Principles

Some of the discussion focused on how the principles should be applied:

- There is a need to be clear on the underlying values on which the principles are based.
- How do we deal with multiple value sets?
- How do we balance the desire to progress with the fear of risk and harm?
- The application of the principles must be sensitive to time, context and culture. The way they are applied will change as society's values evolve.
- The CBAC principles in their current form are good, but they should be applied before and/or after patent process.

Topic 2: What should be patentable?

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 required?

Patenting Plant Materials

Most breakout group participants did not raise objections to patenting plants and their component parts, including proteins, genes and cells. Some participants agreed that the current definition of invention, which sets out some requirements for patentability, was sufficient (i.e. novelty, utility) and correctly interpreted in today's law. For example, for a gene to be patented, it must be isolated, purified, and have a known function. The work and ingenuity required for these steps are, for some participants, sufficient for a gene to justifiably be considered an invention.

Others expressed concern that the interpretation of novelty, utility and non-obviousness criteria for patents over genes was too simple a test to meet, and allowed mere discoveries of genes, as they exist in nature although isolated, to be patented. The mere ability to sequence genes should not enable people to obtain a monopoly through a patent. Something more, for example, modification of the gene, should be required. These participants felt that the current interpretation of the *Patent Act* definition of "invention" creates barriers to research because patented genes would be more costly and difficult to use. Investors are reluctant to fund research using patented genes for reasons of higher cost and less control.

Participants supporting the current definition of invention and interpretation of the criteria for patentability felt that making the criteria more stringent would put Canada at a disadvantage vis-à-vis the rest of the world. Any disadvantage to patenting could generally be offset by the benefit of encouraging research through the information made available by the patent. Agreements for the use of patents can be made between the patent holder and those who want to use the patent for further research to overcome exclusivity imposed by patent.

This discussion led to the observation that public policy needs to take into account the dependence of research on funding from the private sector. Investors require some assurances that they will receive compensation for research and development for their inventions. Public sector funding has been reduced, making it more difficult to undertake research for purely non-commercial ends. Government policy will need to take into account the distinction between research for commercial reasons and research solely for the benefit of humankind without commercial gain.

A concern was expressed if it were possible to grant a patent for a single phenotype of an organism (an organism with particular characteristics) this would effectively give the patent holder a monopoly on the means to create the phenotype through a number of different processes or methods. This would inhibit others from finding other ways to create the same phenotype. This should not be allowed to occur.

On the topic of plant breeder's rights, participants agreed that Canada should amend its laws to conform to the 1991 UPOV. Some suggested that plant breeders' rights are preferred over patenting of plants.

Patenting Human and Animal Material

Participants began the discussion on patenting of human and animal material by exploring whether proteins should be patented. Proteins are chemicals. Some proteins are created by humans (i.e. they do not exist in nature). A patent on a protein does not place any restrictions on the end user or purchaser of these materials. Once the patented protein is purchased, the patent over the protein would not prevent the end user from using the protein as desired. The price imposed by the patent would be included in the cost the protein (as is the case for all patented inventions). In this light, there were no objections raised to patenting proteins with the exception of some participants who were concerned that this might decrease easy and inexpensive access to diagnostic testing.

In the ensuing discussion on patenting genes, the group discussed the difference between discovery and invention in much the same terms as the group dealing with plant materials. The main concern expressed was with regard to the patenting of human genes and cells, which participants suggested should not be allowed because of its effect on the provision of health care. It was suggested that it might be necessary to have mechanisms or regulations outside the *Patent Act* to deal with issues that affect medical treatment.

With regard to animal organs, participants wanted more information on the amount of intervention or modification that would be required for an organ to be patentable. Is a pig's heart modified with anti-bodies patentable? How synthetic does an organ need to be to be considered patentable?

With regard to human organs, it was noted that human organ donation legislation varies by province. Distinctions are made among various types of organs, e.g. skin, hair, as opposed to lungs, kidneys.

It was noted that the real issue might not be patenting *per se* but the regulation of use. There is also a need to distinguish between patenting rights and proprietary rights over a patented object.

The patenting of whole animals gave rise to considerable discussion. Participants expressed particular concern about the following:

- The fundamental problem is that humans are altering forms of life and exerting dominance over animals
- The *Patent Act* does not consider the protection of animal welfare.
- It may not be appropriate to patent life as the act of patenting may devalue life.
- The Act does not consider the issue of sentience (the ability of animals to feel pain).
- To what extent may animals be modified?

Other participants felt that these issues were not insurmountable and that patenting of animals was simply an extension of current practice with respect to the ownership of animals. Animals are already treated as commodities in agriculture (i.e. bought and sold). How would patenting make a difference?

Animal welfare issues can be dealt with within the patenting process. It would be necessary to make the patenting system more responsive to societal views and ensure transparency in the patenting process. One suggested approach was to create a mechanism or process by which to examine patents from a moral perspective, e.g., an ethical examination board. Other participants were concerned that this would become another barrier to obtaining a patent and that it would add time to the already long patenting process.

Some participants felt that the patent system is an inappropriate too with which to deal with animal welfare issues. The purpose of patenting is to create wealth and keep Canada competitive. That objective should remain.

With regard to the patenting of animal varieties, some participants felt that breeders' rights would be preferable to patenting over animals because the latter is likely to be more expensive, possibly placing individual farmers at a disadvantage as compared to large agri-business. Inadequate protection by individuals could result, over time, in the loss of biodiversity.

Further, the question of who owned traditional ecological knowledge needs to be addressed. It was noted that this was being discussed in current trade negotiations.

Patentability of Processes Using Higher Life Forms

The participants chose to separate the question of patenting processes using higher life forms into two major considerations. First, they examined some principles that should guide all patenting of higher life forms. The main considerations are as follows:

- Judgment as to what is or is not of public interest
- Right of inspection of sponsors when public money is involved
- What would be subject to *ordre public* and morality
- Use or patented processes for humanitarian reasons
- Therapies for humans
- Human development
- Human health

In all of these considerations, the balance of benefits and risks of patenting processes using higher life forms needs to be evaluated. Furthermore, the moral issue of the rights of animals will need to be taken into account.

Some participants felt that human therapies should be patentable since they automatically address the common good. Others thought otherwise, stating that the end does not justify the means.

Topic 3: Canada's International Roles and Obligations

The third breakout discussion topic addressed Canada's international obligations and role concerning biotechnological intellectual property and the patenting of higher life forms. The discussion focused on three themes:

1. Is it necessary for Canada to fulfill its current obligations?
2. What actions should Canada consider?
3. What future role should Canada play in developing international agreements?

From the outset, it was recognized that Canada's international obligations would reduce its ability to set its own policy. Indeed, some participants wondered what there was to discuss on this topic, since the international obligations were already decided. Others pointed out that there are some choices that Canada can make, and that in any case, a Canadian position taken on moral grounds should have precedence over international obligations. Still other participants believed that Canada should bring its patent law and patent system in line with that of the US for economic reasons. Moral, social and ethical issues should be addressed in other ways.

A preference emerged for the European model, which seems more similar to Canadian expectations than the US model. It appears that this model, which reflects discussions among a number of countries, was able to identify and meld into its policy nuances that would be sought by Canadians. Among various criteria to be considered was that of not releasing genetically modified animals into the wild, and refraining from engineering changes in animals or human beings.

Regarding the structuring of systems, an independent or parallel body to CIPO would be an interesting approach whereby it would be mandatory to revisit and review decisions periodically. This structure would also have to enable public participation.

The context in which changes should take place should take into account the equitable sharing of benefits derived from biodiversity and the full array of international agreements, not only those pertaining to trade.

Canada's industrial structure, that is small and medium-sized businesses, would allow us to be an important model for countries with a similar industrial structure.

The length of time it takes to get a patent in Canada compared to other jurisdictions was of concern to some participants. This is one area where Canada's performance must be comparable to that of its trading partners. A related issue was the length of time it takes for biotechnological products to get regulatory approval. This time could be shortened considerably if Canada adopted regulatory approval granted by countries with good regulatory processes, e.g., the US or the EU.

One breakout group recommended that Canada look into implementing a patent restoration provision. This would allow patentees who have lost their period of exclusivity for the making, using or selling of their inventions, while meeting or awaiting regulatory approval, to make up for lost time. There seemed to be no reason not to have it.

Two breakout groups noted that they preferred the European Union's approach to experimental use exemption from patent infringement to be more relevant for Canada than the American approach, primarily because it allows more research to take place without fear of patent infringement.

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 or call the CBAC toll-free number at 1-866-748-2222 for additional information or documents related to this or other CBAC projects.