

Final Draft

CANADIAN BIOTECHNOLOGY ADVISORY COMMITTEE
NON-GOVERNMENTAL ORGANIZATION HEARING
on the
Intellectual Property/Patenting of Higher Life Forms Project
Steering Committee

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Rapporteur s Summary

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1. The Non-Governmental Organization Hearing to the Intellectual Property/Patenting of Higher Life Forms Committee (IP/PHL) of the Canadian Biotechnology Advisory Committee (CBAC) brought together representatives from various non-governmental organizations. These non-governmental organizations (NGOs) included groups concerned about the environment; about relations between developed and developing nations; about patient issues; about animal welfare; about consumers concerns; about agricultural communities; about First Nations concerns; and about religious perspectives. While these organizations do not represent the entire breadth of views that exist in the community on the issue of the patenting of higher life forms, this group of organizations represents a cross-section of views that will assist CBAC in formulating its ongoing consultation strategy.
2. As the Co-Chairs of the Hearing made clear, CBAC is interested in examining ways in which to foster biotechnological innovation in a way that is both consistent with Canadian values and contributes to the Canadian economy. IP/PHL is at the beginning of a process of public consultations with the aim of preparing a report on intellectual property and the patenting of higher life forms for the government of Canada. The Hearing was designed to start discussions with various communities across Canada. IP/PHL envisioned that these communities would be further consulted as the consultation process developed.
3. Many of the NGOs present at the Hearing stated that they had not yet had the opportunity of formulating policy on the issue of the patenting of higher life forms. Some organizations had attempted to formulate policy, but had not yet been successful in doing so. Other groups had not yet commenced discussions on this particular issue. All groups welcomed the invitation to present their views to IP/PHL, but many requested the opportunity to present their policies once formulated.
4. Because many NGOs had not developed policies on the broader issue of intellectual property and the patenting of higher life forms, many presented the set of values that motivated them in relation to issues touching on biotechnology. This led necessarily to a general discussion of ethical and social concerns rather than of concrete suggestions in relation to the policies that Canada ought to implement with respect to the patenting of higher life forms.
5. Some organizations, such as the Rural Advancement Foundation International (RAFI), the Canadian Environmental Law Association (CELA), and the Assembly of First Nations (AFN) had, however, developed policies with respect to biotechnology patenting. While the Canadian Council of Churches did not have any formal policy on the issue of patenting higher life forms, several affiliated organizations had studied patent issues. All of these organizations presented their policies at the Hearing.
6. Richard Gold, who was invited to suggest a framework within which ethical and social issues relating to higher life form patenting could be understood, distinguished between two sorts of concerns: those directly related to patenting itself and those for which the patenting process provides a useful opportunity to evaluate commercial and ethical

conduct. The first set of concerns could be further divided into three types: those related to initial research leading to a patentable invention; those related to the patenting of the invention itself; and those relating to commercial development and distribution of the invention.

7. Konrad Sechley, a practising patent agent, explained that the patent system was designed to encourage commercial activity only and was never intended to address other issues. Patents provide an exclusive right to the patent holder in order to encourage individuals to invent and bring their inventions as these are defined by patent law to market. Patent law is, he explained, a very technical area of law in which patent examiners evaluate patent applications to ensure that they disclose a new, nonobvious, and useful invention. By useful, the patent applicant must show that the invention has a specific benefit and is not simply a laboratory curiosity. Provided that higher life forms are considered statutory subject matter and that they are new, non-obvious and useful, they should be patentable in Canada. However, at the present time, a higher life form is not considered statutory subject matter by the Canadian Intellectual Property Office.
8. Both Drs Sechley and Gold questioned whether patent examiners in patent offices had the experience and expertise to make ethical or social judgements with respect to the patenting of higher life forms. Richard Gold suggested that, to the extent that there was a determination that ethical and social concerns ought to be taken into account in the patent process, that this determination be left to an administrative body with expertise in ethics and competition. He further suggested that this body only be involved in an opposition process rather than in the patent application review process.
9. The overall message that the NGOs communicated to IP/PHL was the need to ensure that the values and social concerns that motivate Canadians with respect to biotechnology take priority over commercial concerns. This does not mean, however, that all the NGOs saw any necessary conflict between the concerns of industry and that of Canadians, although some certainly implied that this may be the case. It does mean that, according to most NGOs, IP/PHL ought to identify the values and social concerns at stake before proposing policy on the issue of higher life forms.

GENERAL CONCERNS WITH BIOTECHNOLOGY

10. As stated earlier, many of the concerns that the NGOs raised were of a general nature and related more to biotechnology policy in general than to the patenting of higher life forms in particular. Nevertheless, the NGOs felt that these concerns provide a context within which Canada ought to establish its policy over higher life form patents.
11. Because of the priority that the NGOs attach to the concerns of Canadians over those of industry, several of the NGOs stated that the question of higher life form patents ought to be resolved by Parliament rather than by the courts. These organizations also called for public participation in the legislative process. In this regard, the NGOs viewed IP/PHL's preliminary consultations as a good first step.

12. Two groups, the Sierra Club of Canada (Sierra) and the Canadian Council of Churches (CCC), suggested that these consultations should address a question prior to that of the wisdom of patenting higher life forms. They would have consultations on the issue of whether Canada ought to embrace biotechnology at all.
13. The various NGOs raised a series of concerns relating to biotechnology research, the safety (to humans, to non-human animals, and to the environment) of biotechnology, and to the equitable distribution of the risks and benefits of the products of biotechnology. While some groups were hopeful that biotechnology would eventually result in products that would be beneficial to humans, animals, and the environment, several groups were sceptical that biotechnology would ever result in beneficial technologies. Most NGOs were in agreement that, so far, biotechnology had not resulted in a product that was helpful to the average person. In fact, many of the NGOs present at the Hearing believed that present genetically-modified products were harmful, overall, to health and the environment.
14. Many of the organizations present at the Hearing expressed deep concern over the commodification of life. These organizations believed that awarding patents over life forms would further undermine humanity's respect for the natural world. One participant pointed out, however, that humanity has treated animals, in the agricultural context, as commodities.
15. There was also considerable consensus among the organizations present that the risks and benefits of biotechnology ought to be equitably distributed. The Consumers Association of Canada (CAC) stated, for example, that the risks and benefits of technology ought to accrue to the same people. The AFN, RAFI, and the CCC were concerned that the patent system provides no mechanism by which communities with traditional knowledge would receive a benefit when that knowledge is incorporated into a patented invention. Several organizations stated that, in fact, indigenous peoples have the right to benefit from their own resources and to have their relationship with nature appropriately respected.
16. Several NGOs argued that organized civil society has an important role in acting as honest broker between government, industry, researchers, and the public. NGOs are in a position, for example, to challenge conflicts of interest and distributional inequalities in terms of access and return from biotechnological innovation.
17. A few of the organizations present at the Hearing challenged one of the principal industry arguments made to CBAC in the Presidents/CEO Briefing to IP/PHL held on September 29, 2000. During that Briefing, the industry participants stated that Canada was viewed internationally as being unwelcoming of biotechnology. As a result, investors and head offices were reluctant to invest in Canadian-based research and development. The NGOs argued that Canada has, in fact, a reputation internationally as being one of the strongest supporters of biotechnology and of industry. While it may be true that the international business community does not share this view, the vast majority of developing nations and

communities see Canada as strongly on the side of industry.

ISSUES RELATING TO RESEARCH

18. Apart from the general concerns that the NGOs raised with respect to biotechnology, several organizations discussed both problems and benefits from higher life form patents.
19. Several organizations stated that patents in the biotechnology sector actually discourage innovation and increase the costs of research and development. In their view, patents discourage the sharing of germplasm from developing nations because these nations fear that if they provide this material to industry, industry will patent that germplasm and make it unavailable, in its newest form, to these countries. Even within the developed world, patents may discourage sharing of information among researchers.
20. RAFI argued that patents also discourage innovation by placing roadblocks in front of those conducting research. Researchers may fear that their paths are so blocked by patents that it is not worth conducting research.
21. A couple of presenters believed that patents over higher life forms augment the risk of conflicts of interest due to the increased financial relationship between researchers and industry. While researchers have always had to contend with conflicts arising from competition for acknowledgement and advancement at research organizations, patents have made this situation worse.
22. One presenter, who is a researcher but also has an interest in a biotechnology company, stated that patents encourage research, leading to employment by small companies in Canada. This, and the possibility of financial return from the commercialization of the results of biotechnology research, add to the strength of the Canadian economy.

ISSUES RELATING TO PATENT PROCESS

23. RAFI stated that the patent system is currently overwhelmed by biotechnology-related patent applications and is inefficient at processing these applications. In addition, the costs, in both time and money, of patent litigation has increased dramatically. This makes enforcement of patent rights difficult. As a result, according to RAFI, industry is looking at alternatives to patents in order to protect their inventions. One of these alternatives is the use of contractual provisions limiting the use that individuals may make of technology coupled with increased monitoring of the use of that technology. A second alternative is the development of technological solutions to the use of technology. This includes the so-called "Terminator" technology that renders seeds from genetically-modified plants infertile should a farmer replant the seeds. These alternatives permit industry to set the boundaries on the use that individuals in society may make of their technologies without having to engage in the patent system.

24. The CCC pointed out that the costs of patent litigation has a second negative effect: the inability of traditional communities and developing countries to challenge patents. The CCC pointed to the patent that had been granted over the neem tree. While this patent had been successfully challenged in an opposition proceeding on the basis that the neem tree had traditionally been used in the manner similar to that described in the patent, it had cost millions of dollars and many years to attain this result. This high cost of challenging patents makes it difficult for communities to protect their traditional knowledge.

ISSUES RELATED TO COMMERCIALIZATION

25. There was general concern by those organizations present at the Hearing that the products of biotechnological research be accessible to all and that the benefits of the research be shared with those from whom biological material was taken. Specifically, the NGOs stated that medications produced by biotechnology ought to be available at a reasonable cost, that no one ought to be denied access to the use of the products of biotechnology, and that the financial rewards of biotechnological innovation ought to be shared with those who participated in the research by donating samples.
26. The Canadian Federation of Agriculture suggested that, should Canada permit the patenting of plants, that Canada enact a farmers' privilege exception that would permit farmers to re-use the seeds of plants they have grown. This exception has been incorporated into European rules on biotechnology patenting.

RECOMMENDATIONS

27. Several of the presenters at the Hearing recommended ways to address the ethical and social issues involved with higher life form patenting. These recommendations involved the establishment of independent bodies to oversee parts of the research or commercialization process, changes to patent law, and mechanisms to ensure the fair distribution of the proceeds of biotechnological innovation.
28. One presenter suggested that Canada establish an ombudsperson. This person would handle complaints by communities that feel that their traditional knowledge or biological material has been taken without their consent or without appropriate return to those communities. Another suggestion was that Canada establish an independent oversight committee to review the conduct of biotechnology research and outcomes.
29. RAFI suggested that Canada re-introduce compulsory licensing into patent law. RAFI argued that industry ought to be content with a guaranteed return from the investment. There was no need, according to RAFI, for industry to be able to control access to such important technology.
30. The AFN suggested that Canada establish a trust into which a determined royalty be paid for those using Canada's biological resources. This fund would be used to compensate

First Nations for the use of the biological resources to which they are entitled.

31. Those organizations that were most sceptical about the benefits of biotechnology suggested that there be a moratorium on patenting life forms until we have developed mechanisms to ensure not only that biotechnology is safe but that the benefits of biotechnology are equitably shared.

CONCLUSION

32. The NGO Hearing brought together a representative group of non-governmental organizations concerned about biotechnology. Many organizations have not yet developed policies with respect to the patenting of life forms. Nevertheless, they welcomed the opportunity to present their concerns. They requested, however, that IP/PHL provide them with further opportunities to present their views once they have developed these policies.
33. The NGOs expressed three general types of concern regarding the patenting of higher life forms. First, they argued for policies that would ensure that both the risks and benefits (including financial rewards) of biotechnology be equitably shared among the world's communities. Second, they stated that these technologies ought to be broadly accessible. Third, they said that oversight of biotechnological research and the distribution of the products of that research was needed.