Institute On Governance | Institut sur la gouvernance

Of Mice and Men: Regulating and Using Patents

First Forum Session of the Biotechnology and Governance Program

SUMMARY OF THE DELIBERATIONS

January 2003

The following is a summary of the deliberations that took place during the first of four forum sessions held on governance and biotechnology, on December 12, 2002. The deliberations involved some 50 participants, including senior managers from 12 different federal government departments, as well as representatives from the Ontario government, media, academe, industry and civil society.

The summary is organized in two parts. The first section outlines the scope and purpose of the Forum events, and provides an overview of this particular event, as well as a summary of the outcomes. The second section outlines points raised during panel and plenary discussions of the first Forum event, according to general theme. Annex A summarizes the small table discussions. A list of participants and of sponsors is found in Annexes B and C, respectively.

It should be noted that the discussions operated under a modified version of the Chatham House rule. They are as follows:

- Direct attributions of quotes to specific participants shall not be made without explicit consent.
- Acknowledgement that information was received at a Forum event, however, is allowed. (This second clause allows for written summaries of the event - without attribution - to be produced and circulated to interested parties.)

Scope and Purpose of the Forum Event

"Of Mice and Men: Regulating and Using Patents" marked the first of four evening roundtables (to be run over a period of 10 months, ending in the fall of 2003) that will engage participants around governance issues posed by biotechnology. Designed to benefit senior decision-makers, this series seeks to draw participants from both inside and outside government, and to elicit candid discussion of these complex issues. The general thread joining these events is the following question: *Assuming that biotechnology is "transformative" in its impact on society, governments and industry – what are the governance implications that need to be considered?*

The main purpose of the Forum sessions is to bring participants to a higher appreciation of the complex public policy issues associated with biotechnology, and to make them more aware of the diversity of views from both inside and outside the federal government with respect to these issues. The Forum events, in turn, are part of the Institute's Biotechnology and Governance Program. The objectives of the Biotechnology and Governance Program are as follows:

1) Educate and raise awareness of current policy issues: Promote a wider awareness and shared understanding of some of the big biotech-related policy issues that are currently on society's 'radar screen'.
2) Explore governance implications: In light of the issues raised by biotechnology and the principles of good governance, to consider how existing processes, structures, conventions, or modes of decision-making and consultation may need to be adapted.
3) Anticipate: Look ahead. Examine how this technology may evolve over the longer term, and what may be done to derive the greatest net benefit for society as the technology develops.[1]

This particular event, entitled "Of Mice and Men: Regulating and Using Patents," considered the strategic issues confronting public policy makers with respect to Canada's patents regime. More specifically, the event addressed the challenge associated with the regulation and use of biotechnology patents in contexts as diverse as research and innovation, health care, agricultural markets, environmental trends, economic prosperity, public acceptability and ethics. In light of the breadth of these complex topics, the Institute invited Richard Gold (BCE Chair in E-Governance, McGill University), Arnold Naimark (Chair to the Canadian Biotechnology Advisory Committee), Barbara Slater (Manager, Health Sciences Policy Unit, Province of Ontario), and Andrei Sulzenko (Senior Assistant Deputy Minister, Industry Canada) to speak to these issues.[2] In general terms, the speakers were asked to address issues such as the structure of Canada's patents regime and, within this context, Canada's international obligations, the implications of the Supreme Court decision on the Harvard Onco-mouse, and the notion of establishing a regime that will strike a balance between the public good and the promotion of innovation.

Among the outcomes of this first session, notable was the broad agreement on the need for empirical evidence outlining the impact of various patents regimes on innovation, as well as the need for in-depth analysis on the implications that such regimes hold for the public good. Further, in light of the changes associated with biotechnology, the principles supporting our present patents

[1] Please refer to the Institute's website at www.iog.ca for further information on the Biotechnology and Governance Program.
[2] Please refer to Annex B for the full list of participants.

regime need to be reconsidered. These principles, in turn, need to reflect our societal values; therefore, there needs to be a considerable debate within Canada on the kind of society Canadians want.

What follows in the next section is a summary of the comments made during the evening's discussions, according to theme areas. All of the statements presented below reflect the views and opinions of individuals who participated in the discussions, and in no way represent the views of the Institute.

Plenary – Key Points

Patents Regimes, the Canadian Context, and the Patenting of Higher Life Forms

- It is generally agreed that the primary function of a patents regime is the promotion of the public good. A patents regime does so by providing an incentive to disclose advances of knowledge which will be beneficial to society. In exchange for the disclosure, a limited monopoly for a limited period is granted to the inventor.

- The public good is sought by balancing a) the innovation (R&D), b) the consumer and c) the product/service markets. Tensions arise because the consumer market wants access to affordable goods and services, and the innovation market wants affordable access to knowledge, while the product/service market wants to reap the financial rewards of its inventions. While the first two markets prefer a regime of low patent rights, the latter favours a regime that strongly supports patent rights. The difficulty lies in crafting a patents regime that tries to balance these competing interests.

- The granting of patents falls solely within the jurisdiction of domestic regimes, although some international obligations (i.e., minimum standards) do exist. However, all regimes do recognize the difference between an *invention* and a *discovery* when issuing patents: inventions require human intervention; discoveries do not and, therefore, are not patentable. Further, all inventions must meet the 1) novelty, 2) non-obviousness, and 3) utility criteria in order to be patentable.

- In Canada, a patent gives its holder the right to exclude all others from making, constructing, and using the invention. The patent also effectively provides its holder with the right to exclude others from importing the invention into Canada. In accordance with international agreements, a Canadian patent has a term of 20 years. Following the general trend (but in contrast to the United States), Canada has adopted the "first to file" system under which the first person to deposit a patent application in respect of an invention will be awarded the patent even if someone else invented the invention first.

- The patents regime is crucial to ensuring that Canada is among the world's leaders in innovation. According to innovators, the present regime is causing Canada to lag behind its main competitors. However, there are other avenues, outside of the *Patent Act*, to remedy this

competitiveness issue. Canada's patent regime provides a good balance between the consumer market (seeking price controls) and the product market (seeking rewards for their inventions).

- It is difficult to predict the future importance of biotechnology. The suspicion is that biotechnology will be more significant than the Information Revolution. That is why it is very important that Canada remain a world leader in this technology (presently, Canada ranks second in size and scope of its biotechnology sector).

- In its recent study on biotechnological Intellectual Property entitled *Patenting of Higher Life Forms and Related Issues*, CBAC sought to review Canada's patent regime by analyzing the extent to which social and ethical considerations should enter into the patent granting process. The findings suggest the *Patent Act* is an inappropriate instrument for resolving many of the questions related to the protection of biotechnological Intellectual Property.

- Conclusions of the study include the need to make the *Patent Act* more effective in achieving its aims with respect to biotechnological Intellectual Property by removing inherent ambiguities, clarifying assessment criteria, and explicitly resolving the issue of patentability of higher life forms. Moreover, the study stresses the opinion that patenting policy is a matter for Parliament, not the courts.

- Recommendations of the study include the need to recognize inventions of non-human higher life forms (e.g., plants, seeds and animals) as patentable, so long as provisions are made for Farmers' Privilege, innocent bystanders protection, and a research and experimental use exception. Further, the Act needs to address issues of liability and compensation for adventitious propagation of patented seeds or animals, encourage benefit sharing, support efforts to treat traditional knowledge as a form of intellectual property. Last, the Canadian Intellectual Property Office needs to develop and publish interpretive guidelines for biological inventions, and regularly update and report on performance, while Canada needs to ratify the *Patent Law Treaty* (in accordance with the aim of international harmonization of policies and procedures).

- Patents on genes differ from other patents because: The human gene is more than simply a chemical compound; it is also encoded information. The patent holder can prevent anyone from looking at the patented gene sequence, thus controlling potential tests, treatments, and drugs that involve that gene. A patent on a biological pathway (i.e., genes/proteins through which a drug reaches its target) could limit drugs from reaching the market.

- The following considerations will help address the complex nature of the challenge facing public policy-makers: What constitutes a biotechnological invention? What instruments, outside of the *Patent Act*, need to be developed to deal with the arising social and ethical issues? What new structures or capacities are required to deal with the accelerating pace of innovation? How should government get the advice it needs, and how can citizen engagement be fostered?

The Implications of the Supreme Court Decision on the Patentability of the Harvard Onco-mouse, and the Impact of the Canadian Gene Patent Regime on Innovation

- At present, there is no formal federal government position on the patentability of higher life forms. The Supreme Court decision should be viewed in a narrow sense: Does the *Patent Act* apply to the Onco-mouse? The decision that it does not, should not be applied to a broader question.

- The Supreme Court decision has drawn a distinction between gene patents and the patenting of higher life forms. The decision implies that the Court is content with this distinction.

- The Supreme Court decision on the patentability of the Harvard Onco-mouse is consistent with many of the recommendations made by the Canadian Biotechnology Advisory Committee (for instance, Parliament and not the courts should determine whether and to what degree patent rights ought to extend to plants and animals, and the notion that the *Patent Act* is not well suited, in its current form, to address the unique characteristics possessed by higher life forms).

- The Supreme Court decision suggests that the issue of patenting higher life forms is intertwined with the patenting of other biotechnological aspects, and that the relationship between them demands a legislative approach rather than a judicial one. Further, the decision provides the federal government the opportunity to fully examine the *Patent Act* to ensure that it is adequately performing its intended objectives.

- Patents are very important to the biotechnology industry. They are the life-blood of the industry – critical for securing financing for product development. The recent collapse in the equities market has exacerbated this reality. This sector of the economy is very different from the rest; it is dependent largely on the patents regime.

- Gene patents pose barriers to innovation because: They may lead to patent gridlock (i.e., developing a product that involves accessing many patent holders is a definite barrier) making the development of such product financially impractical. A patent holder may assert claim on subsequent innovations made by others utilizing existing patented material. In the absence of appropriate protection for clinical researchers, increasingly Canadian geneticists are ceasing to disclose new information; over time non-disclosure leads to less data to work with.

- The exorbitant costs associated with patented gene testing in some cases has led to drastic declines in both lab testing and plans to perform such tests. With fewer labs doing a particular test, quality control becomes difficult, thus reducing the opportunity to improve tests. Also, exclusive testing centres become the predominant repositories of information pertaining to the genetic condition in question, thereby becoming dominantly positioned as centres of new research.

Gene Patenting: Striking a Balance between Economic, Health and Environmental, Ethical and Social Considerations

- The fundamental challenge to Canadian public policy-makers is the need to craft policy that enables Canadians to extract significant economic and social benefits from biotechnology, while being mindful of the profound social and ethical concerns that such technology can give rise to. This challenge is intensified by the rapid pace of technological innovation (issues of adaptability of regulatory systems, and the uncertainty surrounding risks and benefits), the lag between the discovery and diffusion of technology and policy formulation, and the tensions that arise between international obligations and domestic interests.

- All healthcare jurisdictions are presently facing the complex and rapidly moving challenges of effectively incorporating genetic medicine into our healthcare system. The rate of growth and costs implications associated with genetic medicine are significant. A range of issues has arisen in light of this new reality. These include: health human resources, health technology assessment, privacy and confidentiality, patenting.

- Since 1993, when the number of genetic tests available in Canada roughly equaled the number of laboratories providing one or more of these tests, the number of tests have increased eight-fold, while the number of laboratories have only increased by four times. Likewise, between the years 1991-95 to the years 1996-2001, the United States witnessed a staggering increase in the number of gene patents issued from just under 5,000 to almost 25,000.

- The Premiers' Report, *Genes, Testing and Gene Patenting*, while supportive of the need to protect intellectual property, recognizes the need to place safeguards for research and public healthcare. Striking a balance between the public good and innovation is an issue of particular relevance to all countries that have a publicly funded healthcare system.

- In Canada, the issue of the impact of gene patents on the healthcare system has been visited by: the Standing Committee on Health on Bill C-56 (calling for a ban on the patenting of human genes, DNA sequences and cell lines); by the Premiers' Report (calling for the examination of the *Patent Act*, as well as other avenues, to deal with the impact of the patenting of genes on healthcare); CBAC Report (calling for some amendments to the *Patent Act*, as well as the need for federal/provincial cooperation in seeking answers to the negative effects of patenting on the healthcare system); the Romanow Commission (calling for the federal government to review the *Patent Act* in relation to the issue of patenting of genes and DNA); the Supreme Court (with its December ruling on the patentability of the Harvard Onco-mouse).

- Globally, the issue of the impact of gene patents on healthcare systems has been visited by: the Australian Law Reform Commission (asked to consider whether changes to their patenting laws in the area of genes and human health were required); the European Commission (calling for a review of the scope of patents relating to gene sequences); the Royal Society - U.K. (investigated whether the use of patent law is helping or hindering progress in the field of genetics); the Nuffield Report - "The Ethics of Patenting DNA" (suggesting that the granting of patents that assert rights over DNA sequences should be the exception, rather than the norm);

the World Health Organization - “Genomics and World Health” (suggesting that the present position on DNA patenting is retarding, rather than stimulating, scientific and economic progress).

- Although possibilities seem to exist within the existing provisions of the *Patent Act* to both limit the costs to the Canadian healthcare system associated with gene patenting, and to promote innovation, the likelihood of implementation of such measures is very unlikely. Policy options thus include the provision of an *ordre public* or morality clause in the Act; an extension of methods of medical treatment exclusion; the introduction of an opposition period; establishing that DNA sequences are ‘scientific principles’ and, as such, are not patentable.

Annex A: Summary of the Small Table Discussions

Tables 1a & 1b: What are the implications of the Supreme Court decision (Harvard mouse) and, in this context, are there elements in the existing *Patent Act* that need to be revised?

- On the whole, the implications of the Supreme Court decision were judged to have been positive. In particular, the decision forces discussions regarding Canada's patent regime (with relation to gene patenting) to take place in the public arena. This, in turn, would force the government to consider the public's attitudes and values regarding this subject. The decision also would force government to rethink the patent principles and to review mechanisms that will foster and facilitate public debate.

- The Act needs to be revised. The revisions should incorporate a preamble reflecting societal values and attitudes regarding the patent regime, some kind of exemption for research (in order to spur innovation), and the Act should try to strike a balance between the promotion of innovation and the public good. The Act also ought to reflect the concern over the patentability of information (the patentability of a process or product is fine; however, concerns are raised when it comes to the patentability of information).

- Other Acts need to be evaluated, in order to make the patents regime more responsive to the promotion of innovation and the public interest.

Tables 2a & 2b: How do we combine patents and pre- or post-patent vehicles in such a way as to protect the broad public interest and strike a balance between economic, health and environmental, ethical and social considerations?

- Little seems to be known about how much patents stimulate research and innovation. We therefore need to consider what tools are available to stimulate research and innovation, outside of the patent regime.

- There needs to be some form of pre-patent issuance 'opposition procedure' or mechanism in place. There also needs to be some consideration given to the idea of holding particular patents within the public domain, with the possibility of universities acting as repositories of such information.

- There needs to be a broad-based societal discourse on where we would like to see Canada fifty years from now, complemented by a dialogue on how best to achieve those goals. The *Patent Act* ought to be only one element of this discourse; there needs to be consideration for other vehicles that may help structure the desired regime.

Tables 3a & 3b: How important are international perspectives in the formulation of domestic policies on issues such as patenting, and what are Canada's responsibilities in the international arena when it comes to patents and related issues?

- Attempts to harmonize domestic regimes ultimately lead to tensions between diverse cultures and their particular values (specifically with regard to issues of privacy, security and human rights) and the desire of the international business community to facilitate the interaction among its membership (this would result in a decrease in the costs of doing business).

- Concerns were raised over the restrictive role that patents have played, and will continue to play in developing countries, particularly with regard to social policies. A related concern is the need to scrutinize the values of many patent holding companies whose net worth, in many instances, exceeds the GDP of developing countries.

- The Supreme Court decision on the Harvard Onco-mouse may send the message to international investors that Canada is not open to innovation, or not willing to recognize/protect innovations made elsewhere. In reality, however, the decision may actually help promote research in Canada, given the fact that possible research would not be inhibited by fees associated with a possible patent.

Annex B: List of Participants

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Annex C: List of Sponsors

The Biotechnology and Governance Program
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Environment Canada / Environnement Canada

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