

**CANADIAN VIEWS ON PATENTING
BIOTECHNOLOGY**

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Executive Summary

The protection of property is one of the principles of liberal democracy. A subsidiary principle of property rights and its protection is the right to develop and profit from one's ideas and, in this vein, a great deal of effort on the part of legislatures and court systems has focused on the need to protect the intellectual property rights of inventors. Additionally, since its inception in the 19th century, the idea of patenting has been viewed as an important mechanism to spur innovation.

With the rapid pace of discoveries in the life sciences and the expansion of biotechnology as a commercial venture, there is increasing interest in and competition to patent inventions that include human and non-human genetic sequences, genes, and even entire plants and animals. These developments have made the issue of patents the subject of much commentary and policy attention. There is corollary recognition that publics have great interest in the products of invention and innovation in biotechnology but also express concerns, reservations, anxieties, and sometimes outright disapproval, not just of the products themselves but their surrounding contexts – who makes them, how they are made, for what purpose and for whose benefit. This review of publics and their views summarizes results from a variety of research reports, most of which have been carried out by commercial research firms for policy bodies.

In general, most Canadians have limited awareness of the specifics of patenting. However, they are generally supportive of the principle of granting inventors legal protection to allow them to profit from the development of their ideas and to spur further innovation. At the same time, this general view is tempered by a case-by-case assessment.

When judging the acceptability of patenting biotechnology applications, it is clear from the various studies that a hierarchy of acceptability is at play that follows the general pattern of an approval continuum for the applications themselves. The patenting of applications that have medical, followed by environmental, benefits is acceptable to a majority. Lower levels of acceptance for agricultural and industrial applications follow the trend in public views for ascribing fewer benefits in these areas.

Acceptability of patenting is also dependent on the object of the patent, with acceptability declining as the object involves increasingly higher orders of life. In addition, there is clear discomfort when the object results from crossing species boundaries (mixing genes between two different species or plant and animal genes), and especially when human genes are involved.

Publics further make distinctions between the patenting of process versus the product. In discussions of the Harvard Oncomouse™, there appeared to be greater comfort with patenting the process that developed the cancer-susceptible mouse than patenting the mouse itself, primarily because of resistance to the idea of patenting living organisms (and especially higher life forms). The same trend is evident as publics support the

patenting of the process by which genetic tests are developed but are resistant to the idea of patenting genetic material.

Public concerns and reservations fall in several areas. First is the idea of what is considered “natural”. The process by which novel organisms are created, involving exchange of genetic material between unrelated species, and the subsequent creation of a new organism, fall in this category of the violation of nature. The provision of patent protection for these organisms is simply an extension of this problematic violation.

Another area of concern is the commodification of life. Patenting of living organisms and their parts makes life a material commodity, a source of discomfort to many Canadians.

Concerns about equity are also relevant for Canadian publics. Most Canadians associate genomic research with development of medical products, and for many, equality of access is viewed as an important consideration, with concerns arising from whether this principle of equitable access will be maintained when products and services are patented.

A range of social concerns has also been identified. While publics are supportive of the inventor’s right to reap rewards from the invention, there is recognition that this right may sometimes conflict with a greater societal good or public interest. For example, some worry that patent interests promoted by corporate interests may sideline other important research, encouraging only those activities that are commercially profitable. There is further concern that medical products and services may be available to only a few if their costs increase (a development associated in the public mind with patenting).

Questions around who has legitimate claims to benefits also trouble some publics. How to protect interests of indigenous people and groups from developing countries whose traditional knowledge might be exploited but whose access to expertise and resources to protect their interests are limited are also of some public concern. The question of fair distribution of benefits, restricted access to inventions, the balancing of societal versus individual inventors’ or commercial groups’ interests remain lingering questions of public interest.

While public opinion is not the determining factor on issues relating to patenting, public views can hardly be ignored if trust in the patent system is to be maintained. While the patent system is clearly designed as an economic incentive, these findings suggest that Canadians judge patents within a broader framework of social and ethical considerations.

Introduction

The protection of property is one of the principles of liberal democracy. With a subsidiary principle being the right to develop and profit from one's ideas, a great deal of effort on the parts of the legislature and courts has focused on the need to protect the intellectual property rights of inventors. Since its inception in the 19th century, the idea of patenting has been viewed as an important mechanism to spur innovation. In essence, patents ensure that inventors are rewarded by making sure their inventions cannot be copied for a period of time and allowing them temporary control over the availability and price of the invention, in exchange for revealing the knowledge embodied in the invention.

With the rapid pace of discoveries in the life sciences and the expansion of biotechnology as a commercial venture, there is increasing interest in, and competition to, patent inventions that include human and non-human genetic sequences, genes, and even entire micro-organisms, plants and animals. The move from patenting non-living inventions to seeking to control innovations involving organisms or their parts, elicits strong responses from the public, prompting some to raise questions about the ethics of patenting and the implications for equity and the social good.

In this report, we examine public perceptions of patenting biotechnology and discuss the implications of research findings for public policy. This report was based on a variety of research reports of public opinion surveys and focus groups carried out among Canadian publics, primarily by commercial research firms.

Public Awareness about Patent Protection

In general, Canadians possess a general knowledge of human genomics research, usually expressed in terms of specific applications they have heard or read about (Earncliffe Report, 2005). Particularly among *involved Canadians*¹, higher levels of awareness of genomics and genetic research and sophistication on issues that surround these topics have been evident (Earncliffe Report, 2005). Canadians associate human genomic discoveries with substantial benefits, and majorities expect these benefits to result in better health treatment and health care in Canada. However, concerns have also been expressed and these have typically clustered around issues of risk, regulation, and ethics (Earncliffe Report, 2005).

When the specific topic of patenting is broached, awareness levels tend to be low about the purpose of patenting and some of its most fundamental elements (Earncliffe, 2002). From a national survey in 2002, Canadians were described as being "ill informed about the purpose of patenting" (Earncliffe, 2002). Focus groups reveal that "most have a notional sense that patenting provides some form of rights but their understanding of the purpose and substantive policy behind patenting is extremely limited" (Earncliffe,

¹ Involved Canadians have typically been identified as the more politically active in terms of media exposure and contact (e.g., letter to editor or call to broadcast outlet) and civic engagement.

2003). While participants in focus groups have some awareness that applications of genetic technologies such as diagnostic tests and gene therapies could be patented, most were unaware that genes or gene sequences could also be patented (Earncliffe, 2005). On other dimensions of patenting, reports carried out on publics suggest that publics have little understanding that:

- Patents are only allowable for inventions, not discoveries or ideas (Earncliffe and Pollara, 2002; Earncliffe, 2003). New organisms must be sufficiently different from known species and its creation must have involved an element of inventing ingenuity (Kevles, 2002).
- There are time limits on patents (Earncliffe and Pollara, 2002; Earncliffe, 2003).
- Patenting makes the invention public and therefore could also promote more research using that public information. Many instinctively believe that patenting inhibits research because a monopoly is created and the patent holders could withhold all information and refuse to proceed with the invention (Earncliffe and Pollara, 2002; Earncliffe, 2003).
- Fewer products and treatments would likely be invented without a patent system (Earncliffe and Pollara, 2002).
- Patents may provide quicker access to health and medical products than without (Earncliffe, 2003).
- A potential alternative to patenting could be a system of trade secrets, where information about inventions is not made public (Earncliffe and Pollara, 2002; Earncliffe, 2003).
- Without patents, companies may move to countries that provide a means of recovering their high investments (Earncliffe, 2003).

In general, reports on public views have tended to describe these discussion outcomes as being “narrow in scope and the gaps in knowledge seemed to form a substantial obstacle to informed discussion” (Earncliffe, 2003). As many had not really thought through the issues and implications of patenting, not surprisingly, it was not easy to sort through the problematic issue of “owning” or “inventing” living things, or parts of living things, and the generally endorsed principle that inventors should derive benefits from their inventions (Earncliffe and Pollara, 2000a). As one report put it, “It took quite a bit of discussion and education for people to begin to take more thoughtful positions on patenting” (Earncliffe and Pollara, 2000a).

In general, there was about a 65-35 split between support and opposition after being informed about patenting issues and processes (Earncliffe and Pollara, 2002). Interestingly, in focus groups, once people were informed about what patenting is and the advantages and disadvantages of such a system, the arguments against patenting higher life forms in particular became stronger than those in favour. Public opinion research on biotechnology has shown that higher levels of knowledge do not always translate directly into higher levels of support (Gaskell et al., 2001). Support or concern about applications has generally been found as occurring on a case-by-case basis and this finding on gene patents likely reflects this overall trend. Thus, even with provision of detailed information and education, the prevailing view regarding patenting, particularly of higher life forms,

has been found to be more negative due to the basic moral resistance people have to the idea of commodifying living beings (Earnscliffe, 2003).

Patenting and Public Opinion: General Acceptance

Since most Canadians are unaware of the gaps in their knowledge, people tend to have formed relatively strong, yet diverse opinions on patenting in the field of biotechnology (Earnscliffe, 2003).

In general, Canadian consumers have expressed support for the principle of patenting (Earnscliffe and Pollara, 2000). Many feel that the idea of patent protection is necessary in the field of biotechnology to encourage inventions for all the benefits they can bring (42% and 47% in Canada and the U.S. respectively). However, a similar or greater proportion in both countries say that they are uncomfortable with the idea of providing patent protection because there is something wrong with the idea of patenting parts of a life form such as an animal or plant (50 % Canada, 45 % U.S.) or because the benefits of new inventions might only be available to those who can afford to pay more (44 % Canada, 38% U.S.) (Earnscliffe, 2003).

A survey of Ontarians on patents in connection with genetic tests showed the majority expressing favourable attitudes toward allowing companies to patent these tests -- over six in ten indicated they had a favourable attitude (Ipsos Reid, 2001). However, when asked whether such patent rights should be extended to “genes or genetic material (companies) identify that are used to develop the tests”, the numbers who express favourable attitudes drops to about half (Ipsos Reid, 2001).

In general, Canadian publics are supportive of the idea of providing incentives for innovation, viewing this as a worthy rationale for patenting. However, as these findings indicate, other imperatives come into play in overall judgments.

Hierarchies of Acceptance

When judging the acceptability of patenting biotechnology applications, it is clear from various studies that publics perceive a hierarchy of acceptability that follows the same general pattern as approval for the use of the applications themselves (Earnscliffe and Pollara, 2000a).

First is the hierarchy of purpose. The intended uses for which the patent is granted play a significant factor in determining acceptability. Canadians are usually more accepting of granting patents for applications that solve medical, environmental and crop challenges (Earnscliffe and Pollara, 2000a), and the least accepting of those for industrial or esthetic purposes (Einsiedel and Sheremeta, 2005). For example, respondents in a 2000 survey indicated that patenting is more acceptable in the context of human health and environmental applications, with two-thirds supporting the patenting of ‘altered bacteria

that clean up toxics,’ and 6 in 10 supporting the patenting of disease resistant rodents bred to find cures for humans (Earnscliffe and Pollara, 2000a). Agricultural and commercial applications were met with less enthusiasm with 55 percent supporting ‘altered trees that grow to maturity quicker’, and 38 percent agreeing with patenting ‘altered cows that produce more milk’ (Earnscliffe and Pollara, 2000a).

Views are also modulated by the perception of the patent contributing to or detracting from societal or public interest. When the purpose achieves broader societal benefits (e.g., encouraging research for a more competitive agricultural sector), greater support for the application is elicited, in contrast to cases where the benefits are restricted to a few (Environics, 1998).

The second observable hierarchy concerns the object of the patent. Acceptability declines as the object of the patent involves increasingly higher orders of life, when it crosses species boundaries (e.g., mixing plant and animal genes), or alters the organism itself (Earnscliffe and Pollara, 2000a). This public sensitivity to the patenting of higher life forms and specifically, the patenting of human genetic material is reflected in some expert communities such as the Nuffield Bioethics Council’s position that patents asserting rights over human DNA sequences should not be allowed on the basis of the special status of human DNA material (Nuffield Council, 2002).

In general, it is more acceptable to Canadian publics to patent the process or technology that creates a novel organism or genetic sequence rather than the novel creation itself. In discussions about the Harvard Oncomouse, people were much more comfortable with the idea of patenting the process that developed the Oncomouse than patenting the mouse itself. Participants expressed that there was a fundamental difference between the two due to their resistance to patenting living beings (Earnscliffe, 2003).

On the topic of patenting genetic tests and the genetic material used to develop such tests, a survey of Ontarians showed that close to two-thirds (64%) supported the patenting of the tests while only half (51%) had a favorable opinion of patenting the genetic material itself (Ipsos-Reid, 2001). Interest in this province in the provision of genetic tests to the public and in accessing such tests are high, with seven in ten Ontarians agreeing that genetic testing should be available to the public (Hay Health Care Consulting Group, 2002). This interest springs from the perception of direct health benefits that can be derived from genetic testing. At the same time, concerns about delivery of these services revolve around issues of privacy, ethics, and lack of control over who is using what test. Questions about gene patents are directly related in the public mind to these areas of concern (Ipsos-Reid, 2001; Hay Health Care Consulting Group, 2002).

Distinctions are also made between the patenting of ‘novel’ and existing genetic material. A survey conducted in Japan asked the public and scientists whether people should be able to obtain patents with regard to new and existing varieties of plants and animals, as well as existing human genes. Support fell in both groups as the focus moved from new varieties to patenting existing plant, animal and human genes. This selective attitude

towards patenting existing genetic material was also evident among members of the New Zealand public (Einsiedel and Sheremeta, 2005).

Human Genes and Higher Life Forms

Human Genes

The success of the mapping of the human genome has led a number of organizations to apply for patents on genes with particular traits within the newly discovered human DNA (Earncliffe and Pollara, 2002). The public has strongly supported the mapping of the human genome, and with the success of this project, has shown increased support for the idea of patenting genes for the purposes of developing genetic therapies or drugs (Einsiedel and Sheremeta, 2005). However relative to DNA mapping, patenting human genes with particular traits was met with resistance, with roughly half of the sample expressing discomfort (in a forced choice on comfort or discomfort about patenting genes). Affordability concerns took precedence over ethical concerns, and overall, Canadians expressed more discomfort than Americans (Earncliffe and Pollara, 2003).

Genes, as the raw material in our bodies, are not patentable. Only when human genes or sequences have been described, isolated, and purified can they be patentable, provided that they meet the criteria of being new, non-obvious and useful (Gold, 2000). It is acknowledged in most jurisdictions that human (and non-human) genes and genetic sequences are acceptable objects of patents. However, debate continues, especially among publics, about the ethical appropriateness of patentability. Specific concerns fall in these areas:

- Whether a gene or gene sequence is truly an “invention”. Some members of the public have expressed skepticism about the patentability of genes which are considered an element of nature or the body (Earncliffe, 2005);
- Allowing patents over human genetic material will create a demand for such biological materials and will increase the likelihood that individuals will be exploited (Einsiedel and Sheremeta, 2005).
- Allowing patents of genes or sequences could actually inhibit research. In group discussions, doubts have been expressed about the rationale for patent protection as a means of furthering research and innovation, with some suggesting that because the patent holder has the right to control access to the patented material, this could mean that other researchers might be unable to carry out research to develop new products. (Earncliffe, 2005).

Higher Life Forms and Their Parts

While patenting is not a new concept, its use to claim ownership over higher life forms (and their parts) raises new public concerns over the commodification of life and the ethics of patenting.

The discomfort associated with the view that there is “something wrong with the idea of patenting parts of a life form,” weighs in the minds of Canadians: a greater proportion of Canadians (50%) are uncomfortable with patenting on this basis, compared with those who say the idea of patent protection is necessary to encourage biotechnology inventions for the benefits they can bring (42%). Similar conclusions are reached in considering entire organisms rather than parts thereof (Earncliffe and Pollara, 2000a). A more even split is observed among Americans, with views of 45% and 47% respectively (Earncliffe and Pollara, 2003).

Plant Patenting

The patenting of entire plants and their parts is acceptable in the minds of the Canadian public. Three quarters (74%) agree that granting patents on new plants is necessary to encourage globally competitive agricultural research, and two-thirds (67%) say “it is okay for someone to have a patent on a new plant modified through the use of biotechnology.” However, this support is tentative and conditional in nature (Environics, 1998).

Specific concerns are raised in the context of agricultural practices. Some fear that patents will provide an incentive for the creation of monocrops to maximize profits (CBAC, 2001) and that granting patents on products of biotechnology would send a signal to the public that the product is socially acceptable. Others opposed patenting on grounds of the unknown risks involved in biotechnology, or the potential abuses of power that may result (CBAC, 2001).

Animal Patenting

Assessments of public views on genetic modification of organisms have demonstrated hierarchies of preferences. This is particularly evident in judgments about plants versus animals, “lower” life forms such as microorganisms versus other non-human animal organisms, and the latter as compared with humans (Einsiedel, 2005). Differential judgments are used in determining the acceptability of patenting plants and animals. In general, there is less support for patenting genetically modified animals than plants (CBAC, 2001), as the public tends to see animal patenting as “breaching an ethical code that plant patenting does not breach” (Earncliffe, 2003).

For some, the patenting of an entire animal offends at an emotional level (Earncliffe and Pollara, 2000b). In discussions, the issue of patenting whole animals (and substantial human body parts such as organs) animated substantial opposition (Earncliffe, 2003). Objections to patenting new animal species are strong, and the type of animal does not

seem to matter in the minds of Canadians. That is, there does not seem to be a differentiation between animals that are closely related to man, and animals commonly associated with medical experimentation. When asked whether it is “permissible to patent a new species of chimpanzee or guinea pig that included human genes,” 70% were opposed to patenting either new species (with 48% strongly opposed to this idea) (Environics, 1998).

Most people carry mental images of inanimate products when they think about patenting. Initially, it was hard for discussion participants to use the word invention when talking about living things or their component parts (Earnscliffe, 2003). Nearly two-thirds (with 41% strongly agreeing) say that granting a patent on an animal modified through the use of biotechnology is different than granting a patent on a consumer product (Environics, 1998). Some stated that humans and primates should be excluded from patentability. Those who were prepared to consider the patenting of animals felt that this right should be limited –with consideration given to the suffering imposed on animals, and balanced with the potential use of the modified animal (with medical uses having the highest priority) (CBAC, 2001).

Areas of Concern

Commodification of Life

The patenting of genetic information, including genes and gene sequences, blurs the distinction that we have traditionally maintained between life forms and material objects (CBAC, 2001). Particularly in the context of higher life forms, many fear that providing patent protection to inventions involving living material or beings may result in the commodification of life (CBAC, 2001). When the Federal Court of Appeal agreed with the patentability of the Harvard oncomouse (a decision since overturned by the Supreme Court of Canada), about 50 percent of Canadians said they were not comfortable with the Appeals Court decision (Earnscliffe and Pollara, 2000b). For some, the idea of patenting a life form involved the commodification of life and was hence seen as morally wrong (Earnscliffe, 2003).

Discussion participants agreed that “allowing patenting for life forms other than humans is a slippery slope to allowing patenting of humans.” This argument resonated among both supporters and opponents of the idea in principle (Earnscliffe, 2003). Treating human biological material and components as property is repugnant to some, as it entails their commodification and paves the way for commercialization. Some recommend that the *Patent Act* be amended to prohibit the patenting of humans as well as any human materials (Government of Ontario, 2002). Many ask whether we should (or if we have the right to) develop and commercialize technologies that include life forms just because we can, and whether a new decision-making process is required to determine the patentability of life forms, which may hold more significance than non-living objects (CBAC, 2001).

In any case, an overwhelming majority of Canadians agree that ethical considerations should be taken into account when determining whether or not to grant a patent, with 61% and 33% rating ethical considerations as ‘very important’ and ‘important’, respectively (Enviroics, 1998).

Consequences of Genetic Manipulation

A common thread in focus group consultations was that the concerns of ethics related more to the acceptability of biotechnology itself than to patenting biotechnology. Many concerns focused on whether biotechnological innovations should be developed and used rather than whether they should be patentable (CBAC, 2001).

For many, the patenting of animals implies interference in the genetic make up, the basis of patenting objections for some. Specific concerns include the unknown human health impacts, altering beings that have evolved in concert with their surrounding environment, and the unknown consequences of escapees –on the environment, on biodiversity, and the possibility of giving rise to new life forms etc. Many focus group participants asked whether the modern patenting process, conceived in an age of mechanical inventions, is really applicable to life forms that can reproduce and/or hybridize with other organisms, and hence cannot be withdrawn once they escape. Who should be held accountable if something goes wrong with biotechnological innovation? In general, many question whether it is wise for society to undertake the modification of life given the uncertainty regarding long-term risks (CBAC, 2001).

Equity Concerns

While moral and ethical considerations weigh in the minds of Canadians, the majority of those who are troubled by patenting issues raise objections on the grounds of access and affordability. The Canadian public understands the argument that patenting creates incentives and rewards innovation and thinks those outcomes important, however they also tend to believe that patenting drives up pricing and reduces accessibility (Earncliffe and Pollara, 2000b).

When asked whether patenting was necessary or made them uncomfortable because the benefits might only be available to those who can afford to pay, a slightly greater number (49%) suggested that the necessity of patenting slightly outweighed equity concerns (44%) (Earncliffe, 2003). Yet, a strong majority (68%) believes that patents allow multinational companies to charge higher than necessary prices for new products (34% strongly agree) (Enviroics, 1998).

Most Canadians associate genome research with medical products and have indicated in a national survey that equality of access should be the primary guiding principle in commercialization, including the patenting of products (Einsiedel and Sheremeta, 2005). Most express strong views that the cost of pharmaceuticals cannot dictate who receives them, and that those of average means should not suffer financial hardship to obtain

them. A majority believes the patenting of genetic information will lead to both of these problems (Earncliffe and Pollara, 2000b).

In the life sciences and pharmaceutical industries, patents are seen as critically important to industrial success, as the research and development costs are high and the likelihood of developing a product that will generate revenue is small (Einsiedel and Sheremeta, 2005). Despite knowing that some sort of incentive is required, a minority “rejects the economic paradigm and drift towards ensuring that no cost accrues to people who require the therapies.” Some argue that researchers are motivated more by finding cures than by money and also that, if important research is not undertaken by the private sector, government should ensure it is performed (Earncliffe, 2000b). Such opponents often reach philosophical or ideological conclusions, driven by mistrust of large corporations and worry over restricted access to important products. They say that patenting is unnecessary as it adds to very high company profits (e.g., drug patenting), and that “it holds back innovation because no one else can develop a similar product.” Often cited examples include patented drugs and seeds with price tags too high for millions to afford, such as the cost of AIDS drugs in Africa, or patenting of seeds by agricultural corporations to force annual repurchase (Earncliffe, 2003).

Social Concerns

In essence, an ultimate objective of property rights and intellectual property regimes is the benefit to be gained by society through the encouragement of innovation. By granting market exclusivity for a limited period (20 years), patents provide an incentive for innovation, allowing inventors an opportunity to recoup research and development costs without competition. In return, the inventor makes public the details of the research leading to the patent, providing a valuable repository of information and the means for other inventors to improve upon the product/technology or to stimulate their own innovative efforts (Einsiedel and Sheremeta, 2005).

However, “the individual right to protect property and profit from its use is sometimes seen to conflict with the wider society’s rights to ensure the protection and well-being of its citizenry” (Environics, 1998). Publics generally accept the idea that the current patent system allows inventors to reap the rewards from their investments (71%). However, a quarter of Canadians believe that such patents “prevent wider societal benefits” and more than two-thirds say that some technologies should not be patented, as they are not in the public interest, suggesting that a strong interest exists in using a “public interest test” as part of the patent process. Responses did not indicate whether the patent should be withheld to allow broad distribution or to prevent the manufacture of the item (Environics, 1998).

Focus group participants have expressed concerns about the negative societal impacts that may result from the monopolies created by patent protection, including the fair distribution of benefits and restricted access to inventions due to high costs. Some fear the costs of obtaining or protecting patents give an advantage to large industries, and small companies may be provided with an incentive to relocate to countries where it is

easier to obtain patents. In addition, some are worried that patent interests promoted by corporate financing may sideline other important research, encouraging only that which is economically viable -rather than what is best for society (CBAC, 2001).

Another key social issue considers how Canada should identify who has a legitimate claim to the benefits, economic or otherwise, of innovation. Many participants expressed unease over patents disadvantaging indigenous peoples and other cultures in less developed countries. If traditional knowledge is used to develop a patented product, are the people or country of origin entitled to a portion of the benefits yielded by the patented product? If a legal battle is required to gain access to benefits, indigenous people may be disadvantaged due to the high costs involved. Lastly, communities may suffer from a lack of traditionally used food or resources due to the increased value of such materials as a result of patenting (CBAC, 2001).

In summary, questions persist about the impacts of patenting genetic material on social welfare, prompting many to question whether the balance between encouraging innovation and enhancing society has been fairly struck.

Policy Implications

Patenting in the area of biotechnology is an issue that affects all Canadians. As such, discussion group participants felt that informed public debate was required to solve the key questions associated with patenting, and that the issues should not be left to the experts to decide (CBAC, 2001), despite the current lack of public awareness. Further, such debates should consider:

- What are and what ought to be the proper limits of “patentable subject matter”? (Einsiedel and Sheremeta, 2005).
- “What should belong to all of society and therefore should not be patentable?” (CBAC, 2001).
- Should sequencing and identification of a gene sequence implicated in a specific biological process be construed as an invention? (Einsiedel and Sheremeta, 2005).
- Who should be entitled to the benefits of patents?
- Has the appropriate balance been struck between encouraging innovation and promoting the social good?
- “Do the benefits that patents bestow on society outweigh the anticompetitive behavior they might also inspire? What is the actual relationship between patenting and innovation?” (Einsiedel and Sheremeta, 2005)
- “Does anyone have the right to prevent or stifle innovation that leads to societal benefits?” Who decides what is right? What is the basis for such a decision?” (CBAC, 2001).
- “Does the public good override the rights of individuals or vulnerable groups?” (CBAC, 2001).

Proposed Patent Reforms

How do Canadian publics view various options that might be utilized to address patent issue challenges? Recent focus group discussions around the country considered a variety of options.

First, there was strong public interest in the notion of price regulation for patented genetic health technologies along the lines of the Patented Medicine Price Review Board (PMPRB) model. This was viewed as one important means to address concerns that were voiced around potential price increases and problematic access to products if they were under patent protection (Earncliffe, 2005). This price control regime (possibly through extending the PMPRB remit to include genetic applications and products) had considerable support in these public discussions.

Second, discussion group participants were in favour of excluding certain products or processes from patentability. This exclusion gave discussants a sense that authorities would have another tool for setting limits on development and patenting of controversial genetic technologies (Earncliffe, 2005). Other surveys and focus group discussions have demonstrated public concern over patenting of higher life forms and it is possible this is the type of exclusion that some would consider acceptable. It is also quite possible that this support for limits, although not articulated in specific terms, is an expression of concern that different elements (concern for the collective interest, ethical considerations) are being taken into account and appropriately balanced.

Third, there was support for the policy option of allowing government to infringe on a patent. Support for this was allowed only under extreme or emergency situations, e.g., an epidemic, or where patent rights might be abused in a way that could endanger lives (Earncliffe, 2005).

Fourth, the idea of compulsory licensing received public support. While there was widespread preference that genes or gene sequences not be patented, recognizing that they are made the idea of compulsory licences an acceptable alternative and a means to ensure that innovation would not be hampered by patents (Earncliffe, 2005).

As the *Patent Act* is a statute dealing with property rights, some view it as an inappropriate mechanism to address the social and ethical issues associated with patenting –that the very wide range of factors involved in biotechnology patenting may be too broad for management through one process. As such, some have suggested the creation of a separate regulatory review mechanism to address these issues (CBAC, 2001). Focus group participants around the country were supportive of the view that the Patent Act or the patent office were not necessarily the best arenas to deal with moral or ethical issues around patenting; many were comfortable with leaving this responsibility to adjudicate these issues with parliament or the courts (Earncliffe, 2005), or vesting other bodies (bodies overseeing price controls) with appropriate regulatory powers.

In response to the concerns over gene patents and the patenting of higher life forms, academics have called for substantial reforms to patent laws, including (Einsiedel and Sheremeta, 2005):

- Creating a statutory definition of “patentable subject matter” that includes or excludes certain biotechnological inventions;
- Adding an “ordre public” or morality clause to the *Patent Act*;
- Adding a statutory opposition procedure similar to that which exists in Europe;
- Creating a narrow compulsory licensing regime that would facilitate access by others to key patented technologies;
- Creating a specialized court to ensure that only judges with expertise in technology and patent law can hear intellectual property cases.

The “public order” or morality clause is the most contentious of the recommendations, as it would enable patent examiners or another ruling body to determine patentability on the basis of morality. Some recommend the creation of an independent, transparent and responsible tribunal of specialists in ethics, research and economics –with power to suspend or withhold patents in limited circumstances. Importance would be given to avoiding delays in the patent-granting process. The advantage of such an approach is that it leaves ethical decisions to specialists, preventing frivolous complaints against patentees (Einsiedel and Sheremeta, 2005).

Alternatively, the Canadian Biotechnology Advisory Committee asserts that the existing range of mechanisms available to restrict or prevent activities determined to be socially or morally undesirable is quite extensive, and the social and ethical considerations raised by biotechnology should continue to be addressed primarily outside of the *Patent Act*. If new limits are required, it is more efficient to modify or expand current regulations than to introduce a completely new mechanism into the Act (Einsiedel and Sheremeta, 2005).

Benefit Sharing

In order to address the unequal distribution of economic and other benefits, the concept of benefit-sharing has emerged in international law. It is argued that the human genome is a unique natural resource, possessing qualities that may render it a “common heritage” resource. Characterized as such, there is a moral and ethical obligation for researchers and exploiters to promote the equitable sharing of this resource and any information gleaned from its use. There is, however, no clear or crystallized legal imperative to insist on or enforce benefit-sharing (Einsiedel and Sheremeta, 2005).

Benefit-sharing may be used as a means to correct inequity or promote more equal distribution of the benefits created by a patent system. As a supplement to the current patent system, the two should provide an incentive to innovators and a mechanism to achieve equitable and sustainable development of human biological resources (Einsiedel and Sheremeta, 2005).

Conclusions

The opinions, values and priorities of the public must be taken into account in policy development to ensure that the potential benefits for society are optimized and that commercial involvement is appropriately managed and aligned with society's interests (Einsiedel and Sheremeta, 2005; Willison and MacLeod, 2002). As Canadians have expressed an interest in participating in informed public discussion, the public must be provided with information about the patenting system –the process, implications, expected benefits for society (including benefit-sharing programs), issues associated with access and affordability of health products and technologies, and descriptions of how the risks of the technology in question are managed. Planners would be well advised to adequately address concerns. Such attention can be used to foster and maintain public trust in the commercial process and the patent system in particular.

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