
Policy Conflicts: Gene Patents and Health Care in Canada

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Key Words

Human gene patents · Health care, Canada · Patent reform

Abstract

Several recent gene patent controversies have energized and refocused the human gene patent debate in Canada. These include the use of the Myriad test for breast cancer by the provinces, patenting of the Severe Acute Respiratory Syndrome virus and a recent Supreme Court decision rejecting the patenting of 'higher life forms'. These cases place the emerging policy conflicts between the innovation and commercialization agenda of the government and the desire to provide equitable access to health care in sharp focus. Another challenge faced by Canada is the powerful influence of the United States in policy decisions. Although these issues have raised awareness about the possibility of reforming the patent system, Parliament has yet to consider any of the suggested reforms of the Canadian patent system and there are no formal proposals pending.

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Introduction

As with many countries throughout the world, Canada has faced a number of recent biotechnology patent controversies. As elsewhere, these controversies have led to

calls for reforms of our patent system. However, Canada is a country that finds itself caught between a European approach to the delivery of health care and social programs and a dominant reliance on the United States for economic growth. This tension creates some unique dilemmas for Canadian policy makers in the context of human gene patents. As with many developed nations, Canada has been struggling to control the cost of its publicly funded health care system. At the same time, the government has sought strategies to further the growth of biotechnology, which has emerged as an increasingly important part of our national economy. Balancing these two laudable policy goals will prove challenging.

The focus of this paper is to provide a sense of the nature of the recent gene patent controversies and their relevance to the broader patent policy debate.

The Canadian Context

Over the past decade, there has been a reasonable degree of Canadian commentary regarding the potential social issues associated with human gene patents [1]. The articulated concerns have often related to the broad ethical issues, such as concern about the impact of gene patents on human dignity and commodification of human tissue. To cite one example, in 2001, the Parliamentary Standing Committee on Health made a recommendation that patents on all human genes should be banned.

'We are deeply disturbed that the Patent Act does not specifically disallow patenting with respect to human genes, DNA sequences and cell lines. Treating human biological components as patentable property is repugnant to many of us. It entails their commodification and paves the way for their commercialization. Given the importance that this Committee attaches to the respect of human dignity and integrity, we urge that patents be denied in relation to human material' [2].

To date, this and other forceful policy recommendations have had minimal impact on federal patent policy. Indeed, despite such commentary, there has been little serious consideration of any substantial patent reform specific to human gene patents – at least until very recently. As in most countries with well-developed biomedical research infrastructure, there have been no major legal impediments to the patenting of human genetic material in Canada. Thousands of patents involving human genes have already been issued. A review of the Intellectual Property Office Canadian Patents database in 2002 found approximately 2,100 patents associated with human DNA [3]. This is a rate of gene patenting comparable, on a per capita basis, with that in the US – Canada's largest trading partner [4, 5].

Adding to this largely 'pro-patent' environment is the recent, and unprecedented, push to tie academic research to regional economic growth. For example, in 2002, the Federal Industry Minister, Alan Rock, suggested that there is a need to commit academic institutions 'to a link between public funding and economic outcomes' [6]. Many of Canada's major public research funding entities, such as the Canadian Institutes of Health Research (CIHR), now have a formal commercialization mandate. For example, the enabling legislation of the CIHR states that the CIHR should 'encourage innovation, facilitate the commercialization of health research in Canada and promote economic development through health research in Canada' [7].

There are, no doubt, sound reasons to be enthusiastic about the role of patents, biomedical research and, especially, biotechnology in the context of economic growth. Biotechnology is perceived to be a rapidly growing sector of the Canadian economy [8]. It has also been suggested that the life sciences may account for over 100,000 jobs in 2003 [9]. Strong intellectual property rules are viewed, rightly or not, as a critical ingredient to a vibrant and successful biotechnology sector [10] – though there is, in fact, surprisingly little empirical data to support this assumption [11].

Gene Patents and the Health Care in Canada

Several recent gene patent controversies have energized and refocused the human gene patent debate in Canada. This is largely because the recent patent developments have concerned access to health care services and, more importantly, the potential cost of providing useful health care services within a publicly funded system [12]. In Canada, containing the cost of providing health care has been a dominant political issue, and the equitable access to affordable health care services has been identified as a strongly held public value [9]. Policies that are perceived as adversely impacting access to and the cost of health care services have generated a debate like few other social concerns.

In this regard, no other event has had as big an impact on the human gene patent debate in Canada as the decision by the US-based Myriad Genetics to take steps to enforce the patents on the BRCA1/2 genes. The case put a practical spin on the abstract concerns often associated with gene patenting, as suggested by Richard Gold: 'While the earlier academic discussion had predicted some negative effects of gene patenting on patients, the Myriad case made these concerns tangible' [13]. The case has thus become a 'harbinger' of the policy challenges created by gene patents and 'a focal point in Canada and Europe for debates about the social and ethical implications of DNA patenting and the commercialization of genetic tests' [14].

Though our understanding of the nature of the relationship of the BRCA1/2 mutations to breast and ovarian cancer continues to evolve [15], offering the test to women with a specific at-risk profile is viewed as part of the clinical standard of care [16]. It was and still is being offered throughout the country as part of the provincial health care schemes, albeit with some degree of variation in clinical and laboratory practice. Often, the genetic analysis does not occur in a commercial laboratory but in one of the public research or provincial diagnostic laboratories.

In the summer of 2001, most Canadian provincial health care ministries received a cease and desist letter from Myriad. They were told that all future genetic testing that utilizes the BRCA1/2 genes must be done through Myriad's laboratories. The Myriad test, which costs approximately CND 3,800, is, in some cases, more than four times the cost of the testing being done within the provincial system. As a result, there were concerns raised by numerous provincial health ministries that their systems could not afford to provide the Myriad test to their citi-

zens. Some provinces, such as Alberta and Ontario, decided to ignore the patent and continue testing. British Columbia simply stopped offering the test, at least temporarily.

The Myriad letter generated a good deal of media attention [17] and an almost immediate policy response. For example, shortly after the Myriad story broke, Mike Harris, then the Premier of Ontario, suggested that the 'benefits of a world-wide effort such as the human genome project should not be the property of a handful of people or companies. Our genetic heritage belongs to everyone. We must share the benefits fairly and do what we can to make genetic tests and therapies affordable and accessible' [18].

In what seems to have been a direct response to the Myriad controversy, the Ontario government struck a policy group to examine the potential adverse social implications of gene patenting [19]. In a comprehensive analysis of the overall health care system, the 2002 federal Commission of the Future of Health Care in Canada called on the government to 'review the current provisions of the patent law in relation to the issue of patenting of genes and DNA' [9].

Most recently, the Ontario government has decided to formally intervene in a high-profile agricultural patenting case that is to be heard by the Supreme Court of Canada in the coming months. The lawsuit between a farmer, Schmeiser, and the multinational biotechnology company Monsanto centers on the nature and extent of patent rights over a genetically modified crop [20]. The Ontario government has decided to get involved as an intervener because, as suggested in the affidavit of the Ontario government to the Supreme Court, the case 'has important implications for the development of public policy in Ontario including the delivery of health care to its residents' [21].

Two other recent patenting controversies are worth noting. The first is the patenting of the Severe Acute Respiratory Syndrome virus (SARS). SARS had a tremendous impact in Canada. With 44 deaths, Canada was the hardest hit country outside Asia [22]. When the British Columbia Cancer Agency and the US Centers for Disease Control and Prevention announced that they were going to patent the SARS genome, it caused commentators to question the ability of the existing patent system to serve the needs of the public [23]. Even though the British Columbia Cancer Agency and the US Centers for Disease Control and Prevention stated that they were seeking patents in order to ensure ongoing public access to the genome (and to pre-empt patent applications from other

entities), many felt that this was yet another example of the inappropriate application of patent law. Should any entity be able to control access to such an important research and clinical tool?

Finally, the impact of the 2002 Supreme Court of Canada decision in *Harvard College versus Canada* (Commissioner of Patents) should be considered [24]. Though not a gene patent case implicating health care, the decision made Canada the only country with a high court decision explicitly rejecting the patenting of 'higher life forms'. The case put the issues associated with biotechnology patents on the policy making table. Indeed, the case emphasized the need for the legislature to take active steps if reforms of the patent system are to occur. Not surprisingly, the case also elicited strong reaction from the Canadian biotechnology industry. For example, Janet Lambert, President of BIOTECCanada, the national association of biotechnology researchers, suggests: 'Today's decision destroys our Canadian infrastructure of knowledge and innovation, creates an even greater brain drain, and we will lose our place at the world table in influencing how and where society accepts this technology' [25]. In fact, it is still unclear if the case has had any real adverse impact on the Canadian biotechnology sector.

The Impact of the Recent Patent Controversies

These cases, and the Myriad controversy in particular, place the emerging policy conflicts between the innovation and commercialization agenda of the government and the desire to provide equitable access to health care in sharp focus [26]. It was recently reported that the motivation of the Ontario government for getting involved in the Schmeiser gene patenting debate was to keep gene patenting laws 'from tilting too far in favour of corporations, or else patients in the publicly funded health-care system will suffer' [27]. But in an era when the university environment has become markedly commercialized and both federal and provincial governments have been aggressively pursuing an innovation agenda, a stated government concern about the impact of gene patents has an ironic taste. For better or worse, the patenting and exploitation of genes found in the context of the research environment, just as Myriad is doing with the BRCA1/2 mutations, is the natural consequence of the push to commercialize research. Can governments have it both ways?

Despite this policy conflict, recommendations for patent reform have emerged. For example, the 2002 Report to the Premiers of the Ontario government recommends a clarification of patent criteria in relation to human genes, the exclusion of broad-based genetic patents covering multiple uses, a clarification of the experimental and non-commercial exceptions and an expansion of the methods of medical treatment exclusion [19]. Another common recommendation is the introduction of a compulsory licensing scheme in order to ensure access within the public system [26]. These recommendations are quite similar to those made in other jurisdictions, including the UK [28] and Australia [29].

Efforts to implement these recommendations could encounter a number of barriers. First, it is unclear how international treaties, specifically the Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) of the World Trade Organization, might affect implementation of these recommendations. While TRIPS makes room for some flexibility in regional patent regimes to accommodate the needs of public health systems [30], countries such as the US have historically taken an aggressively pro-industry view of TRIPS – even in the context of clear public health dilemmas such as the international AIDS crisis [31]. Any patent reforms that may have adverse implications for the growing yet economically fragile biotechnology industry seem likely to attract a good deal of scrutiny in relation to compliance with international trade agreements. At a minimum, this will create a degree of uncertainty for those seeking patent reform.

A second policy challenge, and one that is especially relevant to Canada, is the influence of US policy in this context. The US is by far Canada's biggest trading partner. In the area of biotechnology, the position of the US is particularly important, as it has been a leader in the field, both scientifically and economically [32]. For example, Thomas et al. [33] found that of the human gene patents filed between 1996 and 1999, '62% were filed by organizations in the United States, 20% in the European Union, and 10% in Japan'. This intensifies the conflict between the innovation policy of the Canadian government and the desire to contain the cost of delivering health care. 'Brain drain' to the US and the need to attract venture capital are concerns that are, understandably, consistently articulated by both the government and those advocating for industry. Any lessening of Canada's intellectual property protection will stand in sharp contrast to the policies promoted by the US, thus making it more difficult, at least politically, to move patent reforms forward.

Finally, there is currently a scarcity of data on the actual social benefits and drawbacks of biotechnology patents. There is a huge amount of legal analysis and policy commentary and a small, but growing, body of empirical research on the impact of gene patents on the clinical setting [34]. However, there is little real data specific to Canada or other countries with a national health care system. Ideally, efforts to reform the patent system should be informed by evidence. For example, would the suggested reforms, in the aggregate, really reduce the cost of delivering health care? How would that balance against a loss, if any, in economic growth?

Though the barriers to patent reform remain significant, it is interesting to note that there is some evidence that public opinion about the value of human gene patents has been affected by the recent high-profile patent controversies. A 2002 survey of Canadians found that '46% said there are likely more risks than benefits in allowing such patents, up from 37% in 2000' [35]. The survey also found that more people are 'uncomfortable with the idea of providing patents in the area of biotechnology' because it will adversely impact access to useful technologies (49%) than those who felt that 'patent protection is necessary in the field of biotechnology because we need to encourage inventions in this area for all the benefits they can bring' (33%) [35]. In the end, this kind of public backlash has the potential to be the most significant political motivation for patent reform.

Conclusion

Though the recent gene patenting controversies seem to have created the political momentum in Canada and abroad to seriously consider reforms of the patent system, actual reforms are not imminent. Though a number of provincial governments have become engaged in the issues, patent law falls within the jurisdiction of the federal government. Parliament has yet to consider any of the suggested reforms of the Canadian patent system and there are no formal proposals pending. Altering the existing patent system could take many years. That said, policy makers interested in patent reform should take advantage of the interest created by the recent controversies. A number of steps can be taken immediately. For example, the interplay between the innovation strategy and health care policy of the government should be further explored and made explicit. Is the right balance being struck? Answering this question will require more research on the impact of biotechnology patents. This research should be

formally encouraged, perhaps through one of Canada's major research funding entities, such as the CIHR or Genome Canada. If patent reform is deemed necessary, governments should consider short-term strategies that can be implemented without legislative or regulatory reforms.

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