# The Supreme Court of Canada was Right: Don't Patent Animals

On April 14, 2003, the Intellectual Property Institute of Canada sponsored a debate on the Supreme Court of Canada Decision on the Harvard Oncomouse. In this precedent-setting case, the Court refused Harvard a patent on its genetically-modified mouse, effectively barring patents on multi-cellular life forms in Canada.

Debaters in favour of patents on life were David Morrow of Smart and Biggar in Ottawa and M.Bolduc of BioQuebec. Arguing against life patents were Michelle Swenarchuk of CELA and Canon Eric Beresford of the Anglican Church.

## Argument of Michelle Swenarchuk

**1. Harvard has argued that since single cell life forms are patentable in Canada, there is no logical distinction that justifies excluding higher life forms. However, we do not consider that single cell life forms should have been found patentable in Canada as cells and genes are discoveries, not inventions.**

In the words of Dr. John Sulston, winner of the 2002 Nobel Prize in physiology and medicine[1]:

> The genome sequence is a discovery, not an invention. Like a mountain or a river, the genome is a natural phenomenon that existed, if not before us, then at least before we became aware of it….
>
> . …. Inventing human genes is impossible. So every discovery relating to genes - their sequence, functions and everything else - should be placed in the pre-competitive arena.

Regarding the practice of granting patents on genes if they can be replicated outside the body as in Europe:

> This argument has always seemed absurd to me. The essence of a gene is the information it provides - the sequence. Copying it into another format makes no difference. It is like taking a hardback book written by someone else, publishing it in paperback and then claiming authorship because the binding is different. ….

Regarding patenting of higher life forms, Dr. Sulston says:

> We should not be patenting whole life forms, such as transgenic mice or cotton plants - and not just because they are living organisms. A sounder reason is this: we did not invent these organisms,

> only the specific modification that made the mice susceptible to cancer or the cotton resistant to pests.

Further, Dr. Sulston emphasizes the importance of the **information** contained in genes:

> The future of biology is strongly tied to that of bioinformatics, a field of research that collects all sorts of biological data, tries to make sense of living organisms in their entirety and then makes predictions… If we wish to move forward with this fascinating endeavour, which will undoubtedly translate into medical advances, the basic data must be freely available for everyone to interpret, change and share, as in the open-source software movement.

Or in the succinct expression of Dr. Ursula Franklin, don't patent knowledge.

**2. Patents on single cell and higher life forms are having negative impacts on science, and healthcare. affecting the exchange of knowledge, research tools (like the mouse) and research results. affecting the accessibility of diagnostic tests and potential treatments and cost to the health care system.**

Impacts from biomedical patents are widely discussed in scientific and legal literature and litigated in the courts. According to Dr. Harold Varmus, Nobel prize winner and past Director of the US National Institutes of Health, the proliferation of patenting has

> changed the conduct of biomedical research in some ways that are not always consistent with the best interests of science[2].

Following the grant of a US patent on the Oncomouse to Harvard, Harvard licensed Dupont to distribute the mice. Some scientists objected to the terms of DuPont's distribution licences which included a "reach through" clause requiring anyone who developed a product through the use of the mouse, or any derivative strain, to pay royalties to DuPont. Dr. Varmus, then Director of the National Institutes of Health negotiated for four years with DuPont to obtain an agreement that NIH and its grantees (non-profit academic researchers) may use the patented transgenic non-human mammals without paying royalties for biomedical research purposes.

In effect, senior research scientists have been impelled to reverse the impact of the patents on transgenic mice in order to spur innovation in non-profit medical research. It has been argued that Canada should follow the US example on these patents; however, the US reality is that the mouse is available essentially patent- free to academic researchers.

**Further, a plethora of problems have arisen for science and healthcare from the patenting of genes and partial genes.** Examples include:

- The patenting of a protein, CCR5 involved in HIV replication by Human Genome Sciences Inc.:

  > The patent application covered the gene and its protein and the fragments of DNA used to locate the gene, as well as details related to the chemical components of the gene, and potential application s of this knowledge. Despite the fact that independent researchers at the NIH in the US **subsequently** discovered that the gene functions as a receptor for the entry of HIV into the human body, the patent was eventually granted to Human Genome Sciences. Furthermore, HGS patent on the gene permitted it to use the gene for any purpose, and therefore profit from the later discovery. The patent has resulted in considerable control over the commercial development of a new class of AIDS drugs, even though the role of CCR5 in HIV infection was unknown at the time of filing[3].

- The Myriad Genetics series of patents on two genes implicated in possibly 10% of breast cancer cases, BRCA1 and BRCA2 and on its diagnostic test for the presence of the genes. Myriad essentially claims a monopoly on the whole BRCA 1 and 2 genes; any information relating to or derived from them; all methods developed to diagnose and treat hereditary breast cancer and ovarian cancer. Myriad claims that only its test can be used for these genes, and that all samples must be sent to Utah for analysis. Its test costs significantly more than other tests used in Canada, and is not considered by many experts to be superior to others. Myriad also claims that its patents give it the right to store all new information about BRCA1 and 2 in its own labs, building up the only source of this genetic data in the world.

In July 2001 Myriad told Canadian provincial governments to stop using any other tests to detect the genes. BC stopped using other tests; Ontario has decided to contest the claim[4]. The Institut Curie in France has joined with 17 French research and clinical agencies to oppose the claims in the European Patent Office. The Institut states that the Myriad tests fail to detect 10 to 20% of expected mutations[5].

Tony Clement, Ontario Minister of Health and Long Term Care has stated on September 19, 2001:

> How can publicly-funded healthcare and equitable coverage be sustained when we add to the existing financial pressures on our health system the potential monopoly pricing of a whole new category of diagnostics over which Ontario-and indeed Canada's other provincial and territorial jurisdictions – have little or no control over approval or pricing…. We are therefore forced to ask ourselves the much larger question: Is the entire fruit of human genome project research and the mapping of the human gene going to come down to a series of monopolies setting exclusive prices for tests which most of Canada – indeed most of the world,

especially the poorer countries – cannot afford?

> Patent claims on a gene sequence that cover uses for all diagnostic innovations in the future are not in the public interest or in the interests of the promotion of a competitive market in diagnostic testing. Maintaining the status quo in this regard may actually serve as a disincentive to the improvement of existing products and the development of larger numbers of commercial applications. The concept of improvement is fundamental to the patent system and one in which there appears to be something of a potential dissonance between certain biological and non-biological patents[6].

Documented problems in the conduct of scientific research include:

- inappropriate rewards given by patenting partial and uncharacterized cDNA sequences;
- impediments to development of diagnostics and therapeutics due to costs of patented research data;
- patent stacking (several different ways of patenting a genomic sequence) which discourages product development due to high royalty costs payable to all patent owners;
- secrecy of patent applications resulting in scientists finding, late, that patents have already been granted related to work they are doing, leading to unexpected licensing costs and patent infringement penalties;
- private biotechnology patent holders can monopolize certain gene test markets;
- and patent filings are replacing journal articles as places for public disclosure, reducing the body of knowledge in the literature[7].

Regarding impacts on scientific publication: the literature shows:

- that patents have led to delays in publication of scientific results;
- that conflicts of interest (commercial interests in scientific research) may affect **what** gets published.

These results are harmful to the advancement of science:

> Openness in the sharing of research results is a powerful ideal in modern science ….communalism, the shared ownership and free exchange of research results and approaches, is a fundamental norm underlying the social structure of science. Such sharing is critical to the advancement of science, for without it researchers unknowingly build on something less than the total accumulation of scientific knowledge, and scientific work is slowed by problems for which solutions already exist but are unavailable[8].

3. **Life form patents, in these effects on biomedical research, contradict two fundamental purposes of the Patent Act, disclosure of inventions and spurring innovation**.

The Patent process represents an historic social bargain, in which inventors are granted a period of time for the exclusive use of an invention in return for disclosing their invention in the patent application, so that it can eventually be used by others. However, as the above examples show, in affecting the openness of scientific knowledge, which would otherwise exist, patents **reduce disclosure**. In creating barriers to research, they **deter** rather than **foster** innovation.

4. **The Supreme Court of Canada decision on the Oncomouse gives Canada the opportunity to conduct the public investigations and debate regarding life patents that, in my view, should have occurred before the decision was made to patent single cell life forms. This debate must not be confined to corporate actors and patent professionals.**

Proposals for reforms of the law are widely discussed in the literature and public bodies. We suggested ten areas of consideration to the Supreme Court; the Canadian Biotechnology Advisory Committee proposed others; the comprehensive *Report to the Provinces and Territories* of the Ontario Ministry of Health and Long Term Care makes these proposals:[9]

- **Clear protection for research and clinical non-commercial use**: provide protection from patent infringement actions for healthcare providers and researchers; strengthen existing research exemptions.

- **Implementing clear and modern standards**: as in the US, increase utility standards, train patent staff better and make the Patent Office guiding manuals public.

- **Clarify the definition of patentable subject matter**: patenting of "concepts" or general non-specific utilities is a problem; narrow the subject matter of genetic patents, identify specific use and examine sub-gene and stem cell patents.

- **Methods of medical treatment**: extend non-patentability of medical treatment methods to use of genetic materials in diagnosis; methods could be patented but uses of patented genetic materials in diagnosis would not create liability.

- **Ordre public exception**: include in the Patent Act

- **Opposition period and appeals court**: as in Europe, include a nine month opposition period to challenge scope, content or validity of new genetic patents; establish a specialized court for patent appeals, issues of gene patent validity and infringement.

- **Compulsory licensing**: for patents on genetic diagnostic and screening tests.

All reform proposals share a rationale of **re-balancing** the law. We need Parliament to reform Canadian patent law, not to allow the Harvard mouse patent, but rather to ensure that our exploding knowledge of genetics maximizes public benefits.

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[1] John Sulston, Heritage of Humanity, Le Monde Diplomatique, December 2002
[2] Varmus, Dr. Harold, "Testimony Harold Varmus, Hearing on Gene Patents and Other Genomic Inventions" (The House Judiciary Subcommittee on Courts and Intellectual Property), 13 July 2000, online: <http://www.house.gov/judiciary/varm0713.htm> (date accessed: 15 March 2002
[3] Ontario Report to Premiers: Genetics and Gene Patenting: Charting New Territory in Healthcare January 2002, p.41. Available at: www.gov.on.ca/health/english/pub/ministry/geneticsrep02/report

[4] ww.cancer.ca/ccs/internet/standard
[5] Ibid.,p.2, accessed 4/10/03

[6] Ontario Report to the Premiers, op.cit, p.48
[7] Human Genome Project Information, online: ORNL <www.ornl.gov/hgmis/elsi/patents.html>
[8] Blumenthal *et al*., "Withholding Research Results in Academic Life Science, Evidence From a national survey of Faculty" (1997) 277:15 Journal of American Medical Association 1224 at 1224-1228.
[9] Ontario Report to Premiers, op cit. pp. 47 - 53