


MOUSE TRAP

After its 17-year run through a legal maze, Harvard's patent is squashed by Canada's high court.

By Cynthia Tape and Conor McCourt

 On December 5, the Supreme Court of Canada astonished industry and legal communities with its ruling that the Harvard mouse and other higher life forms are not patentable subject matter in Canada. The 5-to-4 decision in *Commissioner of Patents v. President and Fellows of Harvard College* was surprising because it sets Canada apart from other jurisdictions such as the United States, Europe, and Japan, which permit higher life forms to be patented.

Inventors seeking patent protection for organisms such as plants, seeds, and animals should be aware of this landmark decision, which nevertheless affirmed the continuing patentability of “lower” life forms such as bacteria, fungi, and molds. For now at least, it will be important to ensure that patent applications filed in Canada are carefully tailored to obtain the maximum protection possible in view of the Court’s decision.

The Harvard mouse is not just any mouse. It was developed by Harvard researchers Philip Leder and Timothy Stewart to have a heightened susceptibility to cancer. The predisposition of the Harvard mouse, or oncomouse, to develop cancer is useful for testing the cancer-inducing and treating effects of various agents.

To produce the oncomouse, researchers used tiny packages called plasmids to insert oncogenes, which trigger cancer growth, into mouse embryos. The embryos were implanted into female “foster” mice to gestate. The offspring were tested for the oncogene. Oncogene-positive mice (called “founder” mice) were then mated with ordinary mice. Fifty percent of the offspring carried the oncogene in their cells.

In June 1985 Harvard applied for a Canadian patent. Some of the application’s claims were relatively uncontroversial, such as those covering the plasmids; the process of introducing them into nonhuman mammal embryos; and for various cell lines. The Canadian Intellectual Property Office allowed these claims, but Harvard sought more robust protection. Although higher life forms had never been considered patentable in Canada, the school sought patent rights to the oncomouse and any other oncogene-positive nonhuman mammals produced by the process described above.

The commissioner of patents rejected these claims in 1995, holding that Harvard’s mouse was not patentable subject matter because higher life forms are not an “invention” within the meaning of section 2 of the Canadian Patent Act.

Section 2 defines “invention” as “any new and useful art, process, machine, manufacture, or composition of matter, or any new and useful improvement in any art, process, machine, manufacture, or composition of matter.” The commissioner concluded that a nonhuman mammal does not fit the definition, and that the oncomouse is not an “invention” because its creation and reproducibility are controlled largely by the laws of nature and not by the human hand. The only characteristic of the mouse that is reproducible and subject to human control is the presence of the oncogene. This is insufficient to permit Harvard to claim patent protection to the entire animal.

Harvard appealed the commissioner’s decision to Canada’s Federal Court.

Justice Marc Nadon of the Federal Court trial division (now a member of the Federal Court of Appeal) upheld the commissioner’s rejection of these claims. (*President and Fellows of Harvard College v. Canada*, [1998] 3 F.C. 510.)

Nadon agreed with the commissioner that the inventors had insufficient control over the creation and reproducibility of the oncomouse. The laws of nature played a considerable role in creating the oncomouse, which was in fact a “marriage between nature and human intervention.” Harvard could not claim patent rights for those aspects of the purported inven-

tion which are created or controlled by nature. While the presence of the oncogene was clearly the product of human intervention, all other aspects of the transgenic mice were infinitely variable and largely unknown.

Nadon also held that it was appropriate to draw a distinction between higher and lower life forms when determining whether a given subject matter is patentable. Complex life forms do not fit easily within the ordinary meaning of “manufacture” and “composition of matter.” The appropriate forum for addressing the patentability of higher life forms and the attendant social and ethical concerns was Parliament.

In August 2000, the fate of Harvard’s mouse took a dramatic turn when the Federal Court of Appeal overturned the trial court’s judgment. Justice Marshall Rothstein, writing for the majority, found that the oncomouse is a “composition of matter” as that term was defined in *Diamond v. Chakrabarty* (1980). *Chakrabarty* was a 5-to-4 decision of the U.S. Supreme Court affirming the patentability of a strain of bacteria genetically modified to digest crude oil. There, the Court held that a “composition of matter” includes “all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders, or solids.”

The majority of the Federal Court of Appeal was persuaded that the oncogene DNA and the fertilized mouse egg are both forms of “matter” according to this definition. It followed, therefore, that the transformed embryo, the founder mice, and their oncogene-carrying offspring are all “compositions of matter,” and hence patentable.

The majority also rejected the trial judge’s findings of insufficient control and reproducibility. Aspects of the oncomouse that are irrelevant to the invention need not be reproducible or under the inventor’s control. Furthermore, since most inventions take advantage of at least some of the laws of nature, there was no valid basis for dividing an invention into aspects that rely on human intervention and those that do not. The oncomouse is “the result of a combination of inventive ingenuity and the laws of nature, both of which were central to the invention.”

Rothstein made the powerful observation that “the language of patent law is broad and general and is to be given wide scope because inventions are, necessarily, unanticipated and unforeseeable.” Since the Patent Act does not exclude living organisms from patentability, the Harvard mouse and other nonhuman mammals must be patentable subject matter.

ALTHOUGH HIGHER LIFE FORMS HAD NEVER BEEN CONSIDERED PATENTABLE IN CANADA, HARVARD SOUGHT PATENT RIGHTS TO ITS ONCOMOUSE.

THE SUPREME COURT'S DECISION MAY BE SEEN AS RUNNING AGAINST THE GRAIN OF INTERNATIONAL EFFORTS TO HARMONIZE INTELLECTUAL PROPERTY LAWS.

The commissioner's appeal to the Supreme Court of Canada was heard in May 2002.

The Supreme Court split 5-to-4 on whether higher life forms are patentable subject matter in Canada.

Justice Michel Bastarache, writing for the majority, concluded that Parliament did not intend that every conceivable subject matter be patentable. Rather, the universe of proper subject matter was limited as suggested by the exhaustive definition of "invention" in the Patent Act, and the fact that it is ill-equipped to deal with the unique concerns that would inevitably arise if higher life forms were patentable. In the majority's view, only Parliament has the institutional competence to extend patent protection to plants and animals and to attach the appropriate conditions to the right that is granted.

Bastarache also noted that Parliament had an opportunity to extend protection to higher life forms and chose not to. Canada's Plant Breeders' Rights Act passed shortly after the Supreme Court's decision in 1989 that a new soybean variety could not meet the requirements of the Patent Act. Had Parliament intended to extend patentability to other higher life forms, it would presumably have done so at that time. Furthermore, the Plant Breeders' Rights Act demonstrates that there are mechanisms outside the patent system that may be used to encourage inventors to undertake innovative activity.

At the same time, the majority upheld the patentability of "lower" life forms. There is not explicit language in the Patent Act to support this distinction. The court nonetheless justified its decision on the basis of an unarticulated "common sense difference" between the two.

Justice Ian Binnie, in a spirited decision on behalf of the dissenting judges, declared that the Harvard mouse is a "composition of matter"—a combination of genetic material and the fertilized mouse egg described in the disclosure of Harvard's application. There was no rational or justifiable basis for drawing a line between compositions of matter that are more or less complex. The dissenting judges concluded that there is simply no dividing line between higher and lower life forms—common sense or otherwise—that is free from policy concerns. Any "line in the sand" should be drawn by legislators. Binnie also noted that policy concerns arising in connection with patents for complex life forms can and should be addressed outside of the Patent Act, just as innumerable other dangerous or ethically questionable inventions are regulated.

The Supreme Court's decision has a number of important

implications, both domestically and internationally. Among other things, there is concern that the decision sends a negative signal to current and prospective investors in biotechnology in Canada. The decision may also be seen as running against the grain of international efforts to harmonize intellectual property laws.

Investors and inventors are looking to see if Parliament will step in and provide a legislative fix to the court's decision. In this regard, the Canadian Biotechnology Advisory Committee, an independent committee advising the government on biotechnology related policy issues, has recommended that such patents be permitted (subject to various exemptions, including the human body at any stage of development). The recommendation has not as yet been acted upon.



While Parliament may act in this area, patents for genes, cells, and so on will in the meantime provide similar, or in some cases the same, protection as that which could have been obtained had higher life forms themselves been patentable. Notably, patents for genes and cells confer protection over anything containing the genes and cells, including higher life forms, so backdoor patent protection may be available. For example, in *Monsanto Canada Inc. v. Schmeiser*, (2002), the court upheld a ruling that Percy Schmeiser, a canola farmer, was liable for infringement because he grew canola plants that contained a gene and chimeric cell line patented by Monsanto. Since a plant is considered by Canadian Intellectual Property Office to be a higher life form, Monsanto's patent did not contain a claim to the canola plant itself. Even so, the plant was effectively protected because its constituent genes and cells were patented.

Unless and until Parliament steps into the fray, inventors of multicellular life forms seeking patent protection in Canada should include, where possible, claims to genes, cells, and the like. For those with pending applications, any claims to higher life forms should be similarly converted. With careful drafting, these types of claims may provide reasonably broad protection, as the Schmeiser decision illustrates. But where claims to genes or cells cannot be made, the protection of higher life forms must await a legislated override of the Supreme Court of Canada's decision.

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