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The Mouse that Roared on Animal Pharm:

Canadian Courts Rule that Mammals can be a Patented Invention

"There was considerable fanfare in this appeal that significant policy questions are at stake…there were arguments made against patenting the oncomouse based on human health, environmental and other concerns. However, all that is at issue in this appeal is the interpretation of the Patent Act and the determination of whether, on the basis of the evidence, the appellant's product is patentable in accordance with that interpretation… To the extent the appeal gives rise to policy questions, they are to be addressed by Parliament and not the Court."
Judge Rothstein, for the majority
Federal Court of Appeal, Canada, August 2000

"In all the circumstances of this case, including the limited role that our jurisprudence has assigned to the Courts in this area and the serious moral and ethical implications of this subject matter, it seems to me that Parliament is the most appropriate forum for the resolution of the issues in dispute here."
Judge Isaacs, Dissenting Opinion
Federal Court of Appeal, Canada, August 2000

In a split 2-1 decision, the Canadian Federal Court of Appeal ruled in favour of granting a patent to Harvard Medical School for the 'oncomouse,' a mouse genetically engineered to carry a cancer-causing gene. The decision marks another point in the 15-year battle in the Canadian courts over whether Mother Nature or a Harvard scientist invented the mouse and its offspring. The decision overturned a Federal Court ruling and the decision of Canada's Patents Commissioner. The trial judge in the earlier decision had argued that although Harvard invented a process for inserting a gene into a mouse, "they have not invented the mouse."

The decision to grant a patent for this multicellular, higher life form opens the door to patenting any non-human life form. To date, Canada has granted patents for single-cell life forms, including human cell lines, but not for multi-cellular ones. Harvard modified the mouse by inserting a gene to cause it to develop cancer for use in research. However, the patent that was granted extends to all non-human mammals, "from a shrew to a whale" that might be similarly genetically engineered, even though Harvard has not performed these modifications.

"For the first time in Canada, something that can look you in the eye is considered an 'invention,'" noted Julie Delahanty of RAFI. "The implications of this change in

Canadian patent law are profound and the outcome will be viewed with dismay by many nations who have been following the Canadian case closely." Developing countries are net importers of technologies and patented products, and for the most part are opposed to the patenting of life. Many of them have been following the case in Canada hoping it would strengthen their opposition to the life patenting provisions of the intellectual property (TRIPs) agreement of the World Trade Organization.

Quiet as a Mouse: The Canadian government has been noticeably silent on the political implications of the case. "They have used the courts to sidestep their responsibility to consider the ethics and impact of the patenting of life forms," says Delahanty. "The court rulings on this case have twice agreed that the issue of life patenting is more rightly decided by Parliament, yet the government continues to avoid the democratic process and is instead hiding beneath the judge's robes."

Through other official documents such as the Canadian Biotechnology Strategy, the present government has made it clear that they support the biotechnology industry's desire for patenting anything that moves. The decision in this case leaves them free to avoid broad public debate on the question of patenting life forms in Canada.

The Canadian Environmental Law Association (CELA) intervened in the case, arguing that the Federal Court decision should be upheld and that the patent should not be granted. Michelle Swenarchuk, Counsel and Director of International Programs for CELA argued that the Court is "not the appropriate body to determine this question, since it was not in the position of having before it all the information required for a full examination of the implications of life form patenting. Rather, the decision should be made by legislative review, after a full public debate of all the implications. If Parliament did consider the issue," adds Swenarchuck, "it could then decide whether there should be safeguards such as ethcial and environmental reviews, other public protections for food security and the protection of animals, the appointment of a body of ethical advisors or involvement of the public in decisions made by the Patent Office. Only Parliament, not the Courts, can ensure that such safeguards are in place for the public interest."

Mickey Mouse gets Real: Like the other copyrighted mouse, Mickey, the oncomouse, also serves corporate interests. Although the patent is owned by Harvard Medical School, an earlier commercialization arrangement leaves DuPont, a multinational 'Gene Giant,' not Harvard, entitled to exclusive license of the patent. DuPont has claimed patent protection on any anticancer product ever derived from the mice.

The corporate excitement around the oncomouse reached its pinnacle in 1988 when a major financial magazine labeled the mouse the 'product of the year.' "Animals can now have their genetic makeup altered to serve as a tool for corporate profit. They are no longer animals, but machines that are described as human inventions. This so-called invention is the ultimate 'better mouse trap,'" said Delahanty.

Allowing patents to be applied to engineered animals means that corporate interests can also impose the same kinds of conditions on livestock farming as they have on plant

agriculture elsewhere. In fact, the issue is much clearer since farmers who breed livestock would have to pay a royalty for resulting offspring. “Not only could this lead to further genetic erosion of domestic animals which are already being lost at a rate of 5% each year,” worries Delahanty, “but family livestock farms would resemble a modern version of feudal farms, with serfs paying the company royalties for their animal inventions.”

“This isn’t about curing cancer, this is about making money,” said Paul Muldoon, Executive Director of CELA. “I can see that many animals will be genetically altered, for whatever reason, and that industry will have control.”

Irresistible craving for cheese? There are currently approximately 250 applications pending in the Canadian Intellectual Property Office dealing with animal patents that have been on hold awaiting this decision. When asked to divulge the nature of these patents, Murray Wilson, a spokesman for the Patent Commissioner, stated: “Let your mind run wild… what people could dream up for getting the body of an animal to do.” In Canada, one need not leave all to the imagination. For example, within the next year mice will be incubating the eggs of women who risk damaging their ovaries because of medical treatment. A team at the Mount Sinai Hospital in Toronto has already successfully harvested human eggs from the back muscles of rodents. (see Day, Michael, "Mice to the rescue". New Scientist, 1 July 2000, Page 7).

In the interests of science?: The Canadian lawyers representing Harvard argued that “It is in the interest of the Canadian public to allow patents for higher life forms.” The Federal Court of Appeal majority decision agreed that without patent protection the “creation of inventions” would be discouraged.

Despite these claims, the appeal court judges and the lawyers for Harvard have ignored not only the literature demonstrating that patents stifle rather than encourage research, but also the history of the oncomouse itself. At the outset, DuPont made the oncomouse available for basic research for a comparatively low fee and with no restrictions. In 1988, DuPont entered into an agreement with Charles River Laboratories to breed and distribute the oncomice that included provisions for downstream royalties (in other words, any product developed using the mouse in the research would be subject to royalty payment). As a result, the restrictions have become so limiting on downstream revenues that few scientists are purchasing or using the oncomice in their research.

The need to obtain patent licenses has imposed a significant burden on the research community that is neither necessary nor desirable for research. CELA argues for “the free and unfettered exchange of the results of scientific research, a value now at risk due to increased commercialization of research, non-disclosure agreements, and the treatment of research results as ‘proprietary.’”

Of GM Mice or GM Men?: The court attempted to draw the line at people and warned that the decision does not endorse patents of human life. “The potential extension to human beings is an obvious concern,” stated Judge Rothstein for the majority. “The answer is clearly that the Patent Act cannot be extended to cover human beings. Patenting

is a form of ownership of property. Ownership concepts cannot be extended to human beings." Despite such bland reassurances, critics are not so confident.

The Canadian and other patent offices already allow patents on human genes and cell lines. In 1997, a patent was granted by the World Intellectual Property Organization (WIPO) on a sheep named Dolly, the world's first cloned mammal. The patents held by the Roslin Institute, responsible for the Dolly experiment, cover the use of the technology in all animals, including humans. The Institute claimed that they included humans simply to ensure that nobody else could lay claim to human cloning. Such good intentions are dubious given the rate of corporate takeover of small operations and the knowledge that once the legal precedent has been set for the patenting of humans, turning the clocks back is almost impossible.

The line between what is human and what is not and therefore what multicellular human organisms can be patented is becoming fuzzier everyday. "We're only a few genes ahead of being a salamander anyway," says Pat Mooney, Executive Director of RAFI. "Human genes and cells have already been patented. With the rapid advances in biotechnology and other technologies, it's hard to be overly confident that human beings will not eventually, also be the subject of a patent. Once you accept the patenting of life, there is virtually no way to keep the doors shut on the patenting of organs and any other parts of the human body that have a commercial application."

Source: Federal Court of Canada Docket A-334-98, President and Fellows of Harvard College and Commissioner of Patents et al, Judgment

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