Oncomouse in Canada: The Patenting of Higher Life Forms

Introduction:

Biotechnology is the means or way of manipulating life forms to provide desirable products for man’s use. 1 Typically this manipulation is done through genetic engineering. Genetic Engineering is the selective, deliberate alteration of genes by man in such a way as to allow it to produce endogenous proteins with properties different from those of the normal, or to produce entirely different proteins altogether. 2 By using different genetic engineering techniques, scientists are able to create organisms with specifically designed physical properties and genetic makeup. As a result of progression in biotechnology, many ethical and legal concerns have developed. Especially controversial among these issues is how the Canadian Patent Act 3 should treat the living products of biotechnology. Specifically, should higher life forms, such as the Oncomouse, be patentable under the Canadian Patent Act?

This paper will summarize the patent laws in Canada, highlighting the legal interpretation behind current Canadian policy in the patentability of higher life forms, in particular the genetically engineered Oncomouse, also know as the Harvard mouse.

The “Harvard mouse”:

Two scientists from Harvard Medical School gained the first patent for a living animal by the United States in April of 1988 for a “transgenic mammal, “commonly referred to as the “Harvard mouse” or “Oncomouse.” 4 The
Oncomouse is produced by micro-injecting active human breast cancer Deoxyribonucleic Acid (DNA) into a mouse embryo and next implanting this embryo into a “surrogate” female mouse. The resulting offspring is an organism with a high sensitivity to carcinogens, a predisposition to develop cancerous tumors, and the capacity to pass these unique characteristics on to its own offspring. This mouse provides scientists with a valuable tool for cancer research and carcinogen detection and thus its inventors have a great economic interest in sharing it with the world.

According to respondent’s Canadian patent application in *Commissioner of Patents v. President and Fellows of Harvard College* (a.k.a. “Harvard College”), a cancer-promoting gene (“oncogene”) is injected into fertilized mouse eggs as close as possible to the one-cell stage. The eggs are then implanted into a female host mouse and permitted to develop to term. After the offspring of the host mouse are delivered, they are tested for the presence of the oncogene. Those that contain the oncogene are called "founder" mice. Founder mice are mated with mice that have not been genetically altered. Fifty per cent of the offspring will have all of their cells affected by the oncogene, making them suitable for animal carcinogenic studies.

**Patent Protection in Canada Generally:**

The granting of patents is ultimately governed by the Commissioner of Patents pursuant to the Canadian Patent Act (hereinafter the “Patent Act” or the “Act”). The Act indicates that a patent will only be granted for an "invention," which section 2 defines 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.\textsuperscript{14}

Therefore, section 2 of the Canadian Patent Act sets forth the criteria for patentability. In order to be patentable, the art, process, manufacture or composition of matter must be considered an “invention.” Once considered an invention under section 2, this invention must be considered “new” and “useful.” The question which arises here is whether a higher life form can be considered an “invention,” as defined under the Patent Act, and subsequently whether is patentable. The crux of the legal dispute is what constitutes a "manufacture" or a "composition of matter."\textsuperscript{15}

The Oncomouse Patent in Canada:

\textit{The Patent Examiner’s Decision:}

Harvard filed its Canadian patent application for "Transgenic Animals" on June 21, 1985.\textsuperscript{16} Following a lengthy prosecution battle,\textsuperscript{17} the patent examiner issued a Final Action on March 24, 1993, rejecting claims 1 through 12 for a product patent.\textsuperscript{18} The examiner did, however, allow claims 13 through 26 which claim the process of making the transgenic mammal.\textsuperscript{19}

The examiner rejected the product claims because they did not fall within the definition of "invention" under section 2 of the Canadian Patent Act.\textsuperscript{20} In large part, this refusal was based on a strict reading of statutory subject matter.\textsuperscript{21} The Act 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." In his rejection, the examiner noted that, had Parliament intended to include animals as patentable subject matter, it would have expressly included animals in the definition of "invention." Moreover, the examiner relied on the Manual of Patent Office Practice's express exclusion of animals as statutory subject matter. In issuing his Final Action, the examiner also relied heavily on case law from *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)* (a.k.a. "Pioneer Hi-Bred") as evidence of the statutory bar on patenting animals.

*The Patent Appeal Board's Decision:*

The Commissioner of Patents confirmed the examiner's decision on August 4, 1995, following review and a hearing before the Patent Appeal Board. In particular, the Commissioner found that, in order to be eligible for a patent in Canada, something must be made under the inventor's control and the resulting product must be consistently reproducible. In evaluating these two factors, the Commissioner separated the claims into two distinct phases: (1) the preparation of the genetically modified embryo, and (2) the development of the embryo in the host mother's uterus. While the first phase did fall within the statutory definition of "invention," as a "manufacture" or "composition of matter," the laws of nature took over in the second phase. The Commissioner was strongly influenced by the Federal Court of Appeal's decision in *Pioneer Hi-Bred* in making this conclusion. Lacking "full control over all the characteristics of the resulting mouse," the inventor's influence only extended to the inclusion of the
cancer-forming gene. This lack of full control, the Commissioner found, proved insufficient to support the patentability of the product claims.33

The Harvard mouse at the Trial Division:

Harvard appealed the Commissioner's decision to the Federal Court of Canada Trial Division (Trial Division).34 The Trial Division judge recognized the U.S. Supreme Court decision in Diamond and Commissioner of Patents v. Chakrabarty (a.k.a. “Chakrabarty”) decision but expressed a preference for the dissenting view therein.35 This Chakrabarty dissent relied on the argument that the U.S. Congress would not have had to pass the Plant Patent Act36 and Plant Variety Acts37 using especially limited language if the Patent Act included living matter.38 Second, the dissent in Chakrabarty noted that the U.S. Congress specifically excluded patent protection for bacteria under the Plant Variety Act.39

The Trial Division judge, Judge Nadon, went on to list four distinct reasons for his refusal to grant patent rights to the product claims. First, Judge Nadon found that the inventor does not exercise sufficient control to warrant patentability.40 While Judge Nadon did not look to absolute control over every characteristic of the final product, he felt the complex genetic makeup of a higher life form, such as the oncomouse, did not meet the control requirements of the Patent Act,41 stating that "the ultimate end product which will result from the process is completely unknown and unknowable."42 Essentially, Judge Nadon was saying that, although the presence of the cancer-causing gene might have been new, the mouse itself was not new.43 Second, Judge Nadon found it appropriate to distinguish between human intervention and the laws of nature.44
In so doing, Judge Nadon noted that the complexity of the final product blurred the distinction between the two.\textsuperscript{45} Although the product might exhibit a single genetic characteristic resulting from human intervention, the remainder of the product results from complex laws of nature.\textsuperscript{46} As such, the inventors should not receive patent rights in those aspects that they could not and did not know.\textsuperscript{47} Third, Nadon took issue with reproducibility.\textsuperscript{48} The inventors' inability to predict the location, presence, and quality of the gene indicated a lack of reproducibility.\textsuperscript{49} The Oncomouse cannot truly be reproduced "because too much is left to luck and chance."\textsuperscript{50} Fourth, the judge noted, "a complex life form does not fit within the current parameters of the Patent Act."\textsuperscript{51} Essentially, Nadon believed that the definition of statutory subject matter precluded animal patents. Based on these four issues, the judge dismissed the appeal.\textsuperscript{52}

\textit{The Harvard mouse at the Court of Appeals:}

The Appeal Division later reversed the Trial Division’s decision.\textsuperscript{53} The Appeal Division took the appeal solely to decide "whether the product claims amounted to an 'invention' within the meaning of that term in section 2 of the Patent Act."\textsuperscript{54} The court found that the product claims did in fact qualify, stating that the invention fell within the meaning of a "composition of matter."\textsuperscript{55} Here, the court borrowed the definition of "composition of matter" given in \textit{Chakrabarty} - "all compositions of two or more substances and ... all composite articles, whether they be results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders, or solids."\textsuperscript{56} Canada's Parliament relied heavily on the U.S. patent laws in drafting their own, similar version of a patent
The Appeals Division acknowledged Parliament’s reliance on U.S. patent laws by agreeing with the reasoning in *Chakrabarty*, which found that the U.S. Congress intended the language of the patent law to be read broadly. Literally speaking, the Appeal Division deemed the Oncomouse a composition of matter because it results from the combination of DNA and a mouse egg. More importantly, the majority concluded that the definition of "composition of matter" did not exclude living organisms. Thus, the Patent Act itself, which relies on this definition to determine patentable subject matter, did not exclude living organisms either.

The Appeal Division found that both the Patent Commissioner's inference that *Chakrabarty* bore no relevance and the Trial Division's reliance on the dissenting view in *Chakrabarty* were in error. The Appeal Division felt that the decision in *Chakrabarty* was relevant in large part because U.S. patent law provided guidance to Canada in modeling its own patent laws. While the decisions of U.S. courts do not constitute binding authority under the principle of stare decisis, they could represent persuasive authority in cases where particular statutory similarities exist, as was the case here. Finding the logic of the majority in *Chakrabarty* more persuasive, the majority in the Appeal Division "placed significant reliance on it in concluding that the definition of 'invention' did not exclude from patentability higher life forms such as the oncomouse."

As for the issue of control, the Court of Appeal held that the control test applies only to process claims, not product claims. While a certain degree of control must exist in order for the invention to meet the usefulness requirement of the Patent Act, both the Patent Commissioner and the Trial Court applied a
much broader test. In fact, the court believed that determining the type and degree of control would unnecessarily complicate patentability analysis. The Appeals Division held that the Commissioner of Patents and the Trial Judge read into the definition of “invention” words not expressed by Parliament, or implied by the language used by Parliament, and in doing so, erred in law. On the control issue, the court ruled:

usefulness is necessary for patentability and implies control in the sense that the desired result will be achieved when the product is used or produced. The desired result herein is an oncomouse with susceptibility to cancer for use in carcinogenicity studies. Once that has been achieved, control over other characteristics of the mouse is irrelevant. If the product is a composition of matter that is new, useful and unobvious, it is a patentable “invention”.

Adopting a level of control that meets the usefulness requirement, the court stated:

All that is important for the usefulness of the product ... is that, using the methods described by the inventors, a mouse is produced with all of its cells affected by the oncogene. That the other genes of the mouse are not under the control of the inventors does not detract from the usefulness of the invention.

Thus, the inventor need only control the important usefulness feature; lack of control over other aspects of the invention proved irrelevant.

On the topic of reproducibility, the court found that the specification sufficiently disclosed a process by which a person skilled in the art could compound the same composition of matter. "Provided disclosure is sufficient to enable another person skilled in the science to make and use the product, [the 27(3)(b)] requirements have been met." The statute only requires that the applicant sufficiently disclose the steps for carrying out the manufacture.
Court’s analysis suggests that the process need not work every time. The court noted that if reproducibility truly had been at issue then process claims should have been disqualified as well. Since they were not, the court reasoned, reproducibility was not truly at issue.

The distinction between lower and higher life forms also presented an inappropriate distinction according to the Appeal Division. Here again the court relied on the Chakrabarty decision, noting that no such limitation was found in the similar U.S. patent statute. Moreover, the Appeal Division determined the Trial Judge erred in finding that complex life forms were not within the parameters of the Patent Act when they agreed with the conclusion in Chakrabarty that the issue of patentability for higher life forms was a matter of policy that would be better resolved by the Canadian Parliament. The Appeal Division explained “there may be policy reasons against patentability of higher life forms, however, such arguments are for Parliament, not for courts.”

In contrast to the Trial Division, the Appeal Division noted that the protection afforded by allowing patent rights for the process claims provided insufficient protection for the invention. Because the process for creating the genetically modified mammal involved numerous complicated procedures and was not wholly dependable due to uncontrollable factors in genetic engineering, competitors would instead choose to breed a founder mouse in order to get at the product. To protect the invention itself, "what was needed was a patent on the organism.”

Finally, the Appeal Division believes the Trial Judge and Commissioner of Patents erred in putting too much emphasis on the Federal Court of Appeal’s
decision in *Pioneer Hi-Bred*. In *Pioneer Hi-Bred*, the result of cross-breeding of soybeans was found to be unpatentable because obtaining a new variety of soybean through cross-breeding and cultivated naturally did not represent an invention within the meaning of section 2 of the Patent Act. The findings in *Pioneer Hi-Bred* were distinguished from the case at bar by the Appeals Division, because the oncomouse “involves inventive ingenuity and intervention at the genetic level and the creation of a specific new life form.” As a result, because the Harvard mouse resulted from the addition of genetic material, the *Pioneer Hi-Bred* decision did not bar the issuance of a patent.

In his dissenting opinion, Judge Isaac disagreed with the Appeal Division’s interpretations of the *Pioneer Hi-Bred* and *Chakrabarty* decisions. He remarked that the definitions of "manufacture" and "composition of matter" as defined by the U.S. Supreme Court in *Chakrabarty* were expressly rejected by the Appeal Division in *Pioneer Hi-Bred*. He also argued that the Supreme Court of Canada impliedly refused to adopt the *Chakrabarty* definitions when it dismissed the appeal in *Pioneer Hi-Bred*.

**Supreme Court of Canada Decision:**

The Supreme Court of Canada accepted the Harvard mouse case to determine “whether Parliament intended the definition of invention to be interpreted broadly enough to encompass higher life forms.” In order to make that conclusion, the Court specifically asked “whether the words “manufacture” and “composition of matter,” in the context of the Patent Act, are sufficiently broad to include higher life forms.” In its analysis of this question, the Court
highlighted four distinct areas: the words of the Act, the scheme of the Act, the object of the Act, and related legislation (the Plant Breeders’ Rights Act).

**Words of the Act:**

Both parties in the Harvard mouse appeal submitted definitions of the terms “manufacture” and “composition of matter” that were approved in *Pioneer Hi-Bred Ltd. v. Commissioner of Patents (a.k.a. “Pioneer”)* at the Court of Appeal, but which were originally derived from the United States Supreme Court’s decision in *Chakrabarty*. In *Chakrabarty*, the U.S. court examined the provision 35 U.S.C. 101 of the United States Patent Act, where it stated 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 U.S. Patent Act defines “manufacture” as:

> the production of articles for use from raw materials, prepared by giving to these materials new forms, qualities, properties, or combinations whether by hand labor or machinery.

The Supreme Court of Canada found the Harvard-mouse unpatentable under the words of the Patent Act. In particular, the Court looked at the meaning of the words “manufacture” and “composition of matter”. As to the definition of a “composition of matter,” the court found the *Chakrabarty* definition too broad, finding that the words did not encompass higher life forms. The Harvard-mouse was not a “composition,” as defined by the Oxford English Dictionary, because it did not consist of ingredients or substances that had been
mixed together by a person. Moreover, the word “matter” only captured one aspect of a higher life form. In writing the opinion of the Supreme Court of Canada’s decision, Justice Bastarache stated “higher life forms are generally regarded as possessing qualities and characteristics that transcend the particular genetic material of which they are composed.” With respect to the word “manufacture,” after reviewing a series of dictionary and case-law definitions, the court found “that the word would commonly be understood to denote a non-living mechanistic product or process.” The Court reasoned that “just as “machine and “manufacture” do not imply a living creature, the words “composition of matter” are best read as not including higher life forms.” Consequently, the Supreme Court of Canada decided that the Oncomouse was unpatentable as a higher life form.

Scheme of the Act:

According to the Supreme Court of Canada, the scheme of the Patent Act did not support patentability for higher life forms. The Court repeatedly cautioned that the issues involved were best left to Parliament rather than the courts. The above interpretation of the words of the Act finds support in the fact that the patenting of higher life forms raises unique concerns which do not arise in respect of non-living inventions and which are not addressed by the scheme of the Act. The Supreme Court reasoned that the fact that the Act is ill-equipped to deal appropriately with higher life forms as patentable subject matter is an indication that Parliament never intended the definition of invention to extend to this type of subject matter. While some policy concerns, such as the
environmental and animal welfare implications of biotechnology, are more appropriately dealt with outside the patent system, other concerns are more directly related to patentability and to the scheme of the Act. Justice Bastarache in writing the majority opinion further reasoned that these concerns illustrate the fact that the Patent Act in its current form is not well suited to address the unique characteristics possessed by higher life forms. The lack of direction currently in the Act to deal with issues that might reasonably arise signals a legislative intent that higher life forms are currently not patentable. Therefore, the Supreme Court of Canada felt that they do not possess the institutional competence to deal with issues of this complexity, which presumably will require Parliament to engage in public debate, a balancing of competing social interests, and intricate legislative drafting.

Object of the Act:

The object of the Act did not support a finding of patentability, according to the majority. Acknowledging the central objects of the Patent Act as advancing research and development and encouraging broader economic activity, the Court nonetheless noted that "Parliament did not leave the definition of invention open, but rather chose to define it exhaustively." Thus, despite the objects of the Act, an invention must still be within the terms of the Act to be patentable.

Related Legislation:
In making its decision, the Court focused on the Plant Breeders' Rights Act as a statutory example that the Patent Act did not cover higher life forms. The Plant Breeders' Rights Act, as noted by the Court, was much better suited to protecting the particular characteristics of plants than the Patent Act. "Since other higher life forms share many of these characteristics, it is reasonable to assume that Parliament would choose to protect these life forms through legislation other than the Patent Act or through an amended Patent Act that is better suited to the subject matter." In addition, "the passage of the Plant Breeders' Rights Act demonstrates that mechanisms other than the Patent Act may be used to encourage inventors to undertake innovative activity in the field of biotechnology." Thus, despite economic arguments in favor of patentability, the Court found that Parliament could find alternative modes of protection more in line with higher life forms that the Patent Act.

The Oncomouse in Other Jurisdictions:

The Oncomouse has been held patentable, and is now patented in jurisdictions that cover Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, the United Kingdom and the United States. A similar patent has been issued in Japan. New Zealand has issued a patent for a transgenic mouse that has been genetically modified to be susceptible to HIV infection. Indeed, it seems that no country with a patent system comparable to Canada's (or otherwise) has refused a patent on the Oncomouse upon submission of an application within their jurisdiction.

2 Id. at 103.


5 See Note 4 at 465.


8 Id.

9 Id.

10 Id.

11 Id.

12 Id. at 2.


17 Id. at 538-45 (Isaac, J.A. dissenting) (describing prosecution history).


19 Id.


24 M.O.P.O.P 12.03(a) (Can.) ("Plants and animals are not patentable subject matter.")

The Plant Patent Act of 1930 provides in relevant part: "Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated spores, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated states, may obtain a patent therefore... ." 35 U.S.C. 161 (2000).

The Plant Variety Protection Act of 1970 provides in relevant part: "The breeder of any novel variety of sexually reproduced plant (other than fungi, bacteria, or first generation hybrids) who has so reproduced the variety, or his successor in interest, shall be entitled to plant variety protection therefore .... ." 84 Stat. 1547, 7 U.S.C. 2402(a) (2000).

50 Id.
51 Id.
52 Id.
53 Id. at 606.
55 Id.
56 Id. at 572 (quoting Diamond v. Chakrabarty, 447 U.S. 303, 319 (1980)).
59 Id.
62 Id. at 580.
63 Id.
64 Id. at 582 (citing H.G. Fox, The Canadian Law and Practice Relating to Letters Patent for Invention 6 (4th ed. 1969)).
65 Id. at 585.
66 Id. at 586-87.
67 Id. at 587.
68 Id.
69 Id. at 531
70 Id.
71 Id. at 588.
72 Id. at 591.

73 Patent Act, R.S.C., ch. P-4, 27(3)(b) (1985) (Can.), provides in relevant part: (3) The specification of an invention must ... (b) set out clearly the curious steps in a process, or the method of constructing, making, compounding or using a machine, manufacture, or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it.

75 Id.

76 Id. at 591.

77 Id. at 590.


79 Id.


81 Id.

82 Id.

83 Id.


86 Id. at 532.


89 Id.

90 Id. at 556.

91 Id.


93 Id.


96 Title 35 *U.S.C. 101*

97 *Chakrabarty* at 193.

98 Id.

99 Id. at 29.

100 Id.
101 Id at 38.

102 Id.


104 Id. at 35.


107 Id.


109 Id.

110 Id.

111 Id at 7.

112 Id.

113 Id.


116 Id.


119 Id.

120 Id.


123 Id.

124 Id.