

# Patent Pending

## Are Higher Life Forms Patentable?

PAUL

RATANASEANGSUANG

IS A SECOND YEAR

LAW STUDENT AT

THE UNIVERSITY

OF VICTORIA. HE

COMPLETED HIS

BACHELOR OF SCIENCE

IN PSYCHOLOGY AT

THE UNIVERSITY OF

CALGARY.

Biotechnology” encompasses the activities of science as they are applied to living organisms.<sup>1</sup> It is made up of a number of sub-disciplines, the most notable of these being “genetic engineering.” Genetic engineering involves altering the genetic makeup of cells by deliberately inserting, removing or altering individual genes.<sup>2</sup> By utilizing these techniques, scientists are able to create organisms with specifically designed physical properties and genetic makeup.

It is evident that such an area of scientific research and practice touches on a multitude of ethical and legal dilemmas. Especially controversial among these issues is how the Patent Act<sup>3</sup> should treat the living products of biotechnology. Specifically, should it be possible to patent genetically engineered higher life forms such as plants and animals?

This paper will canvass the law in Canada, illuminate the legal reasoning behind the current Canadian policy, and will attempt to predict the directions that the law may follow when the federal court speaks upon the patentability of the genetically engineered “Oncomouse.”

### Introduction to the Oncomouse

The world’s first patent for a living animal was granted by the United States in April of 1988 to a pair of inventors from Harvard Medical School for a “*transgenic mammal*,” commonly referred to as the “Harvard-mouse” or “Oncomouse.”<sup>4</sup> The Oncomouse is produced by micro-injecting active human breast cancer Deoxyribonucleic Acid (DNA) into a mouse embryo<sup>5</sup> and subsequently implanting this organism 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. The Oncomouse represents a valuable tool for both human breast cancer research and the detection of carcinogens in food and the environment.

The patent owners possess a legal right to prevent other inventors from making, using, or selling any genetically altered mammal with human breast cancer DNA.<sup>6</sup> This

1 *Canadian Dictionary of the English Language* (ITP Nelson: Toronto 1997) at 139.

2 S. Chong, “The Relevancy of Ethical Concerns in the Patenting of Life Forms” (1993) 10 *Canadian Intellectual Property Reporter*, 190.

3 Patent Act, Revised Statutes of Canada 1985, c. P-4.

4 R.E.Fishman, “Patenting Human Beings: Do Sub-Human Creatures Deserve Constitutional Protection?” (1989) *American Journal of Law and Medicine*, 465.

5 See note 4 at 465.

6 See note 4 at 465.

The real issue in this appeal is the patentability of a form of life.

would also include *all* offspring of the genetically altered mice which reveal these traits. Patent protection has also been issued in other parts of the world for the Oncomouse. The Oncomouse is a patented invention in both Japan and Europe.<sup>7</sup>

### The Oncomouse in Canada

A Canadian patent application for the Oncomouse was filed by its inventors on June 21, 1985.<sup>8</sup> This application was initially rejected by the Canadian Patent authorities, but subsequently was submitted to the Patent Appeal Board for review.<sup>9</sup> In August of 1995, the Patent Appeal Board upheld its earlier decision and issued a second rejection which was released on August 4th, 1995.<sup>10</sup> The basis for the rejection, which will be discussed in detail below, was that the patent claims for a “transgenic mammal” fell outside the definition of “invention” as stated in section 2 of the Patent Act.<sup>11</sup>

7 R.A. Rae, “Patentability of Living Subject Matter” (1993) 13 Canadian Intellectual Property Reporter, 43.

8 Decision of the Commissioner of Patents on Application 484,723 released on Aug. 4, 1995 at 1.

9 See note 8 at 2.

10 See note 8 at 1.

11 Appellant’s Memorandum of Fact and Law, in *President and Fellow of Harvard College v. Commissioner of Patents*, Federal Court of Canada Trial Division, Court File No. T-275-96, at 6.

## Patent Protection Generally

The granting of patents is ultimately governed by the Commissioner of Patents pursuant to the Patent Act.<sup>12</sup> 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.<sup>13</sup>

Thus, section 2 indicates that there are two requirements for receiving a patent. First, the item for which the patent is needed must be an “invention,” and second, that invention must be both “new” and “useful.” As will be demonstrated, it is the interpretation of the general term “invention” which has given rise to the debate over whether a higher life form is patentable. In particular, there is considerable disagreement as to what constitutes a “manufacture” or a “composition of matter.”

## Previous Jurisprudence

In the case of the Oncomouse, section 2 has been interpreted as **not** applying to patent claims for a “transgenic mammal.” This interpretation is consistent with the most recent Canadian jurisprudence regarding the patenting of higher life forms. In fact, according to the Commissioner of Patents, the rejection of the Oncomouse as a candidate for a patent was “strongly influenced” by the Federal Court of Appeal decision in *Pioneer Hi-Bred Ltd. v. Commissioner of Patents* (“*Pioneer*”).<sup>14</sup>

Before beginning a discussion of the *Pioneer* case, it will be helpful to examine the jurisprudence that preceded this decision. Prior to *Pioneer*, the Patent Appeal Board had granted patents for fungi and certain living micro-organisms. In fact, it appeared as though this trend would be extended to higher life forms.<sup>15</sup> For example, in *Re Application of Abitibi* (“*Re Abitibi*”) <sup>16</sup> it was held that a culture of five known fungi which had been adapted to live on various effluents produced from wood pulp processing did constitute patentable subject matter. The Patent Appeal Board further suggested in *Re Abitibi* that it saw no reason why the patentability of living organisms should not be extended to higher life forms such as plants and animals provided they meet the requirements of the Patent Act.<sup>17</sup>

Despite the optimistic remarks of the court in *Re Abitibi*, the likelihood that higher life forms such as plants and animals could be patented was attenuated by the decision in *Pioneer*.<sup>18</sup> In this case, the applicant sought to patent a new variety of soybean plant that was produced by traditional cross-breeding techniques, but which still required direct human intervention in the breeding process. Despite this element of scientific intervention, the Federal Court of Appeal in *Pioneer* rejected the soybean patent application on the ground that a plant variety produced by cross-breeding did not fall within the definition of “invention” as set out in section 2 of the Patent Act.<sup>19</sup> The court specifically stated that the plant could not be considered a “manufacture” nor a “composition of matter.” This rejection was appealed, and the issue of higher life form patentability was put before the Supreme Court of Canada in 1989. Unfortunately, the Supreme

12 Patent Act, see note 2.

13 Patent Act, see note 2.

14 Decision of the Commissioner of Patents on Application 484,723 released on Aug. 4, 1995 at 7 affirming *Pioneer Hi-Bred Limited v. Commissioner of Patents*, [1987] F.C. 8 (Federal Court of Appeal).

15 *Re Application of Abitibi Co.* (1982), 62 Canadian Patent Reporter (2d) 81 at 89.

16 See note 15 at 90.

17 See note 15 at 90.

18 *Pioneer Hi-Bred Limited v. Commissioner of Patents*, [1987] F.C. 8 (Federal Court of Appeal) hereinafter “*Pioneer*.”

19 See note 18 at 495-496.

Court disposed of the case on an issue entirely distinct from whether or not higher life forms should be patented.<sup>20</sup> In fact, the decision turned on the fact that the patent application did not properly disclose the invention.<sup>21</sup> Nevertheless, the Supreme Court did indicate that: “*The real issue in this appeal is the patentability of a form of life.*”<sup>22</sup> Further, the court clarified that two types of genetic engineering exist. The first type involves an actual change in the genetic material, via a molecular or chemical process, while the second type consists of crossing different plant breeds through traditional methods.<sup>23</sup> Supreme Court Chief Justice Lamer specifically remarked that the products of the latter method did *not* appear to be patentable subject matter. However, he did not comment on the patentability of organisms produced by the former method presumably because the case could be decided solely upon the technical matter of disclosure.

The decision in *Pioneer* represented both the first and last time that the issue of higher life form patentability has come before a Canadian federal court. Although the Commissioner of Patents has referred to the case as a means by which to interpret section 2 of the Patent Act, it is, in fact, of limited guidance due to the Supreme Court’s reluctance to directly address the patentability issue. Nonetheless, *Pioneer* has clearly set the stage for a court to rule upon the patentability of higher life forms which have been produced by “true” genetic engineering.

#### *President and Fellows of Harvard College v. Commissioner of Patents*

The Commissioner of Patent’s 1995 rejection of the Oncomouse patent application was appealed by its inventors to the Federal Court of Canada in November of 1997. Once again, the subject of higher life form patentability must be addressed by the Federal Court, and in this instance, it is unlikely that the court will be able to side-step the primary issue of whether or not patents should be granted for higher life forms. The decision of the court is still pending.

In their appeal, the inventors will attempt to demonstrate that a number of assertions made by the Commissioner of Patents (Respondent) in the previous decision are incorrect.<sup>24</sup> To this end, the appellants have broken down their analysis into a number of closely related sub-issues. However, the Commissioner submits that these sub-issues are more accurately characterized as *factors* which should be used to determine the “true” issue of whether or not a transgenic non-human animal is an “invention” within the meaning of section 2 of the Patent Act.<sup>25</sup>

The Commissioner’s assertion that there is only one true issue to be decided is a correct one.<sup>26</sup> Are the animals in question “inventions” as defined under section 2 of the Act? The Commissioner submits that the transgenic mammal in question is *not* an “invention” because there has not been a sufficient degree of control exercised in its creation. He distinguishes previously granted patents which have only been for simple organisms and asserts that the Oncomouse is a much more complex organism. The Commissioner argues that the Appellants have claimed a “transgenic mammal with an activated oncogene sequence,” while their disclosure is only sufficient to reproduce *one* of the qualities of the described mammal – a predisposition to cancer.<sup>27</sup> He contends

20 *Pioneer Hi-Bred Limited v. Canada (Commissioner of Patents)*, [1989] 1 Supreme Court Reports 1623 at 1643.

21 Section 23 of the Patent Act requires the inventor to make specification correctly and fully of the apparatus so that an inventor of ordinary skill in the art could recreate the invention. In this instance, the court held this requirement was not met. This conclusion was influenced by the fact that random chance was a factor in the successful manufacture of the invention. See note 20 at 1643.

22 See above at 1632.

23 See above at 1633.

24 See note 11 at 2.

25 Respondent’s Memorandum of Fact and Law, in *President and Fellow of Harvard College v. Commissioner of Patents*, Court File No. T-275-96.

26 See note 25 at 4.

27 See note 25 at 6.

that in order for an organism to constitute an “invention,” the inventors must exert a significant degree of control over the organism.<sup>28</sup> The Oncomouse is not considered “fully invented” because it is a higher life form and as such is characterized by a level of complexity beyond what the inventor has disclosed in his application.

Even if the invention were to meet the “degree of control” test as is set out above, the Commissioner maintains that the patent application must still fail under a broader ground of attack. He would argue that the subject matter does not come within the definition of “manufacture” or “composition of matter” as stated in section 2 without “greatly distorting their ordinary meanings.”<sup>29</sup>

### “Manufacture” and “Composition of Matter” Defined

Both parties in this appeal have submitted definitions of the terms “manufacture” and “composition of matter” that were approved in *Pioneer* at the Court of Appeal, but which were originally derived from the United States Supreme Court decision in *Diamond and Commissioner of Patents v. Chakrabarty* (“*Diamond*”).<sup>30</sup> In *Diamond*, a U.S. court examined the corresponding provision, 35 U.S.C. § 101 of the U.S. Patent Act.<sup>31</sup> It was stated there 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.<sup>32</sup>

The U.S. 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.<sup>33</sup>

The Appellants propose that according to the plain and ordinary meaning of the terms, a transgenic, non-human mammal is both a “manufacture” and a “composition of matter.”<sup>34</sup> It qualifies as a “composition of matter” because it is produced by combining a gene with a fertilized mammalian egg. This necessarily involves both a “mechanical union” (micro-injection) and a “chemical union” (integration of the gene into the chromosomes). This new composition of matter is also a “manufacture” because it is produced by “hand labour” and results in a “new form” – the transgenic mammal.<sup>35</sup> The Appellants submit that the patent application is valid on this basis.

### Summary of the Oncomouse Appeal

The Commissioner and the inventors agree that the central issue to be addressed in the case is whether or not a higher life form can be patented, and that specific definitions should be used to determine whether that subject matter is patentable. Despite this initial accord, each party focuses on different aspects of the patentability issue in order to arrive at its own conclusions.

On the one hand, the Commissioner of Patents has emphasized that because the organism at issue is more complex than organisms which have been patented in the past, the Oncomouse does not fall within the section 2 definition of “invention.” In order for the Oncomouse to qualify as an “invention,” the inventors would have to

28 See note 25 at 5.

29 See note 25 at 8.

30 *Diamond, Commissioner of Patents and Trademarks v. Chakrabarty* (1980), 206 U.S.P.Q. 193 at 193.

31 Title 35 U.S.C. §101

32 See note 30 at 193.

33 See above at 193.

34 See note 11 at 21.

35 See above at 21.

exercise a greater level of control over the entire genetic engineering process. Furthermore, it is contended that the ordinary meanings of “manufacture” and “composition of matter” do not encompass the Oncomouse.

On the other hand, the Appellants contend that this “control” requirement functions to allow for the patenting of lower life forms while denying the patent for higher life forms which are inherently complex. This uneven application of the Patent Act would arguably constitute an error in law. In support of this position, the appellants have held up section 40 of the Patent Act which states that the Commissioner may reject applicants which are not “by law entitled to be granted a patent.” The appellants contend that there is no authority to reject an application merely because the subject matter is increasingly complex. The inventors further argue that the subject matter of the Oncomouse is both a “manufacture” and a “composition of matter” pursuant to section 2 of the Patent Act.

### Considerations

While the Federal Court has been asked to make a decision based upon the above-mentioned legal criteria, it is inevitable that broader policy issues and societal attitudes will play a major role in the final outcome. Although it is not the intention of this paper to provide an in-depth analysis of the moral concerns relating to the patenting of biotechnology,<sup>36</sup> it is important to be aware that these and other factors will influence the final outcome.

The most recent Canadian jurisprudence advocates taking an extremely cautious approach towards the patenting of higher life forms. This reluctance is in direct contrast to the earlier, more liberal interpretation that was established in *Re Abitibi*. The Commissioner of Patents has indicated that the opinions expressed in *Pioneer* at the Court of Appeal have been influential in the previous and continuing rejection of the Oncomouse patent application. However, as suggested above, it is arguable that the remarks in *Pioneer* should be confined to the facts of that case – not only because the Supreme Court eventually decided upon other grounds, but also because there was no statement at the Court of Appeal which indicated anything more than a refusal to extend patentability to a “unique but simple variety of soybean.”<sup>37</sup> Nonetheless, while *Pioneer* does not per se prohibit the patenting of higher life forms produced by true genetic engineering, it clearly establishes that there exists an atmosphere of caution among the judiciary when it comes to the interpretation of section 2.

The Canadian approach to the patentability of higher life forms stands in direct contrast to that of the U.S. which advocates the patenting of “everything under the sun made by man.”<sup>38</sup> Although Canadian courts are often reluctant to use U.S. precedents when interpreting Canadian statutes, in this specific instance, there is a close factual tie between the two jurisdictions which renders the U.S. jurisprudence particularly relevant. In fact, section 2 of the Canadian Patent Act is markedly similar to the 35 USC 101 provision which acts to protect “anyone who invents or discovers, a process,

*The Canadian approach to the patentability of higher life forms is in direct contrast to that of the U.S. which advocates the patenting of ‘everything under the sun made by man.’*

36 Further reading can be found in S. Avisar, “The Ethics of Biotechnology – The Arguments in Favour of Patents” 10 Canadian Intellectual Property Reporter 209; and in S. Chong, “The Relevancy of Ethical Concerns in the Patenting of Life Forms” 10 Canadian Intellectual Property Reporter 189.

37 *Pioneer Hi-Bred Limited v. Commissioner of Patents*. [1987] F.C. 8 at 14. (Federal Court of Appeal).

38 See note 24 at 197.

machine, manufacture, composition of matter, or improvement thereof.” It is a well acknowledged fact that “the statutory provisions of Canadian law have borrowed extensively from the United States system.”<sup>39</sup> Furthermore, in this particular appeal, both the appellants and the respondents advocate that we should define “manufacture” and “composition of matter” according to the U.S. court’s definition in *Diamond*. It should be recalled that in that instance, it was decided that human-made, genetically engineered bacteria were patentable subject matter, and the *Diamond* case has led the way for a U.S. tradition of expansive patent protection. While Canada should certainly maintain an independent jurisprudence, it should also not neglect the fact that its patent legislation has drawn from a U.S. source. The U.S. jurisprudence clearly advocates the patenting of higher life forms. Many Canadian patents are issued for foreign technology that is developed in the U.S. Moreover, the fact that biotechnology is moving towards a trend of international globalization constitutes yet another reason why the Canadian Patent Office should look beyond the Canadian jurisprudence and patenting tradition when it decides the issue of patenting higher life forms.

The movement to procure patent protection for living organisms has been met with substantial resistance from opponents. Individuals who oppose the patenting of higher life forms are generally also opposed to genetic engineering and genetic research. Typically, the concerns of these individuals relate to the sanctity of life, the fear of “playing God,” and the risk that there exists a slippery slope of interference with the natural order that could potentially lead to “unholy” consequences. These are important concerns and should in no way be minimized by trivializing the values that underlie them. Keeping this in mind, it is arguable that the majority of persons who oppose the granting of patents for higher life forms do so because they are opposed to the research activity itself and not to the possibility that such activity might receive patent protection. Therefore, this opposition appears to represent an inappropriate importation of ethical concerns into the patent system.<sup>40</sup>

The Canadian courts and the general public need to be aware that the Patent Act does not regulate (nor does it attempt to regulate) the subject matter over which it considers patentable. The object of the Patent Act is to encourage research and the sharing of information. It attempts to do so by providing the opportunity for an inventor to gain financial reward from the efforts of his or her ingenuity, scientific know-how, and subsequent disclosure of the technology. This opportunity takes the form of an exclusive right to make, use, or sell a particular invention. In essence, the inventor is granted a limited form of property right over a particular manufacture or composition of matter. Should this property right be extended to a genetically engineered mammal? Such rights have already been granted over simple organisms; does the situation differ for complex mammals? These questions become more urgent as the life forms under consideration approach human and human-likeness. The answers to them lie in how society views genetically engineered animal life and where it chooses to draw the distinction between animals that are proper subjects of genetic engineering and those

39 I. Goldsmith, *Patents of Invention* (Toronto: Carswell, 1981).

40 For an opposing viewpoint, see S. Chong, “The Relevancy of Ethical Concerns in the Patenting Life Forms” 10 *Canadian Intellectual Property Reporter* 189.

that are not. This question cannot be answered strictly by the Patent Act.<sup>41</sup>

The fact that the Patent Office refuses applications made upon a particular subject matter simply means that subject matter is unregulated by patent legislation. It does not amount to a prohibition upon the use of that technology, nor does it mean that there will be a reduction in the use of products which utilize that technology. The current practice of refusing to patent higher life forms merely encourages companies to conduct research of this type outside Canada – the products of which are not prevented from being used in Canadian industry. Further, it forces researchers to seek other methods, such as keeping the information secret, in order to protect their inventions. Arguably, a situation where genetic research activities go undisclosed is not a desirable one for the overall good of our society.

While it is possible that revising current policy in order to allow the patenting of higher life forms might conceivably encourage more research in this area (which is the objective of the Patent Act), it does not follow that it will then become more difficult to regulate genetic engineering practices. In fact, by allowing a more liberal interpretation of section 2, the courts arguably make room for Parliament to enact specific legislation regulating the fruits of biotechnology. This is the more appropriate and measured approach to take if we are to achieve a satisfactory resolution to the issue of genetic engineering.

Irrespective of which factors the court eventually considers in its decision, it should be recalled that the “Harvard mouse” patent has led the way in the United States, Europe and Japan for the patenting of higher life forms. Despite the atmosphere of conservatism in the Canadian courts, it is likely that a conclusive decision regarding the patentability of higher life forms will once again follow in the wake of the Oncomouse patent application. The decision is being awaited.

*This paper would not have been possible without the assistance of Michael Manson and Chris Robinson of Smart & Biggar of Vancouver. Any errors remain the responsibility of the author.*

<sup>41</sup> Directly addressed by S. Chong, see above.