

FEDERAL COURT OF APPEALS RULES ONCOMOUSE PATENTABLE

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The Federal Court of Appeal of Canada, in a landmark, but split, decision, rendered on August 3, 2000 (*President and Fellows of Harvard College v. Canada (Commissioner of Patents)*), reported at (2000) F.C.J. 1213), ruled that a transgenic non-human mammal, hereinafter referred to as “oncomouse”, falls within the definition of the term “invention” as defined in section 2 of the Canadian *Patent Act*. In this case, Harvard College has been attempting for more than fifteen years to obtain a patent on its oncomouse, which has been patented in the United States and Europe.

In lower jurisdictions, the oncomouse was deemed unpatentable. The Commissioner of Patents restrictively interpreted the term “invention” of section 2 of the Canadian *Patent Act*, to conclude that the terms “manufacture” and “composition of matter” refer respectively to something that is fabricated under the full control of the inventor and to something that is identically reproducible. In his opinion, and in the opinion of the Patent Appeal Board, these criteria were not met by this invention, in a decision rendered August 4, 1995.

The Trial Division of the Federal Court confirmed the Commissioner’s decision in a judgement rendered by Mr. Justice Nadon (reported at (1998) 3 F.C. 510 (FCTD)). While admitting that most inventions do involve the laws of nature, he ruled that products that are the result of human intervention with the laws of nature are not patentable. According to Justice Nadon, the fact that there had been human intervention in the insertion of a particular gene in a zygote could not give rise to patentability of the resulting embryo, and developed mammal. Nadon J. further distinguished between lower and higher life forms, and judged that lower life forms are patentable in view of the decision rendered in *Pioneer Hi-Bred Ltd.v. Canada (Commissioner of Patents)*((1987) 3 F.C. 8 (FCA), affirmed (1989) 1 S.C.R. 1623), but that higher life forms were not.

In order to be deemed patentable, an invention must meet the conditions of patentability, as defined by sections 2 and 27.3 of the Canadian *Patent Act* (R.S.C. 1985, c. P-4), *i.e.* novelty, utility and inventiveness (or unobviousness). In the case of the oncomouse, both lower jurisdictions had ruled that all three conditions had been met: the oncomouse is novel because it does not exist in nature, useful because of its implication in cancer research and inventive because of the human intervention involved in its production. The issue was to determine whether the oncomouse fit into the definition of "invention".

In the Court of Appeal, the oncomouse was held to be patentable, by a two to one decision. Mr. Justice Rothstein, speaking for the majority, inspired himself of the majority decision in *Diamond, Commissioner of Patents and Trademarks v. Chakrabarty* (1980), 206 U.S.P.Q. 193, to conclude that there is nothing in the Patent Act which prohibits the patentability of higher life forms. Rothstein J. broadly interprets the expressions "manufacture" and "composition of matter" by relying on the *Pioneer Hi-Bred* decision, which did not prohibit the issuance of a patent on a living life form. In the *Pioneer Hi-Bred* case however, the patent was refused since it was simply a cross-breeding of two plants. In another decision relied on by the majority, *Abitibi (Re Application of Abitibi Co., (1982), 62 C.P.R. (2d) 81 (PAB))*, the Commissioner held that micro-organisms could be the subject of patent applications. Rothstein J. further stated that the term "invention" as read in Canadian patent law does not exclude inventions that use the laws of nature. Therefore, the oncomouse as claimed, falls within the definition of the term "invention".

In arriving at his conclusion, Rothstein J. reviewed the previous decisions and found that the Commissioner of Patents erred in rejecting the claims dealing with the oncomouse by including restrictions in the legislative text where no such restrictions existed. As Justice Rothstein states: "The language of patent law is broad and general and is to be given wide scope because inventions are, necessarily, unanticipated and unforeseeable".

Rothstein J. also found that Nadon J. erred in his judgement by applying the following criteria incorrectly: degree of control; reproducibility; separation of the process into phases; and making a distinction between higher and lower life forms.

The degree of control is a criterion that is only referred to in the Canadian Manual of Patent Office Practice, but does not appear in the *Patent Act*. This criterion is used to determine whether or not an invention is useful according to section 2 of Canadian *Patent Act*. The fact that the inventors do not have control over the colour of the mouse's eye, or the length of its tail, is

completely irrelevant to whether or not the oncomouse is patentable, since these features are not claimed as being part of the invention. The degree of control must extend to the features that are claimed; in this case, to the presence of the gene in the offspring.

In the Trial Division of the Federal Court, it was held that the oncomouse was not identically reproducible, and thus not patentable. However, according to Rothstein J., the criteria of reproducibility of an invention should be seen in light of section 27(3)b) of the Canadian *Patent Act*, which only concerns the degree of disclosure which is required from the inventor in exchange for the rights granted to the inventor. Reproducibility is not a condition preliminary to patentability, but rather one of sufficiency of disclosure in the specification of the patent.

Both the Commissioner of Patents and the trial judge separated the process of obtaining an oncomouse into phases: a first phase where the gene is inserted into a zygote, and a second phase where the zygote is inserted in the womb of a mouse for gestation. Rothstein J. judged this separation as being irrelevant to the issue of patentability. Fundamentally, most inventions rely to a certain extent on the laws of nature. It is therefore irrelevant to break down an invention into two phases so as to make a distinction between that which is derived from human intervention and that which is not derived from human intervention. Consequently, the end product, the oncomouse, since it was a creation of human intervention and the laws of nature, was patentable. What is not patentable, and clearly stated in the *Patent Act*, are "inventions" which use only the laws of nature.

The majority in the Court of Appeal also held that the distinction between lower and higher life forms cannot be made, since there is no provision for such distinctions in the *Patent Act*. Since there are no provisions in the Act that exclude living matter, such in any form are patentable, provided that they meet the conventional criteria of patentability. As an aside, the majority, as well as the dissenting opinion, state that the proper forum for excluding subject matter from the scope of the *Patent Act* is the legislative authority – short of an express prohibition, the *Patent Act* should be broadly applied.

Judge Rothstein's judgement is one that is highly coherent in its interpretation and application of the law. Unless the Supreme Court of Canada overrules his judgement, it will have a significant impact on the scope of the Act. It is unknown, at this point, if the Federal government will appeal this decision to the Supreme Court of Canada. The crux of the judgement is that any invention that results from human intervention, and that is controllable, no matter what the degree is, can be patented as long as it meets the conventional criteria of patentability.

In rendering his dissenting decision, Justice Isaac stated that the issue in the present case was not to determine whether the oncomouse constituted patentable subject matter, but rather whether it was appropriate for the courts to review the Commissioner's decision in view of recent administrative law decisions. The Commissioner is an authority in which the Parliament has confided the responsibility to decide matters such as the decision to grant a patent. The Commissioner whose decisions call for the exercise of experience, skill and expertise, is well equipped in resolving complex problems of this nature. Furthermore, Isaac J. quoted at length from the Patent Appeal Board decision to conclude that the decision to refuse the grant of the patent on the oncomouse was motivated and respected the rules. In his opinion, the Commissioner's decision was reasonable, thus it was not appropriate to revise his decision.

With respect, we believe that the dissenting opinion should not find favour. It is true that the Commissioner has the expertise to decide whether or not to grant a patent. This decision is arrived at by evaluating whether the alleged invention meets the criteria of novelty, utility and inventiveness. When it comes to evaluating whether the Commissioner, through one of his Examiners, has properly applied a piece of prior art, we are in agreement with Isaac J. that the courts should not review the decision unless there has been a palpable error. However, when it comes to determining the actual scope of the *Patent Act* by interpreting the definition of "invention", the courts should be more willing to review the decision.

It is submitted that this decision will have an important impact in Canadian law, and may open the door to patentability to areas which were traditionally not held to be patentable, such as software per se, or systems which do not necessarily produce physical results, such as methods of doing business.

It is also interesting to note that the majority addresses the implications for humans. The application for patent dealt with claims directed to a non-human mammal. In stating that the decision should not have an impact on humans, Rothstein J. states that a patent constitutes a right of property. The Canadian *Charter of Rights and Freedom*, at section 7, states that each person has the right to freedom, which is contrary to property. Consequently, the *Patent Act* does not apply to humans. A question remains however in respect of human organs, which could be genetically modified to be "better". Will this decision allow patentability of such organs? Time will tell.

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