

Intellectual Property

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Harvard oncomouse unpatentable: Supreme Court delivers on long-awaited ruling on patentability of higher life forms

In a 5:4 majority ruling delivered on December 5, 2002, the Supreme Court of Canada held that higher life forms are not patentable under Canada's *Patent Act*. This determination means that, while the process of manipulating genes to create a mouse carrying the cancer gene, as well as the fertilized oncomouse egg, remain patentable, the resulting mouse falls outside the protection of the *Patent Act*.

The sole issue before the Court was whether a higher life form comes within the statutory definition of a patentable invention under section 2 of the *Patent Act* as comprising of a "manufacture" or "composition of matter". No matter how ingenious or useful an idea may be, Bastarache J. stated for the majority, the question was not what ought to be patented, but rather what could be patented according to the existing legislation. The majority held the view that the language of the *Patent Act* must be interpreted narrowly, all the while taking into consideration the context and the object of the entire Act. According to the majority, a mouse or any other higher life form - even if it has been genetically altered - is not an "invention" as defined under the *Patent Act* and, as such, falls outside the realm of what can be patented in Canada. Bastarache J. stated that the idea of a mouse being characterized as a mere composition of matter is not in keeping with common understanding of higher life. Harvard cannot be granted a patent on something which would have existed despite its genetic manipulation (i.e. the mouse).

Bastarache J. also placed much importance on the fact that the *Patent Act* is ill-equipped to deal with the patenting of higher life forms. In his view, Parliament never intended for higher life forms to be included in the definition of "invention". Patenting higher life forms is a contentious matter that raises a number of complex issues that require clear legislative action. Issues such as self-replication and the fact that higher life forms include humans are clearly beyond the scope of the *Patent Act* and, as such, demonstrate that the legislator never intended for higher life forms to be patentable.

In Bastarache J.'s view, the existence of subsequent legislation - like the *Plant Breeders' Rights Act* - supports the assertion that Parliament never intended for higher life forms, or even plants, to be patented. Plants were awarded protection under this act after the courts had ruled against the patentability of a plant in *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1987] 3 F.C. 8. As Bastarache J. pointed out, Parliament could have amended the *Patent Act* to protect plants. Instead, it enacted the *Plant Breeders' Rights Act*.

Furthermore, according to Bastarache J., the decision against allowing higher life forms to be patented is in keeping with the widely accepted notion that humans are not patentable. If higher life forms were made patentable, there would still need to be a line drawn between animals and humans as higher life forms. To do so would merely replace the line between lower life forms and higher life forms.

For the majority, the international context was deemed to have minimal persuasive value. In the view of Bastarache J., the fact that Canada's *Patent Act* had to be interpreted in light of the legislative intent and the context which surrounded its implementation and development

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meant that the interpretation of "invention" in other countries with similar legislation was of limited value in deciding this question.

The majority confirmed that the Commissioner of Patents has no discretion to deny a patent on the basis of public interest. Section 40 of the *Patent Act* states that a patent may be denied only if "an applicant is not by law entitled to be granted a patent". In this case, since a higher life form is not an "invention" under the Act, there is no entitlement to patent the oncomouse. A mouse or any other life form is not patentable subject matter under Canadian legislation. Lower life forms, such as unicellular organisms and yeasts, remain patentable.

The dissenting reasons, drafted by Binnie J., emphasized that, although the *Patent Act* was ill-equipped for the patenting of higher life forms, the Act must be considered to be forward-looking, embracing technologies never dreamed of by its founders. Binnie J. agreed with the Federal Court of Appeal's view that a mouse is nothing if not a "composition of matter", and, as such, it should be patentable. Binnie J. placed much importance on the commercial and financial objectives of the *Patent Act*. According to Binnie J., the fact that the oncomouse was granted patents in a number of other countries, including the United States, the nation whose patent legislation had the most impact on our own *Patent Act*, was an important factor in favour of allowing higher life forms to be patented.

What is the common ground between the majority and dissenting judges' reasons? A call upon Parliament to deal with the *Patent Act*. If the legislature disagrees with the majority's ruling, it will have to enact clear legislation in response and address the complex issues that surround the patentability of higher life forms.

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