

## TRANSGENIC ANIMAL PATENTS: HARVARD COLLEGE VS. CANADA

## AUTHOR :SHRRIJIET ROYCHOWDHARY

https://taxguru.in/corporate-law/transgenic-animal-patents-harvard-college-vs-canada.html

Patents have been the most stringent kind of intellectual property rights where patent rights have been acquired for products which have minute levels of novelty & usefulness. Since 1980, the US Supreme Court opened doors for a rare kind of patent which were living micro-organisms who could be patented based on their subject matter. It was interesting and unique for the patenting of micro-organisms as the invention is alive, the invention can reproduce itself, and it is difficult to find the required essentials of a patent in a living organism.

An interesting case in the patentability of transgenic animals is the OncoMouse or Harvard Mouse case, where a transgenic mouse developed by the scientists in Harvard University had been breed for biomedical research specifically cancer treatment. Harvard College applied for the patent in the United States, the European Union, New Zealand, Canada & Japan for the process of creating such a transgenic animal as well as the end product.

In the European Patent Office, Section 53(b) of the European Patent Convention (EPC) stated that "European patents shall not be granted in respect of ... plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof"[1]. The patent was rejected on the basis of this section where patents were not supposed to be granted in respect of animal varieties where even the 'varieties' of animals were not entitled to a patent. The appeal in the Technical Board of Appeals discussed the scope of the German law and French law while addressing this issue. The Board said, that the German version of Article 53(b) excludes "Tierarten" and the French version also excludes "races animale" and the German version of "Tierarten" is broader than the English and French version [2]. Thus, the confusion lied in the interpretation, the intention of the convention, and the scope of the word "animal varieties" which differed from one language to the other.

The Technical Board in this case, disregarded the reading of the sections by the Examining Board where they stated that Section 53(b) of the EPC would obstruct patentability of animals in general and thus, they were wrong in rejecting the patent application for Oncomouse. Though the Examining Board took no efforts in defining the scope and intent of 'animal varieties' under the section, but it looked into the subject matter of the patent application made, where the Examining Division found the subject matter of the claims to animals per se not covered by the three terms of Article 53(b) of the EPC[3].

Meanwhile, in the United States the Supreme Court stated that "*naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolate*", which closed doors for patenting of human genes. But in this case, the court held that, "*manipulation of a gene to create something not found in nature.... Could still be eligible for patent protection.*" Based on that, the United States was very welcoming in granting the patent not just to the product but the process as well. On the other hand, that was not the case in Canada.

The Patent Act, 1985 of Canada defined invention under Section 2 stating-

"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 this case, the process claims were granted but the product claims were rejected. In the several issues dealt by the court, the judges looked into the definition of invention and asked the question- whether a Higher Life Form is a "Manufacture" or a "Composition of Matter". The Court had to look into the broader meaning of the terms "manufacture" and "composition of matter" and whether they included higher life forms. The court reasoned that while the definition of "invention" is broad, the Parliament did not define "invention" as "anything new and useful made by man". The choice of an exhaustive definition signals a clear intention to exclude certain subject matter as being outside the confines of the Act. Thus, the court concluded that the product obtained from the process of making transgenic animals is neither 'composition of matter' nor 'manufacture' within the meaning of invention under Section 2 of the Act.

The reasoning applied by the Canadian Court was shocking as the question asked should not have been whether higher life forms are included in the definition of "inventions", but whether Parliament intended to protect "inventions" that were not anticipated at the time of enactment of the Patent Act. Canada having similar patent legislations to countries like the United States and other European Union countries had granted Oncomouse the patent, as they considered it under the expression of "composition of matter".

Though countries have slowly started to accept the concept of patenting of transgenic animals' plants but it is also important to understand that these animal and plant varieties can have a lot of benefits and the patent owned by huge companies and research groups with a lot of funds would destroy they utility and purpose just by sole use of such an invention. Thus, it is essential that there should be proper legislation understanding such new inventions and granting exceptions so they can be utilised for the proper purpose and this entire process does not become a scheme just for rich companies and research groups to attract a lot of royalty. For example, it shall not be an act of infringement for a person whose occupation is farming to reproduce a patented transgenic farm animal through breeding, use such animal in the farming operation, or sell such animal or the offspring of such animal.

[1] The European Patent Convention, Oct. 5, 1973, http://www.european-patent-office.org/legal/epc/e/ma1.html#CVN.

[2] Matthew B. Sellers, *The Effect of the "Onco-Mouse" decisions on the exception to patentability for "animal varieties" under the European Patent Convention*, University of Oklahoma College of Law, https://digitalcommons.law.ou.edu/cgi/viewcontent.cgi?article=1064&context=okjolt (last visited on April 6, 2023).

[3] HARVARD/Onco-mouse, [1991] E.P.O.R. 525, 526.

\*\*\*\*

Author: Shrrijiet Roychowdhary, LLB'21 Section B, O.P. Jindal Global University