

Box 1.16 Animals and Patents: The Mouse That Went to Harvard!

The idea of patenting life sounds like something straight out of George Orwell's novel *1984*. How ironic then that on June 22, 1984, Harvard University filed a patent application at the US Patent Office for the Harvard OncoMouse...a genetically engineered mouse containing human oncogenes (and hence its name) that predisposes it to developing breast cancer. The application, titled "transgenic non-human mammals," was awarded US Patent No. 4,736,866 on April 12, 1988 (expired in 2005). This is the first patent on an animal and is a true milestone in biotechnology patenting. The mouse, which has been licensed to Du Pont, is sold as a model for breast cancer research. Although, its name is not as inspiring as "Mickey" or "Mighty," the Harvard OncoMouse certainly has something to squeak (or roar) about. Was there some controversy over patenting a living animal? You bet. There still is and there probably always will be. To the outside observer, the notion of patenting a living thing smacks of scientists and businessmen playing God. So how did this patent gain support? The seeds of approval were planted by the landmark 1980 Supreme Court's 5-4 decision in *Diamond v. Chakrabarty*, a ruling that for the first time in the history of patent law established that life was patentable. The Supreme Court stated that "a patent can be granted on anything under the sun which can be made by man" and "the relevant distinction [in patentability] is not between living and inanimate things, but whether living products can be seen as 'human-made inventions.'" Prior to 1980, the US Patent Office did not grant patents on microorganisms and cells developed via recombinant DNA technology, deeming them to be "products of nature." In fact, it routinely rejected patent applications pertaining to life-forms as non-statutory subject matter under the traditional legal doctrine defined by 35 USC § 101. Although no patents were granted on living organisms *per se* at this time, compositions containing living things, such as vaccines containing attenuated bacteria were patentable. A boom in the US biotechnology industry followed the Chakrabarty decision, largely due to the intellectual property protection now available to inventions of life. Based on this decision, the US Patent Office in 1987 found in *Ex Parte Allen* that a radiation-induced variety of oysters were patentable, thereby further reinforcing the concept of granting patents on modified life forms. On April 7, 1987, barely four days after the Allen ruling, the US Patent Office announced that it now considered "nonnaturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 USC § 101."

In other words, the US Patent Office now viewed altered or genetically modified animals to be “naturally occurring” and “a product of human ingenuity.” Following this announcement, the Harvard OncoMouse patent was granted in 1988.

A 1989 challenge by the Animal Legal Defense Fund to the Harvard OncoMouse patent followed but failed. Since then, public outrage and concern about animal patents has been expressed both in court and several sessions of Congress. The courts have stated that the matter of animal patents should be directed to Congress, not the judiciary branch. So far, various legislative efforts in Congress at placing a moratorium on animal patents have been unsuccessful. In fact, as of 2019, over a thousand patents have been granted for various transgenic (genetically altered) animals in the US and other nations, further fueling the biotechnology revolution of the 1980s. The Harvard OncoMouse was finally awarded a patent in Europe (1992, revoked in 2006), Japan (1994), and Canada (2003), following enormous opposition and delay.

Transgenic animals like the Harvard OncoMouse have enormous potential to serve as models for studying human diseases and in various aspects of the drug or device development process. In addition, they can act as “biofactories” for biotherapeutic production; be used to generate organs and tissues for human transplantation; or serve as superior farm animals that are more resistant to disease or have enhanced growth. Certain activist organizations, however, view that it is an unethical and inappropriate use of the patent system to issue patents for sentient beings. In fact, over the years some animal patents have been rescinded by the US Patent Office. Examples include a patent that had been granted for rabbits whose eyes were intentionally damaged to serve as a model for human dry eye syndrome and another to beagles useful in the evaluation of human intraluminal valve prostheses.

Since development of transgenic animals is one of the most research-intensive industries in existence, without the market exclusivity offered by a US patent, development of transgenic animals and their introduction into the marketplace would be significantly hampered. Still, animal patenting continues to be one of the most contentious moral, ethical, economic and legal issues of our times. This issue remains far from settled.