



## PATENT #6,444,872: BEAGLES

In 1999, experimenters at the University of Texas successfully rendered 31 healthy beagles to be immunocompromised in order to 'mimic' humans with weakened immune systems due to various maladies such as HIV infection, chemotherapy, transplant surgeries, or from taking immunosuppressive medications to control cancer. These patients are susceptible to fungal (mold) infections in their lungs. Though similar experiments have been conducted in other animals (e.g. mice, rats, rabbits), the researchers claimed theirs was the first time this type of experiment has been performed on a "large animal."

The dogs received daily doses of steroids (to induce immunosuppression in their bodies) and were exposed to various levels of total body irradiation, which entailed putting individual dogs in a box and exposing them to x-rays. After several weeks, the beagles who survived, though in a weakened state, were infected with a mold, *Aspergillus fumigatus*, which is the mold most commonly present (over 90%) in infections in patients with hematological cancer (e.g., leukemia, lymphoma, Hodgkin's, and multiple myeloma). The mold was deposited into the beagles through a tube inserted down their throats, which allowed for a localized infection in one lung lobe.

In 2002, the experimenters obtained a patent for this impaired beagle model which they consider a "testing vehicle" for various treatments in the future, as well as a model through which they can learn more about the pathophysiology of

systematic fungal infections. The claims of the patent are not just for the sick beagles themselves, but also each and every step taken to make them sick, including the procurement of the beagles and the induction of immunosuppression. In order for the USPTO to grant the patent, the agency first made the judgment that sick beagles are somehow "manufactures" or "compositions of matter." Thereafter, it was established that the steps used to make them sick were "nonobvious."

However, it is questionable as to whether the methods performed to obtain the beagles and infect them would not be nonobvious to those working in the biomedical research field. Moreover, there is no factual basis to consider a beagle as a mere "article of manufacture." In fact, during a preliminary examination of an application to establish this patent in Europe, the European Patent Office failed to find "inventive activity" in the patent and questioned "...whether the claimed treatment of beagle dogs is contrary to public order or morality...."

It has been determined that this patent has been exclusively licensed to Sandra Technology, Inc., a for-profit company in Texas. One can only conclude that this patent was sought in order to earn a profit from making animals very sick and killing them. The experimenters have stated that they see this 'model' as a way of ensuring that clinical drug trials in sick humans will result in greater success. They also suggest the future use of dogs, pigs, sheep, monkeys, and/or chimpanzees.



The American Anti-Vivisection Society, which is opposed to the use of animals in research, testing, and education, and the PatentWatch Project of the International Center for Technology Assessment adamantly assert that this patent, and others like it, do not fulfill the requirement of patent law, because neither beagles, or any other animal fits into any of the patentable categories. In any event, the beagle patent fails to be nonobvious within the field of biomedical research.

### SUMMARY

- It is inappropriate to issue patents for sentient beings such as animals. Patents should only be granted for inventions that are "nonobvious," that is not obvious to individuals with expertise in the field in which the patent is made.
- Also, patents are used to restrict competition. The patent system has become a significant economic incentive for the production and proliferation of animals used in medical and other forms of research, and will discourage the use of alternatives.
- A person or organization can now challenge newly-issued patents through both the USPTO and the federal court system.

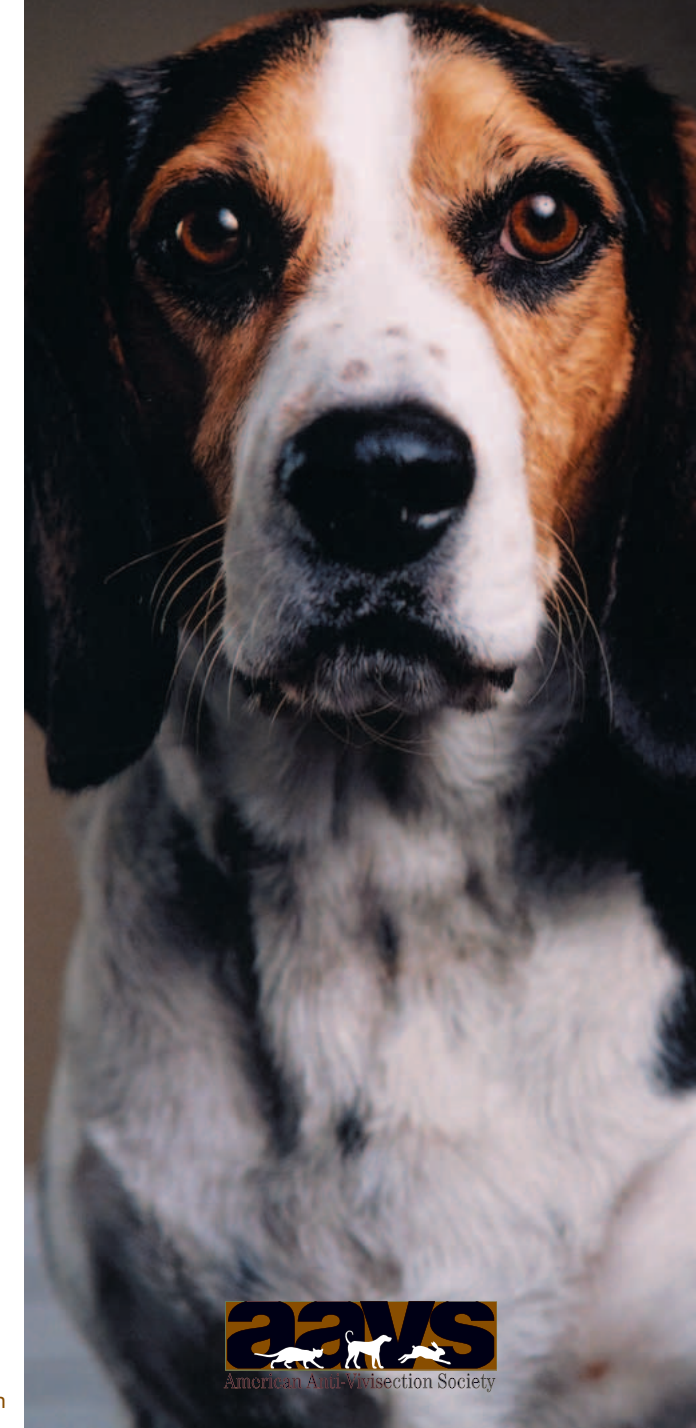
## Key Points

- This patent involves claims on sick beagles as well as the methods of obtaining healthy beagles and causing them to be immunosuppressed and infected with a specific mold species in order to characterize the infection, possibly treating the infection using several experimental methods, and understanding the pathophysiology of the infection.
- The European Patent Office failed to find "inventive activity" in this beagle patent and noted that, by treating dogs in this manner, public order or morality may be violated.
- It is questionable as to whether the methods performed to obtain the beagles and infect them would not be nonobvious to those working in the biomedical research field.
- This patent is owned by University of Texas, but also licensed to a for-profit company.
- The inventors state, "In alternate embodiments, [we] also contemplate the use of other large animals, such as dog, pig, sheep, monkey, or chimpanzee for the animal model."
- The apparent purpose of this and other patents on animals is to profit from making animals sick and then killing them.

*The American Anti-Vivisection Society, along with the PatentWatch Project of the International Center for Technology Assessment, has filed a Request for Re-examination to challenge patent #6,444,872—beagle dogs whose immune systems were weakened by chemicals and radiation and who thereafter were infected with a pulmonary fungal infection. The Request is based on the grounds that (1) animals should not be patented like inanimate objects, and (2) the patent does not fulfill the nonobvious requirement of the USPTO. This is the first time that a specific animal patent has been challenged by a civil society organization.*

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Animals are NOT Inventions





*In the 1600s, the philosopher René Descartes asserted that animals are nothing more than machines, or machina animata, and compared them to clocks. Today, we know better. We recognize that our fellow animals share some of our qualities—once thought to be uniquely human—such as the capacity to not only feel pain, but also to form social relationships, express emotion, and exhibit altruism, among others. Each species also has special characteristics that distinguish them from humans which people recognize as unique and fascinating.*

*As modern societies consider certain rights for animals, a growing and decisive number of people assert that they deserve to live a life with dignity, free from exploitation. Meanwhile, the U.S. government and biomedical research industry continue to operate in ways that treat animals as nothing more than products somehow 'created' by humans, or as inanimate objects.*

## PATENTS

For over 200 years, the U.S. Patent and Trademark Office (USPTO) has issued patents, or exclusive property rights, to inventors of "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." According to the USPTO, "The subject matter sought to be patented must be sufficiently different from what has been used or described before that it may be said to be *nonobvious* to a person having ordinary skill in the area of technology related to the invention" [emphasis added]. Anyone wishing to use the patented product would be required by law to obtain permission from, and usually pay a fee to, the patent holder.

The U.S. Patent Law was recently changed so that challenges to any newly-issued patent can be submitted by any person or organization to the USPTO, and any challengers can now participate in the proceedings. If a challenger is dissatisfied with the decision of the USPTO, an appeal can be made to the Federal Circuit Court, and possibly, the Supreme Court.

## PATENTS ON ANIMALS

Until 1980, the USPTO had prohibited the patenting of living organisms. Organisms were considered "products of nature," and thus not patentable. That all changed, unfortunately, when the U.S. Supreme Court considered an appeal of a denied patent application for an oil-eating bacterium. By a vote of 5-4, the Court ruled that the "relevant distinction is not between living and inanimate things, but whether living products could be seen as 'human-made inventions.'"

Some years later, after deciding that genetically modified oysters could be patentable 'subject



matter,' the USPTO in 1987 announced that it "now considers nonnaturally occurring, nonhuman, multicellular living organisms, including animals, to be patentable subject matter."

The first patent issued for an animal came in 1988 when the 'Oncomouse,' a patent involving mice genetically-manipulated to develop cancers mimicking human diseases, was approved. In issuing a patent to Harvard University for the Oncomouse, the U.S. became the first country in the world to issue a patent for an animal, who later that year was labeled as "Product of the Year" by a popular financial magazine. However, public concern was so strong that legislation for a moratorium on animal patents was considered by Congress in 1987 and 1989, and an unsuccessful legal challenge was filed by an animal protection organization. Since then, the Oncomouse has been patented in both Europe and Japan.

Major universities, government agencies, and corporations that have patented animals have a significant financial incentive to encourage the use of patented animals in biomedical research and testing, thereby discouraging the use of non-animal methods. Since 1987, over 460 patents have been granted on animals. Some examples include: genetically manipulated mice and frogs for use in testing nerve gas, derived through research funded by the U.S. Army; horses and mice who have been implanted with thymus and liver organs from a human fetus of approximately 24 gestational weeks; and rats whose brains were injected with aluminum salts to induce Alzheimer's disease, a uniquely human malady.

## CANADIAN SUPREME COURT RULES

In December 2002, in a 15 year-long case involving the Oncomouse, the Supreme Court of Canada ruled 5-4 against Harvard University, declaring that mice and other higher animals could not be patented according to Canadian laws which feature similar definitions to those in the U.S. Despite the fact that Harvard, which markets mice under the Oncomouse patent through the DuPont company, argued that genetically-altered animals should be legally defined as patentable machines, the Canadian Court disagreed. The Court decision stated that, "Several important features possessed by animals distinguish them from both micro-organisms and plants and remove them even further from being considered a composition of matter or a 'manufacture.' In particular, the capacity to display emotion and complexity of reaction and to direct behavior in a manner that is not predictable as stimulus and response, is unique to animal forms of life." The Court did, however, permit the patent claims on the process to produce the genetically-altered mice.

Other countries, particularly developing countries that have been opposed to genetic engineering, followed this case closely and are hoping for Canada's support in opposing the life patenting provision of the World Trade Organization.

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## ABOUT AAVS

The American Anti-Vivisection Society (AAVS) is a non-profit animal advocacy and educational organization devoted to ending experiments on animals in research, testing, and education. Founded in 1883, AAVS is the oldest organization in the United States with this specific mission. We work with students, grassroots groups, individuals, parents, educators, the media, and members of the scientific community to legally and effectively end the use of animals in science through education, advocacy, and the development of alternative methods to animal use.



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