

# A Damaged Rabbit is Still a Rabbit

## And other reasons why animals shouldn't be patented

**O**n August 2, 2005, the U.S. Patent and Trademark Office issued Patent No. 6,924,413 to the Japanese company, Biochemical and Pharmacological Laboratories, Inc. (BPL) for a rabbit whose eyes have been purposefully damaged to mimic a condition in humans known as 'dry eye,'<sup>1</sup> allowing BPL the potential to profit from intentionally harming animals. AAVS is challenging this patent.

### Animal 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."<sup>2</sup> For most people, a "patentable subject matter" would be something like a toaster, alarm clock, or zipper—not an animal. It is hard to believe that since 1988, the USPTO has, in fact, been issuing patents not just for things like light bulbs and toothbrushes, but also for living, sentient animals.

According to an announcement made by the USPTO in 1987, it "now considers nonnaturally occurring, nonhuman, multicellular living organisms, including animals, to be patentable subject matter."<sup>3</sup> Because of this, over 660 patents have now been issued for animals that have been 'altered' in some way, usually sickened, injured, or harmed in the interest of profit, but under the guise of scientific research, testing, and experimentation. Some examples of animal patents include:

- Cats, dogs, nonhuman primates, mice, rats, sheep, or pigs who have been irradiated to make them immunodeficient and then transplanted with human bone marrow and spleen cells;<sup>4</sup>
- Mice who have been genetically engineered to model human signs of

aging such as hearing loss, muscle loss, and graying hair;<sup>5</sup>

- Mice who have been genetically engineered to be susceptible to stress and depression;<sup>6</sup> and
- Horses and mice who have been implanted with thymus and liver organs from a human fetus of approximately 24 gestational weeks.<sup>7</sup>

### The Rabbit Patent

With the belief that complex, living organisms should not be patented, AAVS is again challenging one such animal patent: Patent No. 6,924,413, rabbits whose eyes are fixed open and then intentionally damaged to serve as models for corneal epithelial damage in humans. Rabbits are traditionally used in eye experiments, such as the infamous Draize eye irritancy test, because their eyes are large, and they are generally docile animals. The patent covers not only the process used to inflict damage on the animals, but also the damaged animals themselves—and not just rabbits, but any nonhuman mammal or fowl, including monkeys, dogs, cats, guinea pigs, rats, mice, goats, cows, sheep, pigs, and chickens who have received the damage are covered under the patent.

According to this patent, the rabbits' (or other animals') eyelids are glued open or held open using retractors so that

**According to an announcement made by the USPTO in 1987, it "now considers nonnaturally occurring, nonhuman, multicellular living organisms, including animals, to be patentable subject matter."**



**As the bunny patent illustrates, animal patents provide an incentive to hurt animals for economic gain.**

“they cannot blink, and the cornea is then treated with water-absorbing substances such as powdered sugar or salt for 20-60 minutes, until the corneal surface layer (epithelium) is damaged. These rabbits can then be used by drug researchers to test the effectiveness of medications for treating corneal epithelial damages such as dry eye in humans.<sup>8</sup>

#### **Dry Eye Disease**

Dry eye, known scientifically as *keratitis sicca* or *keratoconjunctivitis sicca*, is a mild form of corneal epithelial damage caused by insufficient tear production.<sup>9</sup> It is becoming increasingly common in humans due to the growing use of computer displays (which reduce blinking), soft contact lenses (which can absorb tears), and laser surgery (which damages the nerves that stimulate tear secretion). It is estimated that over 20 million Americans suffer from symptoms of dry eye, which include dryness, irritation, itching, redness, sensitivity to light, and blurred vision.

There are numerous treatments for dry eye already available without a prescription, usually in the form of artificial tears or ointments that can be applied directly to the eye. One prescription product is also available—Restasis, a cyclosporine formulation that reduces inflammation of the eye surface in some people.

However, many of these products provide only temporary relief, and some products simply do not work for some people. It is estimated that the market for dry eye treatment will grow from

approximately \$80-100 million in 2004 to \$350-700 million within three to five years, and manufacturers are interested in capitalizing on this growth by developing new therapies.<sup>10</sup>

#### **(Un)Ethics of Animal Patents**

By patenting an animal model of dry eye disease, Biochemical and Pharmacological Laboratories, Inc. will be able to turn injured rabbits into a business. According to U.S. patent law, anyone wishing to use the patented “product” would be required to obtain permission from, and usually pay a fee to, the patent holder. As the bunny patent illustrates, animal patents provide an incentive to hurt animals for economic gain.

Because patents also restrict competition, since no one other than the patent holder can commercialize the patented product, the ability to patent animals also protects and justifies the often substantial investment that corporations, major universities, and government agencies pour into research and development of animal models for biomedical research and testing. If animals could not be patented, pharmaceutical and biotech companies, for example, would have a significantly reduced interest in developing new animal models.

Thus, animal patents encourage research on animals, discouraging research into alternatives and the use of non-animal methods. The increase in animal patenting seen in recent years, due largely to the proliferation of genetic



Dry eye is becoming increasingly common in humans due to the growing use of computer displays (which reduce blinking), soft contact lenses (which can absorb tears), and laser surgery (which damages the nerves that stimulate tear secretion). It is estimated that over 20 million Americans suffer from symptoms of dry eye, which include dryness, irritation, itching, redness, sensitivity to light, and blurred vision.

engineering, represents a serious threat to efforts to reduce animal suffering caused by experimentation.

The unethical nature of issuing patents on animals led philosopher and ethicist Bernard Rollin to write in his 1995 book, *The Frankenstein Syndrome*. "In my view, the Patent Office rushed in where angels feared to tread.... It was a bureaucratic decision made in a value-free context (or value-ignoring context) by an agency that has notoriously avoided engaging the ethical and social issues raised by inventions like switchblades [and] assault rifles.... It disavows concern with issues of safety; danger to humans, animals, or environment; or welfare of animals."<sup>11</sup>

### AAVS Challenge

According to patent law, for a patent to be awarded, the subject matter must be a "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." In addition, "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].<sup>12</sup>

Thus, in order for the USPTO to grant the bunny patent, the agency first made the judgment that injured rabbits somehow fall under the category

of "machine," "manufacture," or "composition of matter," and are thus "patentable subject matter." Thereafter, it was established that the steps used to damage their eyes would be "novel" and "nonobvious" to a person knowledgeable of the field.

AAVS, however, in conjunction with the PatentWatch Project of the International Center for Technology Assessment, is contesting the legality of this patent. We assert that animals are *not* patentable subjects, as they are complex life forms with sentience and self-awareness, and cannot be patented as a mere manufacture or inventor's composition of matter. A rabbit with damaged eyes is still a rabbit. Moreover, the methods used to damage the rabbits' corneas fail the "novel" and "nonobvious" requirements of patent law, because prior literature already suggests using the techniques claimed in the patent. We are thus asking the USPTO to reexamine and rescind the rabbit patent.

Others share AAVS's sentiments that animals are not patentable objects. In 2002, Canada agreed that animals are not patentable subject matter when the Supreme Court there ruled 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 behaviour in a manner that is not predictable as stimulus and response, is unique to animal forms of life."<sup>13</sup>

This is AAVS's second challenge to an animal patent and follows our success in having Texas A&M University drop its patent claims on beagles who were severely sickened and then purposefully infected with a mold in order to test new human drugs on them.<sup>14</sup> AAVS hopes to have similar success challenging the bunny patent.

*Please contact the U.S. Patent and Trademark Office and tell the agency that you support AAVS's Request for Re-Examination of Patent No. 6,924,413. Explain that you are opposed to issuing patents on animals such as rabbits, who are sentient individuals, not machines or, as the Patent Office states, "compositions of matter." Mail Stop Comments-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. AV*

### RESOURCES

1. Katsuyama, I. (2005). U.S. Patent No. 6,924,413. Washington, DC: U.S. Patent and Trademark Office.
2. 35 U.S.C. Sec. 101. Inventions Patentable.
3. U.S. Patent and Trademark Office. (2006). Chapter 2100 Patentability, Section 2105 Patentable Subject Matter - Living Subject Matter. *Manual of Patent Examining Procedure*.
4. Keating, A., & Wu, D. (2000). U.S. Patent No. 6,018,096. Washington, DC: U.S. Patent and Trademark Office.
5. Prolla, T.A., & Kujoth, G.C. (2006). U.S. Patent No. 7,126,040. Washington, DC: U.S. Patent and Trademark Office.
6. Roberds, S.L., & Huff, R.M. (2006). U.S. Patent No. 6,984,771. Washington, DC: U.S. Patent and Trademark Office.
7. Chen, B., Fraser, C., & Weissman, I. (2004). U.S. Patent No. 6,770,260. Washington, DC: U.S. Patent and Trademark Office.
8. Katsuyama, I. (2005). *See Note 1*.
9. Meadows, M. (2005). Dealing with Dry Eye. *FDA Consumer Magazine* 39(3).
10. ISTA Pharmaceuticals - Research and Development. Retrieved March 6, 2007, from [http://www.istavision.com/research/products\\_ecabetsodium.asp](http://www.istavision.com/research/products_ecabetsodium.asp).
11. Rollin, B.E. (1995). *The Frankenstein Syndrome: Ethical and Social Issues in the Genetic Engineering of Animals*. New York: Cambridge University Press.
12. U.S. Patent and Trademark Office. (2005). *General Information Concerning Patents*.
13. Harvard College v. Canada (Commissioner of Patents), 4 S.C.R. 45, 2002 SCC 76 (2002).
14. Andersson, B.S., Sadeghi, T.K., Cromeens, D.M., & Tarrand, J.J. (2002). U.S. Patent No. 6,444,872. Washington, DC: U.S. Patent and Trademark Office.