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U.S. Denies Patent for a Too-Human Hybrid

Scientist Sought Legal Precedent to Keep Others From Profiting From Similar 'Inventions'

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A New York scientist's seven-year effort to win a patent on a laboratory-conceived creature that is part human and part animal ended in failure Friday, closing a historic and somewhat ghoulish chapter in American intellectual-property law.

The U.S. Patent and Trademark Office rejected the claim, saying the hybrid -- designed for use in medical research but not yet created -- would be too closely related to a human to be patentable.

Paradoxically, the rejection was a victory of sorts for the inventor, Stuart Newman of New York Medical College in Valhalla, N.Y. An opponent of patents on living things, he had no intention of making the creatures. His goal was to set a legal precedent that would keep others from profiting from any similar "inventions."

But in an age when science is increasingly melding human and animal components for research -- already the government has allowed many patents on "humanized" animals, including a mouse with a human immune system -- the decision leaves a crucial question unanswered: At what point is something too human to patent?

Officials said it was not so difficult to make the call this time because Newman's technique could easily have created something that was much more person than not. But newer methods are allowing scientists to fine-tune those percentages, putting the patent office in an awkward position of being the federal arbiter of what is human.

"I don't think anyone knows in terms of crude percentages how to differentiate between humans and nonhumans," said John Doll, a deputy commissioner for patents. Yet neither is the office comfortable with a "we'll know it when we see it" approach, he added: "It would be very helpful . . . to have some guidance from Congress or the courts."

The Newman case reveals how far U.S. intellectual-property law has lagged behind the art and science of biotechnology. The Supreme Court has addressed the issue of patenting life only once, and that was 25 years ago.

It also raises profound questions about the differences -- and similarities -- between humans and other animals, and the limits of treating animals as property.

"The whole privatization of the biological world has to be looked at," Newman said, "so we don't suddenly all find ourselves in the position of saying, 'How did we get here? Everything is owned.' "

Newman's application, filed in 1997, described a technique for combining human embryo cells with cells from the embryo of a monkey, ape or other animal to create a blend of the two -- what scientists call a

chimera. That's the Greek term for the mythological creature that had a lion's head, a goat's body and a serpent's tail.

Others had used similar methods to create a "geep," part goat and part sheep. But Newman's human-animal chimeras would have greater utility in medicine, for drug and toxicity testing and perhaps as sources of organs for transplantation into people.

In collaboration with Jeremy Rifkin, a Washington biotech activist and president of the Foundation on Economic Trends, he challenged the patent office: Issue the patent, which would keep others from pursuing such work for 20 years, or reject it, effectively accomplishing the same thing.

The two had until Friday to appeal the latest rejection, but they decided to let it pass and declare victory.

For Rifkin, the case was deja vu in reverse. When U.S. scientist Ananda Chakrabarty applied for the first patent on a living organism -- a genetically engineered bacterium able to digest oil spills -- the case ended up in the Supreme Court because the patent office did not want to patent life forms. That time Rifkin filed the main amicus brief supporting the patent office.

They lost. In a 5 to 4 decision, the court declared that patents could be issued on "anything under the sun that is made by man."

The office has obliged, issuing patents on bacteria, yeast and, as of last fall, 436 animals.

In 1987, the patent office announced it would draw the line with humans, but it offered no legal rationale or statutory backing.

The paper trail created by the Newman claim offers perhaps the best explication yet for that ban. One rationale in the documents sent to Newman is that such a patent would be "inconsistent with the constitutional right to privacy." After all, the office wrote, a patent allows the owner to exclude others from making the claimed invention. If a patent were to issue on a human, it would conflict with one of the Constitution's core privacy rights -- a person's right to decide whether and when to procreate.

Patents on humans could also conflict with the 13th Amendment's prohibition against slavery. That is because a patent permits the owner to exclude others from "using" the invention. Because "use" can mean "employ," officials wrote, a patent holder could prevent a person from being employed by any other -- which "would be tantamount to involuntary servitude."

Finally, the office noted that it is illegal to import products that are made abroad using processes patented in the United States. To show how that could cause a problem in a world where people are patentable, it gave an example in which a person goes overseas and undergoes one of the many surgical procedures patented by U.S. doctors. Simply by returning to the United States, the office said, that "surgically altered human being" could be guilty of patent infringement for illegally importing herself.

Not all those concepts hold water with legal scholars. But the general position was greatly strengthened two years ago when Rep. David Joseph Weldon (R-Fla.) added a rider to an appropriations bill -- renewed this year -- barring patents on humans or human embryos.

Still unresolved by that wording, however, is what is human and what is not.

Last week, patent officials conceded they lack a good way of defining the "human" that Newman's patent supposedly too closely resembles.

The decision letter to Newman notes that many people have heart valves from pigs. A patent has even issued on the use of baboon cells in people to aid in organ transplantation. Those procedures, the letter says, "did not convert the human patient to a non-human."

Similarly, mice that have up to 1 percent human brain cells in their skulls are clearly mice, said Stanford University biologist Irving Weissman, one of the scientists who helped make hybrid rodents.

The tricky part, all agree, is what to do with the middle ground. Weissman and others, for example, have talked about their desire to make mice whose brains are made entirely of human brain cells.

Hank Greely, a professor of law and director of Stanford's Center for Law and the Biosciences, said even those animals would not seem very human to him. "But a chimp brain with human neurons. . . ."

That's exactly the kind of scenario that makes Rifkin, Newman and others want a total ban.

"If the U.S. Congress and president are not willing to do this now, then there is no door that will remain closed to an era of commercial eugenics," Rifkin said. "We'll be on our way to that brave new world that Aldous Huxley warned us about."

Leon Kass, chairman of the President's Council on Bioethics, agreed that Congress should at least get involved.

"The patent office is not the place for society to make its moral decisions," Kass said.

Weldon, the Florida representative, said he is interested in providing such guidance -- and believes the public would favor restrictions.

"There's instant public revulsion when you start talking with the average person about this stuff." For starters, Weldon said, "I'd like to ban the creation of human embryos with animal genes in them."

But many scientists fear that Congress is likely to overreact.

"There are chimeras out there that serve very valuable purposes in medical research, such as mice that make human antibodies," said Michael Werner, chief of policy for the Biotechnology Industry Organization. "This is sufficiently technical scientifically that it should be left to scientific bodies like the National Academy of Sciences to decide."

That organization is now preparing a report, due in April, that will address scientific and ethical issues relating to human-animal chimeras. And although it will not probe deeply into intellectual-property issues, it may at least offer the patent office -- and the nation -- a modicum of the guidance it craves.

Researcher Lucy Shackelford contributed to this report.