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## What Is Patently Offensive?

*Policy on 'Immoral' Inventions Troubles Legal, Medical Professionals*

By RICK WEISS  
*Washington Post Staff Writer*

Attention, all inventors considering making a monster: Forget about getting a patent on your creation.

That's the word from Bruce A. Lehman, commissioner of the U.S. Patent and Trademark Office. Lehman last month announced he will deny patents on "monsters" and other "immoral" inventions—a seemingly innocuous decision that has nonetheless alarmed some legal scholars, patent attorneys and medical researchers.

Who will be the arbiter of morality and monstrosity for the patent office? Would a new, improved "Saturday night special" or nuclear bomb trigger be a moral invention? Are laboratory rats that have been genetically engineered to have horribly deforming human diseases "monsters"?

These examples exist already and have been granted patents. How unpalatable would a thing have to be before it were deemed unpatentable?

"Once you start making those subjective judgments, there's a real danger that they're going to be made in an arbitrary, capricious and inconsistent manner," said Patrick J. Coyne, the Washington patent attorney whose recent and controversial patent application prompted Lehman's comments.

Coyne helped New York Medical College biologist Stuart A. Newman apply for a patent on a method for making research creatures that would be about half human and half animal. Such hybrids, not yet made, could serve many useful purposes in medical and biological research.

But Newman and Washington-based biotech gadfly Jeremy Rifkin, who together submitted the claim, have no intention of actually carrying out their modest proposal. Rather, they want to draw critical attention to current U.S. policy on patenting life, which allows private ownership of human genes, cells, tissues, laboratory-grown animals and novel mixtures thereof.

What better way to drive home

their concerns, they reckoned, than by applying for a patent on a creature that takes current patenting practices to an extreme?

When news of the application broke last month, Lehman sought to assure the public that animal-human hybrids would not be patentable. In a "media advisory," he asserted that U.S. patent law allows him to deny patents for inventions that do not meet certain unspecified "public policy and morality" criteria.

But those comments raised concerns in researchers, worried that some of their gene-altered research animals might be deemed morally questionable, and in attorneys who

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Jeremy Rifkin,

co-applicant for patent on theoretical half-human, half-animal research creature

could not find a legal basis for Lehman's position.

"This is an exaggerated interpretation of his powers," said patent specialist John Barton of Stanford University School of Law. "The real status of the law is, if the patentee, the applicant, can make a claim that there is a reasonable way this technology can be used, then a patent cannot be denied on the basis of the fact that there might also be unethical ways the invention can be used."

Lehman said in an interview that his authority to use moral criteria in deciding patent cases is based on an 1817 case that mentions morality and subsequent legal references to that case.

But critics countered that even that case did not ultimately turn on moral grounds. A 1998 patent law review by Santa Clara University law professor Donald S. Chisum concludes that the 1817 case should be interpreted very narrowly to mean that "a patent will be withheld only if the invention cannot be used for any honest and moral purpose."

Asked whether morality had ever been a factor in the denial of a patent, Lehman said he is legally precluded from speaking about pending or rejected cases. He said he discussed the Newman application because it had received widespread media attention. Although there is no formal system in the Patent and Trademark Office for judging the morality of an application, Lehman expressed confidence in his ability to make the distinction between, say, a legitimate medical research animal and a monster.

"I'm quite certain that when we see one of these, we'll know it," he said, adding that it doesn't make sense to "get all wrapped up in a debate about this and try to define circumstances that have not yet come into existence."

Newman and others argue, however, that such circumstances already exist. The Patent and Trademark Office has for years granted patents on research animals engineered to contain some human genes, cells and tissues in order to learn about human diseases.

"How many genes, how many cells, how much biological material must go into another animal to make it a monster?" Rifkin asked. "What are the criteria Mr. Lehman will use to determine what is morally acceptable or unacceptable in his eyes?"

As another example, Rifkin and Newman point to ongoing work by Johns Hopkins University researcher John Gearhart involving cells taken from aborted human embryos. Gearhart has applied for patents on the cells, which he hopes will further research on embryo development and may even be induced to grow into body parts—the same purposes Newman has proposed for his animal-human hybrids. But his patent



WASHINGTON POST FILE PHOTO

Patent Commissioner Bruce A. Lehman sought to assure that animal-human hybrids would not be patentable.



FILE PHOTO BY JOHN CHADWICK—AGENCE FRANCE PRESSE

**Polly, far left, the world's first cloned sheep containing human genes, with surrogate mother in July in Edinburgh, Scotland. Gene-altered animals such as Polly are at issue in a patent application that tests what constitutes an objectionable hybrid.**

applications, still pending, did not trigger a public reprimand from Lehman.

Gearhart could not be reached for comment. But Kevin Kaster, chief patent counsel for Geron Corp. of Menlo Park, Calif., which holds the license to commercialize Gearhart's cells, said Newman's proposal "should be distinguished clearly and prominently from the good and moral work of researchers like John Gearhart."

When asked on what basis he

made that distinction, however, Kaster said it was a matter of "degree." He acknowledged that some people might be offended by Gearhart's experiments with human embryo cells.

Kaster said Congress ultimately may have to decide how much of life is patentable—a topic that legislators tackled in the 1980s and then dropped in frustration. Rifkin and Newman favor a renewed effort and are petitioning Congress to hold hearings on the issue. They also hope

to bring the issue before the Supreme Court.

Until then, Lehman said, he will remain on the lookout for monsters and deal with them swiftly.

"If the Supreme Court says different, then that's fine," Lehman said. "But it's my position that we would not patent the kind of combination of animal and human life forms described in some of this publicity."

On that point, at least, he has the support of critics Newman and Rifkin.