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Overturning stem cell patents will "blow things wide open."

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Embryonic stem cell research in Maryland and throughout the nation could benefit from a recent federal regulatory decision to overturn the University of Wisconsin's patents on the science.

The U.S. Patent and Trademark Office has issued a preliminary ruling that three controversial patents held by the school since 2001 should be overturned.

The patents cover the method of isolating human embryonic stem cells as well as the cells themselves. Some scientists have expressed outrage that the institution holds the far-reaching patents so closely, making licenses necessary in many cases to work in the field.

"I think this is going to have a major effect," Johns Hopkins University School of Medicine Vice Dean for Research Dr. Chi V. Dang said of the decision. "It alleviates a lot of concerns."

The intellectual property remains valid until the patent office's final decision. The Wisconsin Alumni Research Foundation, or WARF, which holds the patents, has 60 days to respond to the finding.

If the patents are revoked with a final decision, the stem cell industry will flourish, predicted Jonathan M. Auerbach, CEO of GlobalStem Inc. of Rockville.

"This is going to blow things wide open," Auerbach said.

GlobalStem has been sidestepping the Wisconsin patents, using cancer stem cells and damaged or imperfect human embryonic stem cells with extra chromosomes in its research.

The company would consider going as far as to open a stem cell bank in the state, Auerbach said. Such a facility would produce and characterize, or determine what specific type of tissue the cell is likely to grow into, stem cell lines for sale to researchers.

The California Institute for Integrative Regenerative Medicine, funded with \$3 billion in state money, also is investigating creating a stem cell bank.

Hopkins last year began a Stem Cell Resource Center within its Institute for Cell Engineering, the stem cell research outfit Dang directs. The center is a stem cell bank serving Hopkins researchers. The university's lawyers have been examining Wisconsin's rights relative to the center's work, Dang said.

In its decision, which was publicized Monday, the patent office said it preliminarily agreed with the contentions of two consumer groups, the Foundation for Taxpayer and Consumer Rights and the Public Patent Foundation, which challenged the patents last July.

Their main contention was the patented discoveries had resulted from existing science, and the same conclusions made at the University of Wisconsin could have been, and were, reached by other scientists based on those previous discoveries.

The patent review process now could drag on for years. And when that process has run its course, Wisconsin is willing to pursue its case to federal court as well, said WARF spokesman Andy Cohn.

"This is a very preliminary first step in a long and complicated process," Cohn said.

The intellectual property has meant researchers in the field have had to consider Wisconsin's rights to the technology before beginning their work. WARF recently relaxed its rules so more academic researchers could work without a license.

Bioscience firms also must license the technology before working in the field, and the cost of their licensing rights is negotiated on a case-by-case basis, Cohn said.

WARF likely would reap the most money, though, from the royalties a licensee would owe the foundation if that company commercialized a product based on the technology.



WARF has sold 400 licenses to academic researchers since 1998, at \$500 per license, according to Cohn. The foundation has between 15 and 17 corporate licensees, Cohn said.

The technology has brought the foundation a total of \$3.5 million since 1998. "In other words, next to nothing," Cohn said.

Dang said the foundation's patents have tied the hands of academic and private research, already challenged by restrictions on federal funding for the science.

"We don't need more barriers," Dang said.

In academia, discoveries often are shared between fellow researchers, according to Dang.

"It's a little bit mind-boggling that this is going on," he said. "There's a lot of reciprocity between academic institutions."

But Cohn insisted WARF had done nothing wrong. Its \$500 fee for licensing to academics barely covers its costs, he said.

"We want to get the technology out there," he said.

(Above - Jonathan M. Auerbach, CEO of GlobalStem Inc. of Rockville, predicts the stem cell industry will flourish if the University of Wisconsin's patents are revoked.)

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