

## Sweeping stem cell patents rejected

by Terri Somers - CNS

SAN DIEGO - Federal regulators have rejected three sweeping patents that give control of all human embryonic stem cells used for research in the United States to the Wisconsin Alumni Research Foundation.

The ruling released Monday could remove what many scientists say is one of the biggest deterrents to working in the promising field of human embryonic stem cell research - a barrier that has been driving scientists and funding overseas.

The Wisconsin Alumni Research Foundation, commonly referred to as WARF, said it will appeal the preliminary ruling. The U.S. Patent and Trademark Office could let the rejection stand, fully support the patent or narrow its scope.

"If this all falls into place, then the whole landscape of human embryonic stem cell research is going to change," said Jeanne Loring, a Burnham Institute stem cell researcher who was one of the challengers to the patents. "If these patents continue to be rejected, then everyone will be able to use these cells without having to pay WARF. It would remove one of the highest barriers to progress in this exciting field."

It would also put U.S. stem cell researchers on equal footing with the rest of the world, where the patents are not recognized, Loring said.

The patent challenges were filed in July by the Foundation for Taxpayer and Consumer Rights in Santa Monica, Calif., and the New York-based Public Patent Foundation, with supporting declarations from Loring.

The patent office agreed with the challengers, stating the patents should not have been issued because the science they covered was not unique.

The patents were issued in 1998, 2001 and last year for work by University of Wisconsin scientist James Thomson. They cover the process used to pull stem cells out of fertilized embryos. They also cover the embryonic stem cells themselves, making it necessary for researchers to pay a licensing fee to use the cells no matter where the cells are obtained.

These patents, combined with federal funding restrictions on human embryonic stem cell research, have been cited as the two biggest obstacles to the growth of a field that scientists hope will lead to therapies for diseases

such as diabetes, Parkinson's and cancer.

According to patent office reviewers, scientific articles published before the first Wisconsin patent was issued should have made it obvious to someone in the field how to pull stem cells out of a primate embryo and coax them to live for a year in a petri dish.

The examiners cited three articles that the challengers included in their appeal to determine the science was not new. The examiners then went a step further and cited the work of two other scientists to support the notion that Thomson's patented work was not novel.

To receive a patent, something must be new, useful and nonobvious.

"This is a great day for scientific research," said John M. Simpson of the Foundation for Taxpayer and Consumer Rights.

If WARF loses its appeal to the patent office, it could appeal its case in federal court.

"It is inconceivable to us that Dr. Thomson's discovery, which Science magazine heralded as one of the greatest scientific discoveries in history, would be found to not be worthy of a patent," WARF Managing Director Carl W. Gulbrandsen said. "We are confident that when all of the facts are known and the process runs its course, our patents will be upheld."

WARF contends the case was fueled by scientists who want to use groundbreaking science without paying a fair fee.

But three months ago, WARF announced it would waive some of its fees. It also said it would not require the California Institute for Regenerative Medicine, which is distributing \$3 billion in research grants, to obtain a commercial license or negotiate royalties on products that might make it to market as a result of its funding.

Despite those concessions, this patent challenge continues to be watched closely by stem cell scientists and entrepreneurs around the globe.

The preliminary rejection of patents based on a challenge is not necessarily indicative of a win through the

appeals process, said Cathryn Campbell, an intellectual-property lawyer with Needle and Rosenberg in San Diego.

However, it is significant that the patent office went beyond the cases cited by the challengers and found two more examples of prior science in the area, Campbell said.

Embryonic stem cells, pulled from embryos just days after fertilization, have the ability to evolve into more than 200 types of cells in the body. Scientists hope to harness this power to create therapies for devastating illnesses.

WARF pointed out Monday that the patent office decision was preliminary, and that the patents remain enforceable until all appeals are exhausted.

But Dan Ravicher, a lawyer with the Public Patent Foundation, said the patents are substantially crippled in the eyes of scientists.

"It's like a lame duck president. He's technically president, but does Congress really need to negotiate with him to get things passed?" Ravicher said.

Scientists and biotechnology insiders expect the decision to be widely embraced.

"There are a lot of people who feel the WARF patents are overly broad and to see the patent office questioning whether they should have been granted in the first place, I think, for many companies will be seen as a positive sign," said John Wetherell, a biotechnology patent lawyer with Pillsbury Winthrop Shaw Pittman in San Diego.

The science of human embryonic stem cells is still so nascent that many entrepreneurs are not ready to start companies based on the science. And many investors are not ready to back those companies.

Part of their reluctance has been the WARF patents, because they would add a licensing fee and royalty to the already incredible expense, and risky prospect, of bringing a product to market, Wetherell said.

Because of the WARF patents and federal restrictions on human embryonic stem cell funding, philanthropic

organizations and companies have been investing in the field overseas.

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