Defending Stem Cells

Mark Ellinger talks about stem cells, intellectual property, and the biosciences industry.

by Dave Zielinski

It's been 10 years since the discovery of human embryonic stem cells by researchers at the University of Wisconsin-Madison, and despite the efforts of scientists, no FDA-approved stem cell-based therapies have yet emerged to treat diseases such as diabetes and cancer. But stem-cell discoveries are enhancing human health. Adult and embryonic stem cells are increasingly used to test experimental drugs, often as alternatives to using animals as subjects. Pharmaceutical companies, regularly use heart stem cells to test new drugs for toxicity to the cardiovascular system.

Those growing applications have made the protection of stem cell patents at all stages of the cells' life cycle—from discovery to commercial use—vital, says Mark Ellinger, managing principal of Fish & Richardson in Minneapolis and an expert in patent law. Ellinger, who was a tenured professor in cell and molecular biology at Southern Illinois University before getting his law degree at Harvard, says recent court cases, as well as rulings from the U.S. Patent and Trademark Office, have altered the playing field for obtaining and protecting stem cell patents.

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Mark Ellinger, Fish & Richardson

Patents Under Pressure

Intellectual property issues weigh heavily in attracting private sector investment in stem cells, Ellinger says. Patents are among the most important assets organizations like the University of Minnesota or the Mayo Clinic have for luring venture capitalists seeking to create commercial enterprises from research breakthroughs. Biomedical companies such as BioE, a St. Paul-based organization that provides umbilical-cord-blood stem cell products, painstakingly pursue patents for their tools and technologies, knowing how vital they are to attracting investment and building future revenues.

Investors want to know patents have been acquired, or where they stand in the lengthy patent application process, before committing dollars to what are still, in many cases, high-risk investments. In particular, therapies that are designed to repair or regenerate damaged cells in spinal cord injuries, Parkinson's disease, and other intractable medical problems, are still in the experimental phase. They are both highly attractive and highly risky investments.

"Patent applications themselves are heavily scrutinized by the investment community, since in the biotech industry it can take years and years to get a patent approved by the patent office," Ellinger says.

The Wisconsin Alumni Research Foundation (WARF) continues to hold important patents relating to embryonic stem cells—a kind of cell that can be turned into any type of cell and a potential source of a vast array of cell replacement therapies.
of cell or tissue in the body—based on the discoveries of UW-Madison professor Jamie Thomson in the late 1990s. WARF struck a licensing agreement with Geron Corporation, a biotechnology company in California, based on three types of cells Thomson discovered at the time: heart cells, pancreatic cells, and neural cells. Geron had originally financed Thomson's work to isolate the cells and then gained exclusive rights to sell any commercial treatments.

WARF later had those patents challenged by a California-based consumer organization on the charge that the discoveries were "obvious" in light of what was publicly known at the time. Though the patents were upheld, the "obviousness" test remains one of the biggest hurdles facing stem-cell-related patent applicants. A patent must be a "new and non-obvious useful and functional feature of a product or process." To receive a patent, an invention must not be obvious in terms of what was known when it was created.

One of the few stem-cell-patent court cases involved Pharmastem Therapeutics bringing an infringement suit against ViaCell, Inc. Pharmastem claimed that a ViaCell product—which enables families to preserve their babies' umbilical cord blood to repair compromised immune systems, caused by, say, chemotherapy treatments to treat cancer—infringed on a Pharmastem patent. Blood from a newborn infant's cord is an abundant source of hematopoietic stem cells, useful for rebuilding damaged blood or immune systems.

In 2007, the court ruled in favor of ViaCell. Ellinger says, "PharmaStem's claimed invention was found to be obvious, so ViaCell was off the hook," he says. The court also was not persuaded by Pharmastem evidence that it was "unknown in prior art" that cord blood contained hematopoietic stem cells. The court said it was inferred by prior art or other information available at the time.

Future of Therapies

Ellinger believes researchers are "just out of the starting gate" when it comes to finding therapeutic applications for stem cells. He estimates there are 700 to 1,000 clinical trials of various sizes underway around the world of therapies to treat various diseases. "Several of those companies are doing very controlled trials under FDA direction, and many others have applied to do the same," he says.

The trials range from treatment of cardiovascular problems to repair of spinal cord injuries to less-publicized therapies to treat cancer—infringed on a ViaCell patent. Blood from a newborn infant's cord is an abundant source of hematopoietic stem cells, useful for rebuilding damaged blood or immune systems.

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