CENTER'S STAKES HIGH IN PATENT DISPUTE

SEE PAGES 3-4

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CENTER NEWS

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Off the Top

Don't miss party to honor retiring Day on June 19

Dr. Robert Day

Hughes Institute taps Hahn, Roberts for prestigious 7-year appointments

Two researchers in the Center's Basic Sciences Division – Drs. Steve Hahn and James Roberts – joined 68 other scientists nationwide last month in being named to the faculty of the Howard Hughes Medical Institute.

The prestigious appointments last seven years.

The Hahn lab focuses on the complex series of molecular events that start the process of reading, or transcribing, genetic information into a protein blueprint. Roberts' laboratory studies the mechanisms involved in starting and stopping cell division.

Hahn says he is gratified to be named a Hughes investigator, as it offers an opportunity would otherwise be able to do," he says.

Billionaire industrialist Howard Hughes founded the institute in 1953. Instead of building its own research campus, the institute enters into long-term research agreements with universities and other academic research organizations, where

Dr. Steve Hahn

Dr. Jim Roberts

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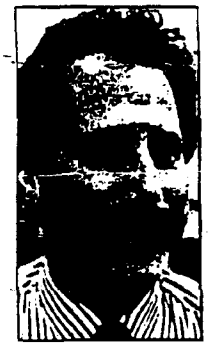
FOCUS ON

Patent dispute: Center's stakes high as rulings awaited on CellPro appeal, 'march in' request

It could be the bitterest patent dispute yet in the young biotechnology industry. And although the Center is not a party to the suit, the stakes for the Center – both for research and revenue – are high.

Since the beginnings of the nation's biotechnology industry in the early 1980s, patent lawsuits have become commonplace. But the dispute between Bothell-based CellPro, Inc., and Baxter International, of Deerfield, Ill., has been especially contentious, with more twists and turns than a daytime soap opera.



'It has implications beyond this case. Whole areas of research such as gene therapy, therapeutic cell expansion are also affected.

'There has to be a balance between allowing commercial development and granting such broadly interpreted rights as to restrict research.'

At stake in this dispute are patient access to a potentially life-saving technology and a market industry estimate of at least $60 million a year.

Founded in 1989 by former Center researcher Dr. Ron Berenson, CellPro, Inc. developed automated systems for purifying large quantities of specific cells for therapeutic and diagnostic applications.

The first cell type targeted by CellPro was the blood-making stem cell, a rare cell produced in bone marrow that gives rise to the body's blood and immune systems.

The Center granted the company an exclusive license to the patented core technology of the company's system, a column device that CellPro calls the Ceprate SC Cell Concentration System. At the same time, CellPro licensed an unpatented monoclonal antibody developed by the Center's Dr. Irwin Bernstein.

In 1991, Johns Hopkins School of Medicine was granted four patents, one of which claims all man-made monoclonal antibodies that bind to a molecule on the surface of stem cells identified as CD34. The other covers any means of isolating stem cells using the CD34 antigen that yields a cell collection substantially free of more mature lymph or marrow cells.

Dr. Bill Bensinger, a researcher in the Center's Clinical Research Division and co-inventor of the CellPro device, believes that such a broad patent is the root of the problem.

"It has implications beyond this case," he says. "Whole areas of research such as gene therapy, therapeutic cell expansion are also affected.

"There has to be a balance between allowing commercial development and granting such broadly interpreted rights as to restrict research."

Despite CellPro's contention that the Hopkins' patent was invalid, in January 1992 Baxter, says it will allow current clinical trials using the CellPro device to continue.

"Baxter has no intention of denying any patient or physician access to technology which can help treat cancer," Spak says. "Our intent is to assure a smooth transition to a licensed technology."

CellPro's Joann Reiter, director of corporate development, says that under the terms of the injunction, CellPro would lose money if it continues the clinical trials.

"We would only be able to treat a very narrowly defined patient population," Reiter says. "We would also have to pay Baxter for all the disposables at a cost of $2,000 per unit, which is more than our profit.

"In the end, the trial results will do us no good, since we won't be able to sell our product. So as a practical matter, CellPro could not continue operating under the terms of the injunction."

While the Center's interest in the case is not on the same scale as the two companies, Catherine Hennings, director of the Center's Technology Transfer Office, says the potential impact is significant.

"Should CellPro be forced out of business, thus leaving the product unsupported, it could disrupt some of our investigators' research," she says.

Dr. Scott Rowley, who heads the Cryobiology Laboratory, where both the CellPro system and Baxter's competing Isolex system are used for clinical trials, says the Center is conducting three clinical trials using the CellPro device, and another is planned.

If CellPro halted

Device was anticipated to be first 'home run' licensed by Center

PATENT
Continued from page 3

Washington and Swedish Medical Center on a kidney transplant study that uses the CellPro system.

"It would be very disruptuve if CellPro could no longer provide the columns," Hansen says. "Theoretically, we could switch to the Baxter system, but that would take time and surely require additional negotiations."

In terms of financial impacts on the Center, Hennings says the CellPro device was anticipated to be the first "home run" licensed by the Center with the potential of generating millions of dollars in royalties.

"The Center has a significant interest in CellPro's ability to sell its device," she says.

In asking Shalala to step in, CellPro is seeking protection under a provision of the Bayh-Dole Act of 1980. That law is widely credited with launching the U.S. biotechnology industry by allowing academic institutions to own and patent technologies developed with federal funding.

To protect taxpayers' research investment, the bill's authors inserted a provision often referred to as "march in rights." Under this provision, the government retains the right to step in if a licensee is not commercializing a technology fast enough, or if there is a compelling public interest.

Hennings says that in the 17 years since the Bayh-Dole Act was passed, the government has never exercised its "march-in" rights.

Whether the government should intervene in this case is the subject of heated debate in the academic community. Technology transfer professionals differ sharply how such action would affect technology licensing.

Some vehemently denounce CellPro and predict that if the government does "march in," it will have a chilling effect on technology transfer. The argument goes that if CellPro succeeds, companies will be reluctant to license technologies developed at federally funded institutions.

Others say the CellPro case is just the type of situation the law's authors had in mind when they included the "march in" provision. Adding credence to that view is the fact that the 18-page letter from CellPro to Secretary Shalala was prepared and signed by former U.S. Sen. Birch Bayh, co-author of the law.

Without commenting on the merits of either party's case, the Center supports CellPro's request.

In a letter to Shalala, Drs. Robert Day, Center president and director, and Lee Hartwell, president and director-designate, express this support strongly.

"At a minimum," the letter states, "we believe it is incumbent upon the Department of Health and Human Services and the National Institutes of Health to ensure that a commercially reasonable license under the Johns Hopkins patents is