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THE SEATTLE TIMES **SECTION D** THURSDAY, APRIL 17, 1997

Patent litigation threatens cell-therapy progress

RON WURZER/SEATTLE TIMES

Litigation threatens *cancer and other research supported by CellPro products. Here Julie Nolan fills columns of protein-coated beads that are used to isolate blood-producing stem cells.*

Trials depend on CellPro product

BY KEITH ERVIN
Seattle Times Eastside business reporter

Nearly three years ago, physicians at Emory University School of Medicine in Atlanta began testing a new therapy in a last-ditch effort to save the lives of children suffering from acute leukemia.

Most of the children died, either from complications from the stem-cell transplant or from a recurrence of leukemia. Four of them are alive and well, apparently cancer-free.

Now, after enrolling more children for a follow-up study using an improved method for removing incompatible donor cells, researchers are worried that a legal dispute between competing rival biotechnology companies could stop the research in its tracks.

The litigation is also taking a heavy toll on CellPro, the 8-year-old Bothell company that produces the system — one used to separate blood-producing stem cells from other types of cells, including tumor cells.

CellPro's Ceprate SC Stem Cell Concentration System was approved by the Food and Drug Administration in December for use in bone-marrow transplants for breast cancer, lymphoma and other cancers. It is also under study in hospitals around the country for treatment of cancers and immune-system disorders such as multiple sclerosis.

The system uses an antibody patented by Johns Hopkins University to isolate stem cells.

A federal court jury in Wilmington, Del., last month found that CellPro had willfully infringed on two Johns Hopkins patents. The jury ordered the Bothell company to pay $2.3 million in damages to Johns Hopkins and its licensees, healthcare giants Becton Dickinson and Baxter International. CellPro stock, once trading for more than $30 a share, is trading now at about $5.50.

A number of cancer researchers are worried that clinical trials will be halted if CellPro is prevented from providing free antibodies. Switching research from the CellPro product to the competing Baxter product would delay research for at least a year, according to research administrators at Emory and Northwestern universities.

CellPro, claiming the Johns Hopkins patent is invalid, plans to appeal the ruling. The company has also asked the U.S. Department of Health and Human Services for permission to continue selling its product, based on a compelling public interest and the fact that the research at Johns Hopkins was supported with federal dollars.

The future of CellPro and continued research using its product are further clouded by motions pending in U.S. District Court for additional damages and for restrictions on sales. Johns Hopkins, Becton Dickinson and Baxter have asked for treble damages of $6.9 million, legal costs of $7 million, and a phase-out of sales of CellPro's product. The phase-out plan would require that CellPro pay royalties of at least $2,000 for each use of its product and cease providing any products for free.

Deborah Spak, spokeswoman for Baxter International, said the phased injunction was proposed as a way of ensuring that patients' needs are met until Baxter's own stem-cell separator receives FDA approval. On Monday, the FDA accepted the application for consideration.

PLEASE SEE *CellPro* ON D 4

Patent dispute threatens clinical trials

CellPro

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"We would have been well within our legal rights to ask for a permanent injunction immediately," Spak said. "We want to make sure there's a smooth transition to a technology that's licensed under the patents. At the same time it's not fair for CellPro to reap financial reward from continued infringement of those two patents."

But CellPro President Richard Murdock accused Baxter and its partners of a public-relations ploy, saying they "know full well" that his company can't afford to sell its product while paying the proposed damages and royalties. Murdock claims the Baxter-proposed injunction would stop clinical trials now underway.

Among those studies is a joint effort by six hospitals, including the Fred Hutchinson Cancer Research Center, using CellPro's Ceprate SC and Ceprate TCD systems to treat children for whom no other treatment is available. The TCD system is intended to remove donors' immune-system cells that can cause complications after peripheral blood stem-cell transplants.

"It's unfortunate that these sorts of things in corporate America can threaten therapeutic clinical trials and potentially life-saving therapies," said Dr. Andrew Yeager, director of Emory University's bone-marrow transplant programs.

Also concerned about possible effects of the litigation is Dr. Richard Burt, director of allogeneic bone-marrow transplants at Northwestern University outside Chicago. He said Ceprate SC has reduced cancer patients' hospital stays after transplants from four weeks to 11 days.

Burt also reports "encouraging results" in using the antibody to treat patients suffering from potentially fatal forms of multiple sclerosis, lupus and rheumatoid arthritis. But more studies are needed, he said.

Biotech stock analysts said CellPro is blessed with enough cash reserves to continue its legal battle. For investors who own CellPro stock, "I would recommend that they keep holding it," said Ragen MacKenzie analyst Andrew Heyward. "But we're not buying or selling it."