

Curt Civin's Long Struggle

CELLPRO'S DISPUTE OVER PATENT RIGHTS IMPERILS BIOMEDICAL RESEARCH AT HOPKINS AND UNIVERSITIES NATIONWIDE.

When Hopkins pediatric oncologist Curt Civin came up with a way in the early '80s to flag the blood's healthy stem cells chemically and separate them from cancerous ones, the end result, he imagined, would offer new hope to leukemia and other patients. What Civin never could have envisioned was that, 15 years later, his discovery also would touch off a national fervor over academic patent rights, when a small Seattle company named CellPro without permission began producing and selling machinery to carry out the cell separation and asked the federal government to sanction these actions.

In May, a federal court ruled that CellPro willfully infringed on patents Hopkins had obtained on Civin's discovery and ordered the company to pay \$2.1 million to Hopkins and the two biotech firms, Baxter Healthcare Corp. and Becton Dickinson, to whom Hopkins had licensed exclusive rights to-commercialize the stem-cell separation. Several times, CellPro had rejected licenses to Civin's technology on the same terms granted by Baxter to two other companies. Now, unbowed by the court's order, CellPro petitioned the federal government to issue it a license at far lower terms — in essence invalidating the Hopkins patent. The firm argued that patients were being denied life-saving medical treatment because Baxter was taking too long to bring the machinery to market.

To counter CellPro's point and assure that the public is not denied access to the therapy, Hopkins

and its licensees have asked the court to allow the Seattle company to continue sales and clinical trials until the FDA approves an equivalent system (Baxter's product). If CellPro removes its machines from institutions that don't have the Baxter technology, to insure there is no hiatus of service, Baxter, at its own expense, will install its system.

The American Cancer Society, meanwhile, an early supporter of CellPro's petition, has reversed its backing, noting that Baxter has demonstrated to its satisfaction that even without CellPro's machines, Baxter's separation equipment would be available and patients wouldn't be denied this life-saving technology.

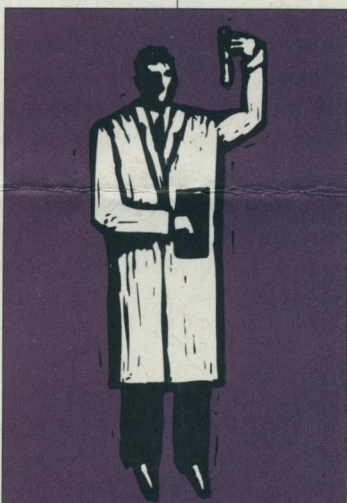
CellPro's petition to the federal government has sent shock waves through academic institutions and medical researchers who fear a ruling in favor of CellPro could send a dire message and jeopardize the future commercialization of university-based medical discoveries.

At stake, should the U.S. Department of Health and Human Services accede to CellPro's request, is the protection offered by the 1980 Bayh-Dole Act, which allows nonprofit organizations like universities to patent discoveries funded by government grants and to offer exclusive licenses to commercial companies to bring their technology to the marketplace. Losing that protection, experts fear, could force biotech firms to jettison their

partnerships with universities in scientific research.

Thanks to the Bayh-Dole Act, academic institutions and private companies have experienced

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dramatic increases in technology transfers and research collaboration. Hopkins, for example, currently has about 300 active licenses with outside companies and \$30 million in commercial research agreements.

"Recently, we've been receiving about 150 disclosures each year and successfully enter into 40 new license agreements yearly," says Howard Califano, Hopkins School of Medicine's director of technology licensing.

That upward trend would be endangered by a ruling in favor of CellPro. Bayh-Dole gives the government the authority to override a university's patent protection through a so-called march-in provision if the National Institutes of Health judges that a licensee has not taken steps to get the technology to consumers in a reasonable amount of time, or if overwhelming health and safety needs are not being met. University and private industry officials nationwide argue that neither of these criteria apply in the CellPro case. A decision by NIH on whether to exercise its "march in" rights is expected next month.

Patent protection is critical to the technology transfer industry because of the long gestation period of bringing a discovery to market. Califano says it takes eight to 10 years in most cases from the time a dis-

covery is made until the final product hits the market. Civin's 1981 discovery, for example, is still available to patients only through clinical trials, although FDA approval is expected in the next few months.

The huge investments can be worth it. Experts believe the technology spawned by Civin's discovery could become a \$100 million-a-year business for Baxter. But William George, chairman and CEO of Medtronic Inc., says companies won't continue to make these huge financial investments in innovative medical technologies if the government undercuts the protection offered by Bayh-Dole.

Califano says Hopkins receives roughly \$3 million a year from royalties, plus another \$3 million for research support associated with such licenses. And the potential for increasing that, he believes, is enormous. Hopkins' intellectual property policy allows for a generous split of these royalties with the scientists and their departments. A CellPro victory could deal a severe blow to this technology transfer process, warns John D. Stobo, vice dean for research and technology.

As for Civin, he worries that the ultimate casualty in the CellPro case could be people with cancer and other life-threatening diseases. "That's what makes me angry," he says. ■