

Lawsuit between Purdue University, Biotech Firm Continues.

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Jan. 12--A lawsuit that seems to grow more bitter by the pleading pits the inventor of a bio-engineered tissue from Purdue University against the university's research licensing arm and a business partner.

In recent months, the lawsuit in U.S. District Court in Lafayette has seen a charge of pilfered Purdue research materials and a counterclaim of financial fraud against one of the state's largest biotech companies.

At the heart of the lawsuit is bio- engineered tissue from pig organs that Purdue developed. The innovative material speeds healing of burns and other tissue damage in people and animals.

Instead of reaping full financial and other benefits from the biomaterial, its main inventor, Stephen F. Badylak, was fired by Purdue in September 2002.

Purdue Research Foundation, which filed the lawsuit in June with licensing partner Cook Biotech of West Lafayette, now accuses the longtime Purdue researcher of misconduct and names him as a suspect in the disappearance of research materials from a Purdue laboratory.

Badylak, who worked at Purdue for 25 years and once advised Cook, has gone on to become chief scientific officer for a Maryland company selling a new version of the biomaterial. That small company, ACell Inc., also is being sued by the Purdue foundation and Cook. They charge ACell with patent infringement.

Cook Biotech, whose majority owner is Bloomington medical device maker Cook Inc. and minority partners are Purdue and Clarian Health Partners of Indianapolis, failed in a recent try to force ACell to stop selling its biomaterial. ACell's product, which is processed, sterilized and sold in thin sheets or as a powder, is used for veterinary wound care.

In a decision mailed recently to attorneys in the case, Judge Allen Sharp denied Cook's injunction request to halt ACell's sales, which run about \$60,000 a month after 11/2 years on the market.

Sharp ruled that patent infringement isn't clearly provable at this point in the case. The judge said Purdue's patent covers biomaterial containing mostly a layer of animal organ tissue called submucosa, while ACell's patent is for a different biomaterial made of two other layers of tissue.

ACell told the judge that halting its sales would have "destroyed" the startup company, put its 26 employees out of work and deprived veterinarians of a product they rely on.

"We're very pleased with Judge Sharp's decision," said ACell's general counsel, Miles Grody. He said no other company official, including Badylak, would comment because of the pending litigation.

The other suspect fingered by the Purdue foundation in the disappearance of the Purdue research is ACell's founder, Dr. Alan R. Spievack, an assistant professor of surgery at Harvard Medical School for 35 years who became interested in tissue engineering while experimenting in his Cambridge, Mass., home.

Spievack, who serves as ACell's vice president and director of technology, later contracted with Purdue to use its laboratories to do development work on the tissue.

Purdue's termination of Badylak's program in 2002 was done so abruptly that "testing animals, mainly dogs, had to be prematurely euthanized," says a document from ACell.

ACell has denied in court documents that it has the missing research materials. It also denied any of its officers took them.

research materials. "The feeling here is the civil courts were the best way to approach this rather than criminal courts," he said.

ACell, which tried to get licensing rights to the newer version of the biomaterial that went instead to Cook, has launched several counterclaims against the Purdue foundation or Cook. They include a charge of fraud against Cook for allegedly underpaying royalties owed to Purdue from sales of the licensed biomaterial. Cook Biotech's sales were estimated at \$7 million to \$9 million last year, court documents show.

Purdue "caught Cook in such wrongdoing" and resolved the dispute over royalties, ACell said. But the resolution was done "in a manner which deprived Dr. Badylak of sums owed to him" as a co-inventor, ACell said.

The fraud allegations against Cook Biotech are "ridiculous," Cook Inc. spokesman David McCarty said Friday.

ACell also has charged Cook Biotech or the Purdue foundation with breach of contract, monopolization and civil conspiracy.

"Cook's goal is to deter the emergence of competitors" by bringing its lawsuit, ACell said.

ACell has said it plans to eventually market its biomaterial for human use. That would put it in more direct competition with Cook, which has only small veterinary sales.

ACell also charged a Purdue foundation senior administrator, Peter Dunn, with conflict of interest. Dunn served as a board member of Cook Biotech when the research foundation granted it a license last year to the newer version of the biomaterial that ACell was angling to get, ACell said.

Purdue spokesman Bennett said that "Dr. Dunn's roles with Cook Biotech and Purdue had no impact on decisions about the licensing of the intellectual properties that are the subject of the lawsuit."

This isn't the first lawsuit over the biomaterial.

Cook previously sued Purdue over licensing rights to newer forms of the biomaterial, the first version of which was licensed to Cook in 1995. Last year the two sides settled that suit by giving Cook rights to use Purdue-developed versions of the biomaterial that were in dispute.

The more recent lawsuit is pending. No trial date has been set.

CHARGES FLY IN BIOMATERIAL FEUD: Cook Biotech, Purdue have yet to prevent small firm, inventor they sued from selling product under dispute.

Biomaterial lawsuit

-- What: Cook Biotech and Purdue Research Foundation sued ACell Inc. of Jessup, Md., and two of its officers in June 2003

-- Charges: Patent infringement, conversion of property and misappropriation of trade secrets

-- At issue: Rights to sell tissue repair material originally developed at Purdue University

-- Status of case: Judge refused Cook's emergency request to order ACell to halt sales. However, the full lawsuit is pending. No trial date has been set.

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