Four-Year Suit Ends in Biogen MS Drug Patent Victory

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What you opt to write down is what you will get.

Berlex Laboratories learned that lesson on Aug. 15, when a federal judge in Boston told the company that it would have to live with the narrow confines of a patent it had hoped would be interpreted liberally.

The ruling by U.S. District Court Judge Mark Wolf of Boston ends, for now, a four-year tussle over control of leading multiple sclerosis drugs and the accompanying billion dollars in revenues.

Treatment for MS

Berlex, a Wayne, N.J.-based subsidiary of Schering A.G., had eyed the profits of its chief rival, Biogen Inc. Biogen makes the leading U.S. treatment for multiple sclerosis, Avonex, which in 1999 generated $620.6 million for the Cambridge, Mass.-based company.

Berlex sells the competing Betaseron, which dominates MS treatment in Europe.

Wolf said Berlex manipulated the U.S. Patent and Trademark Office (PTO) during the case, using "a deliberate narrowing of claims to avoid scrutiny by the PTO to obtain quick allowance, and a subsequent effort to acquire in court the relinquished subject matter."

The companies' dispute revolves around improvements in a 20-year-old process that propagates a protein, human beta interferon, a core ingredient of both medicines.

Biogen and Berlex create their medicines in similar ways. Both grow the protein in Chinese hamster ovary cells. They insert modified DNA into hamster cells, which then yield a harvest of interferon. The companies diverge only in their planting techniques. Berlex sends into the hamster cell one DNA shuttle, packed with two passenger genes. Biogen launches tow (or more) different DNA shuttles, each with one gene.

The judge rejected two separate arguments by Berlex that Biogen's one-by-one method was

functionally equivalent to the all-at-once method its patent protects.

Biogen's patent application specified a numerical range -- 150,000 to 600,000 international units per milliliter -- for production of interferon. It also asserted that its process was capable of values beyond that range. The Patent Office allowed that claim, and the patent issued.

When Biogen began producing interferon using the one-by-one method of gene insertion, the process was yielding 1.5 million units. Berlex sued, charging that under the doctrine of equivalents -- which holds that two different processes yielding similar results may be considered equivalent -- Biogen's method infringed. Berlex asserted that interferon production above 600,000 units was covered by the doctrine of equivalents. The court disagreed.

Wolf further rebuffed Berlex's claim that its patent covered other structures that achieve the same transformation of the hamster cell.

"The prosecution history indicates that the patent was granted to protect only the use of a single DNA construct,'" said the judge. Buying Biogen's contention that Berlex had a patent covering merely a narrow advance that its business brain trust decided needed to be broader, he granted Biogen's motion for summary judgment of noninfringement.

Evolution Taking Place

The ruling reveals evolution in the law, said Biogen's lawyer, Bill Lee of Boston's Hale and Dorr. "This decision tells you to be clearer in what you've done, to give more examples of what you've done and to file not only broad claims," he said.

Crafty patent-drafting is now on judges' radar, said Darius Gambino of Philadelphia's Duane, Morris & Heckscher. He said that recent opinions have declared, in short, "Listen, if you limit your claim for whatever reason, we're not going to give you anything back in litigation."

Berlex has vowed to appeal. The company's lawyers will try to overturn Wolf's reading of the claims.

They have a hope. In a footnote to a 1998 case, *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448 (Fed.Cir.), Judge Randall Rader noted that the U.S. Court of Appeals for the Federal Circuit, the appellate body for patent decisions, rejects almost 40 percent of trial judges' claim constructions.

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