

Judge Hacks Away At Allergan's Restasis Patents

By **Matthew Bultman**

Law360, New York (October 16, 2017, 6:11 PM EDT) -- A federal judge ruled Monday that claims in several patents covering Allergan PLC's dry-eye drug Restasis are invalid, dealing a blow to the drugmaker just weeks after it transferred the patents to a Native American tribe in an effort to shield them from review at the Patent Trial and Appeal Board.

Senior U.S. Circuit Judge William Bryson issued his ruling following a recent bench trial in the Eastern District of Texas, where Allergan accused Mylan Inc. and other generic-drug companies of infringement. The judge ruled that asserted claims in the four patents at issue were obvious.

The patents are among those that Allergan transferred to the Saint Regis Mohawk tribe last month in an effort to use the tribe's sovereign immunity to protect the patents from inter partes review at the PTAB.

The drugmaker did not argue sovereign immunity in district court.

"While Allergan has proved by a preponderance of the evidence that the defendants have infringed the asserted claims of the Restasis patents, the defendants have proved by clear and convincing evidence that the asserted claims of the Restasis patents are invalid for obviousness," Judge Bryson wrote.

The ruling is a significant step in allowing generics makers to sell their own versions of Restasis, which generated about \$1.5 billion in revenue last year. Allergan said in a statement that to date, none of the proposed generic versions have received regulatory approval.

"We are disappointed by the Federal District Court's decision on the Restasis patents," Robert Bailey, Allergan's chief legal officer, said in a statement. "We are carefully reviewing the decision and are considering all options."

Allergan's deal with the tribe — in which it transferred six of its Restasis patents to the Saint Regis



The ruling is a significant step in allowing generics makers to sell their own versions of Allergan's Restasis, which generated about \$1.5 billion in revenue last year. (AP)

Mohawk, then licensed them back — has generated some **criticism**, including from Mylan and other generics makers who challenged the patents at the PTAB.

In a filing with the board on Friday, the companies argued the deal was a “sham” and undermines the patent system.

Allergan has all along maintained the deal would not impact the district court litigation. Judge Bryson, in a separate ruling Monday morning, allowed the tribe to join the case as a co-plaintiff, but said he had “serious concerns” about the licensing deal and the effect it could have on the IPR program.

“If that ploy succeeds, any patentee facing IPR proceedings would presumably be able to defeat those proceedings by employing the same artifice,” the judge wrote. “In short, Allergan’s tactic, if successful, could spell the end of the [U.S. Patent and Trademark Office’s] IPR program.”

The litigation in East Texas involved three generic drug companies: Mylan, Teva Pharmaceuticals USA Inc., and Akorn Inc. Allergan previously reached settlements with Pfizer-owned drugmaker InnoPharma and Famy Care Ltd.

Before trial, Allergan selected a handful of claims from four of the six Restasis patents to be litigated. A five-day bench trial kicked off in late August.

In a 135-page ruling Monday, the judge said Allergan put considerable weight on evidence concerning the commercial success of Restasis and a long-felt need for a pharmaceutical product that would provide relief for dry eyes without significant side effects.

Allergan said this weighed in favor of finding its inventions were not obvious.

The problem with that evidence, Judge Bryson wrote, is that Allergan’s patents have long blocked others from entering the market. The judge said the drugmaker has enjoyed some type of patent protection in this space going as far back as 1993.

“It was Allergan that met that need, not because Allergan was at the forefront of innovation in a competitive setting, but because it had enjoyed a long period of patent protection, which ensured that it would be the only party that would be able to invent and exploit [the relevant] product,” Judge Bryson wrote.

A spokeswoman for Teva and an attorney for Akorn said the companies were pleased with the court’s decision. A representative for Mylan could not immediately be reached for comment.

The patents at issue are U.S. Patent Numbers 8,629,111; 8,648,048; 8,685,930; and 9,248,191.

Allergan is represented by attorneys from Fish & Richardson PC and Ward Smith & Hill PLLC.

Mylan is represented by Wilson Sonsini Goodrich & Rosati PC and Gillam & Smith LLP.

Teva is represented by Sterne Kessler Goldstein & Fox PLLC.

Akorn is represented by Sughrue Mion PLLC, Schiff Hardin LLP and Potter Minton.

The lead case is Allergan Inc. v. Teva Pharmaceuticals USA Inc. et al., case number 2:15-cv-01455, in the U.S. District Court for the Eastern District of Texas.

--Additional reporting by Rachel Graf. Editing by Adam LoBelia.

All Content © 2003-2017, Portfolio Media, Inc.