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PTAB Upholds Vimpat Patent In Generic Makers' Challenge

By **Matthew Bultman**

Law360, New York (March 23, 2017, 8:19 PM EDT) -- The Patent Trial and Appeal Board upheld a Research Corp. Technologies Inc. patent for the anti-epileptic drug Vimpat on Wednesday, just months after a Delaware federal judge refused to invalidate part of the patent in an infringement suit brought against generic-drug makers.

The PTAB said in its final decision that drug companies including Argentum Pharmaceuticals LLC and Mylan Pharmaceuticals Inc. had not shown the patent was invalid. The challengers had argued it would have been obvious at the time of the invention.

"Viewing all of the evidence regarding obviousness together, we conclude that petitioner has not shown by a preponderance of the evidence that the compounds recited in [challenged claims] would have been obvious," the board wrote.

The decision comes on the heels of an August ruling from U.S. District Judge Leonard P. Stark in Wilmington, who similarily found that multiple claims in the patent were not invalid.

Sold by Georgia-based UCB Inc., Vimpat is used to treat partial-onset seizures in adults with epilepsy. UCB and Research Corp. have sued a number of generics makers alleging infringement of the patent. Most of those cases were consolidated in Delaware federal court.

There, several defendant companies conceded that their proposed products infringed some of the patent's claims. But they argued those claims were invalid on various grounds, including obviousness, indefiniteness and improper reissuing.

Following a November 2015 bench trial, Judge Stark issued a lengthy decision and rejected the drugmakers' invalidity arguments. The case has been appealed to the Federal Circuit.

Meanwhile, Argentum filed a petition with the PTAB asking the board to examine the patent in inter partes review. Three drug companies — Mylan, Breckenridge Pharmaceutical Inc. and Alembic Pharmaceuticals Ltd. — joined the challenge after the board agreed to institute review in May.

In it decision Wednesday, the PTAB said, in part, that Research Corp. provided evidence that the drug satisfied a long-felt need, in that the active ingredient in Vimpat, lacosamide, was useful for treating certain patients for which other anti-epileptic drugs were ineffective.

The board said this weighed against finding the patent obvious.

The PTAB also noted that since it was introduced in 2009, Vimpat has generated more than $2.4 billion

in U.S. sales, and that Vimpat's sales have increased significantly each year. Prescriptions for Vimpat domestically have risen from 300,000 in 2010 to approximately 950,000 in 2014.

"We find that patent owner offers significant evidence of satisfying a long felt, but unmet, need, as well as probative evidence of commercial success, which further supports our determination that petitioner has not established by a preponderance of the evidence that the compounds of [certain challenged claims] would have been obvious," the board wrote.

Argentum's CEO, Jeffrey Gardner, nonetheless expressed optimism moving forward, noting the PTAB had come out against Research Corp. with respect to other arguments it made regarding objective evidence of nonobviousness.

On a whole, Gardner said Argentum "believes the PTAB decision hurts, rather than helps, UCB's chances in the pending appeal of the district court case." He noted in a statement that Argentum is also challenging the patent in a pending ex parte re-examination.

Representatives for UCB could not immediately be reached for comment.

The patent at issue is U.S. Patent Number RE38,551.

The petitioners are represented by Matthew L. Fedowitz and Daniel R. Evans of Merchant & Gould PC.

Research Corp. is represented by Andrea G. Reister, Jennifer L. Robbins and Enrique D. Longton of Covington & Burling LLP.

The case is Argentum Pharmaceuticals LLC et al. v. Research Corp. Technologies Inc., case number IPR2016-00204, before the Patent Trial and Appeal Board.

--Additional reporting by Dani Kass. Editing by Aaron Pelc.
