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J&J Tells Fed. Circ. Judge Was Wrong To Nix Zytiga Patent

By **Taylor Arluck**

Law360 (December 4, 2018, 8:11 PM EST) -- A district court judge was wrong to invalidate a patent for a Johnson & Johnson unit's blockbuster cancer drug Zytiga, the company told the Federal Circuit, arguing that the lower court had ignored an America Invents Act provision in finding the patent was obvious.

Janssen Biotech Inc., facing challenges to its U.S. Patent Number 8,822,438 at the Patent Trial and Appeal Board and in federal court, argued on Monday that a New Jersey federal judge had been wrong to entertain generic drugmakers' contention that the company's patent was obvious after the PTAB had already issued a final decision on that front.

U.S. District Judge Kevin McNulty had invalidated the '438 patent in October after finding it was an obvious combination of two known therapies, but said in his ruling that the generic drugmakers — including Mylan Pharmaceuticals Inc., Par Pharmaceutical Inc., Amerigen Pharmaceuticals Inc. and Dr. Reddy's Laboratories Ltd. — would have infringed the patent if it had stayed afloat.

But Janssen argued Monday that Judge McNulty had ignored federal law and case law in favor of his personal opinion about patent policy, according to the company's opening brief.

"The district court acknowledged the statute's plain language, but set it aside based on the court's own view of sound policy and of what Congress must have intended, even if Congress failed to say so," Janssen wrote. "That was improper, as a host of Supreme Court decisions make plain."

The PTAB had invalidated the patent as obvious in January and then Monday — the same day the opening brief was filed in the appeal of Judge McNulty's ruling — the board denied Janssen's bid for rehearing, according to filings in that case.

On Tuesday, the generic drugmakers asked the Federal Circuit to abandon its briefing and argument schedule in Janssen's appeal of the New Jersey case and hold off until the drugmaker files its appeal of that PTAB decision, according to the docket. After that, the cases should be tied together as companion cases to avoid disparate rulings, the generic drugmakers said.

Meanwhile, the U.S. Supreme Court on Friday refused Janssen's request to stop all sales of generic versions of Zytiga while the litigation wages on at the Federal Circuit.

The ‘438 patent is owned by BTG International Ltd. and is exclusively licensed by Janssen. The two companies first sued in 2015, accusing Actavis Laboratories, Amneal Pharmaceuticals LLC, Apotex Corp., Dr. Reddy’s Laboratories Inc., Mylan NV, West-Ward Pharmaceutical Corp., Hikma Pharmaceuticals LLC, Teva Pharmaceuticals Inc., Wockhardt Bio AG and others of infringement.

According to Janssen and BTG, the drug they're trying to protect brought in $5.7 billion in sales between April 2011 and the end of 2017.

In the three years since the litigation began, multiple cases have been consolidated, Actavis and Apotex have settled, the PTAB invalidated all 20 claims of the ‘438 patent, and BTG and Janssen agreed to remove a second patent — U.S. Patent Number 5,604,213 — from the litigation, as it expired in December 2016.

Then, in October, Judge McNulty invalidated the ‘438 patent by finding that the combination of chemotherapy medication abiraterone with prednisone, a steroid to reduce side effects, was obvious.

But that decision ignored the text of 35 U.S.C. §315(e)(2), which governs estoppel in proceedings at the PTAB and in district court, Janssen argued in Monday’s brief.

Plus, the company said that the treatment isn’t obvious because the combination of the two therapies wasn’t widely believed to be commercially viable as a cancer treatment when the patent was filed in 2006.

A representative for Dr. Reddy’s Laboratories declined to comment Tuesday and representatives for the other parties didn’t immediately respond to a request for comment.

The patent-in-suit is U.S. Patent Number 8,822,438.

Janssen is represented by Constantine L. Trela Jr., Carter G. Phillips, Thomas D. Rein, David T. Pritikin, Ryan C. Morris, Paul Zegger and Alyssa Hjemdahl-Monsen of Sidley Austin LLP. BTG is represented by Anthony C. Tridico and Jennifer H. Roscetti of Finnegan Henderson Farabow Garrett & Dunner LLP.

Mylan is represented by Andrew T. Dufresne, Brandon M. White, Dan L. Bagatell, Shannon M. Bloodworth, David L. Anstaett of Perkins Coie LLP. Amneal Pharmaceuticals, Dr. Reddy's Laboratories, Teva Pharmaceuticals, West-Ward Pharmaceuticals and Hikma Pharmaceuticals are represented by Charles B. Klein, Andrew C. Nichols, Jovial Wong and Ryan B. Hauer of Winston & Strawn LLP. Wockhardt Bio AG is represented by Jon E. Wright, Dennies Varughese and Daniel Ritterbeck of Sterne Kessler Goldstein & Fox PLLC. Amerigen is represented by William D. Hare and Christopher Casieri of McNeely Hare & War LLP.

The cases are BTG International Ltd. et al. v. Amneal Pharmaceuticals LLC et al., case number 19-1147, in the U.S. Court of Appeals for the Federal Circuit, and Amerigen Pharmaceuticals Ltd. et al. v. Janssen Oncology Inc., number IPR2016-00286, before the Patent Trial and Appeal Board.

--Additional reporting by RJ Vogt, Dani Kass and Matthew Bultman. Editing by Connor Relyea.