

Purdue's Sleep Aid Patents Are Obvious, Judge Rules

By **Aaron Vehling**

Law360, New York (March 30, 2015, 3:01 PM ET) -- A New Jersey federal judge on Friday found that Purdue Pharmaceutical Products LP's three patents for sleep aid Intermezzo are invalid for obviousness, granting a win to Actavis Elizabeth LLC, Novel Laboratories Inc. and others whom Purdue sued over plans to market their own generic versions of the drug.

In a two-page order, U.S. District Judge Jose L. Linares ruled that the asserted claims of U.S. Patent Numbers 8,252,809; 7,682,628; and 8,242,131 are invalid as obvious, removing an obstacle for defendants Actavis, Par Pharmaceuticals Inc., Dr. Reddy's Laboratories Inc., TWI Pharmaceuticals Inc. and Novel to go through the abbreviated new drug application process for the drug.

The full opinion will be released on April 20, unless the parties move to seal it, as they have for a good portion of their filings.

Jake Holdreith of Robins Kaplan LLP, which represents Novel, was the lead trial lawyer for the defendants and told Law360 on Monday that he was pleased the judge ruled that the claims were invalid.

"We worked hard to make a clear record of obviousness for the court and to meet the clear and convincing burden of proving obviousness," he said.

The judge's order did include language indicating that some of the defendants were found to infringe at least one of the asserted patents that he ultimately invalidated, but Holdreith said there is no claim that was found valid and infringed, "and accordingly we expect that a judgment dismissing all claims will be entered."

The rest of the parties weren't immediately available on Monday to comment.

The decision stems from a lawsuit Purdue and Transcept Pharmaceuticals Inc. originally filed in August 2012, accusing Actavis Elizabeth LLC of infringing its patent for Intermezzo by filing an ANDA with the U.S. Food and Drug Administration for sublingual tablets of zolpidem tartrate, the active drug in the insomnia treatment.

The patents for Intermezzo — designed to aid people who wake up in the middle of the night and can't fall back to sleep — were issued to Transcept in 2010, and Purdue is the exclusive licensee, according to the original complaint.

That original suit only asserted the '628 patent, but over the years Purdue amended its complaints to encompass other drug makers who had sought to make a generic Intermezzo. The suit also grew to assert all three patents that cover various methods that differentiate Intermezzo from previous sleep aids such as Ambien, which is also based on the active ingredient zolpidem.

The judge held a 10-day bench trial before coming to his decision, according to the docket.

In addition to arguing for invalidity, the defendant drug companies had also argued that the patents were indefinite because they didn't adequately described the claimed invention and that they were anticipated by previous inventions, but the judge said on Friday that no finding of indefiniteness or anticipation shall be issued.

Purdue is represented by Michael Dore of Lowenstein Sandler PC.

The defendants are represented by Winston & Strawn LLP, Robins Kaplan LLP, Parness Law Firm PLLC, Saiber LLC, Tompkins Mcguire Wachenfeld & Barry LLP, Cantor Colburn LLP and Flaster Greenberg PC.

The case is Purdue Pharmaceutical Products LP et al v. Actavis Elizabeth LLC, case number 2:12-cv-05311, in the U.S. District Court for the District of New Jersey.

--Additional reporting by Bill Donahue. Editing by Emily Kokoll.