

Fed. Circ. Upholds Invalidity Of Purdue's Sleep Aid Patents

By **Dani Kass**

Law360, New York (January 8, 2016, 12:37 PM ET) -- The Federal Circuit on Friday upheld a New Jersey district court's ruling in favor of Actavis Elizabeth LLC and other drugmakers finding that three of Purdue Pharmaceutical Products LP's patents for the sleep aid Intermezzo are invalid because they were obvious.

In a one-line order, the circuit court shot down Purdue and co-appellant Transcept Pharmaceuticals Inc.'s arguments that the patents were for a different dosage of sleep medication than other insomnia drugs on the market at the time.

U.S. Circuit Judges Alan D. Lourie, Timothy B. Dyk and Todd M. Hughes agreed with U.S. District Judge Jose L. Linares' March decision, which was reached after a 10-day bench trial, in favor of Actavis Elizabeth, Par Pharmaceuticals Inc., Dr. Reddy's Laboratories Inc., TWI Pharmaceuticals Inc., Novel Laboratories Inc. and other companies seeking to market their own generic versions of the drug.

In the appeal, Purdue and Transcept had said the patents took a novel approach by including a lower dosage of zolpidem, a hypnotic drug, to be taken during the middle of the night on an as-needed basis. Purdue told the panel the other drugs on the market called for a high, prophylactic dosage of zolpidem at bedtime to keep patients asleep throughout the night.

Jacob M. Holdreith of Robins Kaplan LLP, on behalf of the defendants, said Purdue was just attempting to retry the case. He pointed to testimony from the defendants' expert who said he had been prescribing his patients to take half an Ambien in the middle of the night to treat insomnia for years. Holdreith said that testimony supports the conclusion that lowering the dosage of zolpidem in the middle of the night was not a novel approach.

The dispute stems from a lawsuit Purdue and Transcept originally filed in August 2012, accusing Actavis of infringing a patent for Intermezzo by filing an abbreviated new drug application 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 were issued to Transcept in 2010, and Purdue is the exclusive licensee, according to the original complaint.

That original suit only asserted U.S. Patent Number 7,682,628, but over the years Purdue amended its complaints to encompass other drugmakers who had sought to make a generic Intermezzo.

The suit grew to assert all three patents, including U.S. Patent Numbers 8,252,809 and 8,242,131, that cover various methods that differentiate Intermezzo from previous sleep aids such as zolpidem-based Ambien.

"Proving obviousness requires careful and thorough work. We are pleased for Novel that it has been vindicated by the summary affirmance of the trial court's invalidity decision and we congratulate Novel on the result," Holdreith said in an email on Friday. "We appreciate Novel's dedication to its mission and we are grateful for Novel's support of our work to make an obviousness case that the Federal Circuit found strong enough to justify the Rule 36 affirmance. It is especially gratifying to receive a decision from the Federal Circuit so promptly."

Counsel for Dr. Reddy's said they were pleased with the decision.

"We maintained from the beginning that the claimed inventions were obvious and worked hard to successfully demonstrate this at trial," Jeffrey B. Arnold of Cantor Colburn LLP said in an email. "We are gratified that the Federal Circuit agreed and promptly upheld the District Court's findings."

Representatives for the remaining companies didn't immediately respond to requests for comment.

Purdue and Transcept are represented by Christopher N. Sipes, Erica N. Andersen and Michael N. Kennedy of Covington & Burling LLP.

Jacob M. Holdreith of Robins Kaplan LLP argued for all defendants.

Novel Laboratories is represented by Holdreith, Miles Finn, Jeffrey A. Hovden and Oren D. Langer.

Actavis is represented by Samuel S. Park, Dan Hoang and Charles B. Klein of Winston & Strawn LLP.

Dr. Reddy's is represented by Jeffrey B. Arnold, Steven M. Coyle and Nicholas Geiger of Cantor Colburn LLP.

The case is Purdue Pharmaceutical v. Actavis Elizabeth LLC, case number 15-1659, in the U.S. Court of Appeals for the Federal Circuit.

--Additional reporting by Jimmy Hoover and Aaron Vehling. Editing by Rebecca Flanagan.
