

## Fed. Circ. Backs PTAB Ax Of J&J Prostate Cancer Drug Patent

By **Matthew Bultman**

*Law360 (May 14, 2019, 6:11 PM EDT)* -- The Federal Circuit on Tuesday upheld a Patent Trial and Appeal Board decision invalidating a patent on Johnson & Johnson's blockbuster prostate cancer drug Zytiga, while leaving open a larger question about the reach of estoppel in America Invents Act reviews.

The appeals court passed on an opportunity to address an argument from J&J unit Janssen that companies successful in invalidating a patent in inter partes review cannot repeat their winning arguments in district court. The U.S. Patent and Trademark Office backed this position.

Instead, the Federal Circuit court upheld a 2018 PTAB decision in a review requested by Wockhardt Bio AG that found the patent was obvious. The court dismissed as moot Janssen's appeal from parallel district court litigation, where a judge similarly said the patent was invalid.

"Because we conclude that the asserted claims are unpatentable as obvious, as the PTAB found in Wockhardt, we need not reach the remaining issues on appeal," the Federal Circuit wrote.

The AIA's estoppel provision prevents challengers from arguing in district court that a patent is invalid on grounds that were raised, or could have been raised, during a completed IPR.

It has been widely accepted that this provision keeps unsuccessful PTAB challengers from reusing failed arguments. But Janssen, as well as the USPTO, suggested the provision applies equally to those who win at the PTAB.

This novel idea captured the attention of attorneys, some of whom suggested such a view of the estoppel provision could wipe out the incentives for generic drug makers to seek PTAB reviews. When the court heard arguments in March, judges indicated they were looking to avoid the question.

A spokeswoman for J&J said the company was considering its options with respect to the decision. Representatives for Wockhardt could not immediately be reached for comment.

Beginning in July 2015, Janssen sued a number of drug companies alleging their planned generic versions of Zytiga would infringe a patent Janssen licenses from BTG International. The patent covers a method of treating advanced prostate cancer with chemotherapy medication abiraterone and prednisone, a steroid.

The PTAB received various requests to examine the patent in inter partes review, including one from Wockhardt. In January 2018 decisions, the PTAB found the patent was invalid because it would have been obvious.

Meanwhile, in district court, the generic companies similarly argued that the patent was obvious. Following a bench trial, Judge Kevin McNulty agreed in an October ruling. The Federal Circuit in November refused to block generic sales while it reviewed Janssen's appeal.

The court's decision Tuesday focused on Wockhardt's IPR and the PTAB's interpretation of the word "treatment," as used in the patent. The court found the board correctly construed the term, despite Janssen's arguments to the contrary.

The Federal Circuit also said there was substantial evidence supporting the PTAB's finding that a physician would have reasonably expected to be successful in combining abiraterone with prednisone, both of which the court said were promising prostate cancer treatments at the time.

The patent at issue is U.S. Patent No. 8,822,438.

Circuit Judges Kimberly Moore, Evan Wallach and Raymond Chen sat on the Federal Circuit panel.

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

Wockhardt is represented by Dennies Varughese, Daniel Ritterbeck and Jon Wright of Sterne Kessler Goldstein & Fox PLLC. Representing the other drug companies on appeal were Winston & Strawn LLP, McNeely Hare & War LLP, Perkins Coie LLP and Crowell & Moring LLP.

The lead case is BTG International Ltd. v. Amneal Pharmaceuticals LLC, case number 19-1147, in the U.S. Court of Appeals for the Federal Circuit.

--Editing by John Campbell.