

Fed. Circ. Wary Of Ruling On AIA Patent Challenge Meaning

By **Matt Bernardini**

Law360 (March 14, 2019, 9:28 PM EDT) -- A Federal Circuit panel Thursday seemed reluctant to rule on a novel argument by a Johnson & Johnson unit, which claims the America Invents Act bars patent challengers who convince the U.S. Patent Office's administrative court to invalidate a patent from repeating those successful arguments in parallel litigation before a federal district court.

The AIA clearly prohibits PTAB patent challengers from repeating losing lines of reasoning to a district court, but J&J's Janssen Biotech Inc., which argues that its prostate cancer drug was wrongly invalidated, told the Federal Circuit on Thursday that challengers are also barred from reiterating winning arguments in district court following a PTAB ruling in inter partes review.

Federal Circuit Judge Kimberly Moore said that she had not seen another plaintiff make that argument and suggested that the instant case could be better resolved on narrower grounds.

"This is a large issue of statutory interpretation," Judge Moore said. "Doctrines like constitutional avoidance ring in my ears when I think about something like this, and think if there is a narrow way to decide this case, why should we go the extra step unnecessarily and decide a bigger issue."

Constantine Trela Jr., of Sidley Austin LLP and representing Janssen, replied that the court should rule on the issue precisely because it is an important one.

"It is not at all unusual for courts to say this is an issue on which lower courts and litigants need guidance," Trela said.

Janssen has sued several drug makers, including Mylan Inc., for patent infringement over their planned generic versions of Zytiga, a blockbuster oncology medication that brought in more than \$5.7 billion in sales between April 2011 and the end of 2017.

The USPTO's Patent Trial and Appeal Board last year found the disputed patent, which Janssen licenses from BTG International Ltd., was invalid as obvious.

The AIA's estoppel provision prevents challengers from arguing in district court that a patent is invalid on grounds they could have raised during a completed review. This provision has been accepted as a way to prevent unsuccessful challengers from reusing failed arguments, but Janssen is also arguing estoppel applies equally to those who win at the PTAB.

A New Jersey federal judge in October rejected Janssen's argument on appeal and found the patent was obvious. The judge said he did not accept "that Congress intended to require a party to stand mute in court because it previously prevailed on the same issue before the PTAB."

In February, the U.S. Patent and Trademark Office filed an amicus brief backing Janssen's position that a winning argument can not be repeated, while admitting that such a rule is "counterintuitive."

Later that month, the Association for Accessible Medicines filed an opposing amicus brief, saying Janssen's interpretation of the law would dramatically reduce the incentive for patent challengers to file petitions for AIA inter partes review and post-grant review at the Patent Trial and Appeal Board.

On Thursday, Federal Circuit Judge Raymond Chen appeared to agree with the New Jersey Judge, asking why the district court didn't issue a stay in the case when the PTAB found the patent invalid.

"Why keep going with any district court litigation and have a full trial," Judge Chen said.

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

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

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

Mylan is represented by Nathan Kelley, Andrew Dufresne, Brandon White, Dan Bagatell, Shannon Bloodworth and David Anstaett of Perkins Coie LLP. Amneal, Dr. Reddy's Laboratories Inc., Teva Pharmaceuticals USA Inc., West-Ward Pharmaceuticals Corp. and Hikma Pharmaceuticals USA Inc. are represented by Charles Klein, Andrew Nichols, Jovial Wong and Ryan Hauer of Winston & Strawn LLP. Wockhardt Bio AG is represented by Jon Wright, Dennies Varughese and Daniel Ritterbeck of Sterne Kessler Goldstein & Fox PLLC. Amerigen Pharmaceuticals Inc. is represented by William Hare and Christopher Casieri of McNeely Hare & War LLP. Argentum Pharmaceuticals Ltd. is represented by Teresa Stanek Rea of Crowell & Moring LLP.

The case is 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.

--Additional reporting by Ryan Davis and Matthew Bultman. Editing by Emily Kokoll.

Correction: An earlier version of story wrongly characterized the relationship between parallel patent challenges at PTAB and in federal district court. Judge Kimberly Moore was also misnamed. The errors have been corrected.