Portfolio Media. Inc. | 111 West 19th Street, 5th Floor | New York, NY 10011 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Teva Gets PTAB To Review Cushing's Syndrome Drug Patent

By **Dani Kass**

Law360 (November 21, 2019, 8:20 PM EST) -- The Patent Trial and Appeal Board will look at whether a patent covering Corcept Therapeutics Inc.'s flagship Cushing's syndrome medication Korlym is invalid, following a challenge from Teva Pharmaceuticals USA Inc.

The board instituted post grant review of all 13 of the patent's claims Wednesday, saying at least one claim is likely to be proved invalid as obvious.

Corcept had urged the board to use its discretion to deny review, saying the validity arguments duplicated what was already playing out in New Jersey federal court. Corcept has sued Teva for infringement, trying to block its generic version of the medication. In response to the suit, Teva has told the court that the patent is invalid, using "identical arguments based on the same references" as at the PTAB, Corcept told the board.

But the PTAB wasn't persuaded that the district court litigation would render its efforts duplicative. First, it said the infringement court litigation isn't in an advanced stage — as in other cases where this argument has succeeded — given that dates for the completion of fact or expert discovery have not been set, let alone a date for trial.

"We can only speculate as to when the district court will provide a final decision," the board said.

The PTAB noted that the PGR petition was filed just three months after the patent was issued, and said there's been no proof that Teva is using this as an "opportunity for tactical advantage." Those factors worked against Corcept.

The board then said a combination of prior art is likely to render the patent invalid as obvious. Namely, it said prior art likely shows that doses higher than 300 milligrams a day were more effective at treating Cushing's syndrome than lower doses.

Korlym, or mifepristone, is used to treat certain patients with Cushing's syndrome, an adrenal gland disease caused by high levels of cortisol. Mifepristone is more widely known for its use in ending pregnancies, but Corcept has said Korlym should not be used for that purpose.

The medication was first approved by the U.S. Food and Drug Administration in 2012 and is Corcept's only approved drug. In the first nine months of 2019, the company's product revenue surpassed $218

million, according to U.S. Securities and Exchange Commission filings.

The FDA has tentatively approved Teva's generic drug, and the only thing blocking it from going to market right now is a 30-month stay triggered by the district court litigation, according to the decision.

Corcept has also accused Sun Pharmaceutical Industries Ltd. of infringement for its planned generic. That suit is pending in New Jersey federal court.

Counsel for Teva declined to comment. Counsel for Corcept didn't immediately respond to a request for comment Thursday.

Administrative Patent Judges Jacqueline Wright Bonilla, Robert A. Pollock and David Cotta sat on the panel for the Patent Trial and Appeal Board.

The patent-in-suit is U.S. Patent No. 10,195,214.

Teva is represented by Deborah Sterling, J.C. Rozendaal, Uma N. Everett, Olga A. Partington and William H. Milliken of Sterne Kessler Goldstein & Fox PLLC.

Corcept is represented by F. Dominic Cerrito and Frank C. Calvosa of Quinn Emanuel Urquhart & Sullivan LLP.

The case is Teva Pharmaceuticals USA, Inc. v. Corcept Therapeutics, Inc., case number PGR2019-00048, before the Patent Trial and Appeal Board.

--Editing by Abbie Sarfo.