

PTAB Rejects Amgen's Bid For Humira Patent Reviews

By **Vin Gurrieri**

Law360, New York (January 14, 2016, 8:23 PM ET) -- The Patent Trial and Appeal Board on Thursday denied two requests by Amgen for reviews of two AbbVie patents covering the megablockbuster Humira, just months after Amgen had asked the U.S. Food and Drug Administration for permission to market a biosimilar version of the autoimmune disease drug.

A three-judge panel for the PTAB issued two decisions denying Amgen Inc.'s petitions for inter partes reviews of two patents — U.S. Patent Numbers 8,916,157 and 8,916,158 — that belong to AbbVie Biotechnology Ltd. In both cases, the PTAB found that Amgen “has not established a reasonable likelihood of prevailing with respect to at least one challenged claim” of each patent.

The PTAB's rulings came on the heels of Amgen's November announcement that it had submitted its long-awaited application for a biosimilar of Humira. The company said that its submission to the FDA was probably the first for a biosimilar of Humira, the world's best-selling prescription drug.

The application to the FDA came about five months after Amgen filed its two petitions asking the PTAB to institute an IPR for the '157 and 158 patents, both of which expire in 2022.

The PTAB said in part that some of Amgen's arguments relating to whether the patents were invalid as obvious over several prior art patents and literature were “too general to be persuasive.”

In each case, the board said Amgen failed persuade that it was likely to establish “that a skilled artisan would have had a reasonable likelihood of success in combining [the prior art] to arrive at the claimed antibody formulation.”

The board said in a footnote that it did not address the parties' arguments with respect to secondary considerations of nonobviousness.

Counsel for AbbVie declined to comment late Thursday, and an attorney for Amgen was not immediately available.

Administrative Patent Judges Rama G. Elluru, Tina E. Hulse and Elizabeth A. LaVier sat on both panels for the PTAB.

The patents-in-suit are U.S. Patent Numbers 8,916,157 and 8,916,158.

Amgen is represented by Sandip H. Patel and Li-Hsien Rin-Laures of Marshall Gerstein & Borun LLP.

AbbVie is represented by David Frazier, Bob Steinberg and Michael Morin of Latham & Watkins LLP

and Tamera M. Weisser, J. Patrick Elsevier and Anthony M. Insogna of Jones Day.

The cases are Amgen Inc. v. AbbVie Biotechnology Ltd., case numbers IPR2015-01514 and IPR2015-01517, before the Patent Trial and Appeal Board.

--Additional reporting by Jeff Overley. Editing by Christine Chun.

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