

PTAB Upholds 3 Teva Migraine Patents Challenged By Eli Lilly

By Britain Eakin

Law360 (April 1, 2020, 4:28 PM EDT) -- The Patent Trial and Appeal Board upheld all claims in three Teva Pharmaceutical patents covering its migraine biologic Ajovy that were challenged by Eli Lilly, giving a boost to Teva's underlying infringement suit against its rival over a competing drug.

In a series of three identical final written decisions that were issued Tuesday, the board said Eli Lilly and Co. had failed to show the challenged claims in Teva's three patents were invalid as obvious.

While the board determined that two printed publications and an earlier patent disclose every element of the challenged independent claims, and that skilled artisans would have had reason to combine them, the board said they would not have been likely to succeed in achieving Teva's claimed invention.

"Petitioner has failed to establish by a preponderance of the evidence that a person of ordinary skill in the art would have had a reasonable expectation of success in achieving the invention of the independent claims of the challenged patents," the decision said.

The board said that at the time the patents were issued, it was not known if the anti-calcitonin gene-related peptide antibodies used in Teva's drug needed to cross the blood-brain barrier to treat migraines or reduce the incidence of headaches, and so given that uncertainty the expectation of failure would've been on par with the expectation of success.

"Although absolute predictability in the art is not required to establish a reasonable expectation of success, the uncertainty and unpredictability about this basic knowledge and the pathogenesis of migraine headache, as well as the skepticism around whether full-length anti-CGRP antibodies would be effective, counsel against finding a reasonable expectation of success," the decisions said.

Tuesday's decisions could give a boost to Teva Pharmaceuticals International GmbH in underlying district court litigation in Massachusetts, which was paused pending the resolution of inter partes reviews of all nine patents Teva asserted in the September 2018 suit. While the board invalidated the challenged claims in the other six patents in a series of decisions in February, Tuesday's decisions marked a change of fortune for Teva.

Teva's suit accused Eli Lilly of developing an infringing biologic, Emgality, that uses the same active ingredient as Ajovy. U.S. District Judge Allison D. Burroughs, who is presiding over the case, had dismissed a 2017 version of the suit, saying it would have been premature to issue the declaratory judgment Teva sought that Lilly infringed since Emgality wasn't yet approved or heading to market.

Teva refiled the suit hours later, after the U.S. Food and Drug Administration approved Emgality, which is being marketed and sold as an anti-migraine medication.

Counsel for the parties did not return a request for comment.

The patents-in-suit are U.S. Patent Nos. 8,586,045; 9,884,907; and 9,884,908.

Patent Trial and Appeal Board Judges Jennifer Meyer Chagnon, James A. Worth and Richard J. Smith sat on the panels.

Eli Lilly is represented by William B. Raich, Erin M. Sommers, Pier D. DeRoo and Yieyie Yang of Finnegan Henderson Farabow Garret & Dunner LLP and in-house by Sanjay M. Jivraj and Mark J. Stewart.

Teva is represented by Deborah A. Sterling, Robert C. Millonig, Gaby L. Longsworth and Jeremiah B. Frueauf of Sterne Kessler Goldstein & Fox PLLC.

The cases are Eli Lilly and Co. v. Teva Pharmaceuticals International GmbH, case numbers IPR2018-01710, IPR2018-01711 and IPR2018-01712, at the Patent Trial and Appeal Board.

--Additional reporting by Dani Kass. Editing by Bruce Goldman.