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Fed. Circ. Axes Teva Antibody IP But Allows Treatment Patents

By **Dani Kass**

Law360 (August 16, 2021, 11:42 PM EDT) -- The Federal Circuit on Monday upheld the Patent Trial and Appeal Board's decision to invalidate patents covering the antibodies in Teva's migraine treatment Ajovy, but rejected Eli Lilly's bid to invalidate Teva's patents applying those antibodies for treatment.

In a pair of precedential opinions, the Federal Circuit said Lilly has proven that the antibody patent claims were obvious over prior art, while failing to make the same showing for the method of treatment patents. The court also issued a third nonprecedential opinion, applying the ruling that Lilly won to another three related antibody patents.

Lilly had lodged claims against nine patents covering Ajovy in a series of PTAB challenges, which were consolidated into these three appeals and heard in June. In 2018, Teva had unsuccessfully sued Lilly for infringement in Massachusetts federal court, hoping to stop the launch of its Ajovy competitor, Emgality.

Both drugs are part of a new class of migraine drugs called calcitonin gene-related peptide antagonists.

In the precedential opinion that Lilly won, the Federal Circuit invalidated claims of U.S. Patent Nos. 9,340,614; 9,266,951; and 9,890,210.

Teva had argued that the board relied on a motivation to combine prior art that Lilly hadn't raised. While Lilly had argued that a skilled artisan would combine the prior art to make a humanized version of this antibody for therapeutic use in humans, Teva claimed the board instead focused on whether a skilled artisan would have been motivated to use or study the antibody. The Federal Circuit disagreed.

"Common sense and scientific reality dictate that scientists do not 'study or use' humanized antibodies with an end goal of treating diseases in test tubes or in rats," the opinion states.

Among many other findings, the panel said the PTAB rightfully found that secondary considerations of nonobviousness don't overcome the obviousness finding.

While the Federal Circuit said the PTAB misstated the legal standard for determining whether there should be a presumption of nexus between the claimed invention and the success of the products, it ultimately found that Teva wasn't entitled to a presumption.

Then, tying in a recent case that invalidated antibody patents over enablement concerns, the Federal

Circuit said Teva's patents have "an extremely broad scope" and "unclaimed features that undisputedly materially affect how" the drugs work, which further harms the nexus analysis.

In a brief opinion, the Federal Circuit then upheld the PTAB's decision to invalidate the related U.S. Patent Nos. 9,346,881; 9,890,211; and 8,597,649 based on the precedential ruling.

Teva's victory came in a case where Lilly unsuccessfully challenged U.S. Patent Nos. 8,586,045; 9,884,907; and 9,884,908.

The decision goes into an issue on claim construction, that ultimately ends with the court reiterating that statements in patent preambles can be limiting on the patent's scope, as opposed to just a statement of intention for the patent. The Federal Circuit upheld the PTAB's claim construction and its impact on the case, which was impacted by the preamble issue.

Then, Lilly said the PTAB had placed too high of a burden on proving that there was a reasonable expectation of success of achieving the desired outcome after combining pieces of prior art. Lilly claimed it was docked because its prior art didn't have clinical data, but the Federal Circuit said that's not accurate.

"In this case, the board followed our case law and did not demand that the prior art include efficacy data," the opinion states. "Lilly directs its argument at isolated, out-of-context statements plucked from dozens of pages of the board's factual findings regarding the reasonable expectation of success."

Representative for Lilly and the intervening U.S. Patent and Trademark Office declined to comment. A representative for Teva didn't immediately respond to a request for comment Monday.

Circuit Judges Alan D. Lourie, William C. Bryson and Kathleen M. O'Malley sat on the panel for the Federal Circuit.

The patents-in-suit are U.S. Patent Nos. 9,340,614; 9,266,951; 9,890,210; 8,586,045; 9,884,907; 9,884,908; 9,346,881; 9,890,211; and 8,597,649.

Teva is represented by William M. Jay, Elaine Blais, Edwina Clarke, Alexandra Lu and Natasha E. Daughtrey of Goodwin Procter LLP and William Milliken and Deborah Sterling of Sterne Kessler Goldstein & Fox PLLC.

Lilly is represented by William B. Raich, Charles Collins-Chase, Pier DeRoo, Erin Sommers and Yieyie Yang of Finnegan Henderson Farabow Garrett & Dunner LLP and in-house by Sanjay M. Jivraj and Mark Stewart.

The USPTO is represented in-house by Monica Barnes Lateef, Thomas W. Krause, Brian Racilla, Farheena Yasmeen Rasheed and Meredith Hope Schoenfeld.

The cases are Teva Pharmaceuticals v. Eli Lilly and Company, case numbers 20-1747, 20-1748, 20-1750, 20-1749, 20-1751 and 20-1752, and Eli Lilly and Company v. Teva Pharmaceuticals, case numbers 20-1876, 20-1877 and 20-1878, in the U.S. Court of Appeals for the Federal Circuit.