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Fed. Circ. Mulls Mixed PTAB Rulings In Teva Antibody IP Fight

By **Britain Eakin**

Law360 (June 7, 2021, 9:18 PM EDT) -- A Federal Circuit panel hinted Monday that the Patent Trial and Appeal Board's reasoning might not have been entirely sound in a battle between Teva and Eli Lilly over a mixed bag of board decisions on antibody patents covering Teva's blockbuster migraine drug Ajovy.

The panel first considered Teva Pharmaceuticals International GmbH's consolidated appeals of the PTAB decisions that nixed three of its antibody patents as being obvious and then considered Eli Lilly and Co.'s appeal of the other PTAB decisions, which upheld the other three patents at issue. The outcome of the appeals could have ramifications for a high-stakes infringement fight in Massachusetts federal court over Eli Lilly's competing antibody product Emgality, with the class of migraine drugs projected to rake in $1 billion annually by 2023.

The dispute at the heart of Teva's appeals revolves around whether a skilled artisan would have been motivated to combine prior art to arrive at the therapeutic use of humanized monoclonal antibodies. Teva contends it was the first to find a way to use antibodies to treat debilitating migraines and said its invention stands apart from the prior art because its methods target ligands rather than receptors.

Teva attorney William M. Jay of Goodwin Procter LLP told the panel during a remote hearing that the prior art also outlined the disadvantages of the claimed antibodies and urged further animal studies before moving forward with human trials. And while the ultimate goal of antibody research may be to develop human therapies, Jay said, the prior art provided no basis for the board to determine that skilled artisans would have been motivated to pursue humanized antibodies targeting ligands.

U.S. Circuit Judge William C. Bryson pushed back on Jay's argument that, for the board to rightfully find a motivation to combine, the ultimate goal of treating humans has to be satisfied in the prior art. The judge noted that the claims themselves aren't directed to that ultimate goal, but are explicitly directed only to the generation of humanized anti-calcitonin gene-related peptide antibodies antagonist antibodies.

"Medicine often proceeds by stages where the ultimate goal is treatment, but that doesn't mean that you have to have an expectation ... in the prior art that the treatment will be successful if your intermediate stage is more modest," Judge Bryson said.

In response, Jay said the prior art warned of negative side effects from targeting ligands, and urged a different path. Judge Bryson countered that the prior art does at least refer to the possibility of creating

human antibodies. And while the references did not discuss it at great length, the judge said, "it's not as if they were saying this isn't workable."

Eli Lilly attorney William B. Raich of Finnegan Henderson Farabow Garrett & Dunner LLP stressed that point to the panel during the first hearing Monday, saying the prior art explicitly encouraged the exploration of humanized antibodies.

"Doing exactly what the prior art says to do is not inventive, it's obvious," Raich said.

But Judge Bryson pushed back on his argument as well, pressing the attorney for a response to Teva's contention that one of the prior art references predates the claimed invention by 10 years, and so the time gap indicates that its invention was not obvious, contrary to the PTAB's ruling.

"Surely it wouldn't have taken 10 years for someone to come up with the idea," the judge said, summarizing Teva's position and calling the board's logic into question.

Raich said research during that 10-year period was ongoing, and that studies during those years showed the supposed safety concerns emphasized by Teva were overblown. He also suggested the time-frame isn't dispositive of the obviousness issue.

Teva said it has licensed the patents for $25 million to Alder Biopharmaceuticals Inc., which acknowledged in the agreement that the patents are valid and enforceable and that its own antibody product would otherwise infringe. The patents were among 188 that were part of the licensing deal, but the PTAB found there was no nexus between the claimed invention and the license, and so gave the deal little weight in its obviousness analysis, according to Teva.

Raich said during the hearing that Teva had failed to show a nexus between the patents at issue and any specific licensing activity. But U.S. Circuit Judge Kathleen M. O'Malley seemed unpersuaded that was the case, saying the patents at issue on appeal appear to be the ones that prompted the licensing discussions.

"The board seemed to simply say, just because there's a lot of patents in the ultimate license ... you can't have a nexus to the very patents that prompted discussions in the first place," Judge O'Malley said, calling that a "problem" with the board's analysis.

In the second case, Eli Lilly said the board erred in upholding the patentability of three related patents based on a finding that skilled artisans wouldn't reasonably expect to achieve successful migraine treatment.

In its decisions on those patents, the board said that at the time the patents were issued, it was not known if the anti-CGRP antibodies used in Teva's drug needed to cross the blood-brain barrier to treat migraines or reduce the incidence of headaches. Given that uncertainty, the board said, the expectation of failure would've been on par with the expectation of success.

Raich, the Eli Lilly attorney, said the board held his client to a heightened obviousness standard, requiring Eli Lilly to prove skilled artisans could reasonably expect to achieve a clinical result he said the claims don't require.

"That's just legally incorrect," he said.

According to court records, Teva's 2018 suit against Eli Lilly over Emgality has been paused pending the completion of the PTAB's patent reviews. The suit accuses Emgality of using the same active ingredient as Ajovy.

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

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

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

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

The cases are Teva Pharmaceuticals v. Eli Lilly and Co., case numbers 20-1747 and 20-1749, and Eli Lilly and Co. v. Teva Pharmaceuticals, case number 20-1876, at the U.S. Court of Appeals for the Federal Circuit.

--Additional reporting by Dani Kass. Editing by Marygrace Murphy.