

## Fed. Circ. Affirms PTAB's Ax Of Acne Drug Patent

By Adam Lidgett

*Law360 (March 14, 2022, 7:20 PM EDT)* -- The Federal Circuit has backed the Patent Trial and Appeal Board's invalidation of an Almirall LLC patent covering the acne drug Aczone, rejecting arguments that the patent wasn't obvious.

The three-judge panel's Monday decision came about two months after Almirall argued that the board erroneously concluded that the patent was obvious based on disclosures in the prior art of ranges of a thickening agent that overlap with the amount claimed in Almirall's invention.

Almirall's counsel had argued that the primary prior art reference that patent challenger Amneal relied on, called Garrett, uses a carbomer gelling agent instead of the type claimed in its patent, acrylamide/sodium acryloyldimethyl taurate copolymer, or A/SA.

But the panel said the PTAB's factual findings back the board's decision that Garrett covers a range "that either fully encompasses or overlaps/abuts the ranges and amounts for those components recited in the challenged claims."

For example, the board gave weight to expert findings that a skilled artisan "would have been able to immediately appreciate that the" A/SA agents and a thickening polymer in Garrett were interchangeable, the panel wrote.

"Indeed, the board credited expert testimony that a skilled artisan 'would not have expected any incompatibilities in substituting' the gelling agents," the panel said. "Thus, the board found that Garrett's gelling agents and A/SA agents are 'used in very similar concentrations for similar formulations.'"

Almirall and Amneal have battled at the PTAB over two patents covering Aczone — including U.S. Patent No. 9,517,219 at issue in the instant proceeding — as Amneal prepared to market a generic version of Aczone. The PTAB had reviewed claims in Almirall's related U.S. Patent No. 9,161,926, but reached a different outcome in that case.

In the instant case, Almirall said Garrett was "crucially different" from its invention, and so the board wrongly found that its patent was obvious on its face based on overlapping ranges. Two secondary prior art references Amneal relied on did disclose the use of A/SA gelling agents, but Almirall said neither of them say anything about Aczone's active ingredient, dapsone, or the solvent used in its claimed method

for treating acne, so the board shouldn't have found that skilled artisans would have combined them with Garrett.

But U.S. Circuit Judge Raymond T. Chen suggested at the **January** hearing that Almirall's counsel might have a problem because the board had determined that carbomer and A/SA gelling agents were interchangeable and that skilled artisans would have been motivated to substitute the carbomer gelling agent in Garrett with the A/SA thickener used in the other two prior art references.

Counsel for Almirall declined to comment to Law360 on Monday.

Counsel for Amneal did not immediately respond to requests for comment.

The patent-in-suit is U.S. Patent No. 9,517,219.

U.S. Circuit Judges Alan D. Lourie, Raymond T. Chen and Tiffany P. Cunningham sat on the panel.

Almirall is represented by James Trainor, Adam Gahtan and Richard Shea of Fenwick & West LLP.

Amneal is represented by Dennies Varughese, Adam LaRock and Kristina Caggiano Kelly of Sterne Kessler Goldstein & Fox PLLC.

The case is Almirall LLC v. Amneal Pharmaceuticals LLC, case number 20-2331, at the U.S. Court of Appeals for the Federal Circuit.

--Additional reporting by Britain Eakin. Editing by Kelly Duncan.