

## **Fed. Circ. Doubts PTAB Erred In Axing Almirall Acne Drug IP**

By **Britain Eakin**

*Law360 (January 12, 2022, 4:46 PM EST)* -- A Federal Circuit panel seemed unlikely Wednesday to undo a win by Amneal Pharmaceuticals LLC at the Patent Trial and Appeal Board, which held that an Almirall LLC patent on its acne drug Aczone is invalid.

Almirall argued during a 40-minute remote hearing in its appeal of the June 2020 PTAB decision 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 attorney James Trainor of Fenwick & West LLP argued that the primary prior art reference 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. Almirall said that makes Garrett "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 Trainor said neither of them say anything about Aczone's active ingredient, dapson, 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.

"All you have are two isolated references that discuss this novel thickening agent and not anything about how they might relate, or whether they might actually function to perform a method of treating acne," Trainor told the panel.

But U.S. Circuit Judge Raymond T. Chen suggested that Trainor 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.

Judge Chen reminded the attorney that the appeals court has to defer to the PTAB decision "unless it's really unreasonable."

"It's hard for me to understand why the board was so off the rails that it was unreasonable to find that A/SA was interchangeable with carbomer on this record," the appellate judge said.

The panel had few questions for Amneal attorney Dennies Varughese of Sterne Kessler Goldstein & Fox

PLLC, who argued during the hearing that the PTAB had relied on decadeslong precedent from the appeals court to reach its decision.

U.S. Circuit Judge Alan D. Lourie did ask Varughese to address Almirall's argument that the board shouldn't have found overlapping ranges since the thickener in Garrett is different from that claimed in its patent.

Varughese told the panel that one of the secondary primary art references discloses the use of both thickeners, carbomer and A/SA, and listed them side-by-side in a short list of preferred thickeners.

When Varughese wrapped up his presentation before his allotted 15 minutes expired, Judge Lourie told the attorney, "no one ever loses points for not using up all of their time."

Almirall and Amneal have battled at the PTAB over two patents covering Aczone, including U.S. Patent No. 9,517,219 at issue in Wednesday's hearing, 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.

The board determined after a contentious hearing in June 2019 on the '926 patent that the same prior art at issue in the case involving the '219 patent failed to disclose the gelling agent in the '926 patent.

Amneal appealed the PTAB decision upholding the '926 patent but later moved to dismiss the appeal. Almirall argued in that case that it was entitled to attorneys' fees because Amneal's failed inter partes review challenge to its acne drug was "exceptional."

The appeals court, however, determined it can't award fees tied to PTAB cases and dismissed the appeal in June 2020.

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 of Fenwick & West LLP.

Amneal is represented by Dennies Varughese 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 Nadia Dreid and Ryan Davis. Editing by Rich Mills.