

## Generics' 2nd Challenge To Acne Drug IP Succeeds At PTAB

By Britain Eakin

*Law360 (June 1, 2020, 10:41 PM EDT)* -- Handing a win to Amneal Pharmaceuticals and Mylan in a battle with Almirall LLC over a patent covering its acne drug Aczone, the Patent Trial and Appeal Board said the generics makers were able to persuasively show that all the challenged claims were invalid.

The board said in a final written decision Friday that the acne treatment was rendered obvious by earlier printed publications that disclosed the claimed 7.5% of the topical dapsone composition in Almirall's patent. A skilled artisan would have been motivated to pursue that composition to optimize dosing, the decision said.

"The evidence of record shows that the recognized safety of dapsone and the desire to optimize the amount of drug delivered to achieve once daily dosing would have served as a motivation to use the claimed 7.5% dapsone concentration," the board said.

An earlier version of Aczone approved by the U.S. Food and Drug Administration contained 5% dapsone and used a different gelling agent that gave the product a gritty quality, according to the decision. To reduce that grittiness, which Amneal's expert testified deterred patients from complying with prescriptions, the board said skilled artisans would have been motivated to reach Almirall's claimed invention by using a different gelling agent disclosed in the prior art.

The PTAB agreed to review the patent in May 2019 after rejecting Almirall's bid to get the board to exercise its discretion to deny Amneal's petition. Almirall argued the petition was serial but the board determined otherwise because an earlier Amneal petition had challenged a different Almirall patent that covers the same topical dapsone composition. Mylan was joined to the case after filing a separate petition challenging the same claims.

The board upheld the challenged claims in the other case in August after a contentious hearing last June, determining that the same prior art asserted in the current case failed to disclose the gelling agent in Almirall's U.S. Patent No. 9,161,926.

In the case at issue in Friday's decision, the board called it difficult to reconcile the various "unpersuasive" positions Almirall took in the proceedings.

While the pharmaceutical company had argued that the amount of the topical dapstone composition in its claimed invention was optimized, it also argued that a skilled artisan would have decreased, rather than increased, it. Almirall also argued that its earlier formulation was ineffective and that grittiness in topical acne medications caused by microparticles was undesirable but wasn't a problem in other dapstone formulations, according to the decision.

"It is unclear how an anti-acne formulation could be at once optimized and FDA-approved, but also ineffective, or how such a formulation's microparticles were at once undesirable, but also required for optimization, or how such microparticles were on the one hand disfavored, but on the other hand any grittiness of such a formulation caused by such visible microparticles was a nonissue," the decision said. "These arguments are incompatible and thus unpersuasive as [a] whole."

According to the board's decision, the topical dapstone composition in Almirall's 9,517,219, which is at issue in underlying district court litigation, has anti-inflammatory properties and has been used to treat leprosy and other skin diseases, and can also treat bacterial infections and malaria.

Counsel for the parties declined to comment.

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

Administrative Patent Judges Susan L.C. Mitchell, Christopher G. Paulraj and Ryan H. Flax sat on the panel.

Amneal Pharmaceuticals is represented by Dennies Varughese, Adam LaRock and Tyler Liu of Sterne Kessler Goldstein & Fox PLLC.

Mylan is represented by Jitendra Malik, Lance Soderstrom, Deepro Mukerjee, Alissa Pacchioli and Heike Radeke of Katten Muchin Rosenman LLP.

Almirall is represented by James Trainor and Elizabeth Hagan of Fenwick & West LLP.

The cases are Amneal Pharmaceuticals LLC et al. v. Almirall LLC, case numbers IPR2019-00207 and IPR2019-01095, before the Patent Trial and Appeal Board.

--Additional reporting by Tiffany Hu and Nadia Dreid. Editing by Haylee Pearl.