

Challenges To Different Patents Not Serial, PTAB Says

By **Tiffany Hu**

Law360 (May 13, 2019, 7:49 PM EDT) -- The Patent Trial and Appeal Board has agreed to review an Almirall patent covering the acne drug Aczone, finding that generics maker Amneal Pharmaceutical LLC's bid for review was not serial because an earlier related challenge involved a different patent.

In a 26-page decision, the PTAB said on Friday that generics maker Amneal Pharmaceuticals LLC was able to show that Almirall LLC's U.S. Patent No. 9,517,219 was invalid as obvious in light of a combination of earlier publications.

Amneal had challenged the '219 patent in inter partes review in November, months after the PTAB agreed to review a related Almirall patent for treating acne, which had also been challenged by the generics maker. That patent, U.S. Patent No. 9,161,926, and the '219 patent cover the same topical dapsone compositions, according to filings.

Almirall had urged the PTAB to exercise its discretion and deny the petition under the General Plastic factors, which are used to address serial challenges, saying that it should not have to defend against Amneal's "serial attacks."

But the board declined to do so, noting that the General Plastic factors are generally used to analyze multiple petitions challenging the same patent, rather than different patents.

"We decline to exercise our discretion under Section 314(a) to deny institution based on those factors because, here, two different patents are at issue, which we find dispositive of the issue," Administrative Patent Judge Ryan H. Flax wrote for the board, referring to part of the America Invents Act dealing with the board's discretion to turn down patent challenges. "[We] are not aware of any case before the board where discretion has been exercised under Section 314(a) to deny institution under such circumstances, and we decline to do so here."

The patent at issue covers a treatment for acne or rosacea that uses compositions including dapsone, which contains "several beneficial medicinal" agents, according to filings.

In Amneal's November petition for review, the generics maker had argued that it would have been obvious for a person of ordinary skill in the art to combine various prior art to arrive at claims in the '219 patent relating to the gelling agents in the compositions used to treat acne.

Almirall had fired back that Amneal's petition challenged claims "covering essentially the same scope" as the ones challenged in the generics maker's earlier petition of the '926 patent. While the drug maker admitted that the language in both patents' claims was not identical, the commonality in the claims was a factor that weighed against institution.

"The accused overlap conceded by petitioner between the claims challenged here and the claims in the '926 IPR petition outweighs the fact that the instant petition challenges nonidentical claims," Almirall argued in its February response.

Repetitive challenges to a patent have long bothered patent owners, who complain it's not fair to have to defend their patent over and over. Last month, two U.S. senators wrote a letter to U.S. Patent and Trademark Office Director Andrei Iancu raising concerns about serial petitions.

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

Counsel for both parties did not immediately respond to requests for comment Monday.

Amneal is represented by Dennies Varughese and Adam C. LaRock of Sterne Kessler Goldstein & Fox PLLC.

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

The case is Amneal Pharmaceuticals LLC et al. v. Almirall LLC, case number IPR2019-00207, before the Patent Trial and Appeal Board.

--Additional reporting by Matthew Bultman. Editing by John Campbell.