Published on *The National Law Review* https://natlawreview.com

Kyle Bass' Another Three IPRs: Targeting Anacor

Article By:

Christina Sperry

Kyle Bass continues to make waves throughout the pharmaceutical industry. Since Bass founded ***Coalition for Affordable Drugs X LLC*** ("CFAD") to challenge pharmaceutical patents, CFAD has filed over three dozen petitions as of this date with the ***Patent Trial and Appeal Board ("PTAB")*** of the ***U.S. Patent and Trademark Office*** ("Office") seeking to institute *inter partes* review ("IPR") proceedings to invalidate a number of pharmaceutical patents.

On August 20, 2015, CFAD filed three separate petitions against Anacor Pharmaceuticals, Inc.'s Orange Book-listed U.S. Patent Nos. 7,582,621 (the "'621 Patent") and 7,767,657 (the "'657 Patent"), — a continuation-in-part of the '621 Patent — covering Anacor's first approved drug, KERYDIN® (tavaborole), an oxaborole antifungal topical solution approved by the U.S. Food and Drug Administration in July 2014 for the topical treatment of onychomycosis of the toenails. On February 23, 2016, the PTAB entered decisions to institute all three IPR proceedings, reaching the conclusions that there is a reasonable likelihood that CFAD would prevail in challenging pertinent claims as unpatentable.

In IPR2015-01776, CFAD sought an IPR of claims 1-12 of the '621 Patent under 35 U.S.C. §103. The '621 Patent describes boron-containing compounds useful for treating fungal infections. The '621 Patent claims a method of treating an infection using tavaborole. The PTAB relied on the testimonies of two declarants submitted by CFAD in reaching its conclusion and found persuasive CFAD's conclusion that a person of ordinary skill in the art would have combined the cited references in the manner recited in the claims with reasonable expectation of success. In particular, the PTAB found it persuasive that "boron-containing compounds are generally considered safe" and that "a person of ordinary skill in the art would have expected that compounds sharing similar structural features would likely share similar functional features, such as the inhibition of additional fungi responsible for onychomycosis" according on the declarants' testimonies.

In IPR2015-01780 and IPR2015-01785, CFAD sought an IPR of claims 1-24 of the '657 Patent under 35 U.S.C. §103. The '657 Patent describes pharmaceutical formulations that include a pharmaceutically acceptable excipient and a boron-containing compound. The sole independent claim of the '657 Patent, claim 1, is directed to a pharmaceutical formulation of tavaborole for topical administration to an animal suffering from an infection by a microorganism. The PTAB again relied quite heavily on the testimonies of two declarants submitted by CFAD in reaching its decisions.

Specifically, the PTAB determined that a person of ordinary skill in the art would have had reason to combine tavaborole disclosed in one reference with topical formulations disclosed in other references because these references all describe boron-based compounds for inhibiting *Candida albicans*, the most common pathogen causing onychomycosis; and tavaborole would have been expected to have better penetration of the nail plate due to its lower molecular weight than the boron-containing compound disclosed in the primary reference.

According to the Office, a majority (72%) of the 529 IPRs proceeding to trial at the PTAB and receiving Final Written Decisions have ended in *all* examined claims being invalidated. This number certainly does not make it optimistic for pharmaceutical patent owners, like Anacor in this case, to face the challenges of IPR reviews. Stay tuned for further updates.

National Law Review, Volume VI, Number 62