

Fed. Circ. Won't Bar Generic Sleep Meds Amid Vanda Appeal

By **Jasmin Jackson**

Law360 (January 3, 2023, 6:55 PM EST) -- The Federal Circuit has rebuffed Vanda Pharmaceuticals' bid to block generic sleep drugs planned by rivals Teva and Apotex while Vanda appeals a district judge's decision to ax four of its patents on brand-name treatment Hetlioz.

In a nonprecedential order issued Dec. 28, the appellate court denied a motion by Vanda Pharmaceuticals Inc. to enjoin Teva Pharmaceuticals USA Inc. and Apotex Corp. from commercially marketing generic versions of sleep disorder drug Hetlioz.

Vanda had asked the Federal Circuit last month to block the competing generics pending its appeal of a Delaware federal court decision, which invalidated four patents that it had asserted against Teva and Apotex in infringement litigation over Hetlioz. But the appellate court determined in the brief order that Vanda hadn't adequately justified the requested injunction.

"Based on the papers submitted to the court and without prejudicing the ultimate disposition of this case by a merits panel, we conclude that Vanda has not established that an injunction pending appeal is warranted," the court said.

Vanda first filed suit against Teva in April 2018, arguing that the drugmaker filed an abbreviated new drug application, or ANDA, that infringed patents issued by the U.S. Patent and Trademark Office from June 2015 to November 2017.

The Hetlioz maker then slapped Apotex and MSN Pharmaceuticals Inc. with two separate suits in May 2018, arguing that they also filed ANDAs that purportedly infringed patents on the brand-name sleep disorder drug.

The three suits were consolidated in May 2020.

Vanda said in January 2022 that it had settled its infringement claims against MSN. Under their deal, MSN could receive a license to manufacture and commercialize a version of Hetlioz as early as March 2035.

Teva and Apotex agreed in a stipulation that same month that their ANDAs would infringe claim 5 of U.S. Patent No. 10,376,487 — if the patent was found to be valid and enforceable.

Teva, Apotex and Vanda took part in a bench trial in March 2022.

Chief U.S. District Judge Colm Connolly invalidated claim 5 of the '487 patent in his corresponding opinion last month, also wiping out three other asserted claims in the trio of patents of which Teva and Apotex didn't stipulate to infringement — U.S. Patent Nos. RE46,604; 10,149,829; and 9,730,910.

Vanda initiated an appeal at the Federal Circuit that same month, also motioning for a temporary injunction in a 470-page filing. According to Vanda, the Hetlioz maker is likely to succeed on appeal since Judge Connolly's decision purportedly "dramatically broadens the law of obviousness."

"It renders obvious work that [U.S. Food and Drug Administration] deems important to the safe and efficacious administration of drugs, and that the Patent Office rewards with protection to encourage innovation," Vanda argued.

The Federal Circuit's latest order did agree to expedite the appeal, finding that Vanda had shown "good cause" to hasten the briefing schedule. The Hetlioz maker's opening brief is due later this month.

Vanda, Teva, Apotex and counsel for Teva and Apotex did not immediately respond to requests for comment Tuesday. Counsel for Vanda declined to comment.

The patents at issue are U.S. Patent Nos. RE46,604; 10,149,829; 9,730,910; and 10,376,487.

Vanda is represented by Nicholas P. Groombridge, Jennifer R. Deneault, Daniel Klein, Michael F. Milea, Eric A. Stone and Josephine Young of Groombridge Wu Baughman & Stone LLP.

Teva is represented by John C. Rozendaal, William Milliken, Byron L. Pickard, Sasha Rao and Deirdre M. Wells of Sterne Kessler Goldstein & Fox PLLC.

Apotex is represented by William B. Coblentz, Aaron S. Lukas and Keri Schaubert of Cozen O'Connor.

The suit is Vanda Pharmaceuticals Inc. v. Teva Pharmaceuticals USA Inc., case number 23-1247, in the U.S. Court of Appeals for the Federal Circuit.

--Editing by Linda Voorhis.