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Fed. Circ. Won't Revive Vanda's Sleep Disorder Patent Claims

By **Jasmin Boyce**

Law360 (May 10, 2023, 5:16 PM EDT) -- The Federal Circuit has backed a district judge's opinion wiping out four Vanda patents on brand-name treatment Hetlioz in an infringement battle with Teva and Apotex over planned generics, agreeing that previous publications rendered the claimed inventions obvious.

The three-judge panel's nonprecedential opinion affirmed a lower court's decision to ax four patents that Vanda Pharmaceuticals Inc. had asserted against two rivals — Teva Pharmaceuticals USA Inc. and Apotex Inc. — in underlying litigation over planned generics for sleep disorder drug Hetlioz. Vanda had argued on appeal that the district judge "disregarded contrary evidence" when deeming the patents obvious. But the panel disagreed and found that referenced prior art, including one that spoke to a clinical trial on a chemical property found in Hetlioz known as tasimelteon, sufficiently supported the district judge's findings.

"There is no error in the district court's use of the then-ongoing clinical trial as one piece of evidence, combined with other prior art references, to support an obviousness determination," the panel detailed.

A spokesperson for Teva told Law360 on Wednesday that the company is "pleased with today's decision from the U.S. Appeals Court affirming its victory in the Delaware District Court and permitting Teva to continue supplying its lower cost version of tasimelteon to patients."

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 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 agreed to expedite the appeal in January but refused to enjoin Teva and Apotex from commercially marketing the disputed generics.

During March oral arguments, counsel for Apotex and Teva urged the appellate court to affirm the patents' invalidation. John Rozendaal of Sterne Kessler Goldstein & Fox PLLC, an attorney representing Teva Pharmaceuticals USA Inc., argued at the time that the claims of Vanda's drug administration method patent warning users to not take Hetlioz with food are telling.

"The claim says, in substance, do it the way most people have been doing it in the prior art," Rozendaal said. "To say, 'Do it the way we've always been doing it' seems to me to be the epitome of obviousness."

The panel said Wednesday that it agreed with the district court's determination that claimed aspects related to administering the drug "without food" would've been obvious.

"A [person of ordinary skill] would have understood that administering a drug with or without food could make it more or less effective," the panel said. "It is clear that food-effect studies were expected to be performed on new drugs, meaning clinicians and others who purchased or prescribed the drug would have expected food effect information about the drug to have been developed."

Vanda, Apotex and counsel for all parties did not immediately respond to requests for comment on Wednesday.

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

U.S. Circuit Judges Timothy B. Dyk, William C. Bryson and Sharon Prost sat on the panel for the Federal Circuit.

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 J.C. Rozendaal, Byron Pickard, Deirdre Wells, Will Milliken, Sasha Rao and Will Rodenberg of Sterne Kessler Goldstein & Fox PLLC.

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

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.

--Additional reporting by Katie Buehler.
