

## Teva, Apotex Win Ax Of Patents In Sleep Drug Suit

By **Jasmin Jackson**

*Law360 (December 13, 2022, 8:05 PM EST)* -- A Delaware federal judge on Tuesday wiped out four patents that Vanda Pharmaceuticals asserted against rivals Teva and Apotex in litigation over a planned generic version of sleep disorder drug Hetlioz, finding that they are invalid as obvious.

Following a four-day bench trial, U.S. Chief District Judge Colm Connolly said in his latest order that four patents held by Hetlioz maker Vanda Pharmaceuticals Inc. are ineligible for patenting. Vanda had alleged that competitors Teva Pharmaceuticals USA Inc. and Apotex Inc. infringed those patents by filing abbreviated new drug applications for generic versions of Hetlioz. But Judge Connolly determined that the claimed inventions are actually rendered obvious by prior art.

According to the opinion, combinations of previous publications released from 2003 to 2011 taught claimed aspects like dosage amounts and administration timing for Hetlioz, which is also chemically known as tasimelteon.

"Vanda argues '[t]hat 20 [milligrams] of tasimelteon proved efficacious was unexpected,'" Judge Connolly said. "As made clear from my finding above, [prior art references] contradict this contention."

He added: "Vanda contends that '[i]t was unexpected that success could be obtained administering tasimelteon before bedtime, rather than several hours earlier.' As discussed above, substantial record evidence contradicts this contention."

A spokesperson for Vanda directed Law360 to a public Tuesday statement in response to requests for comment. According to that statement, "Vanda intends to appeal the decision to the U.S. Court of Appeals for the Federal Circuit and to request a stay of market entry by Teva and Apotex while the appeal is pending."

Vanda first filed suit against Teva in April 2018, arguing that the drugmaker filed an 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 both filed ANDAs that purportedly infringed patents on the brand-name sleep disorder drug.

The three suits were later consolidated in May 2020.

Vanda then announced in January that it had settled its infringement claims against MSN. Under that 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 partook in a bench trial in March.

Judge Connolly invalidated claim 5 of the '487 patent in his corresponding opinion issued Tuesday, 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.

Counsel for Apotex, Vanda and Teva declined to comment on Tuesday.

Apotex and Teva did not immediately respond to requests for comment on Tuesday.

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 Karen Jacobs and Derek J. Fahnestock of Morris Nichols Arsht & Tunnell LLP and Daniel J. Klein, Josephine Young and Nicholas Groombridge of Groombridge Wu Baughman & Stone LLP.

Teva is represented by Deirdre M. Wells, John C. Rozendaal, Sasha S. Rao, Byron Pickard and William H. Milliken of Sterne Kessler Goldstein & Fox PLLC, Karen E. Keller and Nathan R. Hoeschen of Shaw Keller LLP and Michael Bruns of Allen & Overy LLP.

Apotex is represented by Thomas Joseph Francella Jr., Aaron S. Lukas, Barry P. Golob, Derek Gretkowski, Gregory F. Fischer, Kaan Ekiner, Keri L. Schaubert, Kerry B. McTigue and William B. Coblenz of Cozen O'Connor PC.

The suit is Vanda Pharmaceuticals Inc. v. Teva Pharmaceuticals USA Inc., case number 1:18-cv-00651, in the U.S. District Court for the District of Delaware.

--Editing by Melissa Treolo.