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Fed. Circ. Unsure Vanda's Sleep Med Hetlioz Is Patentable

By **Katie Buehler**

Law360 (March 14, 2023, 6:17 PM EDT) -- A Federal Circuit panel seemed wary Tuesday of Vanda Pharmaceuticals' attempt to overturn a Delaware federal judge's decision invalidating four patents related to its sleep disorder treatment drug Hetlioz, questioning whether the drug's dosage and method of administration were obvious before the patents were issued.

Vanda Pharmaceuticals Inc. asked the three-judge panel during oral arguments to reverse a December invalidation ruling based on obviousness, arguing the district judge failed to properly consider the prior art available before the patents were issued and, instead, based his ruling on hindsight. The panel's questions, however, showed that the judges had some doubts about Vanda's arguments.

The four patents at the center of this appeal relate to Vanda's Hetlioz, a brand-name version of the drug tasimelteon, which treats non-24-hour sleep disorder in patients whose circadian rhythm has been thrown off — an issue that mainly affects people who are blind. The patents establish the correct dosage, when the drug should be taken, what drugs have adverse effects on tasimelteon, and whether it should be taken with food.

"What we see here are pervasive errors of law, which, in turn, led to errors of fact," Vanda's attorney, Nicholas Groombridge of Groombridge Wu Baughman & Stone LLP, said about the district court's ruling.

Groombridge argued that the district judge considered only part of prior art studies related to sleep disorder treatments ramelteon and melatonin when deciding whether Vanda's invention was obvious and unpatentable. The judge wrongfully based his ruling on the drugs' similarities while ignoring their differences, he said.

For example, all three drugs can affect a person's circadian rhythm through phase-shifting, or causing them to fall asleep sooner than they would without the drug. But tasimelteon is the only one that synchronizes, or entrains, a person's rhythm to the Earth's 24-hour cycle. Most people who are totally blind become unsynchronized with the Earth's cycle because they cannot observe the changes in light, according to court documents.

The district judge's ruling erroneously equates phase-shifting with entrainment despite expert testimony at a March 2022 bench trial that said they were only slightly related, Groombridge said.

It also assumes that the studies' statement that a dosage lower than 100 milligrams made Vanda's patented 20 milligrams dosage an obvious choice, he said.

U.S. Circuit Judge Timothy B. Dyk pushed back on this statement, telling Groombridge the bench trial record includes expert testimony stating that exact conclusion could be drawn based on the prior art studies.

The witness says there is some evidence that a lower dosage would work, the judge pointed out.

"You can find something in the record that says maybe less than 100, but you can't find — viewing the art as a whole — you can't find anything that says 20 milligram will work," Groombridge retorted.

Judge Dyk also questioned whether Vanda's discovery that Hetlioz should be taken without food was obvious since the U.S. Food and Drug Administration suggests that drug manufacturers study food's effect on a drug's efficacy.

"There's a finite number of possibilities," Judge Dyk said.

Groombridge countered that the question isn't a binary one, explaining the study could conclude only certain types of food should be avoided when taking certain medications. The prior art, he noted, never examined food's effect on sleep disorder treatments' efficacy.

"The fact that it is significant enough here in regards to this treatment — that was not knowable in advance," he said. "The discovery is invented; there's nothing in the art to point to it."

John Rozendaal of Sterne Kessler Goldstein & Fox PLLC, an attorney representing Teva Pharmaceuticals USA Inc., urged the appellate panel to affirm the district court's invalidation ruling.

On behalf of Teva and Apotex Inc. — both of which are challenging Vanda's patents and have applied to develop generic versions of Hetlioz — Rozendaal argued 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," he said. "To say, 'Do it the way we've always been doing it' seems to me to be the epitome of obviousness."

He added the appellate panel should deny Vanda's request to overturn the district court's ruling, accusing the Hetlioz maker of challenging the decision based on sourness over their loss and not actual fact or law.

"The trial of this case was a classic battle of the experts, and Vanda lost it fair and square," Rozendaal said. "The experts had competing narratives and in each instance the district court credited the testimony of Teva's experts."

Vanda sued Teva in April 2018, alleging that Teva's abbreviated new drug application, or ANDA, infringed its Hetlioz patents issued by the U.S. Patent and Trademark Office from June 2015 to November 2017.

The Hetlioz maker then slapped Apotex with a separate suit in May 2018. The lawsuits were consolidated in May 2020.

Following a March 2022 bench trial, Chief U.S. District Judge Colm Connolly invalidated Vanda's four

patents related to Hetlioz on the basis of obviousness. Vanda appealed to the Federal Circuit later that month.

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

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

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

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

Apotex is represented by Aaron S. Lukas, W. Blake Coblentz and Keri L. Schaubert of Cozen O'Connor PC.

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

--Additional reporting by Jasmin Jackson. Editing by Rich Mills.
