

Fed. Circ. Won't Let Jazz Keep System Patent In Orange Book

By **Dani Kass**

Law360 (February 24, 2023, 7:43 PM EST) -- Jazz Pharmaceuticals must remove a patent from the Orange Book listing for its blockbuster narcolepsy drug Xyrem, as it covers neither the drug itself nor a method of using it, the Federal Circuit concluded Friday.

The Federal Circuit affirmed that a computer-implemented system of safely prescribing gamma-hydroxybutyrateB wouldn't be entitled to a place in the database tied to when patent owners are eligible to delay possibly infringing drugs. The U.S. Food and Drug Administration database allows for composition and methods of use patents, but even when inextricably tied to the drug, doesn't allow for system patents.

"That the claimed systems can be used in the course of treating patients suffering from narcolepsy does not alter the fact that these are system claims," the precedential opinion states.

While Jazz had \$1.3 billion in net product sales of Xyrem in 2021, according to its most recent annual statement, most people would know gamma-hydroxybutyrateB as a drug used to incapacitate someone to make them easier to sexually assault, rather than a tightly controlled treatment for a sleeping disorder.

That "heavy misuse" is why the FDA mandated a safety protocol known as a risk evaluation and mitigation strategy, the Federal Circuit wrote. Namely, the drug's distribution was limited to one pharmacy — although that was relaxed in 2017. The 2014 patent being reviewed by the Federal Circuit was about implementing the single pharmacy distribution.

When a generic-drug maker wants to get on the market before patents expire, it usually makes a certification that any patents standing in its way are invalid or not infringed. In return, the patent owner often files a Hatch-Waxman Act suit in district court, which triggers the 30-month stay on FDA approval. The parties then fight over infringement and invalidity to see if — at least on the patent side — the FDA is allowed to approve the generic version.

Here, however, Avadel CNS Pharmaceuticals LLC in December 2020 applied for a new branded drug, which improved how often patients have to take the medication and featured a risk evaluation and mitigation strategy allowing for multiple pharmacies and databases, according to the opinion. Even so, the FDA required a certification like it would for generics with regard to the patent-at-issue, the opinion continues.

Afterward, Avadel sued the FDA and Jazz sued Avadel in Delaware. Avadel then dropped its FDA suit and instead brought a counterclaim in Jazz's asking to delist the patent.

U.S. District Judge Gregory B. Williams in November ordered that the patent be delisted, since it covers a system. Although the Federal Circuit initially stayed the enforcement of Judge Williams' order, it upheld his decision Friday.

The opinion issued 10 days after oral argument declared that all independent claims of the patent involved a "computer-implemented system" with "one or more computer memories," along with a "data processor." The panel was not persuaded by Jazz's attempt to argue that it actually had a method claim.

"As the district court correctly analyzed in its [claim construction order], these claims recite 'an assemblage of components,' defining a system," the opinion states. "Jazz has not identified any description in the patent specification or prosecution history to alter that conclusion. The claims to a system comprising computer memories and a data processor are not claims to a method."

The Federal Circuit also shot down Jazz's argument that the FDA should be given deference in the case, saying that "the FDA has not definitively answered the question of whether [risk evaluation and mitigation strategy] patents" belong in the Orange Book — which is an ongoing dispute.

Counsel for Jazz and Avadel didn't immediately respond to requests for comment Friday.

Circuit Judges Alan D. Lourie, Jimmie V. Reyna and Richard G. Taranto sat on the panel for the Federal Circuit.

The patent-in-suit is U.S. Patent No. 8,731,963.

Jazz is represented by Steven J. Horowitz of Sidley Austin LLP and Gabriel P. Brier, Frank Charles Calvosa, Francis Dominic Cerrito and Ellyde R. Thompson of Quinn Emanuel Urquhart & Sullivan LLP.

Avadel is represented by Gabriel K. Bell, Kenneth G. Schuler, Marc Nathan Zubick, Charles S. Dameron, Sarah Elizabeth Propst and Audra Sawyer of Latham & Watkins LLP, Kira Alexis Davis, Daralyn Jeannine Durie, Katherine McNutt and Rebecca Emily Weires of Morrison Foerster LLP and Daniel M. Silver of McCarter & English LLP.

The case is Jazz Pharmaceuticals Inc. v. Avadel CNS Pharmaceuticals LLC, case number 23-1186, in the U.S. Court of Appeals for the Federal Circuit.

--Editing by Emily Kokoll.