

Amgen Asks Fed. Circ. To Review Merck's \$2.5B Patent Loss

By Tiffany Hu

Law360 (February 3, 2020, 4:50 PM EST) -- Amgen is asking the full Federal Circuit to review a decision that wiped out a Merck subsidiary's \$2.5 billion verdict in a patent dispute against Gilead Sciences, saying in an amicus brief that the ruling will impede patent innovation in the medical field.

In its Friday brief, Amgen Inc. said that the full Federal Circuit should review a panel's precedential ruling in October affirming that Merck unit Idenix Pharmaceuticals LLC's hepatitis C treatment patent was invalid for not adequately explaining how to make the treatment and lacking a sufficient written description.

Idenix — which had hoped to reinstate what had been the largest patent verdict in history — filed a petition for rehearing last month, arguing that the panel's decision “announces” new enablement and written description rules that would have a chilling effect on genus claims “at the heart of breakthrough medical treatments.”

Amgen's brief similarly warns that under the new ruling, inventors may now be discouraged from seeking patent protection for their medical inventions because of the time and effort potentially needed to disclose each embodiment to support a genus claim.

“Resources that the entire industry will now feel forced to devote to synthesizing and screening such cumulative examples will be resources unavailable to discovering the next breakthrough medicine,” Amgen wrote.

Amgen added that the panel's “rigid legal inquiry” does not follow U.S. Supreme Court and Federal Circuit precedent that both traditionally call for a flexible approach when it comes to enablement and written description requirements outlined in Section 112 of the Patent Act.

“Section 112 should not be converted from a practical inquiry about what the patent teaches into a pointless numbers game,” Amgen wrote.

The dispute goes back five years, when both Idenix and Gilead Sciences Inc. were developing drugs to treat hepatitis C. Idenix accused Gilead's blockbuster treatments Sovaldi and Harvoni of infringing its patent.

By the time the trial rolled around in December 2016, Gilead had conceded infringement of the patent, which describes a treatment using compounds with a certain chemical structure. Jurors ultimately found that Gilead failed to prove the patent was invalid and awarded Idenix \$2.54 billion.

But U.S. District Judge Leonard Stark dismantled that award in February 2018, ruling that the patent's claims weren't specific enough for an experienced scientist to successfully recreate the formula. The Federal Circuit panel agreed in October.

U.S. Circuit Judge Pauline Newman, however, dissented from the majority's ruling, which she said "provides a new path of uncertainty and unreliability" for patents. Judge Newman said she would have ruled that the patent's claims are valid but hadn't been infringed by Gilead's treatments.

The Sovaldi and Harvoni infringement dispute is not the first Federal Circuit battle for the two drug companies. Last year, the court upheld the reversal of a \$200 million verdict that Merck had won in a separate patent case against Gilead over hepatitis C drugs, citing misconduct on the part of Merck both in patent prosecution and litigation.

And before that, the Federal Circuit affirmed a Patent Trial and Appeal Board decision finding another Idenix patent failed to enable the practice of the alleged invention.

The patent-in-suit is U.S. Patent No. 7,608,597.

Attorneys for Idenix and Amgen declined to comment Monday. Counsel for Gilead did not immediately respond to a request for comment Monday.

Amgen is represented by Eldora L. Ellison, Jon E. Wright and Kristina Caggiano Kelly of Sterne Kessler Goldstein & Fox PLLC and in-house by Stuart Watt, Wendy Whiteford, Emily Johnson and Erica Olson.

Idenix is represented by Gregory Castanias, Lisa Furby, Calvin Griffith, Anthony Insogna, Ryan McCrum and Jennifer Swize of Jones Day and Jeffrey Lamken, Sarah Newman and Michael Pattillo of MoloLamken LLP.

Gilead is represented by E. Joshua Rosenkranz, Brian Goldman, Edmund Hirschfeld, Elizabeth Moulton and Eric Shumsky of Orrick Herrington & Sutcliffe LLP and Frank Scherkenbach, W. Chad Shear and Jonathan Singer of Fish & Richardson PC.

The case is Idenix Pharmaceuticals LLC v. Gilead Sciences Inc., case number 18-1691, in the U.S. Court of Appeals for the Federal Circuit.

--Additional reporting by Hailey Konnath. Editing by Alyssa Miller.