Gilead Avoids $1.2bn Patent Clash at SCOTUS
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A Bristol-Myers Squibb (BMS) unit has failed again in its bid to persuade the US Supreme Court to reinstate a $1.2 billion win against a subsidiary of Gilead Sciences, despite its overlap with the upcoming ruling in *Amgen v Sanofi*.

SCOTUS handed down its decision against a rehearing without any comments on Monday, January 9.

The dispute arose back in 2017 when BMS-owned Juno therapeutics sued Gilead's Kite Pharma for infringement after it released Yescarta, a CAR-T cell therapy used to treat large B-cell lymphoma.

Kite claimed that it owned a patent that covered a binding element used in Yescarta, a single-chain antibody variable fragment (scFv) that specifically targets and binds a protein known as CD19.

In April 2020, the US District Court for the Central District of California awarded $1.2 billion to Juno and the Sloan Kettering Institute, after a jury found infringement

But in August 2021, the Federal Circuit held that claims of US patent 7,446,190 were invalid, siding with Kite's argument that "no reasonable jury" could find the patent's written descriptions sufficient.

BMS then asked the Federal Circuit to rehear the dispute, arguing that the court had applied a "rigid, formalistic test" for evidence of the inventor's ownership of the "full scope" of the invention.

But the court denied the petition for a rehearing, prompting the parties to appeal to SCOTUS in June 2022, arguing that the Federal Circuit had added patent requirements that don't exist in the Patent Act.

While this was rejected, the companies petitioned again for a rehearing in late November citing SCOTUS' decision to grant a petition for a writ of *certiorari* of *Amgen v Sanofi* earlier that month.

The November 4, 2022 grant in the case of *Amgen v Sanofi* addresses the following question:

"Whether enablement is governed by the statutory requirement that the specification teach those skilled in the art to "make and use" the claimed invention, 35 U.S.C. § 112, or whether it must instead enable those skilled in the art 'to reach the full scope of claimed embodiments' without undue experimentation—ie, to cumulatively identify and make all or nearly all embodiments of the invention without substantial time and effort".

The ruling is expected to have significant implications for the pharma sector. Nicholas Matich, principal at McKool Smith, predicted that the decision could become one of the biggest developments in IP law this year.

"It was a big surprise to see the court grant the petition against the recommendation of the Solicitor General," he explained.

"This is a fairly rare occurrence in the patent realm and, whatever the result is, it will likely be the most significant substantive development in the core of the patent act next year. The case will undoubtedly have big impacts on biologic inventions, but it will be important to see how broadly the court writes its opinion to see how it may affect other areas of technology."

In its rehearing petition, Juno asked the justices to hold its case against Kite while they consider similar issues in the landmark *Amgen* case, arguing that both explore issues concerning written description requirements under Section 112 of the Patent Act.

“These two cases involve the very same sentence of the very same statute, 35 U.S.C. § 112(a),” the company wrote.

“Both ask whether the “make and use” language from the statute provides the proper statutory test, and both ask whether the Federal Circuit’s addition of a “full scope” requirement is an appropriate addition to Congress’s language choice.

“The issues presented are tightly related, and the outcome in Amgen is likely to at least affect, if not be outcome-determinative of, this case. Accordingly, rehearing should be granted.”

Several pharmaceutical companies filed *amicus* briefs in support of BMS, including Amgen, GSK and St. Jude's Children's Research Hospital.

But yesterday, SCOTUS declined to apply Juno’s reasoning and grant a rehearing.