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Fed. Circ. Impeding Biopharma Innovation, Justices Told

By **Dani Kass**

Law360 (August 29, 2018, 10:15 PM EDT) -- Bristol-Myers Squibb Co. and three other drug companies have urged the U.S. Supreme Court to take up a case challenging the Federal Circuit's decision to impose different standards on the written description and enablement disclosures of patents, claiming the decision as it stands will deter companies from innovation.

Bristol-Myers, Morphosys Ag, Bavarian Nordic A/s and UCB Biopharma Sprl on Monday said the Federal Circuit had chipped away at the guarantee of patent protection, making innovator companies less likely to put the funds into researching and developing new drugs.

"The Federal Circuit's approach makes it exceedingly difficult to obtain robust patent protection for biopharmaceutical innovations and consequently impedes progress in this field," the amici stated.

The petition for a writ of certiorari filed by Amgen Inc. in July alleged that the Federal Circuit defied the plain text of the law when holding two patent disclosures to different standards. The Patent Act calls for a patent to describe what an invention is, and how to make and use it, with both those prongs held to the same standard of being " 'in such full, clear, concise and exact terms as to enable any person skilled in the art … to make and use' the invention," the petition states.

By adding an additional requirement that an inventor must possess the claimed invention on the filing date to the description element, the Federal Circuit strayed from the law and made getting patents harder, Amgen says.

The amici echoed Amgen, calling the Federal Circuit's decision a "reimagining of the statutory standard."

"The court should likewise reject the Federal Circuit's misreading of the statute and its rigid test here and instruct that court to analyze § 112(a) [regarding specification] in a flexible, contextual way, with attention to all applicable factors supported by the statute," the brief states.

The case started in 2014 with Amgen suing Sanofi-Aventis and Regeneron Pharmaceuticals Inc. hoping to block their joint drug, Praluent, using patents that cover its own Repatha. The ruling is important because both drugs belong to a new class of "PCSK9 inhibitor" drugs for stubbornly high cholesterol and have historically had list prices of roughly $14,000 annually. The cost of Praluent was slashed in March to between $4,500 and $8,000 annually.

Delaware's U.S. District Judge Sue L. Robinson issued a permanent injunction against Sanofi and Regeneron in January 2017, following a jury verdict in Amgen's favor. The Federal Circuit overturned that ruling in October.

The unanimous panel said Judge Robinson improperly blocked evidence that was developed after the priority date of two Repatha patents. The evidence was intended to show that the patents lacked a sufficient written description. Judge Robinson had concluded that the evidence was not relevant at the time Repatha's patents were filed, but the Federal Circuit balked.

According to the appeals court, Judge Robinson incorrectly equated post-priority-date evidence meant to illuminate the post-priority-date state of the art with post-priority-date evidence meant to show that a patent was not adequately described in the first place. While the former is not allowable, the latter is, the opinion said.

For similar reasons, the Federal Circuit also found that Judge Robinson erred by forbidding evidence about whether Repatha's patents were enabled, or outlined in sufficient detail at the time of their 2008 priority date. The court ordered a new trial on the written description and enablement issues, which are crucial because Sanofi and Regeneron have conceded infringement.

Amgen pushed back on the appellate ruling, asking for a rehearing en banc, but the Federal Circuit declined in February, paving the way for the high court appeal.

Representatives for the companies did not immediately respond requests for comment late Wednesday.

The patents-in-suit are U.S. Patent Numbers 8,829,165 and 8,859,741.

The amici are represented by Jorge A. Goldstein, Eldora L. Ellison, John Christopher Rozendaal and William H. Milliken of Sterne Kessler Goldstein & Fox PLLC.

Amgen is represented by Jeffrey A. Lamken, Michael G. Pattillo Jr and Sarah J. Newman of MoloLamken LLP and Amgen's Stuart L. Watt, Wendy A. Whiteford, Erica S. Olson and Emily C. Johnson.

Sanofi and Regeneron were represented at the Federal Circuit by Paul D. Clement, Nathan S. Mammen and George W. Hicks Jr. of Kirkland & Ellis LLP and Siew Yen Chong, Vishal C. Gupta, Richard Praseuth and John J. Molenda of Steptoe & Johnson LLP.

The case is Amgen Inc., et al., v. Sanofi, et al., case number 18-127, before the Supreme Court of the United States.

--Additional reporting by Jeff Overley. Editing by Peter Rozovsky.