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Amgen Supreme Court Arguments Aren't Just About Biology

By **Dani Kass**

Law360 (March 24, 2023, 10:36 PM EDT) -- The lone patent case the U.S. Supreme Court has agreed to hear this term centers on how pharmaceutical companies claim antibodies in patents and the way that impacts competing cholesterol medications, meaning a decision will clearly have implications for attorneys in the life sciences area. But lawyers who focus on software and other sectors should be paying attention as well.

At oral arguments Monday, the justices will consider how much of a genus needs to be disclosed in a patent to make it enabled under Section 112 of the Patent Act. The patent owner, Amgen, argues that a skilled artisan should be able to "make and use" the invention as required by the statute, but the accused infringers say a skilled artisan should be able to "reach the full scope of claimed embodiments" without undue experimentation.

Having the Supreme Court review a fundamental part of the Patent Act has the potential to impact all industries in the same way now-ubiquitous cases over patent eligibility have done, said Oblon McClelland Maier & Neustadt LLP partner Sameer Gokhale.

"It has a ripple effect that really can't be contained," Gokhale said. "This is a particularly heavy case because it's taking one of our bread-and-butter statutes and clarifying the threshold to meet the requirements of the statute in a way that could make the threshold easier or stricter."

The Supreme Court will be reviewing a Federal Circuit decision from February 2021 when Sanofi and Regeneron were able to invalidate claims of Amgen patents asserted against them.

The patents cover a genus of antibodies that bond with residues of a certain protein, which has the overall impact of lowering cholesterol. The Federal Circuit found that Amgen's claims for its drug Repatha were too broad, handing a win to Sanofi and Regeneron Pharmaceuticals, which sell the competing drug Praluent.

A discussion of meeting Section 112 enablement and written description requirements has been a key part of the case over the course of two trials and various appeals, but the justices will only be reviewing enablement.

While Section 112 is commonly invoked in patent challenges, this is only the second time the Supreme Court has agreed to review it since the 1952 act was implemented. The prior case was over indefiniteness in 2014.

"It shows you how infrequently practitioners get guidance on this issue," said Goodwin Procter LLP partner Natasha Daughtrey.

The justices on Monday will be looking at a genus of antibodies, but just because the language is biology-based doesn't mean there aren't equivalent structures in other patents, said Robins Kaplan LLP partner Jake Holdreith.

In a simplified example, Holdreith said computer-implemented patent claims could involve storing data and having the ability to rapidly access memory. There are multiple ways to accomplish that, including with different data structures and different types of memory, each of which would be a "species" in the "genus."

"Genus and species [are terms] very familiar in biology, but there certainly are instances of genus and species that have nothing to do with biology," he said.

There can be multiple ways to practice a claim, which is how patent owners can sue for infringement of the same claims against multiple parties and products even if the allegedly infringing products aren't exactly the same, Daughtrey said.

"Many claims, regardless of technology, have more than one potential embodiment, more than one example of how to practice the claim," Daughtrey said.

Crowell & Moring LLP partner Mark Remus said it would be surprising for the high court to come out with a decision that applies just to the pharmaceutical industry or antibodies, leaving out technology or other areas.

"That same legal standard is going to apply to both spaces," Remus said. "[The justices are] not going into the nitty-gritty of antibodies. They're going to focus on the legal precedent."

A huge aspect of the Amgen case is that the Federal Circuit found the company's patent claims to be functional, meaning they describe the final result of something, as opposed to the process to get there — which can make showing enablement difficult.

Functional claims are a big part of software patents, said Gokhale of Oblon McClelland.

"No one is going to reinvent the computer. They're going to write new code," he said. "The hardware hasn't changed. It's the software that's trying to do something special."

This is especially shown in artificial intelligence, where a goal like being able to recognize something is what is programmed, Gokhale said. Such functions could include a self-driving car taking a particular action when there's an unmoving object in front of the vehicle, he said.

Of course, how much of an impact the ruling will have on patent attorneys' work will depend on what the justices do. Robins Kaplan's Holdreith said if the law ends up staying broad, there is a fear that patents will claim more than what inventors had discovered, while narrowing the law will create added uncertainty.

"A tighter restriction on requiring the full scope of the invention be enabled creates an additional issue

to litigate and some additional uncertainty about outcomes," he said. "It's one more thing in a complex patent case to litigate, and one more zone of uncertainty that can affect the difficulty in predicting the outcome."

The case is Amgen Inc. et al. v. Sanofi et al., case number 21-757, in the U.S. Supreme Court.

--Editing by Jill Coffey and Dave Trumbore.
