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Justices Clamp Down On Broad Patents In Amgen Decision

By **Ryan Davis**

Law360 (May 18, 2023, 10:15 PM EDT) -- The U.S. Supreme Court sent a clear message Thursday that broad patents covering anything that can perform a certain function are not allowed, meaning patent applications must be tailored more narrowly to what has been discovered, particularly in the biotechnology field, attorneys say.

In a unanimous decision, the high court held that Amgen Inc. patents on the cholesterol drug Repatha are invalid because they cover any antibody that can bind to a certain protein. That does not enable a skilled person to make and use Amgen's claimed invention, as required by patent law, the court said.

"If a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent's specification must enable a person skilled in the art to make and use the entire class," the justices said in an opinion by Justice Neil Gorsuch. "In other words, the specification must enable the full scope of the invention as defined by its claims. The more one claims, the more one must enable."

Patent claims that are written as broadly as Amgen's are common for antibodies and other biotechnology inventions, so the court's holding that they cannot survive "will have enormous impact across industries for decades to come," said Irena Royzman of Kramer Levin Naftalis & Frankel LLP.

Such patents will likely not be asserted going forward, and new patent applications will have to be written differently in order to ensure that they do not "require another scientist to do the work to make the inventions," she said.

The justices made clear that they were not creating new law in applying a reading of the enablement requirement that the court had used in decisions from the 19th and early 20th centuries involving inventions like the telegraph and the light bulb.

The decision emphasizes that cutting-edge biotechnology inventions must meet the same requirements, and "shoots down the idea" that a patent can describe an invention in broad terms and "tell the public, go make it," Royzman said. "That's not the quid pro quo envisioned by the patent system."

Amgen alleged that its patents were infringed by the competing cholesterol drug Praluent made by Sanofi SA and Regeneron Pharmaceuticals Inc. It argued to the Supreme Court that requiring patents to enable a skilled person to make and use the full scope of the invention sets an unnecessarily high bar and "would render unpatentable any invention that covers a 'nontrivial' number of variations."

The justices were unpersuaded, noting that Amgen's patents could potentially cover millions of antibodies, although the company specifically described how to make only 26.

"If an inventor claims a lot, but enables only a little, the public does not receive its benefit of the bargain. For more than 150 years, this court has enforced the statutory enablement requirement according to its terms," the court said.

Jonathan Masur, a professor at the University of Chicago Law School, said that by arguing that patents do not need to enable someone to make and use the full scope of the invention, "Amgen was trying to push the envelope legally, and that attempt was wildly unsuccessful."

"It's very tempting when you're a life sciences firm, and you've discovered an interesting principle of science, to try to claim anything that basically uses that principle," he said. "But the courts have to this point resisted it and now the Supreme Court has made clear that they should continue resisting it."

Going forward, patent applicants will need to ensure that they provide sufficient detail to meet the enablement requirement, as defined by the court. That could mean writing patent claims that are more specific, said Kevin O'Connor of Neal Gerber & Eisenberg LLP.

"The issue was the breadth of the claims in this case. If the claims were more narrowly tailored towards the antibodies that were actually made, you wouldn't have this issue," he said.

The Supreme Court also noted that it would be possible to write a patent that broadly covers the functional embodiment of an invention if it identifies a quality that is common to all of them, which Amgen did not do.

In the life sciences space, such common features could include the structure of a molecule or the sequence of an antibody. Pointing to something like that "might be a position to take to avoid these lack of enablement findings," O'Connor said.

In order for patent applicants to have more time to identify such a common quality, "it might benefit them to file later than sooner," said Andrew Schwerin of Saul Ewing LLP.

"Overall, I think this is going to push people to put a little more in their patents and file later, once they have some more evidence and more experiments in there," he said.

Waiting to file could also let patent applicants identify and describe more of the examples of the invention that anyone would want to use, so that other companies cannot easily design around the patent, Masur said.

Yet he noted that the Supreme Court's decision is "going to make life a little bit tricky for some of the more pioneering firms doing research and development" in the life sciences area. If a company makes a scientific breakthrough and gets a patent that is limited to the embodiments of the invention that it knows about, "you've opened the door for someone else to find another version," he said.

Anne Li of Crowell & Moring LLP said that the court's holding that "you get what you actually did, not what someone could do," has the effect of "bringing the enablement requirement for biotech patents back in line with other technologies."

Beginning in the late 1990s, the U.S. Patent and Trademark Office began allowing patents on antibodies that were described as binding to a specific antigen without further explanation, creating an exception that let antibody patents be defined in terms of their function in a way other patents cannot, said Christopher Cowles of Withers.

He said that practice has largely ended following earlier court rulings, so most antibody patents are now described with more detail, but "I see this as sticking a final fork in that antibody exception," with the court making clear that patents on antibodies must follow the same rules as those for therapeutics and other inventions.

Cowles said he agreed with a point that Sanofi's attorney, Paul Clement of Clement & Murphy PLLC, made at oral argument in the case, when he said, "I think functional claims are terrible. I think they retard the science, and I don't think you have to look beyond this court's cases."

"To me that sealed it, because I think that if you're going to enable a class of anything, you actually need to define the metes and bounds of that class," Cowles said.

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

--Editing by Andrew Cohen.
