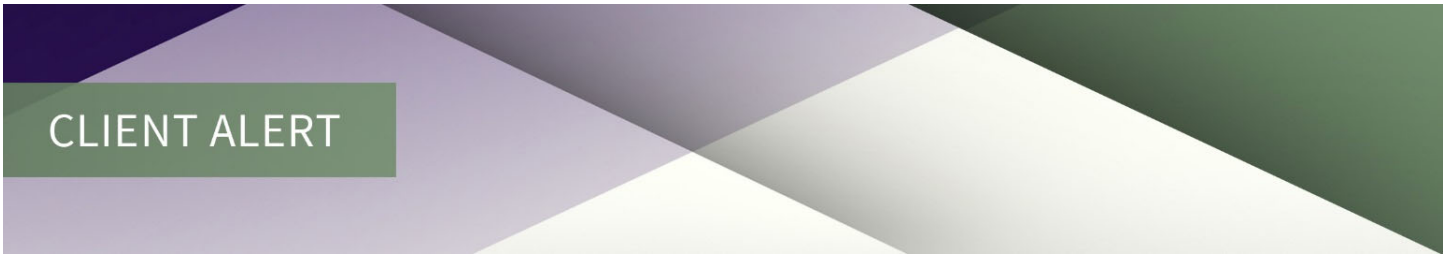

U.S. Supreme Court Highlights Enablement and the Full Scope of Invention in *Amgen Inc. v. Sanofi*

May 19, 2023

AUTHORS

Heather M. Schneider | Michael W. Johnson | Matthew Freimuth

On May 18, 2023, the United States Supreme Court delivered a unanimous decision in the case of *Amgen Inc. v. Sanofi*, which has drawn significant attention and anticipation. The Court's ruling holds that a patent must enable any person skilled in the art to make and use the full scope of the invention as defined by its claims.[1] In particular, when a patent claim covers an entire genus of antibodies, the specification must provide sufficient enablement for the entire claimed genus, allowing for a reasonable amount of experimentation.

This long-awaited decision, supported by dozens of amicus briefs, carries implications for the pharmaceutical industry and the delicate balance between incentivizing inventors while ensuring public benefit.

Case Background

Before 2011, two pharmaceutical companies, Amgen and Sanofi, independently developed drugs that inhibit PCSK9, a naturally occurring protein that helps reduce levels of low-density lipoprotein (LDL) cholesterol.[2] LDL cholesterol is undesirable because it can lead to cardiovascular disease, heart attacks, and strokes.[3] In 2011, both companies obtained separate patents for the antibodies used in their PCSK9-inhibiting drugs.[4] Subsequently, in 2014, Amgen acquired two

[1] *Amgen Inc. v. Sanofi*, No. 21-757, 598 U.S. __, here (May 18, 2023) ("Slip op.").
[2] Slip op. at 4.
[3] *Id.*
[4] *Id.* at 5.

additional patents related to its 2011 patent, covering "the entire genus" of antibodies that "bind to specific amino acid residues on PCSK9" and "block PCSK9 from binding to [LDL receptors]."[5] The patents' specifications disclosed the amino acid sequences of 26 antibodies and provided two methods for making other antibodies meeting the functional limitations of the claims: the "roadmap" and "conservative substitution" techniques.[6]

Simply put, the roadmap instructs scientists to generate a range of antibodies, assess if any of them bind to the targeted section of PCSK9, and subsequently evaluate if any of them block PCSK9 from binding to LDL receptors.[7] The conservative substitution technique involves starting with an antibody that is already known to exhibit the desired binding and blocking functions, modifying its amino acids, and then testing whether the resulting antibody retains the same functions.[8]

Amgen sued Sanofi for infringement after obtaining its 2014 patents.[9] Sanofi replied that the relevant claims were invalid as a matter of law because they covered potentially millions more antibodies than those taught in the specification.[10] Both the district court and the Federal Circuit ruled in favor of Sanofi, finding Amgen's patents not enabled.[11] Amgen appealed to the Supreme Court, which granted certiorari.

Supreme Court Opinion

Justice Gorsuch authored the unanimous opinion of the Supreme Court, which discussed the enablement requirement as an essential aspect of the patent "bargain" rooted in the Constitution.[12] The Court emphasized that in exchange for limited protection from competitive exploitation, inventors must benefit the public by enabling a skilled person in the field to make and use the invention, a principle affirmed in previous Supreme Court rulings such as *O'Reilly v. Morse*, *The Incandescent Lamp Patent*, and *Holland Furniture Co. v. Perkins Glue Co.*[13] All of these cases "reinforce the simple statutory command [that 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."[14]

Nonetheless, the Court acknowledged that a specification need not "describe with particularity how to make and use every single embodiment within a claimed class."[15] An example can be sufficient if the specification discloses a general quality

[5] *Amgen Inc. v. Sanofi*, 872 F. 3d 1367, 1372 (CA Fed. 2017).
[6] Slip op. at 5–6.
[7] *Id.*
[8] *Id.*
[9] *Id.*
[10] *Id.* at 6.
[11] *Id.* at 6–7.
[12] *Id.* at 7.
[13] *Id.* at 8.
[14] *Id.* at 13.
[15] *Id.*

running through the class that would "reliably enable a person skilled in the art to make and use all of what is claimed, not merely a subset."[16] Additionally, "a specification may call for a reasonable amount of experimentation to make and use a patented invention. What is reasonable in any case will depend on the nature of the invention and the underlying art."[17]

Regarding antibodies, the Court recognized their "incredibly diverse" nature in terms of structure and function, and it elucidated that certain aspects of antibody science remain "unpredictable," even with recent advancements.[18] The Court cited the challenges scientists face in predicting the effects of substituting a single amino acid on an antibody's structure and function.[19]

Addressing the patents-at-issue, the Court determined that "Amgen's specification enables the 26 exemplary antibodies it identifies by their amino acid sequences."[20] However, Amgen failed to enable its claim to the "entire genus," even after allowing for a "reasonable degree of experimentation."[21] The Court found that the methods that Amgen proposed—the "roadmap" and "conservative substitution" methods—merely amounted to trial-and-error testing, lacking sufficient enablement for the broader scope of claims.[22] Consequently, the Supreme Court affirmed the judgments of the lower courts.[23]

Possible Implications

The Supreme Court's recent decision attempts to strike a sensitive balance between incentivizing inventors and ensuring that the public receives the full benefit of scientists' innovations. Those seeking to challenge patent validity are likely to welcome the ruling, as it restrains the scope of claims by requiring clear enablement. Some prominent drug makers had expressed support for Sanofi, contending that a decision in favor of Sanofi would encourage the disclosure of specific inventions and breakthroughs over time, without unjustly monopolizing vast areas of research.[24] Conversely, those seeking a broader scope of claims may align with Amgen, who cautioned that the Court's decision could undermine incentives for groundbreaking inventions.[25] Additionally, supporters of Amgen have argued that broader patent claims

[16] *Id.* at 13–14.
[17] *Id.* at 15.
[18] *Id.* at 2–3.
[19] *Id.* at 3.
[20] *Id.* at 15.
[21] *Id.*
[22] *Id.* at 16–17.
[23] *Id.* at 15.
[24] Kelcee Griffis, "Justices Narrow Patent Enablement Scope in Amgen-Sanofi Case (1)," Bloomberg Law, May 18, 2023, https://news.bloomberglaw.com/ip-law/high-court-narrows-patent-enablement-scope-in-amgen-sanofi-case-12.
[25] Slip op. at 19.

foster the development of widely applicable treatments and ensure a reasonable return on investment for drug manufacturers.[26]

Regardless of their stance, both sides, as well as investors in the pharmaceutical industry, should benefit from the Supreme Court's provision of additional clarity and guidance on the scope of the enablement requirement. Moving forward, inventors, patent holders, and entities seeking to invalidate patents will be better equipped to navigate the legal landscape in light of this significant decision. It remains to be seen if further refinement of this doctrine will occur in the future.

If you have any questions regarding this client alert, please contact the following attorneys or the Willkie attorney with whom you regularly work.

Heather M. Schneider
212 728 8685
hschneider@willkie.com

Michael W. Johnson
212 728 8137
mjohnson1@willkie.com

Matthew Freimuth
212 728 8183
mfreimuth@willkie.com

[26] Griffis, "Justices Narrow Patent Enablement Scope in Amgen-Sanofi Case (1)," Bloomberg Law, May 18, 2023.