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May 2023

Supreme Court Reinforces Patent Act's Enablement Requirement in Unanimous Decision for Sanofi

On May 18, 2023, the United States Supreme Court delivered a unanimous decision that upheld the Federal Circuit's ruling on the invalidity of claims in two Amgen patents that purported to cover an entire genus of antibodies for the treatment of high cholesterol. *Amgen Inc. et al. v. Sanofi et al.*, 598 U.S. _____ slip op. (2023). The Supreme Court affirmed that the patents lacked enablement under 35 U.S.C. §112(a), thereby concluding the lengthy dispute between Amgen and Sanofi. The case attracted significant attention from industry players, prompting the submission of numerous *amicus* briefs. This ruling reinforces the significance of the Patent Act's enablement requirement.

Background

In October 2014, Amgen filed a lawsuit against Sanofi, alleging infringement of two patents related to antibody-based treatment for patients with high levels of low-density lipoprotein cholesterol (commonly known as LDL cholesterol or "bad" cholesterol). Op. at 1. The patents at issue purported to claim "the entire genus" of antibodies that (1) bind to a naturally occurring protein in the body (known as PCSK9), and (2) block the protein from degrading LDL receptors in the body (which remove LDL cholesterol from the bloodstream). *Id*. at 5.

Amgen supported the breadth of its claims by providing the amino acid sequences of 26 working antibodies and illustrating the three-dimensional structures of two of these antibodies. *Id*. Additionally, Amgen disclosed two approaches for discovering additional antibodies: a "roadmap" approach involving

the generation and testing of candidate antibodies; and a "conservative substitution" approach where select amino acids were replaced with others possessing similar properties, followed by testing the resulting antibodies. *Id*. at 5-6.

Sanofi argued that the patents lacked enablement because they encompassed "millions" of undisclosed antibodies, and Amgen's guidance amounted to little more than a "trial-and-error" approach. *Id*. at 6. Both the lower court and Federal Circuit sided with Sanofi, invalidating the claims under the enablement requirement of §112, which requires a patent applicant to describe its invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the [invention]." 35 U. S. C. §112(a).

The Supreme Court unanimously affirmed the Federal Circuit's finding of invalidity. While recognizing the unique complexity and unpredictability of antibody research (*id*. at 2-3), the Court drew analogies to landmark decisions spanning centuries, emphasizing that "the more a party claims, the broader the monopoly it demands, the more it must enable" and "[t]hat holds true whether the case involves telegraphs devised in the 19th century, glues invented in the 20th, or antibody treatments developed in the 21st." *Id* at 16.

The Supreme Court also dismissed Amgen's "roadmap" and "conservative substitution" approaches as insufficient "trial-and-error" methods. *Id*. at 16-17. However, the Court clarified that the specification did not need to describe every single embodiment within a claimed class in detail, as long as it disclosed a "general quality" enabling a skilled person to reliably make and use all the claimed embodiments, not just a subset." *Id*. at 13-14.

Furthermore, the Supreme Court rejected Amgen's argument that the Federal Circuit improperly conflated the issue of enablement with the cumulative time and effort required. The Court reaffirmed that the cumulative time and effort is not dispositive. *Id*. at 18. It also emphasized that the Federal Circuit did not establish a heightened standard for "genus claims," reiterating that a uniform standard applies to all claims. *Id*.

The Impact of the Supreme Court's Ruling

The Supreme Court's unanimous decision underscores the significance of the enablement requirement, particularly in the rapidly advancing fields of antibody and biologics research. Patentees should carefully craft their claims to cover specific embodiments disclosed in the specification, helping to protect them from enablement challenges. For broader claims, the specification should disclose the structural attributes which dictate function, to avoid vulnerability to "trial-and-error" enablement rejections.

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