

Alert | Intellectual Property Litigation

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.

Authors

This GT Alert was prepared by:

- **Scott J. Bornstein** | +1 212.801.2172 | Scott.Bornstein@gtlaw.com
- **Benjamin D. Witte** ‡ | +1 305.579.0517 | Ben.Witte@gtlaw.com

‡ Admitted in Georgia and Illinois and before the USPTO. Not admitted in Florida. Practice limited to federal patent and trademark law.

Albany. Amsterdam. Atlanta. Austin. Berlin. ~ Boston. Charlotte. Chicago. Dallas. Delaware. Denver. Fort Lauderdale. Houston. Las Vegas. London.* Long Island. Los Angeles. Mexico City.+ Miami. Milan.» Minneapolis. New Jersey. New York. Northern Virginia. Orange County. Orlando. Philadelphia. Phoenix. Portland. Sacramento. Salt Lake City. San Diego. San Francisco. Seoul.∞ Shanghai. Silicon Valley. Singapore.= Tallahassee. Tampa. Tel Aviv.^ Tokyo.* Warsaw.~ Washington, D.C.. West Palm Beach. Westchester County.

*This Greenberg Traurig Alert is issued for informational purposes only and is not intended to be construed or used as general legal advice nor as a solicitation of any type. Please contact the author(s) or your Greenberg Traurig contact if you have questions regarding the currency of this information. The hiring of a lawyer is an important decision. Before you decide, ask for written information about the lawyer's legal qualifications and experience. Greenberg Traurig is a service mark and trade name of Greenberg Traurig, LLP and Greenberg Traurig, P.A. ~Greenberg Traurig's Berlin office is operated by Greenberg Traurig Germany, an affiliate of Greenberg Traurig, P.A. and Greenberg Traurig, LLP. *Operates as a separate UK registered legal entity. +Greenberg Traurig's Mexico City office is operated by Greenberg Traurig, S.C., an affiliate of Greenberg Traurig, P.A. and Greenberg Traurig, LLP. »Greenberg Traurig's Milan office is operated by Greenberg Traurig Santa Maria, an affiliate of Greenberg Traurig, P.A. and Greenberg Traurig, LLP. ∞Operates as Greenberg Traurig LLP Foreign Legal Consultant Office. ~Greenberg Traurig's Singapore office is operated by Greenberg Traurig Singapore LLP which is licensed as a foreign law practice in Singapore. ^Greenberg Traurig's Tel Aviv office is a branch of Greenberg Traurig, P.A., Florida, USA. »Greenberg Traurig's Tokyo Office is operated by GT Tokyo Horitsu Jimusho and Greenberg Traurig Gaikokuhojimubengoshi Jimusho, affiliates of Greenberg Traurig, P.A. and Greenberg Traurig, LLP. ~Greenberg Traurig's Warsaw office is operated by GREENBERG TRAURIG Nowakowska-Zimoch Wysokiński sp.k., an affiliate of Greenberg Traurig, P.A. and Greenberg Traurig, LLP. Certain partners in GREENBERG TRAURIG Nowakowska-Zimoch Wysokiński sp.k. are also shareholders in Greenberg Traurig, P.A. Images in this advertisement do not depict Greenberg Traurig attorneys, clients, staff or facilities. No aspect of this advertisement has been approved by the Supreme Court of New Jersey. ©2023 Greenberg Traurig, LLP. All rights reserved.*