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PATENTS AND TRADEMARKS

Expert Analysis

Supreme Court To Revisit The Patent Enablement Standard

By **Robert L. Maier**

The Patent Act requires that a patent's "specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms *as to enable any person skilled in the art* to which it pertains … to *make and use the same*"—commonly known as the "enablement requirement." 35 U.S.C. §112(a) (emphasis added). In November, the Supreme Court granted certiorari to review courts' application of this statutory enablement requirement.

The Supreme Court in *Amgen v. Sanofi*, No. 21-757, 2022 WL 16703751 (Nov. 4, 2022), is now set to consider whether a patent, in order to comply with the enablement requirement under 35 U.S.C. §112, must include merely enough detail such that those skilled in the art can "make and use" the claimed invention, or, instead, whether there must be sufficient detail to "reach the full scope" of the claimed embodiments—a heightened standard imposed by the Federal Circuit in this case below. See Petition for Writ of Certiorari, *Amgen*, No. 21-757. The decision has the potential to have a significant impact on inventors and patent drafters, and the breadth with which they may be able to claim their inventions.

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Enablement Requirement Under 35 U.S.C. §112 and the Federal Circuit

The purpose of the enablement requirement is to ensure that a patentee will describe an invention sufficiently "so that others may construct and use it after the expiration of the patent." *Schriber-Schroth Co. v. Cleveland Tr. Co.*, 305 U.S. 47, 57 (1938). This is part of the quid pro quo that patent holders obtain a right to exclude others from making or using their invention for a limited time in exchange for revealing the invention to the world to enrich the public knowledge and

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ultimately promote the progress of science. Following the statutory language, the Supreme Court has held that a patent "satisfies the law" so long as it "sufficiently … guide[s] those skilled in the art to" the "successful application" of the invention. *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261, 271 (1916).

The Federal Circuit previously articulated a test for enablement requiring that "the [patent's] specification teach those in the art to make and use the invention without undue experimentation." See *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (providing eight factors for determining undue experimentation, known as the *Wands* factors). One area that courts have grappled with over the years is the claiming of inventions through broad genus claims, which can provide broad scope of patent protection because they can encompass numerous species. Dmitry Karshtedt, Mark A. Lemley and Sean B. Seymore, *The Death of the Genus Claims*, 35 Harv. J.L. & Tech., at 13 (2021). Such claims can be powerful tools to prevent competitors from reaping the benefits of an invention by making minor changes and variations to a species, because an unauthorized use of any species within the claimed genus would be an act of patent infringement. Id. However, broad genus claims have also raised questions regarding the breadth and depth of disclosure required to enable such claims.

The Supreme Court addressed this issue over 100 years ago in *Consolidated Electric Light Co. v. McKeesport Light Co. (The Incandescent Lamp Patent Case)*, 159 U.S. 465 (1895). There, the Supreme Court held that the patentee was entitled to a narrow claim for a carbonized paper embodiment of a light bulb, but not entitled to a genus claim that included bamboo, because the specification only disclosed light bulbs using carbonized paper and wood carbon. Id. at 472-76. Thus, according to that decision, the scope of a genus claim was limited by what the patent specifically taught. See, e.g., *Nat'l Recovery Techs. v. Magnetic Separation Sys.*, 166 F.3d 1190, 1195-96 (Fed. Cir. 1999).

'Amgen v. Sanofi'

The long procedural history of this case began in 2014, when Amgen filed suit against Sanofi in the District of Delaware alleging that Sanofi's hyperlipidemia product Praluent infringed two patents. The patents claim a class of monoclonal antibodies that can lower LDL cholesterol levels. The claimed genus of antibodies can bind to a particular region on a specific protein, PCSK9, and consequently block PCSK9 from binding with LDL cholesterol. While the Amgen patents provide 39 examples, such a genus claim could potentially encompass millions of antibodies—including those currently unknown.

The case was tried to a jury twice, with both verdicts ultimately supporting a finding that the enablement requirement was met. However, twice the Federal Circuit reversed, finding a lack of enablement because it found that the claimed genus—even with functional limitations—was broader than what is supported by the disclosed examples. *Amgen v. Sanofi*, 227 F. Supp. 3d 333 (D. Del. 2017); *Amgen v. Sanofi*, 872 F.3d 1367 (Fed. Cir. 2017); *Amgen v. Sanofi*, No. CV 14-1317-RGA, 2019 WL 4058927 (D. Del. Aug. 28, 2019).

In reaching its decision, the Federal Circuit examined several *Wands* factors, including the breadth of the claims, nature of the invention, and quantity of experiments needed. *Amgen*, 987 F.3d. The Federal Circuit first found that Amgen's claims "are far broader in functional diversity

than the disclosed examples," based on "their *functional* breath." Id. at 1091. Further, the court determined that Amgen's invention "is in an unpredictable field of science." Id. The court also found that "the patent does not provide significant guidance or direction" "for the full scope of the clams." Id. at 1092. The court reasoned that the only ways to discover the undisclosed claimed embodiments would be through "trial and error" or "by discovering the antibodies *de novo*." Id. Thus, after weighing the *Wands* factors, the court concluded that "substantial time and effort" would be required "to reach the full scope of these claims." Id. at 1093.

In 2021, Amgen appealed to the Supreme Court. Despite the contrary recommendation of the Solicitor General, the Supreme Court granted certiorari to address the following enablement question:

> Whether enablement is governed by the statutory requirement that the specification teach those skilled in the art to "make and use" the claimed invention, 35 U.S.C. §112, or whether it must instead enable those skilled in the art "*to reach the full scope of claimed embodiments*" without undue experimentation—i.e., to cumulatively identify and make all or nearly all embodiments of the invention without substantial "time and effort."

On Dec. 27, 2022, Amgen filed its Brief with the Supreme Court. Among other things, Amgen argued that the Federal Circuit's "reach-the-full-scope" standard "defies text, precedent, history and policy," and that the statutory "make and use standard should govern." Brief for Petitioners, *Amgen v. Sanofi*, No. 21-757 at 21-37. Amgen relied on both the statutory language and the Court's decisions consistent with the text to support its arguments that the Federal Circuit's new standard has no textual basis. While understanding the Federal Circuit's concern that patentees might attempt to monopolize more than they invented through overly broad claims, Amgen emphasized that this concern was addressed in *Incandescent Lamp*, which applied the statutory standard to invalidate claims where there was proof that the patent's instructions were not enabling for large classes of claimed subject matter. Id. at 45-48.

Industry, scholars, and law associations all have expressed keen interest in this case. On Jan. 3, 2023, 13 amicus briefs were filed, including by GlaxoSmithKline, AbbVie, Bristol-Myers-Squibb, Merck and the Intellectual Property Owners Association, in support of Amgen's petition, and expressing concern about the impact of the heightened enablement standard imposed by the Federal Circuit. Sanofi's brief is due to be filed on Feb. 3, 2023, followed by argument and a decision later this year.

Ultimately, the case has the potential to have a significant impact on patent litigation and claim drafting going forward, and academics, professionals and industry participants alike will be looking on with great interest as the Supreme Court takes on this important patent law issue.