Articles + Publications | November 29, 2022

How the Supreme Court's Clarification of Enablement in Amgen May Affect the Future of Patent Law

WRITTEN BY

Dustin B. Weeks | Jacob M. Burr

Authors:
Dustin Weeks
Jacob Burr
Pantelis Takos*

**Pantelis Takos is not admitted to practice law in any jurisdiction; bar application pending in Massachusetts.*

This article was republished in Law360 on December 2, 2022.

On November 4, the U.S. Supreme Court granted Amgen's petition to review the "enablement requirement" of Section 112 of the Patent Act. *See generally Amgen Inc., v. Sanofi,* No. 21-757 (U.S. 2022). The Court's decision will likely come in the late second quarter of 2023 and could require significant strategic adjustments by patent owners and prosecutors.

The enablement requirement originates from Section 112 of the Patent Act of 1952. Only once had the Supreme Court previously granted review of Section 112, but it focused on the definiteness requirement—not the enablement requirement. *See Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014). The Court's decision to take up this issue comes from an appeal of the U.S. Court of Appeals for the Federal Circuit's decision in February 2021 that concluded Amgen's cholesterol medication patents did not meet enablement requirements, as reaching their "full scope" would require "undue experimentation" by a person skilled in the art. *Amgen Inc., v. Sanofi,* 987 F.3d 1080 (Fed. Cir.), *petition for en banc rehearing denied*, 850 Fed. App'x 794 (Fed. Cir. 2021)

In its opinion, the Federal Circuit reaffirmed its use of the *Wands* enablement factors:

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In re Wands, 858 F.2d at 737.[1]

Amgen's patents are directed to a genus of monoclonal antibodies that assist in lowering LDL cholesterol levels by binding amino acids in a protein, which prevents that protein from otherwise binding and destroying LDL

receptors. The Federal Circuit's analysis focused on the applicability of the enablement requirement to genus claims. While stating effort to exhaust a genus was non-dispositive, the Federal Circuit emphasized in its analysis that "[t]he functional limitations here are broad, the disclosed examples and guidance are narrow, and no reasonable jury could conclude under these facts that anything but 'substantial time and effort' would be required to reach the full scope of claimed embodiments." *Amgen Inc., v. Sanofi*, 987 F.3d at 1086. The Federal Circuit ultimately found Amgen's patents non-enabling under the *Wands* factors.

After the *en banc* Federal Circuit declined to rehear the case, Amgen filed a petition for writ of certiorari to the Supreme Court on two grounds. The Supreme Court granted the petition to the question of:

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."

Amgen Inc. v. Sanofi, No. 21-757 (U.S. Nov. 4, 2022) (internal citations omitted)[2]

Considerations for Patent Prosecutors

While patent prosecutors have long battled with the tradeoff between breadth and novelty in patent claims, a third dimension to this calculation has been highlighted in recent years. Prosecutors, specifically in the functional limitation claim space, must additionally weigh the option of pursuing protection of specific embodiments (e.g. the species), which may be narrower but more likely to withstand invalidity attacks, versus attempting to protect the function performed by those embodiments (e.g. the genus), which may be broader but more susceptible to invalidity attacks. A lack of consideration of these competing interests in drafting could lead to rejection/invalidation on the ground of failure to satisfy the enablement requirement. How the Supreme Court rules in *Amgen* will help inform prosecutors on how best to adjust their practices to encompass this third dimension.

Prosecutors might recommend several approaches to their clients, depending on the facts surrounding a particular situation and any direction the Supreme Court might provide in *Amgen*. For instance, prosecutors may advise clients to postpone patent filings until research and development identifies enough experimental species to confidently establish the boundaries of the functional limits for the genus. However, time constraints from both the Patent Act and the threat of competitors can make for a tight rope to walk. Further, some genera may never be fully embodied, no matter the time permitted. As indicated in the district court and Federal Circuit *Amgen* opinions, the magnitude of a potential genus is often unknown and could include millions of species.

Or, as the Federal Circuit's separate denial opinion for rehearing suggests,[3] patent prosecutors could rely more heavily on the doctrine of equivalents by applying for several patents with narrow species claims, representative of the currently discovered embodiments. Over time and through multiple patents, the goal would be to fill out coverage to a genus with claims covering the various known species and equivalents thereof.

Finally, depending on how the Supreme Court rules in *Amgen*, prosecutors may also revert from the now standard practice of functional claiming to structural claiming. Structural claiming provides a more definite description of an object, or in this case, antibody. However, the tradeoff comes from the narrow grounds of coverage limited to that

structure. A key consideration to structural claiming may involve identifying specific regions instrumental to the desired function and then claiming the structure of those specific regions.

Considerations for Patent Owners and Applicants

The Supreme Court's decision in *Amgen* could limit a patent owner's ability to assert genus claims. Genus claims can afford owners broad scope without experimenting to the limits of the claimed technology. Additionally, genus claims can make it more difficult for competitors to avoid infringement by making minor variations to the claimed technology.

On the one hand, a Supreme Court decision limiting a patent owner's ability to claim a genus may reduce the incentive to begin a risky endeavor. The ability to claim a genus provides an applicant considerable incentive to embark on costly research and development for novel technologies. In *Amgen*, the ability to enforce protection of the entire field of LDL receptor blocking antibodies would give Amgen the freedom to explore the genus further without competition. Consequently, its product Repatha would stand alone in the market.

On the other hand, limiting a patent owner's ability to enforce a genus claim allows other researchers and developers to add to the public's knowledge in the field. Heightened competition may benefit the public by introducing a new rival into the market, facilitating competitive production, and encouraging further innovation.

Applicants may still find value in applying for patent protection for genus claims. The Supreme Court's decision in *Amgen* will likely affect how patent owners try to assert their genus claims in infringement actions. However, it is less clear how it will affect the USPTO's likelihood of granting genus claims. There are many reasons to apply for patent protection besides enforcement: notoriety; licensing schemes; luring venture capital investment; or as an underlying asset to a company. A reduction in an ability to assert genus claims may not have a significant effect on the decision to file patent applications.

Conversely, the reduced enforcement capability of genus claims may make trade secret protection a more appealing alternative. Unlike in a patent application, inventors need not make any public disclosure to establish a trade secret. However, safeguarding intellectual property can be costly. The many pros and cons of trade secrets are something potential patent applicants will have to consider.

---

[1] The Federal Circuit added "that the enablement inquiry for claims that include functional requirements can be particularly focused on the breadth of those requirements, especially where predictability and guidance fall short." *Amgen Inc., v. Sanofi,* 987 F.3d at 1086.

[2] The Court did not grant review of whether enablement is a question of fact to be determined by the jury or a question of law that the court reviews without deference.

[3] Circuit judges Lourie, Prost, and Hughes, who presided over the *Amgen* panel decision, authored the separate

denial opinion. *Amgen Inc., v. Sanofi,* 850 F. App'x at 797.

RELATED INDUSTRIES + PRACTICES

- Health Care + Life Sciences Intellectual Property
- Intellectual Property