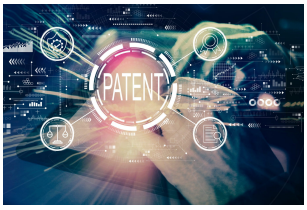

Supreme Court Reaffirms Patent Law's Enablement Requirement

Amgen Inc. v. Sanofi, 143 S. Ct. 1243 (May 18, 2023)

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Daniel A. Murray

In *Amgen Inc. v. Sanofi*, the U.S. Supreme Court addressed the issue of patent enablement, 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 "enablement clause"). Failing to abide by the enablement clause renders a patent invalid.

Amgen involved patents covering scientifically engineered antibodies that help reduce levels of low-density lipoprotein (LDL) cholesterol. Specifically, the patents at issue dealt with monoclonal antibodies that bind to a location on a protein, known as PCSK9, thereby preventing LDL receptors from binding to the protein. Amgen and Sanofi, both pharmaceutical companies, each developed a PCSK9-inhibiting drug. Each company also obtained a patent for the antibody used in its respective drug in 2011. Then, in 2014, Amgen obtained two additional patents that "purport to claim for Amgen 'the entire genus' of antibodies" that (1) bind to specific amino acid residues on PCSK9, and (2) block PCSK9 from binding to LDL receptors. These broad patents are also known as "genus patents." After Amgen obtained the genus patents, it sued Sanofi for infringement.

In an opinion written by Justice Gorsuch, a unanimous Supreme Court held that Amgen's patent was invalid because it was too broad and did not provide enough information to "enable" others to make and use the entire class of antibodies covered by the patent. The Court held that Amgen's description in the patent application required too much work by people of skill in the art to identify further antibodies with the claimed functionality. In doing so, the Court clarified that a patent must explain "how to make and use every single embodiment within a claimed class." While Amgen's patents described 26 specific antibodies in detail, the genus patent included potentially millions more. None of these antibodies was identified. Thus, Amgen's patent application failed under the

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enablement clause.

The holding of *Amgen* is in line with precedent and does not significantly change the practice of patent law. However, *Amgen* does provide increased clarity that enablement of an entire genus is required to secure a patent, at least when the genus as a whole is claimed.

Key Takeaways

- The Supreme Court explained that a patent is not "necessarily inadequate just because it leaves the skilled artist to engage in some measure of adaptation or testing." Further cases may help clarify exactly how much "adaptation or testing" is allowable. But under *Amgen*, patent applicants will want to err on the side of including more detailed explanations in patent applications—especially regarding genus claims.
- Complying with *Amgen* will require patent practitioners to tread cautiously when claiming a genus. Patent applicants should provide details and descriptions to enable every embodiment covered by the claims. When in doubt, it's better to provide too much information than too little.

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