Intellectual Property & Technology Law Journal

Edited by the Technology and Proprietary Rights Group of Weil, Gotshal & Manges LLP

VOLUME 35 • NUMBER 10 • NOVEMBER-DECEMBER 2023

Amgen Inc. et al. v. Sanofi, et al.: "A New Technology, But the Legal Principal Is the Same"—Part II

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The Supreme Court Opinion

Justice Gorsuch authored a unanimous opinion arching back to precedent from the 1800s upholding the Federal Circuit's and district court's determinations that Amgen's patent claims were invalid for lack of enablement.

The Court determined that Amgen claimed an entire genus of antibodies, seeking "to monopolize an entire class of things defined by their function" while only offering "persons skilled in the art little more than advice to engage in 'trial and error.'"

As a result of the decision, future enablement disputes will need to assess whether the patent specification in question provides enough information to enable a POSITA to make and use the invention with just a reasonable amount of experimentation. These determinations will need to be made in view of the nature of the invention and the underlying art. Factors in this assessment will no doubt include the breadth of the claims compared to the breadth of the disclosure, whether the claims are defined by function or structure, and the nature and predictability of the art at issue.

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If the claims extend beyond the disclosure of the invention in the patent, the claims will be invalid for lack of enablement.

The Court's View of Amgen's Invention

One may well have accurately predicted the Court's ultimate decision by the second paragraph of the opinion in which the Court defined Amgen's claimed invention as "a monopoly over all antibodies that (1) bind to . . . and (2) block PCSK9. . . ."

The Court determined that "Amgen purported to claim for itself 'the entire genus' of antibodies that (1) 'bind to specific amino acid residues on PCSK9,' and (2) 'block PCSK9 from binding' to LDL receptors." In contrast, the Court determined that Amgen's patent specifications disclosed only "the amino acid sequences of 26 antibodies that perform these two functions, and . . . the three-dimensional structures of two of these 26 antibodies."

Summing up the relationship of Amgen's claims to the disclosure in its specifications, the Court determined that "Amgen seeks to monopolize an entire class of things defined by their function—every antibody that both binds to particular areas of the sweet spot of PCSK9 and blocks PCSK9 from binding to LDL receptors. The record reflects that this class of antibodies does not include just the

26 that Amgen has described by their amino acid sequences, but a 'vast' number of additional antibodies that it has not."

Amgen argued that its claims were enabled because scientists can "simply follow the company's 'roadmap' or its proposal for 'conservative substitution.'" The Court disagreed and dismissed those as "little more than two research assignments" requiring POSITAs to engage in "painstaking experimentation." The court plainly stated, "[t]hat is not enablement . . . it is a hunting license." The Court also dismissed Amgen's argument that the Federal Circuit relied on the "cumulative time and effort it takes to make every embodiment within a claim," finding instead that Amgen's disclosure offers "little more than advice to engage in 'trial and error.'"

The Well-Established Legal Standard for Enablement Since 1790

The Court made clear that there is only "one statutory enablement standard," which requires that "the more a party claims for itself the more it must enable."

In doing so, the Court related the history of the enablement requirement that has existed since 1790. The Court's decision contains fulsome discussions of the facts and legal principles in its 1854 decision in *O'Reilly v. Morse*,[1] regarding the invention of the telegraph, its 1895 decision in *The Incandescent Lamp Patent*,[2] regarding a suit against Thomas Edison on the electric light, and its 1928 decision in *Holland Furniture Co. v. Perkins Glue Co.*,[3] regarding starch glue. These cases assert the long-standing principle that "the more a party claims, the broader the monopoly it demands, the more it must enable."

Beginning its discussion with *Morse*, the Court noted that the claim at issue in *Morse* covered "*all* means of achieving telegraphic communication, yet Morse had not described how to make and use them all." The Court in *Morse* found this claim to be "too broad and not warranted by law"—"no patent could have issued on such a specification."

The Court described a similar problem in *Incandescent Lamp* in which Sawyer and Man, the patent holders, made a broad claim that encompassed an electric lamp with an incandescing conductor made of any "fibrous or textile material." This broad claim might have been permissible if Sawyer and Man had disclosed "a quality common to fibrous and textile substances that made them peculiarly adapted to incandescent lighting," but the patent did not enable this broad claim and, instead, finding a suitable fibrous or textile substance required "painstaking experimentation."

The Court then turned to the claim in *Holland Furniture* which covered all starch glue that has "substantially the same properties as animal glue." However, the specification only instructed glue makers to "choose a starch ingredient with such qualities that it would yield a product as good as animal glue for wood veneering when combined with three parts of water with alkali." This specification described the starch ingredient in terms of its "use or function" rather than its "physical characteristics or chemical properties," which in turn, required "elaborate experimentation" to make the patented invention.

The Court stated that "[w]hile the technologies in these older cases may seem a world away from the antibody treatments of today, the decisions are no less instructive for it." The Court found that its prior "decisions in *Morse*, *Incandescent Lamp*, and *Holland Furniture* reinforce the simple statutory command."

That command is that "[i]f a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent's specification must enable a person skilled in the art to make and use the entire class. In other words, the specification must enable the full scope of the invention as defined by its claims. The more one claims, the more one must enable."

The Court clarified that it was not requiring that "a specification always must describe with particularity how to make and use every single embodiment within a claimed class." Rather, the Court instructed that broad claims may be enabled by "an example (or a few examples) if the specification also discloses 'some general quality . . . running through' the class that gives it 'a peculiar fitness for the particular purpose.'"

Some measure of experimentation is allowable: "a specification [is not] necessarily inadequate just because it leaves the skilled artist to engage in some measure of adaptation or testing." The Court pointed to *Wood v. Underhill*,[4] and *Minerals Separation, Ltd. v. Hyde*,[5] as establishing that "a specification may call for a reasonable amount of experimentation to

make and use a patented invention. What is reasonable in any case will depend on the nature of the invention and the underlying art."

Here, regarding the nature of the invention and the art, the Court noted that "aspects of antibody science remain unpredictable." As such, the Court found that Amgen's claims "bear more than a passing resemblance" to the claims at issue in *Morse*, *Incandescent Lamp*, and *Holland Furniture*. The Court held that "[m]uch as Morse sought to claim all telegraphic forms of communication, Sawyer and Man sought to claim all fibrous and textile materials for incandescence, and Perkins sought to claim all starch glues that work as well as animal glue for

Table 1

Named Amicus Filers	Filed As In Support of
Abbvie Inc.	Amgen
Alliance of U.S. Startups and Inventors for Jobs (USIJ) and Innovation Alliance (IA)	Amgen
Chemistry and the Law Division (CHAL), American Chemical Society	Amgen
Diversified Researchers and Innovators	Amgen
GlaxoSmithKline plc (GSK)	Amgen
Instil Bio, Inc.	Amgen
Intellectual Property Professors	Amgen
National Association of Patent Practitioners, Inc. (NAPP)	Amgen
Nature's Fynd	Amgen
American Intellectual Property Law Association (AIPLA)	Sanofi
Arnold Ventures, The National Center for Health Research, and Certain Medical Doctors	Sanofi
Association for Accessible Medicines (AAM)	Sanofi
Eli Lilly & Co., Ipsen Bioscience, Inc., and Innovent Biologics, Inc.	Sanofi
Fresenius Kabi USA, LLC	Sanofi
Genentech, Inc., Astrazeneca Pharmaceuticals LP, Bayer AG, Gilead Sciences, Inc., and Johnson & Johnson	Sanofi
Intellectual Property Law Professors and Scholars	Sanofi
Law Professors Joshua D. Sarnoff, Sharon K. Sandeen, and Ana Santos Rutschman	Sanofi
Pfizer Inc.	Sanofi
Professor Robin Feldman	Sanofi
Public Interest Patent Law Institute (PIPLI)	Sanofi
Sir Gregory Paul Winter and Interested Scientists	Sanofi
Small and Medium Biotechnology Companies	Sanofi
Unified Patents, LLC	Sanofi
United States	Sanofi
Viatris Inc.	Sanofi
High Tech Inventors Alliance (HTIA) and Computer & Communications Industry Association (CCIA)	Neither
Intellectual Property Law Association of Chicago (IPLAC)	Neither
Intellectual Property Owners Association (IPO)	Neither
New York Intellectual Property Law Association (NYIPLA)	Neither
Regenxbio Inc., IGM Biosciences, Inc., and Adaptive Phage Therapeutics, Inc.	Neither

wood veneering, Amgen seeks to claim 'sovereignty over [an] entire kingdom' of antibodies."

Amgen's and the Amici's Policy Arguments on Innovation Were Rejected

Amgen argued (and certain amici echoed the argument) that invalidating these claims would stifle innovation, and dry up the billions of dollars needed to find new antibodies, as companies would not make such investments if broad, functional generic claims like those at issue here were unavailable as a reward.

The Court rejected Amgen's policy argument, agreeing with the U.S. Government's position that, if new rules in this area are required, it was up to Congress, not the Court. Specifically, the Court stated that "striking the proper balance between incentivizing inventors and ensuring the public receives the full benefit of their innovations is a policy judgment that belongs to Congress."

What the Court Did Not Address

What the Court did not do in *Amgen* is to specifically state any particular way to determine enablement under what it found to be the well-established law. For example, although many of the briefs and a portion of oral argument related to the long-standing *Wands* factors as a potentially helpful enablement test, the Court did not comment on the *Wands* factors, or any other specific test, at all. Rather, the Court left its discussion of the enablement standard at the high level of its discussion of the prior precedent, noting the factual nature of the inquiry.

Conclusion

As many expected after the oral arguments, the Supreme Court's decision in *Amgen* is a general confirmation of long-standing enablement law with a clear indication that the determination of whether the enablement standard is met is a fact-specific question.

As the Supreme Court ended its opinion, this case involved "new technology, but the legal principle is the same" as it has been since 1790.

Ultimately, one takeaway from the *Amgen* opinion is that broadly sweeping claims defined by function, rather than by structure, will meet the enablement standard only if there is enough disclosure in the specification so that no more than a "reasonable amount" of experimentation is need for a person skilled in the art to make and use the claimed subject matter. Such disclosure can include identifying a quality common to a functional embodiment. However, without a common identifier, the test will fall back to "the more a party claims, . . . the more it must enable."

What seems clear is that this opinion neither dooms nor upholds all genus claims, including functionally defined genus claims. It is equally clear that it leaves unanswered, and at the heart of enablement challenges to come, the question: What is a "reasonable amount" of experimentation? That factual question and how to address it, especially for functional claims and in the unpredictable arts, has been left to the PTAB, the district courts, and the Court of Appeals for the Federal Circuit to refine over the next many years.

Notes

1. O'Reilly v. Morse, 15 How. 62 (1854).
2. The Incandescent Lamp Patent, 159 U. S. 465 (1895).
3. Holland Furniture Co. v. Perkins Glue Co., 277 U. S. 245 (1928).
4. Wood v. Underhill, 5 How. 1 (1846).
5. Minerals Separation, Ltd. v. Hyde, 242 U. S. 261 (1916).