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Locke Lord QuickStudy: The Supreme Court's ?Decision on ?Enablement in *Amgen v. Sanofi*

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Justice Gorsuch authored a unanimous opinion arching back to precedent from the 1800s and upholding the Federal ?Circuit's and district court's determinations that Amgen's patent claims are 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 assess whether the patent specification in question provides enough information to enable a person skilled in the art to make and use the invention with just a reasonable amount of experimentation, in view of the nature of the invention and the underlying art. Factors in this assessment 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. If the claims extend their coverage 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

Those who have followed this case, and others like it, may well have accurately predicted the Court's decision by the second paragraph of the opinion when 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 of its patents, 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." 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 legal standard for enablement has existed since 1790 and is well established by Supreme Court case law

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*, 15 How. 62 (1854) regarding the invention of the telegraph, its 1895 decision in *The Incandescent Lamp Patent*, 159 U. S. 465 (1895) regarding a suit against Thomas Edison on the electric light, and its 1928 decision in *Holland Furniture Co. v. Perkins Glue Co.*, 277 U. S. 245 (1928) regarding starch glue. The Court states that “While 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*, 5 How. 1 (1846) and *Minerals Separation, Ltd. v. Hyde*, 242 U. S. 261 (1916) 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.”

Although the briefs and oral argument included references 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 standard at a high level.

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 such investments would not be made if genus claims like those at issue here are unavailable as a reward.

The Court rejected Amgen's argument, agreeing with the U.S. Government's position that if new rules were required, it was up to Congress, not the Court; noting 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."

Three Amicus Briefs were mentioned

Only three of the numerous amicus briefs were mentioned in the opinion. The amicus brief of Sir Gregory Winters, almost akin to an expert opinion in support of Sanofi's position, was cited as support for certain background facts regarding antibodies, and their function and structure. The Brief for Arnold Ventures was cited as supporting the extensive work on PCSK9 antibodies that occurred in the mid-2000s. And the one hypothetical analogy used by the Court—a combination lock with 100 tumblers that came from the Brief for Intellectual Property Scholars—was cited as capturing "the gist of the problem."

Conclusion

As many expected after oral argument, the Supreme Court's decision 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, there is "new technology, but the legal principle is the same" as it has been since 1790. Likely, this opinion neither dooms nor upholds all genus claims.

Rather, the 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. That factual question will be at the heart of enablement challenges to come, especially in unpredictable arts.

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