ARE Patent Alert: U.S. Supreme Court Issues Ruling on Enablement of Functionally Claimed Composition Claims

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On May 18, 2023, the U.S. Supreme Court issued its decision in *Amgen, Inc. v. Sanofi et al.,* No. 21-757, 598 U.S. ____ (2023), unanimously affirming the Federal Circuit's invalidation of Amgen's claims to a broad class of antibodies for lack of enablement. Although some observers have lamented that the opinion marks a shift in the law of enablement, patent practitioners and industry professionals understand that the claim type at issue—a composition claimed solely by its function—has long been notoriously difficult to support with an enabling disclosure. Indeed, to support its analysis, the Supreme Court reached all the way back to *O'Reilly v. Morse*, in which a claim covering "all means of achieving telegraphic communication" was invalidated by the Supreme Court because it was too broad. *Amgen*, slip op. at 10.

At issue in Amgen were claims of two US patents reciting antibodies that have two functions: (1) binding to one or more of sixteen specified amino acid residues of a particular protein, and (2) blocking that particular protein from binding to a receptor. Commenting on the breadth of these claims, the Court noted 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." *Amgen*, slip op. at 15.

In affirming that the claims lacked enablement across their full scope, the Supreme Court did not provide a deep factual analysis. Instead, they simply held that the two methods provided by Amgen to produce antibodies with the claimed blocking and binding functionality amount to "little more than two research assignment"—characterizing the first method (what Amgen described as a "roadmap" that could be used to generate new antibodies withing the scope of the claims) to be a mere description of Amgen's own "trial-and-error" method for finding functional antibodies, and the second method (of "conservative substitution" of amino acids from the disclosed antibodies) to similarly be nothing more than an invitation to make substitutions and see if the resulting antibody has the same functionality. *Amgen*, slip op. at 16. Notably, the opinion leaves open the possibility that a "roadmap" or "conservative substitution" ***may*** enable other claims in other patents, if the inventor "identifies a quality common to every functional embodiment". The Supreme Court alleged that such a common quality was absent from Amgen's disclosure. *Id* at 17.

Finally, the Supreme Court dismissed Amgen's argument that the Federal Circuit had "conflated the question whether an invention is enabled with the question [of] how long

may it take a person skilled in the art to make every embodiment within a broad claim". *Amgen* , slip op. at 18. Here, the Supreme Court noted, as we have previously commented, that the Federal Circuit went out of its way to say that it "do[es] not hold that the effort required to exhaust a genus is dispositive". *Id.*

In a prior article, we emphasized that that Federal Circuit's decision did not focus solely on the *number* of different antibodies falling within the claims, but their *functional* breadth as well. *Amgen Inc. v. Sanofi*, 987 F. 3d 1080, 1087 ("[W]e are not concerned simply with the number of embodiments but also with their functional breadth. Regardless of the exact number of embodiments, it is clear that the claims are far broader in functional diversity than the disclosed examples"). The Federal Circuit noted that the claims cover antibodies binding up to sixteen residues, while none of their examples bind more than nine. *Id.* n.1. It was possible for the Supreme Court to find the claims invalid for this reason alone, leaving open the possibility of functionally claiming a composition with the disclosure of a sufficient number of examples across the functional scope of the claims. However, a discussion or analysis of this fact is notably absent from the Supreme Court decision. Thus, the Supreme Court holding goes further than invalidating Amgen's claims simply because they did not exemplify antibodies with sufficient functional diversity (i.e. antibodies that bind all sixteen residues as encompassed by the claims). The Supreme Court held that the methods described by Amgen to produce antibodies with the claimed double binding functionality require too much trial and error to warrant granting them a monopoly to all antibodies with that functionality.

As discussed above, practitioners understand that it is difficult to provide enabling support for claims that broadly encompass compositions with a particular functionality. Although reasonable people may not agree that Amgen's screening method for producing antibodies with the claimed double binding functionality was merely "trial and error", as alleged by the Supreme Court, *Amgen v. Sanofi* reinforces the need for inventors to identify and describe "a quality common to every functional embodiment" to support broad functional claims. The case also reinforces the need to pursue a variety of claiming strategies to obtain sufficient scope of protection for biological inventions.

We will continue to monitor developments and provide further updates about the enablement doctrine.

In the meantime, please feel free to contact our attorneys regarding issues raised by this case.

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