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Supreme Court Amgen Ruling's Major Effect On Enablement

By **Irena Royzman and Daniel Williams** (January 16, 2024, 5:55 PM EST)


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Eight months ago, the U.S. Supreme Court interpreted the enablement requirement in the May 18, 2023, Amgen Inc. v. Sanofi decision.[1]

Although the court did not change the law, affirming the U.S. Court of Appeals for the Federal Circuit's approach to enablement, its decision is one of the most impactful for patent enforcement, licensing and prosecution for decades to come across technologies.

And the court understood the importance of providing its view. Indeed, U.S. Supreme Court Justice Brett Kavanaugh expressed during oral argument that "it would be important for this Court to say it essentially agrees with the Federal Circuit because there's been … a lot of critiques of the Federal Circuit's approach."[2]

In doing just that and making clear that patent claims that extend far beyond the discovery actually made do not pass muster under the enablement requirement, the court has had a significant impact.

And although the court did not address the written description requirement and indeed did not take up a petition in Juno v. Kite that would have had the court address that issue, the court's discussion of appropriate disclosure and the quid-pro-quo premise of patent law informs written description as well.

The decisions post-Amgen — most recently, Teva v. Eli Lilly — reflect the enormous impact of the decision on the direction of the law.

Functional Genus Claims

Amgen concerned so-called functional genus claims. The claims at issue before the court were to a genus of antibodies that bind to a naturally occurring therapeutic target, PCSK9, and block PCSK9 from binding to low-density lipoprotein, or LDL, receptors, i.e., receptors that remove cholesterol from the blood.

The claims did not provide the structure for the antibodies but claimed them entirely by function. The court agreed with the Federal Circuit that such claims lacked enablement. Justice Neil Gorsuch, who wrote the unanimous decision for the court, explained:

> 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 … this class of antibodies does not just include the 26 that Amgen has described by their amino acid sequences, but a "vast" number of additional antibodies that it has not.[3]

In the court's view Amgen's purely functional claims sweep much broader than the 26 antibodies disclosed in the specification.[4] The court also stated that the methods of making antibodies disclosed in the specification offered the public "little more" than a "research assignment" for finding additional antibodies within the ambit of its broad genus claims.[5] It held that "Amgen has failed to enable all that it has claimed."[6]

Amgen is already having an impact on other cases with similar types of genus claims for antibodies that include functional language. For example, in the Sept. 20, 2023, Baxalta v. Genentech decision, the Federal Circuit affirmed summary judgment of nonenablement for claims to a broad genus of antibodies that bind to Factor IX/IXa and increase the procoagulant activity of Factor IXa.

The Federal Circuit found the facts materially indistinguishable from those in Amgen and noted that the specification only disclosed 11 out of the "millions of potential candidate antibodies."[7] According to the Federal Circuit in Baxalta:

> The only guidance the patent provides is "to create a wide range of candidate antibodies and then screen each to see which happen to bind" to Factor IX/IXa and increase procoagulant activity. Amgen makes clear that such an instruction, without more, is not enough to enable the broad functional genus claims at issue here.[8]

Another example comes from the Sept. 26, 2023, Teva v. Eli Lilly decision. The U.S. District Court for the District of Massachusetts granted Lilly's motion for judgment as a matter of law of invalidity for lack of enablement and written description after a jury trial in 2022 in which Teva was awarded more than $175M in damages for patent infringement.[9]

The claims there were to methods for treating headaches in humans by administering humanized monoclonal anti-CGRP, or calcitonin gene-related peptide receptor, antibodies.[10] There again broad functional antibody claims fell.

The district court found that a reasonable jury could only have determined that the claims "cover the entire functionally-defined genus of humanized anti-CGRP antagonistic antibodies."

It also found that the specification "disclosed only one covered antibody," that there are "a large number of antibodies that could potentially antagonize CGRP, and the actual number is not knowable," that the claims "did not identify any amino acid sequence or unique structure[s]," and that "antibodies would have to be made and individually tested to determine whether they were viable candidates for antagonizing CGRP."[11]

The district court relied on Amgen in finding that the patent disclosures amounted to "nothing more than a 'roadmap' for a 'trial and error' process to identify and make antibodies within the scope" of the claims.[12]

As in Amgen, the public was presented with what that court called a research assignment that a person of ordinary skill in the art "could routinely make, test, and humanize candidates does not change this

result." [13]

Although written description is a question of fact, the district court did not hesitate in granting judgment as a matter of law for lack of written description for similar reasons as nonenablement.

The district court found that the broad functional antibody claims failed the written description requirement because the specification's disclosure of a single species was insufficient to claim the entire genus of humanized anti-CGRP antibodies for the treatment of a headache.[14]

The court also found that the patents failed to describe common structural features specific to anti-CGRP antibodies.[15]

Both the Baxalta and Teva decisions followed directly from Amgen. Broad functional genus claims that draw a fence around a therapeutic area and do not provide meaningful common structural features are unlikely to survive in court.

Such claims have been repeatedly asserted against pharmaceutical innovators in litigation. As these decisions show, Amgen should curtail the enforcement of broad functional claims, further incentivizing biotech innovation and development of innovative antibody therapeutics.

Non-Functional Genus Claims

While Amgen dealt with functional genus claims in particular, its holding is not limited to functional claims and is being applied by the Patent Office and courts more broadly to genus claims, whether they contain functional language or not. For example, in the June 27, 2023, Medytox Inc. v. Galderma decision, the Federal Circuit affirmed the Patent Trial and Appeal Board's final written decision denying Medytox's motion to amend claims.[16]

The proposed amended claims concerned methods of treating glabellar lines in patients by administering a formulation of botulinum toxin that is free of animal proteins and has a greater length of effect than the same amount of Botox.[17]

The claims also required that the greater length of effect would be determined by a "responder rate at 16 weeks after the first treatment of 50% or greater," which the PTAB interpreted as a broad range between 50% and 100%.[18]

In denying Medytox's motion, the PTAB found the claims not to be enabled across their full scope.[19] The Federal Circuit affirmed, explaining that the specification disclosed "at most three examples of responder rates above 50% at 16 weeks: 52%, 51%, and 62%," and that substantial evidence supported the PTAB's finding that a skilled artisan would not have been able to achieve a response rate higher than those limited examples.[20]

Other Technologies

Amgen is also having an impact across industries, including the computer technology space. For example, In re: Starrett involved claims to methods, systems, media and machines for maintaining certain data.[21] The claims were rejected by the Patent Office for lack of enablement and the PTAB affirmed.[22] In affirming the PTAB, the Federal Circuit relied on Amgen, explaining in its June 8, 2023, decision that:

> The application's disclosure of a broad and abstract organizational structure used to accomplish the maintenance of augmented telepathic data amounts to little more than a "research assignment" requiring a skilled artisan to undertake undue experimentation to discover what types of devices are encompassed by the claim limitations and how they would function.[23]

Post Amgen, claims that effectively amount to research assignments are unlikely to be upheld if they issue in the first place. Amgen will continue to have impact across technologies and on all aspects of the patent system.

In agreeing with the Federal Circuit in Amgen, the Supreme Court provided confidence in the Federal Circuit's approach and a clearer understanding as to the claims that are enforceable and the disclosure needed to comply with the quid-pro-quo premise of the patent system.

The Federal Circuit, district courts, and the Patent Office are implementing the Federal Circuit's approach and using the language of Amgen in doing so. But as practitioners strive to adapt to a post-Amgen world, new questions will undoubtedly arise.

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[1] Amgen Inc. v. Sanofi, 598 U.S. 594 (2023).

[2] March 27, 2023 Transcript of Oral Argument at 105:17-23. (available here: https://www.supremecourt.gov/oral_arguments/argument_transcripts/2022/21-757_cjmb.pdf).

[3] Amgen, 598 U.S. at 613.

[4] Id.

[5] Id. at 614.

[6] Id. at 613.

[7] Baxalta Inc. v. Genentech, Inc., 81 F.4th 1362, 1366 (Fed. Cir. 2023).

[8] Id.

[9] Teva Pharms. Int'l GmbH v. Eli Lilly & Co., 2023 WL 6282898, at *1 (D. Mass. Sept. 26, 2023).

[10] Id. at *4.

[11] Id. at *22.

[12] Id.

[13] Id.

[14] Id. at *16.

[15] Id. at *19.

[16] Medytox, Inc. v. Galderma S.A., 71 F.4th 990, 993 (Fed. Cir. 2023).

[17] Id.

[18] Id. at 993, 996.

[19] Id. at 996.

[20] Id. at 998.

[21] In re Starrett, 2023 WL 3881360, at *1-2 (Fed. Cir. June 8, 2023).

[22] Id. at *1.

[23] Id. at *4.