Amgen Inc. v. Sanofi

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WHY IT MADE THE LIST

The Supreme Court does not often hear patent cases, leaving most of the heavy lifting on patent matters to the United States Court of Appeals for the Federal Circuit. So when the Court takes up a patent case, it becomes canon. Such is the case for *Amgen v. Sanofi*.[1] And while it is undeniably and thoroughly a patent case, its adjacency to the regulation of biologics, especially to the patent-specific provisions of the Biologics Price Competition and Innovation Act (BPCIA), makes it worth a close look by FDA regulatory attorneys.

In *Amgen v. Sanofi*, the Supreme Court examined the statutory "enablement" requirement for patents with claims that essentially recite an antibody by its function. Broadly, the "enablement" requirement necessitates that a patent specification describe a claimed invention in terms that "enable" persons ordinarily skilled in the art "to make and use" the invention.[2] Here, the Court upheld the determinations of the lower courts that Amgen's patent description failed to enable a skilled artisan to make and use the claimed invention over the full scope of the claims. The Supreme Court's holding in *Amgen* is a clear caution signal regarding functionally drafted claims relating to antibodies.

DISCUSSION

Legal Background

It is a foundational concept in patent law that a patent specification must describe the claimed invention in a way that would permit a skilled artisan to make or use it. While a patent provides a monopoly to the inventors for a limited period, the specification's description of an invention will eventually place the innovation into the hands of the public as soon as the patent expires (the so-called *quid-pro-quo* justification of patent law). This bargain dates back to the Constitution itself, which famously provides Congress the authority to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[3] Today, the requirement for an enabling specification is codified by Section 112(a) of the current Patent Act.[4] In

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1 Amgen Inc. v. Sanofi, 598 U.S. 594, 143 S. Ct. 1243 (2023).

2 35 U.S.C. 112(a).

3 U.S. CONST., art. I, § 8, cl. 8.

4 35 U.S.C. § 112(a).

particular, Section 112(a) requires "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same."[5]

Given the longstanding foundational nature of the enablement requirement, it should be no surprise that it has been the subject of significant judicial attention over the years—originally by the Supreme Court and more recently by the Federal Circuit. The Supreme Court's early treatment of the enablement requirement naturally arose outside of the life sciences, often in the context of pioneering nineteenth century technological advances like Morse's electromagnetic telegraph and Edison's incandescent light bulbs.[6] But the rapid expansion of the pharmaceutical and biotechnology industries in the 1980s and 1990s began to generate opportunities for courts to apply the enablement standard to the life sciences. The work of clarifying the enablement standard, especially as applied to the life sciences, was largely taken up by the Federal Circuit beginning with its founding in 1982. This difficult task continues today.

Almost immediately after its inception, the Federal Circuit decided *In re Wands*, which has served as a well-worn touchstone for enablement caselaw.[7] In *Wands*, the Federal Circuit observed that it was "well established that enablement requires that the specification teach those in the art to make and use the invention without undue experimentation."[8] To guide this inquiry, *Wands* articulated the following factors:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.[9]

These factors are known colloquially as the "*Wands* factors."

Over the years, the Federal Circuit was repeatedly faced with evaluating whether a specification was sufficient to enable broad claims reciting a genus of compounds defined largely by function. In making these evaluations, the Federal Circuit often emphasized the breadth of the challenged claims, the limited teachings of the specification, and the unpredictability of the art. For example, in *Wyeth & Cordis Corp. v. Abbott Laboratories*, the Federal Circuit contrasted claims covering tens of thousands of rapamycin compounds with a specification that disclosed the immunosuppressive and antirestenotic activity of a single compound (sirolimus).[10] In *Wyeth*, the Federal Circuit observed that the specification "discloses only a starting point for further iterative research in an unpredictable and poorly understood field."[11]

Other cases followed. In *Enzo Life Sciences, Inc. v. Roche Molecular Systems, Inc*., the Federal Circuit cited the breadth of the claims, the "sparse" guidance given

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[5] *Id.*

[6] *See, e.g.*, O'Reilly v. Morse, 15 How. 62 (1854)*;* The Incandescent Lamp Patent, 159 U.S. 465 (1895); Holland Furniture Co. v. Perkins Glue Co., 277 U. S. 245 (1928).

[7] *In re* Wands, 858 F.2d 731 (Fed. Cir. 1988).

[8] *In re Wands*, 858 F.2d at 737.

[9] *Id.*

[10] Wyeth & Cordis Corp. v. Abbott Lab'ys, 720 F.3d 1380 (Fed. Cir. 2013).

[11] *Wyeth*, 720 F.3d at 1386.

by the specification, and the unpredictability of the art to uphold the district court's decision invalidating a genus of compounds largely defined by function and limited structural requirements.[12] Likewise, in *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc.*, the Federal Circuit yet again affirmed a district court determination invalidating claims where it found that identifying functional compounds would be like "finding a needle in a haystack."[13]

Factual Background

This case arises from a long and winding procedural posture. Amgen initially sued Sanofi and Regeneron in 2014, alleging that the biological product Praluent (alirocumab) infringed, *inter alia*, U.S. Patent Nos. 8,829,165 ("the '165 patent") and 8,859,741 ("the '741 patent").[14] The parties stipulated to infringement of claims 19 and 29 of the '165 patent and claim 7 of the '741 patent.[15] After a jury trial in 2016, the jury found that the patents were not invalid for lack of enablement and written description and the district court entered a permanent injunction.[16]

On appeal, the Federal Circuit vacated the permanent injunction and remanded for a new trial.[17] Critically, the Federal Circuit found that the district court improperly excluded post-priority-date evidence relating to enablement and written description.[18] On remand, the jury again determined that Sanofi failed to show the patents were invalid for failing to satisfy the enablement and written description requirements.[19] This time, however, the district court granted Sanofi's motion for judgment as a matter of law (JMOL) for lack of enablement.[20] Now, Amgen appealed and the Federal Circuit affirmed the district court's decision.[21]

Harnessing tailored antibodies for therapeutic purposes has been one of the major revolutions of modern biotechnology.[22] Antibodies are comprised of amino acid chains and are part of the immune system's natural mechanism of targeting and eliminating antigens from the body.[23] Antibody targeting is accomplished by portions of the antibody known as complementarity-determining regions, or "CDRs," which can uniquely bind to a specific location on an antigen (known as an "epitope").[24] Whether an antibody binds to an epitope depends on whether both have

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[12] Enzo Life Scis., Inc. v. Roche Molecular Sys., Inc., 928 F.3d 1340 (Fed. Cir. 2019).

[13] Idenix Pharms. LLC v. Gilead Scis. Inc., 941 F.3d 1149, 1162 (Fed. Cir. 2019).

[14] *See, e.g.*, Amgen Inc. v. Sanofi, 987 F.3d 1080, 1083–84 (Fed. Cir. 2021) ("*Amgen II*") (describing procedural posture).

[15] *Id.*

[16] *Id.*

[17] Amgen v. Sanofi, 872 F.3d 1367, 1371 (Fed. Cir. 2017) ("*Amgen I*").

[18] *Id.*

[19] *Amgen II*, 987 F.3d at 1084.

[20] *Id.* (the district court denied Sanofi's motion for JMOL on written description).

[21] *Id.*

[22] *See* Brief of Sir Gregory Paul Winter and Interested Scientists as Amici Curiae in support of Respondents at 8.

[23] *Id.*

[24] *Id.* at 9.

compatible interlocking surfaces.[25] This fit depends on the three-dimensional shape of the antibody, which in turn depends on how the amino acid chains of an antibody fold based on their sequences.[26] In *Amgen*, the Supreme Court recognized that "[a]ntibodies are incredibly diverse"[27] and "aspects of antibody science remain unpredictable."[28]

The antibodies claimed by the patents-in-suit bind a protein called PCSK9 and block the binding of PCSK9 to low density lipoprotein receptor (LDLR) protein.[29] Researchers had come to realize that blocking PCSK9 and LDLR interactions could be a way to treat patients with high LDL cholesterol.[30] Normally, LDL receptors extract LDL cholesterol from the bloodstream. Because PCSK9 degrades LDL receptors (leading to less extraction of LDL cholesterol), blocking the interaction of PCSK9 and LDLR by an antibody would facilitate LDL extraction.[31]

The patents-in-suit here claim antibodies by their function.[32] Critically, the claims do not recite the primary amino acid sequence of the claimed antibodies.[33] Rather, the claims are defined by the antibody's ability to bind one or more specified residues in the PCSK9 epitope and its functional ability to block the binding of PCSK9 to LDLR.[34] By contrast, the specification identifies the amino acid sequence of twenty-six antibodies that bind to the required residues in PCSK9 and block the binding of PCSK9 and LDLR.[35]

DECISION

The Supreme Court affirmed the lower court's invalidation of the asserted claims for failure to meet the enablement standard.[36] In an eloquently written opinion, speaking for a unanimous Court, Justice Gorsuch walked through the Court's early enablement cases and then analogized them to antibody technology.[37] The common thread running through the Court's early precedent could be boiled down simply: "[t]he more one claims, the more one must enable."[38] Because Amgen sought to claim "an entire universe of antibodies" and the specification inspired at most "research assignments," the Supreme Court upheld the lower court determinations.[39]

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[25] *Id.* at 10–12.

[26] *Id.*

[27] *Amgen*, 143 S. Ct. 1248.

[28] *Id.* at 1249.

[29] *Id.*

[30] *Id.*

[31] *Id.*

[32] *Id.* at 1250.

[33] *Id.*

[34] *Id.*

[35] *Id.*

[36] *Id.* at 1258.

[37] *Id.* at 1251–55.

[38] *Id.* at 1254.

[39] *Id.* at 1256.

The Court looked to its early cases for instruction. For example, the Court recounted Morse's attempt to patent not only the specific telegraphs he designed, but also the "essence" of his invention, which generally covered the use of electrical current for printing at any distance.[40] The *Morse* Court balked at this breadth, thinking it impossible for any specification to support this general idea.[41] Likewise in *Incandescent Lamp*, the Court described the failed attempt at covering Thomas Edison's bamboo filament light bulbs with a patent seeking "sovereignty over [the] entire kingdom" of all carbonized fibrous or textile material filaments.[42] And finally, the Court pointed to *Holland Furniture*, where the court rejected an attempt to cover not only the starch glue described in the specification, but other starch derivative glues that exhibited qualities "as good as animal glue."[43]

But the Court took pains to emphasize that an enabled specification need not disclose how to make and use every embodiment falling within a recited genus.[44] For instance, citing *Incandescent Lamp*, the Court observed that the disclosure of a "general quality" running through a class could be sufficient to reliably enable the entire class.[45] Along those lines, the Court explained that the specification permitted reasonable experimentation to reach the full scope of the claims.[46] Of course, the line between "reasonable" and "undue" may be a difficult one to draw.

Amgen argued that it would not have been undue experimentation to reach the full scope of the claims based on the specification. Amgen argued that the specification taught skilled artisans to make the entire universe of antibodies in two ways. In the so-called "roadmap approach," Amgen contended that the specification provided a stepwise "roadmap" that would guide skilled artisans to generate and test antibodies in a stepwise fashion.[47] In the so-called "conservative substitution" approach, Amgen argued that a skilled artisan would start with the twenty-six disclosed antibodies and would substitute amino acids known to have similar properties.[48] The Court found neither approach sufficient.[49] Calling the approaches merely a "research assignment" and a "hunting license," the Court found that the specification still left the skilled artisan faced with "painstaking experimentation" and uncertainty given the art.[50]

The Court also dismissed Amgen's criticisms of the Federal Circuit.[51] For example, Amgen argued that the Federal Circuit "conflated" the enablement standard with the length of time necessary to create every embodiment within the claims.[52] While the Court agreed that "enablement is not measured against the cumulative

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[40] *Id.* at 1252–53 (describing O'Reilly v. Morse, 15 How. 62 (1854)).

[41] *Id.*

[42] *Id.* at 1253–54 (describing The Incandescent Lamp Patent, 159 U.S. 465 (1895)).

[43] *Id.* at 1254 (describing Holland Furniture Co. v. Perkins Glue Co., 277 U.S. 245 (1928)).

[44] *Id.* at 1254–55.

[45] *Id.* at 1254.

[46] *See id.* at 1255.

[47] *Id.* at 1250.

[48] *Id.*

[49] *Id.* at 1256.

[50] *Id.* at 1256–57.

[51] *Id.* at 1257.

[52] *Id.*

time and effort it takes to make every embodiment within a claim," the Court did not read the Federal Circuit's opinion as implying anything to the contrary.[53] The Court also disagreed with Amgen's argument that the Federal Circuit's holding established a special standard for genus claims.[54] The Court agreed with Amgen in principle that there is a single unitary enablement standard, but again disagreed that the Federal Circuit applied anything but the correct standard.[55]

IMPACT OF THE DECISION

In some ways, the Court's decision in *Amgen* does not present a departure from Federal Circuit precedent for the enablement of genus claims in the life sciences. The Supreme Court confirmed that broad genus claims defined by function demand a level of disclosure that matches the breadth of the claims. As described above, the Federal Circuit had repeatedly upheld decisions invalidating functionally defined genus claims covering vast numbers of species in uncertain arts. Here, the Supreme Court avoided tangling with Federal Circuit precedent and opted to walk through its own historical precedents, brought to life by Justice Gorsuch's rich and compelling storytelling. But both threads ultimately reach the same conclusion. As summed up by the Court in *Amgen*: the more one claims, the more one has to enable.

It was not a long wait to see the impact of *Amgen*. In *Baxalta Inc. v. Genentech, Inc.*, the Federal Circuit upheld the district court's summary judgment finding claims directed to an antibody that binds Factor IX or Factor IXa and that increases procoagulant activity.[56] The Federal Circuit found the facts in *Baxalta* "materially indistinguishable" from *Amgen*.[57] The Federal Circuit stated that the trial and error testing necessitated by the specification "leaves the public no better equipped to make and use the claimed antibodies than the inventors were" when they set out to discover them.[58] The Federal Circuit also confirmed that *Amgen* did not disrupt the longstanding *Wands* factors.[59]

The issues raised in *Amgen v. Sanofi* are closely adjacent to issues faced by FDA regulatory attorneys in the biologics space. For example, FDA attorneys counseling on Biologics License Applications (BLA) approval requirements should be sensitive to the patent issues faced by their patent attorney colleagues. Moreover, arguments regarding the validity of patents covering antibody biologics are often directly applicable to the patent resolution mechanisms of the BPCIA. In both instances, coordination and communication between FDA regulatory attorneys and patent attorneys are helpful to ensure consistent decision-making.

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[53] *Id.*

[54] *Id.*

[55] *Id.*

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

[57] *Baxalta*, 81 F.4th at 1366.

[58] *Id.* at 1367.

[59] *Id.*