Amgen, Inc. v. Sanofi: The Enablement Requirement of Patent Law: A Bargain for the People Stands the Test of Time

I. OVERVIEW

For over 150 years, the United States Supreme Court has consistently upheld the statutory enablement requirement "according to its terms."[1] And once again, in *Amgen, Inc. v. Sanofi*, a decision long-awaited by patent practitioners, the Supreme Court made clear that as the technological revolution develops, the complexity of these innovations does not alter the principles of patent law.[2] Amgen and Sanofi independently pursued the development of a drug aimed at reducing cholesterol levels by binding or otherwise inhibiting PCSK9, a protein that binds to LDL receptors and blocks them from extracting LDL cholesterol in the bloodstream.[3] In 2011, each company successfully developed and commercialized a unique antibody medication specific to inhibiting PCSK9: Amgen's Repatha and Sanofi's Praluent.[4] However, in 2014, Amgen sought and received broad "genus" patent protection covering this technology.[5] While Amgen's patents specifically identified twenty-six amino acid sequences for antibodies that would block or inhibit PCSK9, Amgen went a step further and claimed "the entire genus," or class, of antibodies.[6]

With this new patent granting broad protection over the entire genus and essentially covering the entire technology, Amgen sued Sanofi for

1. Amgen, Inc. v. Sanofi, 598 U.S. 594, 616 (2023).
2. *See id*. at 613.
3. *Id.* at 601-02.
4. *Id.* at 602.
5. *Id.*
6. *Id.*

infringement.[7] In rebuttal, Sanofi asserted that the genus claims lacked validity due to insufficient enablement.[8] Sanofi argued these claims necessitated extensive experimentation and trial-and-error to produce viable antibodies, thereby failing to meet the enablement requirement 35 of U.S.C. § 112.[9] Notably, Sanofi highlighted that the methods disclosed by Amgen could yield "potentially millions more undisclosed antibodies" capable of performing the same functions of those already disclosed.[10] The United States District Court for the District of Delaware and the Federal Circuit agreed and held that Amgen's broad genus claim failed the enablement standard.[11] The United States Supreme Court *held* that the lower courts correctly determined that Amgen failed to adequately enable all that had been claimed. *Amgen, Inc. v. Sanofi*, 598 U.S. 594, 616 (2023).

II. BACKGROUND

The Constitution vests Congress with the power "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."[12] Accordingly, the federal patent system embodies a meticulously crafted agreement designed to promote the development and disclosure of novel, useful, and non-obvious advancements in technology and design.[13] The inventor has the option to keep their invention confidential, reaping its benefits indefinitely.[14] Alternatively, patents are granted in recognition of the disclosure and the ensuing benefits to society.[15] This arrangement serves as a bargain: an exchange for the exclusive right to implement the invention for a specified period after which the knowledge of the invention becomes accessible to the public.[16] Consequently, the public is enabled without constraints to practice and derive benefits from its utilization.[17] In exchange, the applicant is granted "the right to exclude others from making, using, or selling the invention throughout the United States" for a limited period.[18]

7. *Id.* at 603.
8. *Id.*
9. *Id.*
10. *Id.*
11. *Id.* at 604.
12. U.S. CONST. art. I, § 8, cl. 8.
13. Bonito Boats v. Thunder Craft Boats, 489 U.S. 141, 150-51 (1989).
14. *Id.* at 151.
15. *Id.*
16. *Id.*
17. *Id.*
18. 35 U.S.C. § 154.

Reflecting this quid-pro-quo premise of patent law, the enablement requirement outlined in Section 112 of the Patent Act requires a patented invention's specification to include "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."[19] In this manner, the public is ensured to truly enjoy the fruits of the patent bargain once the inventor's privilege has concluded.[20] A guarantee that "upon the expriation of the patent, the knowledge of the invention inures to the people, who are thus enabled without restriction to practice it."[21] This benefit constitutes the consideration for granting the privilege and forms the basis for the authority to issue a patent.[22] Consequently, if the disclosure is excessively vague, lax, or imperfect to the extent that this transfer of knowledge becomes unattainable, it constitutes a deception of the public depriving it of the consideration upon which the monopoly was granted.[23]

Accordingly, if a patent claims an entire class, the patent's specification must "enable a [person having ordinary skill in the art (PHOSITA)] to make and use the entire class."[24] Akin to the reasonable person standard used as a reference in negligence determinations, the PHOSITA is patent law's hypothetical legal construct that refers to a person presumed to have ordinary skill and knowledge in the particular field or technology related to the invention in question.[25] The full scope of the invention as defined by its claims must be enabled by the patent specification.[26] Thus, "the more one claims, the more one must enable."[27] This does not necessarily mandate an exhaustive description of every embodiment within a claimed class.[28] For example, it might suffice if the specification discloses a "general quality" inherent in the class, conferring

19. 35 U.S.C. § 112(a).
20. Amgen, Inc. v. Sanofi, 598 U.S. 594, 605 (2023).
21. *Id.*
22. *Id.*
23. *Id.*
24. *Id.* at 1254.
25. *Id.*; *see also* Daiichi Sankyo Co., Ltd. v. Apotex, Inc., 501 F.3d 1254, 1256 (Fed. Cir. 2007)("In determining the level of ordinary skill, the court may consider various factors, including (1) the inventor's education level; (2) the kinds of problems present in the art; (3) existing prior art solutions to those problems; (4) how quickly innovations are made in the field; (5) the sophistication of the relevant technology; and (6) the level of education of individuals active in the field.").
26. Amgen, Inc. v. Sanofi, 598 U.S. at 610.
27. *Id.*
28. *Id.*

upon it "a peculiar fitness for the particular purpose."[29] In certain instances, disclosing this general quality may effectively enable a PHOSITA to make and use the entirety of what is claimed, not just a subset.[30] Nor is a specification necessarily inadequate just because it leaves the skilled artist to engage in some measure of adaptation or testing.[31] A valid specification may call for a reasonable amount of experimentation to make and use a patented invention.[32] What is reasonable in any case will depend on the nature of the invention and the underlying art.[33] In *In re Wands*, the Federal Circuit highlighted eight factors a court may consider when determining whether a disclosure requires undue experimentation.[34]

A. The Enablement Requirement Applied to Amgen's PCSK9 Inhibitor

Antibodies are proteins produced by the immune system in response to the presence of foreign substances.[35] These antibodies recognize and bind to specific targets, marking them for destruction or neutralization by other immune cells.[36] Essentially, antibodies help the body identify and fight off harmful invaders, playing a crucial role in protecting us from infections and diseases.[37] Antibodies exhibit remarkable diversity with some scientists approximating the number of unique antibodies to rival the stars in the galaxy.[38] Amgen's patent aimed to assert control over the entire category or "'genus' of antibodies that (1) 'bind to specific amino acid residues on PCSK9,' and (2) 'block PCSK9 from binding to [LDL receptors].'"[39] The patent described twenty-six antibodies exhibiting

29. *Id.* at 611 (quoting Consolidated Electric Co. v. McKeesport Light Co., 159 U.S. 465, 475 (1895)).

30. *Amgen*, 598 U.S. at 611.

31. *Id.*; *see also In re* Wands, 858 F.2d 731, 736-37 (Fed. Cir. 1988).

32. *Wands*, 858 F.2d at 737.

33. *Id.*

34. *Id.* ("(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.")

35. Britannica, T. Editors of Encyclopaedia, *antibody*, ENCYC. BRITANNICA (Apr. 27, 2024), https://www.britannica.com/science/antibody [https://perma.cc/JKL6-TK5F].

36. *Id.*

37. *Id.*

38. Amgen, Inc. v. Sanofi, 598 U.S. 594, 599-600 (2023) (citing Bryan Briney et al., *Commonality Despite Exceptional Diversity in the Baseline Human Antibody Repertoire*, 566 NATURE 393 (2019) ("Some scientists estimate that there may be as many unique antibodies as there are stars in the galaxy.").

39. *Amgen*, 598 U.S. at 602.

these dual functions and included two depictions of three-dimensional structures out of the twenty-six.[40] To fulfill the enablement requirement for the remaining antibodies within the genus, Amgen provided two alternative methods for producing antibodies capable of executing the described functions: the "roadmap" and "conservative substitution" methods.[41]

II. COURT'S DECISION

In the noted case, the Supreme Court affirmed the lower court's holding that Amgen had "failed to enable all that it [had] claimed, even allowing for a reasonable degree of experimentation."[42] The district court granted Sanofi judgment as a matter of law after concluding that the claims at issue "are not enabled."[43] The Federal Circuit affirmed, stating that "no reasonable factfinder could conclude" that Amgen had offered sufficient guidance to create and utilize the claimed antibodies extending beyond the specific twenty-six antibodies identified.[44] Although Amgen had disclosed twenty-six antibodies capable of the described functions, Sanofi alleged that the methods submitted by Amgen necessitate scientists to essentially "engage in little more than a trial-and-error process of discovery."[45] Sanofi highlighted the fact that Amgen's claims extend to potentially millions of undisclosed antibodies capable of the same functions.[46] It argued that neither of Amgen's methods enabled a PHOSITA to reliably produce antibodies with identical functions.[47]

The Supreme Court agreed that the two approaches Amgen provided to satisfy the enablement requirement for the remainder of the genus of antibodies claimed in Amgen's patent "amount[ed] to little more than two

40. *Id.* at 602-03.

41. *Id.* at 603. The "roadmap" method requires scientists to: (1) generate antibodies; (2) test the antibodies to determine if they bind to PCSK9; (3) test the antibodies to determine if they bind to the "sweet spot;" and finally (4) test them to determine if they bind to the "sweet spot" and block PCSK9 from binding to LDL receptors. *Id.* Alternatively, the "conservative substitution" method involves (1) starting with an antibody known to hit all four requirements of the "roadmap;" (2) replacing amino acids with other amino acids that are similar; and (3) testing. *Id.*

42. *Id.* at 613.

43. *Id.* (quoting *Amgen*, No. CV 14-1317-RGA, 2019 WL 4058927, at *13 (D. Del. Aug. 28, 2019).

44. *Id.* (quoting *Amgen* Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080, 1088 (Fed. Cir. 2021)).

45. *Id.* at 604.

46. *Id.* at 603.

47. *Id.*

research assignments."[48] First, the Court found that the "roadmap" method essentially outlined Amgen's own trial-and-error method for discovering functional antibodies.[49] The method instructed scientists to systematically generate various candidate antibodies and subsequently screen each one to identify those that effectively bind to PCSK9 in the appropriate location, preventing its binding to LDL receptors.[50] Next, the Court found that the "conservative substitution" method mandated scientists to introduce substitutions to the amino acid sequences of antibodies already proven effective and, subsequently, assess the viability of the resulting antibodies for the intended application.[51] Effectively, this method left scientists "to engage in 'painstaking experimentation' to see what works."[52]

Falling short in its primary contention that the entore genus of antibodies had been adequately enabled, Amgen explored alternative arguments.[53] First, Amgen contended that the Federal Circuit erred by employing an enablement test divorced from the statutory text.[54] Amgen argued that the Federal Circuit erroneously conflated the question of whether an invention is enabled with the *duration* it might take a PHOSITA to produce every embodiment within a broad claim.[55] The Court rejected this claim.[56] While acknowledging Amgen's point that enablement should not be assessed based on the cumulative time and effort required for every embodiment within a claim, it disputed the assertion that the Federal Circuit had adopted this stance.[57] The Court underscored the Federal Circuit's clarification that the effort needed to exhaust a genus is not determinative.[58] Instead, the Court found common ground with the Federal Circuit, observing that Amgen had provided little more than guidance for "trial and error" to those skilled in the art.[59]

Next, Amgen argued that the Federal Circuit improperly elevated the standard for enablement of claims "encompass[ing] an entire 'genus' of

48. *Id.* at 614.
49. *Id.*
50. *Id.*
51. *Id.*
52. *Id.* (quoting Consol. Elec. Co. v. McKeesport Light Co., 159 U.S. 465, 475 (1895)).
53. *Id.* at 615.
54. *Id.*
55. *Id.*
56. *Id.*
57. *Id.*
58. *Id.* (citing Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080, 1088 (Fed. Cir. 2021)).
59. *Id.* (citing *Amgen*, 987 F.3d at 1088) (internal quotation marks omitted).

embodiments defined by their function."[60] In support, Amgen cited the Patent Act's provision outlining a single, universal enablement standard for all inventions.[61] The Court disagreed with Amgen's interpretation of the Federal Circuit's position.[62] It found that the Federal Circuit, in fact, recognized that the more extensive patent claims, the greater the obligation to enable; a principle aligned with Congress's directive and established legal precedents.[63]

Lastly, Amgen cautioned that an affirmation of the lower court's decision could jeopardize incentives for groundbreaking inventions.[64] However, the Court remained unpersuaded and emphasized that striking the proper balance between incentivizing inventors and ensuring the public benefits from innovations is a policy decision entrusted to Congress.[65] Since 1790, Congress has included an enablement mandate as part of its multifaceted approach to achieving the desired balance, and the Court viewed its role as faithfully applying that mandate.[66]

III. ANALYSIS

The noted decision by the Supreme Court has far-reaching implications for patent law because it reinforces the enablement requirement's enduring importance across varying technological landscapes. The Court underscored the timeless relevance of the enablement requirement, emphasizing its applicability to contemporary technology. The crux of the issue in Amgen's case was the expansive claim to a broad genus of antibodies defined by function.[67] The specification lacked sufficient information for scientists to select viable antibodies, leading to a need for extensive experimentation.[68] Relying on century-old precedent, the Court held that "[t]he more one claims, the more one must enable."[69] To adequately enable a claim for a class of compounds, the specification must instruct "a person skilled in the art [on how] to make and use the entire class."[70] According to the Court,

60. *Id.* (internal citation omitted).
61. *Id.* (internal citation omitted).
62. *Id.* at 615-16.
63. *Id.* at 616.
64. *Id.*
65. *Id.*
66. *Id.*
67. *Id.* at 613.
68. *Id.*
69. *Id.* (citing Cont'l Paper Bag Co. v. E. Paper Bag Co., 210 U.S. 405, 419, (1908) ("[T]he claims measure the invention.")).
70. *Id.*

Amgen's patents failed to do so.[71] At a high level, this decision maintains the status quo regarding the standard for patent enablement, neither narrowing nor broadening it.

Supporters of the Court's decision argue that it effectively "align[s] the enablement requirement in the biotech field" with its broader application across various technologies.[72] They assert that the ruling "reflects 'a growing emphasis on promoting innovation and competition by limiting the scope of patent monopolies,' including 'more focused and narrowly tailored [patent] claims.'"[73] In simpler terms, *Amgen* establishes a principle where patents are granted based on actual achievements rather than speculative possibilities.[74] On the other hand, critics have expressed concerns about its potential to undermine incentives for groundbreaking scientific breakthroughs.[75] They argue the significance and breadth of Amgen's innovation should be dispositive, and the Court's decision introduces uncertainty about the legitimate extent to which inventors can patent their entire breakthroughs.[76]

Interestingly, in the noted case, the Supreme Court did not acknowledge the Federal Circuit's oft-cited Wands enablement factors for determining whether undue experimentation is needed; instead, it solely recounted its own precedent.[77] Consequently, the *Amgen* decision heralds a paradigm shift from a patent litigator's standpoint, promising a diverse array of creative arguments: (1) debates on the decision's wider applicability; (2) the stringency comparison between the "written description" patentability requirement and the post-*Amgen* enablement standard; (3) evaluation of factual resemblances in future cases to the historical cases cited in the *Amgen* decision; and (4) the scrutiny of whether the patent being challenged "discloses some general quality running through the [claimed genus] that gives it a peculiar fitness for the particular purpose."[78] Additionally, accused infringers in non-life science

71. *Id.* at 614.

72. KEVIN HICKEY, CONG. RSCH. SERV., LSB10971, AMGEN V. SANOFI: SUPREME COURT HOLDS PATENTS CLAIMING ANTIBODY GENUS INVALID AS NOT ENABLED 3 (2023).

73. *Id.*

74. *Id.*

75. *Id.*

76. *Id.*

77. *Compare In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988) (establishing circuit precedent for enablement factors) *with* Amgen Inc. v. Sanofi, 598 U.S. 594, 612-15 (2023) (summarizing Supreme Court enablement precedent).

78. Robert Sloss, *5 Takeaways from the U.S. Supreme Court Decision in* Amgen v. Sanofi, PROCOPIO, (Nov. 15, 2023, 10:00 AM), https://www.procopio.com/5-takeaways-scotus-amgen-sanofi/ [https://perma.cc/SG7N-LACS].

cases leveraging *Amgen's* enablement arguments adds an intriguing dimension, leaving one to wonder the extent to which lower courts will entertain such arguments.[79]

This landmark decision is poised to reshape the landscape of patent prosecution. The influence is evident in the ongoing debate over the enablement of claims encompassing millions of variants through the disclosure of a limited set of examples. In light of *Amgen*, the matter appears conclusively settled. The aftermath of this ruling is expected to drive practitioners and their clients towards a strategic shift: either opting for narrower claims or intensifying the disclosure in patent applications.[80] This strategic adjustment involves the presentation of more experimental examples to ensure adequate enablement of broad patent claims.[81] The real challenge arises when, like with Amgen's patent, claims are not restricted to specific structures and instead cover the ability to perform a function per se.[82] Broadly construed, these claims potentially encompass all embodiments performing the function, raising concerns about whether the disclosure adequately enables the claim's full scope. Applicants with broad claim language must align the scope with the enablement provided by the specification. Patent practitioners should refine their approach to ensure clients secure meaningful patent protection, obtaining patents capable of withstanding validity challenges based on a lack of enablement.

The impact of the *Amgen* decision is poised to be particularly pronounced for companies that have traditionally sought to establish a robust patent portfolio to attract external investment. In response to *Amgen*, companies are already recalibrating their approaches to patenting and litigation.[83] Strategies now involve defendants leveraging the decision to challenge the validity of patents, efforts to reissue existing patents with narrowed genus claims, and adjustments in patent prosecution practices to provide more specific technical disclosure.[84] Additionally, the decision is likely to influence how these companies conduct routine patent landscape risk assessments.[85] These assessments, which aim to identify potential impacts of third-party patents on the ability to produce a compound or carry out a claimed process, may now

79. *Id.*
80. *Id.*
81. *Id.*
82. *See generally* Amgen, Inc. v. Sanofi, 598 U.S. 594 (2023).
83. HICKEY, *supra* note 72, at 3.
84. *Id.*
85. Sloss, *supra* note 78.

incorporate more nuanced analyses.[86] The focus could shift towards a thorough evaluation of the validity of third-party patents under the standards set by the *Amgen* decision, particularly those with broad claims covering the entire genus.[87] Ultimately, the opinion suggests that expansive patents may face susceptibility to invalidity challenges based on a lack of enablement, prompting a more intricate examination by companies involved in patent portfolio development.[88]

In summary, the *Amgen* decision stands out as a pivotal ruling with far-reaching implications for patent law, innovation, and competition. Its impact on the delicate balance between fostering innovation and preventing excessive competition is set to shape future legislative discussions and guide the strategies of patent practitioners and companies. Practitioners, highlighting the theme of the patent "bargain," should persist in asserting that in exchange for the patent's limited term of protection, patentees must fully disclose their inventions to the public. Despite the Court's explicit disavowal of considering policy implications, the legal precedent established by *Amgen* significantly influences the fundamental equilibrium within patent law. Congress, as the creator of federal patent law, may respond to *Amgen* by considering adjustments to the statutory enablement requirement or by providing explicit permissions and disallowances for specific types of genus claims. While the long-term implications of the unanimous *Amgen* decision may be the subject of extensive speculation, one certainty prevails: this case will enduringly impact how conscientious legal practitioners approach the preparation of new patent applications and structure their arguments on invalidity before U.S. courts.

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86. *Id.*
87. *Id.*
88. *Id.*

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