AMGEN V. SANOFI: THE U.S. SUPREME COURT ISSUES ONE PATENT DECISION IN 2023

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"CONGRESS HAS THE POWER . . . [T]O PROMOTE THE [P]ROGRESS OF [S]CIENCE AND USEFUL [A]RTS, BY SECURING FOR LIMITED [T]IMES TO [A]UTHORS AND [I]NVENTORS THE EXCLUSIVE [R]IGHT TO THEIR RESPECTIVE [W]RITINGS AND [D]ISCOVERIES[.]"[1]

INTRODUCTION

The United States Supreme Court decided one patent case in 2023 for the 2022 term, *Amgen Inc. v. Sanofi.*[2] In *Amgen,* the Supreme Court, on May 18, 2023, unanimously held that Amgen failed to meet the statutory requirement[3] to enable one ordinarily skilled in the art to make and use Amgen's patented pharmaceutical as claimed.[4] This decision affirmed the judgment of the Court of Appeals for the Federal Circuit.[5] The patent bargain, found in the Intellectual Property Clause of the Constitution, under which the first inventor gets a limited monopoly, and then the patented invention enters the public domain sufficiently enabled to allow others skilled in the art to

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1 U.S. CONST., art. I, § 8, cl. 8.

2 Amgen Inc. v. Sanofi, 598 U.S. 594 (2023); *see infra* notes 88–132 and accompanying text.

3 *Amgen Inc.*, 598 U.S. at 612–16.

4 *See* 35 U.S.C. § 112(a); *see infra* notes 88–132 and accompanying text (explaining the Court's unanimous holding).

5 *Amgen Inc.*, 598 U.S. at 616; Amgen Inc. v. Sanofi, 987 F.3d 1080, 1088 (Fed. Cir. 2021).

make and use the invention,[6] was not met in *Amgen*, according to the Court.[7]

In the last decade, from the 2013 term through the 2022 term, the Court decided a total of twenty-seven patent cases, ranging from zero to six cases per term.[8] Fourteen of these cases, including *Amgen*, were unanimous,[9] while thirteen cases had dissents.[10] The Supreme Court did not decide a patent case in the 2021 term; one, *Amgen*, in the 2022 term; and two patent decisions each in the 2020, the 2019, the 2018, and the 2015 terms.[11] Three patent cases were decided by the Court in its 2017 term and in its 2014 term.[12] Six patent decisions were handed down by the Court in the 2016 and 2013 terms.[13]

In the terms from 2013 through 2022, the Supreme Court affirmed the Federal Circuit in patent cases seven times, including

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[6] *See supra* note 1 and accompanying text; Kris J. Kostolansky & Daniel Salgado, *Does The Experimental Use Exception in Patent Law Have a Future?*, COLORADO LAWYER 32, 32 (Jan. 2018).

[7] *Amgen Inc.*, 598 U.S. at 612–16.

[8] Lisa Larrimore Ouellette et al., *Supreme Court Patent Cases*, WRITTEN DESCRIPTION, https://writtendescription.blogspot.com/p/patents-scotus.html (last visited May 13, 2024).

[9] *Amgen Inc.*, 598 U.S. 594 (2023); Peter v. NantKwest, Inc., 140 S. Ct. 365 (2019); Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc., 139 S. Ct. 628 (2019); Life Techs. Corp. v. Promega Corp., 580 U.S. 140 (2017); TC Heartland LLC v. Kraft Foods Grp. Brands LLC, 581 U.S. 258 (2017); Sandoz Inc. v. Amgen Inc., 582 U.S. 1 (2017); Halo Elecs., Inc. v. Pulse Elecs., Inc., 579 U.S. 93 (2016); Samsung Elecs. Co. v. Apple Inc., 580 U.S. 53 (2016); Medtronic, Inc. v. Mirowski Family Ventures, 571 U.S. 191 (2014); Octane Fitness, LLC v. ICON Health & Fitness, Inc., 572 U.S. 545 (2014); Highmark, Inc. v. Allcare Health Mgmt. Sys., Inc., 572 U.S. 559 (2014); Limelight Networks, Inc. v. Akami Techs., Inc., 572 U.S. 915 (2014); Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898 (2014); Alice Corp. Pty. Ltd. v. CLS Bank Int'l., 573 U.S. 208 (2014).

[10] United States v. Arthrex, Inc., 141 S. Ct. 1970 (2021); Minerva Surgical, Inc. v. Hologic, Inc., 141 S. Ct. 2298 (2021); Thryv., Inc. v. Click-To-Call Techs., LP, 140 S. Ct. 1367 (2020); Return Mail, Inc. v. United States Postal Serv., 139 S. Ct. 1853 (2019); Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC, 584 U.S. 325 (2018); SAS Inst., Inc. v. Iancu, 584 U.S. 357 (2018); WesternGeco LLC v. ION Geophysical Corp., 138 S. Ct. 2129 (2018); SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC, 580 U.S. 328 (2017); Impression Prods., Inc. v. Lexmark Int'l, Inc., 581 U.S. 360 (2017); Cuozzo Speed Tech., LLC v. Lee, 579 U.S. 261 (2016); *Teva Pharms.*, 574 U.S. 318 (2015); Commil USA, LLC v. Cisco Sys., Inc. 575 U.S. 632 (2015); Kimble v. Marvel Ent., LLC, 576 U.S. 446 (2015).

[11] *Amgen Inc.*, 598 U.S. 594 (2023); Sue Ann Ganske, *Arthrex and Minerva Surgical, The U.S. Supreme Court Issues Two Patent Decisions in 2021*, 32 ALB. L.J. SCI. & TECH. 1, 3 (2022); David Crouch, *Supreme Court on Patent Law 2022*, PATENTLY-O (Sept. 26, 2022), https://patentlyo.com/patent/2022/09/supreme-patent-october.html.

[12] Ganske, *supra* note 11.

[13] *Id.*

Amgen;[14] affirmed the Ninth Circuit once;[15] and reversed or vacated the Federal Circuit nineteen times.[16]

Amgen Inc. v. Sanofi is the second time in recent years that Amgen has been a party to a Supreme Court patent precedent.[17] In the 2016 term, the Court unanimously decided *Sandoz Inc. v. Amgen Inc.*[18] This first appellate decision on the Biologics Price Competition and Innovations Act ("BPCIA") vacated and reversed the Court of Appeals for the Federal Circuit and the Court remanded the case.[19] The Court in *Sandoz* held that failure to give notice under the BPCIA is not enforceable by injunction, and the 180-day BPCIA notice may be given before FDA approval.[20] Sandoz largely prevailed at the Court in 2017, and Sanofi prevailed in 2023; Amgen, thus, has not had a great track record at the Supreme Court.[21] Sandoz has also made two trips to the Supreme Court in recent years but lost seven to two in the 2014 term in *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*[22]

This article examines *Amgen Inc. v. Sanofi*, the sole Supreme Court patent opinion in the 2022 term, which affirmed the Court of Appeals for the Federal Circuit, [23] and discusses the importance of adequate enablement in patent jurisprudence and practice.

AMGEN INC. V. SANOFI

"The specification shall contain a written description of the invention, and of the manner and process of making and using it,

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[14] *Amgen Inc.*, 598 U.S. 594 (2023); *Helsinn Healthcare*, 139 S. Ct. 628 (2019); *NantKwest, Inc.*, 140 S. Ct. 365 (2019); *Oil States Energy*, 584 U.S. 325 (2018); *Cuozzo Speed*, 579 U.S. 261 (2016); *Samsung*, 580 U.S. 53 (2016); *Alice Corp.*, 573 U.S. 208 (2014).

[15] Kimble v. Marvel Ent., LLC, 576 U.S. 446 (2015).

[16] *Minerva*, 141 S. Ct. 2298 (2021); *Arthrex*, 141 S. Ct. 1970 (2021); *Thryv*, 140 S. Ct. 1367 (2020); *Return Mail*, 139 S. Ct. 1853 (2019); SAS Inst., Inc. v. Iancu, 584 U.S. 357 (2018); *WesternGeco*, 138 S. Ct. 2129 (2018); *Life Techs.*, 580 U.S. 140 (2017); *SCA Hygiene*, 580 U.S. 328 (2017); *TC Heartland*, 581 U.S. 258 (2017); *Impression*, 581 U.S. 360 (2017); *Sandoz*, 582 U.S. 1 (2017); *Halo*, 579 U.S. 93 (2016); *Teva Pharms.*, 574 U.S. 318 (2015); *Commil*, 575 U.S. 632 (2015); *Medtronic*, 571 U.S. 191 (2014); *Octane Fitness*, 572 U.S. 545 (2014); *Highmark*, 572 U.S. 559 (2014); *Nautilus*, 572 U.S. 898 (2014); *Limelight*, 572 U.S. 915 (2014).

[17] *Sandoz*, 582 U.S. 1 (2017).

[18] *Id.*

[19] *Id.*

[20] *Id.* at 17, 19.

[21] *Sandoz*, 582 U.S. 1 (2017); *Amgen Inc.*, 598 U.S. 594 (2023).

[22] *Teva Pharmaceuticals Inc. v. Sandoz, Inc.*, 574 U.S. 318 (2015).

[23] *Amgen Inc.*, 598 U.S. 594 (2023).

in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention."[24]

Amgen, a biotechnology company founded in 1980 and headquartered in Thousand Oaks, California, had $28.2 billion in sales in 2023.[25] Sanofi, founded in 1994, is a French healthcare company focused on pharmaceuticals, consumer healthcare, and vaccines, with revenue of $50.3 billion in 2023.[26] The United States accounted for 43% of Sanofi's net sales in 2022.[27]

In 2005, Amgen began studying proprotein convertase subtilisin kexin type 9 ("PCSK9"), a naturally occurring protein which binds to and destroys liver cell receptors.[28] These liver cell receptors remove low-density lipoprotein ("LDL") cholesterol (bad cholesterol) from the bloodstream.[29] LDL cholesterol has been linked to heart disease, heart attacks, and strokes.[30] Some patients are prescribed statins to lower LDL cholesterol; statins stop the liver from making as much cholesterol.[31] Some patients on statins have side effects, or the statins don't work adequately for patients with elevated LDL levels.[32] Amgen developed Repatha® (evolumab) as a fully human monoclonal antibody which binds to PCSK9 proteins, thus leaving less LDL cholesterol in the blood.[33] Repatha® was approved by the FDA in August 2015.[34]

In 2007, Sanofi independently started researching antibodies to

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[24] 35 U.S.C. § 112.

[25] *About Amgen*, AMGEN (Apr. 2024), https://www.amgen.com/-/media/Themes/CorporateAffairs/amgen-com/amgen-com/downloads/fact-sheets/fact_sheet_amgen.pdf; *see id.*

[26] Sanofi, Annual Report (Form 20-F), 16 (Feb. 24, 2023); *Sanofi Revenue 2010-2023*, MACROTRENDS, https://www.macrotrends.net/stocks/charts/SNY/sanofi/revenue (last visited May 13, 2024).

[27] *See* Sanofi, Annual Report (Form 20-F), 75 (Feb. 24, 2023).

[28] Amgen Inc. v. Sanofi, 872 F.3d 1367, 1371 (Fed. Cir. 2017).

[29] *Id.*

[30] *Id.*

[31] *Id.*; *Cholesterol-Lowering Medicine*, CTRS. DISEASE CONTROL & PREVENTION, https://www.cdc.gov/cholesterol/treating_cholesterol.htm#:~:text=Statin%20drugs%20lower%20LDL%20cholesterol,is%20already%20in%20the%20blood (last visited May 13, 2024).

[32] *Amgen Inc. v. Sanofi*, 872 F.3d at 1371.

[33] *Id.*

[34] *Id.*

PCSK9, resulting in Praluent®, which also uses a monoclonal antibody to target PCSK9 so that liver cell receptors reduce LDL cholesterol. [35] I n 2011, Sanofi received a patent for Praluent®, and in July 2015, Praluent® received FDA approval.[36] Amgen's and Sanofi's patents each describe the relevant antibody by its amino acid sequence.[37]

On September 9, 2014, the U.S. Patent and Trademark Office ("PTO") issued Amgen U.S. Patent 8,829,165 (the "'165 patent") for "antigen binding proteins that interact with Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9)[,]" for "[m]ethods of treating hypercholesterolemia and other disorders by administering . . . an antigen binding protein to PSCK9."[38] On October 14, 2014, the PTO issued Amgen U.S. Patent 8,859,741 (the "'741 patent"), which was also for antigen binding proteins to PCSK9.[39] The written descriptions and specifications are the same.[40] Both patents describe twenty-six monoclonal antibodies, including evolocumab, which bind to a specific region of PSCK9,[41] the "sweet spot."[42] Amgen thus identified in its patent the amino acid sequences of twenty-six *antibodies*, which bind to PSCK9 and block it from binding to LDL cholesterol receptors, and gave the three dimensional structure of two of these twenty six amino acid sequences.[43] Amgen gave those ordinarily skilled in the art two methods to enable the patent: a roadmap[44] and conservative substitution.[45]

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[35] *Id.* at 1372.

[36] *Id.*

[37] *Amgen Inc.*, 598 U.S. at 602.

[38] U.S. Patent No. 8,829,165 (filed Apr. 10, 2013).

[39] U.S. Patent No. 8,829,741 (filed Apr. 24, 2014).

[40] U.S. Patent No. 8,829,165 (filed Apr. 10, 2013); U.S. Patent No. 8,829,741 (filed Apr. 24, 2014).

[41] '165 Patent; '741 Patent; *Amgen Inc.,* 598 U.S. at 602; Brief for Petitioner at 12, Amgen v. Sanofi, 598 U.S. 594 (2023) (No. 21-757).

[42] *Amgen Inc.,* 598 U.S. at 602.

[43] *Amgen Inc.,* 598 U.S. at 602, 603.

[44] *Amgen Inc.,* 598 U.S. at 603 (explaining that "the roadmap directs scientists to: (1) generate a range of antibodies in the lab; (2) test those antibodies to determine whether any kind bind to PCSK9; (3) test those antibodies that bind to PSCK9 to determine whether any bind to the sweet spot as described in the claims; and (4) test those antibodies that bind to the sweet spot as described in the claims to determine whether any block PCSK9 from binding to LDL receptors.").

[45] *Id.* (Conservative substitution "requires scientists to: (1) start with an antibody known to perform the described functions; (2) replace select amino acids in the antibody with other amino acids known to have similar properties; and (3) test the resulting amino acid to see if it also performs the required function.").

On October 17, 2014, Amgen[46] sued Sanofi[47] for patent infringement of the '165 and '741 patents.[48] In 2015, District Court Judge Sue Robinson held a *Markman* hearing and issued a claims construction order.[49] Before trial in 2016, the defendants stipulated to infringement of some of plaintiff's patents claims.[50] At trial in 2016, the defendant Sanofi argued, among other things, that Amgen's patents were not valid due to enablement and lack of a written description, and also were obvious.[51] The district court granted the defendant's judgment as a matter of law on willful infringement, and the jury found that the patent claims in question were valid.[52] Thus, in January 2017, Amgen's motion for a permanent injunction against Sanofi for their sales of Praluent® was granted.[53] Applying the four factors of *eBay Inc. v. MercExchange, LLC*, although the defendant prevailed on the public interest factor since the public should have a choice of drugs, the court found that the plaintiffs prevailed on the factors of irreparable harm and inadequacy of monetary damages.[54]

In 2017, the Court of Appeals for the Federal Circuit reversed on the issues of enablement and lack of a written description, ordered a new trial, and lifted the permanent injunction[55] because

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[46] The plaintiffs were Amgen Inc., Amgen Manufacturing Ltd., and Amgen USA Inc. Amgen Inc. v. Sanofi, 227 F. Supp. 3d 333, 336 (D. Del. 2017).

[47] The defendants were Sanofi, Sanofi-Aventis U.S. LLC, Aventisub LLC, and Regeneron Pharmaceuticals, Inc. *Id.* Regeneron is responsible for commercialization of Praluent® in the U.S. Sanofi, Annual Report (Form 20-F), 27 (Feb. 24, 2023).

[48] *Amgen Inc.*, 227 F. Supp. 3d at 336.

[49] *Id.* (referring to a hearing established in Markman v. Westview Instruments, 517 U.S. 370 (1996)); Sue Ann Mota, *Markman v. Westview Instruments, Inc.: Patent Construction Is Within the Exclusive Province Of the Court Under the Seventh Amendment*, 3 RICH. J.L. & TECH. 1, 28 (1997)("*Markman* clarifies that patent claim construction is a matter of law for the court. This grants judges leeway in patent cases to interpret claims, thus relegating the jury's role to other issues, such as infringement. The *Markman* decision thus clarifies the judge's role in patent cases. Judges may, as in *Markman*, deal with issues of claim construction in motion form.").

[50] *Amgen Inc.*, 227 F. Supp. 3d at 336.

[51] *Id.* at 338.

[52] *Id.* at 337. The jury found that the patent claims were not invalid due to lack of a written description or enablement. *Id.* at 348. Thus, the defendant's renewed request for a judgment as a matter of law on enablement and lack of a written description were denied. *Id.* at 350.

[53] Amgen Inc. v. Sanofi, No. 14-1317-SLR, 2017 WL 67125, at *3 (D. Del. Jan. 5, 2017).

[54] *Amgen Inc.*, 2017 WL 67125, at *1–3. The injunction was delayed for thirty days to allow the defendant to appeal. *Id.*

[55] Amgen Inc. v. Sanofi, 872 F.3d 1367, 1371 (Fed. Cir. 2017).

the district court erred by not allowing Sanofi's evidence on enablement and lack of a written description and the district court gave an improper jury instruction on the written description.[56] The Patent Act requires the specification to have a written description "in such full, clear, concise, and exact terms as to enable [someone] skilled in the art . . . to make and use the same."[57] Sanofi had sought unsuccessfully to introduce post-priority date evidence that Amgen engaged in lengthy and possibly undue experimentation to fully enable the patent claims, and thus was entitled to a new trial on this issue.[58]

Further, *eBay v. MercExchange, LLC*, was misapplied concerning the public interest factor, in both the application of and the analysis of that factor.[59] First, despite the district court concluding that issuing a permanent injunction would disserve the public interest, the district court issued the permanent injunction.[60] The public interest factor, if met, should have disallowed the permanent injunction.[61] Second, the district court's analysis was incorrect because it concluded, in contrast to the law, that eliminating a choice of drugs alone was sufficient to meet the public interest factor.[62] Thus, the permanent injunction was lifted.[63] After the Federal Circuit Court of Appeals decision, the first petition for a writ of certiorari was denied by the Supreme Court in January 2019.[64]

On remand to the district court in 2019, the jury found claim seven of the '741 patent claim and claims nineteen and twenty-nine of the '165 patent valid.[65] Claim nineteen of the '165 patient is for an isolated monoclonal antibody, which binds to at least two out of a list of fifteen residues of PCSK9.[66] Claim twenty-nine of

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[56] *Id.*
[57] 35 U.S.C. §112.
[58] *See* Amgen Inc. v. Sanofi, 872 F.3d 1367, 1375 (Fed. Cir. 2017).
[59] *Id.* at 1381.
[60] *Id.*
[61] *Id.*
[62] *Id.*
[63] *Id.* at 1382.
[64] Amgen Inc. v. Sanofi, 872 F.3d 1367 (Fed. Cir. 2017), *cert. denied*, 139 S. Ct. 787 (2019).
[65] Amgen Inc. v. Sanofi, No. 14-1317-RGA, 2019 WL 4058927, at *1 (D. Del. Aug. 28, 2019). On remand, the claims were limited to 7, 15, 19, and 29 of the '165 patent, and to claim 7 of the '741 patent. *Amgen Inc.*, 2019 WL 4058927, at *17, n.3. The jury invalidated claims 7 and 15 of the '165 patent for lack of a written description. *Amgen Inc.*, 2019 WL 4058927, at *1.
[66] *Amgen Inc.*, 2019 WL 4058927, at *2; U.S. Patent No. 8,829,165B2 (issued Sept. 9, 2014).

the '165 patent is for a pharmaceutical composition of an isolated monoclonal antibody, which binds to at least two out of a list of fifteen PCSK9 residues, and blocks PCSK9 binding to the bad cholesterol receptor by at least 80%.[67] Claim seven of the '741 patent is for an isolated monoclonal antibody that is the functional epitope of a neutralizing antibody.[68] This antibody binds an epitope of PSCK9 on one of two residues and blocks the binding of PCSK9 and a low density lipoprotein receptor.[69] Amgen thus claimed the "entire genus" of antibodies which bind to PCSK9 and block it from binding to LDL receptors.[70]

On remand in August 2019, U.S. District Judge Richard Andrews denied Sanofi's request for a judgment as a matter of law of no written description and conditionally denied Sanofi's request for a new trial.[71] Sanofi's request for a judgment as a matter of law on enablement, though, was granted by the district court.[72] The enablement requirement, found in 35 U.S.C. §112 requires that someone skilled in the art could practice the claimed invention from the specification.[73] The full scope of the claimed invention must be enabled, without undue experimentation, although every permutation need not be claimed.[74] The judge "must defer to the jury's factual determinations but review the legal question *de novo*, examining the following factors from *In Re Wands*:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance given, (3) the presence or absence of 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 claim.[75]

The defendant's burden to prove invalidity, including enablement, is by clear and convincing evidence, which requires a showing that no reasonable jury could have failed to conclude that enablement was proven.[76] Despite the high standard, the district

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[67] *Amgen Inc.*, 2019 WL 4058927, at *2; U.S. Patent No. 8,829,165B2 (issued Sept. 9, 2014).

[68] *Amgen Inc.*, 2019 WL 4058927, at *2; U.S. Patent No. 8,859,741B2 (issued Oct. 14, 2014).

[69] *Amgen Inc.*, 2019 WL 4058927, at *2.

[70] *Amgen Inc.*, 598 U.S. at 602.

[71] *Amgen Inc.*, 2019 WL 4058927, at *17.

[72] *Id.*

[73] 35 U.S.C. § 112; *Amgen Inc. v. Sanofi*, 872 F.3d at 1375.

[74] *Amgen Inc.*, 2019 WL 4058927, at *6.

[75] *Id.* (citing *In re* Wands, 858 F2d. 731, 737 (Fed. Cir. 1988)).

[76] *Id.*

court granted Sanofi's judgment as a matter of law on enablement.[77]

In its analysis, the district court disagreed with Sanofi's argument that the vast majority of the antibodies within the full scope of the claim are impossible to make but the district court did agree with Sanofi that, using the factors above, undue experimentation is required to practice the full scope of the claims.[78] Concerning the breadth of the claims, due to the experimentation required to test to see if the antibodies bound to PCSK9 and bound the LDL receptors, the factfinder could only reasonably conclude that the "scope of the claims is vast."[79] Further, "a reasonable factfinder could only find that the art is unpredictable."[80] The methods disclosed in the patent were well known in the prior art, and someone ordinarily skilled in the prior art would know how to make at least some of the antibodies.[81] The district court found that there is no genuine dispute of the amount of direction or guidance granted to someone skilled in the art or the number of working examples because the twenty-six working examples do not provide guidance or direction regarding how to predict whether an antibody will bind, which needs to be discovered by trial and error.[82] A substantial amount of time and effort would be needed to enable the full scope of the claims.[83] This experimentation required thus would be "'undue'" and the patent claims were not valid due to lack of enablement.[84] Consequently, Amgen's request for a permanent injunction was dismissed by the district court, because it was moot.[85]

Back to the Court of Appeals for the Federal Circuit in 2021, the appeals court affirmed that the patent claims were not valid because they were not enabled.[86] Reviewing the enablement

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[77] *Id.* at *17.

[78] *Id.* at *5 (explaining that the parties agreed that these claims stand or fall together, for the purpose of enablement), 7, 12.

[79] *Id.* at *8.

[80] *Id.* at *10.

[81] *Id.*

[82] *Amgen Inc.*, 2019 WL 4058927, at *10, 11.

[83] *Id.* at *12.

[84] *Id.* at *12–13. To summarize the factors, potentially millions of antibodies fall within the claim's scope, and the substitution of the amino acids have unpredictable effects. *Id.* at *12 Further, even though the techniques are routine, the person ordinarily skilled in the art would have to do as much work as the inventors. *Id.* There is insufficient guidance, and the amount of experimentation would be substantial. *Id.*

[85] *Id.* at *17.

[86] *Amgen*, 987 F.3d at 1088.

requirement, the appeals court reviewed the *Wands* factors to determine whether the required amount of experimentation was undue, or sufficiently routine for someone with ordinary skill in the art.[87] The appeals court, in an opinion by Judge Lourie, concluded that the district court did not err in deciding that undue experimentation would be needed to practice the full scope of the claims.[88] The scope of the claims was broad in an unpredictable field, there was insufficient guidance for someone with ordinary skill in the art, and the experimentation needed would require substantial time and effort.[89] Therefore, the court of appeals affirmed finding that the district court was correct that the patent claims were not valid for lack of enablement.[90] Amgen's request for a panel rehearing was denied.[91]

In 2022, the Supreme Court granted the petition for a writ of certiorari on the issue of "whether enablement is governed by the statutory requirement that the specification teach those skilled in the art to 'make and use' the claimed invention, 35 U.S.C. §112, or whether it must instead enable those skilled in the art '*to reach the full scope* of claimed embodiments' without undue experimentation–i.e., to cumulatively identify and make all or nearly all embodiments of the invention without substantial 'time and effort.'"[92]

On May 18, 2023, the Supreme Court unanimously affirmed, reaching this conclusion because one skilled in the art was not enabled to make and use the patented invention as described in the relevant claims.[93]

Writing for the Court, Justice Gorsuch began by stating that the intellectual property clause of the Constitution sets out the patent "bargain."[94] It grants the inventor a limited monopoly and when this time period ends, the invention enters the public domain.[95]

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[87] *Id.* at 1084, 1085.
[88] *Id.* at 1082, 1088.
[89] *Id.* at 1087, 1088.
[90] *Id.* at 1088.
[91] Amgen Inc. v. Sanofi, 850 F. App'x. 794, 795 (Fed. Cir. 2021). Amgen argued, to get a panel rehearing, that the appeals court used a new test for enablement. *Id.* at 795. Judge Lourie opined that "what is new today is not the law, but generic claims to biological materials that are not fully enabled." *Id.*
[92] Petition for Writ of Certiorari, *Amgen Inc. v. Sanofi*, 598 U.S. 594 (No. 21-757); *see Amgen Inc.*, 598 U.S. 602–04.
[93] *Amgen Inc.*, 598 U.S. at 612–16.
[94] *Id.* at 597, 605.
[95] *Id.* at 604–05; MICHAEL SCHUSTER, PATENT LAW AND MANAGING INVESTMENTS IN TECHNOLOGY 4 (2016).

Since the first Patent Act of 1790, there has been an enablement requirement; the specification must "enable a workman or other person skilled in the art" to make or use the invention.[96] This enablement requirement has survived and is codified in the current Patent Act.[97]

The Court reviewed its patent enablement precedents, stating that "[w]hile the technologies in these older cases seem a world away from the antibody treatments of today, the decisions are no less instructive[.]"[98] In *O'Reilly v. Morse*, Samuel Morse's 1848 reissue patents for the electro-magnetic telegraph were challenged on the grounds that Morse was not the inventor, that the patents were not valid, and that O'Reilly's telegraph system was different from Morse's patented telegraph system.[99] Chief Justice Taney, writing for the Court, affirmed that Morse was the first and original inventor.[100] Although seven patent claims were valid, the eighth claim was problematic, which stated:

> I do not propose to limit myself to the specific machinery or parts of machinery described in the foregoing specification and claims; the essence of my invention being the use of the motive power of the electric or galvanic current, which I call electro-magnetism, however developed for marking or printing intelligible characters, signs, or letters, at any distances, being a new application of that power of which I claim to be the first inventor or discoverer.[101]

This overly broad claim violated the Patent Act of 1836, which required the enablement of someone skilled in the art to make or use the patented invention.[102] Morse's eighth claim was not allowed under patent law,[103] however, the rest of the patent claims were deemed valid.[104] Since O'Reilly's telegraph infringed on valid claims, the injunction against O'Reilly was affirmed.[105]

The Court in *Amgen* next reviewed the 1895 Supreme Court enablement precedent of the *Incandescent Lamp Patent*, which involved a patent on an electric lamp using an incandescent

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[96] *Amgen Inc.*, 598 U.S. at 604–05.
[97] 35 U.S.C. § 112.
[98] *Amgen Inc.*, 598 U.S. at 605–06.
[99] O'Reilly v. Morse, 56 U.S. 62, 106 (1854).
[100] *Id.* at 106, 108.
[101] *Id.* at 112–13.
[102] *Id*. at 119–20.
[103] *Id.* at 120.
[104] *Id.* at 123.
[105] *Id.* at 123; *see id*. at 124 (discussing that "O'Reilly's [telegraph] can hardly be said to differ substantially and essentially from [Morse's], and the ultimately the Court reversed decree of costs and directed each party to pay their own costs).

conductor made of carbonized "fibrous or textile material."[106] In 1885, Sawyer and Man[107] obtained a patent for an electric lamp using an incandescent conductor, which claimed "every fibrous and textile" material for the incandescing conductor, even though over six thousand such materials studied showed no ability to be such an electric conductor.[108] Thomas Edison, the inventor of one thousand ninety-three patents, including an 1880 patent for the electric lamp, was sued for infringement for his incandescent lamp.[109] Edison's defenses to infringement were: one, that the patent was overbroad and thus not valid because Sawyer and Man claimed every fibrous and textile material used as a conductor for electric illumination and two, that Sawyer and Man were not the first inventors.[110] Edison also studied and tested extensively to find a plant material which would be suitable as such a conductor.[111] Edison found just three species of bamboo, and one or two of agave, which worked as an incandescent conductor.[112]

At that time, the Patent Act required a written description sufficient to enable one skilled in the art to make and use the invention.[113] According to the Court in *Incandescent Lamp Patent*, "[i]f the description be so vague and uncertain that no one can tell, except by independent experiments, how to construct the patented device, the patent is void."[114] Applying this, the Court stated, "how would it be possible for a person to know what fibrous or textile material was adapted to the purpose of an incandescent conductor, except by the most careful and painstaking experimentation?"[115] Further, "the fact that paper happens to belong to the fibrous kingdom did not invest them with sovereignty over this entire

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[106] Amgen Inc. v. Sanofi, 598 U.S. 594, 607–09 (2023); Incandescent Lamp Pat., 159 U.S. 465, 471 (1895).

[107] *Incandescent Lamp*, 159 U.S. at 465. This patent was assigned to the Electric Light Company. *Id.* The lamp claimed in the Sawyer and Man patent was never a commercial success and was not in use at the time of this case, *id*. at 471.

[108] *See id.* at 471, 472 (The third claim, that was upheld, was for a carbonized wood or paper conductor.).

[109] EDMUND MORRIS, EDISON 5 (Random House 2019). "Edison averaged one patent for every ten to twelve days of his adult life[,]" not including inventions such as the X-ray fluoroscope, which he chose not to cover with a patent, *id*; *Incandescent Lamp*, 159 U.S. at 465.

[110] *Incandescent Lamp*, 159 U.S. at 472.

[111] *Id.* at 472–73.

[112] *Id*. at 473.

[113] *Id*. at 474.

[114] *Id.*

[115] *Id.* at 475.

kingdom."[116] Thus, the Supreme Court affirmed the Circuit Court's holding that the Sawyer and Man patent was not valid for lack of enablement.[117]

The Court in *Amgen* then addressed the 1928 Supreme Court enablement precedent of *Holland Furniture Company v. Perkins Glue Company*.[118] Perkins Glue patented a starch glue as a substitute for animal glue which claimed, "all 'starch glue which, . . . will have substantially the same properties as animal glue.'"[119] While Perkins could patent its starch glue, the broad claim of all starch glue was not valid for lack of enablement.[120] One who wanted to use, or avoid the use of, the patented starch glue would have to engage in excessive experimentation.[121]

Under these precedents, according to the Court in *Amgen*, "the more one claims, the more one must enable."[122] The claim does not have to discuss with particularity every single embodiment, and depending upon the nature of the invention and the art, some level of experimentation or testing is acceptable.[123] However, the specification must disclose in such "clear, concise, and exact" language that someone skilled in the art is enabled to "make and use the invention."[124] "Judges may no more subtract from the requirements for obtaining a patent that Congress has prescribed than [Judges] may add to them."[125]

The Court in *Amgen* addressed Amgen's patent claims in light of the Court's enablement precedents.[126] Sanofi contended that Amgen's patents were not valid for lack of enablement because they claimed millions more antibodies than described,[127] and the person ordinarily skilled in the art would have to perform two methods: the roadmap[128] and conservative substitution in a trial-

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[116] *Id.* at 476.
[117] *Id.* at 475–77.
[118] Amgen Inc. v. Sanofi, 598 U.S. 594, 609–10 (2023). The Court in *Amgen* also cited the enablement precedent of Minerals Separation, Ltd. v. Hyde, 242 U.S. 261 (1916)*, Amgen Inc.*, 598 U.S. at 606, 611.
[119] *Amgen Inc.*, 598 U.S. at 609.
[120] *Id.* at 610.
[121] *Id.*
[122] *Id.*
[123] *Id.* at 610–11, 612.
[124] *Id.* at 612.
[125] *Id.*
[126] *Id.*
[127] *Id.* at 603.
[128] *Id.* at 603, 604; *see supra* note 44 (describing the requirements to enable a patent under the "roadmap" method).

and-error method.[129] The Court termed these two methods as a "little more than two research assignments."[130] Antibody science is unpredictable.[131] One ordinarily skilled in the art would have to undergo "painstaking experimentation,"[132] and this isn't enablement, but rather a "hunting license."[133]

The Supreme Court concluded that Amgen enabled the twenty-six antibodies because one ordinarily skilled in the art could make and use those.[134] According to the Court, however, Amgen did not "enable all that it . . . claimed," and affirmed the lower courts.[135] As in *Morse*, *Incandescent Lamp*, and *Holland Furniture*, Amgen failed to enable all that it claimed, even with a reasonable amount of testing.[136] The public received its benefit from the patent bargain.[137]

CONCLUSION

The U.S. Supreme Court decided *Amgen v. Sanofi, Inc.* in 2023 which involved high-stakes pharmaceutical patents for LDL reducing drugs using monoclonal antibodies. [138] Amgen's Repatha sales in 2022 were $1.3 billion while Sanofi's Praluent sales were $408.2 million.[139] The Court unanimously held that the patent must adequately be developed so that one ordinarily skilled in the art is enabled to practice it from the specification, thus voiding some claims of Amgen's patents.[140] Thus, for functional or genus claiming, while not every permutation need be listed, there must be adequate disclosure of the patented invention. This author believes that the Court reached the proper balance, requiring full disclosure and promoting the public good so that one skilled in the

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[129] *Amgen Inc.*, 598 U.S. at 604; *see supra* note 45 (describing the requirements to enable a patent under the "conservative substitution" method).

[130] *Id.* at 614.

[131] *Id.*

[132] *Id.*

[133] *Id.*

[134] *Id.* at 612 ("[W]e do not doubt that Amgen's specification enabled the 26 exemplary antibodies it identifies by their amino acid sequences.").

[135] *Id.* at 613, 616.

[136] *Id.* at 613–16.

[137] *See supra* notes 6, 7 and accompanying text.

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

[139] Jan Wolfe & Joseph Walker, *Sanofi Wins Supreme Court Patent Dispute with Amgen*, WALL ST. J.: HEALTH (May 18, 2023, 1:58 PM), https://www.wsj.com/articles/sanofi-wins-supreme-court-patent-dispute-with-amgen-836df261.

[140] *Amgen Inc.*, 598 U.S. at 612–13.

art is enabled to make the patented invention, here a pharmaceutical, at the expiration of the patent term, without undue experimentation, and leading to further innovation. The more the patent holder claims, the more the patent holder must enable.[141]

[141] *Amgen Inc.*, 598 U.S. at 613.