After *Amgen*: Examining the Supreme Court's Impact on Patents for Therapeutic Antibodies

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ABSTRACT

Therapeutic antibodies treat many serious medical conditions and represent an industry worth over $160 billion. Acquiring intellectual property protection is paramount for drug researchers producing therapeutic antibodies. Early on, antibody inventors received broad patent protection from the United States Patent and Trademark Office through a patenting strategy called functional genus claiming, whereby antibody patents claimed groups of antibodies that bind to a common epitope.

Over the past 20 years, the Federal Circuit has routinely invalidated antibody patents with functional genus claims. The court has held that such patents fail to meet the Patent Act's "enablement requirement," which requires a patent's specifications to contain enough information so it enables a person of skill in the art to make and use the patented invention without resorting to undue experimentation.

Recently, the United States Supreme Court heard *Amgen v. Sanofi*, where the Court considered whether an antibody patent with functional claims met the enablement requirement. In a unanimous opinion, the Court held that it did not. However, the Court explicitly did not foreclose validity on all patents with functional genus claims. The Court's decision has highlighted polarizing views regarding judicial standards for enforcing the Patent Act's enablement requirement.

This Comment analyzes the jurisprudential and scientific inroads underlying the Court's decision in *Amgen.* An analysis of this progression reveals that the Supreme Court attempted to put the issue of enabling antibody patents to rest. Instead, the decision opened the door to future jurisprudential shifts, leaving the Federal Circuit responsible to establish

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clarity in the future. Finally, this Comment recommends that the Federal Circuit should make any future changes to its enablement jurisprudence for antibodies with an eye toward the establishment of specific, bright-line standards to promote certainty across the industry.

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I. INTRODUCTION

For nearly 40 years, therapeutic antibodies have driven medicine forward.[1] From diagnostic tools, to vaccines, to targeted chemotherapy delivery systems, these diverse molecules have countless applications.[2] In 2009, researchers discovered that they could utilize certain antibodies to target and inhibit PCSK9, a protein that contributes to unhealthy, low-density lipoprotein ("LDL") cholesterol levels.[3] High levels of LDL cholesterol lead to the development of several severe conditions, including heart disease and stroke.[4] Thus, the discovery of the PCSK9-inhibiting antibodies began a race between the top pharmaceutical companies to develop a viable therapeutic antibody that targeted PCSK9 and lowered LDL cholesterol levels in humans.[5]

Ultimately, Amgen Inc. ("Amgen") was the first major pharmaceutical company to develop and successfully patent its therapeutic antibody, which it called Repatha.[6] For several years, Amgen enjoyed a monopoly with Repatha.[7] However, Sanofi, a competing pharmaceutical company, developed a PCSK9 inhibiting antibody called Praluent.[8] Sanofi developed Praluent independently, and the two drugs had different chemical structures.[9] However, Amgen's patents for Repatha included

1. *See* Johnathan D. Kaunitz, *Development of Monoclonal Antibodies*, 62 DIGESTIVE DISEASES & SCIS. 831, 831–32 (2017) (detailing the historical developments leading to modern monoclonal antibody therapeutics).

2. *See* Ruei-Min Lu et al., *Development of Therapeutic Antibodies for the Treatment of Diseases*, 27 J. BIOMED. SCI. 1, 1 (2020) (detailing several of the clinical and laboratory applications of antibodies).

3. *See* Christopher J. Duff et al., *Antibody-Mediated Disruption of the Interaction Between PCSK9 and the Low-Density Lipoprotein Receptor*, 419 BIOCHEM. J. 577, 579–81 (2009) (characterizing an antibody that binds to PCSK9 and reverses LDL-cholesterol receptor degradation in vitro).

4. *See* Joep C. Defesche et al., *Familial Hypercholesterolemia*, 3 NATURE REV. DISEASE PRIMERS 1, 2–3 (2017).

5. *See* Krzysztof Jaworski et al., *PCSK9 Inhibitors—From Discovery of a Single Mutation to a Groundbreaking Therapy of Lipid Disorders in One Decade*, 13 ARCHIVES MED. SCI. 914, 917 (2016).

6. *See generally* U.S. Patent No. 8,829,165 (issued Sept. 9, 2014); U.S. Patent No. 8,859,741 (issued Oct. 14, 2014) (conferring Amgen patent protection for Repatha).

7. *See* Amgen Inc. v. Sanofi, 598 U.S. 594, 599 (2023).

8. *See id* at 602.

9. *See id.*

broad claims for *any* antibody used to inhibit PCSK9.[10] Amgen subsequently sued Sanofi for patent infringement.[11]

After nearly ten years of hard-fought litigation, the United States Supreme Court, in a unanimous decision, declared Amgen's patents to be invalid because they failed to meet the Patent Act's "enablement requirement."[12] The enablement requirement ensures that the United States Patent and Trademark Office (USPTO) only grants patents to inventors who disclose enough information in their patent applications that a "person of skill in the art" ("POSITA") can "make and use" the invention.[13] In deciding against Amgen, the Court cemented a shift in antibody patent jurisprudence that began over 20 years ago.[14] During this shift, lower appellate courts have increasingly invalidated antibody patents that make "functional genus claims," which in this context refer to broad claims to groups of antibodies that could perform the same function.[15]

In *Amgen Incorporated v. Sanofi,* the Supreme Court affirmed the Federal Circuit's prior ruling.[16] The Federal Circuit has sole federal appellate jurisdiction to hear patent cases,[17] and it largely bears the responsibility for the shift in the enablement requirement jurisprudence for antibodies.[18] Indeed, in a later case, the Federal Circuit noted that "[it] does not interpret *Amgen* to have disturbed [its] prior enablement case law . . . ."[19] Although *Amgen* itself may not mark a seminal development in patent jurisprudence, the case stands as the Supreme Court's latest word on enablement doctrine and has been cited in many lower court decisions.[20]

This Comment analyzes *Amgen's* impact on modern enablement jurisprudence and the antibody industry. In Part II, this Comment begins by describing the development of the Supreme Court's enablement

10. *See id* at 599.

11. *See id.*

12. *See id.* at 599, 616.

13. 35 U.S.C. § 112(a); *see also* 35 U.S.C. § 2(a) (granting the USPTO the power to grant patents).

14. *See infra* Sections II.C.1-2.

15. *See infra* Section II.C.2.

16. *See Amgen*, 598 U.S. at 616.

17. *See* 28 U.S.C. § 1295(a)(4)(A-C).

18. *See id*; Amgen Inc. v. Sanofi, 227 F. Supp. 3d 333, 340-42 (D. Del. 2017); *see also* Mark A. Lemley & Jacob S. Sherkow, *The Antibody Patent Paradox*, 132 YALE L.J. 994, 1024-34 (2023) (detailing the shift in the Federal Circuit's antibody patent jurisprudence in the past twenty years).

19. Baxalta Inc. v. Genentech, Inc., 81 F.4th 1362, 1367 (Fed. Cir. 2023).

20. *See* Ryan P. Hiler & Andrew E. Levitt, *Amgen v. Sanofi: Seven Months in, Has Anything About Patent Enablement Changed?*, IPWATCHDOG (Jan 9., 2023, 4:15 PM), https://perma.cc/7PSB-5ZVG (highlighting several district court cases, Patent Trial and Appeals Board hearings, and Federal Circuit cases that have cited to *Amgen*).

jurisprudence.[21] Part II then examines the science of antibodies, their clinical and economic significance, and the unique challenges presented when patenting antibodies.[22] Part II further details how the Federal Circuit's enablement jurisprudence shifted regarding functional genus claiming.[23] Finally, Part II summarizes the litigation surrounding *Amgen v. Sanofi*, from the initial jury verdict in federal district court to the final decision rendered by the United States Supreme Court.[24]

Then, Part III argues that the *Amgen* decision restored uniformity to the enablement requirement's application to antibody patents and maintained consistency by leaving the Federal Circuit's enablement tests undisturbed.[25] Part III further argues that *Amgen* presently precludes functional genus claims for antibodies, and predicts positive short-term public policy impacts.[26] Moreover, Part III highlights that the *Amgen* decision leaves an explicit route for genus claims to return.[27] Finally, Part III recommends that if and when genus claims become viable again due to technical innovation, the Federal Circuit should draw a bright line delineating enabling and non-enabling genus claims to prevent further uncertainty for therapeutic antibody inventors and patent-holders.[28]

II. BACKGROUND

Congress designed the patent system to incentivize inventors to disclose their inventions in exchange for a limited, exclusive right to make and use the invention.[29] *Amgen* addressed whether the company's patent application disclosed enough information to enable a POSITA to make and use the invention in accordance with 35 U.S.C. § 112(a).[30] The case (1) highlights the inherent difficulty in reconciling centuries-old precedent with the complexity of modern science and (2) represents the culmination of a decades-long jurisprudential shift toward a full-scope enablement standard for antibody patents.[31]

21. *See infra* Sections II.A.1-2.
22. *See infra* Sections II.B.1-5.
23. *See infra* Sections II.C.1-2.
24. *See infra* Sections II.D.1-2.
25. *See infra* Sections III.A.1-2.
26. *See infra* Section III.C.
27. *See infra* Section III.D.
28. *See infra* Section III.E.
29. *See* 35 U.S.C. § 154 (defining the rights of inventors who have been issued patents).
30. *See* Amgen v. Sanofi, 598 U.S. 594, 599 (2023).
31. *See infra* Sections II.B-C.

A. Introduction to the United States Patent System and the Enablement Requirement

The United States patent system awards inventors a limited right to exclude others from making and using their patented inventions.[32] In exchange, inventors seeking patents must disclose their discoveries to the public.[33] Congress created requirements for how much information a patentee must disclose to obtain a valid patent, known as the disclosure requirement.[34] The disclosure requirements ensure that the public can adequately use the disclosed inventions.[35]

1. The Historical Underpinnings of the Patent Bargain

While *Amgen v. Sanofi* concerned modern antibody technologies,[36] the principles of patent law articulated in the case's decision have centuries-old roots.[37] In the United States, English tradition influenced the concept of government-issued patents.[38] Beginning in the sixteenth century, the Crown issued "letters patent" to individual subjects.[39] These early royal grants tasked the patentee to develop a new industry—often a manufacture or trade that only existed abroad.[40] In exchange, the Crown granted the patentee a limited monopoly over the new industry.[41] Under the letters patent regime, the patentee benefited by having the exclusive right to an entire industry.[42] Reciprocally, Crown and Country benefitted as the new industries expanded England's national economy.[43]

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32. *See* 35 U.S.C. § 154(a)(1).

33. *See generally* 35 U.S.C. § 112 (setting disclosure requirements for patent applications).

34. *See, e.g.*, Amgen Inc. v. Sanofi, 598 U.S. 594, 599, 616 (2023) (invalidating *Amgen*'s patent for failing to sufficiently disclose enough detail in its specification).

35. *See infra* Section II.A.1.

36. *See Amgen Inc.*, 598 U.S. at 599.

37. *See generally* Frank D. Prager, *Standards of Patentable Invention from 1474 to 1952*, 20 U. CHI. L. REV. 69, 70-–73 (1952) (tracing the development of patent law in Europe from 1472–1790).

38. *See* Frank D. Prager, *Historic Background and Foundation of American Patent Law*, 5 AM. J. LEGAL HIST. 309, 316–18 (1961) (describing the English common law principles from which the United States patent system was modeled, as well as ideological principles which distinguished the United States as it established its patent system).

39. Adam Mossoff, *Rethinking the Development of Patents: An Intellectual History, 1550-1800*, 52 HASTINGS L.J. 1255, 1260 (2001).

40. *See id.* at 1261–64 (describing an early letter-patent issued to bring Norwegian glass manufacturing to England); *see also Patentee,* BLACK'S LAW DICTIONARY (11th ed. 2019) (defining a patentee as "[s]omeone who either has been granted a patent or has succeeded in title to a patent").

41. *See* Mossoff, *supra* note 39, at 1261.

42. *See id.* (explicating the national policy goals that led Queen Elizabeth I to issue fifty-five letters-patent during her reign).

43. *See id.*

The United States's founders recognized that invention would stimulate the nation's nascent economy.[44] Consequently, the United States Constitution expressly granted Congress 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."[45] Soon afterward, Congress passed the Patent Act of 1790 (the "Patent Act").[46] The Patent Act described both the requirements for obtaining a patent and the rights afforded to patentees.[47] Over time, subsequent Congresses amended these statutory requirements, but the Patent Act's underlying goal remains the same—to encourage inventors to share their discoveries for the benefit of society.[48]

Today, American inventors continue to receive patents for new inventions.[49] United States patents grant inventors a limited right to prevent others from making and using their inventions in exchange for disclosing the invention to the world.[50] To receive a patent in the United States, an inventor must file an application with the USPTO.[51] Patent applications mainly consist of two components: (1) a list of claims delineating the scope of the invention and (2) a detailed specification describing the invention.[52] The two application components reflect the fundamental nature of the patent bargain.[53] The claims protect the applicant's monopoly by defining the boundaries of the invention, and the specification provides the public access to the invention to spur future progress.[54]

2. The Enablement Requirement and the Emergence of the "Undue Experimentation" Standard

To ensure that inventors uphold their end of the patent bargain, patent specifications must comport with the statutory requirements set forth in 35

44. *See* Prager, *supra* note 38, at 316–18.

45. U.S. CONST. art. I, § 8, cl. 8.

46. *See* Patent Act of 1790, ch. 7, § 2, 1 Stat. 109, 110–12 (1790).

47. *See* Prager, *supra* note 38, at 324.

48. *See, e.g.*, Leahy-Smith America Invents Act, 125 Stat. 284 (amending several provisions of 35 U.S.C. in a large-scale effort to reform the U.S. patent system).

49. *See, e.g.*, U. S. Patent No. 8,829,165 (issued Sept. 9, 2014) (granting Amgen a patent for inventing a therapeutic antibody to treat hypercholesterolemia).

50. *See* 35 U.S.C. § 101 (defining inventions patentable).

51. *See generally id.* § 2 (outlining the powers and obligations of the United States Patent and Trademark Office).

52. *See generally id.* §§ 111-12 (setting forth the statutory requirements for patent applications and specifications).

53. *See* Alan Devlin, *The Misunderstood Function of Disclosure in Patent Law*, 23 HARV. J.L. & TECH. 401, 407-10 (2010) (describing the canonical relationship between the goals of the patent bargain and the framework of the U.S. patent system).

54. *See id.*

U.S.C § 112.[55] One critical provision of § 112 requires that all patent applications include a written description of the invention that "enable[s] any person skilled in the art to which it pertains . . . [to] make and use the [invention]."[56] This statutory command is called the "enablement requirement."[57]

The enablement requirement protects the public's interest in patented inventions by preventing inventors from withholding key information from their specifications.[58] When an inventor withholds information from the specification, a POSITA cannot make use of the invention after the patent expires.[59] Also, investors who withhold information are at risk because they potentially face judicial invalidation of their patents for a lack of enablement.[60]

Beginning in the late nineteenth century, the American economy shifted and large companies born of the Industrial Revolution began focusing on patent enforcement.[61] Several notable cases subsequently arose in which courts interpreted the specification detail necessary to meet the enablement requirement.[62] In *O'Reilly v. Morse*, inventor Samuel Morse, as part of his patent for the telegraph, claimed any device that employed "[t]he combination and arrangement of electro-magnets . . . for transmitting intelligence by signs and sounds . . . ."[63] However, the patent's specification only described the telegraph and did not disclose other means of using electromagnets to transmit information.[64]

55. *See* 35 U.S.C § 112 (describing the required elements and formatting in a valid patent application).

56. *Id.* § 112(a); *see also Person Skilled In The Art*, BLACK'S LAW DICTIONARY (11th ed. 2019) (defining the phrase as "someone who has reasonably developed abilities in the field of the invention at issue").

57. *See* Gene Quin, *Patent Drafting: Understanding the Enablement Requirement*, IPWATCHDOG (Oct. 28, 2017, 9:30 AM), https://perma.cc/MB5D-2WGY.

58. *See* Invitrogen Corp. v. Clontech Lab'ys, Inc., 429 F.3d 1052, 1070 (Fed. Cir. 2005) (noting that the enablement requirement serves to "extract meaningful disclosure of the invention and, by this disclosure, advance the technical arts").

59. *See, e.g.*, Consol. Elec. Light Co. v. McKeesport Light Co., 159 U.S. 465, 476 (1895) (noting that non-enabling patents can "operate rather to discourage than to promote invention").

60. *See, e.g.*, Amgen Inc. v. Sanofi, 598 U.S. 594, 616 (2023); *see also, e.g.*, Idenix Pharms. LLC v. Gilead Scis., Inc., 941 F.3d 1149, 1165 (Fed. Cir. 2019). (invalidating previously issued claims for pharmaceuticals because their specifications failed to meet the enablement requirement).

61. *See* Christopher Beauchamp, *The First Patent Litigation Explosion*, 125 YALE L.J. 848, 878-79 (2016) (charting the exponential increase in patent infringement litigation in the United States from 1840-1910).

62. *See, e.g.*, *Consol. Elec. Light Co.,* 159 U.S. at 474-75 (considering whether patents for filaments in electric light bulbs were sufficiently enabled by their specifications).

63. O'Reilly v. Morse, 56 U.S. 62, 78 (1853).

64. *See id.* at 113.

The United States Supreme Court held that Morse's patent was invalid.[65] The Court reasoned that the specification did not sufficiently enable a POSITA to create every device that could use electromagnets to convey information because Samuel Morse described only the telegraph in the patent's specification.[66] Indeed, the Court noted that validating Morse's patent would stifle innovation by preventing future inventors from creating other devices that employed electromagnets to transmit information.[67] Accordingly, the Court broadly concluded that patents (like Morse's) containing excessively broad claims accompanied with much narrower specifications were unlikely to meet the enablement requirement and that these patents faced a high chance of judicial invalidation.[68]

However, in subsequent cases, the Court noted that the enablement requirement did not compel inventors to exactly describe every iteration of a claimed invention.[69] For instance, in *Consolidated Electric Light Company v. McKeesport Light Company*, the Supreme Court invalidated a broad patent that claimed all light bulb filaments made of any "carbonized fibrous or textile materials."[70] The patent's specification detailed only the use of carbonized paper.[71] In its decision, the Court reasserted its reasoning that "if the description be so vague and uncertain that no one can tell . . . how to construct the patented device, the patent is void."[72] However, the Court noted that it may permit broader claims if the specification described a "general quality . . . g[iving] [the claimed genus of materials] a peculiar fitness for the particular purpose."[73]

Future cases built on *O'Reilly* and *Consolidated*'*s* general principles.[74] For instance, in *Holland Furniture Company v. Perkins Glue Company*, an inventor created a starch-based glue for adhering pieces of wood.[75] The patent claimed any "starch glue which, combined with about three parts or less by weight of water, will have substantially the same

65. *See id.* at 124.

66. *See id.* at 113 ("For aught that we now know some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff's specification.").

67. *See id.*

68. *See id.* at 119–20 ("And if [Morse's patent] stands, it must stand simply on the ground that the broad terms abovementioned were a sufficient description, and entitled him to a patent in terms equally broad. In our judgment the act of Congress cannot be so construed.").

69. *See* Consol. Elec. Light Co. v. McKeesport Light Co., 159 U.S. 465, 474–75.

70. *Id.* at 468.

71. *See id.* at 467.

72. *Id.* at 474.

73. *Id.* at 475.

74. *See* Holland Furniture Co. v. Perkins Glue Co., 277 U.S. 245, 257 (1928).

75. *See id.* at 247.

properties as animal glue."[76] The patent's specification described a process for making glue from starch but did not describe any characteristics that made starch particularly suitable for use in gluemaking.[77] Moreover, the specification never mentioned how the starch had similar properties to animal glue.[78]

Again, the Supreme Court held that the patent was invalid based on a lack of enablement.[79] The Court reasoned that the process described in the patent could conceivably allow a POSITA to make and use every kind of starch-based glue claimed, but doing so would entail "elaborate experimentation."[80] Like in *O'Reilly*, the Court reasoned that specifications requiring elaborate experimentation did not truly allow the public to make use of the claimed invention.[81] Rather, the Court concluded that specifications calling for elaborate experimentation create overly broad monopolies with the potential to impede future innovation.[82]

The Supreme Court in *Holland* established that a patent fails to meet the enablement requirement when the specification requires a POSITA to undergo "undue experimentation."[83] However, determining what constitutes undue experimentation in a particular field is a fact-intensive inquiry.[84] In a later patent invalidity case, *In re Wands*, the Federal Circuit articulated a non-exhaustive list of factors courts could weigh when testing for undue experimentation.[85] These factors include:

> (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.[86]

76. *Id.* at 251.
77. *See id.*
78. *See id.* at 256.
79. *See id.* at 258.
80. *Id.* at 257.
81. *See id.*
82. *See id.* at 257–58.
83. *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988); *see also Holland*, 277 U.S. at 257.
84. *See Wands*, 858 F.2d at 737 ("Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations.").
85. *See id.*
86. *Id.* (citing *Ex Parte* Forman, 230 U.S.P.Q. 546, 547 (Bd. Pat. App. & Int. 1986); *In re* Colianni, 561 F.2d 220, 224 (CCPA 1977) (Miller, J., concurring); *In re* Rainer, 347 F.2d 574, 577 (CCPA 1965)).

In *Wands*, the Federal Circuit designed an analytical framework that considers an invention's field.[87] Today, factfinders use the *Wands* framework when evaluating whether a patent's specification creates undue experimentation for a POSITA.[88]

B. Patenting Antibodies

In the seventeenth century, scientists and physicians discovered that human bodies create substances that confer immunity against diseases.[89] Over time, biologists characterized these substances as proteins, which they named immunoglobins, or antibodies.[90] By 1986, scientists had discovered methods for producing millions of different artificial antibodies for use in research and medicine.[91] However, as inventors began patenting antibody therapeutics, the complex and diverse structures of antibodies soon challenged existing enablement jurisprudence.[92]

1. Characterizing Antibodies

Antibodies are large proteins produced in the bloodstream by immune cells called B-lymphocytes, or B-cells.[93] Antibodies are comprised of four peptide chains assembled into a "Y" shape.[94] The "Y" structures contain several key functional regions, the composition of which varies greatly in different antibodies.[95] One of these regions, known as the "complementarity-determining region" ("CDR"), allows an antibody to bind to other molecules, or "antigens."[96] In the body, antigen bonding allows antibodies to "tag" potentially harmful foreign antigens, such as viruses and bacteria, for destruction.[97]

87. *See id.* at 738-39 (using the factors to compare the amount of experimentation required by the process claimed in the patent with the amount of experimentation generally acceptable in the field of molecular biologic development).

88. *See* Amgen Inc. v. Sanofi, 987 F.3d 1080, 1084 (Fed. Cir. 2021) (applying the *Wands* factors to determine whether the Amgen patent specification failed to meet the enablement requirement by forcing POSITA's to conduct "undue experimentation").

89. *See* Kaunitz, *supra* note 1, at 831, (discussing the practice of inoculation developed to prevent smallpox).

90. *See id.*

91. *See id.*

92. *See infra* Sections II.C-D.

93. *See* María Sofía Castelli et al., *The Pharmacology and Therapeutic Applications of Monoclonal Antibodies*, 7 PHARM. RSCH. DEV. 1, 2 (2019).

94. *See id.*

95. *See id.*

96. *Id.* at 2-3.

97. Jean S. Marshall et al., *An Introduction to Immunology and Immunopathology*, 14 ALLERGY, ASTHMA, & CLINICAL IMMUNOLOGY 5, 10 (2018).

Antibodies in the immune system have a nearly infinite capacity for structural variation.[98] To bind strongly with an antigen, the CDR of an antibody must specifically conform to a region of the antigen, known as the antigen's epitope.[99] Often, the structural "fit" between an antibody's CDR and an antigen's epitope has been analogized to a "lock and key."[100] Fortunately, antibody-producing B-cells produce billions of different antibody conformations.[101] Specifically, B-cells randomly combine parts of genes that contain instructions for producing an antibody's CDR.[102] This adept randomization process produces novel CDR structures on thousands of antibody conformations that can bind to a single antigen.[103]

2. The Development of Therapeutic Antibodies

Creating a viable antibody therapeutic is a massive undertaking.[104] First, researchers must identify an antigen they want to target before the production of antibodies can begin.[105] Then, using traditional production methods, researchers isolate the antigen and use it to infect an animal model.[106] Once the animal has produced antibodies in response to the infection, researchers extract the animal's spleen cells and isolate the B-cells.[107] The extracted B-cells are fused with cancer cells to produce

98. *See* Susumu Tonegawa, *Somatic Generation of Antibody Diversity*, 302 NATURE 575, 575 (1983) (noting that the diversity of antibodies produced by humans makes it impossible for the human genome to contain the individual instructions for every possible iteration).

99. *See* Castelli et al., *supra* note 93, at 2.

100. Mark L. Chiu et al., *Antibody Structure and Function: The Basis for Engineering Therapeutics*, 8 ANTIBODIES 55, 60 (2019). The "lock and key" model is still an apt analogy for the specific conformational fit between an antibody's CDR and its epitope. *See id.* However, modern models now recognize that molecular interactions between the CDR and epitope lead to changes in the three-dimensional structure of a CDR, creating a stronger "induced fit" that further facilitates binding. *Id.*

101. *See* Tonegawa, *supra* note 98, at 575.

102. *See id.* at 575-76.

103. *See* Tal Einav & Jesse D. Bloom, *When Two are Better Than One: Modeling the Mechanisms of Antibody Mixtures*, 16 PLOS COMPUTATIONAL BIOLOGY 1, 3 (2020) (creating models consisting of mixtures of antibodies with the capacity to bind to the same epitope).

104. *See* Carl Mieczkowski et al., *Blueprint for Antibody Biologics Developability*, 15 MABS 1, 2-4 (2023) (describing the antibody creation process and additional testing which should be conducted on antibodies used as biological therapeutics).

105. *See, e.g.*, Ji Woong Kim et al., *Cell Surface GRP94 as a Novel Emerging Therapeutic Target for Monoclonal Antibody Cancer Therapy*, 10 CELLS 670, 679-81 (2021) (identifying a protein involved in the development of chemo-resistant colorectal cancer that may have the potential to be the target molecule for a new antibody treatment).

106. *See* Sanchita Mitra & Pushpa Chaudhary Tomar, *Hybridoma Technology; Advancements, Clinical Significance, and Future Aspects*, 19 J. GENETIC ENG'G & BIOLOGY 1, 3 (2021).

107. *See id.*

immortal "hybridomas," which are cultured for several weeks.[108] Finally, scientists screen the hybridomas to determine whether they produced the desired antibody.[109] Unfortunately, the traditional hybridoma method generates low yields of the target antibody, and the process of culturing hybridomas in the lab is unavoidably slow.[110]

Fortunately, modern advancements in technology have expedited the antibody production process.[111] For instance, scientists now have the technology to sequence the genetic codes of individual B-cells taken from patients directly.[112] Computers then compare the cells' genetic sequences and predict which sequences will produce viable antibodies.[113] Afterward, scientists use the sequences to manufacture the new antibody artificially.[114] New techniques have thus streamlined the antibody development process, and new developments will make the process more efficient in the future.[115]

3. Therapeutic Applications of Antibodies

As scientists standardized antibody production, researchers raced to harness their therapeutic potential.[116] Because antibodies bind to target antigens with high specificity, researchers can create antibodies that bind to and hinder disease-causing antigens.[117] For example, individuals with overactive immune systems may produce an excess amount of a protein called tumor necrosis factor-alpha ("TNF-α").[118] TNF-α is a cytokine, a class of proteins in the immune system which "ha[s] a specific effect on

108. *See id.* at 3-4. "Hybridomas" are myeloma cells fused with B cells to create hybrid cells that divide forever in culture and produce the antibodies of the original B cells. *Id.*

109. *See id.* at 4.

110. *See* Yu A. Merkuleva et al., *Methods to Produce Antibodies for the Prevention and Treatment of Viral Infections,* 48 RUSS. J. BIOORG. CHEM. 256, 261 (2022) (noting that the traditional "hybridoma method" takes at least six months to complete and can result in the cells producing unbeneficial, nonspecific antibodies).

111. *See* Mitra & Tomar, *supra* note 106, at 8-12.

112. *See* Merkuleva et al., *supra* note 110, at 266.

113. *See id.*

114. *See id.*

115. *See id; see also* Ewen Callaway, *How Generative AI is Building Better Antibodies*, 617 NATURE 235, 235 (2023) (describing the use of generative AI to predict the structure of antibodies and synthesize novel antibodies to treat disease).

116. *See* Lu et al.*, supra* note 2, at 2 (highlighting the short timeline between the development of antibody production techniques and the emergence of therapeutic antibodies on the market).

117. *See id.* at 8 (describing a variety of target antigens implicated in the development of diseases which have been treated using therapeutic antibodies).

118. *See* Dan-in Jang et al., *The Role of Tumor Necrosis Factor Alpha (TNF-α) in Autoimmune Disease and Current TNF-α Inhibitors in Therapeutics*, 22 INT'L. J. MOLECULAR SCIS. 1, 2 (2021).

the interactions and communications between cells."[119] In excess quantities, TNF-α binds to cells called synovial fibroblasts.[120] When bound to TNF-α, synovial fibroblasts activate and produce proteins capable of degrading bone and cartilage within joints.[121] This degradation causes rheumatoid arthritis ("RA"), a degenerative condition that results in gradually worsening joint stiffness, pain, and malformation.[122]

To combat RA's progression, researchers created antibodies that bind to TNF-α and block the specific region of TNF-α that binds to synovial fibroblasts.[123] Consequently, RA patients treated with TNF-α inhibitors experience less cartilage and bone degradation, slowing the progression of the disease.[124] TNF-α inhibiting antibody therapies are considered "the most successful and widely used antibody-based therapeutic."[125]

Additionally, therapeutic antibodies facilitate the targeted delivery of small-molecule drugs.[126] For years, oncologists have treated cancer with cytotoxic small-molecule chemotherapies—essentially drugs that kill cancer cells.[127] However, traditional cytotoxic chemotherapies kill healthy cells too, thereby creating negative side effects for the patient.[128] To combat the negative side effects, scientists have created antibody drug conjugates ("ADCs").[129] ADCs consist of antibodies that chemically bind

119. Jun-Ming Zhang & Jianxiong An, *Cytokines, Inflammation, and Pain*, 45 INT'L. ANESTHESIOLOGY CLINICS 27, 27 (2007).

120. *See* Dan-in Jang, *supra* note 118at 3; *see also* Thomas Pap et. al, *Fibroblast Biology: Role of Synovial Fibroblasts in the Pathogenesis of Rheumatoid Arthritis*, 2 ARTHRITIS RSCH. 361, 362-65 (2000) (characterizing synovial fibroblasts, describing changes to synovial fibroblasts in patients with rheumatoid arthritis, and explaining the role of synovial fibroblasts in the progression of rheumatoid arthritis).

121. *See* Dan-in Jang et al., *supra* note 118, at 4.

122. *See id.*

123. *See id.* at 7-10 (detailing commercially available antibody treatments targeting TNF-α).

124. *See* H. Michael Shepard et al., *Developments in Therapy with Monoclonal Antibodies and Related Proteins*, 17 CLINICAL MED. 220, 221 (2017).

125. *Id.* In addition to treating rheumatoid arthritis, physicians use antibodies targeting TNF-α to treat a wide array of autoimmune disorders, including "Crohn's disease, ulcerative colitis, psoriasis, psoriatic arthritis, [and] ankylosing spondylitis." *Id.*

126. *See* Zhiwen Fu et al., *Antibody Drug Conjugate: the "Biological Missile" for Targeted Cancer Therapy*, 7 SIGNAL TRANSDUCTION TARGETED THERAPIES 1, 4-5 (2022); *see also* Huy X. Ngo & Sylvie Garneau-Tsodikova, *What are the Drugs of the Future?*, 9 MED. CHEM. COMMC'NS. 757, 757 (2018) (defining small-molecule drugs as "compounds with low molecular weight that are capable of modulating biochemical processes to diagnose, treat, or prevent diseases").

127. *See* Zhiwen Fu et al., supra note 126, at 1-2; *see also* Eric K. Rowinsky & Ross C. Donehower, *Paclitaxel (Taxol)*, 332 NEW ENG. J. MED. 1004, 1004-05 (1995) (illustrating a mechanism of cytotoxicity using Paclitaxel, a small-molecule chemotherapy drug).

128. *See, e.g.*, Rowinsky & Donehower, supra note 127, at 1005-08 (describing numerous side-effects associated with Paclitaxel due to the drug's cytotoxic effect on healthy cells).

129. *See* Zhiwen Fu et al., supra note 126, at 1.

to cytotoxic chemotherapeutics.[130] Cytotoxic chemotherapeutics alone are small and easily absorbed by cells throughout the body, but ADCs are large and cannot easily enter cells randomly.[131] Instead, ADCs specifically bind to receptors on the surface of target cancer cells,[132] allowing the cytotoxic chemotherapies to kill the target cancer cells without affecting healthy cells.[133]

4. The Modern Therapeutic Antibody Market and the Value of Antibody Patents

The Food and Drug Administration (FDA) approved the first antibody therapy, Orthoclone OKT3 ("OKT3"), in 1986.[134] Over 160 new antibody therapies have entered the global market since.[135] As a result, in 2023, the global antibody market's size surpassed $160 billion.[136] The global therapeutic antibody market is expected to grow quickly over the next decade, with a projected value of $270 billion by 2028.[137]

Even though therapeutic antibodies are lucrative, the antibody market is dominated by seven large pharmaceutical companies which control roughly 86% of the market.[138] Smaller companies often lack the capital to engage in the therapeutic antibody market.[139] Estimates suggest that pharmaceutical companies spend anywhere from $161 million to $4.54 billion bringing a new drug to market.[140] Moreover, only approximately 22% of therapeutic antibodies that enter clinical trials ultimately receive

130. *See id.* at 2-3 (listing and characterizing the key structural components of ADCs).

131. *See id.* at 3, 10.

132. *See id.* at 1.

133. *See id.* ("[ADC therapies] combine[] both the advantages of highly specific targeting ability and highly potent killing effect to achieve accurate and efficient elimination of cancer cells.").

134. *See* Lu et al., *supra* note 2, at 1.

135. *See id.*

136. *See Global Antibodies Market Size, Share, Trends, COVID-19 Impact & Growth Analysis Report – Segmented by Product Type (Monoclonal Antibodies, Polyclonal Antibodies and Anti-body Drug Complexes), Indication, End User, Application and Region - Industry Forecast From 2023 to 2028*, MKT. DATA FORECAST (Mar. 2023), https://perma.cc/8BZL-T5JN.

137. *See id.*

138. *See* Lu et al., *supra* note 2, at 8.

139. *See* Xiaomei Geng et al., *Research and Development of Therapeutic mAbs: An Analysis Based on Pipeline Projects*, 11 HUM. VACCINES & IMMUNOTHERAPIES 2769, 2772 (2015) (noting that "lack of funds or market experience means that the likely destiny of these small companies is to be acquired or incorporated into large pharmaceutical enterprises").

140. *See* Michael Schlander et al., *How Much Does It Cost to Research and Develop a New Drug? A Systematic Review and Assessment*, 39 PHARMACOECONOMICS 1243, 1246 (2021).

governmental approval to enter the market.[141] Large companies can best absorb the risks associated with developing therapeutic antibodies, so these companies produce most treatments on the market.[142]

Given the financial risk of developing new therapeutic antibodies, pharmaceutical companies seek patent protection to maximize their investment.[143] AbbVie is a large global therapeutic antibody producer.[144] Their flagship drug, Humira, is a TNF-α inhibiting antibody that physicians use to treat several autoimmune diseases.[145] Following Humira's invention, AbbVie and its affiliates filed over 300 patents for Humira and received 165.[146] Humira earned AbbVie $208 billion during its patent protection, and $20 billion in 2019 alone.[147] However, most of AbbVie's Humira patents expired in 2023, so prices for Humira are expected to drop sharply as generic versions of the antibody become available.[148]

Therapeutic antibodies are costly for consumers.[149] For example, Humira's list price is roughly $7,000 for a one-month supply.[150] Therapeutic antibodies used in cancer treatment cost patients even more.[151] In response to high costs, companies seek to produce biosimilars—essentially generic versions of therapeutic antibodies.[152] Congress has recognized the public health value of biosimilars and passed the Biologics Price Competition and Innovation Act.[153] The Act expedites FDA approval for biosimilars when applicants demonstrate that their biosimilars are "highly similar" to or "interchangeable" with a previously-

141. *See* Hélène Kaplon & Janice M. Reichert, *Antibodies to Watch in 2019*, 11 MABS 219, 221 (2019).

142. *See* Raquel Ortega-Argilés et al., *R&D in SMEs: a Paradox?*, 33 SMALL BUS. ECON. 3, 4 (2009)("Market imperfections confer an advantage to large firms in terms of being able to secure finance for risky R&D projects, as size appears to be correlated with the availability and stability of internally-generated funds.").

143. *See* Eric Sagonowsky, *AbbVie, Already Famous for its Humira Strategy, Forms Another 'Patent Wall' Around Imbruvica: Report*, FIERCE PHARMA (July 21, 2020, 9:25 AM), https://perma.cc/G27N-SQVS.

144. *See id.*

145. *See* Lu et al.*, supra* note 2, at 8.

146. *See* Rebecca Robbins, *How a Drug Company Made $114 Billion by Gaming the U.S. Patent System*, N.Y. TIMES (Jan. 28, 2023), https://perma.cc/S7XJ-8V9D.

147. *See id.*

148. *See id.*

149. *See* Inmaculada Hernandez et al., *Pricing of Monoclonal Antibody Therapies: Higher If Used for Cancer?*, 24 AM. J. MGMT. CARE 109, 111 (2018) (estimating the cost of antibody treatments for a variety of diseases).

150. *See* Tom Murphy*, Cheaper Competition for Humira is Hitting the Market, but Savings will Depend on Your Insurance*, AP NEWS (June 29, 2023, 3:01 PM), https://perma.cc/9TEG-HAVF.

151. *See* Hernandez et al., *supra* note 149, at 111-12.

152. *See* David L. Carl et al., *Comparison of Uptake and Prices of Biosimilars in the US, Germany, and Switzerland*, 5 JAMA NETWORK OPEN 1, 2 (2023).

153. *See* 42 U.S.C. § 262 (k).

approved biological therapeutic.[154] Still, far fewer biosimilars have entered the United States market than in other countries' markets.[155]

5. The Use of Functional Genus Claims in Therapeutic Antibody Patents

As the therapeutic antibody market has grown with new inventions, patent lawyers have filed antibody patents precluding other pharmaceutical makers from introducing competing therapies.[156] Patentees have employed a strategy called "functional genus claiming" to obtain broad patent protection.[157] Under functional genus claiming, a patentee claims all antibodies that can bind to a specific epitope.[158] Typically, these broad claims are narrowed either by defining the antibodies' binding affinity or by describing the specific location, or locations, on the antigen where the antibody binds.[159]

C. The Evolution of the Federal Circuit's Enablement Standard for Antibody Patents

In the early years of antibody patent litigation, the Federal Circuit and lower federal courts routinely validated functional genus claims.[160] However, over the past two decades, the Federal Circuit has more typically invalidated functional genus claims for lack of enablement.[161] The Federal Circuit's decision in *Amgen v. Sanofi* is the culmination of its functional genus claim jurisprudence and the articulation of the "full scope" enablement requirement that the Supreme Court later affirmed.[162]

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154. *Id.* §§ 262 (k)(2)(A)(i)(I), (k)(4)-(5).

155. *See* Carl et al., *supra* note 152, at 6-7.

156. *See, e.g.*, Chiron Corp. v. Genentech, Inc., 363 F.3d 1247 (Fed. Cir. 2004) (involving a patent excluding competitors from making and using any antibody with the ability to bind to the breast cancer-associated HER-2 protein).

157. *See* Lemley & Sherkow, *supra* note 18, at 1013-16 (describing the use of functional genus claims in antibody patents).

158. *See id.* at 1013 (noting that claims solely characterizing an antigen are extremely broad and likely to face invalidation on several grounds).

159. *See, e.g.*, U. S. Patent No. 8,829,165 (issued Sept. 9, 2014) (using both binding affinity and binding location to contour the boundaries for a functional antibody claim); *see also* Govind Kumar et al., *Binding Affinity Estimation from Restrained Umbrella Sampling Simulations*, 3 NATURE COMPUTATIONAL SCI. 59, 59 (2022) (defining binding affinity as a measurement of "the binding strength between a protein and [the molecule to which it binds]").

160. *See, e.g.*, Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1385 (Fed. Cir. 1986) (reversing a patent invalidation for a functionally claimed antibody used as a diagnostic tool); *see also* Lemley & Sherkow, *supra* note 18, at 1016-20 (characterizing a judicially favorable period for functional claims from 1986 to 2002).

161. *See, e.g.*, *Chiron*, 363 F.3d at 1261 (invalidating a patent on the ground that the specification did not enable a POSITA to create all the antibodies encompassed within the scope of its claims).

162. Amgen Inc. v. Sanofi, 987 F.3d 1080, 1087-88 (Fed. Cir. 2021).

1. Early Jurisprudence Permitting Functional Genus Claims for Antibodies

One of the first major cases to determine the validity of an antibody patent was *Hybritech Incorporated v. Monoclonal Antibodies, Incorporated*.[163] Hybritech Inc. ("Hybritech") developed antibodies for use in diagnostic tools.[164] Hybritech's patent claimed the antibody functionally, describing its ability to bind to a target epitope and its binding affinity for the epitope.[165] The patent's specification did not provide a detailed account of the process by which the antibody was discovered, but disclosed that "[t]he monoclonal antibodies used for the present invention are obtained by the [hybridoma] process discussed by Milstein and Kohler . . . [and that t]he details of this process are well known and not repeated here."[166]

The Federal Circuit held that the patent satisfied the enablement requirement.[167] The court reasoned that the hybridoma method was well known by antibody researchers and manufacturers when Hybritech filed their patent.[168] Additionally, the court reasoned that the methods used to determine antibody-to-epitope affinity were similarly well known at the time.[169] Finally, the court reasoned that a POSITA would not need to undertake undue experimentation to make and use the claimed set of antibodies.[170] Consequently, the court concluded that the specification provided a POSITA adequate information to make and use the claimed antibody.[171]

Hybritech established the Federal Circuit's approval of functional genus claiming, but it did not provide an in-depth analysis as to why Hybritech's patent did not require undue experimentation.[172] However, a more satisfying explanation emerged a few years later in the case *In re Wands*.[173] Like in *Hybritech*, *Wands* involved a patent for antibodies used in a diagnostic assay.[174] Also, like in *Hybritech*, the patentees claimed the antibodies by characterizing the antigen's binding ability and binding affinity.[175] The Federal Circuit held that the patent was enabling and that

163. *See Hybritech*, 802 F.2d at 1375-85.
164. *See id.* at 1370.
165. *See id.*
166. *Id.* at 1384.
167. *See id.*
168. *See id.*
169. *See id.*
170. *See id.*
171. *See id.*
172. *See id.*
173. *See In re* Wands, 858 F.2d 731, 736-37 (Fed. Cir. 1988).
174. *See id.* at 733; *Hybritech*, 802 F.2d at 1370.
175. *See Wands*, 858 F.2d at 734; *see also Hybritech*, 802 F.2d at 1370.

the specification did not require a POSITA to undergo undue experimentation.[176]

The court noted that some experimentation was necessary to generate antibodies with the claimed antibodies' desired characteristics.[177] However, applying the case's evidence to the newly articulated *Wands* factors, the court found that the hybridoma process for creating antibodies was well known to POSITAs.[178] Further, the court held a POSITA could replicate the patentee's success without undue experimentation because the patentee articulated in the specification the method to successfully create the claimed antibodies.[179]

2. Shifting Toward a "Full Scope" Enablement Requirement

Following *Wands*, the Federal Circuit deemed functional genus claims enabling for antibody patents, though the court increasingly held that functional genus claims lacked enablement for other biological patents.[180] However, in 2004, the tide began to shift with *Chiron Corporation v. Genetech, Incorporated*.[181] In this case, Chiron obtained a broad patent for all antibodies binding to HER-2, a protein implicated in breast cancer development.[182] When Chiron filed the patent, therapeutic antibodies had a non-human genetic makeup because scientists used the hybridoma method and harvested the B-cells from non-human animal models.[183] However, later technological advances made it possible for researchers to engineer "chimeric" antibodies—antibodies with some human regions and some non-human regions.[184] Using these technological advancements, Genentech created and sold a chimeric antibody that could bind to HER-2, thus competing with Chiron.[185] Chiron filed suit against Genentech, claiming patent infringement.[186]

176. *See Wands*, 858 F.2d at 736-40.

177. *See id.* at 736.

178. *See id.* at 737-38.

179. *See id.* at 738-40.

180. *See* Enzo Biochem, Inc. v. Gen–Probe Inc., 323 F.3d 956, 964 (Fed. Cir. 2002) (invalidating a genus claim for a DNA technology but noting, in dictum, an exception for antibody genus claims).

181. *See* Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1261 (Fed. Cir. 2004).

182. *See id.* at 1251; *see also* Sandra M. Swain et al., *Targeting HER2-Positive Breast Cancer: Advances and Future Directions*, 22 NATURE REVS. DRUG DISCOVERY 101, 102-07 (2023) (describing the role of HER-2 in the development of breast cancer and the treatment of HER-2 positive cancers using therapeutic antibodies and ADCs).

183. *See Chiron*, 363 F.3d at 1250-51; *see also* Mitra & Tomar, *supra* note 106, at 1-2.

184. *Chiron*, 363 F.3d at 1250-51.

185. *See id.* at 1252.

186. *See id.*

The Federal Circuit held that Chiron's patent did not enable its broad claim to all antibodies binding to HER-2 receptors.[187] The court found that the process of producing chimeric antibodies was "nascent technology requiring a 'specific and useful teaching'" when the patent was filed.[188] Consequently, the court concluded that the patent's specification insufficiently enabled the "full scope of the claimed invention" because the patent's specification did not provide specific guidance to teach a POSITA how to create chimeric antibodies binding to HER-2.[189]

D. Amgen v. Sanofi: Solidifying the Full Scope Enablement Requirement for Antibody Patents

Following *Chiron*, the Federal Circuit increasingly invalidated antibody patents with functional genus claims.[190] However, the court failed to provide a bright line rule declaring that all functional genus antibody claims were invalid.[191] Indeed, only recently, following *Amgen v. Sanofi*, have scholars begun to contemplate "the death of the genus claim" definitively.[192]

1. Case Facts and Lower Court Decisions

In 2014, pharmaceutical giant Amgen received two patents for a therapeutic antibody, Repatha.[193] Repatha binds and blocks the protein PCSK9.[194] In the body, PCSK9 degrades LDL-cholesterol receptors, which remove cholesterol from the bloodstream.[195] Thus, Repatha prevents LDL-cholesterol receptor degradation and increases cholesterol removal from patients' bloodstreams.[196] The patents for Repatha claimed "'the entire genus' of antibodies that (1) 'bind to specific amino acid residues on PCSK9,' and (2) 'block PCSK9 from binding to [LDL receptors].'"[197]

187. *See id.* at 1257.

188. *Id.* at 1255.

189. *Id.* at 1253 (quoting *In re* Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993)).

190. *See* Lemley & Sherkow, *supra* note 18, at 1020-29 (detailing a line of cases where antibody patents using functional genus claims were invalidated by the Federal Circuit).

191. *See* Christopher Loh & Laura Fishwick, *3 Ways to Meet Biotech Patent Written Description Standards*, CORPORATE COUNSEL (June 3, 2015), https://perma.cc/W5WN-WXGP (demonstrating uncertainty in the amount of disclosure necessary to validly specify genus claims).

192. Karshtedt et al., *The Death of the Genus Claim*, 35 HARV. J.L. & TECH. 1, 1 (2021) (coining the phrase).

193. *See* Amgen Inc. v. Sanofi, 227 F. Supp. 3d 333, 337 (D. Del. 2017).

194. *See id.*

195. *See id.* at 338.

196. *See id.* at 337-38.

197. Amgen Inc. v. Sanofi, 598 U.S. 594, 602 (2023) (quoting *Amgen*, 227 F. Supp. 3d at 1372).

In the specifications, Amgen provided the specific genetic makeup of 26 antibodies they had discovered, which fell within the scope of their claims.[198] Additionally, Amgen described two methods to create the claimed antibodies: (1) a "roadmap" for the screening protocol used to develop Repatha and (2) a methodology for using conservative substitution to alter the DNA of the 26 antibodies genetically identified in the patents' specification.[199] After receiving the patents, Amgen sued Sanofi, another pharmaceutical company that had later independently developed a different antibody to bind and inhibit PCSK9.[200]

At trial, Sanofi argued that Amgen's 2014 patents were invalid because they failed to enable the full scope of the claims.[201] Notably, Sanofi brought in experts who testified that there was "nothing in the specification to help a researcher 'hone in on an antibody that satisfies the claims.'"[202] Following closing arguments:

> The court instructed the jury that the specification could disclose either "a representative number [of] species falling within the scope of the claimed invention," or "structural features common to the members of the genus, so that a person of ordinary skill in the art can 'visualize or recognize' the members of the claimed invention." The jury was also instructed that "[i]n the case of a claim to antibodies, the correlation between structure and function may also be satisfied by the disclosure of a newly-characterized antigen by its structure, formula, chemical name, or physical properties if" the creation of such antibodies against such an antigen was conventional or routine.[203]

Weighing the evidence, the jury found that Amgen's patents were enabling and thus valid.[204] The district court denied Sanofi's motions for judgment as a matter of law and its request for a new trial.[205] Sanofi timely appealed to the Federal Circuit, which remanded the case for evidentiary errors.[206]

On remand, the district court granted Sanofi judgment as a matter of law, declaring Amgen's patents to be invalid on grounds of enablement.[207] The district court applied the *Wands* factors to the case.[208] But, unlike in

198. *Id.* at 602-03 (noting that Amgen additionally disclosed the full three-dimensional structures of two representative antibodies).

199. *Id.*

200. *See Amgen*, 227 F. Supp. 3d at 336.

201. *See id.* at 342-44.

202. *Id.* at 344.

203. *Id.* at 347-48 (quoting from the jury instructions given at the federal trial court).

204. *See id.* at 337.

205. *See id.* at 349.

206. *See* Amgen Inc. v. Sanofi, 872 F.3d 1367, 1381-82 (Fed. Cir. 2017).

207. *See* Amgen Inc. v. Sanofi, No. CV 14-1317-RGA, 2019 WL 4058927, at *17 (D. Del. Aug. 28, 2019).

208. *See id.* at *6.

Wands, the district court asked whether undue experimentation would be required to make and use each claimed antibody embodiment rather than any singular claimed antibody embodiment.[209] Amgen then appealed to the Federal Circuit.[210] The Federal Circuit affirmed, claiming that the district court correctly analyzed the *Wands* factors in relation to a POSITA's ability to make and use the full scope of the claimed invention.[211] Amgen then filed for a writ of certiorari to the Supreme Court, which was granted.[212]

2. The Supreme Court's Decision

The Supreme Court granted certiorari to one question presented in Amgen's petition for certiorari:

> [w]hether 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[.]'[213]

In its brief, Amgen argued that a full scope enablement requirement was inconsistent with the statutory language of § 112(a).[214] Instead, Amgen proffered a more relaxed enablement standard that focused on whether a POSITA could reasonably make and use the invention based on the specification.[215] In its reply, Sanofi argued that a full scope enablement requirement comported with § 112(a)'s language and the Supreme Court's enablement jurisprudence.[216] Additionally, both sides contended that their

209. *Compare In re* Wands, 858 F.2d 731, 740 (Fed. Cir. 1988) ("[C]onsidering the [Wands] factors . . . leads to the conclusion that undue experimentation would not be required to *practice the invention*.") (emphasis added), *with Amgen*, 2019 WL 4058927, at *12 ("[A] reasonable factfinder could only conclude that the amount of time and effort required to enable the full scope of the claims would be substantial. Therefore . . . undue experimentation would be needed to *practice the full scope of the claimed invention*.")(emphasis added).

210. *See* Amgen Inc. v. Sanofi, 987 F.3d 1080, 1082 (Fed. Cir. 2021).

211. *See id.* at 1088.

212. *See* Amgen Inc. v. Sanofi, 598 U.S. 594, 604 (2023).

213. Brief for Petitioner at i, Amgen Inc. v. Sanofi, 598 U.S. 594 (2023) (No. 21-757).

214. *See id.* at 22-24.

215. *See id.* at 41-45 (arguing that a reasonableness test should replace the Federal Circuit's full scope enablement test).

216. *See* Brief for Respondent at 25-30, Amgen Inc. v. Sanofi, 598 U.S. 594 (2023) (No. 21-757).

interpretations of the enablement requirement better favored public policy, arguing that the other party's standard would impede innovation.[217]

During oral arguments, the Court attempted foremost to understand the scope of the invention.[218] The Justices posed several questions about the amount of experimentation required to independently manufacture the claimed antibodies.[219] Amgen asserted that the patent's roadmap for testing antibodies sufficiently enabled the patent's claims because all of the claimed antibodies could be produced using the roadmap and routine laboratory techniques.[220] Meanwhile, counsel for Sanofi emphasized that the roadmap procedure would require extensive experimentation using methods typically reserved for discovering new antibodies.[221] Early in the oral arguments, the Court noted that counsel for Amgen did not contradict the Federal Circuit's articulation of the enablement standard.[222]

Ultimately, the Court unanimously sided with Sanofi, affirming the Federal Circuit's decision.[223] In the opinion, the Court recited the enablement jurisprudence that it developed in *O'Reilly*, *Consol. Elec. Light Co.,* and *Holland Furniture Co.*: when a patent makes a large claim, that claim must be supported with a proportionately enabling specification.[224] Moreover, the Court reiterated that its precedent did not require a specification to "describe with particularity how to make and use every single embodiment,"[225] but validly enabling patents should at least identify "'some general quality . . . running through' the class that gives it 'a peculiar fitness for the particular purpose.'"[226]

Applying these principles to Amgen's patents, the Court maintained that Amgen's antibody genus claim was broad given the millions of

217. *See* Brief for Petitioner, *supra* note 213, at 22-24 (arguing that the full scope enablement requirement will discourage innovation by making it impracticable for inventors to secure valid, enforceable patents for antibodies, thereby disincentivizing inventors from developing new, beneficial antibodies); Brief for Respondent, *supra* note 216 at 25-30 (arguing that functional genus claiming discourages innovation by making it impossible for researchers to develop improved antibodies for a target antigen without risking infringement).

218. *See* Oral Argument at 5-7, 59-60, Amgen Inc. v. Sanofi, 598 U.S. 594 (2023) (No. 21-757).

219. *See id.* at 7-12, 18-20, 39-40, 73-77.

220. *See id.* at 44 ("If the [method outlined in the roadmap] is going to give you something across the full spectrum of the claims, that is within the claims.").

221. *See id.* at 65-66 ("[T]his roadmap is not a shortcut at all. It just describes the routine processes that people use to make independent inventions . . . and then it adds additional steps that somebody skilled in the art wouldn't want to do[.]").

222. *See id.* at 26.

223. *See* Amgen Inc. v. Sanofi, 598 U.S. 594, 616 (2023).

224. *See id.* at 598.

225. *Id.* at 610-11.

226. *Id.* at 611 (quoting Consol. Elec. Light Co. v. McKeesport Light Co., 159 U.S. 465, 475 (1895)).

antibodies falling within the scope of the claims.[227] Moreover, the Court noted that Amgen's roadmap forced scientists to undergo "painstaking experimentation."[228] The Court dismissed Amgen's argument that the Federal Circuit created a "heightened enablement standard," concluding that the full scope enablement requirement the Federal Circuit articulated "recognized only that the more a party claims for itself the more it must enable."[229] The Court's decision therefore did not disturb the Federal Circuit's enablement jurisprudence.[230]

Following *Amgen*, some scholars may argue that the debate concerning functional genus claims for antibodies is closed.[231] However, the Court's decision in *Amgen* does not preclude the possibility that an attorney could effectively articulate a "general quality" that ties a genus together in the future.[232] Therefore, the Federal Circuit may need to continue entertaining questions regarding the enablement of functional genus claims in years to come.[233]

III. ANALYSIS

After *Amgen*, neither the Federal Circuit's enablement jurisprudence nor the therapeutic antibody industry appears to have been appreciably impacted.[234] However, the Court did not permanently invalidate functional genus claims for antibodies.[235] Consequently, to avoid further uncertainty in the antibody market, the Federal Circuit should entertain future questions of enablement with an eye toward establishing an industry-wide, bright line enablement standard.[236]

A. The Amgen Decision Largely Leaves the Federal Circuit's Enablement Jurisprudence Undisturbed

When Federal Circuit cases face Supreme Court scrutiny, they are often reversed.[237] Consequently, when the Supreme Court granted certiorari in *Amgen v. Sanofi*, many in the field hoped that the Court would end the Federal Circuit's use of the enablement requirement to invalidate

227. *See id.* at 613.
228. *Id.* at 614 (quoting *Consol. Elec. Light Co.*, 159 U.S. at 475).
229. *Id.* at 616.
230. *See id.*
231. *See infra* Sections III.A.1-2.
232. *See infra* Section III.D.
233. *See infra* Section III.E.
234. *See infra* Sections III.A.1-2.
235. *See infra* Section III.D.
236. *See infra* Section III.E.
237. *See* Paul Gugliuzza, *How Much Has the Supreme Court Changed Patent Law*, 16 CHI.-KENT J. INTELL. PROP. 330, 330-31 (2017) (noting that Federal Circuit cases face a nearly 70% reversal rate at the Supreme Court).

antibody patents.[238] Instead, the Court unanimously affirmed the Federal Circuit's decision and seemingly left its enablement jurisprudence undisturbed.[239]

1. The *Amgen* Decision Affirms Uniformity in the Application of the Enablement Requirement

When deciding cases under the Patent Act, courts must apply statutory requirements for patent applications uniformly, regardless of the specific invention being examined.[240] For nearly a century before the advent of therapeutic antibodies, U.S. courts had been wary of broad functional claims, particularly in the enablement context.[241] However, in early caselaw regarding functional genus claims for antibodies, the Federal Circuit appeared to create a distinct exception.[242] The USPTO's decision to distinguish antibodies in their guidance materials on enablement highlights the jurisprudential dissonance that allowing functional genus claiming for antibodies created.[243] So, why did the Federal Circuit allow for antibody patents to deviate from the established enablement standard in the first place?

The answer may lie in the state of antibody science at the time these early decisions were rendered.[244] When functional genus patents were first litigated, antibody structures were still "quite challenging to solve."[245] Researchers had developed methods to efficiently find antibodies with specific functional characteristics, such as epitope specificity and binding affinity,[246] but they had yet to develop equally sophisticated methods for determining antibody structure.[247] Thus, when early antibody patents were filed, many researchers could only claim their antibodies using functional terms.[248] Because of the exponential structural diversity of antibodies, the inventors' functional claims necessarily encompassed sizable antibody genera.[249] Thus, a looser interpretation of the enablement requirement

238. *See* Angus Liu, *Amgen Garners Wide Support from Pharma Peers in Supreme Court Patent Fight with Sanofi*, FIERCE PHARMA (Jan. 4, 2023, 11:38 AM), https://perma.cc/CT2R-7TV2.

239. *See infra* Sections III.A.1-2.

240. *See supra* Section II.A.1.

241. *See supra* Section II.A.2.

242. *See supra* Section II.C.1.

243. *See* Enzo Biochem, Inc. v. Gen–Probe Inc., 323 F.3d 956, 964 (Fed. Cir. 2002) (recognizing the antibody exception as articulated by the USPTO).

244. *See* Lemley & Sherkow, *supra* note 18, at 1044-46.

245. Ian A. Wilson & Robyn L. Stanfield, *50 Years of Structural Immunology*, 296 J. BIOLOGICAL CHEM. 1, 2 (2021).

246. *See* Mieczkowski, *supra* note 104, at 2-4.

247. *See* Lu et al., *supra* note 2, at 1.

248. *See* Lemley & Sherkow, *supra* note 106, at 1044-46.

249. *See* Tonegawa, *supra* note 98, at 575.

allowed for antibody patents to survive in a period when drafting narrower, more robustly enabled claims was impracticable.[250] In contrast, modern researchers efficiently characterize antibodies structurally by their precise amino acid sequence.[251] Consequently, patent attorneys can now write patent claims that accurately describe the structure of the antibodies an inventor has created, making it possible to draft narrower claims that better comport with the enablement requirement.[252]

As these breakthroughs in structural characterization emerged, the Federal Circuit demonstrated incrementally less willingness to provide antibody patents an exceptional status.[253] In response, patent owners asserted that the Federal Circuit was enforcing a heightened enablement requirement for patents.[254] However, in *Amgen*, the Supreme Court correctly recognized that the Federal Circuit's "full scope" enablement standard did not "erroneously 'raise[] the bar' for enablement,"[255] but rather held antibody patents to the "single, universal enablement standard for all invention[s]."[256]

Using its precedent, the Court illustrated that the enablement requirement had always called for a patent's specification to enable the claimed invention's full scope regardless of the invention's field.[257] Thus, the Court's decision reaffirmed the basic principle that the statutory requirements laid out in the Patent Act apply equally to all inventions.[258] Moreover, the Court illustrated that an evenhanded application of the enablement requirement necessitates that all patent specifications enable the claimed invention's full scope, with no special exception for antibody patents.[259]

2. The Amgen Decision Does Not Abrogate the *Wands* Test

The Supreme Court approved the Federal Circuit's use of the "full scope" enablement requirement.[260] However, the Court did not explicitly

250. *See See* Lemley & Sherkow, *supra* note 18, at 1044-46 (drawing a comparison to the tendency for courts to provide leniency in functional claims for antibiotics in the 1950s before the technology to characterize them structurally was available).

251. *See, e.g.*, U. S. Patent No. 8,829,165 (issued Sept. 9, 2014) (including an appendix detailing the exact amino acid sequence for several monoclonal antibodies within the functional genus of antibodies claimed in the patent).

252. *See id.*

253. *See* discussion *supra* Sections II.C.1-2.

254. *See, e.g.*, Brief for Petitioner, *supra* note 213, at 21-29; *see also* discussion *supra* Section II.D.2.

255. Amgen v. Sanofi, 598 U.S. 594, 615 (2023) (quoting Brief for Petitioner, *supra* note 213, at 25).

256. *Id.*

257. *See id.* at 607-12.

258. *See supra* Section II.A.1.

259. *See Amgen*, 598 U.S. at 607-12.

260. *Id.*

adopt the Federal Circuit's *Wands* test for determining whether a patent specification calls for undue experimentation.[261] Instead of citing the *Wands* factors, the Court instead analyzed whether the specification called for a "reasonable amount of experimentation."[262] Subsequently, some practitioners questioned whether the Supreme Court had supplanted the use of the *Wands* test and implemented a new test based on reasonableness.[263]

The text of the *Amgen* opinion fails to mention *Wands* by name, but several portions of the opinion suggest that the Court approves of the Federal Circuit's undue burden framework.[264] For instance, the Court noted that "[w]hat is [a] reasonable [amount of experimentation] in any case will depend on the nature of the invention and the underlying art."[265] This language serves as a tacit nod of approval to the *Wands* factors, which focus the inquiry of undue experimentation by considering the state of the industry in which the invention and inventor are situated.[266]

At any rate, the Federal Circuit has not interpreted *Amgen* to disturb any of their precedents.[267] Indeed, in several subsequent cases, the Federal Circuit has continued applying the *Wands* test to determine whether an antibody patent's specification calls for undue experimentation.[268] In fact, the Federal Circuit has used *Amgen* as a tool to quickly dispatch of antibody patents with similar specification deficits rather than subjecting them to a full *Wands* analysis.[269] Moreover, months after the *Amgen* decision, the USPTO issued clarifying guidance for patent examiners.[270] The guidance explicitly noted that examiners should continue to use the *Wands* test to evaluate whether a specification calls for undue experimentation.[271] While USPTO guidance does not carry the force of

261. *See* Hiler & Levitt, *supra* note 20 (noting *Amgen*'s silence regarding the *Wands* factors).

262. *Amgen*, 598 U.S. at 612.

263. *See* Dennis Crouch, *The Silent Echo: The Supreme Court's Non-Engagement with the Federal Circuit in Amgen v. Sanofi,* PATENTLYO, May 26, 2023, https://perma.cc/5M4H-54N7.

264. *See Amgen*, 598 U.S. at 612.

265. *Id.*

266. *See supra* Section II.A.2.

267. *See* Hiler & Levitt, *supra* note 20 (noting that cases involving antibody patents have not changed dramatically in federal courts, the Patent Trial and Appeal Board, or the Federal Circuit).

268. *See id.*

269. *See* Baxalta Inc. v. Genentech, Inc., 81 F.4th 1362, 1366-67 (Fed. Cir. 2023) (analogizing an antibody patent specification to the specification in *Amgen* to conclude that the antibody patent did not meet the enablement requirement).

270. *See* Guidelines for Assessing Enablement in Utility Applications and Patents in View of the Supreme Court Decision in Amgen Inc. et al. v. Sanofi et al., 89 Fed. Reg. 1563, 1563 (Jan. 10, 2023).

271. *See id.* ("The Wands factors are probative of the essential inquiry in determining whether one must engage in more than a reasonable amount of experimentation.").

law, the publication's unequivocal approval of *Wands* indicates that the framework remains in force.[272]

B. Following Amgen, Functional Genus Claims for Antibodies are Invalid as a Practical Matter

In *Amgen*, the Court did not foreclose the possibility that a functional genus claim for antibodies could be validly enabled.[273] The Court specifically noted that an antibody genus may be validly enabled in a specification that describes a "general quality . . . running through" the class of antibodies that gives them "a peculiar fitness for the particular purpose."[274] However, many legal and scientific scholars alike do not believe that functional claim specifications are possible given the current state of antibody technology.[275] Consequently, most patent attorneys are advising inventors to avoid genus claims altogether because they are either rejected at the USPTO or later invalidated by courts.[276] Thus, presently, inventors are now left with narrower structural claims that may prove more difficult to enforce than older functional genus claims.[277]

C. The Amgen Decision Will Likely Have Beneficial Public Policy Consequences

Prior to the Supreme Court's decision, Amgen asserted in its briefing that requiring full scope enablement would bring about negative public policy consequences.[278] However, existing data indicates that these fears are overblown.[279] Moreover, the increase in competition caused by *Amgen* may benefit the average consumer.[280]

1. *Amgen* Is Unlikely to Deter Therapeutic Antibody Development Significantly

One of Amgen's central policy arguments was that requiring full scope enablement for antibody patents would disincentivize

272. *See id; see also* Eileen McDermott, *USPTO Says* Wands *Still Controls Post-*Amgen *in New Enablement Guidelines*, IPWATCHDOG (Jan. 9, 2023, 6:30 PM), https://perma.cc/BP3Y-L6ZK.

273. *See* Amgen v. Sanofi, 598 U.S. 594, 611-12 (2023).

274. *Id.* at 611.

275. *See* Lemley & Sherkow, *supra* note 18, at 1034-35.

276. *See, e.g.*, Shawn Foley & Jerry Cohen, *Amgen v. Sanofi and Points Beyond*, JD SUPRA (May 30, 2023), https://perma.cc/DX99-FSEL.

277. *See id.*

278. *See* Brief for Petitioner, *supra* note 213, at 37-41.

279. *See infra* Section III.C.1; *see also* S. Sean Tu & Christopher M. Holman, *Antibody Patents: Use of the Written Description and Enablement Requirement at the Patent & Trademark Office*, 38 BERKELEY TECH. L.J. 1, 10-14 (2023).

280. *See infra* Section III.C.2.

pharmaceutical companies from investing in new antibody technologies.[281] Facially, the assertion appears to have merit. As noted in Amgen's brief, a single new antibody may require billions of dollars in research and development.[282] Exorbitant research and development expenditures are justified considering an antibody's enormous earning potential.[283] Conversely, companies may be unwilling to invest research and development capital into treatments with lower earning potentials.[284] Following *Amgen*, pharmaceutical companies will no longer benefit from the monopoly conferred by broad functional genus claims.[285] Consequently, pharmaceutical companies may scale back research and development for new therapeutic antibodies.[286]

Amgen further argued that companies may draft exceedingly lengthy specifications containing thousands of antibody embodiments.[287] Amgen postulated that the practice would impede therapeutic antibody development because the companies that would draft overly detailed specifications would also (1) divert significant resources to characterize many individual antibodies and (2) maintain the antibodies as trade secrets for longer periods while they exhaustively catalog embodiments.[288]

However, the empirical reality suggests that Amgen's fears will not likely come to fruition.[289] Although *Amgen*'s ruling confirmed that functional genus claims are practically invalid,[290] the Federal Circuit's jurisprudence has routinely invalidated these patents for years.[291] Likewise, since the early 2000s, the USPTO has increasingly rejected antibody patents containing functional genus claims.[292] Patent prosecutors have undoubtedly taken notice of the shift.[293] In 2011, most antibody patents made claims using structural rather than functional terms, a trend that has continued to the present.[294]

Nevertheless, during this period of jurisprudential shift, the number of patents issued for antibodies has continued to increase, refuting Amgen's argument that full scope enablement would deter antibody

281. *See* Brief for Petitioner, *supra* note 213 at 39-40.
282. *See id.* at 40.
283. *See supra* Sections II.B.4-5.
284. *See supra* Section II.B.5.
285. *See supra* Section III.B; *see also* Brief for Petitioner, *supra* note 213 at 37-40).
286. *See* Brief for Petitioner, *supra* note 213 at 40.
287. *See id.* at 40-41.
288. *See id.*
289. *See* Tu & Holman, *supra* note 279 (detailing trends in the prosecution and judicial validation of antibody patents over the past two decades).
290. *See supra* Section III.B.
291. *See supra* Section II.C.2.
292. *See* Tu & Holman, *supra* note 279, at 13-14.
293. *See id.* at 24-27 (describing the evolution of antibody claims over the past twenty years).
294. *See id.* at 12.

inventors from investing in antibody research or engaging with the patent system.[295] Thus, given how pervasively the full scope enablement standard has already influenced modern patent practice, *Amgen* likely will not alter the trajectory further.[296] Moreover, the antibody market has grown exponentially following the shift away from functional claiming, giving no indication that the loss of genus claiming diminished the financial incentive for investing in new antibody therapeutics.[297]

2. The Average Consumer May Benefit from Increased Competition following *Amgen*

Pharmaceutical companies do not seem to be suffering disproportionate impacts from *Amgen*, and the decision may impart positive short-term economic impacts on patients receiving therapeutic antibodies.[298] Following *Amgen*, existing therapeutic antibody patents with functional genus claims have been swiftly invalidated by the Federal Circuit and lower courts.[299] Amgen was forced to drastically lower the price of Repatha as Sanofi's anti-PCSK9 antibody came onto the market.[300] Likewise, as courts use *Amgen* to invalidate existing therapeutic antibody patents, the former patentees will likely need to lower their prices in response to new competition.[301]

However, the long-term pricing impacts are less clear. Many legal and regulatory processes impact the rate at which new therapeutics reach the market, and pharmaceutical companies are adept at exploiting these processes to extend monopolies over classes of drugs.[302] Still, in the realm of antibody therapeutics, full scope enablement places at least one check on these companies, effectively denying them patent protection over broad functional genera of antibodies.[303]

D. "Some General Quality": Resurrecting the Genus Claim for Antibodies?

Much of this Analysis assumed that *Amgen* foreclosed functional genus claiming.[304] However, *Amgen* did not categorically invalidate

295. *See id.* at 18.
296. *See id.* at 24-27.
297. *See supra* Section II.B.4.
298. *See supra* Section II.B.4.
299. *See, e.g.*, Baxalta Inc. v. Genentech, Inc., 81 F.4th 1362, 1366-67 (Fed. Cir. 2023).
300. *See supra* Section II.B.4.
301. *See, e.g.*, *Baxalta*, 81 F.4th at 1366-67 (invalidating a pharmaceutical company's patent for a therapeutic antibody used to treat hemophilia).
302. *See supra* Section II.B.4.
303. *See supra* Section III.B.
304. *See supra* Sections III.C.1-2.

patents containing functional genus claims.[305] The Supreme Court explicitly stated that genus claims would be sufficiently enabled if a specification could adequately describe "'some general quality . . . running through' the class that gives it 'a peculiar fitness for the particular purpose.'"[306] However, scholars and scientists are unsure how a specification could sufficiently tie together a functional genus of antibodies, particularly given their inherent "galactic diversity."[307]

Given the dearth of ideas on how to satisfy the general quality exception, patent examiners and courts may have some time before litigators attempt to uphold a patent with a specification that claims to adequately enable a genus claim.[308] However, the capacity to characterize the structure of antibodies continues to improve.[309] Antibody science may reach a point in which inventors can describe, with sufficient specificity, a structural component found in a genus of antibodies that makes the genus particularly suited to bind to a certain epitope.[310] In the future, the USPTO and courts may have little choice but to find that broader functional claims are enabling.[311]

E. The Federal Circuit Should Issue Bright-Line Clarification Whenever Possible

The uncertainty created by the potential for an antibody functional genus claiming "general quality" exception is not ideal.[312] Generally, one of patent law's primary goals is to create a uniform set of expectations so inventors understand the requirements necessary to obtain a patent.[313] The Federal Circuit's antibody jurisprudence gradually steered antibody patents toward a uniform, full scope enablement standard.[314]

However, in the process of restoring uniformity, the Federal Circuit created significant uncertainty because inventors were forced to rethink their patent strategies and many lost their patents altogether.[315] Similarly, reopening the door to functional genus claims in the future likely would

305. *See supra* Section III.A.1.

306. Amgen v. Sanofi, 598 U.S. 594, 611 (2023) (quoting Consol. Elec. Light Co. v. McKeesport Light Co., 159 U.S. 465, 475 (1895)).

307. Lemley & Sherkow, *supra* note 18, at 1003; *see supra* Section III.B.

308. *See* Lemley & Sherkow, *supra* note 18, at 1034.

309. *See supra* Section II.B.2.

310. *See supra* Section II.B.2.

311. *See Amgen*, 598 U.S. at 611.

312. Kelly C. Mullally, *Legal (Un)Certainty, Legal Process, and Patent Law*, 43 LOY. L.A. L. REV. 1109, 1112 (2010) ("In the patent system, indeterminacy can undermine a fundamental goal-providing an incentive for creators to invent and to publicly disclose their inventions.").

313. *See id.*

314. *See supra* Section III.A.2.

315. *See supra* Section II.C.2.

require inventors to alter their approach to gaining patent protection.[316] American patent jurisprudence would not generate this uncertainty in a multi-billion dollar industry attempting to produce next-generation medicines for pernicious diseases.[317]

Thus, the Federal Circuit should vigilantly monitor cases that assert a novel "general quality" argument. The Federal Circuit may be tempted to conduct a narrow *Wands* analysis to limit bringing functional genus claiming back into antibody patent prosecution.[318] However, the court should resist this impulse. Unlike the shift away from genus patents, a shift back toward them would not place any existing, structurally claimed antibody patent at risk of invalidation. Nor would new, more expansively claiming genus patents risk disturbing the property rights of other patentees because the Patent Act prohibits any encroachment on existing patents.[319] Thus, hyper-individualizing future cases would merely protract the enablement issue and introduce new uncertainty regarding whether broad genus claims are valid under § 112(a). Consequently, any future case asserting that an antibody genus claim is sufficiently enabled should be treated by the Federal Circuit as an opportunity to introduce some bright line clarity to the last nagging piece of the antibody enablement puzzle.

IV. CONCLUSION

Antibody therapies are pushing medicine into the future.[320] Thus, these marvels of biological engineering unsurprisingly challenge patent doctrines that predate them by over a century.[321] The Federal Circuit and the United States Supreme Court have done their best to reconcile the infinite variation of antibodies with the standard of enablement that must apply uniformly to all inventions under § 112(a).[322] However, the Supreme Court refused to close the door on antibody patents with functional genus claims entirely.[323] Given current limitations on characterizing the structure of antibodies, courts may not revisit the issue of enablement for years.[324] At that juncture, the Federal Circuit should provide a bright-line rule, ensuring that practitioners will be aware of how broadly they can claim.[325]

316. *See supra* Section II.B.5.
317. *See supra* Section II.B.3.
318. *See, e.g.*, Enzo Biochem, Inc. v. Gen–Probe, Inc., 323 F.3d 956, 964 (Fed. Cir. 2002) (employing the *Wands* factors but limiting the decision to the facts of the case).
319. *See* 35 U.S.C. § 102 (a)(1-2) (foreclosing patentability on any invention claimed in a previously filed patent).
320. *See supra* Section II.B.3.
321. *See supra* Section II.A.1.
322. *See supra* Section III.A.1.
323. *See supra* Section III.D.
324. *See supra* Section III.B.
325. *See supra* Section III.E.