Missouri Law Review

Volume 89 | Issue 3 Article 12

Summer 2024

Artificial Intelligence and Antibody Genus Claims

Thomas R. Langdon

NOTE

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

Thomas R. Langdon[*]

I. INTRODUCTION

Antibodies are the guard dogs of the human immune system. They travel through the bloodstream, sniffing out foreign invaders (antigens),[1] binding to them, and preventing them from harming the body.[2] Instead of having a nose, four legs, and a tail, antibodies are Y-shaped proteins comprised of amino acids that viciously protect their hosts.[3] Think of the tips of the "Y" as mouths that can bite certain antigens and lock them in place, rendering them

[*]B.S. Chemical Engineering, University of Missouri-Columbia, 2021; J.D. Candidate, University of Missouri School of Law, 2025; Senior Lead Articles Editor, *Missouri Law Review* 2024–2025; Associate Member, *Missouri Law Review*, 2023–2024. I am grateful to Professor Erika Lietzan, Professor Dennis Crouch, and R. Danny Huntington, a partner at Rothwell Figg Ernst and Manbeck PC, for their insight, guidance, and support during the writing of this Note, as well as the *Missouri Law Review* for its help in the editing process.

[1] Antigens are defined as "[a]ny substance that causes the body to make an immune response against that substance. Antigens include toxins, chemicals, bacteria, viruses, or other substances that come from outside the body." *Dictionary of Cancer Terms*, NAT'L CANCER INST., https://www.cancer.gov/publications/dictionaries/cancer-terms/def/antigen [https://perma.cc/HPK6-JHAC] (last visited Aug. 16, 2024).

[2] *See* ROOHI BANSAL, ANTIBODIES AND THEIR ROLE IN THERAPEUTICS 2–3 (2021); *see* S. Sean Tu & Christopher M. Holman, *Antibody Claims and the Evolution of the Written Description/Enablement Requirement*, 63 IDEA: L. REV. FRANKLIN PIERCE CTR. FOR INTELL. PROP. 84, 91 (2022).

[3] *See Antibody*, NAT'L HUM. GENOME RSCH. INST. (June 1, 2024) https://www.genome.gov/genetics-glossary/Antibody [https://perma.cc/MMU3-DV9F]; BANSAL, *supra* note 2, at 7–10; Amgen Inc. v. Sanofi, 598 U.S. 594, 600 (2023).

harmless.[4] Antibodies have the ability to identify a plethora of antigens to bind to and neutralize;[5] "[s]ome researchers have estimated that the theoretical number of different types of antibodies . . . is on par with the number of stars in the galaxy."[6]

Given the sheer number of possible antibodies, they are characterized by their function (i.e., what they accomplish) rather than their molecular make up.[7] With this diversity comes functional differences. A change in a single amino acid in an antibody's sequence could change what that antibody can bind to and block.[8] The functional diversity of antibodies provides countless therapeutic applications.[9] Unlike conventional drugs that indiscriminately attack antigens and human cells alike, antibodies can neutralize a specific antigen, reducing the risk of serious side effects.[10]

While the human body naturally creates antibodies, the pharmaceutical industry develops monoclonal antibodies—"antibodies with the same antigen specificity"—to create therapeutic antibody drugs "tailored" to target specific diseases.[11] These puppies, however, are not cheap. Antibody patents are some of the most valuable in the patent system, with the top ten antibody drugs

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[4] *See* BANSAL, *supra* note 2, at 3–9, 19–28; Mehwish Aziz et al., *Physiology, Antibody*, NAT'L INST. OF HEALTH (May 1, 2023), https://www.ncbi.nlm.nih.gov/books/NBK546670/ [https://perma.cc/5H8K-6EBR].

[5] *See* BANSAL, *supra* note 2, at 94, 124–25 ("We have a countless number of antibodies that can recognize a countless number of antigens."); *see* Aziz et al., *supra* note 4.

[6] Mark A. Lemley & Jacob S. Sherkow, *The Antibody Patent Paradox*, 132 YALE L.J. 994, 1003 (2023).

[7] *Id.* at 998.

[8] *See Amgen*, 598 U.S. at 600.

[9] *See* BANSAL, *supra* note 2, at 94, 124–38, 205–07; *see* Aziz et al., *supra* note 4.

[10] BANSAL, *supra* note 2, at 214–215; *see* Aziz et al., *supra* note 4. "This property of monoclonal antibodies makes them very suitable for therapeutic use in many diseases such as cancer, genetic disorders, HIV, autoimmune diseases, etc." BANSAL, *supra* note 2, at 215.

[11] *See* BANSAL, *supra* note 2, at 205–06; *see* Bilal Malik & Abhijeet Ghatol, *Understanding How Monoclonal Antibodies Work*, NIH (Jun. 26, 2023), https://www.ncbi.nlm.nih.gov/books/NBK572118/ [https://perma.cc/24NF-DEXZ]. Generally, the process of creating monoclonal antibodies involves (1) immunizing an animal, usually a humanized mouse, with the antigen on interest; (2) removing the spleen of that immunized animal; (3) acquiring the newly designed antibodies specific to the antigen from the spleen; and (4) selecting the desired antibodies for production. *See* BANSAL, *supra* note 2, at 205–13; *see Understanding the Complexities of Monoclonal Antibody Development and Manufacturing*, ASTRAZENECA (July 14, 2022), https://www.astrazeneca.com/what-science-can-do/topics/covid-19/understanding-mab-development.html#! [https://perma.cc/4K6A-BR53].

generating $79.1 billion in revenue in 2019.[12] This financial gain reflects antibody drugs' importance to the healthcare system and public.

Antibodies save lives. Cardiovascular diseases are the number one cause of death in the western world,[13] and low-density lipoprotein ("LDL"), colloquially known as bad cholesterol, has a direct correlation with the risk of cardiovascular disease.[14] The human body requires and naturally produces LDL, but too much of it can lead to plaque formation.[15] The concentration of LDL "is the main causal risk factor for atherosclerotic cardiovascular disease."[16] An antigen known as Proprotein Convertase Subtilisin/Kexin Type 9 ("PCSK9") degrades LDL receptors in the human liver, which can cause an increase in LDL levels, leading to the aforementioned health concerns.[17] The case of *Amgen Inc. v. Sanofi* involved antibodies developed to bind to and block PCSK9, preventing the antigen from degrading the LDL receptors in the body and resulting in normal LDL levels.[18] In *Amgen*, two pharmaceutical companies fought for the right to exclude the other from creating and selling those antibodies.[19] The United States Supreme Court held that a pharmaceutical company could not patent an entire genus of antibodies based on their function without sufficiently describing enough antibodies to enable those skilled in the art to create and use every antibody claimed without undue experimentation.[20]

This Note analyzes the Supreme Court's decision on the patent enablement standards for antibody genus claims and whether artificial intelligence could give those claims some bite. Part II presents the facts and holding of *Amgen*. Part III discusses the written description and enablement

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[12] Lemley & Sherkow, *supra* note 6, at 997

[13] Na-Qiong Wu & Jian-Jun Li, *PCSK9 Gene Mutations and Low-Density Lipoprotein Cholesterol*, 431 CLINICA CHIMICA ACTA 148, 149 (2014).

[14] Dhrubajyoti Bandyopadhyay et al., *Safety and Efficacy of Extremely Low LDL-Cholesterol Levels and Its Prospects in Hyperlipidemia Management*, J. LIPIDS 1, 1 (Apr. 23, 2018).

[15] *Id.* at 2.

[16] Wu & Li, *supra* note 13, at 149.

[17] *See* Bandyopadhyay et. al., *supra* note 14, at 2.

[18] *See* Amgen Inc. v. Sanofi, 598 U.S. 594, 599 (2023); Bandyopadhyay et. al., *supra* note 14, at 2.

[19] *See generally Amgen*, 598 U.S. 594. A patent provides only the "right to exclude others from making, using, offering for sale, or selling the invention," "not a positive right to make, use, and sell the patented invention." Jay A. Erstling & Frederik W. Struve, *A Framework for Patent Exhaustion from Foreign Sales*, 25 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 499, 505–06 (2015). "The right to use, sell, or import an item exists independently of the Patent Act." Impression Products, Inc. v. Lexmark Intern., Inc., 581 U.S. 360, 374 (2017).

[20] *Id.* at 616.

requirements, undue experimentation, the level of ordinary skill in the art, and the Court's precedent on genus claims. Part IV explains the Court's reasoning and decision set forth in *Amgen*. Finally, Part V comments on the patent bargain, how the Court was correct in its decision, and how companies could use artificial intelligence to meet the written description and enablement requirements for antibody genus claims in the future.

II. FACTS AND HOLDING

In 2011, the United States Patent and Trademark Office ("USPTO") issued a patent to Amgen, a California-based pharmaceutical company, that claimed a monoclonal antibody that bound to and blocked PCSK9.[21] That same year, Sanofi, a competing pharmaceutical company, also received a patent that specified an antibody with the same function.[22] For these antibodies to prevent PCSK9 from degrading LDL receptors, they had to bind to the sweet spot of the antigen—a row of fifteen amino acids out of PCSK9's total 692 amino acid sequence of the antigen.[23] In 2014, Amgen obtained two additional patents that related back to its 2011 patent: U.S. Patent Nos. 8,829,165 and 8,859,741.[24] Both patents claimed all antibodies that functionally bound to and blocked PCSK9.[25]

A genus claim within a patent acts as an umbrella, covering all related species underneath it.[26] Amgen's 2014 patent claims were genus claims that encompassed all species of antibodies that functionally bound to the sweet spot of PCSK9, blocking PCSK9 and preventing it from inhibiting the body's

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[21] Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080, 1083 (Fed. Cir. 2021), *cert. granted in part sub nom.*, Amgen Inc. v. Sanofi, 143 S. Ct. 399 (2022), *aff'd*, 598 U.S. 594 (2023).

[22] *Amgen*, 598 U.S. at 602.

[23] *Id.*

[24] *Id.*

[25] *Id.* The claims at issue are claims 19 and 29 of the '165 patent and claim 7 of the '741 patent. *Id.*

[26] While patent law uses the taxonomic classification system with "genus" and "species," these terms are not limited to biologics in practice. *Cf.* Consol. Elec. Light Co. v. McKeesport Light Co., 159 U.S. 465 (1895) (disputing a genus claim encompassing all species of fibrous and textile incandescent filament). Amgen Inc. v. Sanofi, 872 F.3d 1367, 1373 (Fed. Cir. 2017) ("[F]or a claim [to be] a genus, a patentee must disclose 'a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can "visualize or recognize" the members of the genus.'") (citing Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1350 (Fed. Cir. 2010)); *see* Dmitry Karshtedt et. al., *The Death of the Genus Claim*, 35 HARV. J.L. & TECH. 1, 13 (2021).

ability to remove LDL from the bloodstream.[27] The first part of Amgen's genus claims identified and disclosed twenty-six additional working antibodies that bound to and blocked PCSK9 in the body.[28] Amgen further depicted the three-dimensional structure of two of the twenty-six antibodies.[29] The second part of the genus claims provided two methods of creating antibodies that bound to and blocked PCSK9,[30] known as the "roadmap" and the "conservative substitution."[31] The roadmap method instructed scientists to (1) create a range of antibodies in the lab; (2) test those antibodies to see which, if any, bind to PCSK9; (3) retest the antibodies that bound to PCSK9 to see if they were also binding to the sweet spot; and (4) take the antibodies that bound to the sweet spot and test whether they also blocked PCSK9 from binding to LDL receptors.[32] The conservative substitution method instructed scientists to (1) take antibodies known to bind to and block PCSK9; (2) swap out certain amino acids in the antibody with other amino acids that had similar properties; and (3) test the newly sequenced antibody to verify whether it bound to and blocked PCSK9.[33]

After Amgen obtained these two much broader patents,[34] it sued Sanofi, claiming that Sanofi's PCSK9-inhibiting drug infringed its patents.[35] Sanofi argued that Amgen's new claims were invalid because they failed to meet the written description and enablement requirements of 35 U.S.C. § 112(a).[36] Amgen argued that its specification fully described the twenty-six working examples and two methods of creating new antibodies that performed the same function, both of which enabled those skilled in biotechnology to create and use all antibodies that functionally bound to and blocked PCSK9 in the

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[27] *See* Amgen, 598 U.S. at 602 (stating that the genus claims here enveloped every antibody in the sweet spot that bound to and blocked PCSK9).

[28] *Id.* at 602–03.

[29] *Id.*

[30] *Id.* at 603.

[31] *Id.*

[32] *See id.*

[33] *See id.*

[34] Since Amgen's new patents claimed all species of antibodies that functionally (1) bound to the sweet spot of PCSK9, and (2) blocked PCSK9, this would have included Sanofi's antibodies, making them infringers. *Id.* at 599.

[35] *Id.*

[36] 35 U.S.C. § 112(a) ("The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to 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."); *see Amgen*, 598 U.S. at 599.

human body.[37] Sanofi, however, contended that Amgen's two methods were too broad, as they encompassed "potentially millions more antibodies than" the twenty-six that Amgen disclosed and enabled scientists to create.[38]

Applying the eight-factor test laid out by the United States Court of Appeals for the Federal Circuit in *In re Wands*, the district court found for Sanofi as a matter of law despite the jury rendering a verdict for Amgen.[39] The Federal Circuit created the *Wands* factors to determine whether a patent claim required undue experimentation.[40] *Wands* involved method claims for using antibodies to detect or measure antigens, specifically the hepatitis B virus.[41] For this method to meet the enablement requirement of Section 112, it did not have to disclose everything well known in the art and also allowed for some experimentation.[42] The claimed method, however, could not impose undue experimentation on those of ordinary skill in the art.[43]

Applying the *Wands* factors, the district court granted judgment for Sanofi as a matter of law, reasoning that Amgen's two patent claims did not enable those of ordinary skill in the art to create or use any antibodies beyond the twenty-six provided.[44] According to the court, a reasonable fact-finder could only have found that Amgen's genus claims were too broad.[45] The twenty-six working examples described in the patent were insufficient; a substantial amount of experimentation would have been required to create additional antibodies.[46] Amgen's methods—which were well known in the prior art—could allow those of ordinary skill in the art to make some

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[37] *See Amgen*, 598 U.S. at 615.

[38] *Id.* at 599.

[39] *See generally* Amgen Inc. v. Sanofi, No. CV 14-1317-RGA, 2019 WL 4058927 (D. Del. Aug. 28, 2019), *aff'd sub nom.*, Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080 (Fed. Cir. 2021), *aff'd sub nom.*, Amgen Inc. v. Sanofi, 598 U.S. 594 (2023); *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988) ("Factors considered in assessing the enablement requirement 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.").

[40] *See Wands*, 858 F.2d at 736–37.

[41] *See id.* at 733–34.

[42] *See id*. at 735–37.

[43] *See id.* at 736–37.

[44] *Amgen*, 598 U.S. 594, 604 (2023); Amgen Inc. v. Sanofi, 2019 WL 4058927, at *1 ("The jury verdict found claim 7 of the '741 patent and claims 19 and 29 of the '698 patent valid, but invalidated claims 7 and 15 of the '698 patent for lack of written description.").

[45] *Amgen Inc. v. Sanofi*, 2019 WL 4058927, at *7.

[46] *See id.* at *10–12.

antibodies that performed the function.[47] But Amgen's description of the two methods provided insufficient guidance for someone skilled in the art—someone "familiar with techniques disclosed in the patent: binning, alanine scanning, x-ray crystallography, immunizing mice, and making amino acid substitutions"—to produce additional antibodies.[48]

While a person of ordinary skill in the field would understand Amgen's conservative substitution method, that person would be unable to find the exact number of substitutions required in the sequence to change the sweet spot of PCSK9 that the antibody must bind to.[49] Further testing would be needed to guarantee the antibodies functioned as planned.[50] The district court ultimately found that the relationship between the amino acid sequence and the final three-dimensional structures was not fully understood and that the "structure-function relationship" of the antibodies was unpredictable.[51] On the basis of the *Wands* factors, the district court held as a matter of law that Amgen's claims would require undue experimentation for those of ordinary skill to perform "the full scope of [Amgen's] claimed invention."[52]

On appeal, the Federal Circuit similarly looked to the *Wands* factors to determine whether Amgen's patent claims were invalid for requiring undue experimentation.[53] The Federal Circuit affirmed the district court's findings, holding that it did not err in finding that Amgen's genus claims required undue experimentation for those of ordinary skill in the art.[54] After granting certiorari, the United States Supreme Court reviewed its precedent regarding patent enablement and found that Amgen's claims enabled the twenty-six disclosed antibodies, but nothing else.[55] Because Amgen's claims claimed too much and enabled too little, the Court affirmed the decision below and held that Amgen's genus claims on all antibodies that bound to and blocked PCSK9 were invalid.[56]

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[47] *Id.* at *10.

[48] *Id.* at *10–11.

[49] *Id.* at *9.

[50] *Id.*

[51] *Id.* at *9–10.

[52] *Id.* at *12.

[53] Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080, 1084–86 (Fed. Cir. 2021), *cert. granted in part sub nom.*, Amgen Inc. v. Sanofi, 143 S. Ct. 399 (2022), *aff'd*, Amgen Inc. v. Sanofi, 598 U.S. 594 (2023).

[54] *Id.* at 1088.

[55] *See Amgen*, 598 U.S. at 610–16.

[56] *Id.* at 614–16.

III. LEGAL BACKGROUND

There is a bargain underlying the exclusive rights provided to an inventor in a patent. In exchange for the inventor's limited monopoly, the invention should benefit the public.[57] The public benefit includes the increase in innovation created by the incentive to exclude and from the increase in knowledge from the disclosure of the invention, which enables the public to utilize it after the rights to the patent expire.[58]

To preserve the balance of this bargain, limitations must be set on the patent.[59] The first limitation is on the patent's term—twenty years from the filing date—which prevents indefinite monopolies on new and useful inventions and processes.[60] A second limitation exists through barring ineligible patent subject matter (i.e., "[l]aws of nature, natural phenomena, and abstract ideas").[61] The third limitation ensures the claimed invention is new, useful, and nonobvious, so the public does not unnecessarily pay for the price of exclusivity.[62] The written description, enablement, and best mode

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[57] *Id.* at 604–05.

[58] *Id.* at 605; Jay David Schainholz, *The Validity of Patents After Market Testing: A New and Improved Experimental Use Doctrine?*, 85 COLUM. L. REV. 371 (1985); 35 U.S.C. § 154(a)(1) ("Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process, referring to the specification for the particulars thereof.").

[59] *See* Markman v. Westview Instruments, Inc., 517 U.S. 370, 390 (1996).

[60] *See* 35 U.S.C. § 154(a)(2) ("Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States . . . ."); *see also* 35 U.S.C. § 101 ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.").

[61] *See* Alice Corp. Pty. Ltd. v. CLS Bank Intern., 573 U.S. 208, 216 (2014) ("Laws of nature, natural phenomena, and abstract ideas are not patentable."); *see also* Brendan Costello, *Rulemaking § 101*, 129 YALE L.J. 2178, 2187–91 (2020).

[62] *See* 35 U.S.C. §§ 101, 102(a), 103; *see also* Matthew Chun, *Artificial Intelligence for Drug Discovery: A New Frontier for Patent Law*, 104 J. PAT. & TRADEMARK OFF. SOC'Y (forthcoming 2024) (accessible at https://ssrn.com/abstract=4566014 [https://perma.cc/4ZXY-GB6K]).

requirements act as a fourth limitation, ensuring the public gets its due from the bargain.[63]

The boundaries of an inventor's property rights are set by the patent claim(s), not the invention.[64] To secure and inform the public of these rights, the inventor must fully specify the scope of the invention in the patent claim(s) in accordance with Section 112.[65] To satisfy Section 112, an inventor must meet the written description and enablement requirements without requiring undue experimentation for those of ordinary skill in the art.[66]

A. Written Description and Enablement

The written description and enablement requirements are two separate and distinct requirements.[67] However, when a genus claim is too broad, the written description analysis will "greatly overlap[] with the enablement analysis."[68] An inventor satisfies the written description requirement when the patent's specification reasonably conveys to those having ordinary skill in the art that they had possession of the invention at the time of filing.[69] For genus claims, the written description should either provide a representative number of exemplary species within the genus or common structural features among species in the genus to assist one skilled in the art in recognizing the

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[63] *See* 35 U.S.C. § 112(a); *see also* Eli Lilly and Co. v. Barr Laboratories, Inc., 251 F.3d 955, 963 (Fed. Cir. 2001) ("[T]he best mode requirement does not extend to production details or routine details."); *see also* Lucas V. Greder, *What Do We Do Now? How the Elimination of the Best Mode Requirement Minimizes Adequate Disclosure and Creates A Potentially Unenforceable Fact Pattern*, 3 CYBARIS 104, 106 (2012) (stating that the best mode requirement is not considered in this analysis because "[t]he United States no longer has a means of policing patents that hide the best mode but otherwise adequately enable one skilled in the art of how to make and use the disclosed invention.").

[64] *See* Karshtedt et. al., *supra* note 26, at 3.

[65] *See Markman*, 517 U.S. at 373.

[66] Amgen Inc. v. Sanofi, 598 U.S. 594, 605 (2023); *see* Permutit Co. v. Graver Corp., 284 U.S. 52, 60 (1931); *see also* Tu & Holman, *supra* note 2, at 91–92.

[67] Idenix Pharms. LLC v. Gilead Scis. Inc., 941 F.3d 1149, 1163 (Fed. Cir. 2019); Ariad Pharms., Inc. v. Eli Lilly and Co., 598 F.3d 1336, 1345 (Fed. Cir. 2010); Denise W. DeFranco & Ashley A. Weaver, *Written Description and Enablement: One Requirement or Two?*, 15 FED. CIR. B.J. 101 (2005).

[68] *See* Tu & Holman, *supra* note 2, at 92 (citing ROBERT MERGES & JOHN DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 462 (8th ed. 2021)).

[69] *Id.* (quoting Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010)).

genus's members.[70] The enablement requirement establishes that a patent claim must specify the invention in a way that is complete and clear enough to enable another skilled in the same field to recreate the invention without undue experimentation.[71] The ability to replicate and use the full scope of the claimed invention without undue experimentation helps fulfill the public's end of the patent bargain.[72]

B. Undue Experimentation

A patent can require a reasonable amount of experimentation from those skilled in the art to make and use the invention, as it is impossible to specify everything in a claim with absolute certainty; however, a patent may never require an *undue* amount of experimentation.[73] *O'Reilly v. Morse* demonstrates the issue of undue experimentation through an overly broad genus claim in an improvement patent for the electromagnetic telegraph.[74] In *Morse*, the eighth claim of the improvement patent claimed "the [entire] use of the motive power of the electric or galvanic current . . . however developed for marking or printing intelligible characters, signs, or letters, at any distances."[75] Essentially, this genus claim encompassed all species of electronic communication over a distance.[76] The Court held that this claim was too broad and failed to enable those of ordinary skill in the art to make and use all of the claimed methods of telegraphic communication without undue experimentation.[77] Claim eight was, therefore, invalid.[78]

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[70] Regents of the Univ. of Minn. v. Gilead Scis., Inc., 61 F.4th 1350, 1358 (Fed. Cir. 2023); *Ariad Pharms., Inc*., 598 F.3d at 1350.

[71] *See* Markman v. Westview Instruments 517 U.S. 370, 373 (1996) (quoting 35 U.S.C. § 112(a)); *see* Tu & Holman, *supra* note 2, at 91–92; *see* DeFranco & Weaver, *supra* note 67, at 102.

[72] *See* Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898, 908 (2014); *see Ariad Pharms., Inc.*, 598 F.3d at 1346; *see In re* Wands, 858 F.2d 731, 735–37 (Fed. Cir. 1988); *see* U.S. PAT. & TRADEMARK OFF., PUBLIC VIEWS ON ARTIFICIAL INTELLIGENCE AND INTELLECTUAL PROPERTY POLICY (Oct. 2020); *see* Karshtedt et. al., *supra* note 26, at 6–8; *see* DeFranco & Weaver, *supra* note 67, at 102.

[73] *See* Amgen Inc. v. Sanofi, 598 U.S. 594, 611–12 (2023); *see also* Nautilus, 572 U.S. at 910 (2014) ("The standard we adopt accords with opinions of this Court stating that 'the certainty which the law requires in patents is not greater than is reasonable, having regard to their subject-matter.'") (quoting Minerals Separation v. Hyde, 242 U.S. 261, 270 (1916)).

[74] *See generally* O'Reilly v. Morse, 56 U.S. 62 (1853).

[75] *Id.* at 62.

[76] *See id*. at 113.

[77] *Id.* at 112–17.

[78] *Id.* at 99.

Similarly, *Consolidated Electric Light Co. v. McKeesport Light Co.* illustrates the invalidity of a genus claim that requires undue experimentation through the invention of the incandescent lamp.[79] Rivals to Thomas Edison, William Sawyer and Albon Man, claimed the genus of "all fibrous and textile materials for the purpose of electric illuminations" in their incandescent lamp patent, but they only described two species of the genus—carbonized paper and wood carbon.[80] Sawyer and Man's lamp was ineffective because the fibers of carbonized paper and wood carbon were unparallel and porous.[81] Edison's filament, however, *was* effective because it was made of a special bamboo with parallel fibers and small cell walls.[82] Despite the differences in the filament and the experimentation on Edison's part to create a practical lamp, Sawyer and Man contended that Edison's filament was a species encompassed by their genus claim, which would make Edison an infringer.[83] The Court found that Sawyer and Man's claim over "all fibrous and textile materials for the purpose of electric illuminations" was not fully enabling, as Edison, a person skilled in the art of creating incandescent lamps, had to perform "painstaking experimentation" to make a commercially viable incandescent lamp.[84] Therefore, Sawyer and Man's genus claim was invalid.[85]

The Federal Circuit developed the *Wands* factors to guide the lower courts in determining whether a claimed invention requires undue experimentation for those of ordinary skill in the art, making these factors the go-to method.[86] This factor test is flexible and applicable to different patent

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[79] *See generally* Consol. Elec. Light Co. v. McKeesport Light Co., 159 U.S. 465 (1895).

[80] *Id.* at 470–72.

[81] *Id.* at 417–74.

[82] *Id.* at 472–73.

[83] *Id.* at 471–72.

[84] *Id.* at 466, 472–77.

[85] *Id.*

[86] *See* Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080, 1085 (Fed. Cir. 2021) (describing *Wands* as "the 'go to' precedent for guidance on enablement . . . ."), *cert. granted in part sub nom.*, Amgen Inc. v. Sanofi, 143 S. Ct. 399 (2022), *aff'd*, Amgen Inc. v. Sanofi, 598 U.S. 594 (2023); *see also* Sean B. Seymore, *Patently Impossible*, 64 VAND. L. REV. 1491, 1526 (2011) ("[T]he Wands factors are ubiquitous in evaluating enablement . . . ."). The United States Supreme Court in *Amgen*, however, did not use the *Wands* factors. *See generally* Amgen Inc. v. Sanofi, 598 U.S. 594 (2023). For the remainder of this analysis, it is important to note that while the Supreme Court did not directly use the *Wands* factors, the USPTO has issued guidance for its examiners to continuing using them in determining whether there is undue experimentation in a patent claim. *See* Guidelines for Assessing Enablement in Utility

claims.[87] The test considers (1) the amount of experimentation required, (2) the direction or guidance provided, (3) the number of working examples, (4) the nature of the claimed invention, (5) the prior art, (6) the level of ordinary skill in the art, (7) the predictability of the art, and (8) how broad the claim is.[88] Because enablement is fact-specific, certain *Wands* factors may carry greater weight than others depending on the claim.[89] For broad or "seemingly impossible" claims, the most relevant *Wands* factors will be those related to the knowledge of the person of ordinary skill in the art.[90]

C. Level of Ordinary Skill in the Art

The key to the written description and enablement requirements is the level of skill in the art, as patents are addressed to those of ordinary skill in the art.[91] Those of ordinary skill in the art are the measure of whether a patent is fully enabling or requires undue experimentation.[92] A "person of ordinary skill in the art is a hypothetical person who is presumed to know the relevant prior art."[93] When determining the level of ordinary skill in a field, courts will look to various factors, including but not limited to the problems in the art; the solutions to such problems in the prior art; the rate of innovation in the art; how advanced the technology is; and the knowledge of the ordinary person in the art.[94] The level of ordinary skill in any given art has generally increased over time.[95] The higher the level of ordinary skill in the art, the less detail a patent needs to enable a person to make and use the invention.[96] But, as the level of ordinary skill in the art increases, so does the bar for

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Applications and Patents in View of the Supreme Court Decision in Amgen Inc. et al. v. Sanofi et al., 89 Fed. Reg. 1563, 1566 (Jan. 10, 2024).

[87] Bernard Chao, *Rethinking Enablement in the Predictable Arts: Fully Scoping the New Rule*, 2009 STAN. TECH. L. REV. 3, 80 (2009).

[88] *See In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

[89] Seymore, *supra* note 86, at 1527–33.

[90] *See id.*

[91] *See* Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898, 909 (2014).

[92] *See id.* at 901; Karshtedt et. al., *supra* note 26, at 54–56; Lemley & Sherkow, *supra* note 6, at 999, 1031–32.

[93] *In re* GPAC Inc., 57 F.3d 1573, 1579 (Fed. Cir. 1995) (citing Custom Accessories, Inc. v. Jeffrey–Allan Indus., Inc., 807 F.2d 955, 962 (Fed. Cir. 1986)).

[94] *Id.*

[95] *See* Jonathan J. Darrow, *The Neglected Dimension of Patent Law's Phosita Standard*, 23 HARV. J.L. & TECH. 227, 248 (2009) ("Skill levels can be expected to rise as longer life spans and increased specialization allow workers to accumulate greater skill at a given task.").

[96] *See* Karshtedt et. al., *supra* note 26, at 54–55.

nonobviousness.[97] If a patent required little to no specification for someone of ordinary skill in the art to create and use the invention, the claim(s) would likely be obvious and, therefore, invalid.[98]

IV. INSTANT DECISION

In *Amgen Inc. v. Sanofi*, the United States Supreme Court reviewed whether Amgen's genus claims enabled those skilled in the art of biotechnology to make and use all antibodies that functionally bound to and blocked PCSK9 without undue experimentation.[99] Tackling the genus claims, the Court stated that when one claims all species under a genus, one must enable those of ordinary skill in the art to make and use every species enveloped in that claim.[100] "The more one claims, the more one must enable."[101] To satisfy the enablement requirement, Amgen did not have to describe every single aspect of its claims, nor did it have to eliminate all experimentation, but the patent claims could not require undue experimentation.[102]

Amgen's patents were found to enable those skilled in the art to make and use the twenty-six working antibodies provided, but they did not fully enable the potentially millions of antibodies claimed.[103] The roadmap and conservative substitution methods required experimentation to see which antibodies actually worked.[104] While Amgen's methods would create functionally working antibodies, they would not enable those skilled in the art to create and use them because, according to the Court, they required "random

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[97] *Id.*

[98] *See* Hotchkiss v. Greenwood, 52 U.S. 248, 261 (1850) ("[T]here must be some new art, machine, manufacture, or composition of matter discovered, or there can be no patent."); Graham v. John Deere Co., 383 U.S. 1, 17 (1966) (stating a fact finder would analyze (1) the scope and content of the prior art; (2) the differences between the prior art and the claimed invention; and (3) the level of ordinary skill in the art to determine whether an invention passes the nonobviousness bar); Ryan Abbott, *Everything Is Obvious*, 66 UCLA L. REV. 2, 8 (2019) ("[O]bviousness is evaluated through the lens of the skilled person, who reflects the characteristics of the average worker in a field . . . . The more capable the skilled person, the more they will find obvious, and this will result in fewer issued patents.").

[99] *See generally* Amgen Inc. v. Sanofi, 598 U.S. 594 (2023).

[100] *Id.* at 610.

[101] *Id.*

[102] *Id.* at 610–12.

[103] *Id.* at 612–14.

[104] *Id.* at 614 (quoting Consol. Elec. Light Co. v. McKeesport Light Co., 159 U.S. 465, 475 (1895)).

trial-and-error discovery."[105] Rejecting Amgen's contention that the Federal Circuit had raised the enablement requirements for functional genus claims, the Court held that only one patent enablement standard applies to all patent claims.[106]

Upon reviewing the balanced incentive structure of the patent bargain, the Court also rejected Amgen's policy argument that affirming the Federal Circuit would destroy the bargain.[107] Congress's directive supported that it "included an enablement mandate as one feature among many designed to achieve the balance it wishe[d]."[108] The enablement feature reflected Congress's decision to protect the public's end of the bargain from those who "claim[ed] a lot, but enable[d] only a little," and the Court needed to only apply the enablement mandate "faithfully."[109] While this case dealt with complex and innovative biotechnology, the enablement principle remained constant through 150 years of judicial precedent.[110] Any change in the balance was deemed a policy judgment for Congress, not the Court.[111]

Because Amgen claimed an entire genus of antibodies that encompassed every antibody that functionally bound to and blocked PCSK9, and because Amgen only provided twenty-six working examples and two methods that required undue experimentation, Amgen failed to enable those skilled in the art to create and use the potentially millions of antibodies it claimed.[112] The claims were therefore invalid.[113]

V. COMMENT

The Supreme Court was correct in affirming the Federal Circuit's decision because Amgen's claims were not fully enabling, as they required undue experimentation. The purpose of the patent system is to promote innovation while benefitting the public.[114] To find Amgen's claims enabling would be inconsistent with the patent bargain: Amgen would have the exclusive rights to potentially millions of PCSK9-inhibiting antibodies for

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[105] *See id.* at 614–15 (quoting Brief for Intellectual Property Law Professors and Scholars as *Amici Curiae* in Support of Respondents, at 21, Amgen Inc. v. Sanofi, 598 U.S. 594 (2023) (No. 21–757), 2023 WL 2026340)).

[106] *Id.* at 615.

[107] *Id.* at 616.

[108] *See id.*

[109] *Id.*

[110] *Id.*

[111] *Id.*

[112] *Id.* at 610–16.

[113] *Id.* at 610.

[114] *See id.* at 604–05; *see also* U.S. CONST. art. I, § 8, cl. 8.

twenty years from the filing date,[115] and the public would receive the full disclosure of only twenty-six working antibodies with a quest to find the rest.[116] Additionally, the overbroad genus claims could hurt the public by disincentivizing others from discovering more efficient methods of binding to and blocking PCSK9 or experimenting with species of antibodies under the genus claims to find other useful functions.[117]

Amgen does, however, have a contrary but valid policy concern: that the standard enablement requirement could stifle antibody innovation.[118] Preventing Amgen from making functional antibody genus claims would allow "free riders" to eat into Amgen's market share by creating a slightly different amino acid sequence modeled after the initial disclosure.[119] This result could reduce a company's incentive to invest in precision medicine or encourage trade secrecy regarding its underlying targets and pathways,[120] both of which would harm the public.[121] While the potential for stifling innovation is concerning, it was not compelling enough for the Court to allow the company to alternatively eat into the public's end of the patent bargain. The public receives its end of the bargain when a claim enables those of ordinary skill in the art to make and use the invention without undue experimentation.[122]

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[115] *See* 35 U.S.C. § 154(a)(2).

[116] *See Amgen*, 598 U.S. at 616.

[117] *Cf.* Consol. Elec. Light Co. v. McKeesport Light Co., 159 U.S. 465, 472, 476 (1895). Sawyer and Man's over-broad genus claim on all "fibrous and textile materials" would "shut out any further efforts to discover a better specimen of that class than the patentee had employed, would be an unwarranted extension of his monopoly, and operate rather to discourage than to promote invention." *Id.*

[118] *See* Brief of *Amici Curiae* of Bristol-Myers Squibb Co. et al. at 17, Amgen, Inc. v. Sanofi, 598 U.S. 594 (2023) (No. 18-127).

[119] *See id.* at 26–27.

[120] Camilla A. Hrdy & Mark A. Lemley, *Abandoning Trade Secrets*, 73 STAN. L. REV. 1 (2021) (stating that trade secrets can potentially last forever).

[121] *See* Brief of *Amici Curiae* of Bristol-Myers Squibb Co. et al. at 27, Amgen. Inc v. Sanofi, 598 U.S. 594 (2023) (No. 18-127) ("The Federal Circuit's approach . . . threatens to incentivize innovators in this field to avoid disclosing in their patent filings discoveries of the targets and pathways that underlie their inventions, and instead to patent one or a few specific antibodies through narrow, sequence-specific claims, without referencing the target. Such use of trade secrecy—even if temporary––will harm the transparency needed for future research and development in this promising area.").

[122] *See generally In re* Wands, 858 F.2d 731 (Fed. Cir. 1988); *see* Markman v. Westview Instruments, 517 U.S. 370, 373 (1996) (quoting 35 U.S.C. § 112(a)); *see also* Tu & Holman, *supra* note 2, at 91–92.

Artificial intelligence could potentially solve this stifling concern for companies like Amgen, as it is already well-integrated into pharmaceutical research. Given the ever-evolving nature of artificial intelligence, it is hard to precisely define it. The Biden Administration defines artificial intelligence as "a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations or decisions influencing real or virtual environments."[123] As it exists today, artificial intelligence is known as "narrow artificial intelligence," a "computer program that is good at performing a defined set of tasks."[124] There are many categories of artificial intelligence-related inventions, but the one at issue here is an artificial intelligence-assisted invention.[125]

Companies like Novartis,[126] AstraZeneca,[127] Zymergen,[128] and Google have already integrated artificial intelligence into their pharmaceutical research and development.[129] Novartis uses "Nerve Live," a set of artificial intelligence platforms, to monitor hundreds of clinical trials across thousands of sites in real time.[130] This monitoring assists Novartis in anticipating,

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[123] *See* Exec. Order No. 14110, 88 Fed. Reg. 75191, 75193 (Nov. 1, 2023) (quoting 15 U.S.C. § 9401(3)).

[124] *IPO/AIPLA Category Definitions for AI-Related Inventions*, INTELL. PROP. OWNERS ASS'N 1 (Aug. 2022), https://ipo.org/wp-content/uploads/2022/09/IPOAIPLA-AI-Definitions.pdf [https://perma.cc/7RE9-EPBF] [hereinafter *IPO/AIPLA Category Definitions*].

[125] *See* Response Letter from Ryan Abbott to the Director of the U.S. Pat. and Trademark Office, *Request for Comments Regarding Artificial Intelligence and Inventorship*, 2 (May 15, 2023) ("'AI-assisted invention' means an invention [in] which an AI functionally assists with reduction to practice."); *see also IPO/AIPLA Category Definitions*, *supra* note 124, at 2–4.

[126] *Novartis AG: Overview*, GLOBALDATA, https://www.globaldata.com/company-profile/novartis-ag/#:~:text=Novartis%20AG%20(Novartis)%20is%20a,products%20and%20eye%20care%20products [https://perma.cc/422U-38KD] (last visited June 7, 2024) ("Novartis . . . is a healthcare company that focuses on the discovery, development, manufacture and marketing of prescription and generic pharmaceutical products and eye care products.").

[127] ASTRAZENECA, https://www.astrazeneca.com/our-company.html (last visited Jul. 23, 2023) (AstraZeneca is "a global, science-led, patient-focused pharmaceutical company.").

[128] Amy Feldman, *The Inside Story of How SoftBank-Backed Zymergen Imploded Four Months After Its $3 Billion IPO*, FORBES (Apr. 21, 2022) (Zymergen is "a California synthetic biology company.").

[129] *See* Email Response from IBM to the Director of the USPTO, *Request for Comments on Patenting Artificial Intelligence Inventions*, 84 Fed. Reg. 44889 (Nov. 8, 2019).

[130] Email Response from Corey Salsberg, Vice President, Global Head IP Affairs, Novartis Services Inc., *Request for Comments on Patenting Artificial*

identifying, and resolving inefficiencies in their clinical testing.[131] AstraZeneca uses artificial intelligence to search for and identify potential drug candidates through large datasets, making the process faster and more efficient.[132] Through artificial intelligence, Zymergen is able to optimize microbe designs and predict the performance of different genetic modifications.[133] Google has used artificial intelligence to increase the efficiency of DNA-encoded small molecule libraries, which trained an artificial intelligence model to predict the best compounds at binding with target mixtures.[134] Google then applied this model to a large library of additional compounds to predict additional "hits."[135] Once these new hits were filtered, they underwent experimentation to ensure their validity.[136] This validity experimentation is the current, primary limitation for antibodies generated by artificial intelligence, as current law suggests that further experimentation is needed "regardless of how confident the [artificial intelligence] may report it is in its outputs."[137] *In silico* modeling,[138] however, coupled with artificial intelligence, could act as a digital lab rat to viably check

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Intelligence Inventions, at 2, 84 Fed. Reg. 44889 (Nov. 8, 2019) [hereinafter Email from Corey Salsberg]; *see Novartis' Commitment to the Ethical and Responsible Use of Artificial Intelligence (AI) Systems*, NOVARTIS (Oct. 2020), at 5, 14 https://www.novartis.com/sites/novartis_com/files/novartis-responsible-use-of-aisystems.pdf [https://perma.cc/4LJJ-SFNQ].

[131] Email from Corey Salsberg, *supra* note 130, at 2.

[132] Letter Response from Brian H. Batzli, President, AIPLA to the Hon. Katherine K. Vidal, Director of the USPTO, *Comments in Response to the Request for Comments on Request for Comments Regarding Artificial Intelligence and Inventorship*, 88 Fed. Reg. 9492 (May 15, 2023).

[133] *Id.*

[134] *See* Response Comment from Laura A. Sheridan & Aaron Abood for Google LLC, *Request for Comments Regarding Artificial Intelligence and Inventorship*, 88 Fed. Reg. 9492 (May 15, 2023), at 5.

[135] *Id.*

[136] *Id.*

[137] *See* Chun, *supra* note 62.

[138] Debmalya Barh et al, *In Silico Disease Model: From Simple Networks to Complex Diseases*, ANIMAL BIOTECHNOLOGY, 385, 403 (2020) ("'In silico' is an expression used to mean 'performed on a computer or via computer simulation.'"). "The advantage of mathematical modeling of disease lies in the fact that such models not only shed light on how a complex process works, which could be very difficult to infer an understanding of each component of this process, but also predict what may follow as time evolves or as the characteristics of particular system components are modified." *Id*. at 391. Currently, "[*i*]*n silico* modeling of disease is quite challenging. Attempting to incorporate every single known interaction rapidly leads to an unmanageable model." *Id*. at 392.

every antibody generated through an artificial intelligence system without a human needing to manually check each proposed sequence.[139]

Artificial intelligence provides two possible solutions to functional antibody genus claim issues. It could allow companies with antibody genus claims to satisfy the Section 112 written description and enablement requirements by improving the quality of the written description or by increasing the level of ordinary skill in the art.[140]

A. Improving the Written Description

Amgen's genus claims were nearly impossible to fully enable through written disclosure, as they involved the sequencing of "living material[s]"—antibodies.[141] Artificial intelligence, however, could be a "non-living" aspect of the invention necessary for a sufficient written disclosure. Instead of providing only twenty-six working examples, artificial intelligence could help produce twenty-six thousand, or even a million, examples. Artificial intelligence accelerates companies' research and development through machine learning by replacing standard algorithms with trained models that "predict outputs for previously unseen inputs."[142] Narrow artificial intelligence, through machine and deep learning, could predict and model numerous antibodies that perform a certain function.[143] To reasonably confirm that the millions of working examples actually perform the claimed function, companies could use a more advanced version of *in silico* modeling or a forthcoming version of artificial intelligence. Future versions of artificial intelligence are hypothesized to have the understanding and reasoning of a human, or even higher, which could improve the written description in a way that allows companies to obtain their antibody genus claims.[144] This improvement would protect these companies from free riders while satisfying the enablement requirements of the Supreme Court and *Wands*.[145]

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[139] *See* Chun, *supra* note 62.

[140] *See* 35 U.S.C. § 112(a).

[141] *See In re* Wands, 858 F.2d 731, 735 (Fed. Cir. 1988) ("Where an invention depends on the use of living materials . . . it may be impossible to enable the public to make the invention (*i.e.*, to obtain these living materials) solely by means of a written disclosure."). Because genus claims are, by their nature, broad, the written description and enablement analyses will overlap. *See* Tu & Holman, *supra* note 2, at 92 (citing ROBERT MERGES & JOHN DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 462 (8th ed. 2021)).

[142] *See* Response Comment from Laura A. Sheridan & Aaron Abood, *supra* note 134, at 5–6; *see IPO/AIPLA Category Definitions*, *supra* note 124, at 1.

[143] *See IPO/AIPLA Category Definitions*, *supra* note 124, at 1.

[144] *See id.*

[145] *See id.*

There are, however, concerns with this artificial intelligence-improved written description. A specification that provides a representative number of example species within the genus, or common structural features to adequately identify all the species, may be too long and detailed for a patent examiner to reasonably review.[146] Patent examiners may need to use artificial intelligence to help them review these patent specifications. While the implementation of artificial intelligence could improve the USPTO's review process in that scenario, doing so would likely create another basis for challenging patents—the validity of the agency's use of artificial intelligence in its decision-making process. Additionally, the agency would need to invest in the artificial intelligence review system, which, for a period, would increase user fees for patent applicants and take a considerable amount of time.[147] This increase in fees could indirectly stifle innovation by acting as a barrier to entry to gain a patent.[148]

Another concern is that the working examples generated for the specification may require too much assistance from an artificially intelligent system, making the system the actual inventor. This presents a significant problem because only a natural person can be named as the inventor of a

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[146] *See* Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1350 (Fed. Cir. 2010) ("[A] sufficient description of a genus instead requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus."). An inventor will need to consider the costs of a lengthy specification. Under 37 C.F.R. 1.16(s), specifications and drawings over 100 sheets of paper will result in a higher fee, with an additional fee being charged for every "additional 50 sheets or fraction thereof." *See* MPEP § 607; *see also* Table 19 of 37 C.F.R. 1.16(s). A specification providing a representative number of working examples to enable a person of ordinary skill in the art to make and use every antibody within a genus claim without undue experimentation could prove expensive.

[147] *See* ERIKA LIETZAN, USER FEE PROGRAMS: DESIGN CHOICES AND PROCESSES (Nov. 9, 2023), at 31 (report to the Admin. Conf. of the U.S.) (The "USPTO is fully dependent on fees derived from patent examination and post-allowance fees . . . ."). In terms of similar, automated large-scale technological infrastructure, the USPTO currently uses an automated routing system that uses Cooperative Patent Classification symbols to send an application to "the best available examiner." *See* MPEP § 909.01(a). The United States Department of Commerce did a report on this classification and routing processes in August of 2023 and determined they were ineffective, demonstrating the difficulty in even implementing basic technological infrastructure at the agency level. *See* U.S. DEPARTMENT OF COMMERCE, REPORT IN BRIEF (Aug. 30, 2023).

[148] *See* Erika Lietzan, *User Fee Programs*, 76 ADMIN L. REV. 375, 405 (2024).

patent.[149] Artificial intelligence cannot even be named as a joint inventor.[150] Each named inventor must make a significant contribution to the claimed invention as prescribed by the *Pannu* factors.[151] Additionally, a person who simply runs an artificial intelligence program to get a result cannot be considered a true inventor.[152] In this hypothetical, an inventor who identifies the specification problem, provides the working samples as a dataset, trains the artificial intelligence program, collects and evaluates the predicted working samples, and reduces the artificial intelligence-assisted invention to practice would likely meet the significant contribution requirement under *Pannu*.[153] A patent examiner reviewing these working examples, however,

[149] Thaler v. Vidal, 43 F.4th 1207, 1210 (Fed. Cir. 2022), *cert. denied*, 143 S. Ct. 1783 (2023) ("[T]he Patent Act requires that inventors must be natural persons; that is, human beings."); Response Letter from Ryan Abbott, *supra* note 125, at 7 ("[I]f patentable, a patent application for which an AI has jointly conceived of an invention will belong entirely to the natural persons listed as inventors or their assignees."); 89 Fed. Reg. 10043, 3 ("Inventors and Joint Inventors Named on U.S. Patents and Patent Applications Must Be Natural Persons").

[150] Inventorship Guidance for AI-Assisted Inventions, 89 Fed. Reg. 10043, 3 ("[P]atent applications that name a machine on an application data sheet (37 CFR 1.76), an inventor's oath or declaration (37 CFR 1.63), or a substitute statement (37 CFR 1.64) as either an inventor or joint inventor will be considered by the USPTO to have improper inventorship.").

[151] Pannu v. Iolab Corp., 155 F.3d 1344, 1351 (Fed. Cir. 1998) ("All that is required of a joint investor is that he or she (1) contribute in some significant manner to the conception or reduction to practice of the invention, (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art.").

[152] Inventorship Guidance for AI-Assisted Inventions, 89 Fed. Reg. 10043, 6 (Feb. 13, 2024) ("In the context of AI-assisted inventions, natural person(s) who create an invention using an AI system, or any other advanced system, must contribute significantly to the invention, as specified by the *Pannu* factors"); *see* Hamidreza Habibollahi Najaf Abadi et al., Comments on Patenting Artificial Intelligence Inventions, at 1, Center for Advanced Life Cycle Engineering (CALCE) (Comment to 84 Fed. Red. 44889).

[153] *See* Inventorship Guidance for AI-Assisted Inventions, 89 Fed. Reg. 10043, 6 (Feb. 13, 2024) ("[A] natural person must have significantly contributed to each claim in a patent application or patent. In the event of a single person using an AI system to create an invention, that single person must make a significant contribution to every claim in the patent or patent application."); *see id*. ("[A] significant contribution could be shown by the way the person constructs the prompt in view of a specific problem to elicit a particular solution from the AI system."); *see id*. at 6–7 ("Reducing an invention to practice alone is not a significant contribution that rises to the level of inventorship . . . . [I]n certain situations, [however,] a person who conducts a successful experiment using the AI system's output could demonstrate that the

would be unable to determine exactly how the inventor utilized the artificial intelligence as a tool.[154] Therefore, it may be in the best interest of the inventor to include the steps taken in using the tool in the specification to quell both inventorship and reproducibility issues.[155] A new, nonobvious, and useful antibody could be created through intensive research, luck, persistence, or "with the help of any number of tools and collaborators."[156] Monoclonal antibodies conceived with the assistance of artificial intelligence should be no different.[157]

B. Increasing the Level of Ordinary Skill in the Art

Artificial intelligence could raise the level of ordinary skill in biotechnology to the point that claims like Amgen's are not seen as requiring undue experimentation. The level of guidance needed to enable an invention is reduced when the amount of knowledge in the art is higher and when the art is more predictable.[158] With the availability of artificial intelligence, a person of ordinary skill in the art may not need as much instruction to make or use the invention.[159] Therefore, as artificial intelligence is further ingrained into the pharmaceutical industry, claim methods like Amgen's may be enough

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person provided a significant contribution to the invention even if that person is unable to establish conception until the invention has been reduced to practice."); *see id*. at 7 ("In some situations, the natural person(s) who designs, builds, or trains an AI system in view of a specific problem to elicit a particular solution could be an inventor, where the designing, building, or training of the AI system is a significant contribution to the invention created with the AI system."); *see also* Abadi et al., *supra* note 152, at 2.

[154] Tabrez Y. Ebrahim, *Artificial Intelligence Inventions & Patent Disclosure*, 125 PENN ST. L. REV. 147, 155 (2020).

[155] *Id.* at 177. Additionally, those filing with the USPTO owe a duty of candor and good faith in dealing with the agency. Inventorship Guidance for AI-Assisted Inventions, 89 Fed. Reg. 10043, 7 (Feb. 13, 2024). If USPTO personnel reasonably believe that any of the named inventors may not have provided a significant contribution to the claimed invention, then they can request information relating to inventorship regardless of whether the information is material to patentability. *Id.* at 7–8.

[156] *See* Biotechnology Innovation Organization, Comments of the Biotechnology Innovation Organization (BIO) to the USPTO February 14, 2023 Request for Comments Regarding Artificial Intelligence and Inventorship (May 15, 2023) (Comment to 88 Fed. Reg. 9492).

[157] *Id.*

[158] *See* Application of Fisher, 427 F.2d 833, 839 (1970); *see also* MPEP § 2164.03.

[159] *See* Email Response from IBM to the Director of the USPTO, *supra* note 129, at 6–9.

to enable a person of ordinary skill to make or use the invention without undue experimentation.[160]

Artificial intelligence is likely to affect the USPTO's and courts' standards for a person of ordinary skill in the art.[161] In the past, "microscopes, calculators, and more conventional software applications" have impacted the level of ordinary skill in the art.[162] Artificial intelligence, then, should similarly increase the level of ordinary skill as it becomes a more prevalent tool in the industry.[163] Like a piece of lab equipment, artificial intelligence would be another tool to aid in the process of researching and developing new antibodies.[164] Unlike other tools, however, artificial intelligence would provide its users with advanced data processing, learning capabilities, and predictive analytics.[165] Accordingly, artificial intelligence would make claims like Amgen's valid by increasing the level of ordinary skill in the art and by making the art more predictable.

As artificial intelligence improves the level of ordinary skill in the art, the obviousness hurdle will become increasingly harder for inventors to clear.[166] Obviousness is directly correlated to the level of ordinary skill in the art.[167] The more sophisticated the person of ordinary skill is in antibody sequencing and modeling, the harder it will be for an inventor of an antibody genus claim to prove that their invention is nonobvious.[168] A higher nonobviousness standard may lead to fewer patents being issued in the field, and ultimately lower the incentive to invent.[169] For an antibody genus method claim that utilizes artificial intelligence to be nonobvious, a person having ordinary skill in the art must view the method used as nonobvious in light of

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[160] *Id.*

[161] USPTO, Public Views on Artificial Intelligence and Intellectual Property Policy, 3 (2020).

[162] Email from Corey Salsberg, *supra* note 130, at 10.

[163] *See* Abadi et al., *supra* note 152, at 3; *see* Response from Edward Ryan, *Request for Comments on Patenting Artificial Intelligence Inventions*, 84 Fed. Reg. 44889 (Nov. 8, 2019), at 4; *see* Email from Corey Salsberg, *supra* note 130, at 10–11.

[164] *See* Abadi et al., *supra* note 152, at 3; *see* Response from Edward Ryan, *supra* note 163, at 4; *see* Email from Corey Salsberg, *supra* note 130, at 10–11.

[165] Letter Response from Brian H. Batzli, *supra* note 132.

[166] *See* Abbott, *Everything Is Obvious*, *supra* note 98, at 42; *see also* Siemens, Response to Request for Comments Regarding Artificial Intelligence and Inventorship, 3 (Oct. 2, 2019) (Comment to 84 Fed. Reg. 44889).

[167] *See* Abbott, *Everything Is Obvious*, *supra* note 98, at 8.

[168] *See id.*

[169] *See id.*

the prior art.[170] Increasing the nonobviousness hurdle would be a necessary limit against unworthy patents that would harm the public.[171]

If artificial intelligence is employed to improve the written description of a patent and increase the level of ordinary skill in the art, it could be a solution for antibody genus claims, like Amgen's, to meet the written description and enablement requirements under Section 112.

VI. CONCLUSION

In *Amgen*, the Supreme Court made it clear that, for the time being, functional antibody genus claims are invalid.[172] No antibody genus claim can exist without sufficiently describing and enabling each specific combination in that claim, which is currently impossible.[173] *Amgen* represents the risks in precision medicine and researching and developing new antibodies. The unpredictability of the art and the vast number of combinations may make it difficult for companies like Amgen to deal with antibody free riders, as they lack the full protection of a genus claim. Despite this serious concern and its possible ramifications on industry and public interests, the Court chose the right dog in this patent bargain fight. It acknowledged and weighed both sides of the patent bargain and chose the most risk-averse side: the public's side.

Amgen's holding will affect the future of the pharmaceutical industry. Companies will either hide the targets and pathways underlying their inventions or accept that free riders may eat into their market share and allocate less money to antibody research and development. Both outcomes could drastically affect the public, with the first delaying the rollout of lifesaving medicine and the second resulting in fewer medical discoveries. Artificial intelligence could resolve the industry's problem by improving an antibody method patent's written description and increasing the level of ordinary skill in the art. But this possibility is not today's reality: a dog-eat-dog world.

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[170] To determine whether an invention is obvious, the decisionmaker must determine (1) the scope and content of the prior art; (2) the differences between the prior art and the claimed invention; and (3) determine the level of skill of someone skilled in the art. *See* Graham v. John Deere Co., 383 U.S. 1, 17 (1966).

[171] *See* Siemens Response, *supra* note 166.

[172] *See* Amgen Inc. v. Sanofi, 598 U.S. 594, 613–14 (2023).

[173] *Id.* at 605.