No. 21-757

In The Supreme Court of the United States

AMGEN INC., AMGEN MANUFACTURING, LIMITED, AND AMGEN USA, INC.,

Petitioners,

v.

SANOFI, AVENTISUB LLC, FKA AVENTIS PHARMACEUTICALS INC., REGENERON PHARMACEUTICALS, INC., AND SANOFI-AVENTIS U.S., LLC,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF *AMICUS CURIAE* PROFESSOR ROBIN FELDMAN IN SUPPORT OF RESPONDENTS

GIDEON A. SCHOR
Counsel of Record
ROBIN FELDMAN
UNIVERSITY OF CALIFORNIA
COLLEGE OF THE LAW
SAN FRANCISCO
200 McAllister Street
San Francisco, CA 94102
(415) 565-4661
schorgideon@uchastings.edu

Counsel for Amicus Curiae Professor Robin Feldman

COCKLE LEGAL BRIEFS (800) 225-6964
WWW.COCKLELEGALBRIEFS.COM

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STATEMENT OF INTEREST OF *AMICUS CURIAE*[1]

***Amicus curiae* Professor Robin Feldman** is an expert in intellectual property law, particularly issues involving biotechnology and the intersection of intellectual property and innovation. She is the Arthur J. Goldberg Distinguished Professor of Law and the Albert Abramson '54 Distinguished Professor of Law Chair at UC Law, as well as the Director of the UC Law Center for Innovation, a think-tank focused on innovation at the crossroads of intellectual property and emerging technology. She has received multiple awards for teaching and scholarship, most recently the Leon I. Goldberg Memorial Lecture award, bestowed by the University of Chicago's Committee on Clinical Pharmacology and Pharmacogenomics, and she has published four books and more than 70 articles on intellectual property. A focus of her scholarship is patent enablement doctrine specific to group claiming by function.[2]

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[1] No counsel for any party had any role in authoring this brief, and no person other than the named *Amicus* and her counsel has made any monetary contribution to the preparation and submission of this brief. *See* Rule 37.

[2] *See* Robin Feldman, *Rethinking Patent Law* (Harvard Univ. Press 2012) ("Feldman, *Rethinking*"); Robin Feldman, *Rethinking Rights in Biospace*, 79 S. Cal. L. Rev. 1 (2005); Robin Feldman, *The Inventor's Contribution*, 9 UCLA J.L. & Tech. 1 (2005); *see also* Robin Feldman, *Coming of Age for the Federal Circuit*, 17 Green Bag 2d 27 (2014); Robin Feldman, *Trade Secrets in Biologic Medicine*, 24 Colum. Sci. & Tech. L. Rev. 1 (2022) (forthcoming) ("Feldman, *Secrets*"). Portions hereof are adapted, with the publishers' permission, from the foregoing.

Professor Feldman's empirical work has been cited by the White House and numerous federal and state agencies. She has appeared before committees of the U.S. Senate and House of Representatives, the Federal Trade Commission, the Department of Justice, the Patent & Trademark Office, and committees of the California legislature.

Professor Feldman has a strong interest in ensuring that the enablement standard adopted by the Court does not inhibit future innovation. The standard should not only ensure that patents do not claim inventions that are unknown as of the time of the grant but also secure future innovation against overly expansive and insufficiently disclosed genus claims. Professor Feldman submits this brief to explain that adoption of Amgen's arguments here would create an insurmountable barrier to biological innovation.[3]

SUMMARY OF ARGUMENT

This Court's precedent holds that the correct standard here is not *undue* experimentation but rather *any* experimentation – which is far less friendly to patentees in Amgen's position. Yet the conflict between *undue* and *any* experimentation is not squarely presented because the parties' arguments *accept* the "undue experimentation" standard, and Amgen instead challenges the Federal Circuit's supposed *extension* of that standard. It would be pointless and misleading for

[3] "Amgen" refers to Petitioners, "Sanofi" to Respondents.

this Court to rule on whether the standard's *extension* is valid when the standard *itself* is arguably invalid.

Were the Court to reach the merits, the Federal Circuit's decision should be affirmed. Amgen's entire merits argument rests on a mistaken premise. According to Amgen, the Federal Circuit's decision requires that patents containing genus claims with functional limitations enable a skilled artisan, without substantial time and effort, to make "all or nearly all" embodiments. But, transparently, the Federal Circuit's decision does not say what Amgen says it says. On the contrary, the Federal Circuit made clear that "exhaust[ion]" of a genus is not required and that only a "reasonable" set of embodiments is needed. In any event, Amgen's effort to weaken the Federal Circuit's power to police claim breadth should be rejected. In the "unpredictable arts," which include biotechnology, genus claims with functional limitations can preclude future innovation. Such claims allow the patentee to monopolize – and thus exclude researchers from access to – not just the specific matter invented but also an entire domain of other matters. Many of those other matters, though unknown at the time of the patent grant, later turn out to be of immense value. Amgen's argument must fail because it could bar scientists and competitors from those building blocks of invention.

ARGUMENT

I. LEGAL AND SCIENTIFIC BACKGROUND

A. Legal Standards

1. The Patent Act

Under the Patent Act of 1952 ("Patent Act"), a patent application must include a "specification" that describes "the invention, and . . . 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 . . . *to make and use the same*. . . ." 35 U.S.C. §§ 111(a)(2)(A), 112(a) (emphasis added).[4] The enablement requirement ensures that the applicant cannot patent more than what was invented, *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 120-21 (1853), and that, when the patent expires, the public may use the invention, *Schriber-Schroth Co. v. Cleveland Trust Co.*, 311 U.S. 211, 214 (1940). The Patent Act thus "embodies a carefully crafted bargain for encouraging the creation *and disclosure* of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989) (emphasis added).

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[4] The specification must conclude with "one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor . . . regards as the invention." *Id.* § 112(b).

2. This Court's Precedents

Under this Court's precedent, the enablement requirement demands that a person skilled in the relevant art (henceforth a "skilled artisan") be able to make or use the invention without "any experiments of his own." *Wood v. Underhill*, 46 U.S. (5 How.) 1, 4 (1847) ("The specification must be in such full, clear, and exact terms as to enable any one skilled in the art to which it appertains to compound and use the invention; that is to say, to compound and use it without making *any experiments of his own*." (emphasis added)). The *Wood* Court emphasized that a patent is not enabled if it leaves the skilled artisan unable to make and use the invention except "by experiment" – where "experiment" has no limiting qualifier, like "undue."[5]

Wood is still good law. It is cited repeatedly in Amgen's merits brief.[6] But Amgen's quotation of *Wood*'s sentence articulating the enablement rule conspicuously omits the "any experiment[ation]" standard.[7]

Wood was cited with approval in *Consolidated Electric Light Co. v. McKeesport Light Co.*, 159 U.S. 465, 474-75 (1895). There, Thomas Edison's competitors had

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[5] *Wood*, 46 U.S. (5 How.) at 5 (holding that patent is invalid where "no one could use the invention without first ascertaining *by experiment* the exact proportion of the different ingredients required to produce the result intended" (emphasis added)); *accord Tyler v. Boston*, 74 U.S. (7 Wall.) 327, 330 (1868).

[6] *See* Brief for Petitioners ("Amgen Br.") 22-23, 30-31.

[7] *Compare Wood*, 46 U.S. (5 How.) at 4, *and* Amgen Br. 22-23.

sued him for infringing their patent on an incandescent lightbulb containing a filament made "from vegetable fibrous or textile material." *Id.* at 467. Siding with Edison, the Court ruled that the patent was not enabled. *Id.* at 472. The Court called the claim at issue "a broad claim for every fibrous or textile material," including "over 6,000 vegetable growths" that did not even work. *Id.* There was no quality common to fibrous and textile substances that suited them to the task; the bamboo chosen by Edison, after months of experimentation, worked not because it was a "vegetable growth" but because its "fibrous structure" had distinguishing "peculiarities." *Id.* at 474.[8] After quoting the then-existing patent statute, whose enablement language was not materially different from that of the Patent Act, the Court set forth the following *legal standard* for enablement: "If the description be so vague and uncertain that no one can tell, except by *independent experiments*, how to construct the patented device, the patent is void." *Id.* (emphasis added). By "independent experiments," the Court meant (as in the case of Edison) experiments independent of the plaintiff patentee, or, as

[8] The Court explained that the patent improperly extended the patentees' monopoly and would foreclose innovation by preventing future inventors from developing even better conductors for lightbulb filaments: "[T]o hold that one who had discovered that a certain fibrous or textile material answered the required purpose should obtain the right to *exclude everybody from the whole domain of fibrous and textile materials*, and thereby *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*." 159 U.S. at 476 (emphasis added).

Wood put it, "experiments of his own." *Wood*, 46 U.S. (5 How.) at 4; *accord Bene v. Jeantet*, 129 U.S. 683, 686 (1889). Above all, the word "independent" was not a *limiting* qualifier. Thus, the *legal standard* announced in *Consolidated Electric* – that enablement fails when "experiment[ation]" is required – was consistent with the standard announced in *Wood*.[9]

The Court then posed a rhetorical question about how *un*enabled the claim there was: "Applying this principle" – i.e., the above-referenced legal standard – "how would it be possible for a person to know what fibrous or textile material was adapted to the purpose of an incandescent conductor, except by the *most careful and painstaking experimentation*?" *Id.* at 475 (emphasis added). In view of the phrase "this principle," the italicized phrase was not a legal standard at all. Rather, it was a hyperbolic assessment of *just how badly* this particular patent failed the legal standard.

In short, *Wood* and *Consolidated Electric* together hold that enablement fails when the patent requires "experiment[ation]," where "experiment[ation]" has no limiting qualifier. Consistent with both *Wood* and *Consolidated Electric*, *Amicus* refers to this as the "any experiment[ation]" standard.

Like *Wood*, *Consolidated Electric* is still good law. It, too, is cited repeatedly in Amgen's merits brief.[10]

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[9] The Court relied on *Wood*'s "by experiment" language. *Id.* at 475; *supra* note 5.

[10] *See* Amgen Br. 3, 44-46, 48.

3. The Federal Circuit's Precedents

(a) "Undue Experimentation" – The standard adopted by the Federal Circuit is not "any experiment[ation]" but rather "undue experimentation." *Alcon Research Ltd. v. Barr Lab'ys, Inc.*, 745 F.3d 1180, 1188 (Fed. Cir. 2014) (holding that patent fails enablement if challenger shows, by clear and convincing evidence, that skilled artisan "would not be able to practice the claimed invention without 'undue experimentation' " (quoting *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988))).[11]

The limiting qualifier "undue" makes the Federal Circuit's standard vastly narrower than this Court's "any experiment[ation]" standard.[12] As one commentator has noted, "The Federal Circuit's approach allows experimentation, while the Supreme Court requires that the inventor obviate experimentation entirely."[13]

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[11] The considerations that determine whether "undue experimentation" is needed are the "*Wands* factors," which include the "unpredictability of the art" and the "breadth of the claims." *Wands*, 858 F.2d at 737.

[12] *See In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991) ("That *some* experimentation may be required is not fatal; the issue is whether the amount of experimentation required is 'undue.' " (citing *Wands*, 858 F.2d at 736-37) (emphasis in original)).

[13] Kevin T. Richards, *Note, Experimentation and Patent Validity: Restoring the Supreme Court's* Incandescent Lamp Patent *Precedent*, 101 Va. L. Rev. 1545, 1546 (2015). The essential point made in this article is recognized in the article on which Amgen heavily relies. *See* Dmitry Karshtedt et al., *The Death of the Genus Claim*, 35 Harv. J.L. & Tech. 1, 22-23 & n.156 (2021) (acknowledging that "some prior precedent exists" for various enumerated "approaches to invalidating patents for inadequate disclosure,"

This Court has never endorsed the "undue experimentation" standard.

For its part, the Federal Circuit has never cited this Court's decision in *Consolidated Electric*[14] and has cited this Court's *Wood* decision only once, for a proposition not relevant here.[15] The only Supreme Court decision to which the "undue experimentation" standard can even arguably be traced is *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261 (1916). *See* Richards, *supra*, at 1563-66. *Minerals Separation* suggests that enablement is not defeated by "preliminary test[ing]." 242 U.S. at 270; *see Wands*, 858 F.2d at 737 n.19. But *Minerals Separation* does not mention, let alone overrule, *Consolidated Electric*; never mentions any form of the words "enable," "enabling," or "enablement"; and never states where "preliminary test[ing]" ends and "experimentation" begins. Richards, *supra*, at 1547, 1571-73.[16]

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and that, in the view of Richards, *supra*, "Supreme Court precedent supports an enablement standard that is less patent-friendly than *Wands*"); Amgen Br. 2-3, 18, 24, 27, 38-39, 42.

[14] Richards, *supra*, at 1547 ("In adopting 'undue experimentation,' the Federal Circuit did not cite *Incandescent Lamp* [i.e., the Supreme Court's opinion in *Consolidated Electric*] – indeed, the Federal Circuit has *never* cited the case, though it appears to be controlling precedent." (emphasis in original)); J. Benjamin Bai, *Enablement Issues Concerning Aggressively Broad Generic Claims*, 7 Nw. J. Tech. & Intell. Prop. 1, 2 n.4 (2008).

[15] *See In re Lockwood*, 50 F.3d 966, 976 (Fed. Cir. 1995), *judgment vacated by American Airlines, Inc. v. Lockwood*, 515 U.S. 1182 (1995).

[16] *See also* Richards, *supra*, at 1572-73 (arguing that *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014), reads *Minerals Separation* as concerning claim definiteness, not enablement).

In short, the Federal Circuit's precedent is in conflict with this Court's holdings in *Wood* and *Consolidated Electric*.

(b) "Full Scope" – At least since 1993, the Federal Circuit has held that a patent's specification must enable a skilled artisan to practice the "full scope" of the claimed invention. *See AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234, 1241 (Fed. Cir. 2003). This Court's precedents, although not using the "full scope" terminology, similarly hold that the "whole domain" of the claimed invention must be enabled. *See Consol. Elec.*, 159 U.S. at 476.

B. Scientific Background

A high level of LDL cholesterol raises the risk of heart disease.[17] LDL cholesterol is naturally removed from the body by the liver's LDL receptors.[18] Unfortunately, the PCSK9 protein in the body binds with and degrades LDL receptors.[19] Of the PCSK9 protein's 692 amino acids, a group of 15 amino acids constitute the

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These many problems with tracing the "undue experimentation" standard to *Minerals Separation* are ignored in the U.S. Patent and Trademark Office's *Manual of Patent Examining Procedure* § 2164.01 (9th ed. 2020), which conclusorily asserts that the "undue experimentation" standard originated in *Minerals Separation* (*see* Amgen Br. 42).

[17] *Amgen, Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080, 1082 (Fed. Cir. 2021).

[18] *Id.*; Brief for the United States as Amicus Curiae ("CVSG Br.") 3.

[19] *Amgen*, 987 F.3d at 1082-83; CVSG Br. 3.

place on the unhelpful protein that binds with LDL receptors.[20] Amgen and Sanofi each separately invented an antibody that binds to the relevant part of the protein and thereby blocks the protein from binding with and degrading LDL receptors.[21] By thus blocking the PCSK9 protein, each invented antibody allows LDL receptors to function longer and thereby helps lower LDL cholesterol.[22]

In October 2011, Amgen obtained a patent on the amino-acid sequence of its antibody.[23] A month later, Sanofi obtained a patent on the amino-acid sequence of its own antibody.[24] But, three years later, Amgen obtained two additional patents, which, unlike Amgen's original patent, contained a genus claim with functional limitations.[25] That is, each of Amgen's two new patents claimed an entire group of antibodies – regardless of amino-acid sequence – with a common functional characteristic, namely, that each antibody in the group binds with at least one or two of the 15 amino

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[20] Petition for a Writ of Certiorari at 7; Amgen Br. 11; *Amgen*, 987 F.3d at 1083; *cf.* Brief for Respondents ("Sanofi Br.") 11 & n.4 (identifying 16, not 15).

[21] Sanofi Br. 8-9; CVSG Br. 3; Brief of Defendants-Appellees, *Amgen, Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080 (Fed. Cir. 2021) (No. 20-1074), 2020 WL 3046260, ("Sanofi App. Br.") at *6-9.

[22] Sanofi Br. 8-9; CVSG Br. 3; Sanofi App. Br. at *6-9.

[23] Sanofi Br. 9.

[24] Sanofi Br. 8.

[25] Sanofi Br. 10.

acids in the PCSK9 protein that bind with LDL receptors.[26]

In this litigation, Amgen sued Sanofi alleging that Sanofi's antibody infringed the two new patents.[27] Sanofi contends that, since Amgen's original patent already protected the antibody it invented, Amgen's obtaining of the two additional patents – with genus claims and functional limitations – was an effort to "corner the market" on inhibitors that block the PCSK9 protein.[28]

C. The Federal Circuit's Merits Decision and Denial of Rehearing

1. Merits Decision

The district court granted Sanofi's motion for JMOL, holding that Amgen's claims were not enabled. Under the "undue experimentation" standard, the Federal Circuit affirmed, applying the *Wands* factors (*supra* note 11), which consider, *inter alia*, the level of unpredictability in the art and how broadly the claims were drawn.[29]

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[26] Sanofi Br. 10-11.

[27] Sanofi Br. 1, 12.

[28] Sanofi Br. 1; Sanofi App. Br. at *1-2; *see also Amgen Inc. v. Sanofi, Aventisub LLC*, 850 F. App'x 794, 796-97 (Fed. Cir. 2021) (noting, in denial of rehearing, that Amgen's original patent already protects its invented antibody).

[29] 987 F.3d at 1084.

Regarding the patent claims in suit, the court observed that "[t]he functional limitations here are broad"[30] and that the scope of the claims is therefore "broad."[31] In contrast, the scope of the disclosed examples is "narrow."[32] Demonstrating that "the claims are far broader in functional diversity than the disclosed examples,"[33] the court noted (i) that "there are three claimed residues [i.e., amino acids in PCSK9] to which not one disclosed example binds," and (ii) that "although the claims include antibodies that bind up to sixteen residues, none of Amgen's examples binds more than nine."[34] Because Amgen's claims had a broad scope, Amgen was required to enable that broad scope. Because Amgen enabled less than that broad scope, Amgen ran afoul of Federal Circuit case law holding that a patent must enable the claims' "full scope."[35]

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[30] *Id.* at 1088; *see also id.* at 1087 (expressing concern over "*functional* breadth" of embodiments falling within claims (emphasis in original)).

[31] *Id.* (noting that "the scope of the claims is broad" and that "these claims are indisputably broad").

[32] *Id.* at 1088 (noting "the narrow scope of the working examples" and observing that "the disclosed examples and guidance are narrow").

[33] *Id.* at 1087.

[34] *Id.* at 1087 n.1.

[35] *Id.* at 1086 (citing cases). In observing that broad functional limitations "pose high hurdles" and "raise[ ] the bar for enablement," *id.* at 1087, the court was not creating a new enablement rule for genus claims but rather was reflecting the principle that disclosure "must be 'at least commensurate with the scope of the claims,' " *id.* at 1084 (citation omitted). *Cf.* CVSG Br.

The court further explained that the "unpredictability of the art"[36] similarly led to "undue experimentation."[37] The specification required the skilled artisan to first generate "millions" of antibody candidates – meaning antibodies that *might* satisfy the claims' functional limitations (i.e., binding with a subset of PCSK9's amino acids and blocking PCSK9 from binding with LDL receptors).[38] Yet, as the court observed, it was impossible to *predict*, from the amino-acid sequence of any antibody candidate, whether that candidate would satisfy those functional limitations.[39] That unpredictability of functionality left the skilled artisan with no choice but to *experiment* – meaning to screen each of the millions of antibody candidates to determine whether it satisfied the functional limitations.[40] Even if one took an antibody concededly within the

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9 ("[W]here a patentee purports to invent an entire genus, it must enable the entire genus.").

[36] *Wands*, 858 F.2d at 737.

[37] 987 F.3d at 1087-88.

[38] *Id.* at 1088. The patents require the skilled artisan to generate antibodies by injecting mice with PCSK9. Amgen Br. 13. Those antibodies would then need to be screened to determine which would bind with any of PCSK9's amino acids. *Id.* 14. The resultant set of antibodies would then need to be screened to determine which would bind with any of the 15 amino acids of PCSK9 where LDL receptors bind. *Id.*

[39] 987 F.3d at 1087.

[40] *Id.* at 1088 ("Here, the evidence showed that the scope of the claims encompasses *millions of candidates* claimed with respect to multiple specific functions, and that it would be necessary to first *generate* and then *screen each candidate antibody* to determine whether it meets the double-function claim limitations." (emphasis added)).

claims (i.e., an antibody that satisfied the claims' functional limitations) and changed just one amino acid to create a new antibody, the one change could sufficiently alter the antibody's functionality that one would also need to screen the new antibody to determine if it, too, satisfied the functional limitations.[41] In short, without screening, it would be impossible to predict whether any particular antibody candidate would satisfy the functional claims; screening each antibody was necessary.[42] Because the claims inherently required the skilled artisan to screen millions of antibody candidates[43] and thus to seek a "'needle in a haystack,'"[44] the court held that "undue experimentation" was required by Amgen's patents.

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[41] *Id.* at 1087. Each antibody contains two heavy amino-acid chains and two light amino-acid chains, *see* Amgen Br. 10; changing just two amino acids in a single chain of each of the 26 disclosed examples of antibodies would yield "'millions'" of antibody candidates, Sanofi App. Br. at *37.

[42] 987 F.3d at 1087-88.

[43] *See supra* notes 40, 41. Amgen's own expert testified that screening millions of antibodies "is 'an enormous amount of work' and not 'practical,'" and that "no 'antibody scientist would even contemplate doing' it." Sanofi App. Br. at *24-25, *28.

[44] 987 F.3d at 1086 (noting that experimentation is undue where patent requires skilled artisan to "synthesize and screen the billions of possible compounds because, given a lack of guidance across that full scope, finding functional compounds would be akin to finding a 'needle in a haystack.'" (quoting *Idenix Pharms. LLC v. Gilead Scis., Inc.*, 941 F.3d 1149, 1160-63 (Fed. Cir. 2019))).

Finally, the court held that "the effort required to *exhaust* a genus is not dispositive."[45] That is, the court held that the experimentation required to generate *all* undisclosed embodiments within the claimed genus is not dispositive of whether the experimentation is "undue." But, where the patent discloses relatively few examples compared to the number of possible embodiments, the court held it proper to consider "the amount of effort needed to obtain embodiments outside the scope of the disclosed examples."[46] Because of the amount of screening that would be needed to obtain such embodiments here,[47] the court held, no reasonable jury could conclude "that anything but 'substantial time and effort' would be required to reach the full scope of claimed embodiments."[48]

2. Rehearing Denial

On rehearing, Amgen argued that biotechnology inventions could never obtain adequate protection if genus claims had to be "supported by disclosure enabling the full scope of the claims."[49] The Federal Circuit disagreed, holding: "[A]ll that the enablement requirement precludes is obtaining protection for inventions broader than are disclosed or enabled, and that were

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[45] 987 F.3d at 1088 (emphasis in original).

[46] *Id.*

[47] *Id.* at 1087 ("The binding limitation is itself enough here to require undue experimentation.").

[48] *Id.* at 1088.

[49] *Amgen*, 850 F. App'x at 796.

apparently not invented by the applicant or patentee, as shown by a lack of enabling disclosure."[50]

Rejecting an argument made in Amgen's merits brief here, the court also held: "If one has disclosed or enabled only a small number of invented species, then one has not invented a broad genus."[51] Far from requiring enablement of *all* undisclosed embodiments, the law requires only reasonableness: "Invention of a genus means to conceive and reduce to practice a reasonable number and distribution of species constituting the genus."[52]

Moreover, the court held, innovation would be discouraged if Amgen's genus claims were held enabled: "[I]f one considers that one has invented a group of compositions defined by a genus but does not know enough to fully enable that genus, one would suppress innovation if one were able to claim such a broad genus, not enhance it."[53] Broad and unenabled claims are unnecessary, as Amgen already has patent protection on the specific PCSK9 antibody that it invented.[54]

Finally, the court noted the "circular[ity]" of Amgen's argument, given its functionally defined claims: "It is not the law that one can put forth an idea, or a result or function, and claim all methods of achieving it; one

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[50] *Id.*

[51] *Id.*

[52] *Id.*

[53] *Id.*

[54] *Id.* at 796-97; *see supra* at 11-12 (noting that Amgen already obtained patent on amino-acid sequence of antibody it invented).

cannot claim everything that works."[55] Rehearing was thus denied.[56]

II. THE GRANT OF CERTIORARI WAS IMPROVIDENT

By ruling on Amgen's arguments, this Court would be implicitly ruling on the validity of the "undue experimentation" standard, even though that standard's validity – i.e., its consistency *vel non* with *Wood* and *Consolidated Electric* – is not squarely presented here. The grant of certiorari was thus improvident.

In the first place, the Federal Circuit's "undue experimentation" standard is in conflict with this Court's "any experiment[ation]" standard, which has no limiting qualifier, such as "undue." *Supra* at 5-10.

Furthermore, Amgen's merits arguments do not challenge, but rather accept, the "undue experimentation" standard as articulated by the Federal Circuit in *Wands* and other cases. *See* Amgen Br. 4 ("To prove patent claims are not enabled, challengers must demonstrate . . . that skilled artisans cannot practice the invention by following the patent's teachings or that doing so would require undue experimentation."), 23-24, 25-26, 29, 41, 45, 46, 48, 49;[57] Sanofi Br. 2. Sanofi,

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[55] 850 F. App'x at 797.

[56] *Id.* at 798.

[57] For that matter, Amgen's merits arguments also accept the "full scope" standard as previously articulated by the Federal Circuit. *See* Amgen Br. 51 ("The jury was correctly instructed that enablement turned on whether skilled artisans could 'make and

too, accepts the "undue experimentation" standard. Sanofi Br. 2.

Amgen instead challenges what it contends is a "new standard,"[58] allegedly created by the Federal Circuit in this case, that *extends* the "undue experimentation" standard.[59] According to Amgen, the new standard provides that, for genus claims with functional limitations, "undue experimentation can include the effort to identify all potential variations of the invention that meet the claim's requirements."[60] Under the new standard, Amgen argues, the patent must enable skilled artisans to "cumulatively identify and make all or nearly all embodiments of the invention without substantial time and effort."[61] Amgen calls the asserted extension "legally erroneous."[62]

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use the full scope of the claimed invention * * * without having to conduct undue experimentation.' " (record citation omitted) (asterisks in Amgen's merits brief)). Indeed, Amgen concedes: "[N]o one denies that a patent must reasonably enable the *entire scope* of the claim – there cannot be large tracts of claimed subject matter that are not enabled." Amgen Br. 28 (emphasis added). *Amicus* detects no meaningful difference between "entire scope" (*id.*) and "full scope."

[58] Amgen Br. 20.

[59] *Id.* 51 (referring to Federal Circuit's "legally erroneous rule"; *see also id.* 25 ("distinct test"), 28 ("different and exponentially more demanding standard"), 45 ("new test"); *see* Sanofi Br. 2.

[60] Amgen Br. 18 (brackets and internal quotation marks omitted).

[61] *Id.* 5 (internal quotation marks omitted); *see id.* 51.

[62] *Id.* (emphasis omitted).

Amicus notes a threshold issue concerning the "undue experimentation" standard: How can this Court address the validity of the standard's *extension* when this Court has never addressed the validity of the standard *itself*? This Court has never endorsed the "undue experimentation" standard, and this Court's precedents are demonstrably inconsistent with "undue experimentation" (*supra* at 5-10, 18). Equally important, Amgen's merits arguments do not challenge the "undue experimentation" standard (*supra* at 18-19). That silence is unsurprising: The alternative standard – this Court's "any experiment[ation]" standard (*supra* at 5-7) – is far less friendly to patentees who would use genus claims with functional limitations to "corner the market" on biological inventions (*supra* at 12). In short, the Court is being asked to rule, implicitly, on the validity of the "undue experimentation" standard when the issue is not squarely presented, and the Court lacks the adversarial briefing it should have before ruling on the issue.

Even if Amgen is inviting the Court to assume (without deciding) the validity of the "undue experimentation" standard, so that the Court can reach and rule on the validity of the standard's *extension*, the invitation should be declined. In the view of *Amicus*, it would be pointless – and likely misleading to observers – for this Court to rule on whether an *extension* of a standard is valid, when the standard *itself* is *in*valid under this Court's own precedent.

In sum, certiorari here was improvident. *Amicus* takes no position as to whether the Court should: dismiss

the petition; hold the petition in abeyance pending briefing on the conflict between "any experiment[ation]" and "undue experimentation" (assuming that the parties here are sufficiently incentivized to brief both sides of the conflict); or remand for the Federal Circuit either to address the conflict or simply to readjudicate the appeal under the "any experiment[ation]" standard.

III. ON THE MERITS, THE COURT SHOULD AFFIRM BECAUSE AMGEN'S POSITION, IF ADOPTED, WOULD WEAKEN THE FEDERAL CIRCUIT'S ABILITY TO POLICE OVERBROAD CLAIMS

A. The Federal Circuit Did Not Adopt the Standard Challenged by Amgen

As noted above (at 18-19), Amgen does not challenge the "undue experimentation" standard as articulated by the Federal Circuit in prior cases. Amgen instead argues that, for genus claims with functional limitations, the Federal Circuit has adopted a new standard that extends the "undue experimentation" standard by requiring a patent to enable "all or nearly all" embodiments (*supra* at 19).

The problem for Amgen is that the Federal Circuit's decision never adopted that extended standard. Simply put, the Federal Circuit's decision does not say what Amgen says it says. In fact, the decision never says, or even implies, "all or nearly all." To the contrary, the Federal Circuit expressly held that "exhaust[ing]" the genus was not dispositive and thus was not

required. 987 F.3d at 1088. *Amicus* therefore sees no basis for Amgen's petition.

Nor is there anything in the "undue experimentation" standard that requires an "all or nearly all" approach. In relation to group (or "genus") claims, the "undue experimentation" standard does not require that the inventor identify each member of the group. Rather, if a skilled artisan must engage in significant experimentation – i.e., sorting through what works and what does not – then the patent does not provide sufficient instruction. It does not matter whether the insufficiency occurred because the inventors lacked sufficient enabling information, or thought they had it but were mistaken, or had it but hid it from competitors. The question is whether the patent makes it possible for those who understand this area of science to make the invention without too much trouble. In other words, did the patent actually "teach." And, as the Federal Circuit held below on rehearing, the "undue experimentation" standard requires enablement only of a "reasonable" set of group members (*supra* at 17), not "all or nearly all."

B. Why Overbroad Claims Are Especially Problematic in the "Unpredictable Arts"

Amgen's bid here to weaken the Federal Circuit's ability to police overbroad claims should be rejected. If overbroad claims are allowed in the "unpredictable arts," innovation will only suffer.

This Court, as far back as *Consolidated Electric*, understood the necessity of policing overbroad claims. Such claims not only permit the patenting of more than what was invented and enabled. They also inevitably preclude *future* innovation.[63] For these reasons, the Court in *Consolidated Electric* re-affirmed the *Wood* standard – that a patent requiring experimentation fails enablement – and thereby prohibited the entire tactic of overbroad claiming. Indeed, the opinion in *Consolidated Electric* makes clear that had this Court not applied the *Wood* standard and not barred overbroad claiming, Edison himself would have been barred from inventing his electric lightbulb. The *Consolidated Electric* Court's resounding rejection of the overbroad-patent-as-commercial-tactic applies as fully today as it did in Edison's era.

Today, the concern that overbroad claims will preclude future innovation is particularly acute in the "unpredictable arts" (also called the "uncertain arts"). Patent law divides the "useful arts" into two categories: predictable and unpredictable.[64] In the former, a change to a system or structure will have predictable effects; in the latter, such a change will have *unpredictable* effects. Pharmacology, for example, is an unpredictable art " 'because small changes in the structure or dose of a drug may have unknown effects in a

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[63] *See supra* note 8 (quoting *Consol. Elec.*, 159 U.S. at 476).

[64] Jeffie A. Kopczynski, *Note, A New Era for § 112? Exploring Recent Developments in the Written Description Requirement as Applied to Biotechnology Inventions*, 16 Harv. J.L. & Tech. 229, 237 (2002).

body.'"[65] Biotechnology is similarly an unpredictable art. *BASF Corp. v. Enthone, Inc.*, 749 F. App'x 978, 983 (Fed. Cir. 2018).

Traditionally, patent law has defined a product by identifying its structure. Once the structure is identified, the inventor then controls the product, no matter what materials are used to make it. Take, for example, a simple mechanical invention: the doorknob. Once the patent holder identifies the "doorknob" invention by describing the structure of a doorknob, the patent holder controls all doorknobs and can exclude others from the full spectrum of the product, including other embodiments of the product.[66] Whether the other doorknobs are made of wood, glass, or plastic is irrelevant.[67]

But the rule applicable to doorknobs is more challenging to apply in the realm of the "unpredictable arts." For example, we know much more about the materials that can be used to construct doorknobs than we do about the constituent molecules. A doorknob is a doorknob, whether made of wood or glass. But, when it comes to patenting a molecule, can we really say that a molecule is a molecule, no matter how it works or what materials it is made out of? And are we prepared to say that molecules are molecules when our

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[65] *Id.* (citation omitted).

[66] *See Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533 (Fed. Cir. 1987) (in predictable arts, "a broad claim can be enabled by disclosure of a single embodiment").

[67] *See id.*

knowledge of why and how particular molecules fit into the body's processes is limited?

In the case of the doorknob, the structural design is what matters. It is what allows the thing to fit in the palm of your hand and rotate easily. Varying the materials used to make the doorknob is unlikely to make much difference. Furthermore, we know the elements that make up the doorknob, such as the grip and the shaft. There are no pieces we cannot explain or hints that the doorknob might be integrating with the door in ways we never dreamed. With biologic inventions, however, we grant rights in the face of significant unknowns.

C. The Example of HIV Treatment Shows How Overbroad Claims Can Stunt Innovation

Consider the case of HIV treatments. Currently, HIV is treated with antiretroviral drugs, which are several drug classes that inhibit different parts of HIV's infection and replication process.[68] For example, two of the drug classes inhibit the protein that converts HIV's genetic information into DNA for insertion into the host genome.[69] Other classes inhibit viral

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[68] Alice Tseng et al., *The evolution of three decades of antiretroviral therapy: challenges, triumphs and the promise of the future*, 79 British J. Clinical Pharmacology 182, 182-83, 190 (2015).

[69] Ashley D. Holec et al., *Nucleotide Reverse Transcriptase Inhibitors: A Thorough Review, Present Status and Future Perspective as HIV Therapeutics*, 15 Current HIV Research 411, 411 (2017).

entry (by preventing HIV from fusing with host cells)[70] or integrase (so that viral DNA cannot be inserted into the host's DNA).[71] In short, different classes of antiretroviral drugs fight HIV in different ways.

Each of these drug classes includes numerous medications that are different from one another.[72] Thus, depending on how much experimentation it required, a genus claim purporting to cover the function of the entire class – such as a claim covering inhibition of viral entry – could have severely curtailed development of other medications in the same class, medications that modern practitioners rely on.

But the problem of overbroad genus claims here goes beyond precluding multiple HIV medications that perform the same function. The problem is what scientists did not know when these drugs were first developed – that is, what unknown effects genus claiming might have had. One especially important unknown (now known) was that *combining* drugs, including

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[70] Gourab Prasad Pattnaik & Hirak Chakraborty, *Entry Inhibitors: Efficient Means to Block Viral Infection*, 253 J. Membrane Biology 425, 428-29, 435 (2020).

[71] Stephen Hare et al., *Molecular mechanisms of retroviral integrase inhibition and the evolution of viral resistance*, 107 PNAS 20057, 20057 (2010).

[72] Tseng et al., *supra*, at 183; *see also* Warner C. Greene et al., *Novel targets for HIV therapy*, 80 Antiviral Research 252, 252 (2008).

drugs within the same class of antiretrovirals, significantly increases life expectancy in HIV patients.[73]

An antiretroviral treatment regimen consisting of a single medication is highly vulnerable to the development of resistance by HIV.[74] However, what scientists eventually discovered is that a *multidrug* regimen – a "cocktail" – is much harder for HIV to develop resistance to.[75] And these cocktails do not just consist of a mix of different drugs from different antiretroviral classes. Most consist of multiple drugs from the *same class* of antiretroviral.[76]

Thanks to the cocktails, HIV patients can live normal lives. But when all of these antiretroviral drugs were first being developed, the need for multidrug regimens was unknown. Combined therapy was not discovered until the mid-1990s; the prior decade saw only

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[73] James Cutrell & Roger Bedimo, *Single-tablet regimens in the treatment of HIV-1 infection*, 33 Federal Practitioner 24S, 24S (2016).

[74] Saleta Sierra-Aragon & Hauke Walter, *Targets for Inhibition of HIV Replication: Entry, Enzyme Action, Release and Maturation*, 55 Intervirology 84, 84-85 (2012); Alison F. Feder et al., *Understanding patterns of HIV multi-drug resistance through models of temporal and spatial drug heterogeneity*, 10 eLife 1 (2021).

[75] Sierra-Aragon & Walter, *supra*, at 85; Feder et al., *supra*, at 1, 3.

[76] Tomas Cihlar & Marshall Fordyce, *Current status and prospects of HIV treatment*, 18 Current Opinion in Virology 50, 50-52 (2016). Each cocktail includes multiple drugs from the same class, but adds at least one drug from another class. *Id.*

non-combination therapy.[77] Yet suppose a single pharmaceutical company had obtained a patent with an overbroad genus claim (to prevent others from developing competing drugs in the same class) and, as important, had pursued only its most promising drug in that class. The motivation to pursue only one is precisely what scholars who warn against broad patents predict:

> When a single rightholder controls the rights to future improvements on a current technology, it can be expected that the rightholder will *underdevelop* the improvements. *The single entity* will have less imagination and take a less wide-ranging approach to exploring possible improvements than would *multiple actors*. Second, when a firm has rights to the improvements, it will *move more slowly in developing the improvements*, because it need not fear that others will develop them first and obtain a monopoly over the improvements.[78]

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[77] *See id.* at 50-52; J. Stein et al., *Barriers to HIV Cure*, 88 HLA 155, 155 (2016); Cutrell & Bedimo, *supra*, at 24S.

[78] Hugh McTavish, *Enabling Genus Patent Claims to DNA*, 2 Minn. Intell. Prop. Rev. 121, 139 (2001) (citing and summarizing Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 Colum. L. Rev. 839, 845-49 (1990) (emphasis added) (footnotes omitted)); *see also* Michael Risch, *A Surprisingly Useful Requirement*, 19 Geo. Mason L. Rev. 57, 70 (2011) ("Distinguishing never-useful from not-yet-useful claims can have an important impact on usefulness. . . . Most utility jurisprudence and scholarship relate to practical utility in the '*unpredictable arts*' . . . because *observers expect that someone will discover utilities for these inventions in the future*. The primary

But if only one drug in the relevant class had entered the market, HIV scientists would not have been able even to experiment with combining drugs in that class. As this alternative history of HIV treatment shows, we cannot know *which* future innovations are precluded by overbroad claims, but we can know that such preclusion will happen.

The example of HIV treatment highlights the problem of granting rights in the face of significant unknowns. In some cases, we know there are things we do not know. In others, experience suggests science will show us things we have never dreamed we did not know. Either way, the patent system must grant rights in the face of incomplete information. This problem is profound in the realm of biological invention, where we may never fully solve the mystery of the human body.

Given the commercial realities for biologic companies, the challenge for courts is to craft rights in a way that ensures economic vitality and acknowledges the inventor's contribution, but without reaching into unknown territory and hindering downstream innovation. That is the role of experimentation-based enablement standards, like "any experiment[ation]" and "undue experimentation."

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concern in such cases is *granting a patent too early, thereby removing others' incentive – and ability – to identify those utilities and potentially depriving the public of any useful benefit.*" (emphasis added) (footnotes omitted)).

D. Experimentation-Based Standards Keep Overbroad Claims in Check

Numerous Supreme Court opinions have explained that the goal of patent law is not the moral rights of inventors, but rather the benefit to the public.[79] We suffer the "embarrassment of an exclusive patent," as Thomas Jefferson wrote, only because we believe the grant of that patent will bring benefit to the public as a whole.[80] And as this Court held in *Bonito Boats*, certain requirements of patentability "embody a congressional understanding, implicit in the Patent Clause itself, that free exploitation of ideas will be the rule, to which the protection of a federal patent is the exception. . . . [T]he ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure."[81]

In this context, patents are meant to teach. Society grants the powerful patent right in exchange for the inventor's decision to share an invention with society. After all, an inventor could choose to keep the invention as a trade secret, guarding the details and hoping

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[79] *See Diamond v. Chakrabarty*, 447 U.S. 303, 315-16 (1980); *Graham v. John Deere Co.*, 383 U.S. 1, 9 (1966); *Brenner v. Manson*, 383 U.S. 519, 534-36 (1966); *see also* Robin Feldman, *Intellectual Property Wrongs*, 18 Stan. J.L. Bus. & Fin. 250, 318 (2013) ("Society has created [intellectual property] rights, removing activities that could be enjoyed by the whole of society and appropriating them to the benefit of the few, in the hopes that the creation of these rights will redound to the benefit of all.").

[80] *See* 13 *Writings of Thomas Jefferson* 335 (Andrew A. Lipscomb & Albert Ellery Bergh eds., Memorial ed. 1904).

[81] *See Bonito Boats*, 489 U.S. at 151.

that no competitor makes the same discovery. Instead, receipt of a patent right requires disclosure, which is frequently described as the "quid pro quo" for receiving the precious patent grant.[82]

We do not ask patentees to teach *everyone* how to make the invention. But we do require that patentees teach someone who understands the art what needs to be done to "make and use" the invention. Most important, the enablement inquiry cannot be answered in the abstract. It is intimately tied to an examination of the practices in the art at the particular moment of the original application.

Enter experimentation-based standards. We look to those skilled in the art, along with what they know and the amount of work they would be required to engage in. There may be some classes or categories for which identifying the structure of the target and a certain number of examples of biologic products that function a certain way in relation to that target may be sufficient. But there may be many others in which the level of information provided, combined with the level of unknowns, means that the inventor stopped short of actually teaching others how to make the invention. Did you really teach us how to practice your invention

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[82] *See Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 484 (1974); Feldman, *Secrets*, *supra*, at 8 n.23 ("A patent, of course, is no guarantee of a return, and many patentees receive little value either directly from revenue or indirectly by serving to build[ ] a portfolio to defend territory around an innovation. Nevertheless, a patent provides an extraordinary opportunity to create value by excluding others.").

or did you give us the alphabet with assurances that we could compose Shakespeare?

A classic application of this notion appears in *In re Ruschig*, 379 F.2d 990 (C.C.P.A. 1967), which concerned a chemical compound used for treating diabetes. Though the specification identified a formula that could encompass a half-million compounds, the patentee argued that a skilled chemist could have narrowed the choices and found the specific compound claimed.[83] The court disagreed, explaining that the patentee had failed to guide anyone toward the actual compound:

> It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail or in finding one's way through the woods where the trails have disappeared – or have not yet been made, which is more like the case here – to be confronted simply by a large number of unmarked trees.[84]

Nor should we allow inventors to stretch their grasp to things that are only somewhat similar to the invention. One should not allow an inventor to say, "Sure, I gave you the Constitution. I just had a few words

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[83] 379 F.2d at 993-94.

[84] *Id.* at 994-95. By citing *Ruschig*, which was not an enablement case, *Amicus* does not intend to suggest that the Patent Act's disclosure language necessitates or even supports a written description requirement separate from the enablement requirement.

mixed around, but I got essentially what America is about."[85]

In short, the experimentation-based enablement standards fully accomplish the goal of the enablement requirement: to provide assurance that no patent claim exceeds what was invented and what was taught to the public. *See MagSil Corp. v. Hitachi Glob. Storage Techs., Inc.*, 687 F.3d 1377, 1380-81 (Fed. Cir. 2012) ("[Enablement] prevents both inadequate disclosure of an invention and overbroad claiming that might otherwise attempt to cover more than was actually invented. Thus, a patentee chooses broad claim language at the peril of losing any claim that cannot be enabled across its full scope of coverage.").

In asking this Court to weaken the "undue experimentation" standard's power to police overbroad claims, Amgen is requesting that the Court follow the widely discredited "prospect theory" of patent law. In 1977, Edmund Kitch suggested that the patent system should be understood as similar to the Gold Rush in the American West.[86] His theory was an effort to challenge the well-established "reward theory" of patents, which regards a patent as society's reward for creating and disclosing an invention.[87] Instead, Kitch argued

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[85] *Amicus* is indebted to Dr. Garry Nolan, Stanford University School of Medicine, Department of Microbiology and Immunology, for this imagery.

[86] Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & Econ. 265, 266-67 (1977).

[87] Feldman, *Rethinking* 30.

that broad patents should be granted at a very early stage of development.

Kitch's comparison of patents to mineral claims, however, has been discredited,[88] including by renowned economist Frederick M. Scherer, who described it as "little influenced by any concern for reality."[89] Most important, the U.S. patent system has remained firmly rooted in the notion that a patent is a reward for creating and sharing a successful invention.[90] In requesting a rule that would allow broad claims to large life science groups in vastly expanded circumstances, Amgen would create a system of wide-open, early claiming instead of a system in which patents are a reward for successfully creating and disclosing a particular invention. Amgen's request should be denied.

[88] *See id.* at 30-31 (citing scholarly criticism).

[89] Frederic M. Scherer, *Industrial Market Structure and Economic Performance* 447 n.30 (2d ed. 1980).

[90] *See Graham*, 383 U.S. at 9.

CONCLUSION

If the Court reaches the merits, the judgment of the Federal Circuit should be affirmed.

Respectfully submitted,

GIDEON A. SCHOR
Counsel of Record
ROBIN FELDMAN
UNIVERSITY OF CALIFORNIA
COLLEGE OF THE LAW
SAN FRANCISCO
200 McAllister Street
San Francisco, CA 94102
(415) 565-4661
schorgideon@uchastings.edu

Counsel for Amicus Curiae
Professor Robin Feldman

February 9, 2023