No. 21-757

In the Supreme Court of the United States

AMGEN INC., ET AL.,

Petitioners,

v.

SANOFI, ET AL.,

Respondents.

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

BRIEF OF UNIFIED PATENTS, LLC AS AMICUS CURIAE IN SUPPORT OF RESPONDENTS

JONATHAN STROUD
ASHRAF A. FAWZY
Unified Patents LLC
4445 Willard Avenue
Suite 600
Chevy Chase, MD 20815
(202) 805-8931

LISA M. FERRI
Counsel of Record
RICHARD J. MCCORMICK
Mayer Brown LLP
1221 Avenue of the Americas
New York, NY 10020
(212) 506-2500
lferri@mayerbrown.com
ANDREW J. PINCUS
Mayer Brown LLP
1999 K Street, NW
Washington, DC 20006
(202) 263-3000

Counsel for Amicus Curiae

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INTEREST OF THE *AMICUS CURIAE*[1]

Unified Patents, LLC is a membership organization dedicated to deterring non-practicing entities (NPEs) from extracting nuisance settlements from operating companies based on low-quality, likely invalid patents. Unified's more than 3,000 members are Fortune 500 companies, start-ups, automakers, industry groups, cable companies, banks, open-source developers, manufacturers, and others dedicated to reducing the drain on the U.S. economy resulting from defense and settlement costs attributable to now-routine baseless lawsuits asserting infringement of patents of dubious validity.

Unified seeks to improve patent quality and deter unsubstantiated or invalid patent assertions through its activities, including analytics, prior art, invalidity contests, patentability analysis, administrative patent review, *amicus* briefs, economic surveys, and essentiality studies. These activities focus on a number of defined technology sectors, with a concentration in the "high tech" industry.

An increase in recent years in the issuance of broad functional claims in high tech patents (particularly software) has flooded the marketplace with patents of questionable validity, on both prior art and overbreadth grounds. The latter implicates the enablement standard at issue in Amgen's appeal to this Court regarding its own functional patent claims. Unified files this brief to explain why this Court

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[1] Pursuant to this Court's Rule 37.6, *amicus* states that this brief was not authored in whole or in part by counsel for any party, and that no person or entity other than *amicus* or its counsel made a monetary contribution intended to fund the preparation or submission of this brief.

should maintain—across all fields of endeavor, including high tech—the vigorous check on functional patent claims that the Federal Circuit has applied over decades of its case law (which in turn rests on 170 years of this Court's jurisprudence). The fact-intensive investigation into enablement required by that court's *Wands* factors provides the appropriate, flexible framework for Patent Office examiners, fact-finders, trial court judges, and reviewing appellate courts to apply in assessing compliance with 35 U.S.C. § 112(a).

INTRODUCTION AND SUMMARY OF ARGUMENT

Amgen's patent claims are directed to a functionally defined genus: a group of compositions or compounds defined not in any precise way but rather by the shared function or "desired action or result" that they all achieve. Pet. Br. 18. These claims "attempt * * * to define something (in this case, a composition) by what it does rather than by what it is (as evidenced by specific structure or material * * *)." *In re Swinehart*, 439 F.2d 210, 212 (C.C.P.A. 1971). "Such claims merely recite a description of the problem to be solved while claiming all solutions to it and * * * cover any compound later actually invented and determined to fall within the claim's functional boundaries." *Ariad Pharms., Inc.* v. *Eli Lilly & Co.*, 598 F.3d 1336, 1353 (Fed. Cir. 2010) (en banc).

This Court has long recognized that functional claims have a tendency towards overbreadth. That is because these patents have a nearly unfettered scope that captures as a matter of infringement any and all embodiments that perform the function. But that broad scope often is accompanied by a specification

disclosure that is extremely narrow and therefore profoundly incommensurate with, and non-enabling of, the scope of the claims.

Functional claiming pervades all technologies, not just in the life sciences space of Amgen's claims. And overbroad functional claiming is a significant problem in the high tech sector, particularly with respect to software.

Functional claims hinder innovation regardless of the technology, "frighten[ing] from the course of experimentation [the] inventive genius [that] may evolve many more devices to accomplish the same purpose." *Halliburton Oil Well Cementing Co.* v. *Walker*, 329 U.S. 1, 12 (1946). And, for the same reason, this Court's enablement decisions have rightly held functional claims to the same "high hurdles" in satisfying the enablement requirement of § 112(a) that the Federal Circuit held Amgen's claims to in the decision below. Pet. App. 12a. The standard that the Court and Federal Circuit apply is one of "full scope" enablement, where the patentee has kept its end of the "quid pro quo" of the patent bargain by enabling its invention as broadly as its monopoly excludes.

Indeed, more than 170 years of this Court's precedents recognize and apply a full scope enablement test—starting with *O'Reilly* v. *Morse*—which rejected a functional claim asserted by Samuel Morse. 56 U.S. (15 How.) 62 (1853). The Court reaffirmed that approach in multiple cases since then.

The Court has identified three relevant factors: (1) whether the patent involves an area of invention where results are unpredictable; (2) whether the claim breadth vastly outstrips the disclosures in the specifi-

cation; and (3) whether the patentee has demonstrated that the proven function of disclosed embodiments can be reliably extrapolated to non-disclosed embodiments within the claim scope. When the area is one where results are unpredictable, the claim is much broader than the disclosed embodiments, and those results cannot be reliably extrapolated to undisclosed embodiments, this Court generally has found claims non-enabled. That is because a skilled artisan would be forced to resort to undue experimentation on each non-disclosed embodiment to determine if it embodies the claimed function.

That is the precise standard that the Federal Circuit applied here. The undisputed facts showed a claim breadth (in an unpredictable art) encompassing many millions of antibodies, only a minute fraction of which were disclosed, where "substantial time and effort" would be needed to experimentally determine on a case-by-case basis whether a non-disclosed antibody possessed the claimed function. Pet. App. 13-15a.

Reversal—and replacement of the full scope enablement test with Amgen's proposed permissive standard—would invite patentees to pursue wildly unsupported functional claims in the Patent Office across a wide range of industries, threatening innovation and contributing to already out-of-control litigation defense and settlement costs.

ARGUMENT

I. Functional Claims Like Amgen's Impede Innovation—and The Federal Circuit's "Full Scope" Enablement Standard Is an Essential Counterweight to Prevent Overclaiming.

Amgen and its *amici* assert that the Federal Circuit's application of the enablement requirement to

these claims in the decision below is a threat to innovation. See, *e.g.*, Pet. Br. 38; Br. of Intell. Prop. Professors 11-12 (IP Profs. Br.); Br. of Diversified Researchers 23-28. But this Court's precedent for well over a century has recognized that functional claiming threatens innovation—and is therefore disfavored.

In *The Incandescent Lamp Patent*, the Court described the *in terrorem* effect that functional claims pose to downstream improvements when the claims capture any and all structures that perform the function without a correspondingly broad enabling disclosure. It explained that permitting a patentee

> who had discovered that a [composition] answered the required purpose, [to] obtain the right to exclude everybody from the whole domain of [the genus of compositions], 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*.

Consol. Elec. Light Co. v. *McKeesport Light Co. (The Incandescent Lamp Patent)*, 159 U.S. 465, 476 (1895) (emphasis added); see also *Halliburton Oil*, 329 U.S. at 12 ("[M]any other devices beyond our present information or indeed our imagination [may] perform that function and yet fit these claims. And unless frightened from the course of experimentation by broad functional claims like these, inventive genius may

evolve many more devices to accomplish the same purpose.").[2]

In the many decades since *Incandescent Lamp* and *Halliburton Oil*, the tendency of functional claiming to dominate future invention in the same space has continued unabated. Both the Federal Circuit and commentators have warned against their wholesale encroachment on prospective innovative endeavors—by "preempt[ing] the future before it has arrived." *Fiers* v. *Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993); see also Kevin Emerson Collins, *Patent Law's Functionality Malfunction and the Problem of Overbroad, Functional Software Patents*, 90 Wash. U. L. Rev. 1399, 1419 (2013) ("[P]atent protection provides sufficient incentives for innovation when it does not encompass entire markets * * *. Functional claims that reach toward markets are unlikely to strike this balance."); Mark A. Lemley, *Software Patents and the Return of Functional Claiming*, 2013 Wis. L. Rev. 905, 964 (2013) (Lemley 2013) ("Allowing inventors to assert ownership over the problem they solved, rather than merely the way they solved it, is inconsistent with history, with the patent statute, and with good patent policy.").

Indeed, some observers argue that functional claiming presents such a serious and sustained threat to innovation that it should be prohibited. Professor

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[2] Indeed, the Court in *Halliburton Oil*, relying on the predecessor patent statute to 35 U.S.C. § 112 (Rev. Stat. § 4888), invalidated a purely functional claim because it "describes this most crucial element [of the invention] in terms of what it will do rather than in terms of its own physical characteristics or its arrangement in the new combination apparatus." 329 U.S. at 9; see also HTIA Br. 22-28 (explaining that Amgen's claims are invalid on this ground).

Lemley, for example, has stated that "it is time to end functional claiming * * * both because of the harm functional claiming causes and because functional patent claims are likely invalid under current law." Lemley 2013, at 964.

Yet for now functional claiming persists. And, contrary to the claims of Amgen and its *amici*, its impact is felt beyond the biotechnological and pharmaceutical fields. Functional claims are pervasive across a broad array of technologies: they are "endemic in software patents," Mark A. Lemley, *Ready for Patenting*, 96 B.U. L. Rev. 1171, 1192 (2016) (Lemley 2016), and, as seen in this Court's and the Federal Circuit's cases discussed below, are also found in other "high tech" fields (such as computer hardware, video imaging, and semiconductors) as well as the chemical, electrical, and electro-mechanical arts.

Section 112(a)'s enablement requirement allows courts to police functional genus claims in all fields for overbreadth. Because these claims can have outsized detrimental effects on innovation, the Federal Circuit correctly stated in the decision below that they present "high hurdles" in fulfilling enablement—because the patentee must demonstrate that the specification supports the "full scope" of the broadly claimed genus. Pet. App. 12a.[3] As Professor Lemley explained, a vigorous check on functional claims can spur innovation

[3] "High hurdles" notwithstanding, the Federal Circuit has not declared all-out war on functional claims. Many such claims will not suffer from the infirmity of overbreadth and will be sustained under § 112. *Swinehart*, 439 F.2d at 213. "Genus claims, to any type of invention, when properly supported, are alive and well." Pet. App. 63a.

by forcing "inventors to affirmatively build their inventions to provide those examples" that support the breadth of their genus. Lemley 2016, at 1192-93.

The Federal Circuit, and district courts, frequently use the *Wands* factors (see *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988))[4] as a framework for determining whether a person skilled in the art would be enabled, without the need to engage in undue experimentation, to practice the full scope of a patent claim. *E.g., ALZA Corp.* v. *Andrx Pharms., LLC*, 603 F.3d 935, 938-39 (Fed. Cir. 2010).

The *Wands* factors, the Federal Circuit's application of them over the last thirty-five years (including in the decision below), and the requirement that a patent specification enable the full scope of a claim are not recent developments in U.S. patent law, created out of whole cloth by the Federal Circuit—they reach back nearly 250 years, through this Court's earliest enablement decisions and to the first U.S. patent statute. The Federal Circuit's analysis and holding here are wholly consistent with this Court's enablement jurisprudence, as we next discuss.

II. The Federal Circuit's Full Scope Enablement Test Rests Upon Nearly 250 Years of Settled Legal Principles.

Amgen and its *amici* characterize the Federal Circuit's "full scope" enablement test as a "new standard" that "depart[s] from the statutory text [of § 112(a)],"

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[4] The factors are: "(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." *Wands*, 858 F.2d at 737.

Pet. Br. 20, 25; a "massive shift in the [court's] enablement doctrine," IP Profs. Br. 7; and a "rewriting" of the law, Br. of GSK 7.

That is wrong. The requirement that a patent specification enable the "full scope" of a claimed invention is deeply embedded in U.S. patent law.

A. Full Scope Enablement Dates Back to the Earliest Days of the Republic and Ensures Balance in the Quid Pro Quo that Is the Foundation of the Patent Bargain.

Full scope enablement is traceable to Section 2 of the Patent Act of 1790, which required patentees to provide a written specification "so particular * * * to enable a workman or other person skilled in the art or manufacture * * * to make, construct, or use the [invention], to the end that *the public may have the full benefit thereof*, after the expiration of the patent term." Patent Act of 1790, § 2, 1 Stat. 109-112 (1790) (emphasis added); see also *Evans* v. *Eaton*, 20 U.S. (7 Wheat.) 356, 433-34 (1822) (specification must "make known the manner of constructing the machine (if the invention is of a machine) so as to enable artizans [sic] to make and use it, and thus to give the public the full benefit of the discovery after the expiration of the patent.").

This essential condition on the patent grant maintains the critical balance between the patentee's privilege of monopoly during the life of the patent and the public's right to fully practice the invention thereafter—the "quid pro quo" that this Court has long recognized as one of the foundations of our patent system. *Universal Oil Co.* v. *Globe Co.*, 322 U.S. 471, 484 (1944). That the full scope of the patentee's claimed monopoly must be enabled commensurate with the

"full benefit" later provided to the public is only fair: disclosure of the "precise scope of the monopoly asserted" warns competitors of the full range of activities they may not undertake (and those that they may) when the patent is extant, while allowing the public after expiration to exploit, to the same breadth, what it could not before. See *ibid.*

B. This Court's "Full Scope" Enablement Jurisprudence Is the Forerunner of the *Wands* Factors and the Manner in Which the Federal Circuit Applies Them to Functional Claims.

This Court's decisions since adoption of the Patent Act of 1790 have recognized and enforced the full scope enablement requirement for functional patent claims whose reach exceeds the specification's teaching of how to make and use the full scope of the invention. The Court has largely applied the same factors assessed by the Federal Circuit in its decision below—the *Wands* factors—including the breadth of the claims, predictability of the art, and amount of experimentation. Importantly, the Court invariably considers the very factor attacked by Amgen in this case—how unpredictability will affect the skilled artisan's ability to extrapolate the function of a disclosed embodiment to undisclosed embodiments captured by the claimed genus, and how that unpredictability, combined with the breadth of the claim, will impact the amount of experimentation necessary to practice the full scope.

The Court first addressed the issue head-on in the seminal decision *O'Reilly* v. *Morse*, which involved Samuel Morse's patenting of the "electric-magnetic telegraph" for transmitting "characters, signs or letters at a distance." 56 U.S. (15 How.) 62, 106, 112-13

(1853). Morse described and claimed "specific machinery" for accomplishing the transmission. *Id.* at 112. But he also claimed a method free of any structural limitations, directed to the functional "essence" of his invention: "the use of * * * electro-magnetism, *however developed* for marking or printing intelligible characters, signs, or letters, at any distances." *Ibid.* (emphasis added).

This Court assessed whether this claim should be allowed to "cover broader ground" than the narrower "manner and process of making, constructing and using" described in the specification. 56 U.S. at 119. It first cited the vast, open-ended breadth of the claim—covering "*every improvement* where the motive power is the electric or galvanic current, and the result is the marking or printing intelligible characters, signs, or letters at a distance." *Id.* at 112 (emphasis added). It then compared the claim breadth to the actual embodiments described in the specification, observing that the patentee "does not confine his claim to the machinery or parts of machinery, which he specifies." *Id.* at 113.

The Court also referenced the state of the prior art, stating that other scientists, aware that sufficient electrical current could not be sustained over long distances to effect transmission, abandoned work in the field for some length of time. 56 U.S. at 107. In assessing the quantity of permitted experimentation, the Court held that the skilled artisan must be able to "us[e] the means [the patent] specifies, without any addition to, or subtraction from them, [to] produce precisely the [claimed] result." *Id.* at 119. Finally, and crucially for the Court's ultimate conclusion, Morse did not demonstrate that the successful use of electromagnetism in the particular machinery embodiments

described in the patent could predictably be transposed to undisclosed embodiments:

> Morse has not discovered, that the electric or galvanic current *will always print at a distance, no matter what may be the form of the machinery or mechanical contrivances through which it passes. You may use electro-magnetism as a motive power, and yet not produce the described effect*, that is, print at a distance intelligible marks or signs * * *. [H]e has not discovered that the electro-magnetic current, used as motive power, in any other method, and with any other combination, will do as well.

Id. at 117 (emphasis added). Based on these factors the Court concluded that the full scope of the claim was not enabled: "[t]he specification of this patentee describes his invention or discovery, and the manner and process of constructing and using it; and his patent, like inventions in the other arts above mentioned, covers nothing more." *Id.* at 119. Morse could "lawfully claim only what he has invented and described, and if he claims more his patent is void." *Id.* at 121.

This Court's decisions following *O'Reilly* take account of the same factual considerations and reach similar conclusions. The patent in *Béné* v. *Jeantet* claimed a method of subjecting hair "to the action of chemicals" (without limitation) defined only by their ability to reduce hair diameter; the specification disclosed a single chemical mixture having that function. 129 U.S. 683, 684 (1889). The Court recognized that

the effectiveness of using chemicals in the method remained unpredictable, even in view of the patent's teachings, and would have to be determined case-by-case through experimentation for each undisclosed chemical candidate:

> [T]he specification is not full and clear enough to give one skilled in chemistry such an idea of the particular kinds and character of the chemicals, or combination of chemicals, with the relative proportions of each, as would enable him to use the invention without having to resort to experiments of his own to discover those ingredients.

Id. at 686. Testing the claim by the statutory enablement requirement, the Court refused to grant it the broad construction urged by the patentee—all chemicals that reduce hair diameter—because it was not sufficiently enabled. *Id.* at 685-86.

The analysis and holding in *The Incandescent Lamp Patent* are much the same. The specification included only a single example (carbonized paper) for use as a conductor of electricity in a light bulb; and the claim encompassed "all fibrous and textile materials for the purpose of electric illumination." 159 U.S. at 472. The record contained evidence of "careful and painstaking" (yet failed) experimentation over months on 6,000 fibrous and textile materials. *Id.* at 472, 475. In the absence of a discovery by the patentee of a "general quality, running through the whole fibrous and textile kingdom, which * * * gave it a peculiar fitness for the particular purpose" there could be no way to predictably extrapolate from the single embodiment of

carbonized paper to success in using fibrous and textile materials generally. *Id.* at 475-76. Because "no one can tell, except by independent experiments, how to construct the patented device," the Court declared the patent "void." *Id.* at 474; see also *Corona Cord Tire Co.* v. *Dovan Chem. Corp.*, 276 U.S. 358, 383, 385 (1928) (claim to all disubstituted guanidines that function as an accelerator in vulcanizing rubber not enabled where the breadth of the claim covered up to 100 substances; only one example in the patent and no "showing that there is any general quality common to disubstituted guanidines which made them all effective as accelerators"; and the art was unpredictable—"[t]he catalytic action of an accelerator cannot be forecast by its chemical composition, for such action is not understood and is not known except by actual test"); *Holland Furniture Co.* v. *Perkins Glue Co.*, 277 U.S. 245, 256-58 (1928) (claim to all starches for making animal-free glues not enabled when only one starch composition was disclosed and "large-scale" and "elaborate" experimentation was required to determine which starch had the claimed property).

The Court's reasoning in these cases rests on two basic principles. First, predictability in the art is inversely proportional to the quantity of experimental effort: the less predictable the art, the more work will need to be done to establish whether the claimed function of a disclosed embodiment is a universal property that can be extrapolated to any one of the undisclosed embodiments within the claimed genus. Second—compounding the amount of experimental effort—is that the broader the claim is, the more undisclosed embodiments it ensnares, and the more work is

needed in the aggregate to determine which undisclosed members of the genus have the same function as the disclosed embodiments.[5]

Thus, the key factor for establishing non-enablement is the amount of experimental work necessary in an unpredictable art to determine if a broad array of non-disclosed embodiments function as claimed. When each non-disclosed embodiment would have to be tested to assess whether it functions as claimed, the claim fails the enablement requirement. As we next explain, that is the very approach applied by the Federal Circuit.

C. The Federal Circuit's Application of the *Wands* Factors Is Wholly Consistent with This Court's Precedents.

The decisions of the Federal Circuit (and of its predecessor, the Court of Customs and Patent Appeals) requiring enablement of the full scope of functional claims are firmly grounded in this Court's precedents. Those courts have articulated the standard somewhat differently: "the scope of the claims must bear a reasonable correlation to the scope of enablement," *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970); the description must enable the invention "as broadly as it is claimed," *In re Vaeck*, 947 F.2d 488, 496 (Fed. Cir. 1991)); and "make and use the invention across the full breadth of the claim," *LizardTech, Inc.* v. *Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005). But all reflect the same basic principle—tracing back nearly 250 years—that full scope enablement

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[5] Factors such as the guidance and examples in the specification and the level of skill in the art can operate as levers to "cure" unpredictability or mitigate the amount of experimentation needed (see *infra* at 17).

flows from the "quid pro quo of the patent bargain," requiring a patentee to enable as broadly as its monopoly excludes. *AK Steel Corp.* v. *Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003); pages 9-15, *supra*.

In applying that principle to functional claims using the *Wands* factors, the Federal Circuit has long relied on the same set of flexible, fact-intensive investigations into the same criteria identified in this Court's decisions. The factors operate as a totality, are "illustrative, not mandatory," and no one factor is dispositive—whether undue experimentation is needed is determined by weighing them all. *Amgen, Inc.* v. *Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir.1991); *Wands*, 858 F.2d at 737.

The relationship between predictability of the art and amount of experimentation (as a function of claim breadth)—recognized in this Court's enablement decisions—has also long been a key consideration in Federal Circuit and C.C.P.A jurisprudence. In finding non-enablement based on overbreadth, the court in *In re Fisher* noted the relationship between these factors:

> In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as

> most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

427 F.2d at 839.

Guidance in the specification can "cure" the unpredictability, but if it does not, extensive experimentation may be required to broadly enable a genus. *In re Goodman*, 11 F.3d 1046, 1052 (Fed. Cir. 1993); see also *AK Steel Corp.*, 344 F.3d at 1244 ("[T]he artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, *depending upon the predictability of the art*." (emphasis added).

The Federal Circuit's case law regularly parallels this Court's analysis by applying the *Wands* factors to find non-enablement at the intersection of unpredictability, breadth of claims, and the amount of experimentation—particularly where those characteristics are not offset by any of the other *Wands* factors. See, *e.g., Idenix Pharms. LLC* v. *Gilead Scis. Inc.*, 941 F.3d 1149, 1157-58, 1161-62 (Fed. Cir. 2019), cert. denied, 141 S. Ct. 1234 (2021); *Enzo Life Scis.* v. *Roche Molecular Sys.*, 928 F.3d 1340, 1348-49 (Fed. Cir. 2019), cert. denied, 140 S. Ct. 2634 (2020); *Wyeth & Cordis Corp.* v. *Abbott Labs.*, 720 F.3d 1380, 1385-86 (Fed. Cir. 2013). The holding below is wholly consistent with that long-settled approach.

III. The Federal Circuit Properly Followed These Long-Settled Principles.

A. The Full Scope Enablement Test Applied Below Mirrors This Court's Approach.

In the decision below, the Federal Circuit began its analysis by examining *Wands* followed by a review of how it has applied the *Wands* factors in its earlier decisions. Pet. App. 9a-11a (citing *Idenix Pharms.*, *Enzo Life Scis.*, and *Wyeth & Cordis Corp.*). What emerged from its synthesis

> is that the enablement inquiry for claims that include functional requirements can be particularly focused on the breadth of those requirements, especially where predictability and guidance fall short. In particular, it is important to consider the quantity of experimentation that would be required to make and use, not only the limited number of embodiments that the patent discloses, but also the full scope of the claim.

Pet. App. 11a.

That standard encapsulates this Court's approach to full scope enablement. It focuses on unpredictability, claim breadth (compared to the limited number of embodiments), and the quantity of experimentation as the deciding factors.

The underlying factual findings associated with each factor (which the Federal Circuit reviewed for clear error, Pet. App. 6a) demonstrated that this was an "unpredictable field of science" in which the claims "encompasse[d] millions of candidates," while the specification disclosed only a "narrow scope" of that

breadth, and where the necessary experimentation would amount to "substantial time and effort." Pet. App. 13a-15a.

The unpredictability of the art was an important factor in the court's conclusion that each undisclosed member of the genus would have to be tested to determine whether it functioned as claimed. *Ibid.* Moreover, the lack of predictability—the inability to extrapolate an expectation of functionality from the limited disclosed embodiments to the undisclosed embodiments without having to test them—was not cured by guidance in the specification.

> [W]e note here the conspicuous absence of nonconclusory evidence that the full scope of the broad claims can predictably be generated by the described methods * * * . [E]ven assuming that the patent's "roadmap" provided guidance for making antibodies with binding properties similar to those of the working examples, no reasonable factfinder could conclude that there was adequate guidance beyond the narrow scope of the working examples that the patent's "roadmap" produced.

Pet. App. 13a-14a.

The Federal Circuit's reasoning is indistinguishable from this Court's analysis in, for example, *Béné* and *Incandescent Lamp*, where the patents did not provide guidance of the "particular kinds and character" of the genus or of a "general quality [that] gave it a peculiar fitness for the particular purpose" that would convert the unpredictable art into a predictable

one from which a skilled artisan could reasonably infer that all members of the genus have the claimed function. *Béné*, 129 U.S. at 686; *Incandescent Lamp*, 159 U.S. at 475.

In both of those cases it was the unpredictability, uncured by the specification, that would have required independent experiments across the genus—and that is what led this Court to conclude that the full scope of the claims was not enabled. *Béné*, 129 U.S. at 685-86; *Incandescent Lamp*, 159 U.S. at 474. The Federal Circuit's reasoning here essentially mirrors the reasoning in *Béné* and *Incandescent Lamp* (as well as in *O'Reilly*, *Corona Cord Tire*, and *Holland Furniture*).

Amgen erroneously asserts that the Federal Circuit "improvised a new test" for full scope enablement that requires the skilled artisan to "to cumulatively identify and make all or nearly all embodiments of the invention without 'substantial time and effort.'" Pet. Br. 5. But the Federal Circuit did not hold that a naked calculation of the time required to reduce to practice every embodiment within the claims is a relevant "test" for enablement, let alone the dispositive test. Pet. App. 64a ("[O]ur opinion specifically resisted what might be termed a simple 'numerosity' or 'exhaustion' requirement.").

The fact that "substantial time and effort" is needed to determine whether any undisclosed embodiment (or many or most of them) possessed the claimed function is not a test itself but a consequence of the unpredictability of the art that Amgen chose to operate in and the breadth of the claims that Amgen chose to pursue, in light of the limited guidance and embodiments in the specification that Amgen was able to generate when it filed the patent application.

In a predictable field, with a claim of narrower breadth, where the function of examples in the specification can be reliably transposed to non-disclosed embodiments, the quantity of experimentation would be far less—perhaps minimal, or none at all, and certainly not undue. The Federal Circuit's conclusion that "substantial time and effort" would be needed to reach the full scope of the claims is simply the result of its consideration of the *Wands* factors, consistent with 170 years of this Court's case law.

B. Amgen's Alternative Standard Would Effectively Overturn This Court's Enablement Precedents and Vitiate Full Scope Enablement.

Amgen invents an alternative standard that it claims is based on the statutory text. Pet. Br. 22, 45. But that test would gut full scope enablement and—in the words Amgen used to describe the Federal Circuit's full scope test—"radically alter" (Pet. C.A. Supp. Br. 11) the standard embodied in this Court's enablement precedents.

Amgen's test in actual application is difficult to pin down—it asserts that the test would be satisfied if the disclosure "enables an artist skilled in the art to make the thing," Pet. Br. 34; "is sufficient to enable one skilled in the art to practice the invention," Pet. Br. 35; or "[is] sufficiently robust to permit skilled artisans to practice claims as needed, without resort to undue experimentation," Pet. Br. 41. As specifically applied to the claims here, Amgen argues that enablement is satisfied because "following the patents' roadmap": (1) "produces claimed antibodies every time," and (2) "could produce all antibodies within the claims." Pet. Br. 3; see also Pet. Br. 17, 25 (same).

Neither of those statements satisfies this Court's enablement test.

As to the first, consistent production of claimed antibodies does not demonstrate enablement of the full scope of a claim if the embodiments that can be produced "every time" represent only a subset of the claim scope. Here, the record evidence was that "every time" Amgen's roadmap was followed in the specification, only a fraction of the claim scope was represented by the antibodies thus generated. Pet. App. 13a & n.1.

As to the second proposition, the factual findings were otherwise: there was no evidence that following the roadmap produced all antibodies within the claims, with the Federal Circuit characterizing Amgen's evidence as conclusory in this regard. Pet. App. 13a ("[W]e note here the conspicuous absence of nonconclusory evidence that the full scope of the broad claims can predictably be generated by the described methods. Instead, we have evidence only that a small subset of examples of antibodies can predictably be generated."). The district court held, based on the testimony of Amgen's expert, that it was "unlikely" that a broad category of embodiments within the genus could be made by following the roadmap. Pet. App. 30a-31a.[6]

For these reasons, Amgen's proposed approach would require abandonment of the enablement principles embodied in a long line of this Court's precedents.

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[6] The existence of those non-working embodiments undermines Amgen's assertion that respondents "failed to identify a single actual embodiment within the claims that could not be made quickly and easily by following the patents' teachings." Pet. 10.

IV. Diluting the Full Scope Enablement Standard Will Open the Door to Overbroad High Tech Patents That Deter Innovation.

Although this case arises in the biotechnology context, the Court's decision will apply across the board. In the high tech sector, the current enablement standard has been an essential tool for policing examination and invalidating illegitimate functional genus patents. The watered-down enablement standard advocated by Amgen will open the door to lawsuits by non-practicing entities based on extremely broad patents that otherwise would be invalidated. That will impose significant burdens on the innovation that drives the U.S. economy.

A. The Full Scope Enablement Standard Is a Valuable Tool for Weeding Out Overbroad High Tech Patents.

The long-established enablement standard requiring patentees to enable embodiments commensurate with the full scope of a claim has provided a consistent check on overbroad claims across technologies and industries.

In the electrical and mechanical arts, as well as life sciences, courts have invoked § 112(a) in enforcing the quid pro quo of the patent bargain to ensure that inventors do not claim more than the invention as disclosed. See *Nat'l Recovery Tech.* v. *Magnetic Separation Sys., Inc.,* 166 F.3d 1190, 1196-97 (Fed. Cir. 1999) ("In order to satisfy the enablement requirement of § 112, paragraph 1, the specification must enable one of ordinary skill in the art to practice the *claimed* invention without undue experimentation.").

For example, in *MagSil Corp.* v. *Hitachi Glob. Storage Techs., Inc.,* which involved the production of sensors for computer storage devices that rely on changes in electrical resistance, the patent broadly claimed a method for achieving an unlimited numerical range in resistance (from "at least 10% up to infinity"). 687 F.3d 1377, 1381-82 (Fed. Cir. 2012). The specification disclosed that the inventors achieved changes in resistance of 11.8%—an improvement over the prior art—but only a small subset of the broad, open-ended claimed range. *Ibid.* On this disclosure and the testimony of the expert witnesses, the court found it would require undue experimentation to reach the full scope of the claim. It stated that "[t]he specification * * * does not contain sufficient disclosure to present even a remote possibility that an ordinarily skilled artisan could have achieved the modern dimensions of this art." *Id.* at 1382.

This is just one of numerous cases in which courts have struck down overbroad claims by applying the Federal Court's enablement standard—in particular, the *Wands* factors—where embodiments could not be made or used without undue experimentation. See, *e.g., Trustees of Boston Univ.* v. *Everlight Elecs. Co.,* 896 F.3d 1357, 1364 (Fed. Cir. 2018) (court invalidated claim to a semiconductor device that encompassed a genus of six different embodiments for failing to enable one of ordinary skill in the art to practice the "full scope" of the invention, where only five permutations were taught and the sixth permutation would have required undue experimentation); *Auto. Techs. Int'l, Inc.* v. *BMW of N. Am., Inc.,* 501 F.3d 1274, 1283 (Fed. Cir. 2007) (claims construed to cover both mechanical and electronic automotive sensors held invalid where the specification did not enable the full

scope of the invention because it did not enable electronic sensors and it was "insufficient to merely state that known technologies can be used to create an electronic sensor."); *Sitrick* v. *Dreamworks, LLC*, 516 F.3d 993 (Fed. Cir. 2008) (broad claims relating to integrating a user's audio signal or visual image into video games and movies invalidated where the court found the full scope of the claims not enabled as the disclosure describes only how the technology works in a video game setting); *Liebel-Flarsheim Co.* v. *Medrad, Inc.,* 481 F.3d 1371, 1380 (Fed. Cir. 2007) (court rejected patentee's claim that disclosure of a single embodiment can enable a broad claim in the predictable arts, finding that "disclosure of an injector system with a pressure jacket does not permit one skilled in the art to make and use the invention as broadly as it was claimed, including without a pressure jacket.").

The dilution of the existing enablement standard would therefore have significant adverse consequences in industries beyond the chemical and pharmaceutical arts. Innovator companies would lose a valuable tool in thwarting overbroad claims and experience uncertainty in bringing new products and technologies to market, as they would likely face broad claims lacking in readily discernible boundaries and untethered to the scope of the invention.

B. Functional Patent Claiming in the High Tech Field Has Led to a Blight of Overbroad Software Patents and Business-Driven Litigation That Ultimately Stifles Innovation.

The concern about the impact of a diluted enablement standard is not theoretical. The high-tech sector already is plagued by broad functional genus claims—

patents where the metes and bounds are unknown because they cover anything that performs the function. *Swinehart,* 439 F.2d at 213 ("'Functional' terminology may render a claim quite broad. By its own literal terms a claim employing such language covers *any and all* embodiments which perform the recited function.") (emphasis added).

Functional claims have presented a particularly serious threat to innovation in the software field—where companies that bring products to market face growing litigation, including claims by non-practicing entities.[7] As Professor Lemley has observed, "[s]oftware patent lawyers are increasingly writing patent claims in broad functional terms. Put another way, patentees claim to own not a particular machine, or even a particular series of steps for achieving a goal, but the goal itself. The resulting overbroad patents overlap and create patent thickets." Lemley 2013, at 905.

Innovative companies, facing a plague of broad functional patent claims, find themselves expending resources fighting costly infringement suits, rather than innovating.[8] Among the resulting problems these

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[7] A study of patent litigations estimated that 100% of NPE-asserted software patents and 50% of non-NPE-asserted software patents utilized functional patent claiming. Colleen V. Chien and Aashish R. Karkhanis, *Functional Claiming and Software Patents* (Santa Clara Univ., Working Paper No. 06-13, 2013), https://ssrn.com/abstract=2215867.

[8] The high tech industry experiences the highest volume of patent disputes in district courts and the Patent Trial and Appeal Board. Approximately 60% of those disputes relate to assertions by non-practicing entities. Unified Patents, *2022 Patent Dispute Report* (Jan. 5, 2023) https://www.unifiedpatents.com/insights/2023/1/4/2022-patent-dispute-report.

companies face is that broad functional claims leave defendants with little to argue as non-infringing, because everything that works necessarily infringes.

In the past decade, in response to a growing problem of litigations instituted quite often by NPEs seeking to enforce broad, functional software patent claims, federal officials undertook several executive actions "to help bring about greater transparency to the patent system and level the playing field for innovators." *Fact Sheet: White House Task Force on High-Tech Patent Issues* (Jun. 4, 2013), https://obamawhitehouse.archives.gov/the-press-office/2013/06/04/fact-sheet-white-house-task-force-high-tech-patent-issues. They recognized that "stakeholders remain concerned about patents with overly broad claims—particularly in the context of software," including those that use functional language to describe inventions in high-tech fields. *Ibid.*

Several initiatives were adopted that were aimed at encouraging innovation and strengthening the "quality and accessibility of the patent system" including the implementation of a training program to help patent examiners "scrutinize" and "tighten" functional limitations with the hope that claims with clearly defined boundaries would help to avoid costly and needless litigation. *See* U.S. PTO, *USPTO-led Executive Actions on High Tech Patent Issues* (Nov. 2, 2022), https://www.uspto.gov/patents/initiatives/uspto-led-executive-actions-high-tech-patent-issues.

As part of this reform, the U.S. Patent Office developed and implemented training materials for "Electrical/Mechanical and Computer/Software-relating Claims" outlining the enablement requirement of Section 112(a), focusing on evaluating functional

claims and improving examination consistency and the clarity of the examination record. *See* U.S. PTO, *Examining Claims for Compliance with 35 U.S.C. 112(a): Part II – Enablement* (Aug. 2015) (Examining Claims), http://www.uspto.gov/sites/default/files/documents/uspto_112a_part2_aug2015.pptx. Specifically, the Patent Office focused on training examiners around the "critical inquiry" of whether the specification provides "enough information so that one of ordinary skill in the art can make and/or use the **full scope** of the claimed invention without 'undue experimentation.'" *Id.* at 3 (citing Manual of Patent Examining Procedure (MPEP) 2160.01, 2164.01, 2164.05). The guidance warns examiners that when functional language is used such that "the claim may cover all devices for/ways of performing the claimed function," that "raises a concern regarding whether the scope of enablement provided by the disclosure is commensurate with the scope of protection sought by the claim." *Id.* at 7 (citing MPEP 2161.01(III)).

The training provides the examiners with an example based on the facts of the *MagSil* decision—demonstrating by an application of the *Wands* factors to the patent claims that there was "no showing that the knowledge of a person of skill in the art at the time of filing would have been able to achieve resistive changes in values that greatly exceed 10% without undue experimentation." Examining Claims 12 (citing MPEP 2164.04). In essence, "the disclosed example does not bear a reasonable correlation to the full scope of the claim" and therefore, there is a lack of enablement under § 112(a). *Ibid.*

That Patent Office guidance—and the process that generated it—further demonstrates the importance of maintaining the current enablement

standard. Broad functional claiming undermines the fundamental balance of the patent bargain by permitting patentees to draft overbroad, unsupported claims that sweep in all manners for achieving a result that patentees did not invent. The ultimate goal of the asserted functional claims is to preempt future innovation as broadly as possible and well beyond the actual contribution of the inventors. If such claims are allowed to issue, they must be subject to the rigorous scrutiny applied through the existing enablement standard.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

JONATHAN STROUD
ASHRAF A. FAWZY
Unified Patents LLC
4445 Willard Avenue
Suite 600
Chevy Chase, MD 20815
(202) 805-8931

LISA M. FERRI
Counsel of Record
RICHARD J. MCCORMICK
Mayer Brown LLP
1221 Avenue of the Americas
New York, NY 10020
(212) 506-2500
lferri@mayerbrown.com
ANDREW J. PINCUS
Mayer Brown LLP
1999 K Street, NW
Washington, DC 20006
(202) 263-3000

Counsel for Amicus Curiae

February 2023