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 NATIONAL ASSOCIATION OF PATENT PRACTITIONERS, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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INTEREST OF AMICUS CURIAE

Amicus National Association of Patent Practitioners (NAPP) is a professional organization representing hundreds of patent attorneys and patent agents across the country who specialize in patent practice before the United States Patent and Trademark Office (USPTO).[1] NAPP focuses on supporting practitioners who draft and prosecute patent applications. As such, NAPP members are frequent users of the United States patent system and highly knowledgeable about U.S. patent matters. The bulk of NAPP's members represent startups, small businesses, and individual inventors before the USPTO. Therefore, NAPP offers insights from a perspective that may not be well-represented otherwise.

NAPP is concerned the Federal Circuit's reasoning in this case leaves patent practitioners guessing about how to advise client-inventors regarding the extent of disclosure required in patent applications to satisfy the court-established standards for enablement under 35 U.S.C. § 112(a). The decision suggests inventors must describe or delineate all or an unreasonably large number of species covered by a genus, at least in certain scenarios —even if that number is astronomical. NAPP is also concerned about Federal Circuit's reasoning spilling over to fields of technology outside of pharmaceuticals, to the detriment of the entire patent system.

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[1] *Amicus* certifies that no person other than the *amicus*, its members, and its counsel (who are members of *amicus*), and no party or counsel for any party, authored this brief in whole or in part or made such a monetary contribution to the preparation or submission of the brief.

Amicus has no personal interest in the outcome of this litigation and instead is writing to share its perspective on the question presented and the impact this decision may have on NAPP's members and their clients. All parties have consented to the filing of this brief.

SUMMARY OF ARGUMENT

NAPP agrees with Amgen's merits brief and with the *amici* brief, cosigned by a host of law professors led by Professor Mark Lemley and based on careful scholarship,[2] both of which conclude the Federal Circuit has deviated too far from established Supreme Court and lower court precedent on the statutory requirement for a patent to enable the public to practice an invention. 35 U.S.C. § 112(a). NAPP considers the "reach the full scope" standard endorsed by the Federal Circuit in this case as unworkable.

To be sure, NAPP agrees patent claims must always be enabled, as required by the statute. *Id.* But NAPP agrees with Amgen and the law professors' brief that the Federal Circuit goes too far by specifying exceptionally high barriers for inventors to satisfy the requirement.[3] For similar reasons, NAPP views the Federal Circuit's "full

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[2] Dmitry Karshtedt, Mark A. Lemley & Sean B. Seymore, *The Death of the Genus Claim*, 35 HARV. J.L. & TECH. 1 (2021), https://ssrn.com/abstract=3668014; Mark A. Lemley & Jacob S. Sherkow, *The Antibody Patent Paradox*, 132 YALE L.J. (forthcoming 2023), https://ssrn.com/abstract=4032912.

[3] To be precise, this brief uses the phrase "reach the full scope" to describe the Federal Circuit's more burdensome requirement, as exemplified by the court's reasoning in the decision below, in distinction from the general statutory requirement for a patent specification to enable its claims.

scope" terminology as unhelpful to the enablement analysis.

NAPP submits this amicus brief separate from the law professors in part because the law professors' brief focuses on how the Federal Circuit's body of case law impacts pharmaceutical patents, whereas NAPP is concerned such case law can disrupt the entire patent system by spilling over to other fields of invention, such as software, mechanical, electrical, and chemical. Careful reading of the Federal Circuit's decision suggests its holding is not limited to pharmaceutical patents. Instead, the Federal Circuit's opinion purports to address functional claiming—which can be used in all technical fields, even outside of the pharmaceutical context. More generally, NAPP is concerned the Federal Circuit's "reach the full scope" terminology will not be limited to just "genus" claims and will not be limited to just "functional" claims. For the reasons discussed below, the terms "genus claims" and "functional claims" have limited usefulness. In all, NAPP has concerns that the Federal Circuit's heightened enablement standard in this case will negatively impact the patent system as a whole, creating uncertainty for inventors to obtain adequate patent protection and reducing the incentive for inventors to disclose their discoveries publicly by filing patent applications.

Several important considerations undermine the Federal Circuit's decision. First, the Federal Circuit's opinion demands more than the statute adopted by Congress, 35 U.S.C. § 112(a), as interpreted by this Court and by lower courts for nearly two centuries. Second, the Federal Circuit decision allows for mischief by patent infringers. The Federal Circuit decision raises the specter of patent infringers

avoiding the consequences of infringement by conjuring hypothetical examples (*i.e.*, species) the infringers allege are not enabled—yet such examples can always be imagined for any patent claim. NAPP also disagrees that the public policy concerns advanced by Respondents and supporting *amici* actually justify the Federal Circuit's decision.

NAPP recommends solving these problems by returning to a standard of reasonableness, which this Court and other lower courts repeatedly emphasize, both in the enablement context and in patent law generally. To the extent any concerns regarding the enablement of functional claim language remain, the Patent Act contains other provisions that ameliorate those concerns.

ARGUMENT

I. The Federal Circuit's "reach the full scope" test is unworkable

The Federal Circuit's recent case law on enablement creates a risk of under-patenting in the United States—*i.e.*, a level of patenting that is lower than socially optimal. If the standard for enablement is too high, then inventions become vulnerable to copying without the armor of patent protection. An enablement standard that is unduly burdensome on inventors also diminishes the incentive for inventors to disclose their inventions, thereby driving these inventors to suppress their inventions through trade secrets—the opposite of what the Founders envisioned in the Patents Clause of the Constitution.[4]

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[4] U.S. Const. art. 1, § 8, cl. 8. This clause has provided the traditional basis for patent and copyright law in the United

NAPP agrees with the conclusions of Amgen and the law professors' brief that the Federal Circuit has gone too far with its enablement case law. As discussed further below, NAPP is especially concerned because the Federal Circuit's reasoning can extend to other technical fields—such as mechanical, electrical, and computing technologies—outside of the pharmaceutical context in which this case arose.[5]

The Federal Circuit's "reach the full scope" test is unworkable because (1) every patent claim arguably defines a "genus"; (2) the fact pattern represented here, in which theoretical embodiments disconnected from practical reality are leveraged by patent infringers to try to escape liability, are problematic from a policy perspective; and (3) the Federal Circuit contains two irreconcilable lines of authority.

1. Although the decision below and the law professors' brief focus on "genus" claims for pharmaceuticals, every patent claim specifies a genus.[6] There are several reasons for this conclusion.

States, which encourage publication. In contrast, trade secrets are traditionally based in state law, and the recent federal Defend Trade Secrets Act, 18 U.S.C. §§ 1839 et seq., appears to be based in the Commerce Clause rather than the Patents Clause. Marina Lao, *Federalizing Trade Secrets Law in an Information Economy*, 59 OHIO ST. L.J. 1633 (1998).

[5] The Federal Circuit opinion has no clear statement limiting its heightened "reach the full scope" standard from infecting other areas of technology covered by the patent system.

[6] The law professors allude to this point briefly without elaborating. *Death of the Genus Claim*, *supra* note 2, at 13, n.70 ("Lefstin argues that most claims are genus claims.") (*citing* Jeffrey A. Lefstin, *The Formal Structure of Patent Law and the Limits of Enablement*, 23 BERKELEY TECH L.J., 1141, 1168 (2008)).

First, the United States adopted a policy of peripheral claiming as distinct from the central claiming of earlier eras. Peripheral claiming defines the scope of protection of a patent strictly based on the language of a claim, whereas in central claiming, a claim defines the center of the invention based on disclosed examples, and the scope of protection depends on what the court determines to be the inventor's contribution to the art.[7] Accordingly, every modern patent claim defines a peripheral boundary—analogous to a fence—that encompasses a set of "embodiments" within that boundary. Because the number of points within such a boundary is unlimited, all patent claims are, therefore, "genus" claims covering a large number of species.

Claims can even be viewed as covering an infinite number of species. Most patent claims are "open-ended," where the scope of protection is defined by a list of included elements, but additions are not precluded. For example, a claim reciting "a car comprising at least four wheels" covers four wheels, five wheels, six wheels, and so on indefinitely. And patent claims in the U.S. have been structured this way for many decades, at least since the adoption of peripheral claiming.[8]

Indeed, a "plurality," which is a term of art used in many patents, denotes "two or more," so again using such a word covers an infinite number of embodiments. For example, an engine containing a

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[7] 1 Anthony W. Deller, PATENT CLAIMS § 5 (Lawyers Coop. 2d ed. 1971) (analyzing the chief difference between central claiming and peripheral claiming).

[8] J. Jonas Anderson & Peter S. Menell, *Informal Deference: A Historical, Empirical, and Normative Analysis of Patent Claim Construction*, 108 NW. U.L. REV. 1, 8-15 (2014).

"plurality of cylinders" covers two, four, eight, sixteen, or a thousand cylinders (any more than one).

It is unreasonable to expect inventors to disclose how to make and use every species within a giant or infinite set of embodiments.[9] Here, for example, Amgen reasonably disclosed not only 26 teaching examples but also a roadmap for making and using any remaining covered embodiments. NAPP strongly supports an enablement standard that allows the common practice of teaching by example.

Second, a patent claim outlines a genus because all patent claims are written in human language, which this Court recognizes inherently contains certain ambiguities.[10] For example, every English common noun defines a category that necessarily covers a large set of theoretical instances. As another example, the word "screwdriver" seems well-defined, but that word covers all instances of screwdrivers—both past and future—including Phillips head,

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[9] Generally, patents, as directed to those of skill in the art, need not explain more than enough for an artisan to understand how to make other alternatives. *E.g.*, *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003) ("That is not to say that the specification itself must necessarily describe how to make and use every possible variant of the claimed invention, for the 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.").

[10] *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002) (stating "[u]nfortunately, the nature of language makes it impossible to capture the essence of a thing in a patent application"). *See also Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014) (recognizing that the definiteness requirement must take into account the inherent limitations of language).

powered, angled, spanners, hex, torque, etc. It is unreasonable to expect inventors to disclose how to make and use every example within such a set.

Third, the large or infinite nature of instances covered by patent claims is reinforced by the common use of the signal "comprising," found in the preamble of most patent claims. That signal denotes a claim covering a combination of features X, Y, and Z, for example, as covering not just instances that include all three of those features only but also instances that include the recited features *and also* any further features that are unrecited. For example, a claim to a "car comprising a tire and a body" is infringed by a car with a tire, a body, *and also* a steering wheel. Again, because the set of such cars with non-recited features is large, all "comprising" claims define a genus covering many species, and it is unreasonable to demand that inventors describe or delineate every example within the genus.

Fourth, after a patent grant, technology continues to advance, and patent claims can therefore encompass later improvements. An advance within the scope of an earlier patent, which is unforeseeable at the time of filing the earlier patent application, cannot reasonably be described in that application. Indeed, this Court has previously reversed the Federal Circuit based in part on recognizing that inventors cannot reasonably be expected to foresee every technological advance because:

> The equivalent may have been unforeseeable at the time of the application; the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question; or there may be some

> other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question.

Festo, 535 U.S. at 740. As in *Festo*, the Federal Circuit below has placed an inflexible rule on American inventors that they "could not reasonably be expected" to satisfy.

In combination, the aspects of patent claims listed above (*i.e.*, peripheral claiming, the ambiguity of human language, the signal "comprising," and the inevitability of future advances) ensure that all patent claims can be considered "genus" claims. From this perspective, the term "genus claim" has limited utility, and there is a risk that the Federal Circuit's "reach the full scope" analysis not only detracts from important incentives to produce pharmaceuticals and advance biotechnology but also infects innovation in other technology areas, as inventors rely on "genus claims" ubiquitously.

2. NAPP is further concerned about the Federal Circuit's decision here having invalidated Amgen's claims based on hypothetical species that nobody—Amgen, Sanofi, Aventis, Regeneron, nor anyone else—has ever made or used. Respondents have conjured up these species and accused Amgen of not enabling them simply as a defense to liability for their admitted infringement. Policy concerns expressed by Respondents do not apply to allegations of non-enablement of phantom species.

Such fanciful concerns distinguish this case from other enablement fact patterns where enablement concerns can have more force. For example, some enablement fact patterns address scenarios where

the entire scope of the claim is allegedly non-enabled (e.g., a claim to a time machine). Other enablement fact patterns address scenarios where the patent describes multiple different embodiments, but none of them actually works. Such scenarios but do not apply here.[11] On the contrary, NAPP is concerned the Federal Circuit's analysis of the fact pattern here—allegations of non-enablement of phantom species, disconnected from practical reality—poses an unreasonable burden for inventors.

The Federal Circuit's decision here creates a risk of mischief because, within the large or infinite set of examples covered by a patent claim, a patent challenger can always conjure a hypothetical species that is arguably not enabled. An enablement standard that always permits an infringer to attack an asserted patent based on hypothetical and imagined species is unworkable.

3. Moreover, the deviation from this Court's precedents effectively creates two divided lines of case law: the earlier settled precedent of this Court and lower courts and the test articulated by the Federal Circuit below. The problem is well recognized.[12] One line of Federal Circuit cases holds that one enabled embodiment, or a sufficient number of embodiments united by a common scientific principle, suffices for enablement.[13] In contrast, the

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[11] Jason Rantanen, *The Doctrinal Structure of Patent Law's Enablement Requirement*, 69 VAND. L. REV. 1679 (2016) (discussing different types of enablement fact patterns).

[12] *Id.* at 1685-94 (summarizing doctrinal split). Although this article summarizes the allegations of two divided lines of case law, NAPP does not endorse the author's proposed solution to that problem.

[13] *Id.* at 1685-87.

other line of cases uses the "reach the full scope" analysis to heighten the standard for enablement, as in this case.[14] The general experience of NAPP practitioners is that examiners and USPTO administrative patent judges[15] now lack guidance about which line of case law to follow—and can arbitrarily or unpredictably choose between them to the detriment of American innovation.

II. This Court can resolve the policy problems resulting from the Federal Circuit's decision by restoring the standard of reasonableness this Court and lower courts traditionally apply to the statutory text

The solution to the problems identified by the petition, and outlined in this brief, is restoring a standard of reasonableness to enablement law. We start with the statutory text that Congress chose, which has remained essentially the same since the Patent Act of 1790.[16] Today, 35 U.S.C. § 112(a) only

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[14] *Id.* at 1687-98.

[15] Administrative patent judges sit in panels of three to hear administrative appeals within the Patent Office. 35 U.S.C. § 6.

[16] The Federal Circuit provided an overview of the earliest statutory text for enablement:

> The very first patent act required that letters patent "describ[e] the said invention or discovery, clearly, truly, and fully." Act of Apr. 10, 1790, ch. 7, § 1, 1 Stat. 109. The applicant for a patent was at the time required to submit "a specification in writing, containing a description ... of the thing or things by him or them invented or discovered, ... which specification shall be so particular ... as ... to distinguish the invention or discovery from other things before known and used." *Id.* § 2.

requires that the patent specification contain "such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use" the claimed invention. That statutory language does not contain—or even suggest—the "reach the full scope" test the Federal Circuit used in its decision. The Federal Circuit did not attempt to ground its test in the statutory language, and its decision warps the statutory phrase "full … *terms* as to enable" into a "reach the full *scope*" test for enablement.

For nearly two centuries, this Court has interpreted the statutory text to impose only a reasonable burden upon inventors. As Amgen and supporting *amici* explain at length, this Court already held "[i]t is enough if [the patentee] describes his method with sufficient clearness and precision to enable those skilled in the matter to understand what the process is, and if he points out some practicable way of putting it into operation." *The Telephone Cases*, 126 U.S. 1, 536 (1888). A patent's disclosure, the Court has stated, "satisfies the law" if it is "sufficiently definite to guide those skilled in the art to" the "successful application" of "the invention." *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261, 271 (1916). That Court recognized the precise difficulty that concerns NAPP of describing all embodiments, stating, "The composition of ores varies infinitely, each one presenting its special problem, and it is obviously impossible to specify in a patent the precise treatment which would be most successful and economical in each case." *Id.*

Markman v. Westview Instruments, Inc., 52 F.3d 967, 996 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996).

Similarly, this Court has clarified that "[p]erhaps [an inventive] process is susceptible of being applied in many modes and by the use of many forms of apparatus [yet] [t]he inventor is not bound to describe them all in order to secure to himself the exclusive right to the process, if he is really its inventor or discoverer." *Tilghman v. Proctor*, 102 U.S. 707, 728-29 (1880).[17] Such decisions captured an important policy insight: The standard for enablement should not be overly burdensome and does not require the inventor to enumerate all species, particularly when the number of species is large. Instead, a standard of reasonableness should prevail.

Consistent with this Court's precedents, lower courts traditionally apply a standard of reasonableness when evaluating enablement. Long before the Federal Circuit rendered its decision here, that same court held:

> Enablement is not precluded by the necessity for some experimentation such as routine screening [...,] [and] [t]he determination of what constitutes undue experimentation in a given case requires the *application of a standard of reasonableness*, having due regard for the nature of the invention and the state of the art.

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[17] Earlier cases do not necessarily distinguish between the modern patent doctrines of utility, enablement, obviousness, and patentable subject matter, but such developments should not obscure this Court's emphasis on a reasonable enablement standard. *See*, *e.g.*, Mark A. Lemley, *The Fractioning of Patent Law*, INTELLECTUAL PROPERTY AND THE COMMON LAW 504, 504–06 (Shyamkrishna Balganesh ed., Cambridge Univ. Press 2013).

In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988) (emphasis added). This Court agrees. *Minerals Separation*, 242 U.S. at 270 (rejecting argument for invalidity because "when different ores are treated preliminary tests must be made to determine the amount of oil and the extent of agitation necessary in order to obtain the best results" because "the certainty which the law requires in patents is not greater than is reasonable, having regard to their subject-matter").

Thus, American patent law historically emphasizes reasonableness when evaluating enablement. Inventors are not permitted to disclose so little as to force skilled artisans to engage in unreasonable amounts of experimentation to practice an invention. For the same policy reasons, the law should not require inventors to provide an enabling disclosure beyond the bounds of reasonableness.

The Federal Circuit decision below deviates from settled Supreme Court and earlier Federal Circuit precedent by faulting Amgen for an amount of experimentation that, according to the district court, "would take a substantial amount of time and effort" in order to make all embodiments within the scope of the claims, one by one.[18] This is a key error in the decision below. "Substantial amount of time and effort" to make all variations of the claimed invention has never been the standard in the United States; rather the standard is whether an artisan's effort to make a desired embodiment following the patent's roadmap would be "undue" or "unreasonable." *Wands*, 858 F.2d at 737. When a patent teaches a

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[18] *Amgen Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080, 1088 (Fed. Cir. 2021).

skilled artisan—whether by example or not—how to practice any embodiment within the scope of a claim, then the fact that the artisan would take significant time or effort to make every single embodiment within the scope of a claim, one after another, should be irrelevant.

Enablement is not the only area of this Court's patent jurisprudence that employs a reasonableness standard. The enablement holding below also flouts the expectation of reasonableness found in this Court's decisions on other patent-law issues such as claim clarity and construction. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014) (reversing Federal Circuit because claim definiteness should be evaluated according to a reasonableness standard); *Cuozzo Speed Technologies, LLC v. Lee*, 579 U.S. 261 (2016) (approving reasonableness standard in claim construction at the USPTO). More generally, "[r]easonableness standards permeate the law."[19]

Respondents' assertion that Petitioner's disclosure is not reasonable is undercut by Respondents' own response to the petition for certiorari, where they argue that the asserted claims "cover … a vast scope of possible antibodies," reaching "millions" if not "an astronomically large number" of antibodies, and that these claims are not enabled because making and using every single one of those embodiments would

[19] Cynthia Lee, *Reasonableness with Teeth: The Future of Fourth Amendment Reasonableness Analysis*, 81 MISS. L.J. 1133 (2012).

be "an enormous amount of work" and not "practical."[20]

Respondents' position places undesirably high barriers to entering the patent system. Rather than racing to the USPTO to seek patent protection for life-saving medicine, Respondents envision a patent system that first requires inventors to identify individually all possible embodiments, and even "test" them, then presumably to describe them all in the patent application, even if there are an "astronomically large number of" embodiments, reaching into the "millions." Respondents are not deterred by the fact that this would be "impractical" or an "enormous amount of work" or that "no antibody scientist would even contemplate" trying to test all such embodiments. *Id*. Such a barrier to patenting exceeds the requirement of reasonably teaching how to make and use an invention.

The American patent system historically incentivizes the "Progress of Science and useful Arts" through a virtuous race to the USPTO to disclose new inventions and "Discoveries." U.S. Const., art. I, § 8, cl. 8. Because NAPP's members specialize in the preparing and filing of patent applications, NAPP appreciates the importance of filing patent applications *promptly* after recognizing an invention.[21] Requiring inventors to explore all territory within the bounds of a patent claim, so as to meet the Federal Circuit's "reach the full scope" test, would either delay patent application filings or

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[20] Resp't Br. in Opp'n to Pet. for Writ of Cert., at 9 (March 14, 2022).

[21] *See also* Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (2011) (changing to a "first to file" system that encourages this race to the Patent Office).

discourage inventors from filing for a patent at all, thus undermining the Constitutional and Congressional incentives, namely to encourage public disclosure of inventions to promote technological progress in exchange for teaching "the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112(a).

A test requiring inventors to articulate a plethora of likely cumulative examples within the scope of their inventions would dramatically increase costs (both for research and for fees charged for drafting applications). Also, the resulting uncertainty about when to file further undermines the incentive to innovate. Patent practitioners like NAPP members expect difficulty balancing between recommending their client include more and more examples, to reduce the uncertainty about how much the courts will require to support what could be considered a broad invention, against the risk of a competitor filing first but disclosing only a single embodiment within the scope of the invention, thus blocking a first inventor from getting patent protection on the category.

NAPP urges this Court to restore a reasonableness standard of enablement that encourages inventors to file patent applications for life-saving medicines or other valuable inventions, and to file such applications sooner rather than later.

Indeed, leading historians and a former USPTO agency head have confirmed that the Founding Fathers deliberately lowered barriers to entering the

patent system.[22] These authors confirm that the Founding Fathers "quite self-consciously" designed a patent system that could do what no other had done before" by lowering barriers to entry in numerous ways—including eliminating the requirement to actually practice the patent—rather than raising barriers as Respondents now suggest:

> The Founders had studied the British patent system and knew that patent fees there were 11 times the per capita income of the average citizen, and that patent holders were required to "work" their patents, i.e., manufacture products from their inventions. [...] Therefore, according to the historians Naomi Lamoreaux at Yale and the late Kenneth Sokoloff of UCLA, the Founders "quite self-consciously" designed a patent system that could do what no other had done before, stimulate the inventive genius and entrepreneurial energy of the common man. [...] The low patent fees, lack of working requirements, and ability to license patent rights turned inventing into a new income-earning career path for thousands of poor but technically creative citizens. Whereas most of Britain's few hundred inventors came from wealth and privilege, the vast majority of America's many thousands of inventors came from humble beginnings.

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[22] Forbes Leadership Forum, *Thank the founding fathers for the open market in patents* (Forbes 2013), https://www.forbes.com/sites/forbesleadershipforum/2013/09/17/thank-the-founding-fathers-for-the-open-market-in-patents/?sh=2247999f220a (last visited Dec. 19, 2022).

Just as the Founding Fathers eliminated an overly burdensome requirement to practice the invention, thus helping to unleash centuries of American technological dominance, so too NAPP urges this Court to reject the Federal Circuit's requirement for inventors to individually test and describe (in Respondents' words in the response to petition for certiorari) an "astronomically large number of antibodies," to "reach the full scope" of a patent claim.

Maintaining the lower but reasonable barriers to the patent system established by the Founders also furthers the democratic ideals of this nation. Some of the technology giants of today, such as Google, Apple, and Amazon, grew into economic powerhouses from "humble beginnings," like the American inventors earlier in the last century.[23] Google, Apple, and Amazon all started in a founder's garage. These giants were all protected in part by patents in their infancy—when they were most vulnerable.[24] NAPP urges this Court to restore a standard of reasonableness to enablement law that will help protect the "next Google," which remains vulnerable in a garage somewhere today.

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[23] *Id.*

[24] *See*, for example, U.S. Patent No. 7,058,628 (issued Jun. 6, 2006) (Google PageRank algorithm); U.S. Patent No. 4,136,359 (issued Jan. 23, 1979) (Apple II computer); U.S. Patent No. 5,960,411 (issued Sept. 28, 1999) (Amazon One-Click algorithm).

III. Other provisions of the Patent Act address any remaining concerns about non-enablement of functional claim language

As to the Federal Circuit's concerns about non-enablement of functional claim language, Congress already addressed such concerns in enacting the 1952 Patent Act, which balanced competing interests to calibrate the patent system.

First, there is no disfavored category of "functional claims." Almost a century ago, Congress addressed an enablement challenge that is essentially similar to the challenge here—and rejected it. Congress effectively overruled case law holding that inventors cannot claim inventions using functional language at the point of novelty.[25] Congress thus already considered the policy issues raised by functional claim language and addressed them in the Patent Act—without imposing the heightened burden that Respondents demand now.

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[25] Congress promulgated 35 U.S.C. § 112, sixth paragraph (now § 112(f)), in the 1952 Patent Act. Patent Act of July 19, 1952, Pub. L. No. 82-593, 66 Stat. 792 (codified as amended at 35 U.S.C. §§ 1-376). A purpose was "to statutorily overrule" the holding in *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946), which invalidated a functional claim based on the Court's concerns, similar to those of Respondents here, that other inventors might be "frightened from the course of experimentation by broad functional claims." *See In re Donaldson Co.*, 16 F.3d 1189, 1194 (Fed. Cir. 1994) (en banc) (§ 112(6) was enacted to overrule *Halliburton*). To be sure, no party asserts that Amgen's patent claims are governed by § 112(f), so Respondents' position in effect would extend the restrictions of § 112(f) to claims that are not subject to that paragraph.

Indeed, NAPP's members possess extensive experience with the USPTO's interpretation of case law in its Manual of Patent Examining Procedure (MPEP), which for decades confirms "[t]here is nothing inherently wrong with defining some part of an invention in functional terms."[26] This guidance creates reliance interests for inventors over the decades—yet Respondents' argument here effectively punishes Amgen for relying in part on that guidance. Indeed, the USPTO blessed the claim language in Amgen's patents by issuing the patents, and this Court presumes that their claims are valid.[27]

Second, the traditional safeguards against overbroad claims are the prior art statutes, 35 U.S.C. §§ 102 and 103. Those statutes ensure that inventions are new and nonobvious. The statutes thereby ensure that the public does not already possess any embodiment within the scope of the claims, which further supports the policy of rewarding inventors such as Amgen with patent protection for only a limited term in exchange for disclosing life-saving medicine to the world.

Third, the American patent system has a rich body of law interpreting the enablement statute that will

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[26] *See* Dept. of Commerce, Patent and Trademark Office, Manual of Patent Examining Procedure § 2173.05(g) (rev. 10, 9th ed. 2020), https://www.uspto.gov/web/offices/pac/mpep/index.html (*citing In re Swinehart*, 439 F.2d 210, 212 (C.C.P.A. 1971)). The quoted statement was introduced in the first revision of the sixth edition in September of 1995. *See* Dept. of Commerce, Patent and Trademark Office, Manual of Patent Examining Procedure § 2173.05(g) (rev. 1, 6th ed. 1995), https://www.uspto.gov/web/offices/pac/mpep/old/index.htm.

[27] 35 U.S.C. § 282 ("A patent shall be presumed valid."); *Microsoft Corp. v. i4i Ltd*. Partnership, 564 U.S. 91 (2011).

suffice to handle any overbreadth concerns. The seminal *In re Wands* decision,[28] for example, identified a flexible set of fourteen different criteria to consider when evaluating enablement. Although the Federal Circuit cited *Wands* throughout its decision below, the panel appears to have applied the factors in an inflexible way, and the panel's reasoning appears constrained by earlier Federal Circuit precedent on pharmaceutical genus claims.[29] In particular, the Federal Circuit appears to have superimposed a "reach the full scope" requirement on top of the more flexible standard of reasonableness that *Wands* established.

Lower courts repeatedly reject proposals for enablement standards that similarly exceed the reasonableness standard. In response to more aggressive demands for enabling disclosure, the United States patent system upholds patent claims even though the claims cover (i) unforeseen future improvements, *Catalina Marketing Intern. v. Coolsavings.com*, 289 F.3d 801, 810 (Fed. Cir. 2002), (ii) inoperable embodiments, *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577 (Fed. Cir. 1984), or (iii) multiple species that are not fully disclosed or described, *Regents of the Univ. of Cal. v. Eli Lilly*, 119 F.3d 1559, 1568 (Fed. Cir. 1997). Such decisions are consistent with the above discussion explaining several reasons why all patent claims constitute genera that cover large or infinite sets of embodiments that cannot reasonably be

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[28] *See* supra at 14.

[29] 987 F.3d at 1088 ("The facts of this case are thus more analogous to those in *Enzo, Wyeth,* and *Idenix,* where we concluded a lack of enablement.").

described in the manner that the Federal Circuit's decision requires.

CONCLUSION

This Court should reverse the Federal Circuit decision below and restore the earlier reasonableness standard for enablement, following the text of 35 U.S.C. § 112(a) requiring a patent specification teach those skilled in the art to "make and use" the claimed invention, rather than requiring a patent disclosure enable those skilled in the art "to reach the full scope of claimed embodiments" without undue experimentation—i.e., to cumulatively identify and make all or nearly all embodiments of the invention without substantial time and effort.

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