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 CHEMISTRY AND THE LAW DIVISION OF THE AMERICAN CHEMICAL SOCIETY AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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## INTEREST OF *AMICUS CURIAE*

The Chemistry and the Law Division ("CHAL") of the American Chemical Society ("ACS") comprises ACS members who profess an interest in and a professional practice that includes both chemistry and law.[1] Founded in 1876 and chartered by the U.S. Congress, ACS is one of the world's largest scientific organizations with membership of over 151,000 in 140 countries. Most of the members of CHAL are attorneys, and a majority of the attorney members of CHAL are patent attorneys. CHAL's purpose is to advance the understanding and application of the interrelationship of the science of chemistry and the relevant legal statutory, regulatory, and jurisprudential decisions. CHAL has no direct interest in the outcome of this appeal.

Nevertheless, this case addresses an issue of great importance to CHAL's members, who rely on a robust system of patent rights in their practice as patent attorneys. CHAL has over 2,000 members, and a significant number of those are patent attorneys who represent clients and/or their employers on pharmaceutical inventions. Clarifying the precedential effect of decisions from the United States Court of Appeals for the Federal Circuit, as well as

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[1] CHAL certifies that no party or party's counsel or person other than CHAL's members and counsel authored in whole or in part or contributed money that was intended to fund the preparation or submission of this brief. Counsel for all parties have filed blanket consents to the filing of any *amicus curiae* brief.

what is required under 35 U.S.C. § 112, is critically important to those who are members of CHAL and the Patent Bar to see that the patent laws are applied in such a way as to provide adequate incentives for innovation.

## SUMMARY OF ARGUMENT

The costs of research and development in the pharmaceutical and biotechnology fields are enormous, and the potential benefits—both to the innovators and those in need of that innovation—are at least equally large if not larger. Those working in these fields often utilize genus claims, an important feature of patent law that allows patentees to protect their inventions where competitors could otherwise evade infringement liability by making minor changes that otherwise do not depart from the heart of the claimed invention.

The substantial investment that research and development in the pharmaceutical and biotechnology fields demands must be encouraged through a robust and predictable patent system wherein innovators are properly compensated for their efforts. Only Congress—not the courts—has the authority to establish and modify patentability requirements. The enablement requirement described in 35 U.S.C. § 112(a) was carefully crafted to achieve the delicate balance of promoting innovation while maintaining the public's access to those inventions.

For decades, the Federal Circuit, the Court of Customs and Patent Appeals, and the United State Patent and Trademark Office have applied a flexible, case-specific enablement test focused on whether the patent disclosure required "undue experimentation." But the Federal Circuit's "full scope" test represents a significant departure from this established standard

that fundamentally alters the balance of incentives by creating an impractical and inefficient enablement requirement that cuts against the reliability of the patent system in a way that stifles innovation and forces an inefficient allocation of resources that harms potential inventors and the public at large. This Court should restore that balance, applying the enablement standard as Congress enacted.

## ARGUMENT

### I. The Federal Circuit's New "Full Scope" Test Is a Higher Bar Than What Congress Contemplated in 35 U.S.C. § 112(a).

#### A. Congress—not the courts—has the authority to set the requirements for patentability.

Section 8 of the United States Constitution provides, as relevant here, "The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8. One of the core tenants of our country is that *Congress* shall have the power to promote innovation and creativity through the patent system. Our founding fathers were clear that this power rests with Congress, not the courts. Congress has exercised this power through codification of Title 35, the Patent Act. In doing so, Congress has carefully crafted legislation explicitly defining the boundaries of patentability to achieve a delicate balance of promoting incentives while maintaining access to innovation. This Court should restore that balance, applying the enablement standard as Congress enacted.

### B. 35 U.S.C. § 112(a) requires a disclosure sufficient "to enable any person skilled in the art" to "make and use" the "invention."

The only appropriate requirements for patentability are those Congress enumerates. One of those is defined in 35 U.S.C. § 112(a). This statutory section provides that a patent specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

This Court has enunciated the plain meaning of § 112: a patent specification must provide a sufficient description of the invention "to enable any person skilled in the art to which it pertains" to "make and use" the invention. 35 U.S.C. § 112(a); *see, e.g.*, *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002) ("[T]he patent laws require inventors to describe their work in 'full, clear, concise, and exact terms,' 35 U.S.C. § 112, as part of the delicate balance the law attempts to maintain between inventors, who rely on the promise of the law to bring the invention forth, and the public, which should be encouraged to pursue innovations, creations, and new ideas beyond the inventor's exclusive rights."); *Minerals Separation, Ltd. v. Hyde*,

242 U.S. 261, 271 (1916); *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 908 (2014). But nowhere in the text of 35 U.S.C. § 112(a) or this Court's precedent is there a requirement that the specification equip a person of ordinary skill in the art ("POSA") to be capable of readily making and using *every* conceivable embodiment of a patent claim.

Congress even revisited 35 U.S.C. § 112 in the America Invents Act of 2011 and recodified the statute to keep the substance of § 112(a) unchanged from earlier versions. In reconsidering § 112, Congress chose to keep the text of the statute from the Patent Act of 1952, adding only paragraph enumerations. *Compare* Patent Act of 1952 § 112, 35 U.S.C. § 112 ¶ 1, (July 19, 1952) *with* 35 U.S.C. § 112(a). And implicitly, Congress endorsed the Federal Circuit's interpretation of the statute up through that recodification in 2011. *See Lorillard v. Pons*, 434 U.S. 575, 580 (1978) ("Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change."); *see also In re Wands*, 858 F.2d 731, 736–37 (Fed. Cir. 1988) (a claim is invalid for lack of enablement, if a person of ordinary skill in the art would not be able to practice the claimed invention without "undue experimentation," assessed by the multifactor factual test considering "(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."). But any different standard asserted after the passage of the AIA has not been endorsed by Congress and is not supported by the statute as Congress intended.

### C. The Federal Circuit's new "full scope" genus claim test is not supported by the precedent Congress endorsed in the America Invents Act.

The Federal Circuit has departed from Congress's intended meaning of the America Invents Act by adopting a heightened standard for genus claims under 35 U.S.C. § 112(a) that violates the canons of statutory construction and contradicts established judicial precedent. Genus claims—those that claim an invention covering multiple related species, typically with broad functionality—have long been accepted as an important part of the patent system. *See In re Kalm*, 378 F.2d 959, 963 (C.C.P.A. 1967) ("When one speaks of a 'genus' in the chemical arts, one ordinarily speaks of a group of compounds closely related both in structure and properties."). For genus claims, the Federal Circuit no longer asks whether a POSA can "make and use" the invention, as § 112(a) and this Court's precedents require.

Historically, the inquiry was whether a POSA could "make and use" the invention "without undue experimentation." *Wands*, 858 F.2d at 736

("Enablement is not precluded by the necessity for some experimentation such as routine screening."). In *Wands*, the Federal Circuit examined a genus claim covering an immunoassay method employing highly sensitive monoclonal antibodies capable of detecting a hepatitis B antigen. While the Federal Circuit concluded a POSA would engage in an extensive amount of experimentation to determine which would bind to the hepatitis B antigen, and further screening to select those with the claimed sensitivity, the Federal Circuit noted "there was a high level of skill in the art at the time when the application was filed, and all of the methods needed to practice the invention were well known." *Id.* at 740. Even though experimentation was required, it was spelled out in the specification or known in the art, and thus the claims were enabled. *Id.*; *see also Webster Loom Co. v. Higgins*, 105 U.S. 580, 586 (1881) ("That which is common and well known is as if it were written out in the patent and delineated in the drawings."); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986) ("[A] patent need not teach, and preferably omits, what is well known in the art.") (citation omitted).

But recently, the Federal Circuit has imposed a heightened "full scope" test, "pos[ing] high hurdles in fulfilling the enablement requirement for claims with broad functional language" evaluating if "'substantial time and effort' would be required to reach the *full scope* of claimed embodiments." *Amgen Inc. v. Sanofi*, 987 F.3d 1080, 1087–88 (Fed. Cir. 2021) (emphasis

added) (explaining "no reasonable jury could conclude under these facts that anything but 'substantial time and effort' would be required to reach the full scope of claimed embodiments" where a jury made the factual finding that a POSA would not require undue experimentation to make and use the claimed invention). This departs from the *Wands* precedent endorsed by Congress in the America Invents Act, which asks whether undue experimentation would be needed to make and use the invention. Instead, the Federal Circuit has substituted an inquiry into how long it would take a POSA to make and use every possible species and "know, without undue experimentation, which [embodiments] would be effective" within the claimed genus, regardless of whether that testing is described with specificity in the specification or even routine and conventional in the art. *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1156 (Fed. Cir. 2019).

The decision below confirms the Federal Circuit has adopted a new "full scope" test departing from the text of 35 U.S.C. § 112(a). Virtually every genus claim would require "substantial time and effort" to practice the *full scope* of the claims. By imposing a sliding scale that is not supported by the Act's text, a genus may lack enablement regardless of the number of working examples identified or how well-understood the processes of identifying the working embodiments are to a POSA. If the genus claims by function, there will be many embodiments. Thus, under this new test, even if the specification describes to a POSA how to

make and use the invention using even routine and conventional screening, because it would take "substantial time" to screen every possible embodiment, the claim would be invalid. The Federal Circuit's departure should be reversed, so that the enablement inquiry recited in This Court's precedent and endorsed in the America Invents Act is restored to its proper, intended standard.

### D. The plain language of 35 U.S.C. § 112 does not support the Federal Circuit's heightened "full scope" test.

There is one standard for enablement: a patent specification must describe 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 (emphasis added). Nowhere in the text of 35 U.S.C. § 112 did Congress enact a special enablement standard for genus claims. And nowhere did Congress use the language "full scope" or prohibit "substantial time and effort" to conduct routine or conventional testing. Thus, the text of § 112 contemplates but one standard for enablement. From the perspective of a POSA, the specification must include a *concise* specification sufficient to "enable any [POSA] . . . to make and use" the claimed invention.

In accordance with the statutory requirement that the specification be concise, courts have long

instructed that "a patent need not teach, and preferably omits, what is well known in the art." *Hybritech*, 802 F.2d at 1384 (citation omitted). Likewise, "enablement is not precluded by the necessity for some experimentation such as routine screening . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is undue, not experimentation." *Wands*, 858 F.2d at 736 (internal quotations omitted). But under the heightened "full scope" enablement standard prohibiting genus claims where "substantial time and effort is required," even if testing is routine, "then all 'experimentation' is 'undue,' since the term 'experimentation' implies that the success of the particular activity is uncertain." *In re Angstadt*, 537 F.2d 498, 503 (C.C.P.A. 1976).

The Federal Circuit's new "full scope" enablement test requirement that a patent drafter make, test, and disclose every embodiment of an invention is impractical and contravenes the intent of the Patent Act. Such a specification would not be concise and would be much more than what is necessary to enable a POSA to "make and use" the claimed invention. If Congress wanted this heightened standard, Congress could have crafted a special enablement standard for genus claims or changed the text of the statute in the overhaul of Title 35 in the America Invents Act. But Congress did not do so.

### E. The Federal Circuit's new "full scope" test departs from earlier Federal Circuit, Court of Customs and Patent Appeals, USPTO, and even Supreme Court interpretations.

Only recently has the Federal Circuit departed from the plain meaning of the Patent Act. *Compare LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005) ("A claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. That is because the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before. Placed in that context, it is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention and to enable such a person to make and use the invention without undue experimentation") (internal citations omitted) and *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1360-61 (Fed. Cir. 1998) ("[A] considerable amount of experimentation is permissible," as long as it is "merely routine" or the specification "provides a reasonable amount of guidance" regarding the direction of experimentation) *with Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380 (Fed. Cir. 2013) (adding a temporal element to the enablement inquiry, shifting the analysis to "whether practicing

the full scope of the claims requires excessive—and thus undue—experimentation" even where "one of ordinary skill could routinely use the assays disclosed in the specification").

Prior to this departure, the Federal Circuit and Court of Customs and Patent Appeals applied a flexible, case-specific enablement test for any patent claim: The specification must teach those skilled in the art to make and use the invention without "undue experimentation." *Wands*, 858 F.2d at 737. Undue experimentation is a case-specific, multi-factor inquiry. *Id.* (applying an 8-factor test that "is not precluded by the necessity for some experimentation such as routine screening"). Consistent with the plain meaning of the Patent Act, that test is built on the foundation of a POSA's level of skill and background knowledge.

The Federal Circuit has historically held that routine experimentation for genus claims is expected and "does not preclude enablement." *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576–77 (Fed. Cir. 1984) (noting that the disclosed 40% failure rate enabled a user to likely only have to try two or maybe three compounds to find one that would work). "The key word is 'undue,' not 'experimentation.'" *Id.*

Likewise, the Court of Customs and Patent Appeals consistently upheld genus claims. *See, e.g.*, *Angstadt*, 537 F.2d at 503-04; *In re Grimme*, 274 F.2d 949, 952 (C.C.P.A. 1960) ("It is manifestly impracticable for an applicant who discloses a generic

invention to give an example of every species falling within it, or even to name every such species. It is sufficient if the disclosure teaches those skilled in the art what the invention is and how to practice it."). It recognized that requiring the patentee to identify and test every possible species in a genus would be unworkable as "the research to do this would quite evidently be endless." *In re Sarett*, 327 F.2d 1005, 1019 (C.C.P.A. 1964).

This Court also has acknowledged that an enabled patent claim may "deal[] with a large class of substances" and "leav[e] something to the skill of persons applying the invention." *Minerals Separation*, 242 U.S. at 270-71 (upholding process with "infinite[]" embodiments as "clearly sufficiently definite to guide those skilled in the art").

Over the last decade, the Federal Circuit began crafting a stricter, "full scope" test for genus claims, particularly in the chemical and biological arts. The Federal Circuit consistently focused on the number of species a genus claim could encompass instead of focusing on the species a POSA would be motivated to pursue, framing the question as "whether practicing the full scope of the claims requires excessive—and thus undue—experimentation." *Wyeth & Cordis*, 720 F.3d at 1384; *see also Idenix*, 941 F.3d at 1163 ("[P]racticing the full scope of the claims would require synthesizing and screening tens of thousands of candidate compounds for the claimed efficacy."). For example, in the case of antibody genus claims, the Federal Circuit held that "practicing the full scope of

the claims would require synthesizing and screening each of at least tens of thousands of compounds." *Wyeth & Cordis*, 720 F.3d at 1384. But the Patent Act says nothing about elevating patentability requirements for genus claims.

### F. This Court has cautioned the Federal Circuit to not add requirements to patentability.

The Federal Circuit's new "full scope" test is inconsistent with its obligation to adhere to the text of the Patent Act. This Court has consistently intervened where the Federal Circuit applies a test that "is inconsistent with the text and the statute's purpose and design," *Bilski v. Kappos*, 561 U.S. 593, 603 (2010), explaining courts may not add "additional rigid and mandatory formulas" that are "inconsistent with [the text of the Patent Act]." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 407, 419, 428 (2007) (rejecting the "'teaching, suggestion, or motivation' test (TSM test), under which a patent claim is only proved obvious if 'some motivation or suggestion to combine the prior art teaching' can be found in the prior art" because it "transforms the general principle [of the Patent Act into a *rigid rule*") (emphasis added). This is such a case. The Federal Circuit's heightened "full scope" test raises the bar for the validity of genus claims and departs from the text of the Patent Act, disturbing the delicate balance Congress crafted. The Federal Circuit's application of such rigid tests is not

supported by the Patent Act and should be reversed. *Cf. Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 553 (2014) (reversing the Federal Circuit's test for attorney fees as "unduly rigid"); *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 579 U.S. 93, 104 (2016) (rejecting Federal Circuit's test for enhanced damages as "unduly rigid").

## II. The Federal Circuit's New "Full Scope" Test Frustrates Innovation.

### A. The patent system is designed to balance the interests of innovators and the public.

Patent law is rooted in the quid pro quo bargain that an inventor may obtain temporary exclusivity in exchange for disclosing an invention to the public. *Universal Oil Prod. Co. v. Globe Oil & Ref. Co.*, 322 U.S. 471, 484 (1944). ("As a reward for inventions and to encourage their disclosure, the United States offers a [] monopoly to an inventor who refrains from keeping his invention a trade secret. But the quid pro quo is disclosure of a process or device in sufficient detail to enable one skilled in the art to practice the invention once the period of the monopoly has expired; and the same precision of disclosure is likewise essential to warn the industry concerned of the precise scope of the monopoly asserted."). The filing of patent applications must be encouraged, because a patent application progresses the art and enriches society. Giles S. Rich, The Principles of Patentability, 28 Geo. Wash. L. Rev. 393, 400 (1960) ("Whenever novel

subject matter, unobvious to the workers of ordinary skill in the art, is published, progress in the art is promoted. The literature of the art is enriched, another way of doing something is made known, and even if it be inferior to the means already known, there is no telling when it may give another inventor an idea or when someone will improve on it in such a way as to surpass all that is known."). As Issac Newton explained, innovation is derived by "standing on the shoulders of giants" and building on the work of those that came before.

Perhaps no other fields depend on patent protection more than do the pharmaceutical and biotechnology industries. As discussed below, the costs of research in these fields are enormous, and the potential benefits—both to the innovators and the patients in need of that innovation—are equally large. Those working in these industries are also among the most likely to take advantage of genus claims. By filing a patent application, the applicant is providing a roadmap to the public, thereby progressing the art and enriching the public, but simultaneously enabling competitors who are now aware of the benefits of the genus and can quickly capitalize off the innovator's discovery.

It is only equitable for inventors to be compensated for this disclosure and the enormous amounts invested in developing it. The significant resources and substantial investment that pharmaceutical research demands require the reasonable means with which to recoup those

expenditures. This is only feasible through a rational and dependable patent system that protects pioneering inventions and the investments that make them possible, thereby encouraging the innovation the public demands. After all, no company will spend its money to develop a product that will be copied without impunity by its rivals after the breakthrough has been made. Thus, to maintain the incentives to innovate while maintaining access to inventions Congress balanced, there must be predictable, workable patent law standards.

### B. Drug discovery is expensive and time consuming.

The demand for innovative healthcare solutions and the groundbreaking research necessary to achieve those solutions has never been higher. Monoclonal antibodies, like the ones covered by the patent claims at issue here, have emerged as a major class of therapeutic agents to meet that demand. Monoclonal antibodies are attractive drug candidates for several reasons, including their potential for increased efficacy through targeted therapy, fewer interactions with other drugs, and fewer off-target adverse effects. Maria Sofia Castelli et al., *The Pharmacology and Therapeutic Applications of Monoclonal Antibodies*, 7 Pharmacology Res. & Persp., 2019, at abstract, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6923804/pdf/PRP2-7-e00535.pdf. This past year, monoclonal antibodies, including Humira®, Keytruda®, Stelara®, Opdivo®, Dupixent®, and Darzalex®, all ranked among the top 15 best-selling

pharmaceuticals. Brian Buntz, *50 of 2021's Best-Selling Pharmaceuticals*, Drug Development & Discovery (Mar. 29, 2022), https://www.drugdiscoverytrends.com/50-of-2021s-best-selling-pharmaceuticals/. As researchers continue to explore the possibilities of antibody-based treatments, their importance is sure to continue to grow.

More than in any other industries, the process for developing new inventions in the pharmaceutical and biotech fields is long, expensive, and unpredictable. *See e.g.*, PhRMA, Biopharmaceuticals in Perspective 27 (Fall 2020), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/ChartPack_Biopharmaceuticals_in_Perspective_Fall2020.pdf ("From drug discovery through FDA approval, developing a new medicine takes, on average, 10 to 15 years and costs $2.6 billion."). Drug development often begins with the identification of a biological target and the application of screening technology and methods in an attempt to identify promising drug candidates that interact with the biological target. This is not a simple process and is fraught with a high rate of failure.

As the process continues, researchers will often identify drug candidates that share common attributes or structural features. This discovery of a promising genus is often considered an important breakthrough reflecting the culmination of a significant investment of time and resources. Once the innovator has reached this stage, it may be routine to make and test similar antibodies that will also

effectively bind to the target and treat the same disease. Innovators will often seek patent protection using one or more genus claims at this stage of development, as Amgen did here. These inventions are worthy of protection and must be encouraged. Once the genus has been discovered, researchers commit even more resources into exploring the genus further, testing and experimenting with species in the hopes of find a promising compound suitable for further development and examination and, hopefully, FDA approval.

### C. Affirming the Federal Circuit will create an impractical and unworkable standard.

The Federal Circuit's new enablement requirement will frustrate the early disclosure of innovations and ultimately harm progress in the pharmaceutical and biotechnology fields. Discovering a promising genus is a long and expensive process by itself. Requiring inventors to subsequently perform every experiment necessary to disclose data for the "full scope" of the claims is impractical and inefficient, cuts against the reliability of the patent system in a way that stifles innovation, and will force an inefficient allocation of resources that ultimately harms consumers.

When inventors make significant advancements and provide specifications that enable the skilled artisan to make and use the claimed invention—as § 112 requires—they should enjoy patent protection commensurate with the scope of

their disclosure. But the Federal Circuit's new test ignores the traditional "undue experimentation" test. Even if a person of ordinary skill in the art could read the specification and readily "make and use" species of the invention—precisely what 35 U.S.C. § 112(a) commands—the Federal Circuit's "full scope" test could still invalidate those claims. And then an inventor is left with no patent and the guide to make and use their invention fully in the public domain.

The Federal Circuit's "full scope" test would require a patent directed to a genus to disclose an exhaustive number of examples. Inventors situated similarly to Amgen here will be discouraged from filing their patent applications unless and until they expend significantly more time and resources trying to achieve the difficult, and sometimes virtually impossible, task of trying to reduce to practice and describe every single member of a claimed genus. Such a requirement is overly burdensome, counter-productive, and a waste of resources that would be better allocated to the pursuit of promising embodiments. *Angstadt*, 537 F.2d at 502-03 ("To require such a complete disclosure . . . would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments. This would tend to discourage inventors from filing patent application in an unpredictable area since the patent claims would have to be limited to those embodiments which are expressly disclosed.").

Without obtainable genus claims that patentees can reasonably expect to stand up to

enablement challenges, researchers cannot rationally devote the time and resources necessary to continue to explore a genus in the search of a breakthrough drug candidate. Even when the uncertainty caused by a rigid and burdensome test can be justified, the additional time and effort necessary to support patent applications with the additional embodiments, experimental results, and related information will substantially delay the filing of patent applications and balloon the costs of obtaining a patent. Pioneering fields that work on the cutting edge, like pharmaceuticals and biotech, are often in a first-to-file race with millions, if not billions, of dollars on the line. Complying with an overly burdensome enablement requirement diverts resources that could have gone toward developing entirely new therapies into making and testing additional and unnecessary individual embodiments.

The "full scope" test, if left undisturbed, will also push innovators to rely on trade secrets, at least in the early stages of development. Not only will this inhibit the pace of progress by delaying innovators from building on each other's discoveries, but some information will never reach the public domain, hindering American innovation. It may also incentivize incremental innovation over ground-breaking advances. For example, rather than researching new drug mechanisms or classes of drugs, the "full scope" test will incentivize researching highly similar cousins of approved compounds because genus claims will not cover those embodiments.

Sanofi will likely argue that the enablement standard is necessary to protect the public and ensure that a patentee does not obtain the exclusive rights that a patent provides without upholding the patentee's end of the bargain by sufficiently disclosing and describing the full scope of the claim genus. *See* Sanofi's Br. in Opp. to Writ of Certiorari at 13. But the Federal Circuit's "full scope" test is not necessary to address this concern. For decades, the Federal Circuit, the Court of Customs and Patent Appeals, and the USPTO have uniformly and effectively applied a flexible, case-specific enablement test that is consistent with the plain meaning of the Patent Act and has effectively protected the public from insufficient disclosures. *See* Section I.E., above. If a patentee in fact has claimed more than he or she actually has invented, a patent challenger still has the opportunity to demonstrate that the patent claims are not enabled, just as has been the case for decades. There is no need to depart from this long-accepted standard and understanding that some experimentation is expected and "does not preclude enablement." *Id.*

Congress understood the delicate balance of incentives in the patent system when codifying the patentability requirements in the Patent Act. The application of the established and plain-text enablement standard by the courts has been endorsed by Congress in the AIA, and is understood by experienced innovators and patent practitioners armed with decades of legal precedent. There is no

reason to depart from that enablement standard now. Thus, this Court should reverse the Federal Circuit and restore the enablement standard to the one Congress intended.

## CONCLUSION

The plain meaning of the text of the Patent Act 35 U.S.C. § 112 has served the country well and, if reaffirmed, will continue to do so. By contrast, the Federal Circuit's heightened "full scope" standard departs from what Congress intended. This has the potential to jeopardize the benefits of many modern chemical innovations. This Court should therefore reaffirm that Congress—not the courts—decides the requirements for patentability and reverse the Federal Circuit's heightened "full scope" test for genus claims.

Respectfully submitted,

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