No. 21-757

In the Supreme Court of the United States

AMGEN INC., ET AL.,

Petitioners,

v.

SANOFI, ET AL.,

Respondents.

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

BRIEF OF *AMICUS CURIAE* GLAXOSMITHKLINE PLC IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE*[1]

GlaxoSmithKline plc ("GSK") is one of the largest pharmaceutical and consumer-healthcare companies in the world. GSK spends billions of dollars annually—including more than $6 billion in 2020 alone—developing groundbreaking drugs, vaccines, and therapies. Those efforts have yielded breakthroughs in the fight against HIV, cancer, shingles, meningitis, asthma, diabetes, malaria, and other diseases. During fiscal year 2020, GSK had fifty-seven new medicines and vaccines under development.

Genus claims are critical to protect innovations of companies like GSK, as well as smaller entities and academic institutions, and to encourage investment and collaboration in the chemical, pharmaceutical, and biotechnological arts. The court of appeals' decision entrenches a harmful trend of imposing new restrictions on genus claiming.[2] GSK respectfully submits this brief to educate the Court on the importance of genus claims to continued innovation.

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[1] Pursuant to Sup. Ct. R. 37.6, counsel for *amicus* certifies that no counsel for any party authored this brief in whole or in part, and that no entity or person other than *amicus* and its counsel made any monetary contribution toward the preparation and submission of this brief. Counsel for all parties received notice of *amicus*'s intention to file this brief more than ten days before it was due, and consented to its filing.

[2] *Amicus* takes no position on the validity of the particular claims at issue, and submits this brief solely to encourage the Court to correct the legal framework that the Federal Circuit applied.

SUMMARY OF THE ARGUMENT

Genus claims have become "ubiquitous" in the chemical, pharmaceutical, and biotechnological industries.[3] Such claims are critical to protecting and advancing innovation. Groundbreaking inventions developed by companies and academic institutions often manifest as a genus after years of discovery efforts and significant investment. When the patentee's contribution to the art is significant, broad claim scope is commensurate with the advancement the invention represents. Genus claims provide commercially meaningful exclusivity against motivated copyists and protection against insubstantial variations aimed toward unscrupulously circumventing patent protection. Thus, genus claims protect those inventions, ensure that innovators receive compensation when others build on top of their advancement, and incentivize continued investment in these arts.

The decision below joins a trend of Federal Circuit decisions that impose obstacles preventing innovators from receiving commensurate protection for their contributions to science. Until recently, courts focused on whether a patent sufficiently enabled ordinarily skilled artisans to "make and use" embodiments of the invention without undue experimentation, rather than on whether the patent enabled an artisan to make and use absolutely all species within the genus (*i.e.*, enabled the claim's "***full scope***"). But the court of appeals here adopted that latter framework. Pet. App. 13a-14a. It endorsed special tests that "raise[] the bar for enablement" depending on how the genus claims are drafted. Pet. App. 13a. By discerning for itself the possibility that some far corners of the genus are not enabled, the court of appeals invalidated the

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[3] Sean B. Seymore, *Patenting the Unexplained*, 96 WASH. U.L. REV. 707, 729 (2019).

claims-in-suit even though two juries had found those claims enabled. *See* Pet. App. 5a-6a, 15a.

That sea change threatens to devastate the incentives for companies like GSK to invest billions of dollars and hundreds of thousands of research hours in discovering breakthrough drugs. Going forward, GSK and other research-oriented companies will be forced to seek inequitably narrow patent claims that underrepresent the full breadth of their inventions or risk invalidation. But such narrow claims would not offer adequate protection. Previously issued claims that were once thought secure under the undue experimentation standard, are being exposed to renewed attacks. Thus, without a course correction, the Federal Circuit's holding risks eviscerating incentives to innovate that the patent system's *quid pro quo* was designed to provide.

The Court should grant the petition because of the importance of genus claims. And the Court should reject the Federal Circuit's recently imposed obstacles for genus claims, by restoring enablement to the case-specific "undue experimentation" analysis.

ARGUMENT

I. GENUS CLAIMING IS ESPECIALLY IMPORTANT FOR CHEMICAL, PHARMACEUTICAL, AND BIOTECHNOLOGY INVENTIONS.

Patent applicants are taught to craft claims so that they cover not only the specific embodiments disclosed in the patent, but also a broader class of related products that share the common advancement of the invention.[4] A patentee does not want her claims to be so narrow that the exclusivity is illusory. If the claims are drawn too narrowly, an unscrupulous competitor could attempt to circumvent the literal scope of the claims with only minor modifications to unfairly benefit from the true inventor's advancement to science. So, in nearly every industry, patentees seek claims broader than the examples disclosed in the patent—and claims broader than a specific commercial embodiment.

In chemistry and biotechnology, it is especially challenging to secure meaningful exclusivity using only narrow, specific claims. Known techniques could permit competitors to circumvent the literal scope of a narrow claim by making insubstantial changes to a chemical compound or biological molecule. For each discovered compound, for example, thousands of close analogues may have similar desired properties and may be suitable for the same utility (*e.g.*, efficacy for treating a disease). Using routine laboratory approaches, a competitor may efficiently synthesize and test variants of the patentee's product, avoiding the need to invest in initial discovery.

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[4] Dmitry Karshtedt, Mark A. Lemley & Sean B. Seymore, *The Death of the Genus Claim*, 35 Harv. J.L. & Tech. (forthcoming 2021), https://dx.doi.org/10.2139/ssrn.3668014 (manuscript at 2).

This is why genus claims become "ubiquitous" in these industries.[5]

When an inventor discovers a new class of chemical or biological products, she rationally seeks a genus claim commensurate with her discovery that covers possible analogues. Anything less would surrender her exclusivity to the copyists lying in wait. Allowing for a wide breadth of protection based on a genus is, as a practical matter, the only means to ensure that an inventor in these arts actually receives a commercially meaningful period of exclusivity contemplated by our patent system. And because a subsequent innovator who discovers unexpected properties of an included species may still obtain a patent on that discovery,[6] others remain incentivized to build upon past innovations. Genus claims do not preempt the continuing progress of science.

GSK and other innovative companies in the pharmaceutical and biotechnology industries depend on genus claims to protect their investments in developing groundbreaking pharmaceuticals and therapeutics. Massive investments are required to do so: in 2020 alone, GSK invested roughly £4.6 billion (over $6 billion) toward the research and development of new therapies, including pharmaceutical drugs.[7] Yet it is estimated that only 8% of drugs in development at a given time will ever reach the market.[8]

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[5] Seymore, *supra* n.3.

[6] *See, e.g.*, *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990).

[7] *See Research & Development*, GSK, https://www.gsk.com/en-gb/research-and-development/ [https://perma.cc/T8AJ-5G8E].

[8] *See* GSK, *GSK Public Policy Positions: Patents & Access to Medicines in Developing Countries* 2 (2019), https://www.gsk.com/media/2958/patents-and-access-to-medicines-in-developing-countries-july19.pdf [https://perma.cc/G338-TN7Q].

Without the robust protection offered by genus claims, companies will not have the same incentive to risk those initial outlays of effort and money—the second a patent is published, a competitor can begin synthesizing "me too" compounds to look for a way around the literal scope of narrow claims, without bearing the research and investment needed to blaze the trail in the first place. And if a patentee could not claim the curtilage around working embodiments to achieve commercially meaningful exclusivity, inventors would prefer to keep their discoveries to themselves, choosing trade secret protection over the *quid pro quo* of patent protection and disclosure—ultimately depriving the public of the knowledge. Genus claims are an integral part of the delicately-tuned patent system, providing an incentive for companies to invest in groundbreaking inventions, and to disclose them to contribute to the cycle of progress.

The special importance of genus claims for these industries is why *amicus* and commentators alike are concerned.[9] The Federal Circuit's trend of erecting "high hurdles" for genus claims, Pet. App. 12a, left unchecked, is already undermining protection for chemical, pharmaceutical, and biotechnology inventions. The Federal Circuit's judicial revisions to enablement doctrine bluntly destroy value in countless inventions disclosed and patented years ago. And the shock waves undermine the patent system's incentives for research-oriented companies, like GSK, to invest in new discoveries.

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[9] Karshtedt et al., *supra* n.4 (manuscript at 3-4).

II. THE FEDERAL CIRCUIT'S SHIFT IN ENABLEMENT DOCTRINE THREATENS EXISTING GENUS CLAIMS AND UPENDS INCENTIVES.

Like any other claim, a genus claim is measured against the patent's disclosures. In exchange for a limited right to exclude, the Patent Act extracts a disclosure, which, among other purposes, ensures that knowledge about the invention inures to the public. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480-81 (1974). A patent must "contain a written description of 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) (emphasis added). This enablement requirement ensures that, once the patentee's exclusivity has ended, others may practice the invention and reap the benefits of that advancement. *See Universal Oil Co. v. Globe Co.*, 322 U.S. 471, 484 (1944).

Practical constraints limit the thoroughness of a patent disclosure. The predecessor court of the Federal Circuit recognized that it would be futile, and unproductive, to require patentees to draft patent applications with thousands of examples and to restate all the contextual knowledge of the art. *In re Angstadt*, 537 F.2d 498, 502 (C.C.P.A. 1976). Such a requirement would be undesirable because it would "force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments" and "discourage inventors from filing patent applications in an unpredictable area." *Id.* at 502-03.

Before the eyes of the law, genus claims ought to stand on the same footing as any other, measured against the same statutory requirements of patentability. The Patent Act does not cap the number of species that a claim

may contain or limit the functional breadth a claim may have if it otherwise passes scrutiny for novelty and non-obviousness. Nor does the Patent Act require ***different***, ***elevated*** tests of enablement for certain types of claims. But that is what the court of appeals has created.

Until recently, the Federal Circuit and its predecessor court had converged on a flexible, case-specific enablement test for any patent claim: The specification must "teach those in the art to make and use the invention without 'undue experimentation.'" *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991) (quoting *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)). That standard ensures that, whether the claims are narrow or broad, enablement is measured along with the technological context and artisans' level of skill and background knowledge. The patentee has satisfied the *quid pro quo* of disclosure if she discloses enough such that artisans do not need to essentially ***re-discover*** the invention through extensive experimentation.[10] Thus, a court or jury applying the test considers many factors:

> (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

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[10] The Federal Circuit explained:

> The key word is 'undue,' not 'experimentation.' The 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. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed…

In re Wands, 858 F.2d at 737 (citations omitted).

> 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.

In re Wands, 858 F.2d at 737. Contextual facts about the art, the accused infringer's real-world success at deriving working embodiments using the patent as a recipe, and expert testimony all may bear on whether the patent is enabled.

Under the undue experimentation test, if artisans can combine known principles of the art with the patent's guidance to arrive at ***working embodiments*** without undue experimentation, the claims will be valid. *See, e.g.*, *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984). That is true even if the genus happens to include some inoperative combinations, because when combined with the knowledge in the art, an artisan would "know how to select" from the ingredients and combine them, to arrive at the useful variants of the invention. *Id.* at 1576. Thus, enablement doctrine was not concerned with directing others to produce every imaginable species contained in the "full scope" of the genus. Common sense dictated that no artisan would be motivated to make every imaginable species.

Applicants draft patent applications against the known context of the law. These settled principles of enablement law have induced inventors to choose to disclose their innovations, describing them in such detail as to enable others to make and use the invention—not only the explicit examples provided, but also useful embodiments within the scope of the genus. Those are the inventions now most threatened by the Federal Circuit's shift in enablement law.

Over the last decade, a troubling trend began to emerge in biotechnology cases at the Federal Circuit. Enablement cases began to stray from the statutory mandate that a patent must teach others to "make and use the same [the invention]," instead crafting a stricter, "full scope" test for genus claims.

In *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380 (Fed. Cir. 2013), the court of appeals began to question the number of species a genus claim encompasses. It framed the question as "whether ***practicing the full scope*** of the claims requires excessive—and thus undue—experimentation." *Id.* at 1384 (emphasis added). Because there were at least tens of thousands of potential candidate compounds that might contain a claimed functional characteristic (and only those that do were within the scope of the claims), the court found that "practicing the full scope of the claims would require synthesizing and screening *each* of at least tens of thousands of compounds." *Id.* at 1385. That, for the court, was too much experimentation. *Id.* at 1386.

But why would an artisan ever make them ***all***?[11] The *Wyeth* court seemed to be more concerned about how to delineate the entire boundary of the claim, rather than what it would take for an artisan to "make and use" the invention. "[M]ake and use the same" in § 112(a) means that an artisan can exploit the invention for its utility. A sane enablement inquiry is not whether an artisan can make every single claimed species, but whether an artisan can arrive at the useful species within the genus that artisans, or competitors, would actually be motivated to make.

The court of appeals extended *Wyeth* in *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc.*, 941 F.3d 1149

[11] Karshtedt et al., *supra* n.4 (manuscript at 41).

(Fed. Cir. 2019). *See id.* at 1162-63 (stating that "practicing the ***full scope*** of the claims would require synthesizing and screening tens of thousands of candidate compounds for the claimed efficacy" (emphasis added)). The court found itself mired in an abstract question of mathematics over how many chemical compounds might meet the structural limitations of the claim. *See id.* at 1157.

The decision below, relying in part on *Wyeth* and *Idenix*, further enshrines a "full scope" test untethered to the statutory command to enable others to "make and use" the invention. While the panel asserts that it was "not concerned simply with the number of embodiments," it reached its conclusion based on the fact that, like *Wyeth* and *Idenix*, here:

> the evidence showed that the scope of the claims ***encompasses millions of candidates*** claimed with respect to multiple specific functions, and that ***it would be necessary to first generate and then screen each candidate antibody*** to determine whether it meets the double-function claim limitations.

Pet. App. 15a (emphases added). It endorsed the notion that certain types of claims, here, genus claims on antibodies, "raise[] the bar for enablement." Pet. App. 13a. Of course, the Patent Act says nothing about elevating patentability requirements for genus claims. The court affirmed the invalidation of the claims-in-suit even though two juries had found those claims enabled. *See* Pet. App. 5a-6a, 15a.

In context, these cases represent a troubling trend of hostility to genus claims covering many embodiments, even where those embodiments all reflect a common inventive breakthrough.

This new view of enablement threatens genus claims that survive scrutiny under the traditional "undue experimentation" test. Patentees who had previously disclosed their secrets in exchange for genus claims face potential invalidation if the scope of the genus includes a large number of embodiments. Even if artisans can readily "make and use" species of the invention using the patent as a guide and known techniques—precisely what 35 U.S.C. § 112(a) commands—the Federal Circuit's "full scope" test demands more. By erecting this high hurdle as a matter of law, the court of appeals is eviscerating rights that patentees reasonably believed to be valid.

It also disrupts future patent applications. Whereas *In re Angstadt* had refused to force applicants to list exhaustive examples because of the burden it imposes (and corresponding discouragement to patenting), 537 F.2d at 502, applicants are forced to shore up their disclosures knowing they may face judicial hostility. That forces a reallocation of resources from discovering breakthrough therapeutics and developing commercial products for the public, toward running experiments for the purpose of writing a patent disclosure. Inventors would turn toward stuffing their patent applications with embodiments, experimental results, and known principles. The rule turns innovators from research scientists into draftsmen. And even then, those disclosures may not be enough to survive the rigid "full scope" test.

Alternatively, entrepreneurs may choose to forgo patent protection altogether to avoid the risk that they make a fulsome disclosure of their secrets only to face judicial invalidation. That is harmful to the public and the progress of science. It stunts the pace of progress by preventing scientists from building on each other's discoveries.

The overall undermining of genus claims weakens the incentives for research-oriented companies, like GSK, to invest in groundbreaking research, and to disclose those discoveries at all. (*See* section I, *supra* pp. 4-6.)

Whatever the intended policy aims of the Federal Circuit's new approach to enablement, bad law makes for a blunt weapon with wide-reaching consequences.

III. "FULL SCOPE" ENABLEMENT IS AN UNDULY RIGID RULE THAT THE PATENT ACT DOES NOT ENVISAGE.

The trend of hostility to genus claims in the chemical and biotechnology arts has led the court of appeals to make bad law. Its "full scope" test for enablement is a mandatory formula that embraces formalism over reason—and one that is engineered to kill genus claims.[12] It hinges on essentially the number of potential embodiments and the time required to exhaustively make ***all*** of them, instead of a factual inquiry into what artisans would have known and been able to do.

When the Patent Act requires enablement sufficient to "make and use" the invention, the statute means that artisans are able to take advantage of the invention, including unenumerated species not disclosed as examples—not that artisans must be capable of readily using every possible embodiment from the universe of ***all*** possible candidates.

"Full scope" enablement is a "fruitless search" and a nearly "impossible task for a genus of any nontrivial size."[13] The court of appeals' fascination with counting the number of unique embodiments within a genus claim—or the number of "candidates" that may be either outside or

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[12] Karshtedt et al., *supra* n.4 (manuscript at 78-79).

[13] Karshtedt et al., *supra* n.4 (manuscript at 4).

inside the genus—is a woefully misguided effort. That number is as insightful as trying to count how many infinite variations of a machine could exist within the scope of an apparatus claim.[14]

A "full scope" enablement test erects a formulaic, inflexible requirement that tends toward a predetermined outcome: invalidating genus claims. It enables judges, and courts of appeals, to set aside expert testimony and real-world facts showing that artisans were able to exploit the invention following its teachings. This "full scope" test is the kind of rigid, atextual test this Court has rejected. *Cf. KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) ("Rigid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it."); *see also Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 553 (2014) (rejecting Federal Circuit's framework 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").

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[14] Courts might be tempted to count species of included chemical compounds because there are scientific ways to come up with a real sum of the permutations, but should not assume that those counts show unusual or illegitimate breadth compared to patent claims in other arts.

To illustrate: Any open-ended claim could embrace virtually infinite variations. Consider, hypothetically, an apparatus claim directed to a typewriter comprising 26 keys lettered A to Z: an artisan could tweak the color of the keys, the size, and rearrange all possible permutations of A-Z, add unclaimed levers, buttons, etc., while remaining inside the broad scope of the claim. When there are already approximately $\mathbf{4 \times 10^{26}}$ permutations of the letters alone (26 factorial), it becomes obvious that counting the ***full scope*** of all potential embodiments—or candidates—is an exercise in futility.

IV. THE COURT SHOULD RESTORE RATIONALITY TO ENABLEMENT.

Genus claims protect continued innovation in the chemical, pharmaceutical, and biotechnological industries. But the court of appeals has been upending such protections. That development is bad policy, as it disincentivizes innovation; and it is bad law, as it imposes arbitrarily "high hurdles" untethered to the mandates of the Patent Act.

The Court should grant the petition to address the proper enablement test, and to reject the Federal Circuit's "full scope" enablement test. A traditional "undue experimentation" test that measures what it takes for an artisan to make and exploit the invention for its utility, rather than a formalistic test that asks what it would take for an artisan to make ***every*** embodiment of the claim (or ***every*** candidate that might lead to a claimed species), would better respect the mandate of § 112(a). And it would reaffirm the viability of genus claims commensurate with a patentee's contribution to the art, of vital importance to *amicus* and the chemical, pharmaceutical, and biotechnology arts.

CONCLUSION

The petition should be granted.

Respectfully submitted,

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DECEMBER 22, 2021