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 Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF OF INTELLECTUAL PROPERTY PROFESSORS AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICI CURIAE*

Amici curiae are intellectual property law professors throughout the United States.[1] We have considerable experience with both patent practice and patent doctrine. *Amici* have no personal interest in the outcome of this litigation, but we share a professional interest in seeing that the patent laws are applied in such a way as to provide adequate incentives for innovation.

SUMMARY OF ARGUMENT

Amici support the petition for writ of certiorari, limited to question two of the petition.[2]

The central feature of patent law in the life sciences industries is the genus claim. Without such claims, a competitor could make a minor change to the chemical the patentee invented and avoid liability while capturing the heart of the invention.

This Court, the Federal Circuit, its predecessor the Court of Customs and Patent Appeals ("CCPA"), and the Patent and Trademark Office ("PTO") have long

[1] Appendix A includes a list of the *amici*. *Amici* certify that no party, person, or entity other than *amici* or their counsel authored the brief in whole or in part or made a monetary contribution to its preparation or submission. All parties received timely notice of *amici*'s intent to file and have consented to the filing of this brief.

[2] *Amici* take no position on question one. *See* Mark A. Lemley, *Why Do Juries Decide If Patents Are Valid?*, 99 VA. L. REV. 1673 (2013).

upheld genus claims, finding that they complied with the enablement requirement of 35 U.S.C. § 112(a) if they taught the person having ordinary skill in the art ("PHOSITA") enough that the PHOSITA could make and use a chemical within the genus without undue experimentation.

But the Federal Circuit has changed the law dramatically in recent years, to the point where it is no longer possible to have a valid genus claim in the chemical and biotechnology industries. Under this new approach, it no longer suffices that the patent gives enough information that the PHOSITA can "make and use" the invention, as § 112(a) requires. Rather, the Federal Circuit now rejects claims as invalid because the genus contains thousands or millions of possible chemicals, unless the patent itself identifies exactly which of those myriad species will work. That is an impossible burden, and it is not one the law imposed until recently. It represents "a categorical shift in thinking away from teaching the PHOSITA and towards a precise delineation of the boundaries of the claim." Dmitry Karshtedt, Mark A. Lemley & Sean B. Seymore, *The Death of the Genus Claim*, 35 HARV. J.L. & TECH. (forthcoming 2021), at 43 ("KLS"), available at https://ssrn.com/abstract=3668014.

This Court should grant review to return the law to its traditional moorings.

ARGUMENT

I. Genus Claims Have Traditionally Been Understood to Be Critical for Meaningful Patent Protection in the Chemical Industry

Genus claims have long been a feature of patent law. Upholding the claims to Alexander Graham Bell's patent on the telephone, this Court observed that "a patent for such a discovery is not to be confined to the mere means he improvised to prove the reality of his conception." *The Telephone Cases*, 126 U.S. 1, 539 (1888). "It 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." *Id.* at 536 (emphasis added). Quoting from a leading patent law treatise, the Court explained in another opinion that "the principle of the invention is a unit, and invariably the modes of its embodiment in a concrete invention may be numerous and in appearance very different from each other." *Cont'l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 419-20 (1908) (quoting 2 WILLIAM CALLYHAN ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 485 (Boston, Little, Brown & Co. 1890)). As the Court said in *Tilghman v. Proctor*:

> Perhaps the process is susceptible of being applied in many modes and by the use of many forms of apparatus. The 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 of discoverer. But he must describe some particular mode, or some apparatus, by which the process can be applied with at least some beneficial result, in order to show that it is capable of being exhibited and performed in actual experience.

102 U.S. 707, 728-29 (1880).

These cases recognize that genus claims are critical for meaningful patent protection. Without them, patentees face "the risk of an infringement being avoided" by a minor modification of the particular embodiments disclosed in the patent's specification. *Carnegie Steel Co. v. Cambria Iron Co.*, 185 U.S. 403, 437 (1902). Applying these principles to a patent on a process of concentrating crushed or powdered ores containing various "metal and metallic compounds," the Court held that the claims at issue "satisf[y] the law" even though "the process is one for dealing with a large class of substances and the range of treatment within the terms of the claims." *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261, 271 (1916). It explained that a contrary result would lead to a patentability standard that cannot be met for any chemical patent claim covering a significant number of species: "[T]he 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.*

To be sure, a genus claim cannot survive if the patentee failed to provide any guidance on how to practice the claimed invention. *Tyler v. Boston*, 74 U.S. (7

Wall.) 327, 330 (1868); *Wood v. Underhill*, 46 U.S. (5 How.) 1, 4-5 (1846). But this Court's precedent does not support the Federal Circuit's conclusion here that a well-defined genus is not enabled unless the patent's specification provides a way for rapidly making and testing numerous species that potentially fall into that genus.

Consistent with Supreme Court precedent, the Federal Circuit, the CCPA, and the PTO had long upheld genus claims. For example, the Patent Office Board of Appeals explained in *Ex parte Sloane* that

> While the number of specific substances mentioned is doubtless important, especially in a case where the generic nature of a case must be inferred from the mention of specific substances, we do not think that a proper determination of the breadth of disclosure can be made solely from a consideration of the specific examples given. If the disclosure, taken as a whole, is generic, an applicant is entitled to generic claims if they are otherwise allowable.

22 U.S.P.Q. 222, 1934 WL 25325, at *2 (P.O.B.A. 1934) (citing *Corona Cord Tire Co. v. Dovan Chem. Corp.*, 276 U.S. 358 (1928) and *Consol. Elec. Light Co. v. McKeesport Light Co.*, 159 U.S. 465 (1895)).

The CCPA's decisions are in accord. *See*, *e.g.*, *In re Angstadt*, 537 F.2d 498, 503-04 (C.C.P.A. 1976) (citing *Minerals Separation*, 242 U.S. at 270-71) (upholding a broad chemical genus claim); *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.").

Early Federal Circuit precedents followed this law. Under those precedents, an invention is enabled if the PHOSITA, armed with the patent's specification, can practice the invention without "undue experimentation." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). What constitutes undue experimentation is supposed to be a case-specific, multi-factor inquiry. *Id.* The PHOSITA is permitted to engage in a reasonable amount of routine experimentation to figure out compounds that can achieve the claimed result. *See id.* at 736-37. Experimentation is a common part of the PHOSITA's work 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). As long as the specification provides some working examples, that disclosure can give PHOSITAs sufficient guidance to enable the full scope of a genus claim. *See* 2 ROBINSON, THE LAW OF PATENTS, *supra*, at § 485 ("The applicant is not required to describe all possible forms" of his invention; "[t]hese belong to the skill of the mechanic, not the inventor; and having one embodiment before them, the public are presumed to be able to construct such others as they desire.").

In sum, enablement has not traditionally turned on whether there are many compounds within the claimed genus or whether routine screening takes

considerable time. *Wands*, 858 F.2d at 736-37. An enabled patent 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 271 (upholding process with "infinite[]" embodiments as "clearly sufficiently definite to guide those skilled in the art"); *In re Angstadt*, 537 F.2d at 502-03 (rejecting an enablement challenge despite "thousands" of possible embodiments within the scope of the genus because the needed experimentation "to determine which catalysts will produce hydroperoxides would not be undue and certainly would not 'require ingenuity beyond that to be expected of one of ordinary skill in the art'" (quoting *Fields v. Conover*, 443 F.2d 1386, 1390-91 (C.C.P.A. 1971))).

II. Recent Federal Circuit Decisions Have Changed the Law of Enablement

A. Recent Cases Have Required Identification of Every Species Within the Genus

More recently, the Federal Circuit has adopted a new "full scope" standard to evaluate enablement. This standard gauges enablement not by whether the experimentation needed to make and test particular species is undue, but by how long it would take the PHOSITA to make and screen *every species within the claimed genus*—even if that work would be routine. *See* KLS, *supra*, at 38-50 (summarizing cases). The Federal Circuit decision in this case is consistent with that new focus. Indeed, the decision below cements it into a hard-and-fast rule, rejecting the factual findings of not

one but two different juries. *Amgen Inc. v. Sanofi*, 987 F.3d 1080, 1088 (Fed. Cir. 2021) ("[N]o 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.").

The decision below confirms the massive shift in the Federal Circuit's enablement doctrine. Even if it is straightforward and routine for the PHOSITA to sort operative from inoperative species, the Federal Circuit invalidates patents where the genus is large regardless of how many working species the patent identifies and how well-understood the process of identifying the working embodiments is. Under this new regime, "[a] chemical genus with any decently large number of species will never be able to satisfy" the Federal Circuit's new enablement standard. KLS, *supra*, at 1. Worse yet, the "substantial time and effort" theory makes it much easier for defendants in patent infringement suits to argue that genus claims are overbroad on their face. Any genus claim covering a significant number of species in the chemical and life sciences fields, which typically come with built-in unpredictability even if the claimed technology is mature, is now in question. Accordingly, few patent claims in this industry survive enablement challenges today. *See id.* at 31.

In response to the petition for rehearing below, the Federal Circuit issued a non-precedential "opinion on the denial of the petition for panel rehearing" in which it denied that it had changed the law. Rather, it said, genus claims might satisfy the enablement

requirement as long as the patentee could show the structural characteristics of the chemicals in the genus that worked and how they differed from the inoperative ones. *Amgen Inc. v. Sanofi*, 850 F. App'x 794, 796 (Fed. Cir. 2021) ("Biological compositions not actually prepared need to be described constructively, if required to enable the full scope of the claims, with procedures and names of resultant compositions, as with chemical compositions."). That defense of the full-scope enablement doctrine rings hollow. First, as KLS document, the Federal Circuit is rejecting essentially every large genus claim challenged on enablement grounds, suggesting that the Federal Circuit's proposed method is illusory. KLS, *supra*, at 38-50. Second, the Federal Circuit's insistence on identifying structural differences between parts of the genus "by procedures and names of the resultant compositions," *Amgen*, 850 F. App'x at 896, misunderstands the science. There might sometimes be a structural chemical difference that divides operative from non-operative species, but often there won't be. And identifying such a structural difference is unnecessary if the PHOSITA can find working embodiments of the invention without undue experimentation even if they don't know the full structure of every chemical in the genus. Finally, a requirement that patentees disclose the structure of every chemical within the genus is at odds with this Court's long-standing precedent we discuss in Part I.

B. The Full-Scope Enablement Standard Misunderstands the Point of the Enablement Requirement

This new approach to enablement is problematic because it focuses on knowing exactly which species of a claimed genus will work instead of knowing how to make and use the invention, which is what the text of § 112(a) actually requires. As the CCPA noted, if this were so "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) (emphasis in original).

If the goal is to enable the PHOSITA to make and use the invention, the inability to predict in advance which species will work does not matter much except at the extremes. The patentee in *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, did not know which of its claimed dynamite compounds would work and which would not, but with a 40% failure rate, a user would likely only have to try two or maybe three compounds to find one that would work. 750 F.2d 1569, 1577 (Fed. Cir. 1984). That required some experimentation, but the law has traditionally allowed claims that require experimentation as long as it is not "undue." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986); *see also* Sean B. Seymore, *Patenting Around Failure*, 166 U. PA. L. REV. 1139, 1165-73 (2018) (explaining that long-standing law has allowed claims to encompass inoperative species without defeating patentability). There may be some genus claims that give so little information that

trying to find a species that works takes too much effort, but that is likely to be rare if the genus is well-defined.

The Federal Circuit's move from a focus on undue experimentation to a search for a clear definition of which species work and which do not misunderstands the basic purpose of the § 112(a) inquiry. True, PHOSITAs may not be able to quickly make *every* working species. But why would they want to? And true, they might have to experiment to figure out whether the species they made works for the intended purpose, but that has never been a problem so long as they do not have to do too much experimentation.

Indeed, the Federal Circuit's rule may result in less, not more, disclosure of new ideas to the public. As the Federal Circuit's predecessor court said in a related context, "[r]equiring specific testing of the thousands of [chemical] analogs encompassed by the present claim in order to satisfy the how-to-use requirement of § 112 would delay disclosure and frustrate, rather than further, the interests of the public." *In re Bundy*, 642 F.2d 430, 434 (C.C.P.A. 1981). But the Federal Circuit's new enablement rules threaten to do just that. In short, the current focus on the amount of time and effort that it would take to identify all the working species within its scope of a broad claim as the reason to reject it misses the point of enablement.

C. This Heightened Enablement Standard Frustrates Patenting and Innovation in the Chemical and Life Sciences

This heightened enablement standard is inconsistent with the purposes of the enablement doctrine, is impossible to meet for large genus claims, and threatens patent protection for many inventions in the chemical and life sciences, where large genus claims are ubiquitous.

The full-scope enablement standard frustrates patenting and innovation. It "force[s] an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments" and ultimately "discourage[s] inventors from filing patent applications in an unpredictable area since the patent claims would have to be limited to those [working] embodiments which are expressly disclosed." *In re Angstadt*, 537 F.2d at 502-03. For a genus claim of any size, it is an impossible requirement to meet, and it does not serve the purposes of § 112. And it is not something patentees can simply draft around. A chemical genus with any decently large number of species will never be able to satisfy the new enablement standard. No matter how much testing the patentee does, there will always be untested species, so we do not know whether they are properly included in the genus. This standard is thus fatal to genus claims.

Patent protection is important in the pharmaceutical and biotechnology industries, perhaps more than anywhere else. Given the importance of strong

patent protection in these industries, the unwillingness of courts to permit chemical genus claims seems quite troubling as a policy as well as a doctrinal matter. The new rule makes it unreasonably difficult for a pharmaceutical company that comes up with an innovative new class of drugs to protect that class against imitation. That result threatens innovation.

CONCLUSION

This Court should grant the petition for writ of certiorari limited to question two.

Respectfully submitted,

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