2020-1074

In the

United States Court of Appeals

for the

Federal Circuit

AMGEN INC., AMGEN MANUFACTURING, LIMITED, AMGEN USA, INC.,
Plaintiffs – Appellants

v.

SANOFI, AVENTISUB LLC, fka Aventis Pharmaceuticals Inc.,
REGENERON PHARMACEUTICALS INC., SANOFI-AVENTIS U.S. LLC,
Defendants – Appellees

Appeal from the United States District Court for the District of Delaware,
in Case No. 1:14-cv-01317-RGA · Honorable Richard G. Andrews, Judge

BRIEF OF INTELLECTUAL PROPERTY PROFESSORS AS *AMICI CURIAE* IN SUPPORT OF REHEARING *EN BANC*

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 2020-1074

Short Case Caption Amgen Inc. v. Sanofi

Filing Party/Entity Intellectual Property Professors (Amici Curiae)

Instructions: Complete each section of the form. In answering items 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance. **Please enter only one item per box; attach additional pages as needed and check the relevant box**. Counsel must immediately file an amended Certificate of Interest if information changes. Fed. Cir. R. 47.4(b).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 04/28/2021

Signature: /s/ Mark A. Lemley

Name: Mark A. Lemley

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☑ None/Not Applicable
See Attached (Appendix A)		

☑ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☑ None/Not Applicable ☐ Additional pages attached

5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

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6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable ☐ Additional pages attached

APPENDIX A

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available at https://ssrn.com/abstract=3668014 ..... 2, 7, 8

Sean B. Seymore, *Patenting Around Failure*,
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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.[2] All parties have consented to the filing of this brief.

SUMMARY OF ARGUMENT

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 Court of Customs and Patent Appeals ("CCPA"), and the Patent and Trademark Office ("PTO") have long 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.

---

[1] Appendix A includes a list of the *amici*.

[2] *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.

But this Court 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, this Court 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 en banc review to resolve the conflict between its current cases and binding precedent that has never been overruled, using this opportunity 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, the Supreme 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). The Court held that "[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." *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).

The Supreme Court recognizes 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 Supreme Court precedent does not support the panel'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, this Court, 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 (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.").

This Court's early 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 Decisions Have Changed the Law of Enablement

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

Despite the case-specific, fact-intensive nature of the enablement inquiry, this Court has more recently adopted a numbers-based 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 panel decision in this case is consistent with that new focus. Indeed, the panel cements it into a hard-and-fast rule, rejecting the factual findings of not one but two different juries. *See* slip op. at 14 ("[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 panel opinion is a 180-degree turn away from *Wands*, where claims survived an enablement challenge *in spite of* the standard of review unfavorable to the inventors. *But cf.* slip op. at 9 (suggesting that "the standard of review" controls).

The panel opinion confirms the massive shift in the Federal Circuit's enablement doctrine. Asking the PHOSITA to sort operative from inoperative species, whether routine or not, is emerging as a critical challenge for patentees facing enablement attacks. When the number of operative species in a chemical

genus seems too time-consuming to identify, this proves fatal to enablement. 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.

B. 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.

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, as it is in the patent claims under review.

This 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. 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.

The heightened 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 rehearing en banc.

Dated: April 28, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 28, 2021, I electronically filed the foregoing Brief *Amici Curiae* with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Dated: April 28, 2021

Respectfully submitted,

/s/ Mark A. Lemley

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Circuit Rule 29(a)(4). This brief contains 2,597 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the typestyle requirements of Federal Rule of Appellate Procedure 32(a)(6). This brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Times New Roman.

Dated: April 28, 2021

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