No. 20-380

IN THE

Supreme Court of the United States

IDENIX PHARMACEUTICALS LLC AND UNIVERSITA DEGLI STUDI DI CAGLIARI,

Petitioners,

v.

GILEAD SCIENCES, INC.,

Respondent.

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

REPLY IN SUPPORT OF CERTIORARI

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INTRODUCTION

This case is about what it takes for a genus claim to satisfy § 112(a)'s demands. In two ways, the Federal Circuit asks too much. First, it holds that genus claims are not enabled, as a matter of law, where "there [are] at least many, many thousands of candidate compounds, many of which would require synthesis and each of which would require screening." Pet.App.25a. Second, it holds that genus claims fail the supposedly separate written-description requirement if the specification does not prove that the patent holder "possess[ed]" the particular infringing compound. Pet.App.26a. Both of those atextual rules—adopted by the Federal Circuit in prior decisions and cemented in the decision below—are wrong. *See* Pet. 17-28. And both threaten genus claims generally, with devastating consequences for fields like biotechnology and pharmaceuticals. *See id.* at 28-35; Amgen Br. 17-24; GSK Br. 5-7; Profs. Br. 21-24.

Gilead concedes that these rules, if adopted, "might well prove problematic for 'life sciences innovation,'" BIO 20, so it rewrites the Federal Circuit's jurisprudence instead. It insists that, contrary to the "many, many thousands" holding quoted above and similar language in *Wyeth & Cordis Corp. v. Abbott Laboratories*, 720 F.3d 1380, 1382 (Fed. Cir. 2013), the Federal Circuit has no rule against large genus claims. And it insists that, despite *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc), and the panel's emphasis on the Idenix patent's failure to mention Gilead's infringing compound, the Federal

Circuit's separate written-description requirement simply mirrors the statutory text.

Make no mistake. The Federal Circuit's categorical approach to § 112(a) is unequivocal. This Court's intervention is needed to prevent the death of the genus claim—and to preserve the lifesaving innovations such claims foster.

ARGUMENT

I. THE FEDERAL CIRCUIT HAS ADOPTED TWO ERRONEOUS AND INTERRELATED BRIGHT-LINE RULES FOR GENUS CLAIMS.

A. The Federal Circuit's Numbers-Based Enablement Rule Is Wrong.

1. Gilead does not defend the Federal Circuit's numbers-based rule for genus claims, for good reason: Neither § 112(a)'s text nor this Court's precedents support *any* subject-matter-specific enablement rules—much less a numerical cutoff for genus claims. *See* Pet. 17-23; BIO 20 (acknowledging such a rule "would certainly defy the 'text' of § 112(a)"). To the contrary, this Court's decision in *Minerals Separation Ltd. v. Hyde*, 242 U.S. 261, 271 (1916), confirms that claims covering "a large class of substances and the range of treatment within the terms of the claims" can satisfy § 112(a).

Gilead's passing swipe at *Minerals Separation* (BIO 22) misses its mark, as neither *Minerals Separation* nor the decision below turned on the optimization point to which Gilead clings. *Cf. In re Angstadt*, 537 F.2d 498, 503-04 (C.C.P.A. 1976) (rejecting an enablement challenge despite the need for experimentation). Gilead's discussion of that case,

moreover, betrays its recognition of the devastating consequences the Federal Circuit's rule has for all genus claims where practicing the invention requires routine experimentation. If Gilead's position is that a genus claim is valid only where "[t]here [is] no dispute that every variation … work[s]," BIO 22, then most chemical genus claims are doomed to failure. *See* Profs. Br. 10-11 ("routine experimentation" is "common" in this field).

2. Gilead argues instead that the Federal Circuit did not actually adopt a numbers-based rule. BIO 15-19. But the Federal Circuit has squarely held that genus claims are invalid as a matter of law when they cover "too many" species. District courts across the country have applied that rule, and commentators have noted (and criticized) it as well.

a. The Federal Circuit's numbers-based enablement rule originated in *Wyeth*. The patent there claimed the use of a "class of compounds" to treat restenosis. *Wyeth*, 720 F.3d at 1382. The specification disclosed one species of that genus, and the patent holder sued when a competitor commercialized a different one. *See id.* The Federal Circuit held the genus claim not enabled. The key question, the court explained, was "whether having to synthesize and screen each of at least tens of thousands of candidate compounds" defeats enablement. *Id.* at 1385. The court's answer was clear: "We hold that it does." *Id.* And it reached that result even though it "accept[ed] as true Wyeth's claims about the state of the art" and "that one of ordinary skill could routinely" screen "candidate compounds" for the desired effect. *Id.*; *see also, e.g.*,

Enzo Life Scis., Inc. v. Roche Molecular Sys., Inc., 928 F.3d 1340 (Fed. Cir. 2019).

The Federal Circuit applied the same rule in the decision below. To be sure, the panel marched through the *Wands* factors. *See* Pet.App.11a-23a. But a *rule* drove its decision about how to balance those factors in cases involving a large genus in unpredictable fields like biotechnology or pharmaceuticals. Like in *Wyeth*, "testimony confirmed that practicing the full scope of the claims would require synthesizing and screening tens of thousands of candidate compounds." Pet.App.25a. And like in *Wyeth*, "screening an individual compound for effectiveness was considered 'routine.'" *Id.* Thus, despite the significant differences in Idenix's favor regarding the state of the art, the nature of the invention, and the extensiveness of the specification's disclosures, *Wyeth*'s rule "control[led]": "[T]he claim [is] not enabled because there [are] 'at least tens of thousands of candidate compounds' and 'it would be necessary to first synthesize and then screen *each* candidate compound.'" *Id.* (quoting *Wyeth*, 720 F.3d at 1385-86).

These decisions make clear that, regardless of what a jury might find about the ease of synthesis and screening, "the Federal Circuit now rejects claims as invalid because the genus contains thousands or millions of possible chemicals." Profs. Br. 2-3.

b. The Federal Circuit's numerical threshold for genus claims has not gone unnoticed. District courts have been bound by it. *See, e.g.*, Pet.App.113a (jury's verdict was "legally erroneous in light of … *Wyeth*"); *Amgen Inc. v. Sanofi*, No. CV 14-1317-RGA, 2019 WL 4058927, at *8, *13 (D. Del. Aug. 28, 2019)

("[P]recedent from the Federal Circuit" made clear that a claim covering "at least millions of candidates" was not enabled.). Experts this Court has consistently invoked have bemoaned it. *See* Dmitry Karshtedt, Mark A. Lemley, & Sean B. Seymore, *The Death of the Genus Claim*, HARV. J.L. & TECH. (forthcoming) (manuscript at 49) (rev. Oct. 8, 2020) ("KLS"), https://ssrn.com/abstract=3668014; *cf. Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1376 (2018) (one of eleven decisions by this Court citing Professor Lemley's work). Industry participants are alarmed by it as well. *See generally* Amgen Br.; GSK Br.

3. Gilead's attempt to characterize the enablement question here as a factbound inquiry into the *Wands* factors proves Idenix's point. Idenix agrees that enablement is a question of fact that *should* be answered by reference to "a variety of case-specific considerations." BIO i. That is exactly what the jury did here. The Federal Circuit, however, overturned that verdict by holding, "as a matter of law," that Idenix's claim covered too many species. Pet.App.23a-26a.

Gilead nevertheless insists "[t]his case presents no question about the jury's role." BIO 23. That is unsurprising, given that Gilead's brief harps on cases involving different patents than the one this jury considered, and different bodies of substantive law than this jury applied. *See id.* at 1, 9-10 (discussing nine unrelated decisions). It also repeatedly ignores this jury's credibility determinations and factual findings—for example, about the size of the genus (thousands, not billions), Pet.App.12a, and about the reason its chemist had Idenix's patent in his hand

(willful copying, not innocent analysis), Pet.App.96a n.16. In any event, the first Question Presented is "Whether, as the Federal Circuit has held, a genus claim is not enabled 'as a matter of law' if it encompasses a large number of compounds—*or whether, as this Court has recognized, enablement is a context-specific jury question*." Pet. i. (emphasis added). Like many questions this Court takes up, it is an either/or. And this Court's precedent—which the Federal Circuit failed to mention and Gilead does not cite or distinguish—provides the answer: It is "the right of the jury to determine … whether the specifications … enable any person skilled in the [art] … to make the [invention] described." *Battin v. Taggert*, 58 U.S. (17 How.) 74, 85 (1854).

That answer matters. It is undisputed that Gilead used Idenix's groundbreaking discovery in its drug sofosbuvir, and that sofosbuvir uses Idenix's patented treatment, without which an HCV cure might never have come about. The jury reasonably found, even after hearing Gilead's attacks on the patent, that the claims are enabled in light of the patent's teachings and the ease of synthesis and screening. The Federal Circuit's "as a matter of law" rule, however, removes that decision from the jury for cases involving such key pharmaceutical and biologic discoveries.

B. The Federal Circuit's Separate "Possession" Requirement Is Wrong.

The Federal Circuit's atextual "possession" requirement is just as indefensible. That the Federal Circuit has been wrong for some time does not mean its error should go uncorrected.

1. Section 112(a) provides:

> The 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.

35 U.S.C. § 112(a).

a. The word "possession" does not appear in § 112. But the supposed absence of "possession" is precisely why the Federal Circuit invalidated Idenix's patent: given the specification's reference to *other* embodiments, it supposedly "could not demonstrate to a[n] [artisan] that the inventor had possession of [a 2'-fluoro-down] embodiment at the time of filing." Pet.App.30a. In other words, the Federal Circuit requires "possession" of the specific infringing product whenever it deems a genus claim too broad.

As with enablement, Gilead runs from the Federal Circuit's actual test, insisting "possession" is simply (bad) shorthand for a "written description" that "show[s] that the inventor actually invented the invention claimed." BIO 30-31 (quoting *Ariad*, 598 F.3d at 1351). But that is not all the Federal Circuit demanded here. Rather, it repeatedly stated and applied its "possession" standard, focusing specifically on whether Idenix possessed *Gilead*'s infringing compound. *E.g.*, Pet.App.26a (asking whether Idenix "was in possession" of 2'-down-fluoro embodiments).

b. More broadly, Gilead, like the Federal Circuit, is mistaken in reading § 112(a) to contain *any* "written description" requirement separable from the enablement inquiry. Each "of" phrase in § 112(a)—"of the invention" and "of the manner and process of making and using it"—modifies "written description" and specifies *what* the written description must contain. The third prepositional phrase—"in such full, clear, concise, and exact terms as to enable" a skilled artisan "to make and use the same"—specifies the *standard* by which the written description is to be judged.

Gilead's contrary suggestion—that this third phrase modifies only the "manner and process" phrase—cannot be right. First, § 112(a) contains two verbs—"shall contain" and "shall set forth." As Gilead's creative use of "line breaks added" illustrates, BIO 29, it is bizarre to cleave the description "of the invention" from its parallel "of the manner and process of making and using it" when both relate to the same verb ("shall contain"). Second, Gilead's construction ignores the object "the same," which is found within the modifying phrase and which can only refer to "invention," the part of the first verb phrase that supposedly goes unmodified. Finally, Gilead's reading makes no practical sense. Why would Congress detail the standard governing the description of how to make and use the invention, but say nothing about how the invention must be described?

2. The Federal Circuit's atextual "possession" requirement is not so entrenched that this Court must accede to the error. This Court has never treated § 112(a)'s "written description" requirement as

separate from enablement. The Federal Circuit's contrary rule dates back only to *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997). *See* Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827, 834 (1999) (explaining how *Eli Lilly* "broke new ground"). It was not cemented in Federal Circuit jurisprudence until the court's 2010 en banc ruling in *Ariad*. 598 F.3d at 1353. And while lawyers for the Patent Office may have taken Gilead's side, *see* BIO 25, 28, the Solicitor General appears never to have weighed in.

Gilead's appeals to statutory *stare decisis* are thus overblown. *See id.* at 26-28. "It is one thing to claim that congressional silence signals approval of a decision from the Supreme Court; it is another thing to claim that congressional silence signals approval of a decision from any of the courts of appeals." Amy Coney Barrett, *Statutory Stare Decisis in the Courts of Appeals*, 73 GEO. WASH. L. REV. 317, 318 (2005). Congress did not address—much less condone—the Federal Circuit's "written description" rule when it passed the America Invents Act. And potential reliance interests here approach zero, since inventors who attempted to comply with the Federal Circuit's made-up "possession" standard will be unharmed by its elimination. In any event, Gilead is free to press *stare decisis* arguments on the merits. They are no reason to decline review.

II. THE QUESTIONS PRESENTED ARE IMPORTANT.

A. Gilead does not dispute the importance of genus claims to biotechnology and pharmaceuticals. *See* BIO 20. Nor could it. Because many variants of

a basic chemical structure will often share the same basic properties, it can be impossible to identify those variants in advance. *See* Pet. 2-3, 29. Without adequate patent protection for genus claims, "[a] potential infringer could readily avoid 'literal' infringement . . . by merely finding another analogous [compound] which could be used" the same way. *Angstadt*, 537 F.2d at 503; *see* Profs. Br. 1-2 (same); GSK Br. 1 (similar). That potential for appropriation is particularly problematic in the biotechnology and pharmaceutical sectors, where genus claims are the "central feature of patent law" and where adequate patent protection is crucial for investment and innovation. KLS, *supra*, at 1.

B. Gilead attempts to minimize the impact of the Federal Circuit's numbers-based rule for genus claims by (again) pretending as if the Federal Circuit has not actually adopted that rule. *See* BIO 20. Gilead concedes, however, that such a rule, if adopted, "might well prove problematic for life sciences innovation." *Id.* (internal quotation marks omitted). Gilead's premise is wrong. *Supra* Part I.A.2. So the (conceded) conclusion follows.

Next, Gilead claims that courts applying the Federal Circuit's approach uphold genus claims all the time. *See* BIO 20. One of its two examples predates *Wyeth*, and the other is a one-sentence summary affirmance. The truth is that, since *Wyeth*, "[i]t is effectively impossible for a genus claim of any non-trivial size to comply with [the Federal Circuit's] enablement standard." Profs. Br. 14. "[T]here are virtually no significant examples of genus claims in the life science fields upheld on appeal as compliant with § 112(a)." KLS, *supra*, at 31.

Finally, Gilead argues that this Court's previous denial of petitions challenging the Federal Circuit's separate, possession-based "written description" requirement means it must do so again. BIO 24-25, 35-36. But this Court regularly takes up questions it has previously turned down. *See, e.g.*, *Oil States*, 138 S. Ct. 1365 (resolving oft-denied issue about PTO practice). The prior petitions were poor vehicles. Amgen's representation that it (not the respondent) would seek to stay trial if certiorari were granted did not change the fact that its interlocutory petition implicated ongoing proceedings that might moot the case. *See* BIO 35 (discussing Cert Reply, *Amgen Inc. v. Sanofi*, 139 S. Ct. 787 (2019) (No. 18-127), 2018 WL 6382975). Contrary to Gilead's argument regarding *Janssen*, *see* BIO 35-36, the distinction between later-added claims and original claims makes all the difference for purposes of the "written description" question. *See, e.g.*, *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 988 (Fed. Cir. 2002) (Linn, J., dissenting) (explaining the "possession" standard should be used "to measure or test entitlement of later filed claims to an earlier priority date" but "should have no place … where the claims … are part of the original disclosure").

III. THIS CASE IS AN IDEAL VEHICLE.

This case involves textbook genus claims exemplifying the "traditional manner of chemical genus claiming." KLS, *supra*, at 16-17. A jury reasonably found that the claims satisfy § 112(a)—*i.e.*, that the invention's description enabled a skilled artisan "to make and use the same." 35 U.S.C. § 112(a). And the Federal Circuit's decision

overturning that verdict hinged on the erroneous construction of § 112(a) challenged here.

Gilead errs in contending that this case is a poor vehicle because—as a result of the very bifurcation of § 112(a) challenged here—the judgment below turned on two purportedly independent questions. *See* BIO 2, 24, 36. In reality, this case presents a singular question—whether genus claims that cover a large number of candidate compounds can satisfy § 112(a)'s unified standard. Enablement and written description comprise independent grounds *only if* one accepts the Federal Circuit's separate "written description" requirement.

Both questions are independently certworthy regardless. Each concerns an atextual rule invented by the Federal Circuit that threatens the viability of genus claims. Together, those rules make it virtually impossible to protect inventions that implicate a family of compounds. Granting a petition presenting both questions will allow the Court to consider § 112(a)'s application to genus claims in a broader context, and with the full suite of potential resolutions on the table.

* * *

"This Court has not provided guidance on the meaning of Section 112(a) in many years." Amgen Br. 17. The costs of waiting longer will be measured not only in dollars, but also in lives. *See id.* at 20. Review is warranted now.

CONCLUSION

The petition should be granted.

December 30, 2020

Respectfully submitted,

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