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

REPLY FOR PETITIONERS

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Sanofi-Regeneron cannot dispute that this Court has repeatedly declared that enablement is "a question of fact" for "the jury." *Wood* v. *Underhill*, 46 U.S. (5 How.) 1, 4 (1846). It ignores Framing-era English practice in "'enablement' cases," where "juries * * * determine[d] whether the specification described the invention well enough to allow" skilled artisans "to reproduce it." *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 379 (1996). It nowhere denies that departing from the historical "common law" standard for re-examining such jury factfinding violates the Seventh Amendment. U.S. Const. amend.

VII. And Sanofi-Regeneron nowhere denies that the Federal Circuit disregarded all of that, deeming enablement "a question of law that [judges] review without deference." Pet. App. 6a. Presented with this Court's precedent, the Federal Circuit found no "reason to change" its law and restore the jury to its historic role. Pet. App. 68a.

Sanofi-Regeneron's insistence that *all* "patent validity" issues are "question[s] of law," Br.in.Opp. 14, disregards this Court's specific holding that *enablement* is a fact question. Sanofi-Regeneron argues the issue is unimportant. But the Seventh Amendment is important. And the issue is recurring. The Federal Circuit's treatment of enablement as a legal question regularly permits courts to substitute their judgments on issues "[i]t was the right of the jury to determine." *Battin* v. *Taggert*, 58 U.S. (17 How.) 74, 85 (1854).

The Federal Circuit's judge-made enablement standard also warrants review. Under § 112, the specification must "enable" skilled artisans "to make and use" the invention. 35 U.S.C. § 112(a). For genus claims, however, the Federal Circuit holds that a patent is not enabled if "'substantial time and effort' would be required to reach the full scope of claimed embodiments." Pet. App. 14a. Sanofi-Regeneron denies the Federal Circuit departed from statutory text. But evaluating the *cumulative* effort to make *every* embodiment within a genus is very different—and more demanding—than asking if skilled artisans can "make and use" individual embodiments. 35 U.S.C. § 112. The Federal Circuit admits its standard "raises the bar" for genus claims. Pet. App. 13a. *Amici* attest to the devastating consequences for innovation.

Both issues are squarely presented. Review is warranted.

I. The Federal Circuit's Treatment Of Enablement As A Legal Question Warrants Review

A. The Federal Circuit's Rule Defies Precedent and History

For over 175 years, this Court has held that enablement is "a question of fact to be determined by the jury." *Wood*, 46 U.S. at 4. Yet the Federal Circuit holds enablement is "a question of law" courts "review without deference." Pet. App. 6a.

1. Sanofi-Regeneron's response is notable for what it omits. Sanofi-Regeneron ignores Framing-era English practice. Pet. 15-16. Sanofi-Regeneron says nothing about the Seventh Amendment or the jury determinations it protects. Pet. 19-21. And Sanofi-Regeneron ignores treatises, reaching back 170 years, confirming enablement is a question of fact. Pet. 14-15.

Sanofi-Regeneron dances around decisions of this Court reflecting that rule. It wrenches from context *Wood*'s statement that it is sometimes "'the duty of the court to declare the patent . . . void.'" Br.in.Opp. 16 (quoting 46 U.S. at 4-5). *Wood* was noting that, *if* the specification were so "ambiguous[ ] and vague[ ]" that it "would be evident" no reasonable jury could find the patent enabled, "it would be the duty of the court" to render decision. 46 U.S. at 4-5. That merely reflects that enablement, like other fact issues, can be decided on summary judgment or JMOL where warranted. It does not contradict *Wood*'s holding that enablement "must, in general, be a question of fact" for "the jury." *Id.* at 4. Sanofi-Regeneron urges that "enablement was 'not disputed'" in *Evans* v. *Eaton*, 20 U.S. (7 Wheat.) 356 (1822). Br.in.Opp. 16-17. But *Evans* explained that, "if there had been any dispute on this subject, it would have been a matter of fact for the

jury, and not of law for the decision of the Court." 20 U.S. at 428.

Attempting to distinguish Amgen's myriad "other cases" (cited Pet. 14-15), Sanofi-Regeneron urges that "the factual issue for the jury related to *the capabilities* of a person skilled in the art," which it characterizes as "one" "factor" relating to the "ultimate" question of enablement. Br.in.Opp. 17 (emphasis added). But the factual question in each case—"whether the specifications * * * were so precise *as to enable any person skilled in the [art] to make* the * * * described" invention, *Battin*, 58 U.S. at 85 (emphasis added)—*is* the ultimate question of enablement. See 35 U.S.C. § 112(a). Sanofi-Regeneron's parentheticals (Br.in.Opp. 17) confirm that. Sanofi-Regeneron identifies no separate, "ultimate 'question of law' " the courts decided for themselves.

Sanofi-Regeneron ignores that, before the Federal Circuit's formation, *five* courts of appeals held enablement a question of fact. Pet. 15. It urges that three circuits deemed enablement a legal question. Br.in.Opp. 18. None of those courts addressed *Wood*, *Battin*, *Evans*, or historical practice. Pet. 17 n.1. And any circuit conflict underscores the need for review. See S. Shapiro *et al.*, *Supreme Court Practice* § 4.7, at 256-257 (10th ed. 2013); Pet. 17 n.1. If there are "no current differences" among the appellate courts, Br.in.Opp. 20, that is because the Federal Circuit now has *exclusive* jurisdiction over appeals in patent cases, 28 U.S.C. § 1295. That the court with sole jurisdiction is defying this Court's precedent—and the earlier holdings of five circuits—confirms the need for review.

2. Denigrating this Court's enablement decisions and historical practice as "antebellum," Br.in.Opp. 17, Sanofi-Regeneron insists the Court's "recent precedents" describe "patent validity [a]s a question of law with underly-

ing factual questions," Br.in.Opp. 14, 18. But that defies still more decisions of this Court holding validity issues factual. See, *e.g.*, *Busch* v. *Jones*, 184 U.S. 598, 604 (1902) (anticipation "a question of fact"). And it attacks Federal Circuit precedent that concededly does likewise. See, *e.g.*, *Vas-Cath Inc.* v. *Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991) (written description "a question of fact"); Br.in.Opp. 19-20.[1]

None of the cases Sanofi-Regeneron cites, moreover, concern enablement. *Sakraida* v. *Ag Pro, Inc.*, 425 U.S. 273 (1976), and *Graham* v. *John Deere Co. of Kansas City*, 383 U.S. 1 (1966), concerned obviousness under § 103. *Microsoft Corp.* v. *i4i Limited Partnership*, 564 U.S. 91 (2011), involved § 102(b)'s "on-sale bar." They do not overrule this Court's specific holdings that *enablement* is "a question of fact to be determined by the jury." *Wood*, 46 U.S. at 4. Those holdings remain binding, regardless of how *other* patent-validity doctrines are characterized.

Adhering to pre-"Civil War" precedent would hardly "create incoherence in [this Court's] jurisprudence." Br. in.Opp. 16, 19-20. This Court applies a "'historical test'" that looks further back, to the Framing era, to determine whether an issue is a question of fact or law. *Markman*, 517 U.S. at 376. And recognizing that enablement is a fact question is consistent with the general proposition that patent *validity* is a legal conclusion. The "inference of law" whether a patent is *valid* is a "conclusion" that follows directly "from the facts" the jury decides regarding whether the specification is enabling. *Grant* v. *Raymond*,

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[1] Sanofi-Regeneron urges that the "differential treatment" of written description and enablement—both derived from § 112—is "beyond the scope of Amgen's petition." Br.in.Opp. 20 n.5. But Amgen invoked that incoherence as supporting review. Pet. 19.

31 U.S. 218, 245 (1832). Amgen explained that. Pet. 18-19 n.3. Sanofi-Regeneron offers no response.

B. The Issue Is Important

Sanofi-Regeneron's protestation that Amgen "overstates * * * importance," Br.in.Opp. 21, rings hollow. Enablement challenges are routine in patent-infringement cases, and whether enablement is a fact question for juries, or a legal question for courts, is implicated in virtually *every one*. Sanofi-Regeneron itself asserts that reinstating the standards of *Wood*, *Battin*, *Evans*, and their Framing-era English counterparts would effect a "radical[ ] change," Br.in.Opp. 24—what the Federal Circuit called "a seismic shift," Pet. App. 68a. And the Seventh Amendment—which preserves the jury's historic role—is important.

By deeming enablement a legal question, the Federal Circuit licenses courts to substitute their judgments on disputed issues that "[i]t was the right of the jury to determine." *Battin*, 58 U.S. at 85. That is now routine. Pet. 20-21. Sanofi-Regeneron likens those decisions to ordinary JMOL cases, where courts grant "judgment as a matter of law based on an insufficient evidentiary showing." Br.in. Opp. 22. Not so. The Federal Circuit's enablement test involves *balancing* a host of "factual considerations." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). By treating enablement as a question of law, the Federal Circuit liberates itself to pick and choose facts and "weigh[ ] each" as it sees fit. *Idenix Pharms. LLC* v. *Gilead Scis. Inc.*, 941 F.3d 1149, 1162 (Fed. Cir. 2019). The panel did that here, "weighing the *Wands* factors" itself, Pet. App. 15a, even deeming disputed facts undisputed, Pet. 23. That defies this Court's holding that enablement is "to be decided by a jury." *Wood*, 46 U.S. at 5-6. And it fosters perceptions of panel-dependency. See Pet. 21.

That the Court has denied prior "petitions raising this question," Br.in.Opp. 20-21—for potentially distinct reasons, Pet. 24—hardly weighs against review. Those repeated pleas for review confirm the issue is recurring and important. So too does *amici*'s plea for the Court "to restore the jury's historic and constitutionally mandated role." AUTM.Br. 5.

II. THE FEDERAL CIRCUIT'S "REACH THE FULL SCOPE" STANDARD WARRANTS REVIEW

A. The Standard Defies Text, Precedent, and Policy

Under §112, a patent's disclosures must be sufficient "to enable any person skilled in the art * * * to make and use the" invention. 35 U.S.C. §112(a). The Federal Circuit, however, has invented a separate standard that "raises the bar" for genus claims, Pet.App. 13a, requiring that the specification enable skilled artisans "to *reach the full scope* of claimed embodiments" without "'substantial time and effort.'" Pet.App. 14a (emphasis added). That warrants review.

1. Sanofi-Regeneron denies the Federal Circuit has created a distinct test for genus claims, urging that the panel "eschewed any bright-line rules." Br.in.Opp. 29. But the decision below proves otherwise. Amgen's patents clearly satisfied §112's make-and-use-the-invention standard: The evidence showed that skilled artisans could, by following the patents' teachings, make claimed antibodies *every time*. See Pet. 32-33. The Federal Circuit invalidated Amgen's claims based solely on the "'substantial time and effort' * * * required to *reach the full scope* of claimed embodiments." Pet.App. 14a (emphasis added).

The Federal Circuit denies imposing a "'numerosity' or 'exhaustion' requirement," Pet.App. 64a, but its "reach the full scope" standard expressly turns on the *cumulative* effort required to make all or nearly all variations of the

invention. In *McRO, Inc.* v. *Bandai Namco Games America Inc.*, 959 F.3d 1091 (Fed. Cir. 2020), the Federal Circuit acknowledged that, "[i]n cases involving" genus claims, it asks whether "*identifying*" which of the "*many*" potential embodiments "satisfy" the "requirement[s]" of the genus would require "undue experimentation." *Id.* at 1100 n.2 (emphasis added). That vastly differs from asking if skilled artisans can "make and use" the invention. 35 U.S.C. § 112.

2. The Federal Circuit did not need to rewrite § 112 to permit challengers to prove overbroad claims are not enabled. Br.in.Opp. 30. That can be accomplished by requiring—as the Federal Circuit does elsewhere—that challengers provide "concrete identification" of a substantial number of embodiments that cannot be made or used by following the patent's teachings. *McRO*, 959 F.3d at 1100; Pet. 28. Sanofi-Regeneron cannot explain why that approach does not "prevent the evil" of over-claiming. Br. in.Opp. 35 (alterations omitted). Significantly, Sanofi-Regeneron failed to meet that burden here.[2]

As Sanofi-Regeneron notes, Br.in.Opp. 31, this Court has recognized that patentees cannot claim inventions by reference to a broad class, while leaving skilled artisans to

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[2] Despite urging Amgen claimed more than it enabled, *e.g.*, Br.in.Opp. 1, Sanofi-Regeneron failed to identify even *one* claimed antibody that could not be made following the patents' teachings, Pet. 10. Sanofi-Regeneron says the panel identified non-enabled embodiments. Br.in. Opp. 32 n.8. That is not true. The panel merely noted there were theoretical antibodies for which no "example" was provided. Pet. App. 13a n.1. And Sanofi-Regeneron's suggestion that Amgen did not invent the full genus of claimed antibodies defies the jury's finding on written description, upheld by the district court, that Amgen "invented what is claimed." Pet. App. 23a (quotation marks omitted). The jury found that the example antibodies in Amgen's patents "were representative of the structural diversity of the genus." Pet. App. 25a.

conduct "painstaking experimentation" to create working embodiments within that class. *Consol. Elec. Light Co.* v. *McKeesport Light Co.*, 159 U.S. 465, 475 (1895). But in each case Sanofi-Regeneron cites, the statutory standard was not met—the patent's disclosures did not "'enable any person skilled in the art * * * to make * * * and use'" the invention at all. *Id.* at 474 (quoting Rev. Stat. § 4888); *Béné* v. *Jeantet*, 129 U.S. 683, 685-686 (1889); *Holland Furniture Co.* v. *Perkins Glue Co.*, 277 U.S. 245, 257 (1928). This Court has *never* suggested that patents are invalid, when skilled artisans can easily make embodiments within the claims, simply because "'substantial time and effort' would be required" for skilled artisans "to reach the full scope" by making *all* embodiments. Pet. App. 14a. Nor can Sanofi-Regeneron explain why that result makes sense.

Sanofi-Regeneron's convoluted effort (Br.in.Opp. 32-33) to distinguish the *facts* of this case from the *facts* in *Minerals Separation, Ltd.* v. *Hyde*, 242 U.S. 261 (1916), fails to reconcile the Federal Circuit's *legal standard* with the standard *Minerals Separation* announces. The patent in *Minerals Separation* claimed a process for concentrating metallic ores, but its disclosures left skilled artisans to conduct "preliminary tests" to identify the "precise treatment" for each of the "infinite[ ]" ore varieties. 242 U.S. at 270-271. Sanofi-Regeneron insists "all 'variation[s] of treatment' worked," and "experimentation was required merely to determine the * * * 'most successful and economical'" formulation "'in each case.'" Br.in.Opp. 32 (quoting 242 U.S. at 270-271). But even that recharacterization of precedent proves the point—the Court focused on the experimentation required for "successful application" to any particular ore, not the cumulative effort to reach the full scope of processes needed to separate the "infinite[ ]" varieties. 242 U.S. at 271. *Minerals Separa-*

tion rejected a standard akin to the Federal Circuit's as "obviously impossible" to satisfy. *Ibid.*; Pet. 26-27.[3]

B. The Issue Is Exceptionally Important

The Federal Circuit concedes its standard "raises the bar" for genus claims, Pet. App. 13a, presenting "high hurdles" to enablement, Pet. App. 12a. Sanofi-Regeneron nowhere denies that the "reach the full scope" standard invalidates inventions based merely on perceived breadth. Pet. 30-32.

Sanofi-Regeneron quotes the panel's remark that genus claims "'are alive and well,'" Br.in.Opp. 34 (quoting Pet. App. 63a), but cites *no* case upholding a genus claim under the Federal Circuit's standard. That is because the test is "impossible" to satisfy for any genus with a "non-trivial" number of embodiments. D. Karshtedt *et al.*, *The Death of the Genus Claim*, 35 Harv. J.L. & Tech. 1, 4 (2021). Sanofi-Regeneron's insistence that research and development has not ceased entirely, Br.in.Opp. 34, is cold comfort. *Amici*—including innovators Merck, GlaxoSmith-Kline, Biogen, and Bristol-Meyers Squibb—attest that the Federal Circuit's standard "destroy[s] value in countless" already-patented inventions, and "undermine[s]" "incentives" for companies "to invest in new discoveries." GSK.Br. 3.[4]

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[3] Far from being an "indefiniteness" case, Br.in.Opp. 32, *Minerals Separation* cited enablement cases as "the law," holding the patent "sufficiently definite to guide" skilled artisans to the invention's "successful application," 242 U.S. at 271.

[4] Genus claims do not destroy the "incentive to develop new therapeutics within the scope of" the genus. Br.in.Opp. 34-35. As commentators recognize, "genus claims" incentivize research into "new classes of treatments" over "'me-too'" drugs (like Sanofi-Regeneron's PCSK9-antibody product here). Karshtedt, *supra*, at 68-69. Sanofi-

III. THIS CASE IS AN IDEAL VEHICLE

Sanofi-Regeneron does not dispute that both issues are squarely presented. Pet. 32-33. It argues that, because reversal would leave *other* issues for remand, this Court's judgment might "not be dispositive of the case." Br.in. Opp. 27 (quotation marks omitted). But this Court grants review to decide important legal questions, not to dictate the victor following remand. Sanofi-Regeneron identifies no barrier to the Court's resolution of the questions presented. The district court rejected Sanofi-Regeneron's position on those other issues; whether the Federal Circuit would agree following remand is of no moment.

Sanofi-Regeneron does not argue waiver. It concedes Amgen raised fact-versus-law in its principal brief and on rehearing, Br.in.Opp. 25; the issue thus was pressed *and* passed upon below, see Pet. App. 67a. Sanofi-Regeneron asks the Court to await a decision where the issue is more "thoroughly ventilated." Br.in.Opp. 26. But the Federal Circuit declared it "see[s] no reason" to revisit the issue. Pet. App. 68a. Nor would this Court "be writing on a completely blank slate." Br.in.Opp. 25. Albeit 40 years late, the Federal Circuit attempted to backfill a rationale below. Pet. App. 68a; Pet. 18 n.2. And this Court has addressed the issue *itself* multiple times.

Sanofi-Regeneron argues the outcome here "would not change" if enablement is a fact question. Br.in.Opp. 26. (It does not deny the second question presented is outcome-determinative.) According to Sanofi-Regeneron, the panel's "decision was based on undisputed facts." Br.in.Opp. 22-23; see *id.* at 26. But the parties disputed *everything*.

Regeneron's theory is at best debatable. See *ibid.* And Sanofi-Regeneron's policy arguments for departing from statutory text are better addressed to Congress than the courts regardless.

Amgen identified three instances where the panel resolved disputed fact questions against Amgen, contrary to the jury's implicit findings. Pet. 23. Sanofi-Regeneron dismisses one as not "relevant," Br.in.Opp. 26, but has no answer to the other two. And those were the iceberg's tip. For example, while the district court acknowledged "conflicting testimony as to the predictability of the art," Pet.App. 35a—a core enablement factor—the Federal Circuit decided for itself that "this invention is in an unpredictable field," Pet.App. 13a. Regardless, by deciding enablement as a legal question, the panel also undertook to "weigh[ ]" the enablement factors itself, Pet.App. 15a, "without deference" to how the jury presumptively weighed them, Pet.App. 6a; see p. 6, *supra*.

Two different juries heard the evidence and found Amgen's patents enabled—yet the Federal Circuit reached a contrary result. *Who* decides enablement was clearly outcome-dispositive.

CONCLUSION

The petition should be granted.

Respectfully submitted.

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