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

SUPPLEMENTAL BRIEF FOR PETITIONERS

JONATHAN P. GRAHAM
STUART L. WATT
WENDY A. WHITEFORD
STEVEN D. TANG
EMILY C. JOHNSON
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320
(805) 447-1000

JEFFREY A. LAMKEN
Counsel of Record
MICHAEL G. PATTILLO, JR.
SARAH J. NEWMAN
WALTER H HAWES IV
MOLOLAMKEN LLP
The Watergate, Suite 500
600 New Hampshire Ave., N.W.
Washington, D.C. 20037
(202) 556-2000
jlamken@mololamken.com

Counsel for Petitioners

(Additional Counsel Listed on Inside Cover)

KEITH R. HUMMEL
ANDREI HARASYMIAK
CRAVATH, SWAINE & MOORE LLP
Worldwide Plaza
825 Eighth Avenue
New York, NY 10019
(212) 474-1000

WILLIAM G. GAEDE, III
MCDERMOTT WILL & EMERY LLP
415 Mission Street
Suite 5600
San Francisco, CA 94105
(650) 815-7435

SARAH C. COLUMBIA
MCDERMOTT WILL & EMERY LLP
200 Clarendon Street, Floor 58
Boston, MA 02116
(617) 535-4074

Counsel for Petitioners

TABLE OF CONTENTS

TABLE OF AUTHORITIES

TABLE OF AUTHORITIES—Continued

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

SUPPLEMENTAL BRIEF FOR PETITIONERS

Rather than address the legal questions the petition presents, the government rewrites them and then argues that *its* questions do not warrant review. Contrast U.S. Br. i with Pet. i. But the government nowhere denies that the *actual* questions Amgen's petition presents—whether enablement is reviewed as a question of fact or law, and what the substantive enablement standard actually is—are exceptionally important. The Federal Circuit's resolution of those issues defies this Court's precedents.

The government nowhere denies that *this Court* holds enablement is "a question of fact to be determined by the jury," *Wood* v. *Underhill*, 46 U.S. (5 How.) 1, 4 (1846), or that enablement was reviewed deferentially under Framing-era precedent, *Hornblower* v. *Boulton*, Dav. Pat.

Cas. 221, 239-240 (KB 1799). Nor does the government deny that the Federal Circuit holds the opposite—that enablement is "a question of law" courts "review without deference" on appeal. Pet. App. 6a. Instead, the government deems *both* wrong, calling enablement "a mixed question of law and fact." U.S. Br. 11. But the government never addresses whether that "mixed question" should be reviewed deferentially as "factual," or *de novo* as "legal," under *U.S. Bank National Association ex rel. CWCapital Asset Management LLC* v. *Village at Lakeridge LLC*, 138 S. Ct. 960, 967 (2018). Given the government's muddled position, its strident tone—like the USPTO's absence from its brief—is puzzling.[1]

The government ignores the Seventh Amendment, which prohibits courts from re-examining jury verdicts except under the standards applied at common law. It is undisputed that enablement historically was treated as factual and reviewed deferentially on appeal. See *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 376 (1996). While the government paints the Federal Circuit's overturning of the jury's verdict here as the ordinary application of JMOL, it was anything but. See Pet. 22-24.

The Federal Circuit's 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. The Federal Circuit admitted that standard "raises the bar." Pet. App. 13a. The gov-

[1] The USPTO did not sign the United States' amicus brief, despite routinely appearing on such briefs in patent cases. See, *e.g.*, U.S. Amicus Br., *Am. Axle & Mfg., Inc.* v. *Neapco Holdings LLC*, No. 20-891 (U.S. filed May 24, 2022).

ernment backpedals, stating that "broad claims naturally require more extensive enablement." U.S. Br. 9. But it never explains why a claim should be invalidated based on the *cumulative* effort to make all claimed embodiments where, as here, it would not require undue experimentation for skilled artisans to make and use any *individual* embodiment. The Federal Circuit's standard defies *Minerals Separation, Ltd.* v. *Hyde*, 242 U.S. 261 (1916), which recognizes that "it is obviously impossible to specify in a patent the precise treatment" for each of an invention's potentially "infinite[]" variations. *Id.* at 271. Amici and academics attest to the issue's importance.

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

A. The Federal Circuit's Rule Defies This Court's Precedents and History

1. This Court has held that enablement is "a question of fact to be determined by the jury." *Wood*, 46 U.S. at 4; see *Battin* v. *Taggert*, 58 U.S. (17 How.) 74, 85 (1854); *Evans* v. *Eaton*, 20 U.S. (7 Wheat.) 356, 428 (1822). Framing-era English courts did as well, Pet. 15-16, and thus reviewed enablement determinations deferentially, *Hornblower*, Dav. Pat. Cas. at 239-240. But the Federal Circuit holds enablement is "a question of law" courts "review without deference." Pet. App. 6a.

The government cannot justify that departure from history and precedent. It purports to "distinguish" *Battin* because the district court there never submitted enablement to the jury, whereas the courts here overrode the jury's verdict on JMOL. U.S. Br. 14. That does not reconcile the conflicting *legal rules* this Court and the Federal Circuit apply for *when* JMOL is permissible. *Battin* held that "[i]t was the right of the jury to determine, from the facts in the case, whether the specifications * * * enable any

person skilled in the [art] to make" the invention. 58 U.S. at 85. Defying *Battin*, the Federal Circuit deems enablement "a question of law" it decides *de novo*—even when the issue was submitted to the jury. Pet. App. 6a.[2]

2. The government ignores the Seventh Amendment. It nowhere denies that, under *Markman*, courts apply a "'historical test'" to determine whether issues are factual or legal, examining "the English common law when" the Seventh Amendment "was adopted." 517 U.S. at 376. Nor does it deny that *Markman* recognized "clear historical evidence" showing enablement was "regarded" as factual under Framing-era "English practice." *Id.* at 377.

While Amgen discussed that history, Pet. 15-16, the government offers no response. It never mentions the Seventh Amendment's prohibition on re-examining jury verdicts except under the standards of common law. Nor does it explain how the Federal Circuit's *de novo* review can be reconciled with those standards.

3. The government does not deny the issue's importance—an impact the Federal Circuit characterized as "seismic." Pet. App. 68a. Nor is it an answer that courts sometimes may properly decide enablement on JMOL, U.S. Br. 13; the question is *when* that is proper. Deciding enablement on JMOL as a "legal question *de novo*," the district court overturned the jury's verdict. Pet. App. 28a. But when ruling on Sanofi-Regeneron's conditional new-trial motion and deferring to the jury, that court "determine[d] that if the JMOL of no enablement is reversed,

---

[2] Citing the *question presented*, the government accuses Amgen of "conspicuously omit[ting]" that the Federal Circuit reviews "'underlying factual findings * * * for clear error.'" U.S. Br. 14 (quoting Pet. App. 6a). But Amgen specifically quoted that language in its petition. Pet. 9 (quoting Pet. App. 6a).

the jury verdict that the asserted claims were enabled was not against the clear weight of the evidence." Pet. App. 45a. Whether the jury's determination is reviewed as factual, or *de novo* as a legal question, clearly matters—here and generally.

B. The Government's Arguments Support Review

Contradicting this Court's view that enablement is a fact question, *and* the Federal Circuit's view that it is a legal issue, the government calls enablement "a mixed question of law and fact." U.S. Br. 11. That disagreement with everyone *supports* review.

Labeling enablement a "mixed question" is unresponsive regardless. While no "categorical rule" controls whether mixed questions are reviewed as factual or legal on appeal, U.S. Br. 11, this Court categorizes them as one or the other: "[T]he standard of review for a mixed question all depends—on whether answering it entails primarily legal or factual work." *U.S. Bank*, 138 S. Ct. at 967. In *U.S. Bank*, this Court held that the "mixed question" whether defendants are "non-statutory insider[s]" is the sort of fact-intensive issue that is "subject only to review for clear error." *Id.* at 969.

The government urges that, "in determining whether a particular issue is for the judge or jury, this Court looks to history, precedent, and functional considerations such as comparative expertise." U.S. Br. 12. But the Federal Circuit has *never* performed that analysis in holding enablement legal. Pet. 17-18. Nor does the government address those factors. It never denies that history and precedent support treating enablement as a fact question—or that, under *Markman*'s historical test, the Seventh Amendment *requires* it. Pet. 13-16. As to functional considerations, the government concedes the work is factual: It says the "inquiries" under the Federal Circuit's "*Wands* fac-

tors * * * are fact-intensive and often require the evaluation of witness credibility or the weighing of competing evidence." U.S. Br. 11. "[D]ecision[s]" based on such factors are the sort "appellate courts" review "with deference." *U.S. Bank*, 138 S. Ct. at 967.

The government urges that enablement derives from the Patent Act and that construing statutes is a "legal task committed to the court." U.S. Br. 10. While courts must construe statutes to "settle on a legal test," that does not resolve whether *applying* that test requires legal or factual judgment. *U.S. Bank*, 138 S. Ct. at 965. Courts set standards, but juries decide—and courts deferentially review—whether the standards were met. See, *e.g.*, *Hana Fin. Inc.* v. *Hana Bank*, 574 U.S. 418 (2015); *City of Monterey* v. *Del Monte Dunes*, 526 U.S. 687 (1999). Myriad Patent Act requirements—like anticipation and written description—are fact questions reviewed deferentially. *Busch* v. *Jones*, 184 U.S. 598, 604 (1902); *Cordis Corp.* v. *Medtronic AVE, Inc.*, 339 F.3d 1352, 1364 (Fed. Cir. 2003). The very purpose of the Seventh Amendment analysis is to determine whether "actions brought to enforce statutory rights" must be decided by a jury rather than a judge. *Granfinanciera, S.A.* v. *Nordberg*, 492 U.S. 33, 42 (1989).

The government observes that enablement "depends on other legal judgments," such as "construction of" patent claims. U.S. Br. 10-11. But the need for claim construction does not transform all *other* issues dependent on that construction into legal questions. Whether a patent is anticipated depends on claim construction, yet anticipation is "a question of fact." *Busch*, 184 U.S. at 604. Whether the "defendant[ ] * * * infringed [the patent's] claims" depends "on a proper construction of the patent," but infringement is "a question of fact." *Royer* v. *Schultz Belting Co.*, 135 U.S. 319, 325 (1890).

Despite its diversionary tactics, the government never says *enablement* should be reviewed *de novo*. Its refusal to defend the Federal Circuit's rule supports review.

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

Section 112 provides one standard: Patents must "enable any person skilled in the art * * * to make and use" the invention. 35 U.S.C. § 112(a). For genus claims, however, the Federal Circuit "raise[d] the bar," 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.

A. The government notes that, when the claimed invention is a genus, "the patent must enable that entire genus." U.S. Br. 16. Amgen *agrees* that, under § 112, patentees must enable skilled artisans to make and use individual embodiments across "the full scope of a patent's claims." U.S. Br. 9. But the Federal Circuit's "*reach* the full scope" standard requires something *different*: It deems claims non-enabled if "'substantial time and effort' would be required" to *cumulatively* identify and make all embodiments within the genus seriatim. Pet. 13 (quoting Pet. App. 14a); see Pet. 2-3, 7, 13, 22, 27. The difference is critical, as this case shows. It was undisputed that following Amgen's patents' roadmap "generate[s] antibodies" within the claims every time. C.A. App. 3908 (756:15-20). And the jury presumptively credited expert testimony that skilled artisans "would be *certain* to make *all* of the claim's antibodies" across the scope of the claims using those procedures. C.A. App. 3909 (762:10-20) (emphasis added). Yet, as the government acknowledges, the district court found the claims non-enabled because Amgen's experts conceded it "'would take a substantial amount of

time and effort'" to make them *all*. U.S. Br. 6 (quoting Pet. App. 42a).

Downplaying that "reach the full scope" approach, the government urges that "broad claims naturally require more extensive enablement." U.S. Br. 9. But it never explains what in § 112's text suggests enablement turns on the *cumulative* time and effort required to make all variations of the invention one-by-one. Nor does the government explain why that rule makes sense. Once inventors teach skilled artisans how to make and use the individual embodiments across the scope of the claim, there is no reason why they should lose their patent simply because it would be a lot of work to make them *all* seriatim.

B. *Minerals Separation* makes that clear. Making all embodiments within the full scope of the claim in that case would have required adjustments to "accommodate differing circumstances," U.S. Br. 20—specifically, "preliminary tests" to identify the "precise treatment" for each of the "infinite[ ]" ore varieties, 242 U.S. at 270-271. That testing could not possibly satisfy the Federal Circuit's standard, because "'substantial time and effort' would be required to reach the full scope of claimed embodiments." Pet. App. 14a; see Pet. 26-27. The government never suggests otherwise. Yet this Court found the claim enabled.

The government states that "[t]his Court's cases confirm that the full scope of the claims must be considered." U.S. Br. 16. Those cases confirm that patentees cannot claim a broad class, while leaving skilled artisans to conduct "painstaking experimentation" to create embodiments within that class. *Consol. Elec. Light Co.* v. *McKeesport Light Co.*, 159 U.S. 465, 475 (1895). But the patents in those cases failed the *statutory* standard—they did not "'enable any person, skilled in the art * * * to make * * * and use'" the invention *at all*. *Id.* at 474; see *Holland*

Furniture Co. v. *Perkins Glue Co.*, 277 U.S. 245, 257 (1928). As Amgen explained, Pet. Reply 10-11, none of those cases suggests that, when skilled artisans can make embodiments within the claims, patents are nevertheless invalid because "'substantial time and effort' would be required" for skilled artisans "to reach the full scope" by cumulatively making *all* embodiments, Pet. App. 14a.

C. The government faults Amgen for not "propos[ing] an alternative standard." U.S. Br. 18. But Amgen did: Challengers can "prove overbroad claims are not enabled" consistent with § 112 by, for example, "provid[ing] 'concrete identification' of a substantial number of embodiments that cannot be made or used by following the patent's teachings." Pet. Reply 8 (quoting *McRO, Inc.* v. *Bandai Namco Games Am. Inc.*, 959 F.3d 1091, 1100 (Fed. Cir. 2020)). That is the standard elsewhere. See, *e.g.*, *FibroGen Inc.* v. *Akebia Therapeutics Inc.* [2021] EWCA (Civ) 1279, ¶ 95 (Eng.). The government nowhere explains why that commonsense standard does not suffice. Nor does it dispute that Amgen would prevail under that standard. See Pet. 10, 28.

III. THIS CASE IS AN IDEAL VEHICLE

The government identifies no impediment to reaching either question presented.

A. The government urges that this is not "an appropriate vehicle" for deciding whether enablement is a fact question because enablement was submitted to the jury. U.S. Br. 12. But the question is whether the jury's determination is factual (and reviewed deferentially) or legal (and reviewed *de novo*). The government elides the question presented and the Seventh Amendment, which prohibits courts from re-examining any "fact tried by a jury" except "according to the rules of the common law." U.S.

Const. amend. VII. Common-law standards were deferential, not *de novo*. Pet. 16.

The government's contention that the courts below merely found the evidence insufficient at JMOL, U.S. Br. 13-14, is circular. The question here is the standard for such determinations. The *Federal Circuit* never suggested the outcome would be the same if it had treated enablement as factual. Sanofi-Regeneron argued precisely that in opposing rehearing. C.A. Opp. to En Banc 15. Far from agreeing, the Federal Circuit instead declared that treating enablement as a fact question would be "a seismic shift." Pet. App. 68a. The district court itself reached different results when reviewing the verdict deferentially and when proceeding *de novo*. See pp. 4-5, *supra*. And the Federal Circuit's ultimate holding was that "*the* [*district*] *court* did not err in *concluding* that undue experimentation would be required to practice the full scope of these claims," Pet. App. 15a (emphasis added)—a legal conclusion, not a sufficiency-of-the-evidence determination.

The government proves the point, invoking facts "*the district court*"—not the jury—"determined." U.S. Br. 20 (emphasis added). The one time the Federal Circuit mentioned the no-reasonable-juror standard, Pet. App. 14a, was in connection with an issue (time and effort required) the government characterizes as one of many underlying factual considerations. Ultimately, the Federal Circuit, "weigh[ing] the *Wands* factors" itself, Pet. App. 15a, afforded no deference to how the jury presumptively weighed them.

The government's denial of "practical significance," U.S. Br. 14, defies credulity. The Federal Circuit does not merely re-examine enablement *de novo*. In doing so, it regularly substitutes its judgment even on underlying issues "[i]t was the right of the jury to determine." *Battin*,

58 U.S. at 85; see Pet. 22-23. For example, the government repeats the Federal Circuit's assertion that the patents lacked "'adequate guidance beyond the narrow scope of the working examples,'" U.S. Br. 15 (quoting Pet. App. 14a), but never explains why a reasonable jury could not have credited expert testimony that skilled artisans following the patents' roadmap "would be *certain* to make *all* of the claim's antibodies," C.A. App. 3909 (762:10-20) (emphasis added). The government's invocation of the district court's statement that the specification required artisans to replicate the inventors' work, U.S. Br. 20, underscores the departure. That contention was so clearly wrong that Sanofi-Regeneron did not defend it and the Federal Circuit never invoked it on appeal. See Pet. C.A. Reply 6.

Regardless, whether the outcome would be different in this case if enablement were a question of fact is at most an issue for the Federal Circuit following any remand. The government's (unsupported) suggestion that this case ultimately would come out the same is not a basis for denying review of this important question.

B. The government's assertion that the Federal Circuit's reach-the-full-scope enablement standard "flowed naturally from the *Wands* factors" here, U.S. Br. 18, says nothing about the propriety of review. Amgen's point is that the "reach the full scope" standard, Pet. App. 14a, radically alters *In re Wands*' "undue experimentation" framework, 858 F.2d 731, 737 (Fed. Cir. 1988)—it considers the *cumulative* experimentation required to make *all* of the embodiments, as opposed to the experimentation required to make *any individual* embodiment within the claim's scope, Pet. 6-7. If not the "sum total" of the Federal Circuit's "analysis," U.S. Br. 17, the government nev-

er denies that the court's framing of that issue was outcome-determinative.

C. The government's insistence that Sanofi-Regeneron raised "evidentiary disputes" below—which could require a "retrial * * * if this Court ruled for petitioners on the present record," U.S. Br. 21—makes no sense. The Federal Circuit might reject those arguments on remand. This Court grants review to decide important legal questions. Prognostications about how this case might be resolved following remand are of no moment to whether review is warranted.

CONCLUSION

The petition should be granted.

Respectfully submitted.

JONATHAN P. GRAHAM
STUART L. WATT
WENDY A. WHITEFORD
STEVEN D. TANG
EMILY C. JOHNSON
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320
(805) 447-1000

KEITH R. HUMMEL
ANDREI HARASYMIAK
CRAVATH, SWAINE & MOORE LLP
Worldwide Plaza
825 Eighth Avenue
New York, NY 10019
(212) 474-1000

JEFFREY A. LAMKEN
Counsel of Record
MICHAEL G. PATTILLO, JR.
SARAH J. NEWMAN
WALTER H HAWES IV
MOLOLAMKEN LLP
The Watergate, Suite 500
600 New Hampshire Ave., N.W.
Washington, D.C. 20037
(202) 556-2000
jlamken@mololamken.com

SARAH C. COLUMBIA
MCDERMOTT WILL & EMERY LLP
200 Clarendon Street, Floor 58
Boston, MA 02116
(617) 535-4074

WILLIAM G. GAEDE, III
MCDERMOTT WILL & EMERY LLP
415 Mission Street
Suite 5600
San Francisco, CA 94105
(650) 815-7435

Counsel for Petitioners

OCTOBER 2022