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, REGENERON PHARMACEUTICALS INC., and SANOFI-AVENTIS U.S., LLC,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether enablement, an issue of patent validity, is a question of law based on underlying findings of fact, as the Federal Circuit holds and this Court has consistently held with respect to issues of patent validity.

2. Whether the lower court erred in applying long-established Federal Circuit law to the undisputed relevant evidence in this case in determining that no reasonable jury could conclude that the patents are enabled.

CORPORATE DISCLOSURE STATEMENT

Respondent Sanofi has no parent corporation, and no publicly held company owns 10% or more of its stock. Sanofi is the indirect parent corporation of Respondents sanofi-aventis U.S. LLC and Aventisub LLC.

Respondent Regeneron Pharmaceuticals, Inc. has no parent corporation, and no publicly held company owns 10% or more of its stock.

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INTRODUCTION

This case is a patent dispute between innovators who independently developed antibody drugs that reduce low-density lipoprotein ("LDL") cholesterol. The antibodies bind to a protein, PCSK9, thus preventing the destruction of receptors that extract cholesterol from the bloodstream. Respondents developed Praluent, the first FDA-approved PCSK9 antibody, and Amgen developed Repatha. These antibodies differ in amino acid sequence and where they bind to PCSK9. Both are used to treat tens of thousands of patients.

Respondents patented Praluent by its amino acid sequence. Amgen likewise initially patented Repatha by its amino acid sequence. But years later, in a blatant attempt to corner the market on PCSK9 inhibitors—and *after* Respondents developed Praluent—Amgen obtained *additional* patents that broadly claim *all* antibodies that bind to certain amino acids on PCSK9 and block its binding to receptors. Amgen then asserted its new patents' broad, functionally defined genus claims against Respondents, arguing that Praluent infringes the claims, and it sought damages and an injunction removing Praluent from the market.

The Federal Circuit rightly rejected this gambit, holding that Amgen's broad functional claims are not enabled and thereby invalid under 35 U.S.C. §112. That decision does not warrant further review by this Court. In its unanimous decision, the panel merely applied well-established law to the undisputed relevant facts and determined that Amgen's broad functional claims require undue experimentation and

thus are not enabled by the particular specification in Amgen's patents. Accordingly, this case presents nothing more than a classic case of factbound error correction that does not merit the Court's intervention.

Amgen nevertheless manufactures two questions presented in an effort to obtain certiorari. Neither provides a valid basis for review. In its first question, Amgen contends that the Federal Circuit treats enablement as a "question of law" while this Court treats enablement as a "question of fact." But this Court has consistently held that patent validity issues like enablement are questions of law based on underlying findings of fact, and the Federal Circuit holds the same with respect to enablement specifically. In its second question, Amgen contends that the decision below created a special test applicable to functional genus claims. But the panel repeatedly disclaimed any bright-line rules or tests; its holding was simply the result of applying factors that the Federal Circuit has long used when evaluating enablement to the undisputed relevant evidence in this case, and that approach is consistent with the statutory text and this Court's precedents. Both questions presented, moreover, do not implicate any current differences of federal law within the lower courts, are of insufficient importance to warrant certiorari, and are the subject of recently denied petitions, and this case suffers from multiple vehicle problems regardless. The petition should be denied.

STATEMENT OF THE CASE

A. Factual Background

High levels of LDL cholesterol can lead to cardiovascular disease, heart attacks, and strokes. *See Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1371 (Fed. Cir. 2017). The human body normally relies on LDL receptors in the liver to remove LDL cholesterol from the bloodstream. Pet.App.3a. In the early 2000s, academic researchers discovered that a naturally occurring protein called PCSK9 binds to and causes the destruction of those LDL receptors, leading to higher levels of LDL cholesterol in the blood. Pet.App.3a; C.A.App.3681. Building on that knowledge, pharmaceutical companies began developing antibodies that would bind to PCSK9, inhibiting it from binding to LDL receptors and so leaving those receptors free to continue removing LDL cholesterol from the bloodstream. C.A.App.3681; C.A.App.3766.

Respondents began work on a PCSK9-inhibiting antibody in 2007. *Amgen*, 872 F.3d at 1372. In November 2011, the Patent and Trademark Office issued Respondents a patent on an anti-PCSK9 antibody described by its amino acid sequence—the long-accepted way to claim a protein. *Id.*; *see* U.S. Patent No. 8,062,640. In July 2015, the Food and Drug Administration approved this antibody for the treatment of high cholesterol under the trade name Praluent, making it the first PCSK9 inhibitor on the market. 872 F.3d at 1372.

While Respondents were developing Praluent, Amgen was independently pursuing its own PCSK9 inhibitor. Amgen ultimately isolated an antibody and,

in October 2011, it obtained a patent on that antibody by claiming its amino acid sequence—a sequence different from Praluent's amino acid sequence. *See* U.S. Patent No. 8,030,457. In August 2015, the FDA approved that antibody for the treatment of high cholesterol under the trade name Repatha. *Amgen*, 872 F.3d at 1371.

B. The Patents-In-Suit

This case does *not* involve Amgen's patent claiming Repatha by its amino acid sequence. It is undisputed that Praluent does not infringe that patent. Instead, this case involves two *additional* patents obtained by Amgen three years later, after Respondents developed Praluent. Unlike Amgen's earlier patent, which claimed an antibody by amino acid sequence, Amgen's new patents included broad claims that purported to "cover the entire genus of antibodies that bind to specific amino acid residues on PCSK9 and block PCSK9 from binding to" LDL receptors. *Amgen*, 872 F.3d at 1372; *see* Pet.App.4a-5a; U.S. Patent Nos. 8,829,165 ("'165 patent"), 8,859,741 ("'741 patent").[1] In other words, Amgen's new patents claimed any antibody with the *function* of binding to particular residues and blocking PCSK9 from binding to LDL receptors.

For instance, claim 1 and dependent claim 19 of the '165 patent claim:

> 1. An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least one of the following

[1] A "residue" is a particular amino acid in the amino acid sequence forming a protein. *Amgen*, 872 F.3d at 1372 n.3.

> residues [followed by a list of 15 amino acid residues], and wherein the monoclonal antibody blocks binding of PCSK9 to [LDL receptors].
>
> 19. The isolated monoclonal antibody of claim 1 wherein the isolated monoclonal antibody binds to at least two of the following residues [followed by the same list of 15 amino acid residues as in claim 1].

Pet.App.4a. By its terms, claim 19, which was asserted in this litigation, covers any isolated monoclonal antibody that binds to at least two of the identified amino acid residues on PCSK9 and blocks PCSK9 from binding to LDL receptors.

The two Amgen patents at issue in this case share a common specification, which describes the "trial-and-error process [Amgen] used to generate and screen antibodies that bind to PCSK9 and block PCSK9 from binding to" LDL receptors. *Amgen*, 872 F.3d at 1372; Pet.App.3a. The specification discloses that Amgen identified 3,000 antibodies that bind to PCSK9, which Amgen narrowed down to 85 that blocked the interaction between PCSK9 and LDL receptors by 90% or more. *Amgen*, 872 F.3d at 1372. The specification only discloses the amino acid sequences of roughly two dozen antibodies purported to be within the scope of the claims. *Id.* And of those antibodies, the specification provides the three-dimensional structure of all of two antibodies. *Id.*

C. Proceedings Below

In October 2014, mere days after obtaining the '165 and '741 patents, Amgen sued Respondents for infringement, asserting that Praluent fell within the

broad class of antibodies those patents claimed. Pet.App.5a. Respondents stipulated to infringement, but, as relevant here, claimed that the '165 and '741 patents are invalid for failure to satisfy the Patent Act's enablement and written description requirements. Pet.App.5a; *Amgen*, 872 F.3d at 1372; *see* 35 U.S.C. §112(a) (requiring every patent to include a specification that contains "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").[2]

1. First Trial and Appeal

A jury ruled for Amgen, and the district court granted a permanent injunction removing Praluent from the market. *Amgen*, 872 F.3d at 1372-73. The Federal Circuit stayed the injunction pending appeal. *Id.* at 1373.

On appeal, Respondents argued that the district court erroneously excluded evidence showing that even after Amgen filed its priority application for the patents, it continued its trial-and-error search for antibodies within the genus; such post-priority-date evidence, Respondents contended, was relevant to both the enablement and written description requirements. *Id.* Respondents also contended that the court had erroneously instructed the jury that it could find adequate written description if Amgen's

[2] Section 112 was amended by the America Invents Act, Pub. L. No. 112-99 (2011). The pre-AIA statute applies to the patents at issue in this case.

specification disclosed a "newly characterized antigen," rather than properties of the claimed antibodies. *Id.* at 1376.

The Federal Circuit unanimously agreed with these arguments and vacated the jury verdict and permanent injunction. *Id.* at 1371. It held that the exclusion of post-priority-date evidence was erroneous because such evidence was relevant to determining whether the patents satisfied the enablement and written description requirements. *Id.* at 1374-75. And it held that the "newly characterized antigen" test embodied in the challenged jury instruction "flout[ed] basic legal principles of the written description requirement." *Id.* at 1378-79. The Federal Circuit remanded for a new trial on enablement and written description. *Id.* at 1381-82.

2. Second Trial

On remand, the case was reassigned to a new district judge given the previous judge's retirement. Before trial, Amgen again sought to exclude some of the same evidence that Respondents raised in the first appeal—including some of the same documents that had previously been excluded. As before, this evidence showed that, for years after the priority date, Amgen continued to look for certain desirable antibodies known to fall within the scope of the claims but was unsuccessful, despite having the '165 and '741 patents in hand—thus demonstrating the patents' lack of enablement and written description. The court nevertheless prohibited Respondents from introducing this evidence for any purpose—even to impeach Amgen's lead inventor, whose testimony was flatly contrary to the excluded evidence. *See*

C.A.App.3686-3687, 3807-3808, 3869-3870, 5248-5431.

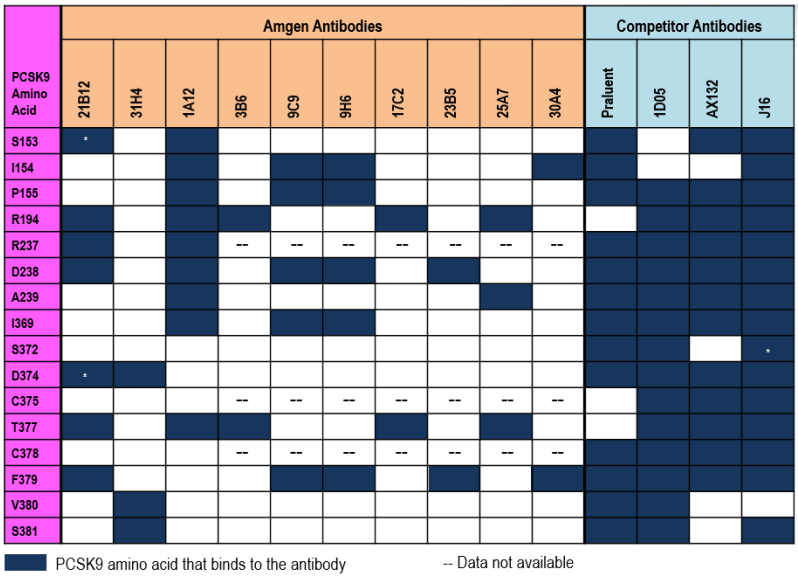
Despite being hamstrung by the evidentiary rulings, Respondents presented undisputed evidence demonstrating that the asserted claims are not enabled. For example, as to the breadth of the claims, Respondents' expert testified that the patents "cover … a vast scope of possible antibodies," reaching "millions" if not "an astronomically large number" of antibodies. C.A.App.3750, 3688, 3759. Amgen's witnesses did not disagree; they were unable even to estimate the number of antibodies within the claims' scope. One "d[id]n't know a specific number," C.A.App.3869, and the other said he couldn't "give … a number" and agreed that following the patents' teaching would generate "millions and millions of antibodies," C.A.App.3902.

Furthermore, Amgen's witnesses conceded that given the unpredictability of antibody science, a skilled person would have to test every single antibody generated by Amgen's disclosed methods to determine whether it had the necessary functional properties and thus was encompassed by the claims. As one Amgen expert admitted, knowing "the amino acid sequence of an antibody" does not "tell you the property of where it binds," so to determine if generated antibodies actually "bind and block" and thus fall within the claims' scope, "you'd have to test" each of them. C.A.App.3914-3918. Another Amgen expert acknowledged that "[c]hanging a single amino acid in an antibody's sequence can change that antibody's function," so to determine an antibody's functionality after changing "a single amino acid," a

skilled person "would test." C.A.App.3891. And an Amgen inventor conceded that even "conservative substitutions"—*i.e.*, changing one amino acid of an antibody disclosed in the patent—are unpredictable, because "sometimes what you think is a conservative mutation is not conservative at all … in terms of the protein function"; thus, the "only way to know" if an antibody resulting from a "conservative mutation" falls within the claims' scope "is to test it." C.A.App.3768-3769.

Given the vastness of the claims' scope, the unpredictability of the art, and the need to test every generated antibody to determine if it falls within the claims' scope, Amgen's experts admitted that the amount of experimentation necessary to make and use (*i.e.*, enable) the claimed antibodies was "an enormous amount of work" and not "practical"; no "antibody scientist would even contemplate doing" it. C.A.App.3902, 3914.

In addition to this non-enablement evidence, Respondents also presented undisputed evidence that Amgen's patents lacked sufficient written description because the antibodies disclosed in the patents were not representative of or structurally similar even to four antibodies discovered by Amgen's competitors and known to fall within the claims—much less to the millions of additional antibodies that the claims encompassed. For example, Respondents showed that those four antibodies bound to PCSK9 at more (and markedly different) residues than Amgen's disclosed antibodies, as shown in the following table:



C.A.App.4283. The jury found two of the five asserted claims invalid for lack of adequate written description but found the three remaining claims valid.

Respondents moved for judgment as a matter of law that the patents are invalid due to lack of enablement and written description. The district court granted Respondents' motion as to enablement, concluding that, under the Federal Circuit's long-established multi-factor test for evaluating enablement, *see In re Wands*, 858 F.2d 731 (Fed. Cir. 1988), Amgen's patents require undue experimentation and thus are not enabled. Pet.App.27a-44a. Among other things—and repeatedly noting testimony from Amgen's own witnesses—the court determined that "there is not a genuine material dispute of fact as to the breadth of the claims, and a reasonable factfinder could only conclude on this factual record that the scope of the claims is vast," Pet.App.34a; "a reasonable factfinder

could only find that the art is unpredictable," Pet.App.35a-38a; "any reasonable factfinder would conclude" that the patent "do[es] not teach a person of ordinary skill in the art how to predict from an antibody's sequence whether it will bind to specific PCSK9 residues," Pet.App.38a, 40a; and "a reasonable factfinder could only have determined that the experimentation necessary to enable the full scope of the claims would take a substantial amount of time and effort," Pet.App.42a-43a. Accordingly, "any reasonable factfinder would find that practicing the claims' full scope" would require "substantial" and "undue experimentation." Pet.App.43a-44a.

3. The Second Appeal

Amgen appealed to the Federal Circuit, arguing that the district court had erred in its application of the multi-factor *Wands* test. *See* Amgen.C.A.Br.26 (contending that "[t]his Court's seminal enablement decision, *Wands*, demonstrates that Amgen's patents are enabled"); Amgen.C.A.Br.28 (contending that the district court's "*Wands* analysis" was "flawed"); Pet.App.8a (noting that "Amgen contends that, under a proper analysis of the *Wands* factors, the claims at issue were enabled").

The Federal Circuit unanimously affirmed. Pet.App.1a-15a. The court first observed that enablement is "a question of law … review[ed] without deference, although the determination may be based on underlying factual findings, which we review for clear error." Pet.App.6a.

The court next explained that "[w]hile functional claim limitations are not necessarily precluded in claims that meet the enablement requirements," such

limitations "pose high hurdles in fulfilling the enablement requirement." Pet.App.12a. It then held that, under the *Wands* factors, "undue experimentation" was necessary to enable the "full scope" of Amgen's "double-function claims." Pet.App.12a. The court remarked that the claims "were indisputably broad," and "far broader in functional diversity than the disclosed examples." Pet.App.12a-13a. The court also observed—citing Amgen's own witnesses—that the "field of science" was "unpredictable," and it noted "the conspicuous absence of nonconclusory evidence that the full scope of the broad claims can predictably be generated by the described methods." Pet.App.13a. Next, the court concluded that, even after giving Amgen the benefit of the evidence, "any reasonable factfinder would conclude that the patent does not provide significant guidance or direction to a person of ordinary skill in the art for the full scope of the claims." Pet.App.14a. "[U]nder these facts," the court explained, "no reasonable jury could conclude … that anything but substantial time and effort would be required to reach the full scope of claimed embodiments." Pet.App.14a. Thus, "weighing the *Wands* factors," the court concluded, "undue experimentation would be required to practice the full scope of these claims." Pet.App.15a.

Amgen sought rehearing en banc. The Federal Circuit denied rehearing without any call for a vote. Pet.App.60a-61a. The panel issued an opinion respecting the denial of rehearing. Pet.App.62a-68a. The panel devoted the vast majority of that opinion to rejecting Amgen's argument that it had "created a new test for enablement." Pet.App.62a. The panel

explained that the opinion had merely "examined the relevant *Wands* factors and their interaction in a case-specific manner" and that what was "new" was "not the law, but generic claims to biological materials that are not fully enabled." Pet.App.63a, 64a-65a. As the panel explained, "[c]laims defining a composition of matter by function raise special problems," because "one may not know whether a species is within the scope of a generic claim until one has made it and one can ascertain whether it possesses the claimed function, hence that it has been enabled." Pet.App.66a. The enablement requirement precludes obtaining a patent "for inventions broader than are disclosed or enabled, and that were apparently not invented by the applicant." Pet.App.64a. Allowing such overly broad genus claims where an inventor has not done the work of filling in the gaps, the panel observed, "discourages invention by others." *Id.* When "properly supported," however, "[g]enus claims, to any type of invention … are alive and well." Pet.App.63a.

The panel also briefly addressed Amgen's argument in its rehearing petition that the court should overrule its precedent treating enablement as a question of law based on underlying factual findings. Pet.App.66a-67a. The panel observed that this Court has "made clear that interpretation of claim scope, a question inexorably intertwined with enablement, is a question of law"; thus, "it is no surprise that enablement, which involves interpreting the specification and the scope of the claims, is also a question of law, if one that accommodates underlying factual inquiries where applicable." Pet.App.68a.

REASONS FOR DENYING THE PETITION

I. The First Question Presented Does Not Warrant This Court's Review.

A. The Federal Circuit's Treatment of Enablement Is Consistent With This Court's Precedents.

Amgen's first question asks "[w]hether enablement is a question of fact to be determined by the jury … or a question of law that the court reviews without deference." Pet.i (alterations omitted). Amgen contends that the Federal Circuit has adopted a "contrary rule" that diverges from this Court's caselaw and that certiorari is warranted to correct the Federal Circuit's "opposite" approach. Pet.12, 13, 24. Amgen is incorrect. The Federal Circuit's treatment of enablement is consistent with this Court's treatment of patent validity issues.

This Court has long held that patent validity is a question of law with underlying factual questions. Thus, the Court held in *Microsoft Corp. v. i4i Ltd. Partnership*, 564 U.S. 91 (2011), that "the ultimate question of patent validity is one of law," with "the same factual questions underlying the PTO's original examination of a patent application" also "bear[ing] on an invalidity defense in an infringement action." *Id.* at 96-97. Similarly, in *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273 (1976), which addressed the invalidity defense of obviousness, the Court explained that "[t]he ultimate test of patent validity is one of law, but resolution of the obviousness issue necessarily entails several basic factual inquiries." *Id.* at 280 (citation omitted); *accord KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 427 (2007). The Court likewise observed in

Graham v. John Deere Co. of Kansas City, 383 U.S. 1 (1966), that "patent validity" is "ultimate[ly]" a question "of law," but one that "lends itself to several basic factual inquiries." *Id.* at 17. In short, "[t]he Supreme Court's modern case law clearly and consistently holds that patent validity is a question of law based on underlying findings of fact." Paul R. Gugliuzza, *Law, Fact, and Patent Validity*, 106 Iowa L. Rev. 607, 615 (2021).

Enablement is a patent validity issue; it is one of the conditions of patent validity, and its absence is "an invalidity defense in an infringement action," *Microsoft*, 564 U.S. at 96; *see* 35 U.S.C. §§112(a), 282(b)(3)(A); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002). And consistent with this Court's precedent governing patent validity issues, the Federal Circuit has long held that enablement also is ultimately a question of law based on underlying questions of fact. As the Federal Circuit recently observed, "[W]hether a patent satisfies the enablement requirement is a question of law based on underlying factual findings." *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 959 F.3d 1091, 1096 (Fed. Cir. 2020); *see also, e.g.*, *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1154 (Fed. Cir. 2019) ("Whether a claim satisfies the enablement requirement is a question of law" with "the factual underpinnings of enablement" reviewed for "substantial evidence" following jury trial); *Wands*, 858 F.2d at 735 (explaining that enablement is reviewed "as a question of law" with "underlying facts found" by PTO reviewed under "clearly erroneous standard"); *In re Brandstadter*, 484 F.2d 1395, 1406 (C.C.P.A. 1973) (considering impact of affidavits "on

the ultimate legal question of enablement"). Thus, just like this Court's cases addressing patent validity issues such as enablement, "the Federal Circuit views enablement to present a question of law based on underlying findings of fact." Gugliuzza, *supra*, at 638.[3]

To demonstrate a supposed conflict between this Court's caselaw and the Federal Circuit's caselaw, Amgen cites a handful of this Court's decisions predating the Civil War. But none of these decisions contradicts this Court's and the Federal Circuit's current aligned approach that treats invalidity issues like enablement as questions of law based on underlying questions of fact. For example, in Amgen's leading case, *Wood v. Underhill*, 46 U.S. (5 How.) 1 (1846), the Court explained that while the "sufficiency of the description" is "in general" a question of fact, "when the specification of a new composition of matter gives only the names of the substances which are to be mixed together, without stating any relative proportion, undoubtedly it would be the duty of the court to declare the patent … void." *Id.* at 4-5. In *Evans v. Eaton*, enablement was "not disputed," so the Court had no occasion to assess the interplay of the

[3] As the consistency with this Court's cases demonstrates, moreover, that approach is eminently correct. This Court has "made clear that interpretation of claim scope, a question inexorably intertwined with enablement, is a question of law." Pet.App.68a; *see Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-90 (1996). Because the determination of claim scope is at the core of the determination of whether a patent meets the enablement requirement, it makes perfect sense to treat enablement as an ultimate question of law based on underlying factual findings.

jury's factfinding with the court's ultimate conclusion. 20 U.S. (7 Wheat.) 356, 428 (1822). Similarly, *Hogg v. Emerson* merely notes that the jury found, based on the court's instructions on the law, that ordinary mechanics could make the steam-propelled machines. 52 U.S. (11 How.) 587, 606 (1850).

In Amgen's other cases, the factual issue for the jury related to the capabilities of a person skilled in the art. *See Battin v. Taggert*, 58 U.S. (17 How.) 74, 85 (1854) (jury to determine whether specification was sufficiently precise "to enable *any person skilled in the structure of machines*" to make invention (emphasis added)); *Gray v. James*, 10 F.Cas. 1015, 1018 (C.C.D. Pa. 1817) ("Whether the specification in this case be defective … must depend upon the evidence *of the practical mechanicians*." (emphasis added)); *Lowell v. Lewis*, 15 F.Cas. 1018, 1021 (C.C.D. Mass. 1817) ("[I]t is a question of fact, whether the specification be so clear and full, *that a pump-maker of ordinary skill* could, from the terms of the specification, be able to construct" invention (emphasis added)). That is fully consistent with Federal Circuit caselaw, which treats the capabilities of a person skilled in the art to make the invention as a factual issue determined by the jury. *See Wands*, 858 F.2d at 737 (factors for determining enablement include "the relative skill of those in the art"). That factor is just one of the "underlying factual findings" that goes toward the ultimate "question of law" regarding enablement. *McRO*, 959 F.3d at 1096.

In short, none of the antebellum decisions of this Court cited by Amgen establishes that enablement is *purely* a question of fact for the jury, as Amgen's

argument presupposes and as the Court's far more recent precedents reject. Indeed, as early as 1870, this Court explicitly recognized that enablement is "always open to legal construction as to [its] sufficiency." *Seymour v. Osborne*, 78 U.S. (11 Wall.) 516, 540 (1870). That proposition is consistent with the Court's (and the Federal Circuit's) recent jurisprudence, and pre-Federal Circuit courts of appeals recognized it as well. *See Minn. Mining & Mfg., Inc. v. Carborundum*, 155 F.2d 746, 749 (3d Cir. 1946) (enablement is a "question of law, open to this court"); *Watson v. Bersworth*, 251 F.2d 898, 901 (D.C. Cir. 1958) (same); *see also Carter-Wallace, Inc. v. Otte*, 474 F.2d 529, 547 (2d Cir. 1972) ("The adequacy of a patent application's disclosure is a mixed question of law and fact, on which the court must ultimately apply a legal standard to a complex set of facts.").[4]

Amgen selectively invokes not just this Court's decisions but the Federal Circuit's decisions, too. Although the Federal Circuit has repeatedly—and recently—described enablement as "a question of law based on underlying factual findings," *McRO*, 959 F.3d at 1096, Amgen seizes upon a smattering of decades-old decisions where the Federal Circuit or its predecessor used the shorthand phrase "question of law" to describe its approach. *See* Pet.17 (citing *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960 n.6

[4] Amgen dismisses *Seymour* as addressing the "requirements … to patent issuance" rather than "enablement … as a defense." Pet.18. But the very point of an invalidity defense is that the patent failed to meet the requirements for issuance, including enablement. *See* 35 U.S.C. §§102, 103. And the context of the Court's explanation was a case where invalidity was raised as a defense. *See Seymour*, 78 U.S. at 539, 560.

(Fed. Cir. 1983), and *In re Hogan*, 559 F.2d 595, 604 (C.C.P.A. 1977)). Indeed, Amgen mischaracterizes the panel's decision *in this case*. It repeatedly contends that the panel merely observed that enablement is a "question of law" that it "reviews without deference." Pet.i, 2, 12, 13, 17. But in each of these instances, Amgen omits what the panel proceeded to say in that *very same sentence*: "although the determination may be based on underlying factual findings, which we review for clear error." Pet.App.6a. That language is perfectly aligned with both this Court's precedents describing patent validity issues and the Federal Circuit's precedents describing enablement (a patent validity issue).

Finally, Amgen observes that the Federal Circuit treats one §112 requirement, written description, as a "question of fact," while it treats another §112 requirement, enablement, as a "question of law." Pet.19. Amgen insinuates that this discrepancy—which Amgen does not actually challenge—is a reason for changing the Federal Circuit's approach to enablement. But if anything, it is the Federal Circuit's approach to written description that is the outlier. *See* Gugliuzza, *supra*, at 636 ("The notion that written description is a question of fact is … inconsistent with Supreme Court precedent stating that patent validity is ultimately a question of law."). In any event, to the extent the Federal Circuit has adopted an "internally incoherent" approach to §112 invalidity defenses, Pet.19, the solution is for the Federal Circuit to address that internal incoherence—not for this Court to create incoherence in its own jurisprudence by

holding, contrary to its own precedent, that enablement is purely a question of fact.[5]

B. The Question Presented Is of Insufficient Importance to Warrant Certiorari.

Amgen's first question presented also lacks the traditional indicia of an issue warranting this Court's intervention. To begin with, Amgen identifies no current differences of federal law among the federal courts of appeals. And while this Court does occasionally grant certiorari to review Federal Circuit decisions involving patent law, the overwhelming majority of those decisions generated a panel dissent, en banc proceedings, or at least a call for rehearing en banc, *see, e.g.*, *Peter v. Nantkwest, Inc.*, 140 S.Ct. 365, 370 (2019); *Hologic, Inc. v. Minerva Surgical, Inc.*, 957 F.3d 1256, 1275 (Fed. Cir. 2020) (Stoll, J., additional views), *vacated*, 141 S.Ct. 2298 (2021). None of that is present here.

Additionally, as Amgen acknowledges, Pet.24, this Court has repeatedly denied petitions raising this

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[5] Amgen engages in further misdirection when it repeatedly quotes the opinion respecting en banc denial as "acknowledg[ing] that '[o]ne can reasonably ask … why enablement is a question of law.'" Pet.2, 11, 12, 17 (quoting Pet.App.67a). In these instances, Amgen omits the rest of the sentence: "when written description … is not." Pet.App.67a. The omitted material underscores that the panel was speculating why Federal Circuit law treats written description as an exception to the general rule that invalidity, including enablement, is ultimately an issue of law. The genesis of the Federal Circuit's differential treatment of written description as a question of fact is not only arcane but beyond the scope of Amgen's petition, which does not challenge that distinction.

question, including as recently as last year. *See Idenix Pharms. LLC v. Gilead Scis., Inc.*, 141 S.Ct. 1234 (2021); *Johnson v. I/O Concepts, Inc.*, 537 U.S. 1066 (2002); *Musco Corp. v. Qualite, Inc.*, 522 U.S. 814 (1997). Amgen does not identify any changed circumstances warranting different treatment here. Amgen merely contends that the most recent petition was "plagued by vehicle issues," but that is hyperbole; the brief in opposition identified a single "vehicle problem." BIO.36, *Idenix Pharms. LLC v. Gilead Scis. Inc.*, No. 20-380 (U.S. filed Dec. 16, 2020). Regardless, Amgen's petition suffers from multiple vehicle problems, too. *See* pp.24-28, *infra*.

Amgen also vastly overstates the importance of this issue. By Amgen's own telling, the Federal Circuit's purported "rule" has been in place without modification since 1983. Pet.17. Not only does that suggest a stale legal principle in no urgent need of this Court's review, but in the nearly 40 years since, the Federal Circuit's "rule" has been challenged in only a handful of petitions for certiorari. That is not the hallmark of a legal principle that supposedly "depart[s] from this Court's precedents and historical practice," creates "doctrinal uncertainty," and "routinely lays waste to innovative patents." Pet.20-24.

Amgen contends that "[b]y deeming enablement a question of law, the Federal Circuit licenses courts to substitute their judgments … on disputed issues that it was the right of the jury to determine." Pet.20. It then cites a selection of cases where Federal Circuit panels or district courts purportedly "exercis[ed] their *own* judgment to hold patents not enabled." *Id.* But

the judgments in those cases simply reflected a judicial conclusion that the evidence could not reasonably support a determination that a patent was enabled. They are no different from any other case where the court declares summary judgment or other judgment as a matter of law based on an insufficient evidentiary showing—even in cases involving purely factual issues. *See Hepner v. United States*, 213 U.S. 103, 115 (1909) ("The defendant was, of course, entitled to have a jury summoned in this case, but that right was subject to the condition, fundamental in the conduct of civil actions, that the court may withdraw a case from the jury and direct a verdict according to the law if the evidence is uncontradicted and raises only a question of law."); *see also Weisgram v. Marley Co.*, 528 U.S. 440, 447-48 (2000). Indeed, even Amgen's leading case, *Wood*, makes clear that if the undisputed evidence demonstrates that a patent does not sufficiently enable an invention, "undoubtedly it would be the duty of the court to declare the patent void." 46 U.S. (5 How.) at 5; *see also KSR*, 550 U.S. at 426-27 (holding that "summary judgment is appropriate" when "questions of fact" underlying obviousness determination are "not in material dispute," since "[t]he ultimate judgment of obviousness is a legal determination").

That is precisely what occurred in this case. Both the district court and the Federal Circuit panel concluded, based on the undisputed relevant facts, that no reasonable juror could conclude that Amgen's claims are enabled, because "undue experimentation would be required to practice the full scope of [Amgen's] claims." Pet.App.15a. Amgen contends that the panel "inva[ded] … the jury's role," but the

panel repeatedly emphasized that its decision was based on undisputed facts. *See, e.g.*, Pet.App.13a (discussing what "[o]ne of Amgen's expert witnesses admitted" and "[a]nother of Amgen's experts conceded"); *id.* (noting "the conspicuous absence of nonconclusory evidence that the full scope of the broad claims can predictably be generated by the described methods"). Again, this is no different from any court concluding, as a matter of law, that a verdict cannot be sustained given insufficient evidence under the applicable law. And, given that the lower court decisions are rooted in undisputed facts, the outcome would have been the same regardless of the standard of review.[6]

Amgen also broadly attacks the Federal Circuit, invoking the specters of a "second jury" and "panel dependency." Pet.21. Tellingly, however, Amgen supports these claims only by citing four academic articles spanning 24 years. Three of those articles, moreover, do not even mention enablement, and the fourth does so largely in a footnote. None of them has anything to do with Amgen's first question presented.[7]

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[6] Amgen repeatedly insinuates that the Federal Circuit's action was especially egregious because "*two different juries*" found its claims enabled. Pet.App.3, 8, 9, 22, 23, 32. But the first jury verdict was vacated due to instructional and evidentiary errors (including as to enablement). *See* pp.6-7, *supra*. Amgen's insistence that the Court should give weight to a vacated jury verdict resulting from multiple trial errors is mystifying.

[7] Federal Circuit precedent refutes Amgen's contention that the court has been improperly disregarding the factfinding role of juries in deciding enablement. The Federal Circuit routinely reverses district court judgments finding no enablement, on the ground that the underlying facts are in dispute. *See, e.g.*, *McRO*,

Amgen is left to latch onto the panel's passing observation that adopting Amgen's position would be a "seismic shift." Pet.App.68a. But the panel was merely describing what would occur if the Federal Circuit departed from decades of its own caselaw and this Court's precedents establishing that enablement is a question of law based on underlying factual findings. Amgen provided "no compelling reason" to the Federal Circuit to radically change course and diverge from this Court's caselaw. Pet.App.68a. Amgen likewise provides no valid reason for this Court to do the same here.

C. This Case Is an Exceptionally Poor Vehicle to Address the Question Presented.

Even if Amgen's first question presented otherwise warranted review, this case would be a very poor vehicle for numerous reasons. *First*, the question whether enablement is a "question of fact" or a "question of law" was not briefed on the merits below,

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959 F.3d at 1099; *Vasudevan Software, Inc. v. MicroStrategy, Inc.*, 782 F.3d 671, 684-85 (Fed. Cir. 2015); *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1356 (Fed. Cir. 2012). Indeed, Amgen cites *Martek Biosciences Corp. v. Nutrinova Inc.*, 520 F. Supp.2d 557, 558 (D. Del. 2007), as an example of a court supposedly substituting its judgment for the jury, *see* Pet.20, but Amgen fails to note that the Federal Circuit actually *reversed* the district court's judgment of no enablement in that case on some claims because "the evidence support[ed] the jury's implicit finding that one need not perform undue experimentation to practice" those claims. *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1378-79 (Fed. Cir. 2009). The Federal Circuit thus respects the role of juries to decide underlying factual issues and will not hesitate to reverse district court decisions that invade the province of the jury.

not addressed at oral argument, and not addressed in a merits opinion. In its merits briefing, Amgen simply noted the purported "discrepancy" between Federal Circuit and Supreme Court precedent in a single sentence in its standard-of-review section and included a footnote stating, "Amgen notes this discrepancy for preservation purposes." Amgen.C.A.Br.30 & n.8. Even Amgen's petition for rehearing devoted barely three pages to the issue, and the statement on denial of rehearing offered barely a page addressing it.

This Court, however, prefers "the benefit of thorough lower court opinions to guide [its] analysis of the merits." *Zivotofsky ex rel. Zivotofsky v. Clinton*, 566 U.S. 189, 201 (2012). And while the Court occasionally grants review of unpublished or summary decisions with little analysis, *see Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S.Ct. 1365, 1372 (2018) (granting review of Federal Circuit summary affirmance), in those circumstances, the lower court had already set forth a thorough analysis on the merits in a different decision, *see id.*; Reply Br.2, *Oil States*, No. 16-712 (U.S. filed May 15, 2017) (explaining in seeking certiorari that "this Court now has the benefit of [the Federal Circuit's] analysis on both sides of the issue," and citing other Federal Circuit decisions); *see also, e.g.*, *Rita v. United States*, 551 U.S. 338, 346 (2007). But by Amgen's own telling, the decisions giving rise to the Federal Circuit's purported rule provided "no analysis." Pet.17. Nor does Amgen identify any other opinions to help "guide" this Court's "analysis of the merits." The Court would thus be writing on a completely blank slate—which is always suboptimal, but especially here, since "[t]he

distinction between law and fact is one of the most perplexing concepts in all of law." Gugliuzza, *supra*, at 609; *see Pullman-Standard v. Swint*, 456 U.S. 273, 288 (1982) (noting "the vexing nature of the distinction between questions of fact and questions of law"). Were the Court ever inclined to review the first question presented, therefore, it should do so in a case where the issue was more thoroughly ventilated below.

Second, even if enablement were purely a factual question, it would not change the outcome below as to whether Amgen's patents are enabled. Amgen admits that even under its view that enablement is purely a question of fact, a court must hold that a patent is invalid for lack of enablement if "no reasonable juror" could conclude that the evidence supports enablement. Pet.22 (emphasis omitted). As noted, that is exactly what both the district court and Federal Circuit did here. *See* pp.21-23, *supra*. Amgen claims that there were "hotly contested fact issues," Pet.22-23, but Amgen misstates the decision and the evidence, both of which establish that there are no *relevant* factual disputes in light of applicable law. As just one example, Amgen contends that "[t]he Federal Circuit acknowledged that '[t]he parties dispute[d]' the size of the claimed genus." Pet.23. What the panel actually observed, however, is that the parties disputed "the exact number of embodiments falling within the claims," and the panel then proceeded to explain why that purported dispute is immaterial given that "we are not concerned simply with the number of embodiments but also with their *functional* breadth." Pet.App.12a-13a (emphasis added).

In short, assuming *arguendo* that enablement is a purely factual question, a reasonable jury could still only conclude—based on the undisputed, relevant evidence here—that Amgen's narrow disclosure failed to enable Amgen's broad claims. Amgen's question presented would be "better resolved in other litigation where … it would be solely dispositive of the case." *Relford v. Commandant*, 401 U.S. 355, 370 (1971).

Third, even if this Court granted certiorari, held that enablement is purely a question of fact, and reversed the Federal Circuit's decision holding that Amgen's claims are invalid for lack of enablement based on the present record, that still would not be "dispositive of the case." *Id.* Before the panel, Respondents sought affirmance of the district court's invalidity judgment not only for lack of enablement, but also on the alternative ground of lack of adequate written description. Additionally, Respondents argued that even if invalidity were inappropriate on the admitted evidence, a new trial was necessary given the improper exclusion of key post-priority-date evidence demonstrating lack of enablement and written description.

These were not trifling contentions: They occupied fifteen pages in Respondents' brief. In particular, the written-description argument identified numerous differences between Amgen's disclosed antibodies and other antibodies within the claims' scope (which the panel itself acknowledged, *see* Pet.App.13a n.1), and Federal Circuit precedent establishes that broad functional claims like Amgen's are likely invalid for insufficient written description. *See Idenix*, 941 F.3d at 1163-65. Indeed, Amgen's own

amici admit that the Federal Circuit's first decision in this case contains a "strong suggestion" that Amgen's claims are "invalid under" the written-description requirement, indicating that the Federal Circuit would so hold if it addressed the issue on remand. Dmitry Karshtedt, et al., *The Death of the Genus Claim*, 35 Harv. J.L. & Tech. 1, 46 (2021). Respondents' evidentiary argument, moreover, concerned exclusion of critical evidence supporting enablement and written description—including the *very same* documents the Federal Circuit considered in previously holding that the district court improperly excluded key evidence.

The panel did not address these two compelling alternative arguments for Respondents, however, given its enablement holding. Thus, if this Court granted Amgen's petition and resolved the first question presented favorably for Amgen, the written-description and evidentiary issues would still have to be addressed on remand by the Federal Circuit, and even Amgen's *amici* suspect that the claims will again be found invalid, this time on written-description grounds. If this Court were ever inclined to address Amgen's first question presented, it should do so in a case where its resolution would definitively resolve the appeal, rather than—as here—serve as a precursor to confronting additional unaddressed issues (that are likely to go against the petitioner, no less). Indeed, if Amgen is correct that the Federal Circuit's supposed approach to enablement "routinely lays waste to innovative patents that juries upheld at trial," Pet.24, there should be no shortage of such better vehicles in the future.

II. The Second Question Presented Does Not Warrant This Court's Review.

A. The Federal Circuit Did Not "Create[] a Special Test" for Enablement of Functional Genus Claims.

Amgen's second question asks "[w]hether enablement is governed by the statutory requirement that the specification teach those skilled in the art to 'make and use' the claimed invention, 35 U.S.C. §112, or whether it must instead enable those skilled in the art '*to reach the full scope* of claimed embodiments' without undue experimentation—*i.e.*, to cumulatively identify and make all or nearly all embodiments of the invention without substantial 'time and effort,' Pet.App.14a (emphasis added)." Pet.i; *see also* Pet.2, 7, 13, 24-25. As that cumbersome formulation suggests, this question is nothing more than a request for factbound error correction dressed up as a supposed legal dispute.

Amgen accuses the Federal Circuit of having "created a special test" for genus claims that has "rewritten the substantive enablement standard." Pet.6, 12. But the panel repeatedly eschewed any bright-line rules or tests. *See* Pet.App.12a ("functional claim limitations are not necessarily precluded in claims that meet the enablement requirement"); *id.* ("that the scope of the claims is broad … does not close the analysis"); Pet.App.13a ("some need for testing by itself might not indicate a lack of enablement"); Pet.App.14a ("We do not hold that the effort required to exhaust a genus is dispositive."). Instead, the panel reached its conclusion that Amgen's claims required "undue experimentation" after a case-specific

"weighing [of] the *Wands* factors" that the Federal Circuit has long used to evaluate enablement. Pet.App.15a; *see* Pet.App.7a (noting that *Wands* analysis involves "weighing many factual considerations"). Amgen does not challenge the use of the *Wands* factors, and it does not dispute that one of the *Wands* factors is the "breadth of the claims." *See* Pet.App.7a (quoting *Wands*, 858 F.2d at 737). That factor, moreover, reflects decades of Federal Circuit precedent explaining that to meet the enablement requirement, the "disclosure of the specification [must] be commensurate in scope with the claim under consideration." *In re Hyatt*, 708 F.2d 712, 714 (Fed. Cir. 1983); *see Crown Operations, Int'l, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1378-79 (Fed. Cir. 2002) (noting enablement must be "to a degree at least commensurate with the scope of the claims").

Amgen contends that the purported "'reach the full scope' requirement" is "atextual," Pet.24-25, but the requirement that a patent disclosure enable the "full scope" of the claim is grounded in the statute. A patent applicant must explain to a skilled person how to "make and use" the invention. 35 U.S.C. §112(a). "The requirement of enablement, stated in 35 U.S.C. §112, enforces the essential *quid pro quo* of the patent bargain by requiring a patentee to teach the public how to practice the full scope of the claimed invention." *McRO*, 959 F.3d at 1099-1100. A patentee has not fulfilled this statutory requirement—or its end of the bargain—if the patent describes how to make and use only *part* of the invention. All of this explains why Amgen never disputed below that enablement requires making and using the "full scope" of the claimed invention. To the contrary, it explicitly

agreed to jury instructions stating that "[i]n order to be enabling, the patent must permit persons having ordinary skill in the field of technology of the patent to make and use *the full scope* of the claimed invention without having to conduct undue experimentation." Dist.Ct.Dkt.714 at 24 (emphasis added); *see* Dist.Ct.Dkt.812 (final jury instructions).

The Federal Circuit's approach to enablement for broad functional claims, or broad claims of any kind, is also consistent with this Court's precedent. For instance, in *Consolidated Electric Light Co. v. McKeesport Light Co.*, the Court invalidated a claim to "the use of all fibrous and textile materials for the purpose of electric illuminations" where the patent left others to engage in "painstaking experimentation" among "different species of vegetable growth, for the purpose of ascertaining the one best adapted to an incandescent conductor." 159 U.S. 465, 472-73, 475 (1895). Likewise, in *Holland Furniture Co. v. Perkins Glue Co.*, the Court invalidated a claim to all starch glues functioning like animal glue because the patent described only "a particular starch glue" and others could be found only "after elaborate experimentation." 277 U.S. 245, 256-57 (1928); *see id.* at 257 ("One attempting to use or avoid the use of Perkins' discovery as so claimed and *described functionally* could do so only after elaborate experimentation." (emphasis added)). And in *Béné v. Jeantet*, the Court invalidated a claim to a method of shrinking coarse hair by "subjecting it to the action of chemicals" because the patent merely disclosed one chemical "solution" and did not "enable [a person skilled in chemistry] to use the invention without having to

resort to experiments of his own to discover those [other] ingredients." 129 U.S. 683, 684-86 (1889).[8]

Amgen wrongly contends that the Federal Circuit's decision conflicts with *Minerals Separation Ltd. v. Hyde*, 242 U.S. 261 (1916). Pet.26-27. To start, the part of *Minerals Separation* that Amgen invokes concerned indefiniteness, a different patent validity requirement. *See* 242 U.S. at 271 (holding that patent "is clearly sufficiently definite to guide those skilled in the art"); *see Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014) (citing *Minerals Separation* for definiteness requirement). But even viewing *Minerals Separation* as relating to enablement, there is no conflict. The claims at issue there covered a process for separating metals from ores using oil and air bubbles. 242 U.S. at 265. There was no dispute that all "variation[s] of treatment" worked and were within the "scope of the claims," and experimentation was required merely to determine the variables that "would be most successful and economical in each case" in order "to obtain the best results." *Id.* at 270-71. Unlike *Minerals Separation*, Amgen's claims do not implicate a question of optimization of known variables. Rather, as the panel explained, "the only ways for a person of ordinary skill to discover undisclosed claimed embodiments would be through

[8] This Court, moreover, has long struck down claims that encompass a range of embodiments not enabled by the specification. *See O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 112, 120-21 (1853). A patentee "can lawfully claim only what he has invented and described." *Id.* at 121. Here, however, the Federal Circuit identified a range of non-enabled embodiments. *See* Pet.App.13a n.1.

either 'trial and error' … or else 'by discovering the antibodies *de novo*.'" Pet.App.14a.

In sum, as the panel patiently explained in its opinion respecting denial of rehearing en banc, the proposition that it "created a new test for enablement" is "incorrect." Pet.App.62a. "What is new today is not the law," the panel observed, "but generic claims to biological materials that are not fully enabled." Pet.App.63a. If "one has invented a group of compositions defined by a genus but does not know enough to fully enable that genus," claiming "such a broad genus" would "suppress innovation." Pet.App.65a. Amgen "is doing just that," the panel concluded, "by asserting such broad, unsupported claims." *Id.* Amgen does not confront—much less rebut—this sensible analysis, confirming that the decision below is correct and, in all events, presents nothing more than a request for factbound error correction that does not merit the Court's review.

B. The Question Presented Is of Insufficient Importance to Warrant Certiorari, and this Case Is a Poor Vehicle.

As with its first question, Amgen vastly overstates the importance of its second question presented. Amgen contends that the Federal Circuit's "'reach the full scope' requirement" will have "profound impacts on innovation" and produce "severe consequences," especially "for pharmaceuticals and biotech." Pet.29-31. But its argument principally relies on news articles published shortly after the Federal Circuit's decision, and even those articles acknowledge that the Federal Circuit "left the door

open" to the sort of claims that Amgen has asserted. Dani Kass, *Biologics Face Tougher Patent Scrutiny After Amgen Ruling*, Law360 (Feb. 18, 2021), https://bit.ly/2Q5fvKM; *see also* Adam Houldsworth, *The CAFC's* Amgen v. Sanofi *Decision Spells Trouble for Broad Functional Patent Claims* (Feb. 16, 2021), https://bit.ly/3tf5k4Q (noting that "the Federal Circuit has not handed down a blanket prohibition on functional genus claims"). Companies will simply "have to be more careful about crafting their patents." Ed Silverman, *A U.S. Court Ruling May Force Biologics Makers To Review Patent Protections*, Stat (Feb. 25, 2021), https://bit.ly/3uzmzhD. Meanwhile, in the year-plus since the Federal Circuit's decision, pharmaceutical companies continue to innovate groundbreaking, lifesaving antibody treatments. *See* Peter Loftus, *FDA Authorizes Use of New Eli Lilly Covid-19 Antibody Treatment*, Wall St. J. (Feb. 11, 2022), https://on.wsj.com/3oZ3jtG. The panel was thus entirely correct when it observed in its opinion respecting en banc denial that "[g]enus claims, to any type of invention, when properly supported, are alive and well." Pet.App.63a.

Even the academic article upon which Amgen heavily relies grudgingly admits that the pharmaceutical and biotechnology industries "seem to be doing just fine" after the decision below, and "innovation … seem[s] to be proceeding apace." Karshtedt et al., *supra*, at 64-65. This should come as no surprise. Broad, unsupported genus claims like Amgen's actually "discourage[] invention by others." Pet.App.64a. Had Amgen prevailed here, there would be "even more of a chilling impact on innovation," for other companies would have no incentive to develop

new therapeutics within the scope of Amgen's broad functional claims—even if those therapeutics might ultimately prove more effective for patients. Jane Byrne, Amgen v Sanofi *ruling: It is time to kiss goodbye to broad, functional patent claims for antibodies*, BioPharma-Reporter.com (Mar. 25, 2021), https://bit.ly/3bZUVnp. Thus, to the extent the decision below or other Federal Circuit precedent is used to "den[y] patent rights," Pet.31; *see, e.g.*, *Baxalta Inc. v. Genentech, Inc.*, 2022 WL 420479 (D. Del. Jan. 13, 2022) (invoking decision below in determining that patent was not enabled), that is the natural and salutary consequence of requiring "a disclosure commensurate with the scope of the genus," Pet.App.63a, which prevents the "evil" of an inventor "claim[ing] more than he has invented" and impeding innovation, *O'Reilly*, 56 U.S. (15 How.) at 120.[9]

Reflecting the relative unimportance of Amgen's second question presented, this Court has recently denied petitions presenting similar issues, in cases on which the panel here heavily relied. *See* Pet.2, *Idenix*, No. 20-380 (U.S. filed Sept. 21, 2020) (faulting Federal Circuit for "adopt[ing]" an enablement "rule for genus claims based on the assumption that an artisan must be able to identify every covered compound—what the

[9] Amgen contends that the decision below threatens "*any* genus claim, in *any* field." Pet.31 (emphases added). Amgen's only support for this sweeping statement, however, is a single decision where the Patent Trial and Appeal Board merely applied the *Wands* factors and concluded that "undue experimentation would be required to make and use the full scope of the claimed invention." *Ex Parte Beall*, 2021 WL 1208966, at *3 (P.T.A.B. Mar. 26, 2021). Nothing in that garden-variety reasoning turned on any supposed new "test" in the decision below.

court calls the patent's 'full scope'"), *cert. denied*, 141 S.Ct. 1234 (2021); *Enzo Life Scis., Inc. v. Roche Molecular Sys., Inc.*, 928 F.3d 1340 (Fed. Cir. 2019), *cert. denied*, 140 S.Ct. 2634 (2020); *see* Pet.App.10a-12a, 15a. As here, both petitions claimed a conflict with *Minerals Separation*, and the recent *Idenix* petition relied on the same academic article Amgen repeatedly invokes. Nevertheless, the Court denied certiorari in both cases. The same result should follow here.[10]

Finally, this case is a poor vehicle for reviewing Amgen's second question presented because, as with its first question presented, the issue is not dispositive. Even if Amgen were to prevail, the alternative written-description and evidentiary issues would have to be addressed on remand by the Federal Circuit, and even Amgen's *amici* suspect that the Federal Circuit will again rule against Amgen. *See* pp.27-28, *supra*. For this additional reason—one among many—the Court's review is unwarranted.

CONCLUSION

The Court should deny the petition.

[10] To be sure, the questions presented in the three petitions are not precisely identical. But that merely reflects different attempts by petitioners to manufacture legal issues in cases implicating only factbound error correction.

Respectfully submitted,

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