NO. 18-127

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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QUESTION PRESENTED

Whether this Court should disturb longstanding Federal Circuit law regarding the written description requirement of 35 U.S.C. §112(a) when, in this case, petitioners never challenged that law at any point and instead affirmatively relied on existing law, no court passed on the issue, and the issue is not dispositive to the ongoing dispute between the parties, which is being actively litigated in district court.

CORPORATE DISCLOSURE STATEMENT

Sanofi has no parent corporation, and no publicly held company owns 10% or more of its stock.

Sanofi is the indirect parent corporation of sanofi-aventis U.S. LLC and Aventisub LLC.

Regeneron Pharmaceuticals, Inc. has no parent corporation. Sanofi, through its directly and indirectly owned subsidiaries, owns 10% or more of Regeneron's stock.

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INTRODUCTION

Nearly a decade ago, in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010), the *en banc* Federal Circuit reaffirmed that 35 U.S.C. §112(a) contains both a "written description" requirement and an "enablement" requirement, and that the written description requirement is designed to determine whether "the inventor had possession of the claimed subject matter as of the filing date." 598 F.3d at 1344, 1351. Although *Ariad* did not itself generate a petition for certiorari, two years later, this Court denied a petition for certiorari contending that the written description requirement set forth in *Ariad* "departs sharply from" the text of 35 U.S.C. §112(a). Petition at 10, *Janssen Biotech, Inc. v. Abbott Labs.*, 2011 WL 5548738 (U.S. Nov. 10, 2011), *cert. denied*, 565 U.S. 1197 (2012). Since then, the written description requirement as articulated by the Federal Circuit has gone unchallenged in that court and in this Court. In turn, parties, counsel, judges, and juries have all relied on that law in determining a patent's validity.

This case is no exception. Amgen's petition presents the question whether the standard for assessing compliance with 35 U.S.C. §112(a)'s written description requirement "should be as the statute says" or whether "court-created standards should control instead"—specifically, "the Federal Circuit's self-created 'possession' standard." Pet.i-ii, 2. But at no prior point in this case has Amgen raised that question or in any way challenged the Federal Circuit's written description requirement—not in the district court, not before the Federal Circuit panel,

and not in its petition for rehearing *en banc*. On the contrary, at literally every level, Amgen cited with *approval* the written description law it now challenges. In fact, before the Federal Circuit, it argued for *expansion* of that law, urging the Federal Circuit to extend one of the very "sub-tests" that it now claims are emblematic of the infirmity of the existing law.

The Federal Circuit correctly rejected that effort, and it correctly rejected Amgen's other argument that the district court properly excluded evidence relevant to respondents' written description defense. Tellingly, those holdings are buried in Amgen's petition, *see id.* at 29-32, and Amgen does not directly challenge them. Instead, Amgen invokes the Federal Circuit's decision in this case only as an "illustrat[ion]" of the supposed "instability" engendered by the Federal Circuit's purportedly improper written-description law. *Id.* at 17. But this Court is a "court of review, not of first view," and it does not address issues neither raised nor addressed below. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 913 (2014). That well-established principle is fatal to Amgen's petition. In addition, the question presented is not dispositive to the outcome of this case and may well be mooted by the parties' upcoming trial in February 2019.

And those are just the vehicle problems. Amgen fares no better on the merits. The written description requirement that Amgen belatedly challenges has roots going back to the mid-1800s, and the "possession" standard has been settled patent law in its current form for at least half a century. That law has never been questioned by this Court or any

individual Justice, and there is no contrary precedent on the issue. Quite the opposite: In *Ariad*, the Federal Circuit took the question *en banc* and reaffirmed the established understanding of the written description requirement by a decisive 9-2 vote. Numerous *amici* urged that outcome, *including Amgen*, in a brief that flatly contradicts nearly all of its arguments here. Since then, the existing written description requirement has been applied almost entirely without question, and the limited criticism that initially greeted *Ariad* has receded in the ensuing years.

In short, Amgen presents a question that was not raised below, was not considered below, is not dispositive, and may become moot, and on which the decision below accords with the statutory text, history, precedent, and a near-unanimous *en banc* Federal Circuit decision issued nearly a decade ago in which Amgen itself backed the winning side. The petition for certiorari should be denied.

STATEMENT OF THE CASE

A. Factual Background

1. This case is a patent dispute between two innovators who each independently developed antibodies designed to reduce levels of low-density lipoprotein cholesterol ("LDL-C") in human patients. Pet.App.4. High levels of LDL-C can lead to cardiovascular disease, heart attacks, and strokes. The human body normally relies on LDL receptors in the liver to remove LDL-C from the bloodstream. Pet.App.4. 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-C in

the blood. Pet.App.4; *see* C.A.App.1200-02. 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-C from the bloodstream.

Respondents began work on a PCSK9-inhibiting antibody in 2007. Pet.App.6a. 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. Pet.App.6a. 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. Pet.App.6a. The FDA approved two dosage options: a "low-dose" version that reduces LDL-C by approximately 45%, and a "high-dose" version that reduces LDL-C by approximately 60%. C.A.App.2392. As such, doctors prescribing Praluent have more flexibility to adjust the dosage to avoid reducing LDL-C below normal levels, since abnormally low levels of LDL-C may have uncertain long-term medical effects. C.A.App.2422.

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. In August 2015, the FDA approved that antibody for the treatment of high cholesterol under the trade name Repatha. Unlike Praluent, there is no FDA-approved "low-dose" version of Repatha. Pet.App.4a; C.A.App.2346-47.

2. It is undisputed that Praluent does not infringe the Amgen patent that claims Repatha by its amino acid sequence. Instead, this case involves two *additional* patents obtained by Amgen three years later—after respondents developed Praluent—in a broad attempt to corner the market on PCSK9 inhibitors. Those additional patents purport to claim not just one particular antibody but the entire genus of antibodies that bind to specific amino acid residues on PCSK9 and block PCSK9 from binding to LDL receptors. Pet.App.4a-5a; *see* U.S. Patent Nos. 8,829,165 ("'165 patent"), 8,859,741 ("'741 patent").[1] Claim 1 of the '165 patent, for instance, claims:

> An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least one of the following residues [followed by a list of 15 amino acid residues], and wherein the monoclonal antibody blocks binding of PCSK9 to [LDL receptors].

Pet.App.5a. By its terms, that claim covers any isolated monoclonal antibody that binds to at least one of the identified amino acid residues on PCSK9 and blocks PCSK9 from binding to LDL receptors—a nearly infinite genus of antibodies.

The two Amgen patents at issue in this case share a common specification, which describes the trial-and-error process that Amgen used to search for antibodies that bind to PCSK9 and prevent it from binding to LDL receptors. Pet.App.5a. The specification

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[1] A "residue" is a particular amino acid in the amino acid sequence forming a protein. Pet.App.5a n.3.

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. Pet.App.5a. The specification then discloses the amino acid sequences of roughly several dozen antibodies purported to be within the scope of the claims. Pet.App.5a-6a. And of those several dozen antibodies—and in contrast to the nearly infinite number of antibodies claimed by the patents—the specification provides the three-dimensional structure of all of two antibodies. Pet.App.5a.

B. District Court Proceedings

In October 2014, shortly 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.6a. 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 written description and enablement requirements. Pet.App.6a.

The Patent Act requires every patent to include a specification that contains a "written description of the invention." 35 U.S.C. §112(a). For at least half a century, it has been established law that this written description of the invention must be specific enough to show that "the inventor actually invented the invention claimed." *Ariad*, 598 F.3d at 1351. In other words, the written description must show that the inventor "had possession of the claimed subject matter as of the filing date." *Id.*; *see Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991); *In re*

Wertheim, 541 F.2d 257, 262 (C.C.P.A. 1976); *In re Ruschig*, 379 F.2d 990, 995 (C.C.P.A. 1967) (specification must "disclose[] the [invention] … as something [the patentee] actually invented").

Furthermore, since *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), and as reaffirmed by the *en banc* Federal Circuit in *Ariad*, where a patent claims a genus using functional language to define a desired result—as the patents here do, by claiming all antibodies that bind with particular residues and block PCSK9 from binding with LDL receptors—the written description requirement is satisfied by disclosing either "a representative number of species falling within the scope of the genus" or "structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Ariad*, 598 F.3d at 1350 (quoting *Eli Lilly*, 119 F.3d at 1568-69). These are commonly referred to as the "representative species" and "common structural features" tests. *See AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1299 (Fed. Cir. 2014).

Throughout the district court proceedings, Amgen vigorously contended that its patents satisfied the Federal Circuit's established written description requirement. Not once did Amgen challenge the existing written description requirement or otherwise argue that current written description precedent was problematic. On the contrary, Amgen repeatedly accepted and relied upon the very Federal Circuit law, including *Ariad*, that it now declares incorrect.

For instance, over respondents' objection, Amgen moved before trial to exclude evidence of antibodies that were developed after the patents' priority date, arguing that such evidence was irrelevant to the written description requirement. Pet.App.59a. In so contending, Amgen did not challenge any aspect of the written description requirement but affirmatively relied on it. It stated: "The Federal Circuit, sitting *en banc*, has held that the written description requirement for a genus claim may be satisfied in several ways, including by evincing *either* a representative number of species … *or* common structural features that allow a skilled person to visualize or recognize the members of the genus." Dist.Ct.Dkt.195, at 14 (citing, among other cases, *Eli Lilly*, *Ariad*, and *AbbVie*).

The district court granted Amgen's motion and excluded respondents' post-priority-date antibody evidence. Pet.App.62a. When respondents moved for reconsideration, Amgen opposed, arguing again that the written description requirement should be tested only against antibodies that existed on or before the priority date. *See* Dist.Ct.Dkt.287. Once again, Amgen did not challenge any aspect of that requirement, and instead affirmatively invoked and relied on it. And, once again, the district court accepted Amgen's argument and denied the motion for reconsideration. Pet.App.64a-65a.

Amgen likewise raised no challenge to the Federal Circuit's written description requirement at trial. Quite the opposite: Amgen *agreed* to jury instructions stating that "[t]he patent law contains [a] requirement … called the written description requirement," and

that under this requirement the patent must show "that the inventor actually possessed the full scope of the invention on or before the priority date." C.A.App.1578. Consistent with *Eli Lilly*, *Ariad*, and *AbbVie*, the instructions proceeded to articulate that because the claims in this case "are directed to … a 'genus,'" sufficient written description could be established by disclosing "a representative number of species falling within the scope of the claimed invention, or … structural features common to the members of the genus, so that a person of ordinary skill in the art can 'visualize or recognize' the members of the claimed invention." Pet.App.12a-13a; C.A.App.1578-79.

Not only did Amgen not object to this instruction, it sought an *additional* basis for satisfying written description—specifically, that written description could also be satisfied "[i]n the case of a claim to antibodies … by the disclosure of a newly characterized antigen" to which those antibodies would bind, as long as the "production of antibodies against such an antigen was conventional or routine." Pet.App.13a; C.A.App.1370-71, 1580. Respondents objected to inclusion of this so-called "newly characterized antigen" test for satisfying written description, but the court overruled the objection and included it in the jury instructions.

After the jury returned a verdict for Amgen, respondents moved for judgment as a matter of law on written description and enablement grounds. Pet.App.28a. Amgen opposed the motion on the ground that the specification was sufficient to meet those requirements. Again, Amgen took no issue with

any aspect of those requirements, including the written description requirement, and it in fact touted the very standards it now disdains. *See* Dist.Ct.Dkt.352, at 6 ("Amgen presented overwhelming evidence that the Selected Claims satisfy the written description requirement under each of the three tests enunciated by the Federal Circuit to support antibody claims: representative species, common structural features … and newly characterized antigen."). The district court denied the motion and proceeded to enter an injunction removing Praluent from the market. Pet.App.7a, 52a.[2]

C. Federal Circuit Proceedings

Respondents appealed to the Federal Circuit and obtained a stay of that medicine-removing injunction pending appeal. Respondents argued, *inter alia*, that the district court had erred by (1) excluding post-priority-date evidence relevant to the written description and enablement requirements, and (2) allowing the jury to find the written description requirement satisfied under the "newly characterized antigen" test. Pet.App.6a. In response, Amgen once again took no issue with the propriety of the Federal Circuit's written description requirement—either its separate existence from the enablement requirement,

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[2] Similarly, at no point during the district court proceedings did Amgen challenge the Federal Circuit's enablement requirement—either that it constitutes an obligation separate from the written description requirement, *see Ariad*, 598 F.3d at 1347, or that it requires a patent's specification to "teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation," *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997).

its "possession" standard, or the various ways to satisfy that standard in the context of functional genus claims (*i.e.*, representative species, common structural features, or, in Amgen's view, through a "newly characterized antigen"). To the contrary, Amgen invoked the "multiple grounds" upon which it could satisfy the written description requirement: "representative species, common structural features, or newly characterized antigen." C.A.Br.56-57. And, in just one of many times where it cited *Ariad* with approval, it affirmatively argued that "the application of the written description requirement 'will necessarily vary depending on the context,'" and it urged the Federal Circuit to establish the "newly characterized antigen" test as an additional basis for finding the written description requirement satisfied. *Id.* at 45 (quoting *Ariad*, 598 F.3d at 1351); Pet.App.13a.

In a unanimous and thorough opinion, the Federal Circuit reversed in part, vacated the judgment, and remanded the case for a new trial. First, the court held that the district court had erred by categorically excluding respondents' post-priority-date evidence as irrelevant to the written description requirement. Pet.App.7a-12a. The court reversed the district court on that issue and remanded for a new trial on written description.

Second, the court held that the categorical exclusion of respondents' post-priority-date evidence also required a new trial on enablement. The court concluded that this evidence could have been relevant to determining whether the enablement requirement was satisfied, that the district court erred by excluding

it, and that a new trial on enablement was required. Pet.App.12a.

Third, the Federal Circuit held that the district court had erred in giving the "newly characterized antigen" instruction to the jury as a basis for finding the written description requirement satisfied. The court determined that this basis for establishing written description "is not legally sound and is not based on any binding precedent." Pet.App.13a. The court did not question the propriety of any other aspect of the written description requirement—only the "newly characterized antigen" test, which *respondents* had specifically challenged as improper.

Amgen filed a petition for panel rehearing and rehearing *en banc*. At the point where Amgen could not only preserve objections to Federal Circuit precedent (which it never once did) but ask the full Federal Circuit to reconsider it, Amgen declined to do so. Amgen once again raised no challenge to the written description requirement generally, to the "possession" standard for written description, or to the representative-species or common-structural-features tests for satisfying that standard in the context of functional genus claims. Instead, as before, Amgen specifically *relied* on those tests in its petition, asking the *en banc* Federal Circuit to hold that, in the context of functional genus claims, the written description requirement could be met *not only* through those tests *but also* through the "newly characterized antigen" test. C.A.Dkt.163 at 4-11. The Federal Circuit denied Amgen's petition without dissent. Pet.App.69a-70a.

After the Federal Circuit issued its mandate, the case returned to the district court. Amgen made no

attempt to stay the proceedings pending the filing and disposition of a petition for certiorari but rather demanded a new trial on an expedited basis. *See* Dist.Ct.Dkt.437, at 10. The district court permitted a period of limited discovery and scheduled a jury trial on written description and enablement for February 2019. Dist.Ct.Dkt.458.

REASONS FOR DENYING THE PETITION

Amgen asks this Court to grant review of an issue that it never raised below—not in the district court, not before the Federal Circuit panel, and not in its petition for rehearing *en banc*. Despite reams of briefing at every level, including its *en banc* petition, not even in a passing footnote did Amgen so much as hint that it was challenging the propriety of any aspect of the Federal Circuit's written description requirement. To the contrary, throughout this case, including in its *en banc* petition, Amgen affirmatively relied upon the Federal Circuit's existing law governing written description, including the various tests for satisfying that standard in the context of functional genus claims, and thus the courts below had no opportunity to address the issue Amgen now raises. Amgen neither preserved this issue nor asked the full Federal Circuit to revisit its precedent. This Court is a court of review, not of first view, and a petition for certiorari that presents a question neither pressed nor passed on below—particularly in the relatively complex field of patent law—should be dead on arrival.

On top of that, the issue on which Amgen seeks review is not dispositive. Amgen never explains how its preferred interpretation of the Patent Act's written

description requirement would result in the rejection of respondents' contention that the patents do not satisfy the requirement and are thus invalid. And even if this Court were to construe the Patent Act in a way that Amgen would necessarily prevail on written description, the case would still have to be remanded to the district court for a new trial on whether Amgen's patents are invalid for failure to satisfy the separate enablement requirement, an issue on which Amgen does not challenge the decision below. Finally, the interlocutory posture of this case, which Amgen acknowledges, counsels heavily against review here. The petition is not just technically interlocutory; the unstayed district court proceedings are well under way, and this entire dispute may well become moot when the jury renders its verdict in the trial scheduled for this coming February.

Even if the petition did not suffer from these fatal vehicle defects, there is no good reason for this Court to review the well-established patent law at issue. For at least half a century, it has been settled that the "written description of the invention" required by section 112 must be precise enough to "show that the inventor actually invented the invention claimed"—that is, that the inventor "had possession of the claimed subject matter as of the filing date." *Ariad*, 598 F.3d at 1351; *see Wertheim*, 541 F.2d at 262; *Ruschig*, 379 F.2d at 995. That requirement has never been questioned by this Court or any Member of this Court, and there is no contrary precedent on the issue. Quite the opposite: The Federal Circuit considered this issue *en banc* almost ten years ago, and it correctly reaffirmed the established understanding of the written description requirement by a lopsided 9-2

vote. *Ariad*, 598 F.3d 1336. In that case, moreover, Amgen filed an amicus brief in *support* of the existing written description requirement, flatly contradicting its current position and casting substantial doubt on its newfound criticisms. And despite the supposedly "exceptional" importance of the issue, it has been the subject since *Ariad* of a single petition for certiorari—which this Court denied—and the purportedly widespread criticism of the Federal Circuit's standard amounts to little more than the opinions by the two dissenting judges in *Ariad* (neither of whom is still an active member of that court) and a smattering of pre-*Ariad* commentary. The petition should be denied.

I. This Petition Is An Exceptionally Poor Candidate For Certiorari.

Even before reaching the merits of the question presented, there are no fewer than four threshold issues that make this petition an exceptionally poor candidate for certiorari.

A. The Question Presented Was Not Raised Below.

First, the petition seeks review of an issue that Amgen failed to raise below. That fatal flaw is dispositive here. Before the district court, before the Federal Circuit panel, and even in its petition for rehearing *en banc*, Amgen never once argued—not even in a footnote—that the Federal Circuit's existing written description requirement is in any way incorrect. "Because th[at] argument was not raised below, it is waived." *Sprietsma v. Mercury Marine*, 537 U.S. 51, 56 n.4 (2002). That alone is enough to make the petition unfit for certiorari. *See, e.g.*, *Kingdomware Techs., Inc. v. United States*, 136 S. Ct.

1969, 1978 (2016) ("The Department failed to raise this argument … below, and we normally decline to entertain such forfeited arguments."); *OBB Personenverkehr AG v. Sachs*, 136 S. Ct. 390, 398 (2015) ("Absent unusual circumstances—none of which is present here—we will not entertain arguments not made below."); *Rent-A-Center, W., Inc. v. Jackson*, 561 U.S. 63, 75-76 (2010) (argument "not mentioned below" is "too late, and we will not consider it"); *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 147 n.2 (1970) ("Where issues are neither raised before nor considered by the Court of Appeals, this Court will not ordinarily consider them."); *Lawn v. United States*, 355 U.S. 339, 362 n.16 (1958) ("Only in exceptional cases will this Court review a question not raised in the court below.").

The failure to raise the question presented below is not excused by the fact that Amgen challenges well-settled Federal Circuit law. Amgen still had an obligation to preserve the issue before the district court and Federal Circuit panel, *see, e.g.*, *Finch v. Hughes Aircraft Co.*, 926 F.2d 1574, 1576 (Fed. Cir. 1991), and has no excuse for not asking the *en banc* Federal Circuit to reconsider the issue in Amgen's *en banc* petition. In light of the Federal Circuit's exclusive jurisdiction over patent disputes, the Federal Circuit has been particularly willing to reconsider its precedents *en banc*, even when the prior precedent was itself an *en banc* decision. *See, e.g.*, *Lighting Ballast Control LLC v. Philips Elec. N.A.*, 744 F.3d 1272 (Fed. Cir. 2014) (en banc) (reconsidering *Cybor Corp. v. FAS Techs.*, 138 F.3d 1448 (Fed. Cir. 1998) (en banc)). Thus, Amgen's failure to give the *en*

banc Federal Circuit an opportunity to consider its precedent is a sufficient reason to deny certiorari.

But not only did Amgen never raise its objections to the Federal Circuit's law below; Amgen repeatedly endorsed and relied upon that same law in defending its patents as not invalid. Among other things, while Amgen now criticizes *Ariad* as causing "legal instability and resulting damage to the incentives to innovate," Pet.16-17, Amgen consistently cited *Ariad* with approval in the district court and the Federal Circuit, and it approved jury instructions containing written description law drawn directly from *Ariad* and its progeny. While Amgen now disdains the established "sub-tests" for proving written description in the context of functional genus claims as "unstable and uncertain," Pet.17, Amgen not only accepted these "sub-tests" below but argued to the Federal Circuit that there should be *another* "sub-test"—specifically, the "newly characterized antigen" test. And while Amgen now complains that "the 'possession' mandate and sub-tests impose unique barriers on biotechnology," *id.* at 32, Amgen urged the Federal Circuit to accept the "newly characterized antigen" test—a *uniquely* biotechnology-focused test—by arguing that "the application of the written description requirement 'will necessarily vary depending on the context.'" *See* pp.8-11, *supra*.

Accordingly, even if there were any error in the decision below—and there is not—that error was invited by Amgen's repeated reliance on the written

description law that it now criticizes.[3] Amgen cannot challenge a purported error that it condoned and encouraged. *See, e.g.*, *Minneapolis & St. Louis R.R. Co. v. Winters*, 242 U.S. 353, 355-56 (1917) (petitioner "cannot complain of a course to which it assented below"). And even if its conduct had not invited the purported error, Amgen simply cannot raise an issue for the first time in this Court after never mentioning that issue in any of the proceedings below, including in its *en banc* petition. *See, e.g.*, *Kingdomware*, 136 S. Ct. at 1978.

B. The Question Presented Was Not Addressed Below.

The second threshold issue follows from the first: Because Amgen failed to raise this issue below, the courts below had no opportunity to take up the arguments that Amgen now advances. That is likewise a sufficient reason to deny the petition. As this Court has explained many times, it is "a court of review, not of first view," and so finds it "generally unwise to consider arguments in the first instance" that the lower courts "did not have occasion to address." *Byrd v. United States*, 138 S. Ct. 1518, 1527 (2018); *see, e.g.*, *Town of Chester v. Laroe Estates, Inc.*, 137 S. Ct. 1645, 1652 n.4 (2017) ("[I]n light of … the lack of a reasoned conclusion on this question from the Court of Appeals, we are not inclined to resolve it in the first instance."); *City & Cty. of S.F. v. Sheehan*, 135 S. Ct. 1765, 1773 (2015) ("The Court does not ordinarily decide questions that were not passed on

[3] Indeed, even during the current proceedings on remand before the district court, Amgen still has not challenged any aspect of written description law and has instead embraced it.

below."); *Cutter v. Wilkinson*, 544 U.S. 709, 718 n.7 (2005) ("Because these [arguments] were not addressed by the Court of Appeals, and mindful that we are a court of review, not of first view, we do not consider them here.").

To be sure, almost a decade ago in *Ariad*, the *en banc* Federal Circuit did consider many of the same arguments Amgen now advances—and it rejected them, in a thorough and well-reasoned opinion, by a lopsided 9-2 vote. *See* 598 F.3d 1336. But even assuming that challenging the written description requirement in this case would have been an exercise in futility in the district court given *Ariad*, that does not excuse Amgen from not raising the issue in its *en banc* petition to give the Federal Circuit a chance to pass on the issue, or otherwise justify a departure from this Court's usual practice of refusing to consider issues that were "neither raised nor decided below." *Clingman v. Beaver*, 544 U.S. 581, 598 (2005); *see Byrd*, 138 S. Ct. at 1527.

Nor is *Ariad*, a nearly ten-year-old case, enough to ensure that this Court will have the full benefit of the Federal Circuit's *current* views on the written description requirement. That decision necessarily reflected the views of the judges then assembled on the record before the court, which included an *amicus* brief from Amgen extolling the virtues of the rules reaffirmed in *Ariad*. The composition of the *en banc* court has now changed, with both *Ariad* dissenters no longer on the *en banc* court.[4] Amgen relies in part on

[4] One (Judge Rader) no longer serves on the Federal Circuit, and one (Judge Linn) has taken senior status.

events since *Ariad* to challenge the written description requirement, claiming (albeit with little support) that subsequent experience shows that this longstanding requirement has now become unworkable. *See, e.g.*, Pet.17 (arguing that since *Ariad*, "the legal instability [has] become acute"). The Federal Circuit, however, has not yet had any occasion to consider how the written description requirement has fared since *Ariad* was decided. If this Court were ever to grant review on this issue, it should do so only in a case where the Federal Circuit has at least had an opportunity to provide its most recent thinking on the question. *Byrd*, 138 S. Ct. at 1527; *Clingman*, 544 U.S. at 598.

In short, Amgen's assertion that this case "squarely presents the issue for review," Pet.33, blinks reality. The most Amgen can muster in support of that claim is to note that the decision below recited and applied the Federal Circuit's existing written description law. *Id.* Of course it did—this case involves the written description requirement. But Amgen identifies nothing indicating that it preserved a challenge to that law at any point below or gave the *en banc* Federal Circuit an opportunity to consider the issue. Because it is indisputable that the question presented was neither pressed nor passed on below, the petition should be denied.

C. The Question Presented Is Not Dispositive.

Even if Amgen had raised the question presented in the courts below and the Federal Circuit had addressed it, review would still be unwarranted because the written description issue is not outcome-determinative in this case. At the outset, Amgen

never contends that its preferred interpretation of 35 U.S.C. §112(a) would result in a determination that its patents necessarily satisfy the written description requirement. It is unclear, therefore, whether any decision by this Court on the question presented would even make a difference as to respondents' claim that the patents are invalid for failure to satisfy the written description requirement.

Regardless, the question presented is not dispositive because the Federal Circuit remanded this case not only for a new trial on written description, but also for a new trial on enablement, since the district court had incorrectly excluded relevant post-priority-date evidence that respondents sought to obtain and introduce. *See* pp.11-12, *supra*. Amgen's question presented does not address enablement, and nothing in the petition questions the Federal Circuit's ordering of a new trial on enablement.

Consequently, even if this Court were to grant the petition and construe the Patent Act in a way that Amgen would *necessarily* prevail on written description (a showing Amgen has not even attempted to make), the case would still be remanded to the district court for a new trial on the validity of Amgen's patents, just as the Federal Circuit has already ordered. *See* Pet.App.12a, 24a. To be sure, the new trial would focus just on enablement rather than on both written description and enablement. But that is far from a compelling reason to grant certiorari in this case. Even putting aside all the other problems with Amgen's petition, the 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). Indeed, if current written description law is as flawed and destabilizing as Amgen claims, there will doubtless be other petitions that present the question in a far better posture than this case does.

D. The Case Is Ongoing and May Soon Be Resolved on Other Grounds.

Finally, as Amgen recognizes, Pet.34, this petition challenges an interlocutory decision in an ongoing case—another well-recognized reason for denying certiorari. As explained in the very treatise that Amgen cites on this point, this Court ordinarily "should not issue a writ of certiorari to review … an interlocutory order." S. Shapiro et al., *Supreme Court Practice* §4.18, at 282-83 (10th ed. 2013) (quoting *Am. Constr. Co. v. Jacksonville, Tampa & Key W. Ry. Co.*, 148 U.S. 372, 384 (1893)); *see also, e.g.*, *Va. Military Inst. v. United States*, 508 U.S. 946, 946 (1993) (statement of Scalia, J.) ("We generally await final judgment in the lower courts before exercising our certiorari jurisdiction.").

But this case is not just technically interlocutory, with the lower courts awaiting this Court's action before proceeding further. Instead, the ongoing proceedings are moving forward expeditiously toward a February 2019 trial date, making this an especially poor candidate for interlocutory review. *See* Shapiro et al., *supra*, at 285. When the trial court on remand has made "[s]ubstantial progress toward a final decision" since the challenged ruling, it "creates the possibility that the issues before the Supreme Court will become moot and lessens the likelihood that a Supreme Court ruling will save the parties and the

courts from wasted effort," circumstances that weigh heavily against certiorari. *Id.*

This case is a perfect example. Because Amgen made no attempt to stay the district court proceedings while it petitioned for certiorari (and could not meet the standard for a stay if it tried), the case has continued to make rapid progress in the district court since the Federal Circuit denied rehearing and issued the mandate. The parties have now completed discovery, are in the midst of summary judgment briefing, and are scheduled for trial in February 2019—just three months from now, and well before this Court would be able to hear and decide this case on the merits. As such, nothing this Court might eventually say about the written description requirement could save the parties from wasted effort at trial.

More important, the pending trial creates a substantial risk of mootness. If Amgen loses on enablement at trial, its patents will be invalid, and its written description challenge here will be moot. Likewise, if Amgen wins on written description at trial, its challenge here will again be moot (since that verdict would mean its patents satisfy the written description requirement in any event). Either way, this Court will have wasted any effort it spent on reviewing the case before eventually dismissing it as moot. This Court need not and should not risk that needless dissipation of judicial resources, and should instead deny the petition.

II. There Is No Reason For This Court To Disrupt More Than Fifty Years Of Settled Precedent By Reviewing The Federal Circuit's Written Description Law.

The significant vehicle problems detailed above are more than sufficient to deny the petition. But even without those vehicle problems, the question presented still would not warrant review. Put simply, there is no persuasive reason for this Court to disturb more than half a century of settled patent law by granting review on the meritless issue presented here—especially when even Amgen itself took the opposite view on that issue less than a decade ago. *See* Br. of Amicus Curiae Amgen Inc. at 2, *Ariad*, 598 F.3d 1336 (Fed. Cir. filed Nov. 19, 2009), 2009 WL 4616154 ("Amgen *Ariad* Br.") ("Amgen supports the continued application of the written description requirement, as exemplified and consistently stated in this Court's precedent."); *id.* at 6 (arguing that the written description requirement "ensures that the applicant possessed—at the date of application—what he later claims as his invention").

Amgen is reduced to arguing that longstanding and well-settled written description law that it affirmatively endorsed in *Ariad* (and the proceedings below) is *so wrong* that this Court should upend at least half a century of precedent to reverse it. That argument is unpersuasive on numerous levels, which is presumably why this Court previously denied the only other petition to challenge the written description requirement in the nearly ten years since *Ariad* was

decided. *See Janssen Biotech, Inc. v. Abbott Labs.*, 565 U.S. 1197 (2012).[5] No further review is warranted.

A. The Federal Circuit's Written Description Law Is Correct on the Merits.

1. At the outset, it is far from clear what, exactly, Amgen is challenging with respect to the Federal Circuit's written description law. The question presented addresses only "the standard for determining the adequacy of the 'written description of the invention,'" Pet.i, and throughout the petition, Amgen appears to take issue with what it claims is the Federal Circuit's "possession" standard for written description, *see id.* at 2, 17, 23-24. This contention appears to accept that 35 U.S.C. §112(a) contains separate written description and enablement requirements.

At other times, however, Amgen seems to take issue with the very notion that 35 U.S.C. §112(a) contains both a written description requirement and an enablement requirement. *See, e.g.*, Pet.3 (contending that §112(a) requires "'*a* written description'" but "[t]he Federal Circuit divides §112(a) into distinct 'written description' and 'enablement' requirements, applying different standards for each"); Pet.17 (contending that §112(a) "requires *a single* written description covering two topics"); Pet.20 (criticizing Federal Circuit for "divid[ing] the written-

[5] This Court also denied the few other petitions raising this issue before *Ariad*. *See Chiron Corp. v. Genentech, Inc.*, 543 U.S. 1050 (2005); *Univ. of Rochester v. G.D. Searle & Co.*, 543 U.S. 1015 (2004).

description requirement into separate 'written description' and 'enablement' mandates, each subject to different standards").

In the end, the confusion is immaterial to the merits, since, as discussed below, the Federal Circuit has correctly concluded for at least five decades *both* that there is a separate written description requirement *and* that it requires sufficient detail to show that the inventor actually invented what is claimed, encapsulated in the Federal Circuit's "possession" standard.

2. The grounds supporting the current written description requirement were laid out in detail in *Ariad*, where the Federal Circuit went *en banc* to consider whether §112 includes a separate written description requirement and what that requirement entails. *Ariad*, 598 F.3d at 1342. In addition to the briefs filed by the parties, the court received 25 amicus briefs: 17 in favor of the party defending the written description requirement (including Amgen's brief), 7 in favor of neither party, and only one in favor of the party attacking the written description requirement. The decision by the *en banc* Federal Circuit was only slightly less lopsided than the amicus count, with a solid 9-2 vote in favor of the written description requirement. In a careful and thorough opinion, the *en banc* court explained why the statutory text, history, and precedent all demonstrate that §112 requires a written description detailed enough to show that the inventor has actually invented the invention claimed. Those reasons are equally correct today.

a. First and foremost, the statutory text makes clear that Congress intended to establish a separate

written description requirement in addition to the enablement requirement. Section 112(a) requires that the specification contain "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art … to make and use the same." 35 U.S.C. §112(a). The most natural reading of this text is one that the *Ariad* court gave it: the specification must contain both (i) "a written description of the invention" that provides adequate detail to show what the inventor has actually invented, and also (ii) "a written description … of the manner and process of making and using it" that will "enable any person skilled in the art … to make and use the same." *Id.*; *Ariad*, 598 F.3d at 1344-45. At least three textual indicators support that interpretation.

First, the *Ariad* interpretation avoids surplusage, by giving independent content to Congress' decision to require a written description of the invention (which must show possession of the invention) *as well as* a written description explaining how to make and use the invention (which must show enablement). Amgen's view, by contrast, would turn the required description of the invention into "unnecessary words." *Ariad*, 598 F.3d at 1344-45; *see Advocate Health Care Network v. Stapleton*, 137 S. Ct. 1652, 1659 (2017) (courts should "give effect, if possible, to every clause and word of a statute").

Second, distinguishing the written description requirement from the enablement requirement respects the "parallelism of the language" that Congress chose. *Ariad*, 598 F.3d at 1344. The

description of "the manner and process of *making* and *using*" the invention is judged by whether it enables practitioners "to *make* and *use* the same," 35 U.S.C. §112(a) (emphasis added). That parallel structure is clearly intentional, especially insofar as it has existed in the federal patent statutes since 1793. *See* Pet.App.76a (Patent Act of 1870) (description of "the manner and process of making, constructing, compounding, and using" the invention must be sufficient to enable one skilled in the art to "make, construct, compound, and use the same"); Pet.App.74a (Patent Act of 1836) (similar); Pet.App.73a (similar). The description of the invention itself, by contrast, has no similar parallel in the enablement clause—strongly suggesting that it is judged by its own standard, not by the enablement standard. *Ariad*, 598 F.3d at 1344.

Third, if Congress had intended both the description of the invention and the description of how to make and use the invention to be judged under the enablement standard, it could easily have combined the two requirements into a single "written description of the invention and the manner and process of making and using it." Instead, Congress textually separated the two criteria—requiring a written description "of the invention*, and of* the process … of making and using it"—indicating once again that Congress intended two different standards to apply. 35 U.S.C. §112(a) (emphasis added). By ignoring the textual separation (both the comma and the repeated preposition) between those two requirements, Amgen's interpretation "disregards Congress's careful punctuation." Pet.21.

Amgen claims that the traditional interpretation of §112(a) makes the statute "nonsense" by failing to define the standard by which to judge whether the "written description of the invention" is adequate. Pet.21-22. Of course, calling this standard "nonsense" would certainly be news to the Federal Circuit, hundreds of district court judges, and thousands of patent examiners, all of whom have been applying it for decades. And it constitutes a remarkable change of heart for Amgen, which less than a decade ago embraced the traditional interpretation while declaring its present view to be a "grammatical deconstruction" that "misreads the statute's plain meaning." Amgen *Ariad* Br.8.

In any event, as the Federal Circuit has correctly recognized, the standard for what constitutes an adequate "written description of the invention" is inherent in the statutory term: the description must give enough detail to show that the inventor has actually invented a new "invention." That is precisely the standard that the Federal Circuit applies. *See Ariad*, 598 F.3d at 1351 (written description must "clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed" (brackets omitted)); Amgen *Ariad* Br.6 (written description "ensures that the applicant possessed—at the date of application—what he later claims as his invention").

b. The same conclusion follows from history and from this Court's precedent. *Contra* Pet.24-27. As for history: Since the first Patent Acts, Congress has consistently distinguished between the required description of the invention and the required

enablement of how to make and use the invention. *See* Pet.App.72a (Patent Act of 1790) (requiring description to "not only … distinguish the invention … from other things before known and used, but also … enable [a person skilled in the art] to make, construct, or use the same"); Pet.App.73a (Patent Act of 1793) (similar). Since at least 1938, and arguably since 1853, this Court has likewise recognized a separate written description requirement in addition to the enablement requirement. *Ariad*, 598 F.3d at 1345-47 (citing *Schriber-Schroth Co. v. Cleveland Tr. Co.*, 305 U.S. 47, 56-57 (1938)); *see O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 112-13, 120-21 (1853). And in enacting the Patent Act of 1952, Congress tacitly approved that established judicial interpretation. *See* Amgen *Ariad* Br.10 (in enacting §112, "Congress necessarily adopted the policies underlying [the written description] requirement as previously interpreted and elaborated by the Supreme Court").

On top of that, since at least 1967, the Court of Customs and Patent Appeals and the Federal Circuit have specifically set forth the same "possession" standard applied today: that the required written description must be detailed enough to show that the inventor actually invented what is claimed. *Ariad*, 598 F.3d at 1351; *see Ruschig*, 379 F.2d at 995. Despite amending the patent statutes on numerous occasions during those years, Congress did nothing to disturb that settled understanding—a strong clue that it approves of the existing written description doctrine. *See* pp.33-34, *infra*. Congress was hardly required to explicitly codify a doctrine that the courts were already correctly applying. *Contra* Pet.24

(complaining that §112(a) does not specifically recite the existing written description standard).

And as for this Court's precedent: As *Ariad* explained, this Court has often recognized that the written description requirement is independent from and serves purposes different from the enablement requirement. *See, e.g.*, *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002); *Permutit Co. v. Graver Corp.*, 284 U.S. 52, 60 (1931); *Gill v. Wells*, 89 U.S. (22 Wall.) 1, 25-26 (1874); Amgen *Ariad* Br.9 (arguing that this Court has "carefully explained the separate statutory policies underlying the written description and enablement requirements"). In *Festo*, for instance, this Court succinctly summarized the three separate requirements of §112: the specification must "describe, enable, and set forth the best mode of carrying out" the invention. 535 U.S. at 736. As that concise phrase implicitly acknowledges, there is a clear distinction between "description" and "enablement," just as there is a clear distinction between either of these two requirements and the separate "best mode" requirement.

The distinction between description and enablement also played a key role in this Court's decision in *Schriber-Schroth*, as *Ariad* and the decision below recognized, Pet.App.16a; *Ariad*, 598 F.3d at 1345-46, and notwithstanding Amgen's passing footnote to the contrary, *see* Pet.26 n.6. In *Schriber-Schroth*, the patent described a piston for internal combustion engines with an "extremely rigid" web connecting it to its guide wall. 305 U.S. at 55. This Court held that patent could not be amended to

cover a piston with a flexible web: "Even if those skilled in the art would have known that a piston … would work most effectively if the webs were laterally flexible rather than rigid, that was not the invention which [the inventor] described by his references to an extremely rigid web." *Id.* at 58-59. Regardless of what the patent enabled, the patent "does not extend beyond the invention described and explained as the statute requires." *Id.* at 57. So too here. Whatever Amgen claims to have enabled, it cannot have a valid patent when its specification never provided any sufficient description showing what Amgen actually invented. *Id.*; *see Morse*, 56 U.S. (15 How.) at 113 (rejecting Morse's attempt to claim an invention that "he has not described and indeed had not invented, and therefore could not describe when he obtained his patent").

3. Finally, the settled nature of the law in this area weighs heavily against disrupting the longstanding understanding of the written description requirement. For at least half a century, the Federal Circuit and its predecessor the Court of Customs and Patent Appeals have explained in countless cases that the written description requirement means the inventor must disclose the invention "as something [he] actually invented," *Ruschig*, 379 F.2d at 995—in other words, must show that he "had possession of the claimed subject matter as of the filing date." *Ariad*, 598 F.3d at 1351; *see also, e.g.*, *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 619 F.3d 1329, 1345 (Fed. Cir. 2010); *Eli Lilly*, 119 F.3d at 1566; *Wertheim*, 541 F.2d at 262. District courts across the country—including, of course, the district court in this case—have applied that same requirement in numerous cases. *See, e.g.*,

Oxford Immunotec Ltd. v. Qiagen, Inc., 271 F. Supp. 3d 358, 367 (D. Mass. 2017); *McDavid, Inc. v. Nike USA, Inc.*, 892 F. Supp. 2d 970, 976-78, 983-86 (N.D. Ill. 2012). The U.S. Patent and Trademark Office (USPTO) has likewise relied on the written description requirement in evaluating countless patent applications. In short, judicially revising written description law would repudiate decades of law and practice and require significant changes in USPTO's public guidance and its examination procedures. Under these circumstances, it would require an exceptionally weighty justification to disrupt that well-established law.

That is all the more true because the written description requirement is a pure question of statutory interpretation—meaning that Congress can correct any mistake it sees in the well-established precedent. For decades, the federal courts have recognized and applied the written description law that Amgen challenges—and in all that time, Congress has made no attempt to alter that law. Not only that, but Congress has "spurned multiple opportunities to reverse [the written description requirement]—openings as frequent and clear as this Court ever sees." *Kimble v. Marvel Entm't*, 135 S. Ct. 2401, 2409-10 (2015). Although Congress has "repeatedly amended the patent laws" in the last fifty years—including a major overhaul in the Leahy-Smith America Invents Act just one year after *Ariad*, *see* Pub. L. No. 112-29, 125 Stat. 284 (2011)—it has never once hinted at any disagreement with the established written description doctrine. *Kimble*, 135 S. Ct. at 2410. "Congress's continual reworking of the

patent laws—but never of the [written description] rule—further supports leaving the [law] in place." *Id.*

B. Amgen Vastly Overstates the Importance of the Question Presented.

Amgen contends that review is warranted because the Federal Circuit's existing written description law has produced "devastating results for legal stability and innovation." Pet.16; *see also id.* at 27-33. Far from it. Amgen invokes "intense dissents and academic criticism" of that law. *Id.* at 27. But with one exception, the "dissents" are all from the two *Ariad* dissenters, neither of whom remains an active member of the Federal Circuit. *See id.* at 9, 27-28; n.4, *supra*. The one exception is a 40-year-old dissent by a judge who retired two decades before *Ariad*. *See* Pet.27. And the "academic criticism" consists of pre-*Ariad* commentary and two articles published shortly after *Ariad*. Amgen does not cite a single criticism of the Federal Circuit's written description law since 2010—much less anything supporting its claims of "legal instability"—demonstrating that the law has become even more well-settled and well-accepted since the *en banc* Federal Circuit reaffirmed it by a lopsided vote nearly a decade ago.

Amgen further asserts that the Federal Circuit's current written description law imposes "unique barriers on biotechnology." Pet.32. That statement is hard to take seriously given that *Amgen* has been arguing throughout this case that it should be permitted to satisfy the written description requirement based on a test—the "newly characterized antigen" test—that is *unique to biotechnology*. Equally awkward for Amgen, it took

the exact opposite position in *Ariad*, where it argued that the Federal Circuit's written description law—the same law it now challenges—"promotes rather than quells innovation" and "is appropriately applied in biotechnology." Amgen *Ariad* Br.7, 27-28. The Federal Circuit agreed, observing that there was "no evidence of any discernable impact on the pace of innovation" caused by its articulation of the written description requirement. 598 F.3d at 1353. To the extent Amgen believes that developments since *Ariad* now require a different result, that only underscores that Amgen should have presented those developments below in arguing for changes to written description law, rather than embracing that law in the courts below and challenging it for the first time in this Court.

CONCLUSION

The Court should deny the petition.

Respectfully submitted,

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