No. 21-1566

IN THE
Supreme Court of the United States

JUNO THERAPEUTICS, INC.; SLOAN KETTERING INSTITUTE FOR CANCER RESEARCH,

Petitioners,

v.

KITE PHARMA, INC.,

Respondent.

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

PETITIONERS' PETITION FOR REHEARING

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INTRODUCTION

On November 4, this Court granted certiorari in *Amgen Inc. v. Sanofi* (No. 21-757) to resolve:

> Whether 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. for a Writ of Cert. at i, *Amgen Inc. v. Sanofi*, No. 21-757 (U.S. Nov. 4, 2022) (emphases added).

But on November 7, the Court in this case denied review of the question presented by Petitioners here:

> Is the adequacy of the "written description of the invention" [in 35 U.S.C. § 112] to be measured by the statutory standard of "in such full, clear, concise, and exact terms as to enable any person skilled in the art to *make and use* the same," or is it to be evaluated under the Federal Circuit's test, which demands that the "written description of the invention" demonstrate the inventor's "possession" of "the *full scope* of the claimed invention," including all "known and unknown" variations of each component?

Pet. at i (emphases added); *see Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 598 U.S. __, 2022 WL 16726060 (Nov. 7, 2022).

These two cases involve the very same sentence of the very same statute, 35 U.S.C. § 112(a). Both ask whether the "make and use" language from the statute provides the proper statutory test, and both ask whether the Federal Circuit's addition of a "full scope" requirement is an appropriate addition to Congress's language choice. The issues presented are tightly related, and the outcome in *Amgen* is likely to at least affect, if not be outcome-determinative of, this case. Accordingly, rehearing should be granted.

REASONS TO GRANT REHEARING

Rehearing of the denial of certiorari is appropriate in situations involving "intervening circumstances of a substantial or controlling effect or … other substantial grounds not previously presented." S. Ct. R. 44.2. This has included "when [the Court] has granted review of a related issue in another case." Stern & Gressman, *Supreme Court Practice* at Ch. 15.6.(B) (11th ed. 2019); *see also id.* at Ch. 15.5 (describing this as a "recognized categor[y]" supporting rehearing). Because this is just such a case, the Court should grant this petition for rehearing of its order denying the petition for certiorari, vacate that order, and hold this case in abeyance pending the resolution of *Amgen*. At minimum, the Court should hold this rehearing petition pending the resolution of *Amgen*, the outcome of which will likely bear critically on the sole question presented here.

1. There can be no question that the question the Court agreed to review in *Amgen* is closely "related" to the question presented in this case. *See Supreme Court Practice* at Ch. 15.6. Each of the two questions presented addresses the same, single-sentence provision of Section 112(a) of the Patent Act, 35 U.S.C. § 112(a). Section 112 is titled "Specification," and in turn, subsection (a) is titled "In General." Laying out the manner in which an inventor must "reveal to the public the substance of his discovery," *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150 (1989), this provision states that "[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same …."

In addressing this same statutory language, both questions presented ask whether the inventor's duty under § 112(a) is governed, on one hand, by the "statutory requirement" (*Amgen* Pet. at i) or "statutory standard" (Pet. at i) set out by § 112(a)'s "make and use" language. And both ask whether, on the other hand, the Federal Circuit erred by demanding an atextual inquiry into the "full scope" of the "claimed embodiments" or "claimed invention." *Compare Amgen* Pet. at i *with* Pet. at i.

Beyond the substantial similarity of the questions presented, the arguments raised by the respective petitioners are fundamentally alike. Both petitions explain that the Federal Circuit's interpretation of § 112(a) conflicts with the plain statutory text. *Compare Amgen* Pet. at 25-26 *with* Pet. at 18-24. In

doing so, the petition in *Amgen* explains why a "roadmap" meets the statutory standard, while Petitioners here explain why a "cookbook" is enough. *Compare, e.g.*, *Amgen* Pet. at 32-33 *with* Pet. Reply at 8. Both petitions explain that constitutionally grounded considerations of patent policy condemn rather than support the Federal Circuit's interpretation of § 112(a). *Compare Amgen* Pet. at 27-32 *with* Pet. at 29-36. And both petitions explain how this Court's precedent forecloses the Federal Circuit's interpretation of § 112(a). *Compare Amgen* Pet. at 25-27 *with* Pet. at 24-29.

Indeed, in making this last point, the two petitions rely on much of the same authority. In particular, both point to the same portions of this Court's opinions in *Universal Oil Products Co. v. Globe Oil Refining Co.*, 322 U.S. 471, 484 (1944) (specification must teach those skilled in the art "to practice the invention"), and *The Telephone Cases*, 126 U.S. 1, 535-36 (1888) (specification must "point[] out some practicable way of putting [the invention] into operation"), as evidence that the statute means precisely what it says—that the test to measure compliance with § 112(a) or its predecessors has always been whether the disclosure adequately teaches a person skilled in the art to practice the invention. *Compare Amgen* Pet. at 25 *with* Pet. at 24-25.

The *Amgen* petition's reliance on *Minerals Separation v. Hyde*, 242 U.S. 261 (1916), further underscores the close relationship between the issue granted review in *Amgen* and the question presented in this case. In *Minerals Separation*, this Court confronted a patent for "improvements in the process

for the concentration" of various metallic ores. *Id.* at 263. The Court explained that although "[t]he composition of ores varies infinitely, each one presenting its special problem," and although "it is obviously impossible to specify in a patent the precise treatment which would be most successful and economical in each case," the patent was valid and "satisfie[d] the law" because it was "sufficiently definite to guide those skilled in the art to its successful application," even if it "l[eft] something to the skill of persons applying the inventions." *Id.* at 271. As Amgen's petition explains, this reasoning is flatly inconsistent with the "full scope" test the Federal Circuit applied in Amgen's case. *Amgen* Pet. at 26-27. So too would the patent in *Minerals Separation* have failed the "full scope" test the Federal Circuit applied in the present case to invalidate Sloan Kettering's patent because, rather than demonstrating that the inventor "possessed the full scope of the claimed invention," *see* Pet.App.9a, the *Minerals Separation* patent "l[eft] something to the skill of persons applying the inventions," 242 U.S. at 271.

Given these striking similarities, it is scarcely surprising that many of the same entities (including Amgen, St. Jude Children's Research Hospital, Corning, GlaxoSmithKline, the Association of University Technology Managers, as well as overlapping law professors), as parties or amici, urged review in both cases, raising similar concerns about the deleterious effects the Federal Circuit's interpretation of § 112 will have on incentives to innovate.

It makes no difference that the Federal Circuit decided *Amgen* under its so-called "enablement" rubric and this case under its so-called "written description" rubric. These purportedly distinct standards derive from the exact same statutory sentence of § 112(a) whose meaning is now under review in *Amgen*, and, as the substantial overlap in the arguments and authority demonstrates, are plainly related to each other. If the Court concludes in *Amgen* that the Federal Circuit's importation of an atextual "full scope" requirement into its "enablement" test is mistaken, that will call into serious question that court's "possessed the full scope" test that it applies to assess "written description" and that is challenged in this case. In such circumstances, a grant of the petition in this case followed by either full merits consideration, or vacatur and remand for the Federal Circuit's further consideration in light of *Amgen*, would be in order. *See, e.g.*, *Wellons v. Hall*, 558 U.S. 220, 225 (2010) (per curiam) ("A GVR is appropriate when intervening developments reveal a reasonable probability that the decision below rests upon a premise that the lower court would reject if given the opportunity for further consideration, and where it appears that such a redetermination may determine the ultimate outcome of the matter." (internal quotation marks and ellipsis omitted)).

2. As noted above, this Court has repeatedly granted rehearing from denials of certiorari where, as here, "it has granted review of a related issue in another case." *Supreme Court Practice* at Ch. 15.6.(B). For example, in *Melson v. Allen*, 561 U.S. 1001 (2010), the Court considered a petition to rehear a denial of certiorari after the Court granted certiorari

in a case that also raised issues regarding the availability of equitable tolling in habeas corpus cases. *See Holland v. Florida*, 560 U.S. 631 (2010). After the Court clarified the law in *Holland*, it granted the rehearing petition in *Melson* and granted, vacated, and remanded for further consideration in light of *Holland*. *Melson*, 561 U.S. 1001. Indeed, the Court has taken this approach even when the rehearing petition was filed before the Court even granted review in the case presenting the related issue. *See Florida v. Rodriguez*, 461 U.S. 940 (1983) (granting rehearing petition filed while petition for certiorari in related case remained pending and had not yet been granted). Given the grant of certiorari in *Amgen*, the likelihood of clarifying guidance from this Court is far greater here, making rehearing all the more appropriate.

Similarly, on June 28, 2011, the Court entered orders on two petitions raising Confrontation Clause issues. It granted one, *Williams v. Illinois*, 564 U.S. 1052 (2011), but denied the other, *Smith v. Florida*, 564 U.S. 1052 (2011). The petitioner in *Smith* sought rehearing, and the Court held that petition for the several months during which *Williams* was heard on the merits, denying the *Smith* rehearing petition only after the Court resolved *Williams* in a manner that made clear that decision would be of no aid to Smith. *See Smith v. Florida*, 567 U.S. 954 (2012). Similarly here, the Court should grant this rehearing petition, or at minimum hold it in abeyance until the *Amgen*

merits decision clarifies whether or not there is cause to reconsider the denial of certiorari in this case.*

3. Finally, there are no vehicle problems that would preclude reconsideration in light of the Court's ruling in *Amgen*. As explained, this case—as with the question granted review in *Amgen*—presents the single, clean, legal issue of the proper interpretation of § 112(a). *See* Pet. at 36. If, as appears likely, that critically important issue is affected by the Court's forthcoming *Amgen* decision—for example, via a holding that the language of Section 112(a) controls, and that the Federal Circuit's "full scope" elaboration of that statutory provision is foreclosed—then this Court, or the Federal Circuit on remand, should apply that teaching to this case as well.

CONCLUSION

For the foregoing reasons, Petitioners respectfully request that the Court grant rehearing of its order denying the petition for certiorari, vacate that order, and hold this case in abeyance pending the resolution of *Amgen Inc. v. Sanofi* (No. 21-757).

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* The grant of certiorari in *Amgen* came three days before the denial in this case, but the decisions in both cases followed distribution for the Court's November 4, 2022 Conference, making the situation here functionally indistinguishable from the one presented by *Smith* and *Williams*.

November 23, 2022

Respectfully submitted,

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CERTIFICATE OF COUNSEL

Pursuant to Rule 44.2, I, Gregory A. Castanias, counsel for Petitioners, hereby certify that the petition for rehearing is restricted to the grounds specified in Rule 44.2. I further certify that the petition for rehearing is presented in good faith and not for delay.

November 23, 2022 /s/ Gregory A. Castanias
Gregory A. Castanias