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

REPLY TO BRIEF IN OPPOSITION

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INTRODUCTION

Kite's BIO cannot evade three fundamental facts compelling review:

- The Federal Circuit's "possession" test for assessing a patent's "written description of the invention" contradicts the statute's text. Indeed, all Kite can say about "possession" is that it is supposedly an "imperfect shorthand," yet Kite offers no reason to prefer atextual, "imperfect shorthand" over the textual standard Congress enacted.
- As a broad array of amici and commentators reinforce, this legal error is stifling innovation, in the biotechnology sector and beyond.
- This case is an ideal vehicle to address this sole, purely legal question.

This Court should grant certiorari, or, at minimum, request the Solicitor General's views.[1]

ARGUMENT

I. TEXT AND PRECEDENT FORECLOSE THE FEDERAL CIRCUIT'S READING OF § 112.

1. The statute requires "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

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[1] Kite repeatedly references the government's 2009 Federal Circuit brief in *Ariad*, but admits that multiple amici who once supported *Ariad* now support review here. BIO 31. Given the ever-clearer unworkability of the Federal Circuit's standard, the government may well do likewise, especially because the Solicitor General's office did not sign that 2009 brief.

to which it pertains, … to make and use the same." 35 U.S.C. § 112(a). This language answers the question "What standard determines the adequacy of the 'written description of the invention'?" with the textual measuring stick "such full, clear, concise, and exact terms *as to* enable any person skilled in the art to which it pertains … to make and use the same." *See* Pet. 18-24.

Tellingly, this Court explicated this portion of § 112 in precisely this fashion, writing in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* that "Section 112 requires *only* a 'written description of the invention … in such full, clear, concise, and exact terms as to enable any person skilled in the art … to make and use the same." 566 U.S. 66, 90 (2012) (emphasis added; ellipses in original; quoting § 112).

None of Kite's three reasons for stubbornly insisting the textual standard applies only to the "written description … of the manner and process of making and using [the invention]," not to the "written description of the invention" itself, holds water.

First, Kite echoes *Ariad*'s appeal to "parallelism," suggesting that statutory standards can measure only statutory requirements stated in similar terms. BIO 15. Neither Kite nor *Ariad* supports this proposition with any authority, and Congress often uses words different from a requirement to measure that requirement. *E.g.*, 35 U.S.C. § 102(a) (defining standard for "novelty" requirement without using "novelty"). Moreover, "parallelism," whatever its merits, is hardly served by reading a statute to

contain two requirements, but state a standard for only one.

Second, the multiple treatises cited in *Facebook, Inc. v. Duguid*, 141 S. Ct. 1163, 1170 (2021), demonstrate that Kite's reference to authorities involving the last-antecedent canon, BIO 16, are inapplicable where, as here, Congress separates the last antecedent from a modifier with a comma. Even *United States National Bank of Oregon v. Independent Insurance Agents of America, Inc.*, which Kite invokes to caution against resting statutory interpretation "only on punctuation," concedes that "the meaning of a statute will typically heed the commands of its punctuation." 508 U.S. 439, 454 (1993). Here, far more than "only" punctuation supports the proper interpretation, including the statute's lack of any other standard to measure the "written description of the invention." Nor is a "concise integrated clause" a prerequisite for the series-qualifier canon, BIO 16; it is, per *Facebook*, an additional reason that "also" supports its application. 141 S. Ct. at 1169-70.

Third, Kite's "surplusage" argument ignores Petitioners' showing that "[s]ometimes the better overall reading of the statute contains some redundancy." *Rimini Street, Inc. v. Oracle USA, Inc.*, 139 S. Ct. 873, 881 (2019); *see* Pet. 23-24. Indeed, *Mayo* read § 112 exactly this way, using ellipses to omit the phrase Kite insists cannot be superfluous, and stating that the statute "only" requires "a 'written description of the invention … in such full, clear, concise, and exact terms as to enable any person skilled in the art … to make and use the same." 566 U.S. at 90 (ellipses in original; quoting § 112). This Court has previously looked to the way it "described"

a statute in dicta from a single past decision to support its construction of the statute, *Mount Lemmon Fire Dist. v. Guido*, 139 S. Ct. 22, 26 (2018); here, *Mayo* plus this Court's other repeated statements on assessing a patent's written description, *see* Pet. 24-26, provide even more compelling grounds to grant review and reverse the Federal Circuit.

2. Kite also has no answer to the fundamental question its position invites: if the textual standard doesn't govern, what does? The Federal Circuit's answer—inventors must demonstrate "possession" of every possible embodiment, "known and unknown," of every component of the claimed invention—is wholly atextual. Kite agrees by calling "possession" "an imperfect shorthand." BIO 24. Imperfect, to be sure, but hardly shorthand: The Federal Circuit invalidated Sloan Kettering's patent explicitly *because* the inventors supposedly did not "convey that they *possessed* the claimed invention, which encompasses all scFvs, *known and unknown*, as part of the claimed CAR that bind to a selected target." Pet.App.13a (emphases added). Yet Kite's BIO nowhere disputes that Sloan Kettering's patent satisfies the statutory text's standard—disclosure to the public adequate to practice the invention.

Furthermore, Kite never explains what "possession" is "shorthand" for, except to circularly reference "disclosure" and "written description," without any yardstick to measure their adequacy. BIO 24. Kite even asserts this approach is "exactly what the statute says." *Id.* Nonsense. The only test that requires "exactly what the statute says" is *the one that's actually in the statute*—sufficient "to enable any

person skilled in the art to which it pertains … to make and use the same."

3. Without a textual leg to stand on, Kite leans hard into claiming this Court has already adopted Kite's interpretation. That's of course untrue, *see* Pet. 24-26, as even Kite's cited cases show.

Kite asserts *The Telephone Cases*, 126 U.S. 1 (1888), provide an example of "two distinct disclosure requirements." BIO 21-22. But that opinion embraced the statutory standard, not some ersatz "possession" requirement, for *both* "the invention" *and* "the manner and process of making and using it." In language Kite quotes, the Court explained that the inventor adequately described *the invention* because he disclosed "accurately, and with admirable clearness, his *process*,—that is to say, the exact electrical condition that must be created *to accomplish his purpose*." 126 U.S. at 535 (emphases added). That is precisely Petitioners' interpretation—as the statute says, the patent must contain a "written description of the invention, and of the manner and process of making and using it," permitting "any person skilled in the art … to make and use the same."

O'Reilly v. Morse, which Kite also highlights, BIO 19, likewise contradicts Kite's interpretation—and embraces the statutory text's standard—by stating that "[w]hoever discovers that a certain useful result will be produced … is entitled to a patent for it; provided he specifies the means he uses in a manner so full and exact, that any one skilled in the science to which it appertains, can … produce precisely the result he describes." 56 U.S. (15 How.) 62, 119 (1853). So too does Kite's 19th century treatise. 3 William C.

Robinson, *The Law of Patents for Useful Inventions* § 515 (1890) ("described in such a manner that any person skilled in the art could practise it from such Description"). Kite's remaining older cases address inapposite issues of timing, priority, and the relation between original and later-added claims. *Schriber-Schroth Co. v. Cleveland Tr. Co.*, 305 U.S. 47, 58 (1938) (specification failed to demonstrate amended claims "were not new matter"); *Gill v. Wells*, 89 U.S. (22 Wall.) 1, 25-27 (1874) (reissued patent could not add matter the original patent *neither* claimed *nor* described); *see* Pet. 15-16, 27.

Finally, any passing dictum in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002), has since been clarified by the Court's emphatic statement in *Mayo*—which long postdates *Festo* and Kite's other cited cases—that "Section 112 requires *only* a 'written description of the invention'" that meets the statutory standard. 566 U.S. at 90 (emphasis added; quoting § 112); *see* Pet. 25-26 (collecting other cases reading the statute similarly).

Because this Court's decisions contradict Kite's position, Kite's repeated appeals to stare decisis and congressional ratification based on them necessarily fail, too. BIO at i, 1-2, 23-24. Nor can Kite invoke either principle with Federal Circuit precedent, which neither merits stare decisis weight in this Court nor offers a proper basis for inferring congressional acquiescence. Amy Coney Barrett, *Statutory Stare Decisis in the Courts of Appeals*, 73 Geo. Wash. L. Rev. 317, 330-39 (2005).

II. THE FEDERAL CIRCUIT'S ERRONEOUS INTERPRETATION PRESENTS SEVERE DANGERS TO LIFE SCIENCES AND OTHER RESEARCH.

1. The Federal Circuit's interpretation of § 112(a) is as practically devastating as it is legally erroneous. As Petitioners showed, this case epitomizes how that interpretation imperils essential research by foreclosing meaningful patents for a wide swath of inventions. Pet. 29-36. Dr. Sadelain and his Sloan Kettering colleagues invented a revolutionary cancer-fighting tool. In combination with the well-known scFv element, this groundbreaking two-part backbone dramatically advanced the art of treating cancer.[2]

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[2] Kite's BIO rehashes numerous misleading factual claims. In one egregious example, Kite suggests that "neither [Petitioner] ever created a successful therapy with the claimed invention," and refers to deaths that occurred during a clinical trial. BIO 3, 10. Kite omits that: the trial achieved complete remission for 56% of patients with a particularly aggressive form of leukemia—more than double the rate without the treatment, C.A.App.33093-33098; likely causes of the deaths included patients' ages and "class effect[s]" common to many CAR-T products, including Kite's, C.A.App.33099-33102; and the FDA allowed Juno to resume the trial (Juno had meanwhile made an economic decision to focus its limited resources on a different treatment for a different form of cancer), C.A.App.33103-33104. The jury rejected Kite's portrayals of these and other issues, like its suggestion that the patent taught how to make scFvs only from pre-existing mouse antibodies, its implausible excuses for its intensive efforts to obtain a license from Sloan Kettering, and its attempts to minimize the backbone's importance relative to the scFv element. The jury found Kite a willful infringer, and the trial court found Kite's "wanton, malicious, and bad-faith behavior" justified enhancing damages by 50%. Regardless, such disputes are irrelevant to the clean legal issue presented here.

The inventors fulfilled their end of the patent bargain by disclosing their invention and teaching the public to make and use it. Their patent "put the public in possession" of the invention, *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 433-35 (1822), by disclosing the backbone's nucleotide sequence and providing the "cookbook" to make scFvs that will bind to any target antigen of interest. Even Kite agrees that the "public takes possession *from the inventor*'s written description," BIO 25, which is precisely what happened here.

As is frequently true in the biological arts, however, the underlying science makes it impossible for CAR-T inventors to provide "common structural features" or "representative species" as the Federal Circuit has demanded—much less to demonstrate their "possession" of all "known and unknown" embodiments, as it now requires. Even if some biotechnology inventions may have common structural features or be amenable to representative species, *see* BIO 28 (citing four Federal Circuit decisions over fifteen years), that says nothing about the many discoveries in this critically important field for which neither option is feasible. Indeed, Kite never disputes this is such a case, as the only suggestion Kite offers for a patent the inventors could have obtained on Kite's view of the law is "the two-part 'backbone' along with the specific scFvs they actually used." BIO 29.

Yet Kite ignores Petitioners' demonstration that such a patent would be worthless, because the ordinarily skilled artisan could trivially evade it with other scFvs that were already known or easily created using techniques already well-known as of the

patent's filing date. Pet. 30-35. That's effectively what Kite did here: Once Kite and its collaborators were given the backbone, they had no difficulty using a different scFv. Internal emails authored by Kite's Chief Scientific Officer and introduced at trial confirmed Kite's awareness that no meaningful distinction existed between its scFv and Sloan Kettering's. C.A.App.35437 ("both are good"; "[b]oth are old and from academia"). Kite's attempts to muddy the waters about the Orlandi method of scFv creation are similarly misguided: Its own expert testified to Orlandi's straightforward method for reverse-engineering scFvs that will bind to any targeted antigen. C.A.App.33678-33679.

Thus, Kite's "overclaiming" concerns are overblown. Sloan Kettering's invention is the combination of the revolutionary backbone and the well-known scFv element, which the patent teaches a skilled scientist to obtain for any target antigen (including, for the narrower claims, CD19). The invention is *not* any particular scFv. Accordingly, the scope of the patent's exclusivity is fully commensurate with its disclosure, which provides not just "one functioning" embodiment, BIO 19, 27, but also detailed directions allowing the ordinarily skilled artisan to practice the invention generally. Sloan Kettering's patent leaves researchers at Kite or anywhere else free to develop, practice, and even patent new scFvs for CD19 or other antigens to their hearts' content. The sole thing Sloan Kettering's patent prevents Kite or others from doing with an scFv is combining it with Dr. Sadelain's revolutionary backbone without obtaining a license from Sloan Kettering permitting them to use that breakthrough. Likewise, a company developing a

revolutionary new component for COVID-19 vaccines could secure patent protection for that breakthrough, but not, as Kite scaremongers, "monopolize all vaccines against COVID-19." BIO 32.

2. Kite ridicules as "counterintuitive" the idea that cancer centers need compensation for their research to fund further research. BIO 30. That breathtakingly naïve view ignores both common sense and record evidence. C.A.App.33049 (Sloan Kettering employee testifying that "any revenues we receive under licenses … go to fund [further] cancer research"). As demonstrated by a diverse coalition of amici—cutting-edge cancer-research and treatment institutions, innovative companies that help commercialize their discoveries and make them available to the public, and patent scholars—resources are finite, research at the frontier of human knowledge is expensive, and funding is always needed.

Other voices have likewise warned that the Federal Circuit's approach has gone further and further off the rails. *See, e.g.*, Judge Paul Michel (Ret.), *The Federal Circuit's 'CAR T-Cell' Decision: Courting a Disaster for American Innovation*, IPWatchdog (Aug. 4, 2022) (explaining the need for this Court to correct the Federal Circuit's "extremely rigid, legalistic, and harmful rule that ignores the science" in order to avoid "the chilling effect those errors will have if they remain the law of the land");[3] Christopher M. Holman, *In* Juno v. Kite*, the Federal Circuit Strikes Down Patent Directed Towards Pioneering Innovation in*

[3] https://www.ipwatchdog.com/2022/08/04/federal-circuits-car-t-cell-decision-courting-disaster-american-innovation/id=150663/.

CAR T-Cell Therapy, 40 Biotechnology L. Rep. 372 (2021).

Kite's BIO is deaf to this swelling chorus, instead oddly focusing on two organizations—PhRMA and BIO—that filed amicus briefs in a different case. BIO 31, 37. Kite implies that this Court should draw some sort of negative inference from these organizations' absence here. But in that other case, PhRMA and BIO are supporting the petition of a member against a nonmember; here, those organizations have members on both sides of the case in a dispute relating to a branded product, thus those organizations did not weigh in.[4] (PhRMA and BIO have authorized Petitioners to make this representation.)

III. THIS CASE IS AN IDEAL VEHICLE.

Kite also has precious little to say about any vehicle issues. That is unsurprising. The judgment below is final, the petition presents a single issue of statutory interpretation, and the decision below rests on no alternative grounds. These features distinguish this case from the other post-*Ariad* petitions raising written-description issues. Pet. 36. Kite never acknowledges, much less rebuts, these distinctions, instead claiming without citation that "[n]othing distinguishes Juno's petition from the others previously denied." BIO 14.

Worse, Kite ignores the manner in which the Federal Circuit's ever-more-extreme interpretations—culminating in requiring inventors

[4] https://phrma.org/About (last visited Sept. 6, 2022) (Kite's parent company, Gilead Sciences, is a member); https://www.bio.org/bio-member-directory (last visited Sept. 6, 2022) (same, as is Kite).

to demonstrate "possess[ion]" of all "known and unknown" embodiments of every component of their inventions, Pet.App.13a—have caused those who previously supported (or, in Judge Michel's case, signed onto) *Ariad* to now recognize the urgent need for this Court's review. *See, e.g.*, Michel*, supra*; BIO 31 (conceding multiple amici that supported *Ariad* support review here). The Federal Circuit's continued march away from the statutory text also rebuts Kite's claim that review should be denied because the biotechnology industry has not yet collapsed, BIO 31, or because of supposed reliance interests, BIO 34-35. Indeed, the inventing community's need for certainty is reason to *grant* review, for only this Court can conclusively construe § 112(a).

Kite's halfhearted "vehicle" objections, BIO 35-37, are unpersuasive. Its claim that Petitioners have not offered an "alternative formulation[]" from the Federal Circuit's "inventor possession" standard makes no sense—the statute supplies the standard; no "alternative" formulation is needed. Kite's claim that Petitioners' evidence of written description was "thin" assumes the Federal Circuit's erroneous framework—which is what Petitioners seek this Court's review to address. Plus, Kite's BIO never disputes that Sloan Kettering's disclosure satisfies the statute's plain language.

Finally, Kite's observation that the Federal Circuit's interpretation has become entrenched in that court is reason to grant, not deny review—further percolation there will serve no purpose, and the issue cannot percolate anywhere else, so this Court must now step in to restore the written-description requirement to its proper, textual mooring.

CONCLUSION

The petition should be granted.

September 7, 2022

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