No. 21-1567

IN THE

Supreme Court of the United States

BIOGEN INTERNATIONAL GMBH AND BIOGEN MA INC.,
Petitioners,

v.

MYLAN PHARMACEUTICALS INC.,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF FOR PETITIONERS

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INTRODUCTION

Mylan provides no sound reason for this Court to deny review of the important question of statutory interpretation presented in this case. By its plain text, the written description requirement of 35 U.S.C. § 112 requires only "a written description of the invention." The district court, however, imposed additional requirements not found in the statute: It demanded proof in the patent specification that the claimed invention was effective, and it faulted Biogen for not emphasizing the claimed invention by singling it out or describing it more than once. Instead of correcting the district court's legal errors, a sharply divided panel of the Federal Circuit embraced them in a precedential opinion.

Contrary to Mylan's attempt to portray the Federal Circuit's decision as factbound, the Federal Circuit's imposition of additional requirements not found in the statute presents a fundamental question of law regarding the scope of the written description requirement. That legal question has ramifications far beyond this case and warrants review.

Mylan would prefer to ignore the four judges who dissented from the panel decision or the denial of rehearing en banc. But the dissents demonstrate the legal errors in the panel majority's analysis and the deep disagreement within the Federal Circuit regarding the contours of the written description requirement. As Judge Lourie explained, the panel majority's decision "imports extraneous considerations into the written description analysis and blurs the boundaries between the written description requirement and the other statutory requirements for patentability." Pet.App.41a. The dissents also emphasize the significance of the majority's misinterpretation, noting that its "erroneous broadening

of the written description inquiry" goes far beyond just "one case" and alters the "proper boundaries of the written description requirement." Pet.App.54a.

Mylan's remaining arguments against certiorari are unpersuasive. Its suggestion that Biogen's position threatens innovation both mischaracterizes Biogen's arguments and ignores the multiple amicus briefs that discuss how the Federal Circuit's precedential decision will chill investment in innovative technologies and medical progress.

As for Mylan's suggestion that this case is a poor vehicle for review, Mylan merely repeats its flawed argument that the case involves only a narrow factual dispute. This case squarely presents an important, recurring legal question regarding the scope of the written description requirement. The Court should grant certiorari to clarify the written description standard and conform it to the text of Section 112.

ARGUMENT

I. THE COURT SHOULD GRANT REVIEW TO CLARIFY THE WRITTEN DESCRIPTION REQUIREMENT

Mylan's attempt to downplay the legal issue at the heart of this case misstates the nature of the dispute before this Court. Biogen is not seeking review of a case-specific factual determination. It seeks review of the *legal framework* applied by the Federal Circuit—in particular, its decision to graft additional requirements onto Section 112's plain text by demanding proof of an invention's efficacy and insisting that the specification single out the invention and describe it more than once. A conclusion that results from demanding more than the statute requires is a legal error, not a factual finding.

Nor does the petition merely "assume[]" the "factual premise" that the specification described the claimed invention. Opp.20, 22. The words of the specification are undisputed and there for all to see. The specification (1) discussed and described multiple sclerosis, C.A.J.A.66(1:15-52); (2) disclosed the administration of a "therapeutically effective" amount of DMF to slow or prevent the hallmarks of MS, C.A.J.A.67(4:33-38); and (3) described the "effective" doses of DMF, expressly including a 480 mg/day oral dose, C.A.J.A.74(18:58-62). *See also* Pet.11-13. By any ordinary meaning of the term "written description," this was a description of the claimed methods of treating multiple sclerosis by orally administering a therapeutically effective amount of DMF, defined to be about 480 mg/day. That is the same invention that the district court found Biogen scientist Gilmore O'Neill had conceived four years before the patent application was filed. Pet.App.59a; *see also* Pet.App.86a (noting O'Neill's "strong belief that a 480mg/day dose of DMF (BID) would effectively treat MS"); C.A.J.A.1612-1613.[1]

The Federal Circuit's insistence on additional disclosure "erroneously imposed a heightened burden on the patentee." Pet.App.45a (Lourie, J. dissenting). Mylan insists that the lower courts never imposed any additional requirements, but the lower courts' analysis unambiguously held otherwise. The district court held that the Patent did not adequately describe the claimed invention because it did not include "efficacy data … or clinical trials," "graphs or data," or "Phase I data" from

[1] Mylan (at 20-21) misunderstands the significance of the district court's finding regarding Dr. O'Neill's conception of the invention, which rebuts Mylan's attempt to paint a false picture of Biogen discovering the claimed invention long after filing its patent application.

an early-stage clinical trial. Pet.App.88a. Without such proof of efficacy, the district court held, a skilled artisan "would not have expected a 480mg/day dose of DMF … to be efficacious in 2007." *Id.* The district court also found it "[s]triking[]" that the "480mg dosing is mentioned only once." Pet.App.79a.

For its part, the Federal Circuit repeated these analytic errors. The panel majority reasoned that a skilled artisan could not "deduce simply from reading the specification that DMF480 would be a therapeutically effective treatment for MS" "before the Phase III study even commenced." Pet.App.18a. Thus, the panel majority held that the Patent failed for lack of written description because the Phase III insights had not been "translated to clinical use" at the time of the original disclosure. *Id.* That can only be understood as a demand for proof of "clinical use" as a condition of satisfying the written description requirement. Like the district court, the Federal Circuit also found it significant to the written description analysis that "[t]he DMF 480 dose is listed only once" among other disclosures. Pet.App.16a.

These errors are fundamentally *legal*, not factual, as they bear on the standard to be applied under Section 112. Section 112's plain language requires "a written description of the invention." In ruling for Mylan, the Federal Circuit inserted additional requirements beyond this plain language, thereby heightening the legal burden all patent applicants—not just Biogen—must meet. The Federal Circuit also deviated from the "well settled" rule "that an invention may be patented before it is reduced to practice." *Pfaff* v. *Wells Elecs., Inc.*, 525 U.S. 55, 61 (1998) (citing *The Telephone Cases*, 126 U.S. 1, 535 (1888)).

In arguing otherwise, Mylan repeatedly emphasizes (at 15-18, 23, 26) that the court of appeals was applying clear-error review. That is no answer. Here, the district court's error was not just in how it "weigh[ed] evidence [or] ma[de] credibility judgments." *U.S. Bank Nat'l Ass'n* v. *Village at Lakeridge, LLC*, 138 S. Ct. 960, 966 (2018). The district court's error was more fundamental—it misunderstood what the written description requirement demands. The Federal Circuit was well-equipped to correct the district court's legal errors and clarify the proper scope of Section 112 for all litigants. *See id.* (describing appellate courts' role in "developing auxiliary legal principles of use in other cases"). Instead, the Federal Circuit added to the confusion surrounding the written description standard in a precedential opinion that will have ramifications far beyond this one case. It therefore falls to this Court to clarify the meaning of Section 112.

The dissents below, which Mylan attempts to minimize, correctly recognized that the panel majority's errors were neither factbound nor minor. Although Mylan claims (at 30) that Judge O'Malley's disagreed only with the majority's application of the test for judicial estoppel, Judge O'Malley's disagreements with the majority's affirmance of the district court's decision went much deeper. She explained that "clinical data demonstrating effectiveness is not required to satisfy written description," but that the district court nonetheless "went on to find that the 514 patent does not demonstrate possession because it lacks clinical efficacy data." Pet.App.29a. She then criticized the panel majority for deferring to findings that were based on the district court's "misguided interpretation" that led "it to erroneously require clinically efficacy data for the written description inquiry." Pet.App.31a-32a n.1. Contrary to Mylan's argument (at

17 n.2), Judge O'Malley also rejected the panel majority's opinion that a patent fails the written description requirement unless it discloses the claimed subject matter more than once, Pet.App.34a n.1.

Mylan largely ignores the dissent from denial of en banc review, dismissively claiming (at 30) that the "en banc dissenters"—Judge Lourie, Chief Judge Moore, and Judge Newman—"accepted Biogen's mischaracterization of the proceedings below." Putting to one side Mylan's suggestion that the dissenters were somehow taken in by mischaracterizations, Mylan says nothing about the substance of the en banc dissent. The dissent called for en banc review because it recognized the panel majority's legal errors and the consequences of those errors. The dissent stressed that "this case, in which every claim limitation is expressly described in the disclosure of the patent specification, is at the farthest end of the spectrum where written description has not been found." Pet.App.41a. It identified multiple legal errors that produced that extreme result. For example, the panel majority "erroneously imposed a heightened burden on the patentee to show that the specification provides efficacy." Pet.App.45a.[2] The panel wrongly concluded that "written description support for the claimed 480 mg per day dose is … undermined by the fact that it only appears one time in the specification." Pet.App.47a. And the panel "overly emphasized unclaimed disclosures in the specification, Pet.App.45a, implying "that a patent fails the written description requirement … when it contains too much disclosure beyond the claimed invention," Pet.App.48a.

[2] To be sure, Judge Lourie acknowledged, there is a role for proof of efficacy, but that is "the province of the United States Food and Drug Administration," rather than courts applying the written description requirement. Pet.App.48a (quotations omitted).

The en banc dissent also recognized that the panel majority improperly "blurr[ed] the lines between written description" and other distinct principles of patent law, such as the enablement and 'best mode' requirements. Pet.App.50a-51a. For instance, the district court stated that a skilled artisan "would be *drawn to* … the 720mg/day dose of DMF included in each dosing example," and "would not know which dose provided in Column 18 … would be *most effective* for treating MS." Pet.App.51a (internal quotation marks omitted). This observation was legally irrelevant, Judge Lourie observed, because the written description requirement does not require a skilled artisan to be "draw[n]" "towards the claimed embodiment." *Id.* Judge Lourie warned that the panel majority's blending of distinct patent requirements "creates confusion for future patent applicants and litigants" regarding the *legal* question of "what is required to meet the written description requirement." Pet.App.51a-52a.

In sum, the en banc dissent incisively identified the critical legal questions at the heart of this case and the serious consequences of letting the panel majority's decision stand. Mylan's attempt to pretend otherwise fails.

Moreover, Mylan does not seriously deny that the Federal Circuit's test for written description has become unmoored from the text and purpose of Section 112. The Federal Circuit has developed a "possession" test for written description, and then grafted additional requirements onto that test. *See* Pet.8-10; *Ariad Pharm., Inc.* v. *Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). Mylan insists (at 11) that the possession test is "settled law," but ignores that the Federal Circuit's standard does not appear in the statute and that, since *Ariad*, the court of appeals has

struggled to apply it. *See* Pet.8-10. The decision below adds to this welter of confusion.

Mylan's only response, quoting *Ariad*, is to half-heartedly insist that the apparent "'inconsistencies'" in the written description analysis should be chalked up "'not [to] the legal standard but [to] the different facts and arguments presented to the courts.'" Opp.23. But it makes no sense to cite *Ariad* to deny the post-*Ariad* confusion that has come to characterize the written description inquiry. In fact, no less an authority than the author of the en banc decision in *Ariad*, Judge Lourie, criticized the panel majority's decision for further "muddying … the written description requirement." Pet.App.41a.

In short, the Federal Circuit's jurisprudence has increasingly drifted away from Congress's straightforward command that a patent specification "contain a written description of the invention." 35 U.S.C. § 112(a). The accretion of sub-tests and legally irrelevant considerations has warped the written description requirement. That trend has reached its apex in this case. This Court's review is needed to elucidate Section 112 and bring clarity to a confused area of the law.

II. MYLAN'S ADDITIONAL ARGUMENTS LACK MERIT

1. The Federal Circuit's erroneous interpretation of the written description requirement will have grave consequences. Indeed, multiple groups filed amicus briefs urging review precisely because they recognize the threat that the Federal Circuit's decision represents to a sound patent system. Pharmaceutical Research and Manufacturers of America ("PhRMA") and the Biotechnology Innovation Organization ("BIO") explain that "[t]he Federal Circuit's approach cannot be

squared with the text of § 112," PhRMA Br.5, and warn that "the decision below, if left undisturbed, would threaten innovation and create uncertainty," *id.* at 2.

The Chemistry and Law Division of the American Chemical Society makes clear that "this case addresses an issue of great importance to [its] members who rely on a robust system of patent rights." The CHAL Br.2. It notes that the decision below, if allowed to stand, "will cause confusion among patent practitioners and fundamentally change the statutory requirements under Section 112." *Id.* at 3. It therefore seeks "[c]larity in establishing what is required under 35 U.S.C. § 112," as such a question is "critically important to … members of the Patent Bar." *Id.* at 2.

Similarly, the New England Legal Foundation explains that the Federal Circuit's "conflation of … separate patentability requirements" in this case causes "uncertainty, lack of predictability, confusion and undue expense in this highly important area." New England Legal Foundation Br.2; *see also id.* at 10 (warning of "a lack of clarity in patent law, inconsistency in patentability decisions, as well as added expense and time for the courts and the Patent Office").

Commentors have also underscored the importance of this case. *E.g.*, Handler, *Pharma Patents Threatened by Federal Circuit, Petitions Say*, Bloomberg Law (July 1, 2022), https:// tinyurl.com/2vsdr374 (decision causes "'significant worry'"); Coletti & Jang, *Federal Circuit Denies Rehearing in Biogen v. Mylan* (Apr. 1, 2022), https://tinyurl.com/34cxd5zp (decision "expose[s] fissures among the circuit judges on the written description standard" that "create uncertainty for patent owners and practitioners"); Fitzgerald et al., *Heightened Standards for Satisfying Written Descrip-*

tion in Pharma Patients, Outsourced Pharma (July 27, 2022), https://tinyurl.com/yb24bwf5 (decision adopted "a significantly heightened (and ambiguous) standard as to what is necessary to provide sufficient written support" and "seemed to indicate that clinical/human data was required"); Gummow et al., *Written Description*, Haley Guiliano (Aug. 18, 2022) https://tinyurl.com/4zwfwey5 (investment discouraged "where even a specification that explicitly discloses every element of a claim can be found to lack written description").

Mylan responds that it is Biogen's approach, not the Federal Circuit's, that threatens innovation. Mylan cautions (at 29) that overbroad patent applications could "cover the field," including by making scattered references to "a class of diseases," "a group of drugs," and "hundreds of doses" throughout a patent specification. This argument misstates Biogen's position. Biogen does not suggest that the written description requirement is satisfied whenever a patent specification makes "sweeping yet vague" statements that do not describe an invention. Rather, Biogen's point is that the written description inquiry cannot turn on whether the specification proves efficacy, shows actual reduction to practice, or repeatedly discloses the claimed subject matter—as the lower courts erroneously required. The written description inquiry begins and ends with a description of the claimed invention in the patent specification.

Nor should this Court credit Mylan's version of how to promote innovation over the views of the innovators themselves. As PhRMA and BIO warn (at 8), forcing "innovators to wait until successful clinical evidence is in hand before they file their patent applications will effectively prevent patenting of their innovations." The reason is simple. Requiring disclosure of proof of efficacy forces innovators to make an impossi-

ble choice: either (1) delay filing a patent application until proof of efficacy is gathered via clinical trials, risking loss of patent rights based on the public disclosures required to conduct those trials, or (2) file the patent application before conducting trials, risking loss of patent rights for lack of proof of efficacy under the Federal Circuit's heightened written description standard. *See* Pet.29-30; PhRMA Br.8-9.

This Catch-22 was created by the Federal Circuit, not Congress. The statute as written requires only "a written description of the invention." The Federal Circuit's decision deviates from that requirement and should be reversed.

2. Mylan next attempts to deny (at 30) the split within the Federal Circuit, insisting in the face of all evidence that there was "no dispute about the governing legal principles" below. As explained, that argument incorrectly characterizes the multiple conflicting opinions below. *See supra* pp. 5-7. Those decisions reflect a deep disagreement on an important legal question in the only court of appeals with authority to hear patent appeals. Uncertainty and confusion about such a foundational question is insupportable and must be corrected.

3. Finally, this case is an ideal vehicle for the Court to address a recurring and important legal question. Mylan's argument to the contrary rises and falls with its previous flawed arguments that the case involves only factual disagreements.

The question presented by the petition is a legal one: Does Section 112's requirement to provide "a written description of the invention" mandate that the specification also disclose data that demonstrates the claimed invention is "effective" and emphasize the

claimed invention by singling it out and describing it more than once? That question is critically important to inventors, investors, and everyone else who relies on a stable patent system.

The role of the courts is to effectuate Congress's intent as reflected in the statutory language, not to impose judicially-crafted considerations with no basis in the text. This Court should grant certiorari to correct the lower courts' legal errors.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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