No. 21-1567

IN THE

Supreme Court of the United States

BIOGEN INTERNATIONAL GMBH, *et al.*,

Petitioners,

v.

MYLAN PHARMACEUTICALS INC.,

Respondent.

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

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Biogen's '514 patent claims a method for treating multiple sclerosis (MS) by orally administering a daily dose of 480 mg of dimethyl fumarate (DMF). After a four-day bench trial, the district court found that the claims were invalid because the patent's specification lacked an adequate "written description of the invention" as required by 35 U.S.C. § 112. That finding was supported by extensive evidence, including expert and lay witness testimony and the text of the patent itself. The court of appeals reviewed the district court's factual finding for clear error and affirmed because it found no such clear error.

The question presented is:

Whether the court of appeals correctly concluded that the district court did not clearly err in finding that the asserted patent claims lacked an adequate written description of the claimed MS treatment, where nothing in the patent's specification demonstrated the named inventors' possession of the claimed method of treating MS using a therapeutically effective dose of DMF at 480 mg per day.

RULE 29.6 STATEMENT

Mylan Pharmaceuticals Inc. is wholly owned by Viatris Inc., a publicly held company.

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BRIEF IN OPPOSITION

Respondent Mylan Pharmaceuticals Inc. respectfully submits that the petition for a writ of certiorari should be denied.

JURISDICTION

The judgment of the court of appeals was entered on November 30, 2021. Petitioners (collectively "Biogen") filed a petition for rehearing, and the court of appeals denied that petition on March 16, 2022. The petition for a writ of certiorari was filed on June 14, 2022. Biogen invokes this Court's jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

35 U.S.C. § 112 (2006) provides, in relevant part:

> The 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, and shall set forth the best mode contemplated by the inventor of carrying out his invention.[1]

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1. Section 112 was amended in the Leahy-Smith America Invents Act (AIA) of 2011. *See* Pub. L. No. 112-29, § 4(c), 125 Stat. 284, 296 (2011). Because the asserted patent has a priority date of 2007, the pre-AIA language governs.

INTRODUCTION

Biogen's petition purports to present the question whether providing sufficient written description under 35 U.S.C. § 112 requires providing data to demonstrate effectiveness and describing the claimed invention "more than once." That has never been the issue in this case. The issue was whether the claimed method—treating a specific disease (MS), using a specific drug (DMF), at a specific dose (480 mg/day)—was described *even once* in the specification of the asserted patent. The district court found that the patent's specification never described such a method, and the Federal Circuit majority found no clear error in the district court's factual findings.

Biogen's arguments at trial recognized the lack of express disclosure in its specification. That deficiency resulted directly from Biogen's strategic decision to co-opt a previously filed, unrelated patent application to pursue an earlier priority date for claims to treating MS with 480 mg/day DMF—a dosage level Biogen had treated as an afterthought until receiving unexpectedly positive results in a clinical trial. Biogen's effort to seize earlier priority offered a chance to avoid potentially invalidating prior art, but it also carried a significant cost. Because the preexisting application was drafted to describe different subject matter, it lacked any express disclosure of the specific MS treatment method that Biogen found itself scrambling to claim. Biogen thus had to rely on a strained theory of indirect description, arguing that the repurposed specification "linked" scattered references to individual claim elements together into the claimed method.

After conducting a bench trial, the district court considered the full record and rejected Biogen's "linking" theory, finding that the specification lacked adequate written description of the specific, later-claimed treatment method. The district court's conclusion turned largely on credibility determinations as to competing testimony from the parties' expert witnesses.

That was the sole dispositive issue decided by the district court and reviewed by the court of appeals. In seeking certiorari, Biogen tries to reengineer this case into something it never was, just like it tried to reengineer the patent application that gave rise to this case in the first place. But the case remains what the district court and the Federal Circuit correctly recognized it to be: a narrow, factual dispute over how one of ordinary skill in the art would have interpreted the written description of the unusually drafted patent at issue. That case-specific issue was correctly decided below and does not warrant any further attention from this Court.

The petition for certiorari should be denied.

STATEMENT

A. Section 112's written description requirement

Patents provide inventors with the right to exclude competitors for a limited time, but only if they comply with the statutory conditions for patentability specified in the Patent Act. One of those prerequisites appears in 35 U.S.C. § 112, which requires patent applicants to provide a "written description of the invention" within the patent document itself.

The written description requirement ensures timely disclosure sufficient to show that the applicant actually invented what it claimed in the patent. *See, e.g.*, *Reiffin* v. *Microsoft Corp.*, 214 F.3d 1342, 1345–46 (Fed. Cir. 2000). The requirement is especially important when an inventor adds new claims to an existing application and tries to maintain the original filing date as the new claims' priority date. In such cases, the patent examiner or reviewing court must determine whether the patent's specification, as filed on the asserted priority date, demonstrated possession of the newly claimed subject matter. The written description requirement thus protects against manipulation of the patent system by those who try to obtain early priority dates for inventions that they did not both actually invent and publicly describe by the asserted priority date. *See, e.g.*, *Schriber-Schroth Co.* v. *Cleveland Tr. Co.*, 305 U.S. 47, 58–59 (1938).

Whether a patent satisfies the written description requirement is a question of fact. *Evans* v. *Eaton*, 20 U.S. 356, 428 (1822) (explaining that any dispute over sufficient description "would have been matter of fact for the jury, and not of law for the decision of the Court"); *see also Kappos* v. *Hyatt*, 566 U.S. 431, 435 (2012) (discussing the review standard for "the PTO's factual findings" in an appeal arising from written description rejections); *Ariad Pharms., Inc.* v. *Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). When a patent's validity is challenged on written description grounds, the factfinder—here, the district court—hears evidence on whether a person of ordinary skill in the art would have read the patent specification as showing "possession of the claimed subject matter as of the [asserted] filing date." *Ariad*, 598 F.3d at 1351. As with most questions of fact, the inquiry is

holistic and can draw from expert testimony, lay-witness testimony, and documentary evidence. No single fact or piece of evidence is dispositive, and a reviewing court will affirm unless the district court has committed clear error. *Teva Pharms. USA, Inc.* v. *Sandoz, Inc.*, 574 U.S. 318, 326 (2015).

B. The '514 patent

This case turns on the validity of the asserted claims of Biogen's U.S. Patent No. 8,399,514 (the '514 patent) (C.A.J.A.52–80). Those claims recite methods for treating MS with a therapeutically effective dose of 480 mg of DMF per day. C.A.J.A.79 (27:58–67) (claim 1).

1. Prosecution history

The origins of the '514 patent trace back to Biogen's research between 2005 and 2007 into a biological function known as the Nrf2 pathway. Biogen believed that the Nrf2 pathway could be "an endogenous protective mechanism" for many neurological diseases, including ALS, Alzheimer's disease, Parkinson's disease, and MS. C.A.J.A.66 (1:6–2:17). A Biogen scientist, Dr. Matvey Lukashev, learned that several known compounds, including DMF, had been shown to activate the Nrf2 pathway, and he began to look for new drug candidates that could do the same. C.A.J.A.66 (2:39–50). This work was exploratory in nature and had "nothing to do" with Biogen's separate clinical development of DMF for use as an MS treatment. Pet.App.83a. Dr. Lukashev was not assessing clinical dosing of DMF or other drugs, and his efforts were not focused specifically on MS treatments. Pet.App.10a, 83a.

Dr. Lukashev's research led Biogen to file a patent application on February 8, 2007. C.A.J.A.3379–3424 (Biogen's initial U.S. filing of its 2007 international filing, C.A.J.A.3383–3424). Reflecting the subject matter of that research, the 2007 application was titled "Nrf2 Screening Assays and Related Methods and Compositions." C.A.J.A.3383. Dr. Lukashev was the only inventor named in the 2007 application. *Ibid.*

Meanwhile, Biogen was pursuing a separate clinical development program for its drug Tecfidera® to treat MS using DMF. The Tecfidera program included Phase II clinical trials between 2004 and 2006 using three potential doses of DMF: 120, 360, and 720 mg per day. Pet.App.8a–9a. Biogen did *not* test a 480 mg/day dose at that time. Pet.App.9a. The Phase II results revealed that, of the tested 120, 360, and 720 mg/day dosage levels, only 720 mg/day was effective against MS. *Ibid.*

Biogen began larger Phase III clinical trials for the Tecfidera program in March 2007. It again tested the 720 mg/day DMF dose and, at the urging of the U.S. Food and Drug Administration (FDA), also included a dose of 480 mg/day. *Ibid.* Biogen received the results from that Phase III testing four years later, in 2011. The results unexpectedly showed that the 480 and 720 mg/day DMF doses were equally effective at treating MS. *Ibid.*

With those test results in hand, Biogen quickly filed a new patent application in May 2011 covering the 480 mg daily dose. C.A.J.A.3451–3480. The 2011 application was titled "Methods of Treating Multiple Sclerosis and Preserving and/or Increasing Myelin Content," and it listed among its inventors Dr. Gilmore O'Neill, a

clinician involved in the Tecfidera development program. C.A.J.A.3451. The specification described methods for treating MS by administering DMF at 480 mg/day (C.A.J.A.3470 ¶3) and incorporated Biogen's results testing the 480 mg daily DMF dose (C.A.J.A.3478–3479). The accompanying claims likewise recited methods of treating MS by administering DMF at 480 mg/day. C.A.J.A.3480.

Unfortunately for Biogen, intervening art between 2007 and 2011 posed patentability problems for the 2011 application. And so began Biogen's revisionism.

To avoid that prior art, Biogen returned to the long-pending 2007 application based on Dr. Lukashev's work, which had a priority date of February 2007. Biogen changed the title of the 2007 application from "Nrf2 Screening Assays and Related Methods and Compositions" to "Treatment for Multiple Sclerosis." C.A.J.A.3491. It deleted the pending claims and—for the first time—added new ones covering methods for treating MS with DMF administered at a dose of 480 mg/day. C.A.J.A.3482–3484. Biogen also added Dr. O'Neill, who had nothing to do with Dr. Lukashev's work on Nrf2 (Pet.App.10a), as a co-inventor with Dr. Lukashev on the 2007 application. C.A.J.A.3437–3438. But Biogen did not change the specification of the 2007 application because doing so would have endangered the 2007 priority date it dearly desired. *See* 35 U.S.C. §§ 119(e)(1), 120.

Having overhauled the 2007 application, Biogen resumed prosecution, which culminated in issuance of the '514 patent in 2013. C.A.J.A.52. The resulting '514 patent retained the priority date of the 2007 application,

but its claims bore little resemblance to the underlying specification. Biogen then abandoned the 2011 application that had been filed by Dr. O'Neill and other clinicians involved in the Tecfidera development project. Pet. App.63a.

2. Specification and claims

The issued claims of the '514 patent recite methods for treating MS by administering DMF and/or its structural analog monomethyl fumarate (MMF) at 480 mg per day. Claim 1 is illustrative:

> 1. A method of treating a subject in need of treatment for multiple sclerosis comprising orally administering to the subject in need thereof a pharmaceutical composition consisting essentially of (a) a therapeutically effective amount of dimethyl fumarate, monomethyl fumarate, or a combination thereof, and (b) one or more pharmaceutically acceptable excipients, wherein the therapeutically effective amount of dimethyl fumarate, monomethyl fumarate, or a combination thereof is about 480 mg per day.

Pet.App.5a.

The claims thus combine a particular target disease (MS), with a particular drug (DMF), at a particular dose (480 mg/day). By contrast, the specification supposedly supporting those claims focuses broadly on screening drug candidates for treating a variety of diseases. It describes a host of drugs similar to DMF as potentially suitable candidates for activating the Nrf2 pathway.

C.A.J.A.68 (5:16–20) (describing DMF as a member of a large group of antioxidant molecules); C.A.J.A.69 (7:12–33) (listing many drug "candidates"); C.A.J.A.70–71 (9:22–11:47) (identifying compound variations). It details several experimental assays that can be used to evaluate whether a given compound activates the Nrf2 pathway and exhibits neuroprotective properties. C.A.J.A.72–73 (13:54–16:18). It contains three experimental examples, all of which relate solely to techniques for identifying and evaluating candidate drug compounds—not to treating any disease. C.A.J.A.68–69 (6:18–8:33). And it casts an extraordinarily wide net for potentially relevant neurological diseases including ALS, Parkinson's disease, Alzheimer's disease, and Huntington's disease, as well as MS "or other demyelinating diseases." C.A.J.A.73 (16:18–23). This last category is especially broad: the specification describes more than 25 other demyelinating disorders. *Id.* at 16:42–62.

The specification devotes far less space to using such compounds for treating disease. It generically refers to "methods of treating a neurological disease by administering to the subject in need thereof at least one compound that is partially structurally similar to DMF or MMF," which it grouped under the umbrella category "Method 4." C.A.J.A.69 (8:34–53). It also refers to combination therapies based on administering an activator of Nrf2 together with a second drug having a different effect. C.A.J.A.69–70 (8:55–9:21).

The specification's references to drug dosing are similarly vague. According to the specification, a "therapeutically effective amount" of a compound can have any number of possible effects, including preventing

a neurological disorder in a subject; delaying onset of a neurological disorder in a subject; ameliorating symptoms of a neurological disorder in a subject; or attaining a desired biological outcome, which may include outcomes such as reduced neurodegeneration (including but not limited to demyelination, axonal loss, and neuronal death) or reduced inflammation of the cells of the central nervous system. C.A.J.A.68 (5:52–59).

The patent mentions potential dosage levels for DMF in a single paragraph in column 18. That passage makes no mention of using DMF to treat any specific disease at *any* dosage level. Instead, it teaches that an appropriate DMF dose for a disease will vary depending on multiple factors, and it provides a speculative series of potential "effective dose" ranges that fall between 100 and 1,000 mg per day:

> For DMF or MMF, an effective amount can range from 1 mg/kg to 50 mg/kg (e.g., from 2.5 mg/kg to 20 mg/kg or from 2.5 mg/kg to 15 mg/kg). Effective doses will also vary, as recognized by those skilled in the art, dependent on route of administration, excipient usage, and the possibility of co-usage with other therapeutic treatments including use of other therapeutic agents. For example, an effective dose of DMF or MM[F] to be administered to a subject orally can be from about 0.1 g to 1 g per [d]ay, 200 mg to about 800 mg per day (e.g., from about 240 mg to about 720 mg per day; or from about 480 mg to about 720 mg per day; or about 720 mg per day). For example, the 720 mg per day may be administered in separate administrations of 2, 3, 4, or 6 equal doses.

C.A.J.A.74 (18:52–64). That paragraph, with its passing reference to "about 480 mg to about 720 mg per day," contains the specification's sole reference to 480 mg/day of DMF as one point among a broad range of doses. And it does not mention MS at all.

C. District court proceedings

Biogen sued Respondent Mylan Pharmaceuticals Inc. ("Mylan") in the United States District Court for the Northern District of West Virginia, alleging that Mylan had infringed six Biogen patents by seeking FDA approval to market generic versions of Tecfidera. Eventually, the case narrowed to a single question of fact: whether the asserted '514 claims to treating MS by orally administering DMF at 480 mg/day satisfied the written description requirement of Section 112.

The district court recognized that under settled law, "[t]he test for sufficiency is whether *the disclosure of the application relied upon* reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." Pet.App.69a (quoting *Ariad*, 598 F.3d at 1351) (emphasis added). The district court held a four-day bench trial to resolve that factual question. It heard extensive testimony from numerous witnesses, and it considered the parties' closing arguments and comprehensive post-trial briefing on the written description issue. After reviewing all the evidence, the district court issued a lengthy opinion finding that the specification of the '514 patent did *not* describe the claimed MS treatments, and that the asserted claims in the '514 patent were therefore invalid for lack of written description. Pet.App.85a, 91a.

At trial, Biogen did not contend that the '514 patent's specification expressly described any integrated method (1) for treating MS, (2) by administering DMF, (3) at a dose of 480 mg/day. Instead, Biogen argued that the specification "linked" separate references to those individual elements, scattered across the '514 patent, through the generic "Method 4" referencing treatment of neurological disease in general. Pet.App.75a.

The district court rejected Biogen's strained "linking" theory. It noted that "[t]he description of Method 4 is limited in scope and makes no mention of treating MS with a 480mg/day dose of DMF." Pet.App.75a. It explained that Method 4 "broadly describes treating neurological diseases with a therapeutically effective amount of DMF; MS is merely one such disease 'among a slew of competing possibilities.'" Pet.App.76a. And it found both that nothing in Method 4 linked a therapeutically effective amount of DMF to a dose of 480 mg/day, and that nothing anywhere in the specification linked its isolated reference to a dose of 480 mg/day to treating MS. Pet.App.78a.

The parties' technical experts—Dr. Benjamin Greenberg for Mylan and Dr. Daniel Wynn for Biogen—proved especially important to the district court's factfinding. Dr. Greenberg and Dr. Wynn were both neurologists experienced in treating MS patients, and both were qualified as persons skilled in the art. Each expert testified about whether the '514 specification described the claimed methods for treating MS using a therapeutically effective dose of DMF administered at 480 mg/day. The district court weighed the competing opinions and credited Dr. Greenberg's testimony over Dr. Wynn's. For example, the court found that Dr. Greenberg

"credibly testified at trial that nothing in Column 18" of the '514 patent—which contained the specification's only reference to a 480 mg DMF dose—"ties an effective dose of DMF specifically to the treatment of MS." Pet.App.78a. The court observed that same passage in the specification "offer[ed] only a broad range of what an effective dose 'can be'" (i.e., from 100 to 1,000 mg). Pet.App.78a–79a.

The district court further found Dr. Wynn's testimony that the 480 mg/day value would have commended itself as a therapeutically effective MS treatment to be "neither credible nor persuasive." *Ibid.* Dr. Wynn had contended that 480 mg/day appeared in the narrowest range among the specification's various DMF dose ranges (100–1,000 mg/day, 200–800 mg/day, 240–720 mg/day, 480–720 mg/day, or about 720 mg/day), and that 480 mg/day was "anchored" to 720 mg/day, which was already known to be an effective dose for treating MS. The district court found that one of skill in the art considering the '514 patent's specification would have known from Biogen's own prior-art publications that 720 mg/day DMF was therapeutically effective for treating MS, and that 240 mg/day and 360 mg/day were not. *Ibid.* That scuttled Dr. Wynn's theory because the 240 mg/day dose—known to be *ineffective* for treating MS—was likewise "anchored" to the 720 mg/day dose in the very same passage that Dr. Wynn cited from the specification. Consistent with testimony from Dr. Greenberg and Dr. Wynn, the district court found that in the eyes of a skilled artisan, nothing in the disclosed ranges would have differentiated the 480 mg dose as a treatment specifically for MS from other similarly described doses known to be ineffective for treating that same disease.

Based on the testimony of record and other evidence including the text of the specification itself, the district court rejected Biogen's "linking" theory as an attempt "to satisfy the written description requirement of § 112 by selectively plucking specific words" from different corners of the specification that separately "correspond to each element of the claimed invention." Pet.App.83a–85a.

Having reached that conclusion, the district court went on to explain why additional "extrinsic evidence" about the history of the '514 patent further confirmed its finding of a lack of written description. Pet.App.85a. The court observed that Biogen first attempted to patent methods for treating MS with DMF at 480 mg/day in 2011, after it received "unexpected" efficacy results from Phase III tests. *Ibid.* The court also noted that Biogen initially filed the corresponding 2011 application but, facing the risk of prior-art challenges, decided to revamp the earlier-but-unrelated 2007 application to capitalize on that application's 2007 priority date. Pet. App.86a. The district court recognized that although written description "does not require experimental data demonstrating effectiveness," the lack of any such examples may nonetheless be considered when evaluating the overall sufficiency of a patent's written description. Pet.App.87a–88a. Accordingly, the court observed that the 2007 application, unlike Biogen's 2011 application, did not include any clinical testing data related to DMF. Pet.App.88a. The district court found that Biogen's strategy to reengineer the 2007 application "came with a cost"—namely, "a specification written in 2007 that bore no resemblance to the '514 patent's title and claimed invention." Pet.App.87a.

D. Appellate proceedings

Biogen appealed to the Court of Appeals for the Federal Circuit, arguing that the district court clearly erred in finding the asserted claims invalid for lack of written description. Biogen also raised various other issues separate from the district court's core holding, many of which it repeats now in its petition for certiorari.

The court of appeals affirmed in a 2–1 decision. The majority first noted that written description is "a question of fact" that is "review[ed] for clear error on appeal." Pet.App.12a. It also assumed, without deciding, that the '514 specification could "convey to a skilled artisan that the invention supports method-of-treatment claims directed to MS and, perhaps, that the use of DMF may be therapeutically linked to MS treatment." Pet.App.16a.

The majority then turned to the "primar[y]" basis for the district court's written description ruling: its finding that the specification lacked an adequate written description of using the claimed 480 mg/day DMF dose for treating MS. The majority catalogued the record evidence supporting the district court's factual finding. For example, it observed that testimony from Mylan's expert Dr. Greenberg and from other witnesses supported the district court's finding, Pet.App.17a, and it "found no principled reason to disturb the district court's assessment as to the credibility of Biogen's expert testimony," Pet. App.19a–20a. The majority noted that the specification's "focus on drug discovery and basic research further buttresse[d] the district court's conclusion." Pet.App.18a. And the majority concluded that the district court did

not clearly err in rejecting Biogen's theory that one of skill in the art would have recognized 480 mg DMF as an effective MS treatment because it was "anchored" to the known effective 720 mg dose in the disclosed 480–720 mg/day range. The majority observed that "the very same sentence in the specification that discloses the DMF 480–720 mg/day range also 'anchors' DMF240 (a known ineffective dose) to DMF720 (according to the DMF 240–720 mg/day range)." Pet.App.19a.

The majority thus considered and rejected Biogen's various factual challenges, finding them insufficient to show clear error. And it characterized Biogen's additional assertions of legal error, including issues regarding judicial estoppel that the district court's opinion addressed in a footnote, as raising "ancillary" and "superfluous" issues that were irrelevant to its holding. Pet.App.20a–21a.

Judge O'Malley, who has since retired from the bench, dissented. In her view, the district court committed a "threshold error" under Fourth Circuit law when it deemed Biogen judicially estopped from distinguishing between "clinical" and "therapeutic" effects. Pet.App.24a, 26a. She believed that "this threshold error impacted the district court's entire written description analysis." Pet.App.24a; *see also* Pet.App.35a ("I believe the entire course of the district court's analysis might well change if the court were to adjust the lens through which it considers the evidence and testimony . . . ."). She would have reversed and remanded for reconsideration "in light of a proper understanding of the distinction between the two effects and the written descriptions needed for each." Pet.App.24a. Notably, nothing in the dissent suggested

that the majority opinion involved an error regarding any fundamental principle of patent law.[2]

Biogen then filed a petition for rehearing en banc. Like Biogen's current petition for certiorari to this Court, Biogen's rehearing petition distorted the opinions of the district court and the panel majority and raised arguments that presumed the central disputed issue—whether the specification of the '514 patent in fact described, even once, the claimed methods for treating MS, with DMF, at 480 mg/day. Although the three dissenting judges appeared to accept Biogen's flawed premise, Pet.App.44a, the court of appeals denied the petition by a 6–3 vote, Pet. App.37a–38a.

Biogen now petitions for a writ of certiorari.

ARGUMENT

I. The Federal Circuit evaluated the district court's factfinding under settled written description law, finding no clear error.

The dispositive issue in this case was whether Biogen's '514 patent described treating MS with DMF at 480 mg/day—at all. The issue was not whether the patent

2. Biogen misleadingly characterizes the dissent as saying that "the panel majority erroneously appeared to 'establish a requirement that a claim element must be disclosed multiple times' to satisfy the written description requirement.'" Pet. 16. Judge O'Malley cautioned against reading the majority opinion as Biogen suggests. *See* Pet.App.34a n.1 ("*To the extent the majority's opinion may be read to* establish a requirement that a claim element must be disclosed multiple times, I dissent from that holding as well." (emphasis added)).

described a particular level of effectiveness of such a treatment, whether it described less than the full scope of the claims, or whether the claimed methods had to be described multiple times to show possession of the claimed invention.

The court of appeals has articulated a consistent, clear test for district courts to use in written description cases: to satisfy Section 112's written description requirement, a patent specification must "reasonably convey[ ] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad*, 598 F.3d at 1351. That is a question of fact, and Biogen's petition does not challenge the applicable standard.

Applying the same standard, the district court assessed the evidence presented at trial—including the competing testimony of the parties' expert witnesses—and found that the '514 patent's written description did not demonstrate to those skilled in the art that Biogen possessed a method for treating MS using DMF at 480 mg per day when it filed the underlying application in 2007. The court of appeals found no clear error in that heavily factual and case-specific determination.

Biogen tries to recast the court of appeals' opinion as creating a "new, more stringent written description requirement" that requires a patent applicant to "*prove* the claimed invention works as described" and to "repeatedly describe and single out the claimed invention." Pet. 19. But the court of appeals did no such thing. It simply applied clear-error review. Biogen's revisionist history should be rejected, and the Court should deny the petition.

1. Under the first paragraph of 35 U.S.C. § 112, a patent specification must "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 . . . to make and use the same." The written description requirement prevents a patentee from extending its exclusive right "beyond the invention described." *Schriber-Schroth*, 305 U.S. at 57 (discussing an earlier version of the statute and adding that the "patent monopoly . . . cannot be enlarged by claims in the patent not supported by the description").

Following this Court's precedent, the Federal Circuit has held that Section 112's textual reference to "written description" is an independent statutory requirement. *See Ariad*, 598 F.3d at 1340. Whether a patent complies with the written description requirement is a question of fact requiring an "objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Ariad*, 598 F.3d at 1351. The test, as repeatedly and consistently articulated by the court of appeals, is "whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ibid.*

That standard accords with the purpose of Section 112. The patent system protects "actual invention[s]," not inchoate ideas, and it seeks to maintain a balance between rewarding inventors with patent protection and allowing further innovation in the field. *Ariad*, 598 F.3d at 1353; *see also Pfaff* v. *Wells Elecs., Inc.*, 525 U.S. 55, 66 (1998) ("The word 'invention' must refer to a concept that

is complete . . . ."). As this Court put it nearly 150 years ago, inventors must "fully and exactly describe[ ]" their inventions so that "other inventors may know what part of the field of invention is unoccupied." *Gill* v. *Wells*, 22 Wall. 1, 25–26 (1874); *see also Schriber-Schroth*, 305 U.S. at 57. A sufficient written description is thus "the quid pro quo of the right to exclude." *Kewanee Oil Co.* v. *Bicron Corp.*, 416 U.S. 470, 484 (1974).

2. The court of appeals correctly affirmed the district court's factual findings and judgment that the '514 specification lacked a written description of the later-claimed method of treating MS with DMF at a dose of 480 mg/day.

Biogen's first ground for certiorari depends on its factual premise that the '514 patent's "specification linked all elements of the claimed invention together." Pet. 20–21 (citing passages scattered across the specification). But the district court considered and properly rejected Biogen's "linking" theory at trial. Through its expert, Dr. Wynn, Biogen contended that a skilled artisan reading the '514 patent's specification would have connected (a) the discussion of MS in column 1; to (b) the discussion of treating diseases according to Method 4 in column 8; and also to (c) the reference to 480 mg/day DMF in column 18. The district court found that testimony wholly unconvincing given the testimony of Mylan's expert, Dr. Greenberg. Pet.App.78a–79a.

This Court has repeatedly emphasized the importance of deferring to a district court's factfinding through clear-error review in patent cases. *See Teva*, 574 U.S. at 327–28 (noting the "particular[ ]" importance of clear-

error review in the patent context (quoting *Graver Tank & Mfg. Co.* v. *Linde Air Prods. Co.*, 339 U.S. 605, 610 (1950))). Having presided over a trial, the district court judge "has a comparatively greater opportunity to gain . . . 'familiarity'" with the scientific principles underpinning the patent "than an appeals court judge who must read a written transcript or perhaps just those portions to which the parties have referred." *Ibid.*

By advancing arguments that presume a factual premise the district court rejected, Biogen has highlighted why its petition should be denied. The court of appeals did not "erroneously graft[ ] additional requirements onto the statute," Pet. 21; it merely found that the district court did not clearly err in rejecting Biogen's "linking" theory.

Page 20 of Biogen's petition illustrates its effort to conceal the factual dispute at the heart of this case. There Biogen pronounces that the '514 specification includes a written description of the invention. As support, it cites a finding by the district court that Dr. O'Neill, an inventor added to the 2007 application years after its initial filing date, conceived of an MS treatment method in 2003. Biogen then argues that its claims to an MS treatment method using 480 mg/day of DMF are "consistent" with that conception. *Id.*

That argument ignores that none of the evidence Biogen offers to show Dr. O'Neill's supposed conception was part of the description in the '514 patent. When discussing the personal beliefs and a hypothesis Dr. O'Neill allegedly developed after reviewing prior-art studies by a different entity, Biogen cites a discussion of Dr. O'Neill's trial testimony (Pet.App. 86a, 59a) rather than

the '514 patent's specification because Biogen described none of that in the '514 patent. And the pages Biogen cites from the appendix on appeal, C.A.J.A.1612–1613, merely include more trial testimony about Dr. O'Neill's private beliefs. Whether Dr. O'Neill subjectively conceived of the claimed MS treatment method does not answer the critical question—whether that method was described *in the '514 patent*, whose specification was written to describe Dr. Lukashev's research. On that point, Dr. Lukashev testified that his work had "nothing to do" with Biogen's clinical development of Tecfidera. Pet.App.83a.

Turning to what matters—what the '514 specification says—Biogen can only reiterate its "linking" theory to this Court. Pet. 20 (citing phrases from columns 1, 4, 5, and 18 of the '514 patent and asserting that the patent "linked all elements of the claimed invention together"). Biogen then concludes that "[n]othing more should have been required to satisfy the written description requirement." *Ibid.*

If Biogen were correct that its specification linked together the elements of the claimed invention, then it would be right that nothing more should have been required. But the district court found, and the court of appeals affirmed, that the patent did not, as a matter of fact, link together MS, DMF, and a dose of 480 mg/day. Pet.App.17a, 78a. Biogen did not lose because something more was required; Biogen lost because what it assumes was present—a written description that *linked* the claimed disease, drug, and dose—was missing from the specification of the '514 patent.

Citing dictionary definitions of "description," Biogen argues that "written description" should mean

nothing more than "a written statement setting forth the characteristics of the invention." Pet. 20–21. Even if that were true, the '514 patent does not include any such written statement, leaving Biogen to rely on its rejected "linking" theory. After hearing the experts and fact witnesses, the district court found the claimed treatment method was not disclosed.

3. The court of appeals also did not "heighten the written description requirement," as Biogen argues. Pet. 21. It simply applied clear-error review to the district court's factfinding.

Biogen claims that the court of appeals has implemented a "creeping expansion of the written description requirement" through its post-*Ariad* case law. *Ibid.* But what Biogen characterizes as "atextual sub-tests" and "new requirements not found in the statute" are simply the natural result of determining whether different patents, involving different specifications and different technologies, satisfy the written description requirement. As the en banc court of appeals recognized in *Ariad*, "whatever inconsistences may appear to some to exist in the application of the [written description] law . . . rest not with the legal standard but with the different facts and arguments presented to the courts." 598 F.3d at 1352. Different facts will of course lead to different outcomes. But that is no reason to grant a petition for certiorari.

4. Biogen and its *amici* also suggest that the courts below "effectively" imposed a new "proof of efficacy" requirement for written description cases. Pet. 22–25; PhRMA/BIO Br. 2. They did not.

The district court correctly focused on whether the '514 patent's specification described treating MS with 480 mg/day of DMF. The court examined the text of the specification, expert testimony about what the text disclosed to skilled artisans, and other relevant evidence, and it concluded that Biogen's "selective[ ] plucking" of words scattered across the '514 specification did not satisfy the written description requirement. Pet.App.83a–85a. Significantly, neither the district court nor the court of appeals suggested that Biogen's written description problem turned on proof of a particular kind or level of efficacy. Both courts' analyses turned on the specification's failure to provide *any* description of the claimed method, not its lack of efficacy data. Pet.App.21a (agreeing with the district court that distinguishing between different levels of efficacy was unnecessary).

The district court's discussion of efficacy and other data came *after* the court made its critical finding. Indeed, the district court expressly explained that the efficacy data and other extrinsic evidence related to the 2007 and 2011 patent applications merely "confirm[ed]" its written description finding. Pet. App.85a. Its observation about the lack of data in the '514 specification was thus dictum. The court did not rely on that evidence in reaching its written description finding. The discussion of clinical data may have been unnecessary—as the district court acknowledged, Pet.App.87a—but it was not reversible error. And it is certainly no basis to grant certiorari.

Biogen also errs in asserting that the court of appeals' opinion "has the effect of requiring actual reduction to practice before a patent application can be filed." Pet. 24. As support, Biogen cites the panel majority's statement

that the "'written description requirement limits patent protection only to individuals who perform the difficult work of producing a complete and final invention.'" *Ibid.* (citing Pet. App.18a). Biogen takes that language out of context in suggesting that the court required a reduction to practice. In the portion of the opinion Biogen cites, the court of appeals was discussing the subject matter described in the '514 patent, i.e., Nrf2 activation and drug screening. Pet.App.18a. When contrasting that subject matter with "producing a complete and final invention," the court of appeals cited a section of its *Ariad* precedent discussing the requirements of conception and description, not reduction to practice. *Ibid.* (citing *Ariad*, 598 F.3d at 1353 (clarifying that by "invention," the en banc court meant that an inventor must "conceive of the complete and final invention with all its claimed limitations—and disclose the fruits of that effort to the public")). Regardless of whether Dr. O'Neill subjectively conceived of the claimed invention, this case turned on whether that invention was described to the public *in the '514 patent's specification* as Section 112 requires.

The court of appeals' reasoning was consistent with this Court's precedent. Although the Court has recognized that an invention may be patented before it is actually reduced to practice, *Pfaff*, 525 U.S. at 61, the Court has never held that an invention may be patented without an adequate written description. Unlike Alexander Graham Bell's patent application in *The Telephone Cases*, the '514 patent did not "describe accurately, and with admirable clearness . . . the exact . . . condition that must be created to accomplish [the invention's] purpose." *The Telephone Cases*, 126 U.S. 1, 535–36 (1888); *see also O'Reilly* v. *Morse*, 15 How. 62, 119 (1853).

5. Finally, Biogen takes issue with the court of appeals' observation that the 480 mg/day dosage level "is listed only once" in the specification, which the court called "a significant fact that cuts against Biogen's case." Pet. 25–28. Once again, Biogen's objection boils down to disagreement with how the district court weighed the evidence and with the court of appeals' subsequent application of clear-error review.

At trial, Biogen argued that the '514 patent disclosed treating MS with DMF at 480 mg/day because it "listed four increasingly narrow dose ranges," including a range of 480–720 mg/day. Biogen's expert Dr. Wynn testified that a skilled artisan would have known that the inventors possessed a 480 mg/day dose for treating MS because that dose was "anchored" to a known effective dose for treating MS, 720 mg/day. Mylan's expert, Dr. Greenberg, testified the opposite. The district court considered the evidence, found Dr. Wynn's testimony neither credible nor convincing, and rejected Biogen's anchoring theory. *See supra* p. 13.

The court of appeals reviewed that finding and discerned no clear error. The court of appeals did not, as Biogen suggests, hold that "a claim element must be disclosed multiple times" to satisfy the written description requirement. Pet. 26 (also mischaracterizing Judge O'Malley's dissent). At most, it recognized that depending on the facts of the case, a word mentioned in the specification only once, in passing, and far removed from other allegedly "linked" parts of the asserted disclosure might not be enough to satisfy the written description requirement. The problem for Biogen was not that a 480 mg dose was mentioned only once. The courts below reasonably concluded that this specification's sole

reference to that dose, amongst a host of other doses, was too attenuated and too far removed from any mention of MS to demonstrate possession of the claimed invention on the original filing date in 2007.

Finally, the court of appeals nowhere "insist[ed] on singling out the claimed dose as preferred" or "import[ed] 'best mode' concepts into the written description requirement," as Biogen and its *amici* would have the Court believe. Pet. 27; New England Legal Foundation Br. 9.[3] Indeed, the court of appeals expressly declined to reach Biogen's best-mode attack, which it characterized as "ancillary." Pet.App.20a–21a. Even if the court of appeals' refusal to reach the issue was error (which it was not), it certainly did not create a new rule that would warrant this Court's review.

* * *

Through 35 U.S.C. § 112, Congress has required patent applicants to include a "written description of the invention" in every patent specification. The written description requirement serves the patent system's dual goals of rewarding inventors for their "actual invention[s]" while fostering innovation in other areas. *See, e.g.*, *Ariad*, 598 F.3d at 1353; *see also Gill*, 22 Wall. at 25–26; *Pfaff*, 525 U.S. 55 at 66.

In this case, the district court and the court of appeals correctly applied the longstanding written description

3. The Foundation also discusses other issues, such as conflation and enablement, unrelated to the arguments Biogen makes in the petition.

requirement and reached a fact-specific decision regarding a particular patent specification. They did not create new law. They did not change the boundaries of written description jurisprudence. And, as explained below, they have not threatened innovation or created a risk of confusion in the patent system.

II. It is Biogen's approach that would threaten innovation.

The patent system strikes a balance between rewarding inventors for their inventions and promoting the public interest by allowing for further innovation. *See, e.g.*, *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996). To maintain this balance, the inventor must, in the patent document itself, "describe the exact scope of an invention and its manufacture to 'secure to [the patentee] all to which he is entitled, [and] to apprise the public of what is still open to them.'" *Id.* (alterations in original) (quoting *McClain* v. *Ortmayer*, 141 U.S. 419, 424 (1891)). The written description requirement of Section 112 is essential to the statutory scheme because it "ensure[s] that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art." *Reiffin*, 214 F.3d at 1345.

It is Biogen's position, not the judgment below, that would chill investment in innovation and harm the public interest. If the written description requirement were so minimal that that an inventor could "selectively pluck[ ]" words from various columns scattered across a distinct specification and later assemble them together like puzzle pieces to describe an otherwise absent invention, the statutory directive would be meaningless. Pet.App.83a–

84a. Biogen's argument would read important text out of the statute. *Cf. Parker Drilling Mgmt. Servs., Ltd.* v. *Newton*, 139 S. Ct. 1881, 1890 (2019) (noting the "'cardinal principle' of interpretation that courts 'must give effect, if possible, to every clause and word of a statute'" (citation omitted)).

Consider Biogen's hypothetical "pharmaceutical company developing a lifesaving drug." Pet. 29. If Biogen's understanding of written-description law were correct, that development program might never come to pass. Any innovator would need to worry about other sophisticated pharmaceutical companies having long since filed sweeping yet vague patent applications to cover the field. Biogen's proposed written description test could be met by any application listing a class of diseases in one part of the specification, a group of drugs in another, and hundreds of doses in a third, without ever putting any of the doses together with a specific drug or disease. Even though the patentholder might not have actually invented any treatment at all, the patent would have created a zone of uncertainty making it too risky for other inventors—and especially the "emerging companies" for which Biogen expresses concern, Pet. 31—to try to innovate in the same field.

That outcome would be devastating both to innovation and to the public. It would also turn the patent system on its head. The Court should decline Biogen's invitation to upend the balance Congress struck when it enacted the Patent Act more than 200 years ago. *See* Patent Act of 1793, § 3, 1 Stat. 318, 321.

III. Biogen's efforts to manufacture an "internal division" within the Federal Circuit should be rejected.

Biogen contends that the court of appeals "is sharply divided on the question of the written-description standard." Pet. 32. Not so. All the opinions below—including those of the district court, the panel majority, Judge O'Malley, and the en banc dissenters—applied the same legal test: whether the "disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad*, 598 F.3d at 1351. To be sure, the judges did not agree on how to resolve the factual dispute presented here, but there was no dispute about the governing legal principles.

None of the arguments in the two dissents creates even a plausible case for certiorari. Judge O'Malley's dissent rested on her belief that the district court misapplied the test for judicial estoppel under Fourth Circuit precedent, not on a belief that the panel decision created a risk of inconsistent decisions. Pet.App.24a, 26a. For their part, the en banc dissenters accepted Biogen's mischaracterization of the proceedings below, but the majority of the court of appeals was unpersuaded. If a meaningful dispute about the law of written description arises, the court of appeals can address the issue then.

Biogen also errs in suggesting that the outcome of a written description dispute depends on the composition of the panel on appeal, rather than on the evidence presented to the district court. Pet. 33. If anything, this case highlights the importance of presenting strong evidence to

the finder of fact in the first instance, given the clear-error standard of review on appeal. At bottom, Biogen's evidence *in this case* failed to convince the district court that the '514 patent's specification demonstrated possession of the claimed methods for treating MS using DMF at 480 mg per day in the eyes of one skilled in the art. A different case, with different underlying facts, may lead to a different outcome. *See Ariad*, 598 F.3d at 1352. That is true for any question of fact. It does not mean a conflict exists in the law or that this Court's review is warranted.

IV. This case is a poor vehicle for resolving the question presented.

Finally, this case is a poor vehicle for the Court to address Section 112's written description requirement. As explained above, the court of appeals' opinion was fact-bound, and it correctly applied longstanding law to the specific patent at issue. The panel did not make any sweeping pronouncements on Section 112, it did not decide a case of first impression, and it neither created nor resolved any intra-circuit conflict. The court of appeals did not hold (as Biogen would have it) that inventors must "provide proof of efficacy" or "describe the claimed invention more than once." The panel simply applied settled law requiring that a patent's written description must demonstrate that the inventors actually invented the claimed subject matter.

Even the dissenters could not agree on the root of any perceived problem. Judge O'Malley's dissent was premised on her belief that the district court misapplied Fourth Circuit precedent on judicial estoppel—hardly a complaint about written-description law, much less a

"fundamental" legal issue for the patent system. *Cf.* Pet. 34. In contrast, the three judges who dissented from the denial of Biogen's petition for rehearing en banc claimed the panel (1) "overly emphasized unclaimed disclosures," (2) "erroneously imposed a heightened burden" to show efficacy, (3) "imported legal factors from other patentability requirements," and (4) "were influenced by irrelevant extrinsic evidence." Pet.App.45a. Even if any of those complaints were meritorious (they are not), the legal issues are hardly "crystalized." Pet. 34.

The issues Biogen raises in its petition are neither "legal" nor "fundamental." *Ibid.* Moreover, this fact-bound dispute is not an appropriate vehicle to resolve broader questions about written description jurisprudence.

CONCLUSION

The petition for a writ of certiorari should be denied.

August 15, 2022

Respectfully submitted.

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