No. 21-

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Biogen's asserted patent, which claims methods of treating multiple sclerosis by orally administering 480 mg/day of dimethyl fumarate (DMF), expressly states that "an effective dose of DMF … to be administered to a subject orally can be from … about 480 mg to about 720 mg per day." Over a dissent from the panel decision and the dissent of three additional judges from the denial of rehearing en banc, the Federal Circuit nonetheless held that Biogen's patent did not satisfy 35 U.S.C. § 112's requirement to provide a "written description of the invention" because the patent's description of the claimed dose did not include data proving the 480 mg/day dose's efficacy, the claimed effective dose was "listed only once" in the specification, and the patent disclosed other inventions as well.

The question presented is:

Is 35 U.S.C. § 112's requirement that a patent specification "contain a written description of the invention" met when the specification describes the invention, or must 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?

CORPORATE DISCLOSURE STATEMENT

Petitioners Biogen International GmbH and Biogen MA Inc. (collectively "Biogen") are owned directly, or indirectly, by Biogen Inc. No other publicly held company owns 10% or more of Petitioners' stock.

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The opinion of the Federal Circuit (App.1a-35a) is reported at 18 F.4th 1333. The Federal Circuit's order denying rehearing en banc, along with the dissenting opinion (App.37a-54a), is reported at 28 F.4th 1194. The district court's memorandum containing its findings of facts and conclusions of law (App.55a-93a) is unreported.

JURISDICTION

The Federal Circuit entered judgment on November 30, 2021. The court denied Biogen's timely petition for rehearing en banc on March 16, 2022. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

Section 112 of Title 35 of the U.S. Code provides in part:

> The [patent] 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.

INTRODUCTION

This case presents a fundamental question of law that has fractured the Federal Circuit, and generated considerable confusion: What is required to satisfy 35 U.S.C. § 112's requirement that a patent provide a

"written description of the invention"? Rather than apply the statute's plain text, the Federal Circuit has created additional, atextual requirements that distort the statute's simple command to provide "written description of the invention" and conflict with this Court's precedent. This is an important and recurring issue, and the Court should grant review to restore the proper understanding of the statute as written and previously interpreted.

Biogen obtained a patent for a groundbreaking multiple sclerosis ("MS") treatment comprising orally administering a therapeutically effective amount of dimethyl fumarate ("DMF"), wherein a therapeutically effective amount is about 480 mg/day ("DMF480"). The patent's specification disclosed and linked together all elements of the claimed invention and expressly stated that "an effective dose of DMF … to be administered to a subject orally can be from … about 480 mg to about 720 mg per day." Nonetheless, a divided panel of the Federal Circuit held that Biogen's patent was invalid because it did not satisfy Section 112's written description requirement. The Federal Circuit reasoned that the patent specification did not include data *proving* the efficacy of the claimed dose, the claimed dose was "listed only once" in the specification, and the claimed dose was not singled out from the other inventions described in the patent.

The Federal Circuit's decision ignores Section 112's plain text, which requires only "a written description of the invention." That straightforward statutory language does not require proof of efficacy. Nor does it require that the patent applicant repeatedly describe or single out the claimed invention from other unclaimed disclosures. "Written description" means written description, no more and no less.

The flaws in the Federal Circuit's ruling were laid bare by Judge O'Malley's dissent from the panel decision and the opinion of the three additional judges who dissented from the denial of rehearing en banc. Judge Lourie, writing for the en banc dissenters, explained 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 of cases where written description has not been found." App.41a. The panel majority's decision, they noted, "imports extraneous considerations into the written description analysis and blurs the boundaries between the written description requirement and the other statutory requirements for patentability." *Id.* These are not simply "errors in one case" but rather an "erroneous broadening of the written description inquiry" that will affect future litigants. App.54a. Judge Lourie warned that this decision "creates confusion for future patent applicants and litigants regarding what is required to meet the written description requirement of 35 U.S.C. § 112." App.51a-52a.

Indeed, the atextual requirements imposed by the Federal Circuit are flatly inconsistent with this Court's precedent. For example, more than 130 years ago, this Court upheld Alexander Graham Bell's patent for the telephone, even though he had not yet constructed a working model. His patent was valid, this Court explained, because it "describe[d] accurately" the process of creating a telephone. *The Telephone Cases*, 126 U.S. 1, 535 (1888). More than a century later, this Court, citing that decision, reaffirmed 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). The Federal Circuit's demand for proof of efficacy upends this long-standing principle.

The consequences of the Federal Circuit's erroneous decision will be dramatic, and will chill investment in innovative technologies, including life-altering medical treatments. And because every patent must comply with Section 112's written description requirement, the Federal Circuit's error will be felt well beyond the pharmaceutical industry.

The internal divisions within the Federal Circuit also promise to generate yet more confusion about what is necessary to comply with the written description requirement. The disagreement below reflects deep divisions over a fundamental feature of patent law. Those divisions create an unacceptable risk of inconsistent, panel-dependent decisions that will undermine the stability and certainty on which the patent system depends.

Because of the Federal Circuit's stark departure from the text of the statute and this Court's precedent, this case is an ideal vehicle to address an important question of law. This Court should act promptly to correct the Federal Circuit's serious errors and restore clarity to an issue integral to patent law. This Court should therefore grant the petition for certiorari and reverse.

STATEMENT

A. Patents And Patent Prosecution

A patent is divided into two main parts, the specification and the claims. The specification begins by providing relevant background and teaching the public about the improvements conceived by the inventors. The claims, which appear at the end of the patent, define the scope of the invention that the patent owner

has the exclusive right to make, use, sell, offer to sell, and import.

The claims of a patent often do not take their final form until long after a patent application has been filed. Applicants can amend their claims in response to the Patent and Trademark Office's rejections during the process known as patent "prosecution." In addition, a single "parent" patent application may disclose multiple improvements that are ultimately claimed in separate patents. For example, an applicant can file continuation or continuation-in-part applications that rely on the original disclosure contained in an earlier "priority" application but that issue as separate "child" or "grandchild" patents with different claims.[1] A patent's term is measured from its earliest claimed priority date, so although a series of patents linked to the same priority application may issue over time, the patents will ordinarily expire at the same time. *See* 35 U.S.C. § 154(a)(2).

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[1] A continuation application "must not include any subject matter" that was not disclosed in the original parent application. *Manual of Patent Examining Procedure* 201.07 (9th ed. rev. 10, June 2020). A continuation-in-part application retains a portion of the original disclosure but adds new matter. *Id.* at 201.08. Whether a continuation or continuation-in-part is filed, the named inventors as well as the title of a patent application often change as multiple patents each claiming different improvements are prosecuted from a single "parent" application. *See* 4A Chisum, *Chisum on Patents* § 13.07 (2022) ("The 1984 amendment [to 35 U.S.C. § 120] directly allows continuation, divisional, and continuation-in-part applications to be filed even though there is not a complete identity of inventorship between the parent and subsequent applications."); *Manual of Patent Examining Procedure* 606.01 ("Where the title is not descriptive of the invention claimed, the examiner should require the substitution of a new title that is clearly indicative of the invention to which the claims are directed.").

B. Section 112's Written Description Requirement

Section 112 of the Patent Act, as interpreted by courts, imposes three distinct requirements on patent applicants, only the first of which is at issue in this case. First, applicants must include a "written description of the invention." 35 U.S.C. § 112(a). Second, they must satisfy the "enablement" requirement by disclosing "the manner and process of making and using [the invention], 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." *Id.* The enablement requirement tests whether the claimed invention can be practiced without "undue experimentation." *In re Wands*, 858 F.2d 731, 736-737 (Fed. Cir. 1988). Third, applicants must "set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention." 35 U.S.C. § 112(a). The challenge to Biogen's patent in this case was based solely on the written description requirement.[2]

The requirement to provide a "description" of the invention originated in the Patent Act of 1790. Patent Act of 1790, § 2, 1 Stat. 109, 110. The phrase "written description" was first used in 1793. Patent Act of 1793, § 3, 1 Stat. 318, 321. At the time, patents were not required to have claims, so the written description served to inform the public of the scope of the invention. Thus,

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[2] Respondent did not argue at trial that the patent was invalid for lack of enablement because undue experimentation would be required. App.56a-57a n.2. Nor did it argue that Biogen had failed to disclose the best mode. Respondent's sole challenge under Section 112 alleged that Biogen's specification did not "contain a written description of the invention."

alongside an enablement requirement, the Patent Act of 1793 stated that the written description should "distinguish" the invention "from all other things before known." *Id.* This Court explained that the "object" was to inform the public of "what the party claims as his own invention, so as to ascertain if he claim[s] anything that is in common use, or is already known, and to guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented." *Evans* v. *Eaton*, 20 U.S. (7 Wheat.) 356, 434 (1822).

In 1836, Congress overhauled the patent system by creating the Patent Office and introducing a system of administrative examination of patent applications. Patent Act of 1836, §§ 1, 7, 5 Stat. 117, 117, 119. The Patent Act of 1836 first introduced the requirement that a patent contain claims "specifying what the patentee claims as his invention or discovery." *Id.* § 5, 5 Stat. at 119. At the same time, Congress amended the precursor to Section 112(a) to state that an applicant "shall deliver a written description of his invention or discovery, and of the manner and process of making, constructing, using, and compounding the same, in such full, clear, and exact terms, avoiding unnecessary prolixity, as to enable any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, construct, compound, and use the same." *Id.* § 6, 5 Stat. at 119. This language remains in the statute with only limited modification. *See* 35 U.S.C. § 112(a).

The written description requirement, consistent with its origin, has traditionally been understood to serve a public notice function. This Court explained that a patent must "'inform the public during the life of the patent of the limits of the monopoly asserted, so

that it may be known which features may be safely used or manufactured without a license and which may not.'" *Schriber-Schroth Co.* v. *Cleveland Tr. Co.*, 305 U.S. 47, 57 (1938) (quoting *Permutit Co.* v. *Graver Corp.*, 284 U.S. 52, 60 (1931)). Patent claims thus "cannot be broadened by amendment so as to embrace an invention not described in the application." *Id.* For example, in *Schriber-Schroth*, the original patent application described the webs that had been invented as "'extremely rigid,'" *id.* at 55, but the patentee later amended his claims to cover webs that were "'laterally flexible,'" *id.* at 53. This Court held that the patent could not claim webs with "antithetical properties" to what had been described. *Id.* at 58.

This Court's long-standing focus on whether the specification provides a "description" of the invention has never required that the specification also *prove* the invention's efficacy. For example, this Court "upheld a patent issued to Alexander Graham Bell even though he had filed his application before constructing a working telephone." *Pfaff*, 525 U.S. at 61. Likewise, this Court has never required that an invention be described more than once or singled out from other unclaimed disclosures.

The Federal Circuit has struggled in recent years to interpret and apply the written description requirement. Several judges on the Federal Circuit questioned whether there even is separate a written description requirement given the focus of the statutory language on enablement.[3] The Federal Circuit resolved

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[3] *See, e.g.*, *Enzo Biochem, Inc.* v. *Gen-Probe Inc.*, 323 F.3d 956, 976 (Fed. Cir. 2002) (Rader, J., dissenting from denial of rehearing en banc); *id.* at 987 (Linn, J., dissenting from denial of rehearing en banc); *Moba, B.V.* v. *Diamond Automation, Inc.*, 325

this internal debate in 2010 by recognizing a separate written description requirement. *Ariad Pharm., Inc.* v. *Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). New debates, however, have followed in the wake of the *Ariad* en banc majority's announcement that "the test for sufficiency" of a patent's written description is whether the patent "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.*

Since *Ariad*, courts have struggled to consistently apply the "possession" test. Some decisions have turned to an array of additional, atextual sub-tests applied by the Federal Circuit. *See, e.g.*, *Novozymes A/S* v. *DuPont Nutrition Bioscis. APS*, 723 F.3d 1336, 1346-1347 (Fed. Cir. 2013) (applying "blaze marks" test). Other recent decisions have invented new requirements out of whole cloth. *See, e.g.*, *Nuvo Pharm. (Ire.) Designated Activity Co.* v. *Dr. Reddy's Labs. Inc.*, 923 F.3d 1368, 1384 (Fed. Cir. 2019) (requiring proof that disclosed compound and formulation "would be efficacious"). And tests that might have made sense in one context have been applied where they do not belong. *See, e.g.*, App.32a-35a (O'Malley, J., dissenting) (criticizing extension of "blaze marks" test); App.46a (Lourie, J., dissenting) (same).

The result has been a pronounced expansion of the written description requirement beyond its original

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F.3d 1306, 1322 (Fed. Cir. 2003) (Rader, J., concurring); *University of Rochester* v. *G.D. Searle & Co.*, 375 F.3d 1303, 1307 (Fed. Cir. 2004) (Rader, J., dissenting from denial of rehearing en banc); *id.* at 1325 (Linn, J., dissenting from denial of rehearing en banc); *LizardTech, Inc.* v. *Earth Res. Mapping, Inc.*, 433 F.3d 1373, 1376 (Fed. Cir. 2006) (Rader, J., dissenting from denial of rehearing en banc).

purpose and substantial disagreement over how to apply the requirement. This trend reached its apogee in this case, resulting in a dissent from the panel opinion by Judge O'Malley and splitting the Federal Circuit 6-3 on whether to grant rehearing en banc. Indeed, the panel decision in this case prompted the author of the *Ariad* en banc decision—joined by the Chief Judge of the Federal Circuit and the Federal Circuit's longest-serving member—to criticize "the muddying of the written description requirement." App.41a.

C. Biogen's Development Of Tecfidera®

Biogen's Tecfidera® (DMF) is a widely prescribed, oral treatment for MS that was approved by the FDA in 2013. Biogen began developing what would become Tecfidera® ten years earlier in 2003. At that time, the only FDA-approved drugs for the treatment of MS were administered by injection. C.A.J.A.2127.

In 2003, based on confidential data and consideration of DMF's pharmacology, Biogen scientist Gilmore O'Neill conceived of treating MS with an oral dose of 480 mg/day of DMF based on his insight that peak levels of medication in the blood stream were driving the efficacy of DMF in the treatment of MS. App.9a, 59a. Biogen did not immediately put Dr. O'Neill's invention into clinical trials. Instead, Biogen's Phase II study, which took place between 2004 and 2006, tested the clinical efficacy of the lower and higher DMF doses of 120, 360, and 720 mg/day. App.8a-9a, 60a; C.A.J.A.2184, 2188. The results of the Phase II trial showed that 720 mg/day ("DMF720") effectively treated MS based on certain measurements collected via magnetic resonance imaging ("MRI"), such as the number of brain lesions, but the 120 and 360 mg/day doses did not have a statis-

tically significant effect. App.60a; C.A.J.A.2188-91, 1708, 2052-2059.

In 2007, Biogen began two Phase III clinical trials of DMF in MS patients, which both included the 480 mg/day dose ("DMF480") that Dr. O'Neill had conceived, as well as the DMF720 dose tested in the Phase II trial. In the Phase III trials, DMF480 not only met all MRI endpoints and clinical endpoints, but it unexpectedly performed similarly on each clinical endpoint to the higher DMF720 dose, which had itself outperformed its own Phase II results. C.A.J.A.2059-2069.[4]

D. The Patent

In February 2007, after receiving the Phase II study results and shortly before starting one of the Phase III trials that included the 480 mg/day dose, Biogen filed the provisional patent application that established the priority date for Biogen's U.S. Patent No. 8,399,514 ("the Patent"). App. 9a, 62a; C.A.J.A.52, 3290-3291. That priority application disclosed methods of screening chemical compounds for the treatment of neurological diseases and methods for treating the same. C.A.J.A.3295.

The application was originally titled "NRF2 Screening Assays and Related Methods and Compositions," and Dr. Matvey Lukashev was named as the inventor on the application based on his contributions to work relating to a specific biologic pathway (the Nrf2 pathway). C.A.J.A.3290-3291, 3337. In June 2011, Bio-

[4] The clinical endpoints in Biogen's Phase III clinical trials were: (1) proportion of relapsing MS patients at two years; (2) annual relapse rate; and (3) sustained 12-week disability progression. C.A.J.A.2059-2060.

gen amended the application's title to "Treatment for Multiple Sclerosis" and added Dr. O'Neill as a named inventor to reflect the prosecution of claims to specific methods of treatment that were disclosed in the application and that were based on Dr. O'Neill's inventive contribution. C.A.J.A.3437-3439. The Patent was issued by the USPTO on March 19, 2013. C.A.J.A.52.

MS is discussed throughout the specification of the Patent and is the only disease for which the Patent describes disease pathology, epidemiology, and the goals of treatment. Indeed, the first substantive sentence of the Patent states that "Provided are certain compounds for treating neurological diseases, including demyelinating neurological diseases, such as, e.g., multiple sclerosis." C.A.J.A.66(1:12-14); *see also* C.A.J.A.52 (Abstract) ("[P]rovided are certain methods of utilizing such compounds in therapy for neurological disease, particularly for slowing or reducing demyelination, axonal loss, or neuronal and oligodendrocyte death.").

The first column of the specification provides a detailed discussion of MS and explains that MS is "an autoimmune disease" that "is characterized by inflammation in parts of the" central nervous system, "leading to the loss of the myelin sheathing around axonal neurons (demyelination), loss of axons, and the eventual death of neurons, oligodendrocytes and glial cells." C.A.J.A.66(1:15-52). The focus on MS continues throughout the Patent. MS is often the only example of a demylineating disease that is given, C.A.J.A.67(3:10-14), and is the only disease for which multiple subtypes are described, C.A.J.A.73(16:23-26).

Method 4 of the Patent discloses the administration of a "therapeutically effective" amount of DMF, C.A.J.A.67(4:29-32), and describes administering the

compound in an amount "sufficient to slow or prevent demyelination, axonal loss, and/or neuronal death," C.A.J.A.67(4:33-38). The Patent's definition of "therapeutically effective amount" includes treatment of the same outcomes, C.A.J.A.68(5:52-59)—which both parties agreed are "hallmarks" of MS, C.A.J.A.1461-1462, 1501-1502.

Column 18 of the Patent expressly addresses the doses of DMF to be administered in Method 4. It discloses several increasingly narrowed dosing ranges, and in the narrowest range, states that "an effective dose of DMF … to be administered to a subject orally can be … from about 480 mg to about 720 mg per day." C.A.J.A.74(18:58-62).

The specification of the Patent therefore describes illustrative claim 1 of the '514 Patent, which states:

> A method of treating a subject in need of a 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 [DMF], 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.

C.A.J.A.79(27:59-67).

E. Trial Court Proceedings

Biogen filed an action against Mylan for patent infringement in the Northern District of West Virginia. App.4a, 56a. Mylan stipulated that its product would

infringe the Patent but challenged the Patent's validity. C.A.J.A.6154-6157. At trial, Mylan's expert argued that the claims of the Patent would have been obvious and testified that a skilled artisan in the field "would have [had] a reasonable expectation of success in treating multiple sclerosis patients with 480 milligrams a day of dimethyl fumarate." C.A.J.A.1116-1117. But, during the trial, the Patent Trial and Appeal Board issued a final written decision concluding that the claims would not have been obvious to a skilled artisan. *Mylan Pharm. Inc.* v. *Biogen MA Inc.*, IPR2018-01403, Paper No. 98 (P.T.A.B. Feb. 5, 2020). Mylan then pivoted to arguing that the Patent was invalid because it allegedly lacked a written description of DMF480 for the treatment of MS.

The district court found that Dr. O'Neill had conceived of the invention in 2003 and had a "strong belief that a 480mg/day dose of DMF (BID) would effectively treat MS." App.86a, 59a, *see* C.A.J.A.1612-1613. Nonetheless, it found a lack of written description because Dr. O'Neill and Biogen allegedly "did not know that to be true" until Biogen had completed its Phase III studies. App.86a.

The district court reasoned that the Patent failed to include proof such as "examples discussing efficacy data … or clinical trials," "graphs or data regarding proportion of relapses" and other metrics, or "Phase I data" from an early-stage clinical trial. App.88a. The district court concluded that the absence of clinical data was fatal "because a [skilled artisan] would not have expected a 480mg/day dose of DMF (BID) to be efficacious in 2007" and the "efficacy of the 480mg/day dose

… (BID) was 'unexpected' four years later in April 2011." *Id.*[5]

The district court also found it "[s]triking[]" that the "480mg dosing is mentioned only once in three examples." App.79a. It further relied on testimony that a person of ordinary skill reading the specification "would not know which dose provided … would be *most effective* for treating MS," App.80a (emphasis added), and concluded that a skilled artisan reading the specification would "be *drawn to* … the 720 mg/day dose" instead of the undisputedly disclosed 480 mg/day dose, App.79a (emphasis added). The district court reached this conclusion despite Congress's express instruction that best mode "shall not be a basis" to hold a patent "invalid or otherwise unenforceable." 35 U.S.C. § 282(b)(3)(A).

F. Appellate Proceedings

A divided panel of the Federal Circuit affirmed the district court. Over a dissenting opinion by Judge O'Malley, the panel majority held that the Patent did not describe the DMF480 dose—even though it was expressly disclosed in the specification as an endpoint of the narrowest dosing range. The panel reasoned that "before the Phase III study even commenced," a skilled artisan could not "deduce simply from reading the specification that DMF480 would be a therapeutically effective treatment for MS." App.18a. Conceding that Biogen "later established the therapeutic efficacy of DMF480," the panel majority nonetheless deter-

[5] The district court's decision did not acknowledge the express definition of "therapeutically effective amount"—a claim term defined in, and used throughout, the specification of the Patent.

mined that "[a]t the time of filing the original disclosure … insights that proved critical in the Phase III study had not yet been translated to clinical use." *Id.* The majority further wrote that "[t]he written-description requirement limits patent protection only to individuals who perform the difficult work of producing a complete and final invention." *Id.*

The panel majority separately faulted the Patent because "[t]he DMF480 dose is listed only once" in the specification "at the end of one range among a series of ranges" of DMF doses. App.16a. The panel dismissed Biogen's remaining arguments—including that the district court misapplied Federal Circuit precedent and disregarded the specification's express disclosures—as "ancillary" and "superfluous." App.20a-21a.

Judge O'Malley dissented. She observed that the district court found "that the '514 patent does not demonstrate possession because it lacks clinical efficacy data," but that "[t]his cannot be right." App.29a-30a. Judge O'Malley explained that the district court's written description holding contravened Federal Circuit precedent and ignored the Patent's "explicit[] mention[] [of] the claimed DMF480 dose." App.35a. Judge O'Malley also noted 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. App.34a n.1.

The Federal Circuit denied Biogen's petition for rehearing en banc by a 6-3 vote.[6] App.37a-38a. Judge Lourie, joined by Chief Judge Moore and Judge New-

[6] Judges Stoll and Cunningham did not participate, and Judge O'Malley, who had dissented at the panel stage, retired shortly before the order denying rehearing en banc.

man, dissented from the denial of rehearing en banc. Surveying precedent, Judge Lourie emphasized 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." App.41a. He warned that the panel decision imported "extraneous considerations into the written description analysis and blurs the boundaries between the written description requirement and the other statutory requirements for patentability." *Id.*

Judge Lourie "identif[ied] four individual points of error that the en banc court should have corrected." App.44-45a. First, the panel majority unduly emphasized "unclaimed disclosures in the specification," *id.*, which, Judge Lourie observed, "implies that a patent fails the written description requirement … when it contains too much disclosure beyond the claimed invention." App.48a.

Second, the panel majority "erroneously imposed a heightened burden on the patentee to show that the specification proves efficacy." App.45a. Judge Lourie explained that it is "the province of the United States Food and Drug Administration"—not courts applying the written description requirement—to determine whether "a claimed pharmaceutical compound actually achieves a certain result." App.48a (quotations omitted).

Third, the panel majority imported "extraneous legal considerations" into the written description requirement. App.49a. For example, it "blurr[ed] the lines between written description and enablement" even though enablement "has its own legal test and its own substantial body of precedent separate and apart

from the written description requirement." App.50a. The district court "also imported aspects of a 'best mode' requirement into the written description analysis." App.51a. 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." *Id.* This observation was irrelevant, Judge Lourie explained, because the written description requirement does not require that a skilled artisan be "draw[n]" "toward the claimed embodiment and away from un-claimed embodiments." *Id.* Certainly, there is "no requirement that patent claims be limited to only the 'most effective' embodiment disclosed in the specification." *Id.* Yet, Judge Lourie concluded, that is precisely what the panel majority erroneously required. This error, he warned, "creates confusion for future patent applicants and litigants regarding what is required to meet the written description requirement of 35 U.S.C. § 112." App.51a-52a.

Fourth, the panel majority "affirmed a district court decision that is replete with reasoning that extends far beyond the confines of the disclosure contained in the patent specification." App.52a. As Judge Lourie observed, the written description analysis is an "objective inquiry into the four corners of the specification." *Id.* (quotations omitted). Yet the district court went "far beyond the confines of the disclosure contained in the patent specification." *Id.* It improperly "placed considerable weight on whether Biogen's clinical trials before the filing date would have been sufficient to show the efficacy of particular doses of DMF to treat multiple sclerosis," and went "so far as to … speculat[e] about Biogen's motivations for its patent prosecution decisions based on the timing of Biogen's clinical

trials and the possible desires to avoid prior art." App.53a. "Simply put, none of that is relevant to the question whether the '514 patent specification contains sufficient written description to support what is claimed." App.54a.

This petition for certiorari followed.

REASONS FOR GRANTING THE PETITION

I. THE FEDERAL CIRCUIT'S DECISION CONFLICTS WITH THE TEXT AND PURPOSE OF SECTION 112 AND LONGSTANDING PRECEDENT

This case addresses the fundamental and recurring question of what is required to be disclosed in a patent's specification under the written description requirement of 35 U.S.C. § 112. Biogen's Dr. O'Neill conceived of a new invention—treating MS with DMF480—and described it in the Patent specification. Under the text of Section 112 and well settled precedent, nothing more was required to satisfy the written description requirement. The Federal Circuit, however, ignored the plain text of the statute and longstanding precedent to apply a new, more stringent written description requirement. It held that it is not enough to *describe* the claimed invention; a patent applicant must also *prove* the claimed invention works as described—in this case by including in the specification evidence of the efficacy of its claimed method. The court further erred by faulting Biogen for disclosing the claimed DMF480 dose "only once" in the Patent, App.16a, holding, in effect, that a specification must repeatedly describe and single out the claimed invention. These rulings disregard the text and purpose of Section 112 and break with settled patent law.

1. Biogen's Patent specification satisfied Section 112's requirement that a specification contain "a written description of the invention." The district court found that Dr. O'Neill had conceived of the invention in 2003 and had a "strong belief that a 480mg/day dose of DMF (BID) would effectively treat MS," App.86a, 59a; *see* C.A.J.A.1612-1613. Consistent with Dr. O'Neill's conceived invention, the Patent claims methods of treating MS by orally administering a therapeutically effective amount of DMF, wherein the therapeutically effective amount is about 480 mg/day. App.66a; *supra* p. 13.

The Patent specification linked all elements of the claimed invention together. It provided a detailed discussion of MS and described it as a disease "leading to the loss of the myelin sheathing around axonal neurons (demyelination), loss of axons, and the eventual death of neurons, oligodendrocytes and glial cells." C.A.J.A.66(1:15-52). It disclosed the administration of a "therapeutically effective" amount of DMF to "slow or prevent demyelination, axonal loss, and/or neuronal death," C.A.J.A.67(4:33-38)—which both parties agreed are "hallmarks" of MS, C.A.J.A.1461-1463, 1501-1502. It referenced those same hallmarks of MS in its definition of "therapeutically effective amount." C.A.J.A.68(5:52-59). And it expressly addressed the "effective" doses of DMF to be administered, stating that "an effective dose of DMF … to be administered to a subject orally can be … from about 480 mg to about 720 mg per day." C.A.J.A.74(18:58-62); *supra* pp. 12-13.

Nothing more should have been required to satisfy the written description requirement. As relevant, Section 112 requires only a "written description of the invention." The term "description," on its face, requires only a written statement setting forth the characteris-

tics of the invention. *See, e.g.*, *Merriam-Webster Dictionary*, https://www.merriam-webster.com/dictionary/description ("a representation in words of the nature and characteristics of a thing"); *Black's Law Dictionary* (11th ed. 2019) (defining "description," in the context of "a patentable process" to mean "[a] delineation or explanation of something by an account setting forth the subject's characteristics or qualities"); *American Heritage College Dictionary* (4th ed. 2004) (a "statement or an account describing something"); *Webster's Third New International Dictionary* (1976) ("a statement of the properties of a thing").

This understanding of the word "description" comports with this Court's precedent and the well-understood purpose of the written description requirement. *See supra* pp. 6-8 (describing development of written description requirement). By disclosing the elements of the invention—namely, that an orally administered dose of 480 mg of DMF per day would be therapeutically effective in treating MS—the Patent specification provided notice about the scope of the claimed invention. The written description requirement demands nothing more.

2. The Federal Circuit ruled against Biogen by erroneously grafting additional requirements onto the statute to heighten the written description requirement. This is a culmination of a long-term trend in the Federal Circuit's written description precedent, which has become increasingly unmoored from the text and purpose of Section 112.

For example, the Federal Circuit has interpreted the straightforward written description requirement to demand that a patent specification "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 (Fed. Cir. 2010). The amorphous nature of this "possession" test has caused the Federal Circuit to rely on atextual sub-tests and impose new requirements not found in the statute. *See supra* pp. 8-10 (describing Federal Circuit's struggle to apply written description requirement). The result has been an "unsatisfactory patchwork of band-aid, ad hoc solutions." Yu, *The En Banc Federal Circuit's Written Description Requirement: Time for the Supreme Court to Reverse Again?*, 33 Cardozo L. Rev. 895, 898-899 (2012); *see also, e.g.*, App.32a-35a (O'Malley, J., dissenting) (criticizing extension of "blaze marks" test); App.46a (Lourie, J., dissenting) (same).

The creeping expansion of the written description requirement reached new heights in this case. This Court's review is urgently needed to clarify Section 112's requirements.

3. The Federal Circuit found lack of written description because Biogen did not disclose clinical trial results in its patent application. In so holding, the Federal Circuit effectively required that the specification *prove*—rather than just describe—the claimed effect. Such a judicially-crafted requirement goes far beyond the text of the written description requirement and ignores this Court's explanation that an invention "may be patented before it is reduced to practice." *Pfaff* v. *Wells Elects., Inc.*, 525 U.S. 55, 61 (1998).

The insistence on efficacy data began in the district court, which held that the Patent does not satisfy the written description requirement because "nothing in [the specification] teaches a [person of ordinary skill in the art] that a 480 mg/day dose of DMF … is therapeutically effective for treating MS." App.80a. The dis-

trict court noted that the "Patent does not include examples discussing efficacy data," "graphs or data" regarding patient outcomes, or "Phase I data" from the development program. App.88a. As Judge O'Malley summarized in her dissenting opinion: "Somewhat circularly, after acknowledging that clinical data demonstrating effectiveness is not required to satisfy written description, the district court went on to find that the 514 patent does not demonstrate possession because it lacks clinical efficacy data." App.29a.

Rather than correct the district court's legal error, the Federal Circuit endorsed it. The Federal Circuit stated that "[w]hat matters … is whether, at the time of filing the disclosure, … a skilled artisan could deduce simply from reading the specification that DMF480 would be a therapeutically effective treatment for MS." App.18a. This is incorrect. Judge Lourie's dissent observed that where, as here, a patent expressly describes a dose as effective, a skilled artisan is not required to "deduce" anything. App.49a. The panel majority's misguided focus on "whether the patentee *proved* that 480 mg per day is an effective amount to treat multiple sclerosis" "blur[s] the lines" of the written description requirement. App.50a.

Contrary to the Federal Circuit's holding, the written description requirement does not require the USPTO or the court to examine whether a claimed pharmaceutical treatment actually is effective. As Judge Lourie noted in dissent from denial of en banc rehearing, that is the province of the U.S. Food and Drug Administration, not a court applying patent law. App.49a-50a; *see also In re Brana*, 51 F.3d 1560, 1567 (Fed. Cir. 1995). By concluding otherwise, the court below flouted the plain text of Section 112.

The Federal Circuit's insistence on proof of efficacy also has the effect of requiring actual reduction to practice before a patent application can be filed. The district court found that Dr. O'Neill had conceived of the claimed invention in 2003 and had a "strong belief that a 480mg/day dose of DMF … would effectively treat MS." App.86a, 59a; *see* C.A.J.A.1612-1613. But the Federal Circuit stated that "[r]egardless of whether O'Neill had in fact … conceived the idea of treating MS with a DMF480 dose as early as 2003, the law is clear that a patent cannot be awarded for mere theoretical research without more" because the "written-description requirement limits patent protection only to individuals who perform the difficult work of producing a complete and final invention." App.18a (citation omitted).

This holding conflicts with this Court's precedent. In *Pfaff* v. *Wells Electronics, Inc.*, 525 U.S. 55, 61 (1998), this Court restated the "well settled" rule "that an invention may be patented before it is reduced to practice." *Pfaff* cited *The Telephone Cases*, 126 U.S. 1 (1888), in which this Court "upheld a patent issued to Alexander Graham Bell even though he had filed his application before constructing a working telephone." *Pfaff*, 525 U.S. at 61. When considering Bell's patent, this Court wrote:

> It is quite true that when Bell applied for his patent he had never actually transmitted telegraphically spoken words so that they could be distinctly heard and understood at the receiving end of his line; but in his specification he did describe accurately, and with admirable clearness, his process—that is to say, the exact electrical condition that must be created to accomplish his purpose—and he also described, with

> sufficient precision to enable one of ordinary skill in such matters to make it, a form of apparatus which, if used in the way pointed out, would produce the required effect, receive the words, and carry them to and deliver them at the appointed place.

Telephone Cases, 126 U.S. at 535-536.

Applying that reasoning here, the Federal Circuit's error is manifest. When it filed its Patent, Biogen had not yet gathered clinical data proving the efficacy of DMF480 treatment—much as Bell had not yet produced a device that could reproduce the words spoken into it. But Biogen's Dr. O'Neill had conceived of an invention (the treatment of MS using DMF480) and described the dose and its usage in the Patent—just as Bell had developed and described the telephone.

Contrary to this Court's precedent, the Federal Circuit imposed a heightened written description burden on Biogen to show that the specification proves that its invention works. That holding cannot be squared with the plain text of Section 112, the statute's purpose, or this Court's reasoning in *The Telephone Cases* and *Pfaff*.

4. Compounding its erroneous application of the written description requirement, the Federal Circuit noted that the 480 mg/day dose "is listed only once" in the specification. App.16a. In the court's view, this was "a significant fact that cuts against Biogen's case." *Id.* But the written description requirement does not demand that a specification repeat or single out a claimed embodiment. The specification listed four increasingly narrow dose ranges. The DMF480 dose was specifically named, along with another dose tested in Biogen's Phase III MS trials (DMF720), as an endpoint

of the narrowest range described in the specification as effective.

The Federal Circuit erroneously insisted that there must be some further repetition, or specific singling out, to satisfy the written description requirement. But the term "description" indicates only that a specification must identify an invention—not that it must do so repeatedly, or with special emphasis. As Judge O'Malley rightly observed in dissent, the panel majority concluded, in substance, "that a claim element must be disclosed multiple times." App.34a n.1. This judicial requirement has no basis in statute or in case law. *See Vanda Pharm. Inc.* v. *West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1137 (Fed. Cir. 2018) ("The disclosure of a dose outside of the claimed range does not compel a finding that the asserted claims lack adequate written description."). Or, as the dissent from denial of rehearing en banc succinctly put the point, under the written description requirement, "[o]nce is enough." App.48a.

Relatedly, the Federal Circuit erroneously faulted Biogen for including unclaimed disclosures in the specification. It noted that the disclosure of DMF480's efficacy "appears at the end of one range among a series of ranges." App.16a; *see also* App.17a-18a ("the specification's only reference to DMF480 was part of a wide DMF dosage range and not listed as an independent therapeutically effective dose"). This mirrored the district court's reliance on testimony that a skilled artisan "would not know which dose … would be most effective for treating MS" or "preferred." App.80a.

The Federal Circuit's demand that the specification single out DMF480 was incorrect. This Court has explained that a patent application is allowed to disclose

multiple inventions that can be covered by multiple distinct claims, or not claimed at all:

> [T]he law is well settled that if the several combinations are new and useful, and will severally produce new and useful results, the inventor is entitled to a patent for the several combinations, provided that he complies with the requirement of the Patent Act and files in the Patent Office a written description of each … He may give the description of the several combinations in one specification, and in that event he can secure the full benefit of the exclusive right to each of the several inventions by separate claims referring back to the description in the specification[.]

Gill v. *Wells*, 89 U.S. (22 Wall.) 1, 24 (1874).

The Court of Customs and Patent Appeals (the Federal Circuit's predecessor) similarly explained that "there would seem to be little doubt that the literal description of a species provides the requisite legal foundation for claiming that species" and "fail[ed] to see the relevance of the listing of several inoperative species when the species claimed is operative and performs as 'speculated.'" *Snitzer* v. *Etzel*, 465 F.2d 899, 902-03 (C.C.P.A. 1972).

Furthermore, the Federal Circuit's insistence on singling out the claimed dose as preferred erroneously imports "best mode" concepts into the written description requirement. App.51a. Making the court's error worse, Congress has specifically provided that any "failure to disclose the best mode shall not be a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable." 35 U.S.C. § 282(b)(3)(A).

By holding that the mention of other unclaimed disclosures somehow undermines the written description support for the claimed DMF480 to treat MS, the Federal Circuit imported into the written description analysis considerations found nowhere in that statutory requirement's plain text. *See* App.32a-35a (O'Malley, J., dissenting); App.46a (Lourie, J., dissenting).

* * *

This Court has repeatedly cautioned the Federal Circuit against importing extraneous and atextual requirements into the Patent Act. *See Halo Elecs., Inc.* v. *Pulse Elecs., Inc.*, 579 U.S. 93, 107 (2016) (rejecting the Federal Circuit's extraneous framework for enhanced damages as "inconsistent" with 35 U.S.C. § 284); *Octane Fitness, LLC* v. *ICON Health & Fitness, Inc.*, 572 U.S. 545, 554-55 (2014) (rejecting the Federal Circuit's "exceptional" case rule for attorneys' fees under 35 U.S.C. § 285 as "overly rigid"); *Nautilus, Inc.* v. *Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014) (rejecting "insolubly ambiguous" test for indefiniteness under 35 U.S.C. § 112(b)).

Yet that is precisely what the Federal Circuit did here. It required that the specification prove the described effect and indicated that a specification must repeat or single out a claimed embodiment. Each of these errors broke with Section 112's straightforward text and created a new, more stringent written description requirement that is based in neither law nor logic. As described in more detail below, these errors, if allowed to stand, will harm inventors, investors, potential licensees, and members of the public who rely on a stable and predictable patent system to encourage innovation.

II. THE FEDERAL CIRCUIT'S DECISION THREATENS INNOVATION AND WARRANTS REVIEW BY THIS COURT

This Court's review is urgently needed to align the Federal Circuit's application of the written description standard with the plain text of Section 112. Because the Federal Circuit has nationwide jurisdiction over patent cases, its decisions govern proceedings in the USPTO and district courts across the country. Unless this Court acts, the Federal Circuit's erroneous rule will stifle innovation and generate enormous confusion.

As explained, the Federal Circuit's rule in effect requires that inventors provide proof of efficacy and actually reduce their inventions to practice before a patent application can be filed. *See supra* p. 22-25. That rule puts inventors in a bind. Under the Federal Circuit's approach, if an inventor files a patent application after conception of the invention but before acquiring proof of efficacy, she runs the risk that her patent will be invalidated for lack of a written description under Section 112. If she instead waits to gather data demonstrating proof of efficacy—as the Federal Circuit would have it—she runs the risk that public disclosures made in an effort to gather proof of efficacy will become prior art that bars the granting of a patent under 35 U.S.C. § 102 or § 103 altogether.

Although the problem will affect numerous industries, an example in the context of the pharmaceutical industry illustrates the point. Consider a pharmaceutical company developing a lifesaving drug treatment. The company ordinarily would seek a patent before all clinical trials are completed and the results are analyzed. But such a patent could be invalidated under the panel majority's heightened application of the written description requirement. To comply with the Federal

Circuit's new rule, the company would have to delay seeking a patent until clinical trial results are in hand. Yet for new treatment methods, pharmaceutical companies are typically required to publicly disclose important details as part of the clinical-trial process, including disclosing dose information to enroll patients before the trials begin and disclosing interim clinical findings. *See* 42 U.S.C. § 282(j); 42 C.F.R. §§ 11.2-66. If the company waits until it has fully analyzed clinical trial results in hand to file a patent application, it likely would be unable to obtain patent protection for its new treatment method because its public clinical-trial disclosures could well render its invention either anticipated or obvious in light of the prior art and, thus, unpatentable. In short, whenever the patent application was filed, it would either be deemed too early or too late.

The Federal Circuit's rule will chill investment in innovative technologies. Few would be willing to incur considerable research-and-development costs without the prospect of patent protection. To return to the example of pharmaceuticals, the "process of developing a new drug and bringing it to market is long, costly, and risky." Grabowski et al., *The Roles of Patents and Research and Development Incentives in Biopharmaceutical Innovation*, 34 Health Affairs 302, 302 (2015). The cost of developing new pharmaceutical treatments is extraordinary, running an average of nearly $1.4 billion in out-of-pocket costs. *See* DiMasi, et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 20, 31 (2016). None of these investments pays off quickly. *See* Thomas, et al., *Clinical Development Success Rates and Contributing Factors 2011-2020*, BIO 3, 10 (2001) (showing 10.5 year average development time from initial human trials to

FDA approval). Most do not pay off at all. *See id.* (showing only 8% of drugs obtain FDA approval).

Businesses and investors therefore assume considerable costs and business risk. Without the promise that their investment will be protected by effective patent rights, there will be no incentive to invest in important innovative technologies. This risk is especially acute for emerging companies, many of which do not yet have approved products that they can market. These emerging enterprises must seek patent protections as soon as possible to attract investment. The decision below fatally undermines their ability to do so.

The Federal Circuit itself has long recognized the serious consequences that would flow if courts demanded that inventors obtain clinical data before seeking a patent. In that case, "the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer." *Brana*, 51 F.3d at 1568.

The ruling below ignores this critical lesson and threatens to usher in an era of heightened uncertainty and confusion surrounding the patent system. This Court should intervene now before the Federal Circuit's erroneous application of the written description requirement upends the field and impedes the very sort of "technological growth and industrial innovation" that the Federal Circuit was created to "foster." *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 390 (1996) (quotation marks omitted) (quoting H.R. Rep. No. 97-312, at 20-23 (1981)).

III. THE FEDERAL CIRCUIT IS INTERNALLY DIVIDED ON A FREQUENTLY RECURRING QUESTION, CREATING A SUBSTANTIAL RISK OF INCONSISTENT AND PANEL-DEPENDENT DECISIONS

Compounding the confusion and uncertainty created by the decision below, the Federal Circuit is sharply divided on the question of the written-description standard. Disagreement on such a fundamental and recurring question creates additional uncertainty and raises an intolerable risk of panel-dependent decisions. Because the Federal Circuit has nationwide authority to hear patent appeals, and because it declined to hear this case en banc, only this Court can clarify the written description standard and settle this intra-circuit conflict.

The conflicting opinions in this case reflect a fundamental disagreement on an important legal question that will affect many future cases. Judge O'Malley dissented from the majority's conclusion that the Patent did not describe the DMF480 dose. The three additional judges who dissented from denial of rehearing en banc also cataloged multiple errors in the panel majority's reasoning. They stressed that the panel incorrectly "imported operability considerations into the written description analysis" by "focusing on whether the patentee *proved* that 480 mg per day is an effective amount to treat multiple sclerosis—as distinct from whether the … [Patent] specification *discloses* that 480 mg per day is an effective amount to treat multiple sclerosis." App.50a. The en banc dissent also laid out the grave consequences of the panel majority's opinion: It "creates confusion for future patent applicants and litigants regarding what is required to meet the written description requirement." App.51a-52a. En banc review was therefore warranted not to "simply … cor-

rect errors in one case" but instead to restore "clarity for future litigants by reaffirming the proper boundaries of the written description requirement." App.54a.

As is clear from these conflicting opinions, the Federal Circuit is deeply divided on the written-description standard. This internal split on something as fundamental as the written description requirement is untenable and adds to the substantial uncertainty that already existed. *See, e.g.*, Rabinowitz, *Ending the Invalidity Shell Game: Stabilizing the Application of the Written Description Requirement in Patent Litigation*, 12 Minn. J.L. Sci. & Tech. 127, 148 (2011) ("Proper application of the written description doctrine is challenging" because "the Federal Circuit's development of the law surrounding the written description requirement has been turbulent" and "the contours of the legal test for written description are ever-evolving.")

This Court has explained that "predictability and stability are of prime importance" in matters affecting "property rights." *Landgraf* v. *USI Film Prods.*, 511 U.S. 244, 271 (1994). As the dissent from denial of en banc rehearing recognized, the panel majority's decision weakens that stability and instead injects considerable confusion into patent law. The split in the Federal Circuit only compounds that uncertainty because application of the written description requirement is likely to turn on the happenstance of which panel is assigned to a case. And the question of what the written description requirement demands is sure to recur many times in the future because Section 112 mandates that every patent provide a "written description."

This uncertainty undermines the purpose of the Federal Circuit, which is to "produce desirable uniformity in this area of the law." S. Rep. No. 97-275, at 5

(1982), *reprinted in* 1982 U.S.C.C.A.N. 11, 15; *see also Markman*, 517 U.S. at 390 (stating that "[i]t was just for the sake of such desirable uniformity that Congress created the Court of Appeals for the Federal Circuit as an exclusive appellate court for patent cases"). And it leaves inventors, investors, licensees, and the public with little guidance to navigate the patent system. This Court must step in to restore clarity to that system by enforcing the statute as written rather than as rewritten by the Federal Circuit.

IV. This Case Is An Ideal Vehicle For Addressing This Important Legal Question

This case is an ideal vehicle for this Court to address the written description requirement. The question presented was raised and squarely addressed by the Federal Circuit in a published, precedential decision. The panel majority's decision extends the atextual approach that the Federal Circuit has taken to Section 112. The dispute between the panel majority and dissenters has crystalized the disputed legal questions regarding the written description standard. The district court expressly found that Biogen scientist Dr. O'Neill had conceived of the claimed invention by 2003. App.59a, 86a; *see* C.A.J.A.1612-1613. And multiple amici weighed in below to elaborate on the stark consequences of the panel's decision and urged the court of appeals to rehear the case en banc.

Because the Federal Circuit declined Petitioner's request to clarify the written description standard, it falls to this Court to ensure Section 112 is correctly applied and faithfully implemented. The Federal Circuit's application of a heightened written description requirement conflicts with the statute and precedent. The legal issues are fundamental, and the stakes are

high. This Court must act promptly to ensure that the lower court's decision is not permitted to destabilize the patent system. This Court should therefore grant the petition and reverse.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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