No. 21-1567

IN THE

Supreme Court of the United States

BIOGEN INTERNATIONAL GMBH AND BIOGEN MA INC.,
Petitioners,

v.

MYLAN PHARMACEUTICALS INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF *AMICI CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA) AND BIOTECHNOLOGY INNOVATION ORGANIZATION (BIO), IN SUPPORT OF PETITIONERS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

TABLE OF AUTHORITIES – continued

INTEREST OF *AMICI CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association representing the country's leading research-based pharmaceutical and biotechnology companies.[2] PhRMA's mission is to advocate public policies encouraging innovation in life-saving and live-enhancing new medicines. PhRMA's member companies are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives, and they have led the way in the search for new cures. PhRMA's members make significant contributions to serve the collective goals of enhancing and lengthening human life. Since 2000, PhRMA members have invested more than $1 trillion in the search for new treatments and cures—including $91.1 billion in 2020 alone. PhRMA members rely on the assurance of patent exclusivity for their innovations when they make these investments and their product development decisions.

The Biotechnology Innovation Organization (BIO) is the principal trade association representing the biotechnology industry in all fifty states and more than 30 countries.[3] BIO has more than 1,000 members, ranging from small start-up companies and biotechnology centers to research universities and Fortune

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[1] Counsel of record for all parties received timely notice of *amici*'s intent to file this brief and have consented to its filing. No counsel for any party authored this brief in whole or in part, and no person or entity other than *amici* and their counsel contributed funds for its preparation or submission.

[2] PhRMA's members are listed at www.phrma.org/about#members (last visited July 15, 2022).

[3] BIO's members are listed at www.bio.org/bio-member-directory (last visited July 15, 2022).

500 companies. The majority of BIO's members are small companies that have yet to bring products to market or attain profitability. Approximately 90% of BIO's corporate members have annual revenues of under $25 million. These members rely heavily on the patent system to structure their businesses, protect their inventions, and to access venture capital and other private investment. Strong and reliable patents are critical to ensuring a steady stream of capital investment that supports the massive development costs of new biotechnology products and services.

Amici have a substantial interest in this case because the decision below, if left undisturbed, would threaten innovation and create uncertainty about the disclosure needed to support a claim to a new therapeutic method under 35 U.S.C. § 112. Critically, the decision appears to read a statute that calls for "a written description of the invention," *id.*, to require human clinical evidence proving that an inventive therapeutic method literally described in the patent is safe and effective in humans. If that were the rule, it would make it difficult—in many cases impossible—to obtain patent protection for new methods of treatment, which in turn would make it difficult to recoup the substantial investments necessary to bring such methods to patients for treatment. Moreover, the decision reflects divisions within the Federal Circuit regarding the requirements of the "written description" standard, which only exacerbate the uncertainty generated by the decision.

Certiorari should be granted.

SUMMARY OF ARGUMENT

This Court should grant review to resolve a question that could profoundly affect the patent system's incen-

tive for innovation in the pharmaceutical and biotechnology industries—must innovators defer pursuing patent protection for a new human therapeutic method until they have actually proven it is safe and effective in human patients? For many good and practical reasons, the patent law has never preconditioned patent grants on such proof, and doing so via the written description requirement not only conflicts with the statutory language of 35 U.S.C. § 112, but creates irreconcilable conflicts with other patent law standards.

Amici's concerns in this case are concisely framed by the three judges who dissented from the Federal Circuit's decision to not rehear the panel decision below. As they explained, the panel decision improperly imported "extraneous considerations" into the written description analysis—most notably a requirement for evidence demonstrating the claimed method was "therapeutically effective" in humans—which "blurs the boundaries between the written description requirement and the other statutory requirements for patentability." Pet. App. 41a.

The dissent was correct on both points. The written description requirement of § 112 has never required a patent application claiming a human therapy to contain human clinical evidence—all that is required is what the statute states: a "written description of the invention." And other requirements of the patent statute do not demand clinical evidence, which can only be obtained by testing the method in human patients.

The decision threatens to hinder innovation in the field of human therapy. Requiring drugmakers to wait to file their patent applications until after they have conducted the human clinical trials necessary to prove a new human therapy is safe and effective will effectively foreclose patenting, as the public disclosures required for securing FDA approval will operate to bar

patenting of these necessarily later filed applications. Demanding that innovators wait to file their applications also runs counter to the primary objective of the patent system of inducing early public disclosures of inventions. Biogen's petition should be granted.

ARGUMENT

I. THE DECISION BELOW INJECTS CONFUSION INTO THE WRITTEN DESCRIPTION REQUIREMENT.

Under 35 U.S.C. § 112, patents must "contain a written description of the invention." As this Court has recognized, this requirement ensures that the scope of patent protection defined by a patent's claims is commensurate with the invention described in the specification: "exclusive patent rights are given in exchange for disclosing the invention to the public," and "[w]hat is claimed by the patent application must be the same as what is disclosed in the specification." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002); *see also O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 118 (1854) ("the patent issues for the invention described in the specification").

"Description" means "description," not demonstrated proof that the inventor has actually made a product or service embodying the invention, much less one that is ready to be commercially marketed. Indeed, this Court confirmed the validity of Alexander Graham Bell's telephone patents despite the fact that Bell had not, at the time of his application, actually "transmitted telegraphically spoken words so that they could be distinctly heard and understood at the receiving end of his line." *The Telephone Cases*, 126 U. S. 1, 535 (1888). It was enough that Bell's specification "describe[d] accurately, and with admirable clearness, his process,

that is to say, the exact electrical condition that must be created to accomplish his purpose." *Id.*

As the dissent explained, findings made by the district court and recognized by the majority demonstrated that Biogen's patent did provide a "written description of the invention." One was that the patent disclosure described a "therapeutically effective" dose of dimethyl fumarate can treat neurodegenerative diseases like multiple sclerosis. *See* Pet. App. 8a. A second was that the patent described an "effective dose" of dimethyl fumarate being "from about 480 mg to about 720 mg per day," taken "orally." *Id.* (emphasis omitted). Those findings, as the dissent reasoned, were sufficient to provide a written description of a method of administering a specific drug (DMF) at a specific dose (480 mg per day) to treat a specific disease (multiple sclerosis), as the claims required.

The Federal Circuit demanded more. Most concerning was the panel's conclusion that Biogen's patent had to provide evidence that the claimed therapeutic method worked. The Federal Circuit thus reasoned that Biogen's patent should have included clinical evidence that administering 480 milligrams of dimethyl fumarate is "efficacious" in treating multiple sclerosis in humans. Pet. App. 17a.

The Federal Circuit's approach cannot be squared with the text of § 112, which requires only a "description of the invention"—not proof that it was actually made, that it "works," or that it is in a form ready to be commercially marketed or used by patients. Imposing a requirement for human clinical testing via the written description requirement also conflicts with the other disclosure standards in the patent law that have

long held that such evidence is *not* necessary to support human therapeutic inventions.[4] Rather, courts have consistently found such support if the patent applicant provides a scientifically plausible basis for believing that the human therapeutic method may work, which is routinely accomplished using data from experimental assays and suitable animal models.[5]

The decision below thus muddies the written description requirement, creating uncertainty about the information that a patent must disclose to support a claim to a human therapeutic method. This Court should intervene to clarify that the written description requirement of § 112 does *not* require evidence from human clinical trials.

II. THE DECISION BELOW THREATENS INNOVATION.

Without this Court's intervention, the decision below could deter early disclosure of inventions and upset the "delicate balance" of patent incentives for developing new human therapies. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 590 (2013).

a. There is a long and uncertain path between discovery of a promising new human therapy and FDA approval of it. Generally, that process starts when scientists identify a "promising molecule" or therapeutic

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[4] *See, e.g.*, *In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995) ("FDA approval . . . is not a prerequisite for finding a compound useful within the meaning of the patent laws." (citing *Scott v. Finney*, 34 F.3d 1058, 1063 (Fed. Cir. 1994))).

[5] *See id.* at 1567 ("Our court's predecessor has determined that proof of an alleged pharmaceutical property for a compound by statistically significant tests with standard experimental animals is sufficient to establish utility." (citing *In re Krimmel*, 292 F.2d 948, 953 (C.C.P.A. 1961) and *In re Bergel*, 292 F.2d 958 (C.C.P.A. 1961))).

use of it that could potentially "become a new medicine."[6] Next comes "extensive testing to determine if [it is] ready to be studied in humans." *Id.* at 8. Only after those tests are complete and positive do scientists begin clinical trials, which usually take six to seven years. *See id.* at 10.

Commencing clinical trials, however, does not guarantee success—most clinical trials do not result in an FDA approval. In fact, studies have shown that fewer than 1 in 5 products that enter clinical trials emerge with an FDA approval, and for many therapeutic areas that figure is much lower.[7] The costs of conducting those clinical trials also can be staggering, with the average cost of developing a single medicine reaching more than two billion dollars including the costs incurred for the many projects that never reach FDA approval.[8]

b. Recognizing this, courts thus have long observed that a patent applicant need not prove with clinical evidence that a claimed human therapy is safe or fully

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[6] PhRMA, *Biopharmaceutical Research & Development: The Process Behind New Medicines* 4 (2015), http://phrmadocs.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf.

[7] *See* Shingo Yamaguchi et al., *Approval Success Rates of Drug Candidates Based on Target, Action, Modality, Application, and their Combinations*, 14 Clinical & Translational Sci., 1113, 1117 (2021); Asher Mullard, *Parsing Clinical Success Rates*, 15 Nature Reviews 447, 447 (2016); Biotechnology Innovation Org., *Clinical Development Success Rates and Contributing Factors 2011–2020* at 26 (Feb. 2021), https://go.bio.org/rs/490-EHZ-999/images/ClinicalDevelopmentSuccessRates2011_2020.pdf; Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ., 20, 23, 25 (2016) (finding only 11.8% of products that commenced clinical testing emerged with an FDA approval).

[8] *DiMasi*, supra note 7, at 25–26.

effective. *See, e.g.*, *In re Brana*, 51 F.3d at 1568; *In re Sichert*, 566 F.2d 1154, 1160 (C.C.P.A. 1977); *In re Hartop*, 311 F.2d 249, 260 (C.C.P.A. 1962). For similar reasons, the Patent and Trademark Office does not require patent applicants to include human clinical evidence in their applications or to provide such evidence as a condition precedent to obtaining valid claims to methods of treatment. *See* M.P.E.P. ¶ 2107.03(I) (9th ed. rev. June 2020) (explaining that the applicant need not provide "actual evidence of success in treating humans" (citing *Nelson v. Bowler*, 626 F.2d 853, 857 (C.C.P.A. 1980))). In fact, the Office explicitly instructs patent examiners to "not impose on applicants the unnecessary burden of providing evidence from human clinical trials." *Id.* § 2107.03(IV) (citing, *inter alia*, *In re Isaacs*, 347 F.2d 889 (C.C.P.A 1963), and *In re Langer*, 503 F.2d 1380 (C.C.P.A. 1974)).

c. Those past practices make sense. Requiring clinical evidence that a therapeutic method described in a patent is safe and effective in humans as a condition precedent to filing a patent application or securing the grant of a patent would, as a practical matter, foreclose patenting such inventions.

First, most drug candidates (*i.e.*, more than 4 out of every 5 candidates) will never generate clinical evidence that results in FDA approval. Reading the written description requirement as requiring compliance with a test that causes the vast majority of the patents to fail is implausible at best.

Second, forcing pharmaceutical innovators to wait until successful clinical evidence is in hand before they file their patent applications will effectively prevent patenting of their innovations. That is because pharmaceutical innovators are required to publicly disclose details of their clinical investigations and results of their clinical trials before the FDA approves their

products.[9] But those same public disclosures can foreclose the grant of a patent to the pharmaceutical innovator, since the patent laws preclude the grant of patents on inventions that are the same as or obvious from information disclosed to the public. *See, e.g.*, 35 U.S.C. §§ 102(a), 103; *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). In other words, requiring pharmaceutical innovators to wait for clinical evidence could result in denial of their patent applications *in light of their own compelled public disclosures*.

c. The public also will be harmed by a disclosure standard that demands successful clinical trials to precede patent filing or to delay grants until such evidence exists. A central purpose of the patent system is to prompt *early* disclosure of scientific advances, thereby benefitting both patients and the scientific community at large.[10] A standard that requires pharmaceutical innovators to delay filing their patent applications until clinical evidence is in hand would run directly counter to that central objective of the patent system for *prompt* public disclosure of inventions, and would "deprive[] society of the benefits of public disclosure of the invention which it is the policy of the patent

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[9] Under the Food and Drug Administration Amendments Act, for example, pharmaceutical innovators must publish elaborate "clinical trial information" and "results" to ClinicalTrials.gov, a website run by the National Institutes of Health. 42 U.S.C. §§ 282(j)(2)(A), (j)(3)(c). The securities laws may require detailed disclosures, too. *Cf. Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 47 (2011) (finding "evidence of a biological link between [a] key ingredient and anosmia" to be material).

[10] Deferring patent grants until successful clinical evidence is in hand also will extend the period of exclusivity granted by patent, thereby delaying market entry of biosimilar and generic products. *See* 35 U.S.C. § 154(b) (providing that the term of a patent is to be extended to account for delays in the grant of the patent by the Patent and Trademark Office).

laws to encourage." *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 494 (1974) (Marshall, J., concurring). There is no basis in text, first principles, or sound policy for creating such artificial tension between patenting and early public disclosure of new and useful therapies.

d. Finally, the decision below could reduce incentives to create new therapies. As the past few years have shown, more incentives, not fewer, are warranted to encourage the rapid discovery and clinical development of therapies that address unmet medical needs, such as those caused by COVID-19. A particularly important area to incentivize is research to discover new therapeutic uses of known compounds—particularly those that have already been shown can be used safely in human patients, but have not been shown to be effective in treating the new disease. Recent experiences of *amici* validate this point—in response to the COVID-19 pandemic, they devoted tremendous time, money, and effort to screening many known drugs for efficacy against COVID-19, achieving remarkable success that has delivered important new and life-saving therapies for patients afflicted with COVID. Foreclosing patent grants absent successful clinical testing erodes the patent incentive that otherwise would encourage such companies to investigate new therapeutic uses of these older compounds. The decision below thus could diminish the patent system's incentive for such efforts, impeding—rather than promoting—"the Progress of Science and useful Arts." U.S. Const. art. I, § 8, cl. 8.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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