No. 2020-1933

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BIOGEN INTERNATIONAL GMBH, BIOGEN MA INC.,
Plaintiffs-Appellants,

v.

MYLAN PHARMACEUTICALS, INC.,
Defendant-Appellee.

On Appeal from the United States District Court for the Northern District of West Virginia in Case No. 1:17-cv-00116-IMK-JPM

BRIEF OF *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA) IN SUPPORT OF PANEL REHEARING AND REHEARING *EN BANC*

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CERTIFICATE OF INTEREST

I, Jeffrey P. Kushan, counsel for Pharmaceutical Research and Manufacturers of America, certify the following:

1. **Represented Entities.** Provide the full names of all entities represented by undersigned counsel in this case. Fed. Cir. R. 47.4(a)(1).

   Pharmaceutical Research and Manufacturers of America.

2. **Real Party in Interest.** Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. Fed. Cir. R. 47.4(a)(2).

   None.

3. **Parent Corporations and Stockholders.** Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. Fed. Cir. R. 47.4(a)(3).

   PhRMA has no parent corporation and no publicly held corporation owns 10% or more of its stock. However, its membership includes companies that have issued stock or debt securities to the public. A list of PhRMA's members is available at www.phrma.org/about#members. Appellant Biogen MA Inc. is a PhRMA member but has played no role in the preparation of this brief.

4. **Legal Representatives.** List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

   None.

5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5).

None.

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

Not Applicable.

January 13, 2022

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INTEREST OF THE *AMICUS 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 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

[1] No counsel for any party authored this brief in any part, and no party, counsel, or person other than amicus contributed money to fund the preparation and submission of this brief. *See* Fed. R. App. P. 29(a)(4)(E).

[2] PhRMA's members are listed at www.phrma.org/about#members (last visited January 13, 2022).

innovations when they make these investments and their product development decisions.

PhRMA members have a substantial interest in this case because the panel majority's decision, if left undisturbed, would cause irreconcilable conflicts in the law governing the disclosure necessary to support a claim to a new therapeutic method under 35 U.S.C. § 112. One arises from the panel majority's incorporation *into the written description standard* of a new requirement—human clinical evidence—in addition to the patent's literal description of the claimed therapeutic method. A second arises because the panel majority's requirement for clinical proof of effectiveness of therapeutic methods conflicts with this Court's long-settled standards governing the "practical utility" of a human therapeutic invention, under which such clinical evidence is not required. The panel majority's decision, at a minimum, introduces substantial confusion over the nature of disclosure required for patents claiming unquestionably inventive and useful therapeutic methods. For these reasons, PhRMA supports Biogen's petition for panel rehearing or rehearing *en banc*.

ARGUMENT

In its decision, the panel majority affirmed the district court's finding that a patent's disclosure of administering a specific compound ("dimethyl fumarate") ("DMF") in a specific amount ("from about 480 mg …") to treat a specific disease ("multiple sclerosis") ("MS") was insufficient to establish written description of a claim to a method of administering 480 mg of DMF to a human to treat MS. The district court, and then the panel majority, found that despite what the patent specification states, the inventors had not "'actually invented'" that method or established that a 480 mg dose of DMF "would be therapeutically effective for treating MS." (Op. 11 (citing Appx45, Appx31).)

But the test for written description has never required an inventor to actually make the invention before filing a patent application. And to the extent a question exists about whether a human therapeutic invention described in the specification "works," it is to be answered under the framework of the "practical utility" standard, which does not require clinical evidence, much less that such evidence be included in the patent disclosure. By conflating these distinct requirements of the

patent law, the panel majority's decision creates inconsistent disclosure obligations for human therapeutic method inventions and immense confusion over what information applicants must include in their patent applications to support claims to new and useful therapeutic methods. Rehearing should be granted.

I. The Panel Majority's Decision Imposes an Improper Disclosure Requirement Upon the Written Description Standard.

As the panel majority properly recognized, the written description requirement is satisfied if the specification conveys with reasonable certainty to those skilled in the art that the inventor was in possession of the claimed invention at the time of filing. (Op. 14.) "Possession" is demonstrated by describing the claimed invention, "with all of its limitations," through words, structures, figures, diagrams, formulas, and the like. (*Id.* (citing *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997)).) Despite articulating this well-settled law, the panel majority's decision then demanded far more than what was needed to describe the therapeutic method claimed here—clinical evidence that the claimed method worked. That cannot be justified under the law governing written description.

Importantly, this case involves a *species* claim—the claims require orally administering a *single* compound (*i.e.* DMF) at a *single* dosage (*i.e.*, 480 mg/day) to treat a *single* disease (*i.e.*, MS).[3] The panel majority recognized findings by the district court that show this method is described in the patent specification. First, it observed that "the specification may arguably provide adequate information to 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." (Op. 15.) It also quoted the specification's statements that neurodegenerative diseases such as MS can be treated by orally administering "a therapeutically effective amount" of DMF. (Op. 8.) And it recognized the specification 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." (*Id.* (citing '514 Patent col. 18 ll. 54–64 (emphases added).) Because the specification expressly discloses in words the claimed invention "with all of its

[3] This case does not implicate concerns raised in the context of functionally defined genus claims, such as whether the entire genus is sufficiently described in a patent disclosure. *See Ariad Pharms., Inc. v. Eli Lilly & Co*, 598 F.3d 1336, 1352–53 (Fed. Cir. 2010) (en banc).

limitations," there was no basis for the district court (or an appellate panel reviewing that court's decision) to decide that a person of ordinary skill would doubt that the inventors had possession of the invention as claimed.

The panel majority's observation that this is not a "blaze marks" case is both correct and irrelevant. (Op. 19–20.) That is because there is no real dispute that Biogen's disclosure did far more than provide "blaze marks" that could be followed by a skilled person to find the particular "tree" being claimed. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570 (Fed. Cir. 1996) (citing *In re Ruschig*, 379 F.2d 990, 994–95 (C.C.P.A 1967) (finding written description insufficient because "blaze marks" in specification did not "single out particular trees" being claimed)). Instead, it described administering a *specific* drug in a *specific* manner at a *specific* dose for the treatment of a *specific* disease, corresponding precisely to the method that was claimed. That easily satisfies the written description requirement of 35 U.S.C § 112 under this Court's precedent.[4]

[4] "Although the applicant does not have to describe exactly the subject matter claimed, the description must clearly allow persons of ordinary

II. The Panel Majority's Decision Conflicts with the Long-Settled Requirements for Practical Utility of Human Therapeutic Inventions.

The demands for disclosure imposed by the district court and the panel majority are also flatly inconsistent with the disclosure requirements for establishing the "practical utility" of a human therapeutic invention.[5] Indeed, neither of the reasons why the district court and panel majority found the written description deficient—that it did not contain information proving the applicant had "actually made" the claimed method or that it was effective in humans—would have rendered the patent's disclosure deficient under that standard.

Under this Court's long-established precedent, a patent applicant need not demonstrate that a claimed human therapy is safe or fully effective to demonstrate it has "practical utility." *See, e.g.*, *In re Sichert*,

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skill in the art to recognize that he or she invented what is claimed." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991) (quoting *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989)) (cleaned up).

[5] "The how to use prong of section 112 incorporates as a matter of law the requirement of 35 U.S.C. § 101 that the specification disclose as a matter of fact a practical utility for the invention." *In re Ziegler*, 992 F.2d 1197, 1201 (Fed. Cir. 1993) (citing *Cross v. Iizuka*, 753 F.2d 1040, 1042–44 (Fed. Cir. 1985)); *see also In re Brana*, 51 F.3d 1560, 1564 (Fed. Cir. 1995).

566 F.2d 1154 (C.C.P.A. 1977); *In re Hartop*, 311 F.2d 249 (C.C.P.A. 1962); *In re Anthony*, 414 F.2d 1383 (C.C.P.A. 1969); *In re Watson*, 517 F.2d 465 (C.C.P.A. 1975).[6] Instead, as this Court has consistently held:

> FDA approval … is not a prerequisite for finding a compound useful within the meaning of the patent laws …. Were we to require [clinical] testing in order to prove utility, 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.

In re Brana, 51 F.3d at 1568 (citing *Scott v. Finney*, 34 F.3d 1058, 1063 (Fed. Cir. 1994)).[7]

Consistent with this precedent, the Patent & Trademark Office (PTO) does not require a patent disclosure to include human clinical evidence to support claims to methods of treatment. Instead, it focuses the inquiry for "practical utility" and the associated "how to use" prong of enablement of therapeutic method claims on the scientific credibility of the practical utility identified for the method. *See* M.P.E.P.

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[6] C.C.P.A. precedent is binding on this Court. *South Corp. v. United States*, 690 F.2d 1368, 1370 (Fed. Cir. 1982).

[7] The panel majority makes no reference to *In re Brana* and its progeny, case law firmly establishing that human clinical data are not required in patent applications.

¶ 2107.03(I) (explaining that the applicant does not have to provide "actual evidence of success in treating humans" and "all that is required is a reasonable correlation between the activity and the asserted use") (citing *Nelson v. Bowler*, 626 F.2d 853 (C.C.P.A. 1980)). It also recognizes that data from "*in vitro* assays, or from testing in an animal model … almost invariably will be sufficient to establish" practical utility, *id.* at § 2107.03(III), and affirmatively instructs examiners to "not impose on applicants the unnecessary burden of providing evidence from human clinical trials," *id.* at § 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)).[8]

The dissent correctly criticizes the panel majority for proceeding "[s]omewhat circularly" by first acknowledging that clinical data are not required to satisfy written description but then finding the district court's decision correct because the '514 patent lacks clinical efficacy data. (Dissent 6–8.) More directly, the panel majority's conclusion that

[8] As these standards make evident, evidence establishing the practical utility of an invention does not have to be included in the patent disclosure—it can be supplied later, during examination. *See, e.g.*, *In re Citron*, 325 F.2d 248, 253 (C.C.P.A. 1963).

Biogen was required to include in its patent disclosure clinical evidence proving that administering 480 mg of DMF was "efficacious in the treatment of MS" in humans (Op. 17) cannot be reconciled with the law governing "practical utility," which is satisfied by nothing more than a scientifically credible explanation. Indeed, there was no dispute below that the claimed method of treating MS with 480 mg of DMF has practical utility: it was approved by the FDA, and Mylan sought its own FDA approval for the same method based on the clinical evidence generated originally by Biogen.

The panel majority (like the district court) also criticized the prophetic nature of the patent's disclosure of the DMF480 dose, stating that "[t]he written-description requirement limits patent protection only to individuals who perform the difficult work of producing a complete and final invention …." (Op. 18; *see also id.* at 16–17 (contrasting 480 mg dose with 720 mg dose that "was known to be effective as of the February 2007 priority date," crediting "critical" post-filing scientific insights).) But this Court's precedent consistently recognizes that a patent applicant is not required to include actual working examples of the invention to describe or enable a therapeutic invention. *See Ariad*,

598 F.3d at 1357 ("Prophetic examples are routinely used in the chemical arts, and they certainly can be sufficient to satisfy the written description requirement."); *see also Alcon Rsch. Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1189–90 (Fed. Cir. 2014) (patentee not required to provide "actual working examples" to enable claims); *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1310 (Fed. Cir. 2015) (same).

The panel majority's decision thus confuses the distinct purposes of the practical utility and written description requirements and imposes inconsistent standards for the information that must be included in the patent disclosure to support a claim to a human therapeutic method.

III. The Panel Majority's Decision May Diminish the Patent System's Incentives for Developing and Disclosing Innovative Methods of Treating Humans.

The panel majority's decision, if left undisturbed, would put innovators in a difficult position, interfering with the optimal functioning of patent law's incentive system. Under the rationale of the majority, patents claiming novel human therapies must be supported by data from successful human clinical trials, which means innovators would need to delay the filing of their patent applications until human

clinical trials are in hand. But such delays would likely doom the ability of these innovators to secure patents on their new and useful methods. That is because pharmaceutical innovators routinely make meaningful disclosures about new therapies in development long before clinical trials of those therapies are completed, and such disclosures would become prior art to these delayed patent filings.

There is no justification for creating this artificial tension between patenting and early public disclosures of therapeutic advances. Simply stated, early public disclosures of new therapies should not be discouraged, as they can benefit patients and the scientific community at large. Such disclosures also may be compelled by securities laws and FDA regulations. And a central purpose of the patent system is to prompt these early disclosures of scientific advances for the public benefit. The panel majority's demand that completed clinical investigations precede patent filings on new and useful therapies runs counter to all of these public policies.

Finally, the panel majority's new requirement, if left undisturbed, could diminish the patent incentive for innovators to conduct research and development of new methods of treatment using known and

otherwise unpatentable compounds. There has not been a more pronounced need in recent memory for incentives for the biopharmaceutical industry to discover new therapeutic uses for known drugs—over the past two years, PhRMA members have devoted tremendous time, money and effort into screening known drugs for efficacy against COVID-19. Leaving the panel majority's decision intact, could diminish the patent system's incentive for such efforts, which would impede rather than advance scientific progress and innovation as the patent laws intend.

CONCLUSION

Rehearing is warranted.

January 13, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Circuit Rule 35(g)(3). The brief contains 2,451 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Century Schoolbook font.

January 13, 2022

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