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 AMICUS CURIAE THE CHEMISTRY AND THE LAW DIVISION OF THE AMERICAN CHEMICAL SOCIETY IN SUPPORT OF PETITIONERS

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INTEREST OF THE AMICUS CURIAE

The Chemistry and the Law Division ("CHAL") comprises members of the American Chemical Society who profess an interest in and a professional practice that includes both chemistry and law. Most of the members of CHAL are attorneys, and a majority of the attorney members of CHAL are patent attorneys. CHAL's purpose is to advance the understanding and application of the interrelationship of the science of chemistry and the relevant legal statutory, regulatory and jurisprudential decisions. All funding for CHAL comes from membership dues and other allocations from the American Chemical Society in accordance with its Constitution and Bylaws.[1, 2]

The Executive Committee of CHAL, by majority vote, authorized the undersigned to file this *amicus curiae* brief. All parties to this matter have consented to the filing of this *amicus curiae* brief. This *amicus curiae* brief was authored in whole by the undersigned. No funds from the parties or their counsel or any other

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[1] The undersigned is the only author of this brief and is representing The Chemistry and the Law Division of the American Chemical Society. The author of this brief paid for the cost of preparing the brief. Both Petitioner and Respondent have consented to this filing.

[2] CHAL has no parent company or stock. However, members of CHAL may include those who are employed by publicly held companies. A list of members of CHAL is available at www.acs.org.

entity have been contributed to the author for the preparation or filing of this *amicus* brief.[3]

CHAL has no direct interest in the outcome of this appeal. Neither the undersigned author nor The Carver Law Firm, LLC has any direct interest in the outcome of this appeal. Nevertheless, this case addresses an issue of great importance to CHAL's members, who rely on a robust system of patent rights in their practice as patent attorneys. CHAL has over 2,000 members, and a significant number of those are patent attorneys who represent clients and/or their employers on pharmaceutical inventions. Clarity in establishing what is required under 35 U.S.C. § 112 and what "possession" of a claimed invention means is critically important to the members of CHAL who are members of the Patent Bar.[4]

This matter initially came before the United States District Court of the Northern District of West Virginia.[5] In a decision on an infringement claim by BIOGEN INTERNATIONAL GMBH, BIOGEN MA INC., ("BIOGEN") against MYLAN PHARMACEUTICALS INC. ("MYLAN"), the Court held that the claim for treating multiple sclerosis ("MS") in U.S. Patent No. 8,399,514, held by Biogen, was invalid because the '514 patent failed to comply with 35 U.S.C. § 112. The United States Court of Appeals for the Federal Circuit affirmed the decision, and the Motion for Rehearing was

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[3] This brief does not represent the American Chemical Society as a whole.

[4] This *amicus curiae* brief should not be considered the position of all individual members of CHAL or their employers.

[5] Civil Action No. 1:17CV116

denied. The dissent by Judge O'Malley on the appeal appears to be consistent with precedent, as does the dissent by Judge Lourie on the denial of the Motion for Rehearing.[6]

This decision is particularly important to CHAL and its members, as many members of CHAL are registered patent attorneys and patent agents. This decision, if it is allowed to stand, will cause confusion among patent practitioners and fundamentally change the statutory requirements under Section 112. Members of CHAL seek consistent requirements for drafting and defending patents in accordance with the patent laws, precedence, and guidance from the MANUAL OF PATENT EXAMINING PROCEDURE ("MPEP"). The accompanying brief is relevant to the issues raised in Petitioners' Petition for a Writ of Certiorari and will aid this Court in maintaining the long-standing understanding of what is required in the written description a patent application.

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[6] Joined by Chief Judge Moore and Judge Newman.

SUMMARY OF ARGUMENT

Biogen's patent claims methods of treating MS by orally administering a therapeutically effective amount of dimethyl fumarate ("DMF"), wherein the therapeutically effective amount is disclosed to be between about 480 mg per day ("DMF480") and about 720 mg per day. Ultimately, Biogen found the DMF480 was the most effective therapeutic dose. In defense of a claim of infringement, Mylan asserted this claim was invalid for failing to provide a written description of the invention in the specification. The district court held, and the court of appeals affirmed, that Biogen's disclosure in the specification did not show that it had possession of the claimed DMF480 dose. The Court reasoned that Biogen had not yet conducted its Phase III clinical trials at the time the application was filed, and that the "DMF480 dose is listed only once."[7] Thus, the Court found that Biogen did not have proof of the efficacy of the claimed dose.

The panel majority's decision departs from precedent and 35 U.S.C. § 112's plain text requiring only "a written description of the invention," and instead requires that the specification itself prove the described effect at the DMF480 dose. This holding is contrary to the plain language of the statute, and counter to long-standing precedent, creates confusion among practitioners, as it is contrary to the practice delineated in the MPEP for Section 112.

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[7] Civil Action No. 1:17CV116 at p. 1338.

ARGUMENT

I. THE PANEL MAJORITY'S DECISION APPLIES A HEIGHTENED WRITTEN DESCRIPTION REQUIREMENT

Section 112 requires that a patent's specification contain "a written description of the invention."[8] The panel majority's decision, if upheld, would require a heightened standard for patent prosecution that conflicts with the statute and precedent. To satisfy the requirement of Section 112 as currently understood, the specification must "allow one skilled in the art to visualize or recognize the identity" of the claimed subject matter.[9] However, a disclosure does not require proof that an invention works. "There is no requirement that the disclosure contain 'either examples or an actual reduction to practice.'"[10] The panel majority, in contradiction to this settled law, found the written description in the patent to be inadequate despite the specification's description of DMF480 (Appx 74 (18:58-62)).

To support its decision, the panel majority relied on *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (*en banc*). The majority's analysis fundamentally misapplies *Ariad*. The patent at issue in *Ariad* claimed a functional result without

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[8] 35 U.S.C. § 112.

[9] *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1190 (Fed. Cir. 2014) (quotation marks and alteration omitted).

[10] *Id.*

adequately describing what compounds would achieve that result. *Ariad* at 1355-1357. By contrast, Biogen's patent described and linked all elements of the claimed invention, including the "effective" DMF480 dose. The holding in *Ariad* that the description was insufficient because it did not identify the compounds being claimed is fundamentally different from the holding in the instant matter that Biogen's disclosure of the claimed invention was insufficient because Biogen had not completed its clinical trials. Judge O'Malley's dissent recognizes this misinterpretation of precedent.

Further, whether an invention works, or in the instant matter, whether the dosage had been demonstrated to be effective, is not the test for sufficiency of a description of an invention. The patent clearly expresses a range of effective dosages, including the dosage at issue in this appeal. As this Court has previously explained, "written description is about whether the skilled reader of the patent disclosure can recognize that what was claimed corresponds to what was described; it is not about whether the patentee has proven to the skilled reader that the invention works, or how to make it work." *Alcon* at 1191. Review by the United States Supreme Court on this issue is warranted to remove the confusion on Section 112 interpretations from this decision.

Further, practitioners rely on the United States Patent and Trademark Office as the authoritative interpreter of the Patent Law as set forth in the MPEP. At paragraph 2017.02, the MPEP states that "an applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. 101 and 35 U.S.C. 112." Further, under 37 C.F.R. § 1.17 of the MPEP we find the requirements

for the detailed description and specification of the invention to include,

> (a) The specification must include a written description of the invention or discovery and of the manner and process of making and using the same, and is required to be in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which the invention or discovery appertains, or with which it is most nearly connected, to make and use the same.
>
> (b) The specification must set forth the precise invention for which a patent is solicited, in such manner as to distinguish it from other inventions and from what is old. It must describe completely a specific embodiment of the process, machine, manufacture, composition of matter or improvement invented, and must explain the mode of operation or principle whenever applicable. The best mode contemplated by the inventor of carrying out his invention must be set forth.

The MPEP sets forth no requirement that the specification include proof of the invention, nor is there a requirement that the specific best mode be described more than once. The instant decision, if upheld, will be confusing to practitioners. Members of CHAL support granting this Petition for Writ of Certiorari.

CONCLUSION

For the reasons stated in the Petition for Writ of Certiorari and this amicus curiae brief, this Court should grant the Petition for Writ of Certiorari.

Respectfully submitted,

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