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,
No. 1:17-cv-00116-IMK-JPM, JUDGE IRENE M. KEELEY

BRIEF OF THE CHEMISTRY AND THE LAW DIVISION OF THE AMERICAN CHEMICAL SOCIETY AS *AMICUS CURIAE* IN SUPPORT OF REHEARING *EN BANC* AND REVERSAL

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January 13, 2022

CERTIFICATE OF INTEREST

Pursuant to Circuit Rule 47.4, counsel for *Amicus Curiae* Chemistry and The Law Division (CHAL) of the American Chemical Society (ACS) certifies the following:

1. The full name of every party or *amicus* represented by me in this case is:

   The Chemistry and The Law Division of the American Chemical Society.[1]

2. The name of the real party in interest represented by me is:

   N/A.

3. Parent corporations and publicly held companies that own 10% of the stock in the party:

   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.

4. The names of all law firms and the partners or associates that appeared for the party in the lower tribunal or are expected to appear for the party in this Court and who are not already listed on the docket for the current case are:

   None.

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal:

   None.

6. Organizational Victims and Bankruptcy Cases.

   None/Not Applicable

January 13, 2022

/s/ James C. Carver
James C. Carver

[1] This *amicus* is not being offered on behalf of the ACS as a whole.

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STATEMENT OF *AMICUS CURIAE*

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.

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

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.[2]

The dissent by Judge O'Malley appears to be consistent with precedent, but if the majority opinion is allowed to stand, confusion among patent attorneys will increase. Thus, this case is of great interest to the members of CHAL to assure the consistent application of the patent laws to patent applications. CHAL believes that the accompanying brief is relevant to the issues raised in Appellants' rehearing petition and will aid the Court in resolving that petition to avoid confusion among practitioners.

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

SUMMARY OF ARGUMENT

Biogen's patent claims methods of treating multiple sclerosis ("MS") by orally administering a therapeutically effective amount of dimethyl fumarate ("DMF"), wherein the therapeutically effective amount is about 480 mg/day ("DMF480"). The district court found that a Biogen scientist had conceived the claimed invention. However, on appeal, the panel majority nonetheless held that this disclosure did not show possession of the claimed DMF480 dose, noting that Biogen had not yet conducted its Phase III clinical trials, and the "DMF480 dose is listed only once."

The panel majority's decision departs from precedent and 35 U.S.C. § 112's plain text requiring "a written description of the invention," and instead requires that the specification itself prove the described effect, which would require that the written description requirement mandated actual reduction to practice of the invention.

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." 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. *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1190 (Fed. Cir. 2014) (quotation marks and alteration omitted). However, a disclosure does not require proof that an invention works, and "there is no requirement that the disclosure contain 'either examples or an actual reduction to practice.'" *Id*. The panel majority, in contradiction of this settled law, found the written description in the patent to be inadequate despite the specification's description of DMF480, Appx74(18:58-62), and the district court's express finding that the inventor had conceived the claimed invention before the earliest priority date.

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*). This analysis fundamentally misunderstands *Ariad*. The patent at issue in *Ariad* claimed a functional result without 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 that the description in *Ariad* 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 *en banc* Court on this issue is warranted to remove the confusion on Section 112 interpretations resulting from this decision.

CONCLUSION

This rehearing petition should be granted for the reasons given above.

Respectfully submitted,

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January 12, 2022

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rules of Appellate Procedure 29 and 32 and Federal Circuit Rule 35, I certify the following:

1. This brief complies with the type-volume limitations of Federal Circuit Rule 35(g) because it contains 940 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

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) because it has been prepared using Microsoft Word 2016 in 14-point Times New Roman font.

January 13, 2022

/s/ James C. Carver
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CERTIFICATE OF SERVICE

I hereby certify that on January 13, 2022, I electronically filed the foregoing brief with the Clerk of Court using the CM/ECF system, thereby serving it on all counsel of record via the CM/ECF system.

/s/ James C. Carver
James C. Carver
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