

Nos. 20-2073, 20-2142

**United States Court of Appeals
for the Federal Circuit**

INDIVIOR UK LIMITED,

Appellant,

v.

DR. REDDY'S LABORATORIES S.A.,
DR. REDDY'S LABORATORIES, INC.,

Cross-Appellants.

ON APPEAL FROM THE UNITED STATES PATENT AND TRADEMARK
OFFICE, PATENT TRIAL AND APPEAL BOARD, NO. IPR2019-00329,
ADMINISTRATIVE PATENT JUDGES MITCHELL, YOUNG, AND R. SMITH

**CORRECTED 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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February 14, 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

February 14, 2022

/s/ Justin J. Hasford

Justin J. Hasford

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

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STATEMENT OF AMICUS CURIAE

Pursuant to Federal Rule of Appellate Procedure 29(b) and Federal Circuit Rule 35(g), the Chemistry and The Law Division of the American Chemical Society (CHAL) submits, along with its unopposed motion for leave, this *amicus curiae* brief in support of the rehearing petition filed by Appellant Indivior UK Limited. All parties have indicated that they do not oppose the relief sought in CHAL's motion.

CHAL comprises members of the American Chemical Society who have an interest in and a professional practice that includes both chemistry and law.² 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 issues.

CHAL has no 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. Clarifying the precedential effect of decisions from this Court and its predecessor Court of Customs

² CHAL certifies that no party or party's counsel or person other than CHAL's members and counsel authored in whole or in part or contributed money that was intended to fund the preparation or submission of this brief.

and Patent Appeals, as well as what is required under 35 U.S.C. § 112 and what “possession” of a claimed invention means, is critically important to those who are members of CHAL and the Patent Bar.

The dissent by Judge Linn appears to be consistent with precedent. The majority opinion, however, seems to dismiss the written description standard established by this Court and its predecessor court in cases such as *In re Wertheim*, 541 F.2d 257 (C.C.P.A. 1976). If the majority opinion is allowed to stand, confusion among patent attorneys will increase, and it may cast doubt on the validity of claims prosecuted under *Wertheim*’s framework. The consistent application of the patent laws to patent applications is of great interest to CHAL. CHAL believes that the accompanying brief is relevant to the issues raised in Appellant’s rehearing petition and will aid the Court in resolving that petition to avoid confusion among practitioners.

SUMMARY OF ARGUMENT

Indivior's U.S. Patent No. 9,687,454 ("the '454 Patent") claims pharmaceutical films that adhere to a patient's mucosa without falling apart, allowing for the delivery of active ingredients. At issue is the written description support for the claimed amounts of polymer in the films. Claim 1 recites "about 40 wt % to about 60 wt %" polymer. Claim 7 recites "about 48.2 wt % to about 58.6 wt %" polymer. The '454 Patent claims priority to U.S. Patent Application No. 12/537,571 ("the '571 Application"), which describes films having "polymer in an amount of at least 25% by weight," films having 48.2 wt % polymer, and a film having 58.6 wt % polymer.

The Board concluded in its Final Written Decision that the polymer content ranges described in Claims 1 and 7 of the '454 Patent lacked written description support in the '571 Application, and Claims 1 and 7 were consequently found to be anticipated by the prior art. On appeal, a divided panel affirmed the Board's decision.

In doing so, the panel majority's decision departs from decades-old precedent for evaluating written description support for claimed numeric ranges, and instead applies an overly demanding standard for written description for ranges.

ARGUMENT

I. THE PANEL MAJORITY’S DECISION APPLIES A HEIGHTENED WRITTEN DESCRIPTION REQUIREMENT THAT CONTRADICTS ESTABLISHED PRECEDENT

Section 112 requires that a patent’s specification contain “a written description of the invention.” 35 U.S.C. § 112. The panel majority’s decision, if upheld, would require a heightened standard for patent prosecution that conflicts with this 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.*

In the case of numerical ranges, a closed range recited in the claims need not be recited verbatim in the written description. Instead, a broader described range will support a narrower claimed range unless the party challenging written description shows otherwise. *See In re Wertheim*, 541 F.2d at 264. In assessing written description support, “[r]igidity should yield to flexible, sensible interpretation” of the disclosure. *Nalpropion Pharm., Inc. v. Actavis Labs. FL, Inc.*, 934 F.3d 1344, 1351 (Fed. Cir. 2019), cert. denied sub nom. *Actavis Labs. FL, Inc.*

v. Nalpropion Pharm. LLC, 140 S. Ct. 2804 (2020). Under *Wertheim*, it was the patent challenger's burden to show that the broader described range does not support the narrower claimed ranges. See *In re Wertheim*, 541 F.2d at 264. Yet the panel majority, in contradiction of this settled law, improperly shifted the burden to Indivior and found the written description in the patent to be inadequate.

As the majority recognizes, the disclosure in paragraph 65 describes a closed range of "at least 25%" and, in the alternative, "at least 50%." Both claimed ranges are within this expressly disclosed preference. Thus, under *Wertheim*'s framework, there was written description support for the claimed range. The majority, however, seeks to hold Indivior to a higher standard, despite failing to cite any controlling authority for doing so. Moreover, the strict rule imposed by the majority is illogical because the disclosed ranges are no different than if they were restated as "25%-100%" and "50%-100%," respectively.

The majority also misreads the polymer percentage levels disclosed in Tables 1 and 5 of the '571 Application, which describe 48.2% and 58.6% aggregate polymer percentages. The majority contends that identifying the 48.2% and 58.6% values in the embodiments in Tables 1 and 5 requires "pluck[ing] out the polymer components," and "cobbling together numbers after the fact." Maj. Op. at 10:14–19. But the majority fails to properly consider that the Board determined the ordinary level of skill in the art to be an experienced person with a Master's or Ph.D.

in pharmaceutical sciences. Dissent at 4. A person possessing such a high level of skill would be fully capable of performing the straightforward mathematical calculation needed to arrive at the claimed polymer amounts. As *Wertheim* explains, a “lack of literal support” for a claimed range in a priority application “is not enough” to conclude that the claimed range is unsupported by the application. *In re Wertheim*, 541 F.2d at 265; *see also Nalpropion*, 934 F.3d at 1349-51 (concluding that a claimed range was supported by disclosure of specific embodiments within the range, even though the claimed range was not disclosed).

As this Court made expressly clear in the opening of its very first published opinion nearly 40 years ago, *Wertheim* is binding precedent. *South Corp. v. United States*, 690 F.2d 1368, 1369 (Fed. Cir. 1982) (“We hold that the holdings of our predecessor courts, the United States Court of Claims and the United States Court of Customs and Patent Appeals, announced by those courts before the close of business September 30, 1982, shall be binding as precedent in this court.”). Review by the *en banc* Court is warranted to remove the confusion relating to the precedential effect of *Wertheim* and Section 112 interpretations resulting from this decision.

CONCLUSION

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

Respectfully submitted,

February 14, 2022

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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 1293 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.

February 14, 2022

/s/ Justin J. Hasford

Justin J. Hasford
Counsel for Amicus Curiae

CERTIFICATE OF SERVICE

I hereby certify that on February 14, 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/ Justin J. Hasford

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