No. 22-671

IN THE

Supreme Court of the United States

NOVARTIS PHARMACEUTICALS CORPORATION,

Petitioner,

v.

HEC PHARM CO., LTD., HEC PHARM USA INC.,

Respondents.

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

BRIEF OF *AMICI CURIAE* INTELLECTUAL PROPERTY PROFESSORS IN SUPPORT OF PETITIONER

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INTEREST OF *AMICI CURIAE*[1]

Amici curiae are intellectual property law professors who have considerable experience with patent practice and patent doctrine. They have no personal interest in the outcome of this case. They submit this brief to apprise the Court of conflicts between the Federal Circuit's June 21, 2022 decision and Supreme Court and Federal Circuit precedent on the law of written description. *Amici* respectfully urge the Court to grant Novartis's petition to address those conflicts.

INTRODUCTION AND SUMMARY OF ARGUMENT

On January 3, 2022, the first Federal Circuit panel in this case affirmed the district court's judgment of patent validity over a written description challenge. The January 2022 decision adhered to Supreme Court and Federal Circuit written description precedent, eschewing the application of wooden rules—specifically, the need for *in haec verba* recitation of patent claim limitations in a patent specification—and emphasizing the fact-based nature of the written description inquiry. Pet. App. 39a, 48a. In accordance with that precedent, the decision affirmed the district court's finding, based on the unrebutted testimony of four experts, that the written description requirement had been met. *Id.* at 49a–52a.

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[1] Pursuant to Supreme Court Rule 37.6, counsel for *amici* represent that no counsel for a party authored the brief in whole or in part, and that none of the parties or their counsel, nor any other person or entity, made a monetary contribution intended to fund the preparation or submission of this brief. Pursuant to Supreme Court Rule 37.2, counsel for *amici* provided counsel of record for all parties with notice of *amici*'s intention to file this brief at least 10 days prior to the due date.

On June 21, 2022, the second Federal Circuit panel in this case reversed. That June 2022 decision ignored Supreme Court and Federal Circuit precedent to announce a new written description standard: a patent owner now must show that any claim limitation not recited *in haec verba* in the specification must be understood by a skilled artisan to be "always" or "necessarily" present. Pet. App. 8a. That rigid rule conflicts with the Supreme Court's and Federal Circuit's flexible approach to written description. It also upsets settled expectations and discourages incentives to invent by depriving patentees the ability to limit their claims to avoid the prior art.

In addition, the Federal Circuit's June 2022 decision engaged in appellate fact-finding in violation of Fed. R. Civ. P. 52(a)(6) and this Court's precedent. By failing to defer to the unrebutted fact-finding of the district court and four experts, the Federal Circuit added further unpredictability to the written description inquiry and undermined the independent authority of district courts to resolve questions of fact. The Federal Circuit should not be permitted to engage in *de novo* fact-finding on written description contrary to the record below.

ARGUMENT

I. The New Written Description Standard Conflicts with Supreme Court and Federal Circuit Precedent

While the June 2022 decision purports to create no new written description standard, that is incorrect. The June 2022 decision states that written description exists only if there is express support or if "a particular limitation would ***always*** be understood by skilled artisans as being ***necessarily***" present. Pet. App. 8a

(emphasis added). The decision explains that, "[w]hen the specification is itself silent regarding a negative limitation, testimony from a skilled artisan as to possibilities or probabilities that the recited element would be excluded would not suffice, lest such testimony could effectively eliminate the written description requirement." *Id.* That rule forecloses reliance on testimony about how a person having ordinary skill in the art ("PHOSITA") would understand not only the text and structure, but also the technological context, of the specification. And although a negative claim limitation here is at issue, the decision suggests that the new "always/necessarily" standard should apply equally to positive and negative limitations. Pet. App. 14a (emphasizing that the same standard applies "for positive limitations" as "for negative limitations").

The new "always/necessarily" standard for written description is contrary to Supreme Court and Federal Circuit precedent.

As a procedural matter, the new written description standard erroneously places the burden of proving validity upon the owner of an issued patent. The June 2022 decision states that "[i]f . . . ***a patent owner*** could establish that a particular limitation would always be understood by skilled artisans as being necessarily excluded from a particular claimed method or apparatus if that limitation is not mentioned, the written description requirement would be satisfied despite the specification's silence." Pet. App. 8a (emphasis added). That articulation of the written description standard is at odds with Supreme Court and Federal Circuit precedent holding that the burden of proving the invalidity of an issued patent rests with the patent challenger, not with the patent owner. *Microsoft Corp. v. I4I Ltd. Partnership*, 564 U.S. 91,

100 (2011); *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1329 (Fed. Cir. 2008).

As a substantive matter, the new written description standard conflicts with the flexible approach to written description advocated by this Court and by the *en banc* Federal Circuit. In *Smith v. Snow*, 294 U.S. 1, 11 (1935), the Court asserted that the statutory written description standard did not require the recitation in a specification of "all possible forms in which the claimed principle may be reduced to practice." In *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351–52 (Fed. Cir. 2010) (*en banc*), the *en banc* Federal Circuit affirmed that written description does not require any "particular form of disclosure." And on the specific issue of negative claim limitations, the Federal Circuit in *Inphi Corp. v. Netlist, Inc.*, 805 F.3d 1350, 1356 (Fed. Cir. 2015) clarified that there is no "reason to [] articulate a new and heightened standard for negative claim limitations."

Decisions like *Smith, Ariad* and *Inphi* establish that a patent specification's written description must be evaluated in its proper technological context, without wooden rules. To be clear, although the Federal Circuit has held that written description can ***also*** be shown based upon inherent disclosure, in which a claim limitation not expressly disclosed in the specification would be understood by the PHOSITA to be necessarily present, *e.g.*, *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159 (Fed. Cir. 1998), the Federal Circuit until now has never suggested that, absent an express disclosure, the written description requirement can ***only*** be met through inherent disclosure, wherein the specification "always" or "necessarily" includes a positive limitation or excludes a negative one.

An apt illustration of the Federal Circuit's flexible approach to written description is provided by *Pozen Inc. v. Par Pharm., Inc.*, 696 F.3d 1151 (Fed. Cir. 2012). There, patent claims to a drug's packaging and container were challenged for lack of written description because those ideas were nowhere in the specification. *Id.* at 1166. The district court nevertheless found that a PHOSITA "would know that medications are not simply handed out to patients. Rather, pharmaceutical products, like the claimed tablets, are routinely administered in containers or packages." *Pozen Inc. v. Par Pharm., Inc.*, 800 F. Supp. 2d 789, 821–22 (E.D. Tex. 2011). The Federal Circuit affirmed for lack of clear error. 696 F.3d at 1167.

The same flexible approach adopted by the Federal Circuit in *Pozen* should have yielded the same result here. But it did not. Instead, the June 2022 decision applied the sort of rigid rule the Supreme Court has repeatedly admonished against in patent law. *E.g.*, *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 407, 419, 428 (2007) (rejecting rigid Federal Circuit requirements for obviousness inquiry under 35 U.S.C. § 103); *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 553 (2014) (reversing "unduly rigid" Federal Circuit fee-shifting rule under 35 U.S.C. § 285); *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 579 U.S. 93, 104 (2016) (rejecting "unduly rigid" Federal Circuit test for enhanced damages under 35 U.S.C. § 284). In so doing, the June 2022 decision jeopardizes the validity of thousands of issued patent claims and upsets settled expectations over how the written description requirement should apply to future claims.

II. The New Written Description Standard Deprives Patentees of the Ability to Limit Claims to Avoid the Prior Art

In addition to the June 2022 decision's broader implications, its new "always/necessarily" written description standard will deprive patentees of the ability to limit claims to avoid the prior art through negative limitations. Doing so will have widely felt adverse policy consequences.

Negative claim limitations often are introduced during patent prosecution for the purpose of narrowing claims to avoid prior art. Negative limitations readily understood by PHOSITAs thus are an important tool in ensuring that claims are of appropriate scope. If allowed to stand, however, the new "always/necessarily" written description standard will in many situations deprive patent applicants of that option.

Consider the situation described by the Federal Circuit's predecessor court, the Court of Customs and Patent Appeals: a patent applicant discovers, while prosecuting its patent application at the United States Patent and Trademark Office, that the prior art covers part of its invention as originally claimed and described. *In re Wertheim*, 541 F.2d 257, 263 (C.C.P.A. 1976). The applicant in that circumstance should be able to narrow its original claims with a negative limitation to carve out that aspect of the invention. Doing so would serve the public interest by allowing the applicant to limit its patent claims to a scope commensurate with the invention, without impairing the rights of others to practice subject matter covered by the prior art. Indeed, prior decisions have encouraged patentees to include negative limitations in their claims—even if not specified in their written descriptions—so long as a PHOSITA reasonably would

understand that the patentee possessed the narrowed invention. *E.g.*, *Union Oil Co. of Cal. v. Atl. Richfield Co.*, 208 F.3d 989, 1000 (Fed. Cir. 2000); *In re Johnson*, 558 F.2d 1008, 1018–19 (C.C.P.A. 1977).

As the Federal Circuit's predecessor court observed in *Wertheim*:

> That what appellants claim as patentable to them is less than what they describe as their invention is not conclusive if their specification also reasonably describes that which they do claim . . . "To rule otherwise would let form triumph over substance, substantially eliminating the right of an applicant to retreat to an otherwise patentable species merely because he erroneously thought he was first with the genus when he filed."

541 F.2d at 263 (quoting *In re Saunders*, 444 F.2d 599, 607 (C.C.P.A. 1971)).

Under the new "always/necessarily" standard, by contrast, patent claims amended during prosecution to include negative limitations would often be invalid for lack of written description. Indeed, it is difficult to imagine a scenario in which the amended claims, coupled with the original specification, will satisfy the new standard. After all, if the original specification were drafted to support the original claims—which did not include the negative limitation—then the original specification is unlikely to have "necessarily" excluded that limitation.

In depriving patent applicants of the option to rely on negative limitations, the new standard imperils meaningful patent protection for all inventions. This burden, however, likely will fall heaviest upon pharmaceutical and biotechnology inventions, which often

are capable of addressing an array of diseases through the same mechanism of action. John Carroll, *One Drug, Many Uses*, 2 Biotechnol. Healthc. 56, 58–61 (2005). For example, fingolimod—the drug at issue in this case—not only can be used to treat relapsing remitting multiple sclerosis ("RRMS"), but also has utility in treating transplant rejection, viral myocarditis, and autoimmune disorders other than RRMS. U.S. Patent No. 8,324,283 at col. 12, ll. 19–37. To meet the new "always/necessarily" standard any time treatment-related prior art is cited during prosecution, specifications for drug patents would have to include every detail of every treatment protocol for every disease for which the drugs have been found useful, even if those details were already well-known in the art. Such a standard would be prohibitive and would endanger a significant percentage of drug patents.

Likewise, pharmaceutical and biotechnology patent applicants often must file broad genus claims at the start of each drug development cycle to cover all potential drug candidates that may later enter clinical trials. D. Karshtedt *et al.*, *The Death of the Genus Claim*, 35 Harv. J.L. & Tech. 1, 63–65 (2021). The law should not limit the ability of these applicants to pare back the scope of their original genus claims, including through the use of negative limitations, in order to avoid the prior art and to align patent scope with the subset of drug candidates ultimately selected for development.

The new standard thus would undermine the value of pharmaceutical and biotechnology patents and in turn undermine incentives to develop innovative new medicines. Patents are pivotal to protecting the multi-year and multi-billion dollar investments necessary to develop new products. *E.g.*¸ J.A. DiMasi *et al.*,

Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, 47 J. Health Econ. 20, 24–25, 31 (2016) (estimating costs exceeding $1.395 billion for development of a pharmaceutical, and a synthesis-to-market approval timeline totaling more than 10 years); Jorge Mestre-Ferrandiz *et al.*, *The R&D Cost of a New Medicine*, Off. Health Econ. (2012), (https://www.ohe.org/wp-content/uploads/2014/07/380-RD-Cost-NME-Mestre-Ferrandiz-2012.pdf) (similar). Absent the prospect of obtaining appropriate patent protection, most pharmaceutical and biotechnology companies would not be able to bear the time and cost associated with developing new medicines.

III. The Second Federal Circuit Panel Engaged in Improper Fact-Finding

Fed. R. Civ. P. 52(a)(6) states that a court of appeals "must not . . . set aside" a district court's "[f]indings of fact" unless they are "clearly erroneous." In *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318 (2015), this Court characterized that rule as a "clear command," *id.* at 318, and criticized the Federal Circuit there for engaging in improper appellate fact-finding to overturn the district court's conclusion that a patent was valid based upon the testimony of the patentee's expert. *Id.* at 335–36.

This case presents an even more egregious case than *Teva* of improper appellate fact-finding. Here, the June 2022 decision by the second Federal Circuit panel overturned both the district court's finding of patent validity and the January 2022 affirmance by the first Federal Circuit panel of the district court's finding—all of which were consistent with fact findings by four prior judges (three Administrative Law Judges in a parallel *inter partes* review proceeding on the '405 patent-in-suit, and then-District Judge

Leonard P. Stark on a motion for a preliminary injunction). The second panel did so by treating the "plain text" of the specification as negating, as a matter of law, the unrebutted testimony of four experts. Pet. App. 9a. The sole decision the second panel cites to support its disregard of lower-court fact-finding is not about written description, but instead is about claim construction and *de novo* review. *Id.* at 9a–10a (citing *Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys.*, 132 F.3d 701, 706 (Fed. Cir. 1997)).

The second panel engaged in improper fact-finding, notwithstanding that the written description requirement is a pure issue of fact addressed from the perspective of the PHOSITA. *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1308 (Fed. Cir. 2015); *Ariad*, 598 F.3d at 1351. *See also Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005) (written description "varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence"). And the second panel did so with respect to a quintessentially factual question not amenable to "plain text" analysis: whether a PHOSITA, based upon the state of the art, reasonably would have understood the specification of the '405 patent-in-suit to have excluded administration of a "loading dose" of fingolimod to treat RRMS patients.

By failing to defer to the unrebutted fact-finding of four experts and the district court on that question, the June 2022 decision by the second Federal Circuit panel added a further layer of unpredictability to an already intractable written description requirement. Decisions like these create uncertainty over the value of existing patents and discourage incentives to seek future ones; fuel the perception of the Federal Circuit

as an overactive and unpredictable court;[2] diminish the importance of expert testimony in patent litigation; and undermine the independent authority of district courts to resolve questions of fact.

Last, the June 2022 decision contradicts the Federal Circuit's long-standing assurance that, to satisfy the written description requirement, a patent specification need not teach, and "preferably omits," that which is already known in the art. *E.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc*., 802 F.2d 1367, 1384 (Fed. Cir. 1986). The June 2022 decision ignores that written description—like enablement—requires consideration of the PHOSITA's knowledge of the art at the time the invention was made. *Ariad*, 598 F.3d at 1351; *Capon*, 418 F.3d at 1358. As the three Administrative Law Judges found in the above-mentioned parallel IPR proceeding, "the use of loading doses [according to both expert testimony and supporting evidence], 'are not today, and were not in June 2006, part of the accepted

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[2] *E.g*., Andrew Karpan, *Fed. Circ. Reverses Initial Panel To Find Gilenya IP Invalid*, LAW 360, June 21, 2022 (https://www.law360.com/articles/1504555?scroll=1&related=1) (describing how the second panel's "sudden about-face startled" patent practitioners); Kaitlin Farrell and Austin Keith, *Federal Circuit Rehearing Panel Vacates its January Decision and Reverses District Court Finding of Sufficient Written Description for Negative Claim Limitation*, J.D. SUPRA, July 6, 2022 (https://www.jdsupra.com/legalnews/federal-circuit-rehearing-panel-vacates-7497636) (describing how the panel decisions here "expose discord among Federal Circuit Judges" and create uncertainty); Luke T. Shannon and Andrew M. Solomon, *Silence is Not Golden - Federal Circuit Invalidates Method of Treatment Patent for Lack of Written Description*, THE NATIONAL LAW REVIEW, June 24, 2022 (https://www.natlawreview.com/article/silence-not-golden-federal-circuit-invalidates-method-treatment-patent-lack-written) (noting how the second panel decision can be used to create uncertainty).

MS or RR-MS treatment protocols.'" *Apotex Inc. v. Novartis AG*, IPR2017-00854, 2018 WL 3414289 (P.T.A.B. July 11, 2018), at *10. A PHOSITA therefore clearly would have known that a loading dose was not part of what was the standard regimen in the art, and thus not part of the '405 patent's claimed RRMS treatment method as of its 2006 invention date.

Contrary to the rigid approach of the June 2022 decision, the Federal Circuit previously has allowed patentees to rely on prior art to demonstrate that a PHOSITA would have understood that the inventor had invented what was claimed. *E.g.*, *Falkner v. Inglis*, 448 F.3d 1357, 1366–68 (Fed. Cir. 2006); *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1285–87 (Fed. Cir. 2012); *Union Oil Co. of Cal.*, 208 F.3d at 999–1001. And because avoidance of loading doses was known in the art, the exclusion of a loading dose could not have been a novel or "essential element" of the invention for which written description support was particularly important. *Cf. Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479–80 (Fed. Cir. 1998) (invalidating claims for lack of written description of "essential element"); *Capon*, 418 F.3d at 1358 (finding error in Board of Patent Appeals and Interferences' requirement that written description specify prior art element unrelated to novelty of claimed invention). The written description inquiry here thus did not warrant any contrary, "plain text" fact-finding by the second Federal Circuit panel.

CONCLUSION

The Court should reverse the Federal Circuit's June 2022 decision because it is contrary to Supreme Court and Federal Circuit precedent.

Respectfully submitted,

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APPENDIX

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APPENDIX

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