No. 21-1070

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

NOVARTIS PHARMACEUTICALS CORPORATION,

Plaintiff-Appellee,

v.

ACCORD HEALTHCARE INC., AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC., DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., EMCURE PHARMACEUTICALS, HERITAGE PHARMACEUTICALS INC., GLENMARK PHARMACEUTICALS INC., USA, GLENMARK PHARMACEUTICALS LIMITED, HETERO USA INC., HETERO LABS LIMITED UNIT-V, HETERO LABS LIMITED, MYLAN PHARMACEUTICALS, INC., PRINSTON PHARMACEUTICALS INC., STRIDES GLOBAL PHARMA PRIVATE LIMITED, STRIDES PHARMA, INC., TORRENT PHARMA INC., TORRENT PHARMACEUTICALS LTD., ZYDUS PHARMACEUTICALS (USA) INC., CADILA HEALTHCARE LIMITED, APOTEX INC., APOTEX CORP., SUN PHARMACEUTICAL INDUSTRIES LTD., SUN PHARMACEUTICAL INDUSTRIES INC., SUN PHARMA GLOBAL FZE,

Defendants,

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

Defendants-Appellants.

Appeal from the United States District Court for the District of Delaware,
Case No. 1:18-cv-01043-KAJ, Circuit Judge Kent A. Jordan

NOVARTIS PHARMACEUTICALS CORPORATION'S PETITION FOR PANEL AND EN BANC REHEARING

JULY 21, 2022 *Counsel listed on inside cover*

Deanne E. Maynard
Seth W. Lloyd
MORRISON & FOERSTER LLP
2100 L Street, NW, Suite 900
Washington, DC 20037
(202) 887-8740

William M. Jay
GOODWIN PROCTER LLP
1900 N Street, NW
Washington, DC 20036
(202) 346-4000

David Zimmer
Edwina B. Clarke
GOODWIN PROCTER LLP
100 Northern Avenue
Boston, MA 02210
(617) 570-1000

Jane M. Love, Ph.D.
Principal Attorney
Robert Trenchard
GIBSON, DUNN & CRUTCHER LLP
200 Park Avenue
New York, NY 10166
(212) 351-4000

Thomas G. Hungar
Jacob T. Spencer
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, NW
Washington, DC 20036
(202) 955-8500

Counsel for Novartis Pharmaceuticals Corporation

CERTIFICATE OF INTEREST

Counsel for Novartis Pharmaceuticals Corporation certify under Federal Circuit Rule 47.4 that the following information is accurate and complete to the best of their knowledge:

1. **Represented Entities.** Provide the full names of all entities represented by undersigned counsel in this case.

Novartis Pharmaceuticals Corporation

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.

Novartis AG

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.

Novartis AG

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.

Gibson, Dunn & Crutcher LLP: Christine L. Ranney, Laura Corbin, Kyanna Sabanoglu, Sung Bin Lee, Shyam Shanker, Jordan Bekier, Andrew Blythe

McCarter & English LLP: Daniel M. Silver, Alexandra M. Joyce, Benjamin A. Smyth

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.

Novartis Pharmaceuticals Corp. v. Handa Neuroscience, LLC et al., Case No. 1:21-cv-00645 (D. Del.); *Novartis Pharmaceuticals Corp. v. Handa Neuroscience, LLC et al.*, Case No. 1:22-cv-00352 (D. Del.)

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).

Not applicable

Dated: July 21, 2022 /s/ *Jane M. Love, Ph.D.*

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

RULES

OTHER AUTHORITIES

FEDERAL CIRCUIT RULE 35(b)(2) AND 40(a)(5) STATEMENT

Based on my professional judgment, I believe the panel decision is contrary to the following decisions of the Supreme Court of the United States and this Court: *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351-52 (Fed. Cir. 2010) (en banc); *Universal Restoration, Inc. v. United States*, 798 F.2d 1400, 1406 n.9 (Fed. Cir. 1986); *Inphi Corp. v. Netlist, Inc.*, 805 F.3d 1350, 1356-57 (Fed. Cir. 2015); *Nike, Inc. v. Adidas AG*, 812 F.3d 1326, 1347-48 (Fed. Cir. 2016); *All Dental Prodx, LLC v. Advantage Dental Prods.*, 309 F.3d 774, 779 (Fed. Cir. 2002); *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 324 (2015); *Anderson v. City of Bessemer City*, 470 U.S. 564, 572-76 (1985).

Based on my professional judgment, I believe this appeal requires answers to the following precedent-setting question of exceptional importance: Whether 35 U.S.C. §112 and this Court's precedent require that, to have adequate written description, a claim limitation must be either expressly disclosed in the specification or necessarily present in some express disclosure, even if a skilled artisan would otherwise read the specification to disclose possession of the limitation.

In addition, the Supreme Court and nearly every other circuit agree, and this Court observed in *Universal Restoration*, that panel rehearing is not to be granted except with the vote of at least one judge who concurred in the panel decision. The

panel appears to have overlooked this principle and misapprehended Circuit Rule 47.11 to authorize appointing a new judge to consider panel rehearing.

Dated: July 21, 2022 /s/ *Jane M. Love, Ph.D.*

INTRODUCTION

This case is extraordinary—both in the unprecedented way in which a change in panel membership overturned a precedential opinion on rehearing, and in the new opinion's rewriting of written-description law. This Court should grant rehearing to correct these procedural and substantive flaws.

The trial court made thorough factual findings detailing how Novartis's specification, as read by a skilled artisan, discloses possession of the relevant claim limitation. Its findings were consistent with those of four earlier factfinders who had addressed essentially the same question. Over a dissent, this Court affirmed in a precedential opinion, applying settled written-description law and concluding that the district court's findings were not clearly erroneous.

But after HEC sought rehearing, Judge O'Malley retired. Three months later, a new panel—with a new judge replacing Judge O'Malley—simultaneously granted rehearing and reversed the outcome. The dissent became a majority, the dissenter became the author, and the dissent's reasoning became new circuit precedent. Apparently for the first time in this Court, a precedential opinion has been abrogated—and the outcome flipped—on panel rehearing based merely on the replacement of one judge.

This Court has previously called it "troubling" when "simply changing the composition of a panel" (of a subordinate tribunal) reversed the outcome, and

emphasized that rehearing is for when a panel changes its mind, not its membership. *Universal Restoration, Inc. v. United States*, 798 F.2d 1400, 1406 n.9 (Fed. Cir. 1986) ("[A] member of the original majority must vote for the change."). Here no panel member changed position, and the new decision identifies no traditional basis for rehearing, such as something "overlooked or misapprehended." Panel rehearing should have been denied. Under the practice of the Supreme Court and nearly every other circuit, it would have been.

What's more, the new decision upends written-description law, in two critical ways. First, this Court has long held that Section 112 does not require any "particular form of disclosure," so long as the specification "reasonably conveys" possession of the invention—to a skilled artisan, not a layperson. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351-52 (Fed. Cir. 2010) (en banc). The original majority opinion followed that precedent and rejected the "new rule" advocated by the original dissent. Original.Op.18. The new majority opinion adopts that new rule and contradicts precedent: it holds "implied" disclosures insufficient as a matter of law *even if* they would "reasonably convey[]" possession of the invention to a skilled artisan. The new rule is that each limitation must be disclosed either explicitly or "inherently"—meaning that, as in the law of anticipation, each limitation must be "necessarily" present in some explicit disclosure.

Second, the new majority opinion marginalizes the skilled artisan's role in understanding the specification and the factfinder's role in determining that understanding, subject only to clear-error review. In its place is a rigid *per se* rule allowing appellate panels to do what the new majority did here: brush aside *unrebutted* expert testimony and multiple factual findings about how a skilled artisan would read the specification.

The Court should not allow this unprecedented procedure or this incorrect decision to stand. It should grant rehearing, vacate the grant of rehearing and the resulting decision, and reinstate the original opinion. Alternatively, it should rehear the case en banc.

BACKGROUND

A. The district court finds that the specification discloses the claimed limitation to a skilled artisan.

U.S. Patent No. 9,187,405 claims methods for treating relapsing-remitting multiple sclerosis ("RRMS") with a new, lower dose of fingolimod: "a daily dosage of 0.5 mg, absent an immediately preceding loading dose regimen." Appx24741-24742. A loading dose is a "higher-than-daily dose … usually given as the first dose." Appx27. The district court (Third Circuit Judge Jordan, sitting by designation) found, after a four-day bench trial, that the specification discloses possession to a skilled artisan. Appx21-22, Appx37-38. That conclusion accorded with decisions by then-Chief Judge Stark at the preliminary-injunction stage,

concluding that "[t]he properly defined POSA" would find "adequate written description," Appx18861-18862, and by the PTAB in a priority-date dispute.[1]

The specification describes how the inventors discovered the lower dose's efficacy through animal testing. Appx24740-24741; Appx23217. Citing HEC's own expert, the district court found that the animal example discloses, to skilled artisans, a "dosing regimen which does not involve a loading dose." Appx27 (citing Appx22793, Appx23209, Appx23345).

The specification also describes a prophetic clinical trial in which "20 patients with [RRMS] receive [fingolimod] at a daily dosage of 0.5, 1.25, or 2.5" mg; "[i]nitially patients receive treatment for 2 to 6 months." Appx24741(11:8-14). Novartis presented expert evidence that a skilled artisan would read this description to preclude a loading dose. Appx22791-22793 (Lublin); Appx23342-23345 (Steinman); Appx23442 (Jusko). That evidence went *unrebutted*; HEC's expert conceded on direct examination that he was unqualified to opine on this key specification passage. Appx23117.

Based on that evidence, the district court found that this example "tells a person of skill that on day 1, treatment begins with a daily dose of 0.5 mg, not a loading dose." Appx26 (citing Appx23343-23344). Because a "loading dose is necessarily a higher-than-daily dose[,]" "starting with a daily dose plainly implies

[1] *Apotex Inc. v. Novartis AG*, 2018 WL 3414289, at *19-20 (P.T.A.B. July 11, 2018).

that there is no loading dose." Appx27. And relying on testimony about known risks of increased fingolimod dosing, he found that skilled artisans "would not expect a loading dose to be used to treat RRMS with fingolimod." Appx27 (citing Appx23126-23127, Appx23129).

B. A panel of this Court affirms, over a dissent.

This Court affirmed in a precedential decision written by Judge O'Malley and joined by Judge Linn. The panel rejected HEC's attempt—endorsed by the dissent—to impose a "new rule that a limitation which is not expressly recited in the disclosure is never adequately described, regardless of how a skilled artisan would read that disclosure." Original.Op.18. It also refused to apply "heightened written description standards" only to "negative limitations," which this Court has "several times" declined to do. *Id*. The panel emphasized that the written-description "requirement is essentially a fact-based inquiry," turning on each case's particulars, because "it is how a skilled artisan reads a disclosure that matters." Original.Op.17-18.

The panel found ample evidence to support the district court's "quite carefully" conducted "'objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill.'" Original.Op.18-19. Detailing testimony from Novartis's experts, the majority saw no clear error in the findings that skilled artisans would have understood the patent's description of both the

animal study and human-clinical trial to exclude a loading dose. Original.Op.18-21. Chief Judge Moore dissented, arguing that the specification's "silence" about loading doses should have been dispositive. Moore Dissent 3-5.

C. A different panel grants rehearing and reverses, essentially adopting the prior dissent.

HEC petitioned for rehearing on February 23, after a three-week extension. On March 11, one week after Novartis filed an expedited response, Judge O'Malley retired. Three months later, a panel of Chief Judge Moore (originally in dissent), Judge Linn (originally in the majority), and Judge Hughes (not previously on the panel) granted HEC's petition, vacated the prior opinion, and entered a new precedential decision reversing the district court. The opinion identified no basis for granting rehearing—for example, a point of law or fact that the original panel "overlooked or misapprehended," Fed. R. App. P. 40(a)(2)—and never noted the change in panel membership.

The new decision was, in substance, the original dissent recast as a majority. The new majority held that disclosure generally must be express, not implicit, so that silence "may often be dispositive" of invalidity. New.Op.6 & n.2, 12. It allowed just one possible exception: if the "patent owner could establish" that the specification "inherently," or "necessarily," discloses a limitation, "written description could be satisfied." New.Op.6-7, 12. Despite the district court's factfinding that a skilled artisan would read the specification to teach daily dosing

without a loading dose, the majority rejected such evidence, New.Op.7, because the specification did not go further and "*necessarily exclude* a loading dose." New.Op.11. The new majority insisted it was not creating "a heightened standard for negative claim limitations"—*i.e.*, its requirement that each limitation be expressly disclosed or "necessarily be present in a disclosure" applies throughout written-description law. New.Op.12.

Judge Linn dissented, adhering to the original majority opinion's reasoning and criticizing the new majority decision's "heightened written description standard" of "necessary exclusion." Linn.Dissent.2-3.

REASONS TO GRANT REHEARING

I. The retirement of one judge after the panel decision should not have reversed the outcome.

Novartis has found no other case in which this Court granted panel rehearing and reversed the outcome after a change in panel composition. This case should not have been the first. Under principles followed by the Supreme Court and other circuits (on which the panel received no briefing), panel rehearing should not change the outcome unless a judge in the panel majority actually changes her mind. And this Court's rules do not authorize appointing a new judge at the rehearing-petition stage. The grant of panel rehearing and the new panel's decision should be vacated, by the full court if necessary.

This Court has previously noted the "troubling" and "serious questions" raised when a tribunal changes a result based solely on the retirement and replacement of one panel member after decision. *Universal Restoration*, 798 F.2d at 1406 n.9. This Court reversed that tribunal (a Board of Contract Appeals) on the merits, but took pains to note the settled principle that for a panel to reconsider an issued decision, "a member of the original majority must vote for the change." *Id.* "[S]imply changing the composition of a panel" is a different matter; no "*reconsideration*" occurs when "[a] different panel simply disagree[s] with the first decision." *Id.* If a retirement means the remaining members are divided about rehearing, "the decision stands on reconsideration." *Id.*

For that proposition, this Court cited (*id.*) the rules and centuries-old practice of the Supreme Court, which insists that "a Justice who concurred" must vote for rehearing. Sup. Ct. R. 44.1; *Brown v. Aspden's Adm'rs*, 55 U.S. (14 How.) 25, 26-27 (1853) ("[N]o reargument will be heard in any case after judgment is entered, unless some member of the court who concurred in the judgment afterwards doubts the correctness of his opinion"). New Justices who did not participate in a decision generally do not vote on rehearing, even if their vote would be "enough to change the decision" or create a majority. S. Shapiro et al., *Supreme Court Practice* 15-14 (11th ed. 2019); *see, e.g.*, *Hartigan v. Zbaraz*, 484 U.S. 171 (1987) (equally divided Court), *reh'g denied*, 484 U.S. 1082 (1988) (Justice Kennedy not participating);

Gundy v. United States, 139 S. Ct. 2116 (4-1-3 decision), *reh'g denied*, 140 S. Ct. 579 (2019) (Justice Kavanaugh not participating); *Brown*, 55 U.S. at 27-28.

The appellate rules confirm that mere disagreement with the decision is not a basis for seeking panel rehearing. That is why petitions for panel rehearing must identify some "point of law or fact" that the panel "overlooked or misapprehended." Fed. R. App. P. 40(a)(2). Adhering to that principle promotes the stability of the Court's precedent, avoids any suggestion of panel-dependent outcomes, and—consistent with this Court's guidance—discourages litigants from requesting a mere do-over on "issues previously presented that were not accepted by the merits panel." *Petitions for Rehearing and Rehearing En Banc*, https://cafc.uscourts.gov/home/case-information/case-filings/petitions-for-rehearing-rehearing-en-banc/. Indeed, before the Rules of Appellate Procedure were adopted, most circuits expressly required a change of mind by a participating judge. W.S. Simkins, *Federal Practice* 1015, 1268-69 (1923).[2]

And virtually every circuit abides by the same principle to this day: after a judge in the majority on a divided panel leaves the court, other circuits routinely deny panel rehearing without appointing a new judge. *E.g.*, *Williams v. Jones*, 583 F.3d 1254 (10th Cir. 2009) (Judge McConnell had resigned). Additional examples

[2] The exception was the Ninth Circuit, Simkins 1269-70, which continues to allow new judges to reverse panel decisions on rehearing, *Carver v. Lehman*, 558 F.3d 869, 878-79 (9th Cir. 2009), unlike the circuits discussed in the text.

from the D.C., Second, Fourth, Fifth, Sixth, Seventh, Eighth, and Eleventh Circuits appear in the supplemental addendum. Some expressly deny rehearing 1-1. *E.g.*, *Mexichem Fluor, Inc. v. EPA*, No. 15-1328 (D.C. Cir. Jan. 26, 2018); *Martin Cty. Coal Corp. v. Universal Underwriters Ins. Co.*, No. 11-5773 (6th Cir. Oct. 25, 2013); *Reeder-Simco GMC, Inc. v. Volvo GM Heavy Truck Corp.*, No. 02-2462 (8th Cir. Oct. 6, 2004) (Judge R. Arnold had died). Others deny rehearing without recorded dissent. *E.g.*, *United States v. Blaszczak*, No. 18-2811 (2d Cir. Apr. 10, 2020); *Feldman v. Pro Football, Inc.*, No. 09-1021 (4th Cir. Apr. 22, 2011); *United States v. Portillo-Munoz*, No. 11-10086 (5th Cir. Aug. 4, 2011); *Van Dyke v. Vill. of Alsip*, No. 20-1041 (7th Cir. Oct. 19, 2020); *Fluor Intercontinental Inc. v. IAP Worldwide Servs. Inc.*, No. 12-10793 (11th Cir. Nov. 18, 2013).[3]

Here, HEC identified nothing "overlooked or misapprehended." Like the new majority opinion, it merely repeated the substance of the original dissent, which the original decision had considered and rejected. And no judge on the original panel changed position. That should have disposed of HEC's petition.

Consistent with those principles, Circuit Rule 47.11 is not properly read to authorize appointing a new judge to consider panel rehearing petitions. The Rule governs a vacancy on a panel that has "heard oral argument [on] or taken under

[3] Similarly, the Third Circuit's practice in denying rehearing is to note that no "judge who concurred in the decision" sought rehearing. *E.g., United States v. Safehouse*, 991 F.3d 503, 505 (3d Cir. 2021).

submission an[] appeal, petition, or motion." Panel rehearing petitions are not argued, Fed. R. App. P. 40(a)(2), nor are they "taken under submission," *see* I.O.P. #1(2) ("'Submission' occurs immediately after hearing, or on the date a case is submitted on the briefs."). Rather, once a decision issues, "resubmission" occurs only *after* "a petition for rehearing is granted." Fed. R. App. P. 40(a)(4). As this Court recognized in *Universal Restoration*, if no panel member changes position, then "the decision stands on reconsideration," even if by an equally divided vote. 798 F.2d at 1406 n.9; *see* p. 10, *supra*. The outcome should be no different just because *one* judge from outside the panel disagrees with that decision. Once an opinion issues, disagreement by judges outside the panel is voiced through rehearing en banc—the prerogative of the full Court. *See* 28 U.S.C. §46(c) (a case is "heard and determined" by "a" panel, unless "hearing or rehearing before the court in banc is ordered").

Here, a panel's precedential decision was reversed not by the full Court, but because a single judge, not on the initial panel, disagreed with it after the author retired. If the original panel members stand by their votes, and if their decision did not warrant rehearing en banc, then that decision should not have been undone through panel rehearing. The panel, or if necessary the full Court, should vacate the grant of panel rehearing and thus reinstate the original decision.

II. The panel created a new, heightened standard for written description that eliminates both implicit disclosure and clear-error review.

The shifting majority also illustrates why this case warrants rehearing en banc. Two judges of this Court have already explained why the dissent's "new rule," later adopted by two different judges of this Court, conflicts with circuit precedent. Original.Op.13-18. If the new opinion is not vacated, the full Court should resolve the divide.

A. The new express-or-inherent rule conflicts with precedent.

The basic inquiry for written description has always been the same regardless of what is claimed: whether the "skilled reader of the patent disclosure can recognize that what was claimed corresponds to what was described" in the specification. *Alcon Rsch. Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1191-92 (Fed. Cir. 2014). In answering that question, this Court has long held (including en banc) that "the description requirement does not demand *any particular form* of disclosure or that the specification recite the claimed invention *in haec verba*." *Ariad*, 598 F.3d at 1352 (citation omitted; emphasis added). The specification need only "reasonably convey[] to those skilled in the art that the inventor had possession of the claimed subject matter," *id.* at 1351, "regardless of *how* it conveys such information." *E.g.*, *Inphi Corp. v. Netlist, Inc.*, 805 F.3d 1350, 1354 (Fed. Cir. 2015) (citation omitted); *In re Smith*, 481 F.2d 910, 914 (C.C.P.A. 1973). There are no bright-line rules.

The new majority's inflexible "heightened standard" conflicts with a substantial body of precedent. It makes written description turn not on what the specification "reasonably conveys to those skilled in the art," but on what the specification expressly or "necessarily" discloses. Linn.Dissent.3-7. And because the new majority expressly declined to limit its holding to negative claim limitations, New.Op.12, that holding could be applied to reverse *any* written-description finding.

This Court has repeatedly found disclosure of limitations not expressly mentioned in the specification, when the evidence shows that a skilled artisan would understand that the specification reasonably conveys possession. And that principle applies "regardless of *how* [the specification] conveys [the] information, and regardless of whether the disclosure's words [a]re open to different interpretation[s]," *Inphi*, 805 F.3d at 1354 (citation omitted; brackets in original)—which is irreconcilable with the new panel's heightened "necessarily excluded" rule.

"Implicit" disclosure, despite the new majority's skepticism, New.Op.6 n.2, is firmly grounded in longstanding precedent and explicitly adopted by the MPEP. *See Marconi Wireless Tel. Co. of Am. v. United States*, 320 U.S. 1, 34 (1943) (claims may permissibly "ma[k]e explicit what was already implicit" in specification); *In re Robins*, 429 F.2d 452, 456-57 (C.C.P.A. 1970) (where there is no explicit description of a genus, description of representative compounds "may provide *an implicit description* upon which to base generic claim language") (emphasis added);

MPEP §2163(II)(A)(3)(b) ("[E]ach claim limitation must be expressly, *implicitly*, or inherently supported in the originally filed disclosure.") (emphasis added). The point is the substance, not the label: written description turns on what the specification "reasonably conveys" to a skilled artisan, not what judges find express or inherent in the disclosure.

This Court has emphasized that what matters is "what the specification shows" to a skilled artisan, even if the disclosure is not "a model of clarity." *All Dental Prodx, LLC v. Advantage Dental Prods.*, 309 F.3d 774, 779 (Fed. Cir. 2002). Thus, this Court upheld claims with "no mention of" claimed elements "anywhere in the patent specification," because a skilled artisan "would recognize upon reading the specification" that the claimed invention was "described in the specification, albeit not *in haec verba*." *Id.*; *see Pandrol USA, LP v. Airboss Ry. Prods.*, 424 F.3d 1161, 1166 (Fed. Cir. 2005) (holding that "the specification provides adequate distinctions between clamping and adhering to show possession of [using 'adhering material' as] the 'sole means' [of connecting a plate to a railroad tie] of the claimed invention," without holding that the specification "necessarily exclude[s]" clamping or any other means of connecting the two). But here, the new majority held precisely the opposite—a supposed lack of "clarity" *did indeed* override what the specification showed to a skilled artisan.

Limiting the holding to negative claim limitations would not alleviate the intracircuit conflict. As both the original opinion (at 13-18) and new opinion (at 12) recited, negative claim limitations are held to the same "customary standard" for written description. *Nike, Inc. v. Adidas AG*, 812 F.3d 1326, 1347-48 (Fed. Cir. 2016), *overruled on other grounds by Aqua Prods. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017) (en banc); *Inphi*, 805 F.3d at 1356-57. Thus, in *Inphi*, this Court had no trouble finding possession of a negative claim limitation even without the "necessary exclusion" the new majority would require. It sufficed that "the specification properly distinguishe[d]" between the elements excluded and the element included. *Id.* at 1355, 1357. The Court specifically refused to require some higher form of clarity, such as "*disclaimer*." *Id.* at 1356.

If the '405 patent's specification had "describ[ed] alternative features" without expressing a preference, *id.* at 1355, such as by listing a loading dose as something a regimen might or might not include, that would have been sufficient to show possession of the no-loading-dose limitation under *Inphi*. Yet the actual specification discloses multiple dosage regimens, *none of which contemplates a loading dose*, and does so in a context that (the district court found) tells a skilled artisan that each regimen is given without a loading dose. That should provide *even stronger* written-description support for the no-loading-dose limitation. Yet under the new majority's heightened standard, that is legally insufficient to show

possession, because it does not "necessarily," "inherently," or "always" rule out using a loading dose. Indeed, the adoption of this sort of "judicial gloss" on Section 112, which does not expressly require possession at all, deserves reconsideration more broadly. *See* Pet. for Cert. 21-22, *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, No. 21-1566 (U.S. filed June 13, 2022).

B. The new majority's express-or-inherent rule wrongly overrides the skilled artisan and the factfinder.

As the original opinion pointed out (at 17) in rejecting the dissent's reasoning, the express-or-inherent standard wrongly "ignores that it is how a skilled artisan reads a disclosure that matters." The district court made detailed findings on exactly that point—yet the new majority applied its new standard to reject them.

The testimony establishes, and the district court found, that the specification is not "silent" to a skilled artisan, who would read it to disclose administering fingolimod without a loading dose. But the new majority concluded for itself that the specification is silent—and used that purported silence to justify disregarding any extrinsic evidence that would not meet its newly heightened standard. New.Op.7 (rejecting "testimony from a skilled artisan as to possibilities or probabilities" "[w]hen the specification is itself silent," because it "could effectively eliminate the written description requirement"). That ignores the clear-error standard for review of this factual question: what seems unambiguous to an appellate panel or layperson may be understood differently with the skilled artisan's

background knowledge, as it was here. Physicians read drug-dosing instructions with a context unavailable to a layperson or judge. That is why the Supreme Court has reminded this Court to "constantly have in mind that [its] function is not to decide factual issues *de novo*." *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 324 (2015) (quoting *Anderson v. Bessemer City*, 470 U.S. 564, 573 (1985)).

The new majority's insistence that the specification is silent as a matter of law led it to dismiss the unrebutted "expert testimony that the specification discloses the absence of a loading dose." New.Op.10-11; Appx23344-23345 (Steinman); *see* Appx23117 (HEC expert declining to testify about key paragraph on ground that he lacks relevant "expert[ise]"). That approach transforms an intensely factual question—what the specification "reasonably conveys" to skilled artisans, *Ariad*, 598 F.3d at 1351-52—into a predominantly legal one—whether the specification "necessarily" discloses the limitation to a judge's standard of clarity. And the majority wrongly placed the burden on the "patent owner" to show such a necessary disclosure. New.Op.7. That is contrary to decades of written-description precedent.

CONCLUSION

This Court should grant rehearing.

Dated: July 21, 2022

Respectfully submitted,

/s/ Jane M. Love, Ph.D.

Jane M. Love, Ph.D.
Principal Attorney
Robert Trenchard
GIBSON, DUNN & CRUTCHER LLP
200 Park Avenue
New York, NY 10166
(212) 351-4000

Thomas G. Hungar
Jacob T. Spencer
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, NW
Washington, DC 20036
(202) 955-8500

Deanne E. Maynard
Seth W. Lloyd
MORRISON & FOERSTER LLP
2100 L Street, NW, Suite 900
Washington, DC 20037
(202) 887-8740

William M. Jay
GOODWIN PROCTER LLP
1900 N Street, NW
Washington, DC 20036
(202) 346-4000

David Zimmer
Edwina B. Clarke
GOODWIN PROCTER LLP
100 Northern Avenue
Boston, MA 02210
(617) 570-1000

Counsel for Novartis Pharmaceuticals Corporation

ADDENDUM

United States Court of Appeals for the Federal Circuit

NOVARTIS PHARMACEUTICALS CORPORATION,
Plaintiff-Appellee

v.

ACCORD HEALTHCARE, INC., AUROBINDO PHARMA LTD., AUROBINDO PHARMA USA, INC., DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., EMCURE PHARMACEUTICALS LTD., HERITAGE PHARMACEUTICALS INC., GLENMARK PHARMACEUTICALS INC., USA, GLENMARK PHARMACEUTICALS LIMITED, HETERO USA, INC., HETERO LABS LIMITED UNIT-V, HETERO LABS LIMITED, MYLAN PHARMACEUTICALS, INC., PRINSTON PHARMACEUTICAL INC., STRIDES GLOBAL PHARMA PRIVATE LIMITED, STRIDES PHARMA, INC., TORRENT PHARMA INC., TORRENT PHARMACEUTICALS LTD., ZYDUS PHARMACEUTICALS (USA) INC., CADILA HEALTHCARE LTD., APOTEX INC., APOTEX CORP., SUN PHARMACEUTICAL INDUSTRIES, LTD., SUN PHARMACEUTICAL INDUSTRIES INC., SUN PHARMA GLOBAL FZE,
Defendants

HEC PHARM CO., LTD., HEC PHARM USA INC.,
Defendants-Appellants

2021-1070

Appeal from the United States District Court for the District of Delaware in No. 1:18-cv-01043-KAJ, Circuit Judge Kent A. Jordan.

Decided: June 21, 2022

JANE M. LOVE, Gibson, Dunn & Crutcher LLP, New York, NY, argued for plaintiff-appellee. Also represented by PAUL E. TORCHIA, ROBERT TRENCHARD.

PAUL SKIERMONT, Skiermont Derby LLP, Dallas, TX, argued for defendants-appellants. Also represented by SARAH ELIZABETH SPIRES; MIEKE K. MALMBERG, Los Angeles, CA.

Before MOORE, *Chief Judge*, LINN and HUGHES, *Circuit Judges*.

Opinion for the court filed by *Chief Judge* MOORE.

Dissenting opinion filed by *Circuit Judge* LINN.

MOORE, *Chief Judge*.

HEC Pharm Co., Ltd. and HEC Pharm USA Inc. (collectively, HEC) petition for rehearing of our prior decision in this case, 21 F.4th 1362 (Fed. Cir. 2022), in which we affirmed a final judgment of the United States District Court for the District of Delaware. The district court determined that claims 1–6 of U.S. Patent No. 9,187,405 are not invalid and that HEC infringes them. Because the '405 patent fails to disclose the absence of a loading dose, the district court clearly erred in finding that the negative claim limitation "absent an immediately preceding loading dose" added during prosecution to overcome prior art

satisfies the written description requirement of 35 U.S.C. § 112(a). We grant HEC's petition for panel rehearing, vacate our prior decision, and reverse the district court's judgment that Novartis' claims are not invalid for inadequate written description.

BACKGROUND

The '405 patent discloses methods of treating relapsing-remitting multiple sclerosis (RRMS) using the immunosuppressant fingolimod. *E.g.*, '405 patent at claim 1, 8:56–60. Each claim of the '405 patent requires administering fingolimod "at a daily dosage of 0.5 mg, absent an immediately preceding loading dose regimen." *Id.* at claim 1. A loading dose is a "higher-than-daily dose . . . usually given as the first dose." J.A. 27 ¶ 63 (internal quotation marks omitted). The patent's specification does not mention loading doses, much less the absence of a loading dose. Instead, it describes administering fingolimod at regular intervals (e.g., once daily, multiple times per day, or every other day). '405 patent at 11:20–38.

Novartis owns the '405 patent and markets a drug under the brand name Gilenya that purportedly practices the patent. HEC filed an abbreviated new drug application (ANDA) with the Food and Drug Administration seeking approval to market a generic version of Gilenya. Novartis sued HEC in the District of Delaware, alleging that HEC's ANDA infringes all claims of the '405 patent.[1]

After a four-day bench trial, the district court found that HEC's ANDA infringes and that the claims are not invalid, either as anticipated by Kappos 2006 or for inadequate written description of the no-loading-dose or daily-

[1] Novartis sued several other defendants who also filed ANDAs, but those cases were settled or stayed before trial.

dosage limitations. HEC appeals as to written description. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

"Whether a claim satisfies the written description requirement is a question of fact that, on appeal from a bench trial, we review for clear error." *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1308 (Fed. Cir. 2015) (quoting *Alcon Rsch. Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1190 (Fed. Cir. 2014)). Under the clear error standard, we defer to the district court's findings "in the absence of a definite and firm conviction that a mistake has been made." *Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365, 1374 (Fed. Cir. 2008) (cleaned up). Inadequate written description must be shown by clear and convincing evidence. *Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1351 (Fed. Cir. 2011) (citing *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1376 (Fed. Cir. 2009)).

A

To satisfy the written description requirement, a patent's specification must "reasonably convey[ ] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). Such possession must be "shown in the disclosure." *Id.* It is not enough that a claimed invention is "an obvious variant of that which is disclosed in the specification." *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). Disclosure is essential; it is "the *quid pro quo* of the right to exclude." *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 484 (1974); *see also Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 970 (Fed. Cir. 2002) ("[D]escription is the *quid pro quo* of the patent system.").

For negative claim limitations, like the no-loading-dose limitation at issue here, there is adequate written

description when, for example, "the specification describes a reason to exclude the relevant [element]." *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1351 (Fed. Cir. 2012); *Inphi Corp. v. Netlist, Inc.*, 805 F.3d 1350, 1355 (Fed. Cir. 2015) (same); *Nike, Inc. v. Adidas AG*, 812 F.3d 1326, 1348 (Fed. Cir. 2016) (same), *overruled on other grounds by Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1301 (Fed. Cir. 2017) (en banc). A reason to exclude an element could be found in "statements in the specification expressly listing the disadvantages of using" that element. *Santarus*, 694 F.3d at 1351. Another reason could be that the specification "distinguishes among" the element and alternatives to it. *Inphi*, 805 F.3d at 1357; *see also In re Johnson*, 558 F.2d 1008, 1017–19 (C.C.P.A. 1977) (reversing rejection for inadequate written description where specification disclosed several species of a genus and claims recited genus but excluded two species of lost interference count).

The common denominator of these examples is disclosure of the element. That makes sense because "the hallmark of written description is disclosure." *Ariad*, 598 F.3d at 1351; *see also Lockwood*, 107 F.3d at 1571 ("It is the disclosures of the applications that count."). Silence is generally not disclosure. *See Seabed Geosolutions (US) Inc. v. Magseis FF LLC*, 8 F.4th 1285, 1288 (Fed. Cir. 2021) ("[S]ilence does not support reading the claims to exclude gimbaled geophones." (citations omitted)); MPEP § 2173.05(i) (9th ed. Rev. 10.2019, June 2020) ("The mere absence of a positive recitation is not a basis for an exclusion."). If it were, then every later-added negative limitation would be supported so long as the patent makes no mention of it. While a negative limitation need not be recited in the specification *in haec verba*, there generally must be something in the specification that conveys to a skilled artisan that the inventor intended the exclusion, such as a discussion of disadvantages or alternatives. Consistent with our precedent in *Santarus*, *Inphi* and *Nike*, the

written description requirement cannot be met through simple disregard of the presence or absence of a limitation.

While a written description's silence about a negative claim limitation is a useful and important clue and may often be dispositive, it is possible that the written description requirement may be satisfied when a skilled artisan would understand the specification as inherently disclosing the negative limitation.[2] For example, if the record established that in a particular field, the absence of mention of a limitation necessarily excluded that limitation, written description could be satisfied despite the specification's silence. *See Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159 (Fed. Cir. 1998) ("[M]issing descriptive matter must necessarily be present in the . . . specification such that one skilled in the art would recognize such a disclosure." (citing *Cont'l Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991))); *see also In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) ("To establish inherency [for purposes of anticipation], . . . evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." (internal quotation

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[2] Novartis contends the written description requirement may be satisfied by "implicit disclosure" as distinct from express or inherent disclosure. Novartis Br. 50–51. Yet it fails to identify any case holding that "implicit disclosure" (whatever that means) is sufficient. Novartis cites *In re Kolstad*, a non-precedential decision involving *express* disclosure. 907 F.2d 157 (Fed. Cir. 1990) (non-precedential). If an implicit disclosure is one that would render the limitation obvious to a skilled artisan, such a disclosure cannot under our precedent satisfy the written description requirement. *Lockwood*, 107 F.3d at 1572 ("A description which renders obvious the invention for which an earlier filing date is sought is not sufficient.").

marks and citation omitted)). When 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. If silence were generally sufficient, all negative limitations would be supported by a silent specification. If, however, 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.

B

The district court found that because there is no recitation of a loading dose in the specification, the no-loading-dose limitation is supported. J.A. 26 ¶ 61. The district court further found that the no-loading-dose limitation is disclosed in the specification because "[t]he Prophetic Trial describes giving a 'daily dosage of 0.5 . . . mg' fingolimod to treat RRMS, started 'initially.' The Prophetic Trial tells a person of skill that on day 1, treatment begins with a daily dose of 0.5 mg, not a loading dose." J.A. 26 ¶ 62 (citations omitted). Novartis, likewise, argues that the specification satisfies the written description requirement for the no-loading-dose limitation because it indicates that the dosing regimen starts by "initially" administering a daily dosage. Novartis Br. 44.

The district court's finding that the specification discloses "initially" starting with a daily dose was clearly erroneous. The specification nowhere describes "initially" administering a daily dosage. The specification says, "Initially patients receive treatment for 2 to 6 months." '405 patent at 11:13–14. This sentence speaks to the initial length of treatment, not the dosage with which treatment

begins. Dr. Lublin, one of Novartis' physician experts, admitted this:

> Q. And then . . . there's a sentence that begins: Initially, patients receive treatment for two to six months. Do you see that?
>
> A. I do.
>
> Q. And what does that tell you about how the dosing would work?
>
> A. It suggests to me they're taking the dosing that's outlined in that first sentence *continually for two to six months*.

J.A. 22792 (emphasis added).

The contrary testimony of Novartis' second physician expert, Dr. Steinman, is inconsistent with the plain text of the specification and therefore carries no weight. J.A. 23343 (testifying that "initially" is "really zooming in on Day 1" and conveying that treatment starts with "a daily dose of 0.5"). "[E]xpert testimony that is inconsistent with unambiguous intrinsic evidence should be accorded no weight." *Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys.*, 132 F.3d 701, 706 (Fed. Cir. 1997) (citations omitted). As HEC argues in its rehearing petition, the district court's reliance on a misquotation "ferreted into trial testimony by Novartis' experts" was clearly erroneous. Pet. for Reh'g 6; *see* J.A. 26–27 ¶¶ 62–63 (district court relying on testimony that specification describes "initially" administering daily dosage).

The '405 specification discloses neither the presence nor absence of a loading dose. Loading doses—whether to be used or not—are simply not discussed. Novartis' experts readily admitted this. J.A. 23344 ("Q. Is there anywhere in [the specification] that you saw reference to the loading dose? A. No."); J.A. 22791 (Dr. Lublin testifying that "information of having a loading dose is not there"). Dr.

Lublin also agreed that "[n]othing in the text of the specification of the '405 patent discloses a rationale for the negative limitation prohibiting an immediately preceding loading dose." J.A. 22872–73. The fact that the specification is silent about loading doses does not support a later-added claim limitation that precludes loading doses.

The district court also found, independent of the misquoted "initially" language, that the specification's disclosure of a daily dosage combined with its silence regarding a loading dose would "tell a person of skill that loading doses are excluded from the invention." J.A. 26 ¶ 61. That, too, was clearly erroneous. Novartis does not defend this finding.[3] And for good reason.

There is significant tension in the district court's finding that the specification's disclosure excludes a loading dose, but that the Kappos 2006 abstract does not. Both are silent regarding loadings doses, and both disclose a daily dosage. The district court defended this inconsistency by claiming that "[u]nlike a patent, which is presumed complete, an abstract [like Kappos 2006] is not presumed to contain all of the necessary information about the study." J.A. 30 ¶ 74. This concept that a patent is presumed "complete" infected the district court's analysis and the experts' testimony regarding the no-loading-dose limitation. For example, Dr Lublin testified:

> Q. What would a person of skill reading the patent have thought about [the] question [of written description]?
>
> A. They would have viewed the patent as a document, as a complete document, that should give you

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[3] Nor could it. Novartis admittedly did not "argue below that inherency . . . applies to the '405 Patent's method claims." Novartis Br. 50. Any defense of the district court's finding is thus forfeit.

> all the information you need to carry out the claims, and that information of having a loading dose is not there, and what's instead there is examples of daily dose, daily dose, daily dose.

J.A. 22791. A patent is not presumed complete such that things not mentioned are necessarily excluded. We presume only that a patent has adequate written description, not that it is complete. *Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1195 (Fed. Cir. 1999) ("The presumption of validity includes a presumption that the patent complies with § 112." (citing *N. Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 941 (Fed. Cir. 1990))).

Importantly, the disclosure of a daily dosage cannot amount to a disclosure that there can be no loading dose, because such a finding is at odds with the prosecution history. The Patent Office allowed the claims only after the applicants added the no-loading-dose limitation. J.A. 23903 (examiner's rejection in parent application); J.A. 23892–93 (applicants' response); *see also* Novartis Br. 11–12. The applicants explained that they added the no-loading-dose limitation "to specify that the [daily dosage] cannot immediately follow a loading dose regimen" and "to further distinguish their claims from the disclosure of [prior art]." J.A. 23892. If reciting "daily dosage" without mentioning a loading dose necessarily excluded a loading dose, there would have been no reason for the applicants to add the no-loading-dose limitation. Neither the applicants nor the examiner understood the words "daily dosage" without the words "no loading dose" to convey the absence of a loading dose. Accordingly, the district court's contrary finding was clearly erroneous.

There is expert testimony that the specification discloses the absence of a loading dose. Dr. Steinman testified:

> Q. And do you see the sentence there, it says, "Initially patients receive treatment for 2 to 6 months." What would that tell a person of skill?
>
> A. Well, there were two places [in the specification] that if there were going to be an immediately preceding loading dose, you would give it before the initial treatment, so you would really necessarily want to put it right there. And the second place was earlier when you talked about a daily dosage of 0.5. But there were two gates that if you wanted to interject something about a loading dose, those were the opportunities in this. And it was zero out of two places where they, I think, necessarily would have put it in.

J.A. 23334–35. This expert testimony is focused on where in the specification the patentee would have mentioned a loading dose if they intended a loading dose to be included. But the question is not whether the patentee intended there to be a loading dose; the question is whether the patentee precluded the use of a loading dose. On this record, there is no evidence that a skilled artisan would understand silence regarding a loading dose to *necessarily exclude* a loading dose. In fact, all the experts agreed that loading doses are sometimes given to MS patients. *See* J.A. 22780 (Dr. Lublin explaining that loading doses have been used in trials of MS drugs and with fingolimod in particular); J.A. 22794; J.A. 23347–48 (Dr. Steinman acknowledging that loading doses are used in MS treatments); J.A. 23475 (Dr. Jusko, Novartis' pharmacology expert, testifying that fingolimod was given to transplant patients with a loading dose, and that he "could envision the possibility of starting with a loading dose"). And, importantly, there is intrinsic evidence that a skilled artisan would not understand reciting a daily dosage regimen without mentioning a loading dose to exclude a loading dose.

We do not today create a heightened standard for negative claim limitations. Just as disclosure is the "hallmark of written description" for positive limitations, *Ariad*, 598 F.3d at 1351, so too for negative limitations. That disclosure "need not rise to the level of disclaimer." *Santarus*, 694 F.3d at 1351. Nor must it use the same words as the claims. *Lockwood*, 107 F.3d at 1572 ("[T]he exact terms need not be used *in haec verba*." (citing *Eiselstein v. Frank*, 52 F.3d 1035, 1038 (Fed. Cir. 1995))). Rather, as with positive limitations, the disclosure must only "reasonably convey[ ] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad*, 598 F.3d at 1351. While silence will not generally suffice to support a negative claim limitation, there may be circumstances in which it can be established that a skilled artisan would understand a negative limitation to necessarily be present in a disclosure. This is not such a case.

CONCLUSION

The district court's finding that the no-loading-dose limitation meets the written description requirement was clearly erroneous. We grant HEC's petition for panel rehearing, vacate our prior decision, and reverse the district court's judgment that the claims of the '405 patent are not invalid. We need not reach HEC's argument that the district court also clearly erred in finding adequate written description for the "daily dosage of 0.5 mg" limitation.

REVERSED

COSTS

No costs.

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Appeal from the United States District Court for the District of Delaware in No. 1:18-cv-01043-KAJ, Circuit Judge Kent A. Jordan.

LINN, *Circuit Judge*, dissenting.

The majority, while recognizing that written description support is a fact-based inquiry based on the understandings of a person of ordinary skill in the art, and while ultimately recognizing that the standard for negative limitations is the same as for any other limitation, nonetheless applies a heightened written description standard to the facts of this case in requiring not only a "reason to exclude" but a showing that the negative limitation in question was "necessarily excluded." In doing so, the majority characterizes the district court's fact finding as clearly erroneous and concludes that written description support for the no-load limitation is lacking. In my opinion, the district court applied the correct standard and found ample support in the written description for the no-load limitation. For these reasons, I respectfully dissent.

I

A specification that "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date" has adequate written description of the claimed invention. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). "[T]he test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Id.* Our case law makes clear that "[c]ompliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed.'" *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 963 (Fed. Cir. 2002) (quoting *Vas-Cath Inc. v.*

Mahurkar, 935 F.2d 1555, 1562 (Fed. Cir. 1991)). It is well established that there is no "new and heightened standard for negative claim limitations." *Inphi Corp. v. Netlist, Inc.*, 805 F.3d 1350, 1356 (Fed. Cir. 2015). While the court in *Santarus, Inc. v. Par Pharmaceutical, Inc.* observed that "[n]egative claim limitations are adequately supported when the specification describes a reason to exclude the relevant limitation," we did not hold that a specification *must* describe a reason to exclude a negative limitation. 694 F.3d 1344, 1351 (Fed. Cir. 2012). A specification that describes a reason to exclude the relevant negative limitation is but one way in which the written description requirement may be met.

The majority begins its opinion with the recognition that a written description's silence about a negative claim limitation, while serving as a "useful and important clue," is not necessarily dispositive of whether that limitation is adequately supported. Maj. at 6. I agree. The majority concludes with a citation to *Ariad* for the proposition that "as with positive limitations, the disclosure must only 'reasonably convey [] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.'" Maj. at 12 (citing *Ariad*, 598 F.3d at 1351). With that, I also agree. But the majority in its analysis employs the heightened standard of "necessary exclusion" against which to assess the district court's fact findings in this case and uses that standard to conclude that the district court clearly erred. With that, I cannot agree. While a showing of "necessary exclusion" would most certainly provide written description support for a negative limitation, it is not and should not be a requirement in every case. As noted above and as *Ariad* makes clear, the critical question in assessing written description support for a negative limitation is the same as for any other limitation: "Does the written description reasonably convey to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date?" *See Ariad*, 598 F.3d

at 1351. How that question is resolved depends on the facts of each case, assessed through the eyes of the skilled artisan. Our precedent makes that clear.

For example, in *Santarus*, we found that claims directed to a method of treatment with a pharmaceutical composition containing no sucralfate were adequately described by a specification that explained that, although sucralfate is "possibly the ideal agent for stress ulcer prophylaxis," it was known to have occasional adverse effects. 694 F.3d 1344, 1350–51 (Fed. Cir. 2012). In *Santarus*, as in this case, there was expert testimony providing a person of ordinary skill's understanding of the patent specification. *See id.* at 1351. The expert testimony in *Santarus* showed that "a person of ordinary skill in this field . . . would have understood from the specification that disadvantages of sucralfate may be avoided by the [claimed] formulation." *Id.*

In *In re Bimeda Research & Development Ltd.*, we held that a claim that excluded a specific anti-infective, acriflavine, was not adequately described by a disclosure that was inconsistent with the exclusion of acriflavine but not other anti-infectives or antibiotics. 724 F.3d 1320, 1324 (Fed. Cir. 2013). The claim at issue in *Bimeda* was directed to a method of preventing mastitis in dairy cows by sealing the teat canal of a cow's mammary gland with a seal formulation that excludes acriflavine. Other claims in the same patent excluded all anti-infective agents. We noted that the patent repeatedly distinguished the invention as able to prevent mastitis without the use of antibiotics. Based on the written description's consistent description of the invention's non-antibiotic approach to preventing mastitis, we concluded that the patent's disclosure was "inconsistent with a claim which excludes acriflavine, but *not* the presence of other anti-infectives or antibiotics." *Id.* (citation and quotation marks omitted). We did not require that the specification describe a reason to exclude acriflavine specifically; rather, we found only that a negative limitation

which is inconsistent with the disclosure is not adequately described.

In *Inphi*, we confirmed that the written description requirement is satisfied where "'the essence of the original disclosure' conveys the necessary information—'regardless of *how* it' conveys such information, and regardless of whether the disclosure's 'words [a]re open to different interpretation[s].'" 805 F.3d at 1354 (quoting *In re Wright*, 866 F.2d 422, 424–25 (Fed. Cir. 1989) (citation and internal quotation marks omitted, emphasis in *Inphi*)). We explained that "*Santarus* simply reflects the fact that the specification need only satisfy the requirements of § 112, paragraph 1 as described in this court's existing jurisprudence." *Id.* at 1356. And we noted that the "'reason' required by *Santarus* is provided, for instance, by properly describing alternative features of the patented invention." *Id.* (citing *In re Johnson*, 558 F.2d 1008, 1019 (C.C.P.A. 1977)).

In *Inphi*, we found that substantial evidence supported the Patent Trial and Appeal Board's ("Board") finding that a negative limitation which had been added during prosecution ("DDR chip selects that are not CAS, RAS, or bank address signals") was adequately described by an original specification which did not expressly articulate a reason to exclude RAS and CAS signals. We found the Board's decision was supported by evidence of (1) standards set by the Joint Electron Device Engineering Council, a global standard-setting body for the microelectronics industry, incorporated by reference in the patent, which specify that DDR signals, including CAS, RAS, CAS, and bank address signals, are distinct from each other; (2) a table in the specification which excludes RAS and CAS signals; and (3) various passages from the specification, including a figure which distinguishes chip select signals, command signals (including RAS and CAS signals) and bank address signals. We concluded that the specification's disclosure of

alternative features was sufficient to satisfy the written description standard for the negative limitation. *Id.* at 1357.

In *Nike, Inc. v. Adidas AG*, we reiterated that *Santarus* did not create a heightened standard for written description of negative limitations. 812 F.3d 1326, 1348 (Fed. Cir. 2016), *overruled on other grounds by Aqua Prods., Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017) (en banc). We stated that negative limitations, like all other limitations, are held to "the customary standard for the written description requirement." *Id.* In *Nike*, we found a limitation of "flat knit edges," which Adidas characterized as a negative limitation, was adequately described by three figures in the specification depicting the claimed textile element which Nike's expert opined could be made using flat knitting in contrast to another figure's textile element which is formed using a circular knitting machine. *Id.* at 1348–49.

The central tenet of our written description jurisprudence—that the disclosure must be read from the perspective of a person of skill in the art—further recognizes that the disclosure need not describe a limitation *in haec verba*. *See, e.g.*, *All Dental Prods., LLC v. Advantage Dental Prod., Inc.*, 309 F.3d 774, 779 (Fed. Cir. 2002) (citing *Eiselstein v. Frank*, 52 F.3d 1035, 1039 (Fed. Cir. 1995) ("[T]he failure of the specification to specifically mention a limitation that later appears in the claims is not a fatal one when one skilled in the art would recognize upon reading the specification that the new language reflects what the specification shows has been invented."); *see also Ariad*, 598 F.3d at 1351.

The Manual of Patent Examining Procedure ("MPEP") similarly provides for written description in various forms. In addition to stating that the "mere absence of a positive recitation" is not enough, the MPEP also correctly states that no specific form of disclosure is required and provides

for implicit written description.[1] MPEP § 2173.05(i) states that "a lack of literal basis in the specification for a negative limitation may not be sufficient to establish a *prima facie* case for lack of descriptive support." And MPEP § 2163 states that "newly added claims or claim limitations must be supported in the specification through express, *implicit*, or inherent disclosure." MPEP § 2163 (emphasis added). What is critical is how a person of skill in the art would read the disclosure—not the exact words used.

In other words, context and the knowledge of those skilled in the art matter. And, as the Supreme Court has made clear, when assessing what the written description reveals to a skilled artisan, common sense also matters. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) (holding that, in an obviousness analysis, "[r]igid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it").

II

Here, the district court conducted "an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art" and found sufficient written description in the EAE model and the Prophetic Trial. J.A. 37 (citing *Ariad*, 598 F.3d at 1351). The district court found that the "Prophetic Trial describes giving a 'daily dosage of 0.5 . . . mg' fingolimod to treat RRMS, started 'initially.'" J.A. 26 ¶ 62 (quoting '405 patent col. 11 ll. 8–13). The court found, crediting expert testimony, that, "[i]f a loading dose were directed, the Patent would say that a loading dose should be administered 'initially.'" J.A. 26 ¶ 62 (citing J.A. 23334–35 (Tr.

[1] I cite the MPEP, not because the court is bound by it but because I find its reasoning informative and persuasive.

756:16–757:8); J.A. 23441–42 (Tr. 863:22–864:18)). The district court thus made the unremarkable, and factually supported, determination that "starting with a daily dose plainly implies that there is no loading dose." J.A. 27. Similarly, the district court found that the "EAE example discloses a dosing regimen which does not involve a loading dose." J.A. 27 ¶ 64 (citing J.A. 23345 (Tr. 767:3–5); J.A. 22793 (Tr. 215:16–21)). The district court held that the description in the specification of administration of a daily dose "would tell a person of skill that loading doses are excluded from the invention." J.A. 26 ¶ 61. The court also found that "[a] loading dose is necessarily a higher-than daily dose." J.A. 27 ¶ 63 (Tr. 766:4-766:6). Finally, the court found that, while the patent describes alternate dosing regimens, such as "intermittent dosing," it does not describe administering those regimens with loading doses. J.A. 27 ¶ 65. Thus, the district court concluded, "[t]he EAE model and the Prophetic Trial . . . indicate to a person of ordinary skill that the claimed invention did not include the administration of a loading dose." J.A. 37–38. The cited passages of the specification provide clear disclosure of a dosing regimen that is not dependent upon or subject to the administration of a loading dose.

The majority finds that the word "initially" "speaks to the initial length of treatment not the dosage with which treatment begins." Maj. at 7–8. Here, the district court found that the "Prophetic Trial describes giving a 'daily dosage of 0.5 . . . mg' fingolimod to treat RRMS, started 'initially.'" J.A. 26. While other interpretations of the word "initially" might be reasonable, the language, used in context, also supports the district court's finding that the written description discloses excluding a loading dose. We are not free to substitute our own factual findings for those of the district court absent clear error because "a district court judge who has presided over, and listened to, the entire proceeding has a comparatively greater opportunity to gain the necessary 'familiarity with specific scientific problems and principles,' . . . than an

appeals court judge who must read a written transcript or perhaps just those portions referenced by the parties." *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 319 (2015) (quoting *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 610 (1950)).

The majority asserts that the disclosure of a daily dosage cannot amount to a disclosure that there can be no loading dose, because such a finding is at odds with the prosecution history and the fact that the examiner allowed the claims only after the no-load limitation was added. Maj. at 10. According to the majority, if reciting a "daily dosage" necessarily excluded a loading dose, there would have been no reason to add the no-dose limitation. *Id.* at 10:19-22. But Novartis, in adding the no-load limitation was doing no more than what applicants regularly do to secure allowance in making explicit that which was implicit prior to the amendment. There is no basis to read more into the prosecution history and certainly no basis to negate the clear disclosure of a "daily dosage" and the expert testimony describing the understanding of that expression to skilled artisans.

The majority asserts that "the question is not whether the patentee intended there to be a loading dose; the question is whether the patentee precluded the use of a loading dose." Maj. at 11. I submit that the question posed by the majority is misstated. The question is not whether the patentee precluded the use of a loading dose but whether the claim language that precludes the administration of a loading dose is supported by the written description passages that disclose the effective administration of nothing more than a "daily dose." In context, that disclosure, according to the testimony of the Novartis's experts, implies the absence of a loading dose to the ordinarily skilled artisan. That is all that is required.

Finally, the majority finds significant tension between the district court's finding that the specification's

disclosure excludes a loading dose, but the Kappos 2006 abstract does not. Maj. at 9. I see no tension or legal inconsistency in the district court's treatment of the Kappos 2006 abstract. As the court explained, Kappos was an abstract with no presumption of enablement or completeness, and it in any event did not include the animal trials that form an important part of Novartis's arguments with respect to the '405 patent. As importantly, the district court also found no evidence that Kappos 2006 was publicly available before the priority date because there was no evidence of public access. J.A. 28.

For all these reasons, I respectfully dissent.

CERTIFICATE OF COMPLIANCE

I hereby certify that this petition complies with the type-volume limitation of Fed. Rs. App. P. 35(b)(2) and 40(b)(1) because it contains 3,863 words excluding the parts exempted by Fed. R. App. P. 32(f) and Fed. Cir. R. 32(b)(2).

This petition complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2019 in 14-point Times New Roman font.

Dated: July 21, 2022 /s/ *Jane M. Love, Ph.D.*