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

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

---

[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

---

[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.

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.

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.*

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 SUPPLEMENTAL ADDENDUM

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 J. 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

TABLE OF CONTENTS

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: January 3, 2021

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 O'MALLEY, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* O'MALLEY.

Dissenting opinion filed by *Chief Judge* MOORE

O'MALLEY, *Circuit Judge*.

HEC Pharm Co., Ltd. and HEC Pharm USA Inc. (collectively, "HEC") appeal from a district court bench trial in which the court found that a patent assigned to Novartis Pharmaceuticals Corp. ("Novartis"), U.S. Patent No. 9,187,405 ("the '405 patent"), is not invalid and that HEC's Abbreviated New Drug Application ("ANDA") infringes. HEC argues that the district court erred in finding that the '405 claims do not fail the written description requirement of 35 U.S.C. § 112(a). Because we do not discern any clear error in the district court's decision, we affirm.

I. BACKGROUND

Novartis markets a 0.5 mg daily dose of fingolimod hydrochloride under the brand name Gilenya. The medication is used to treat relapsing remitting multiple sclerosis ("RRMS"), a form of multiple sclerosis ("MS"). MS is a debilitating immune-mediated demyelinating disease in which the immune system attacks the myelin coating the nerves in the central nervous system. Most MS patients initially present as RRMS patients, but many eventually develop a secondary progressive form of MS, causing them to experience growing disability. There is currently no cure for MS. The disease is managed by reducing or preventing relapses and thereby slowing disability.

HEC filed an ANDA seeking approval to market a generic version of Gilenya. Novartis sued, alleging that HEC's ANDA infringes all claims of the '405 patent.[1]

A. The '405 Patent

The '405 patent claims methods to treat RRMS with fingolimod (also known as FTY720 and 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol in the '405 patent) or a fingolimod salt, such as fingolimod hydrochloride (also known as Compound A in the '405 patent), at a daily dosage of 0.5 mg without an immediately preceding loading dose. '405 patent col. 12 ll. 49–55.

A loading dose is a higher than daily dose "usually given 'as the first dose.'" J.A. 27 (¶ 63) (quoting J.A. 23125 (Tr. 547:12–18) and citing J.A. 23344 (Tr. 766:4–6)). Both parties' experts agreed with this definition. J.A. 23125 (547:12–18) (HEC's expert, Dr. Hoffman, testifying that "a

---

[1] Novartis sued several other defendants who had also filed ANDA applications. The cases as to those other defendants all settled or were stayed prior to trial, which proceeded only as to HEC.

loading dose is a higher-than-therapeutic level dose, usually given . . . as the first dose in order to get therapeutic levels up quickly . . . and it's usually for more acute situations"); J.A. 23344 (Tr. 766:4–6) (Novartis's expert, Dr. Steinman, agreeing that "a loading dose is a higher-than-daily dose"). It is undisputed that loading doses were well-known in the medical field generally and in the prior art. And the experts in this case agree that loading doses are used for some medicaments used in connection with MS.

The '405 patent has six claims. Claim 1 of the '405 patent recites:

> A method for reducing or preventing or alleviating relapses in Relapsing-Remitting multiple sclerosis in a subject in need thereof, comprising orally administering to said subject 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol, in free form or in a pharmaceutically acceptable salt form, at a daily dosage of 0.5 mg, absent an immediately preceding loading dose regimen.

Claims 3 and 5 are similar but are directed to a "method of treating" RRMS and a "method of slowing progression of" RRMS, respectively, rather than a "method for reducing or preventing or alleviating relapses in" RRMS. *Id.* col. 12 ll. 59–64, col. 13 ll. 1–6. Claims 2, 4, and 6 are dependent claims that limit the methods of claims 1, 3, and 5, respectively, to administration of 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol hydrochloride, i.e., fingolimod hydrochloride. *Id.* col. 12 ll. 56–58, col. 12 ll. 65–67, col. 13 ll. 7–9.

The '405 patent was filed on April 21, 2014. It claims priority to a British patent application that was filed on June 27, 2006. The parties, for the most part, focus their discussion on the specification of the '405 patent, despite HEC's argument that the inventors did not possess the invention *as of the 2006 priority date*. HEC's argument that the 2006 application does not contain adequate written

description of the '405 claims requires reference to the 2006 application itself. Thus, we find it necessary to look to the specification of the 2006 priority application, despite the parties' failure to fully explain the contents of that application. Although the specifications are different from each other, they are, in all aspects relevant to this appeal, substantively similar.

The specifications of the '405 patent and the 2006 priority application both describe the use of a class of S1P receptor modulators, including fingolimod, to treat or prevent "neo-angiogenesis associated with a demyelinating disease, e.g. multiple sclerosis." '405 patent col. 1 ll. 5–8; J.A. 23751. The specifications each identify fingolimod hydrochloride (Compound A) as a particularly preferred compound within the class of S1P receptor modulators. '405 patent col. 8 ll. 17–30; J.A. 23759–60.

Both specifications describe the results of an Experimental Autoimmune Encephalomyelitis ("EAE") experiment. '405 patent col. 10 ll. 32–col. 11 ll. 2; J.A. 23762–63. In the EAE experiment, a disease that mimics RRMS was induced in Lewis rats.[2] The rats suffered acute disease within 11 days after immunization, with almost complete remission around day 16 and relapse around day 26. The specifications report that an S1P receptor modulator, e.g., Compound A (fingolimod hydrochloride) "significantly blocks disease-associated neo-angiogenesis when administered to the animals at a dose of from 0.1 to 20 mg/kg p.o."[3] '405 patent col. 10 ll. 61–64; J.A. 23763. They further report that disease relapse was completely inhibited in rats to which Compound A was "administered daily at a dose of

---

[2] Lewis rats are inbred laboratory rats used to study disease. *Inbred Rats*, CHARLES RIVER, https://www.criver.com/sites/default/files/resources/InbredRatsDatasheet.pdf (last visited November 5, 2021).

[3] P.o. indicates oral administration.

0.3 mg/kg" or "administered p.o. at 0.3 mg/kg every 2nd or 3rd day or once a week." '405 patent col. 10 ll. 64–col. 11 ll. 3; J.A. 23763.

Both specifications then describe a prophetic human clinical trial ("Prophetic Trial").[4] '405 patent col. 11 ll. 3–38; J.A. 23763–64. The Prophetic Trial describes a trial in which RRMS patients would receive 0.5, 1.25, or 2.5 mg of an S1P receptor modulator, e.g., Compound A (fingolimod hydrochloride), per day for two to six months. '405 patent col. 11 ll. 8–14; J.A. 23763. The specifications do not mention a loading dose associated with the Prophetic Trial. '405 patent col. 11 ll. 8–14; J.A. 23763.

Both specifications then describe a wide range of potential dosages, which "will vary depending upon, for example, the compound used, the host, the mode of administration and the severity of the condition to be treated." '405 patent col. 11 ll. 20–24; J.A. 23764. Those potential dosages include a "preferred daily dosage range [of] about from 0.1 to 100 mg" and "a dose of 0.5 to 30 mg [of Compound A] every other day or once a week." '405 patent col. 11 ll. 24–38; J.A. 23764.

B. The District Court Proceedings

After a four-day bench trial, the district court found that HEC's ANDA product would infringe claims 1–6 of the '405 patent. The court also found that HEC had not shown that the '405 patent is invalid for (1) insufficient written description for the no-loading-dose limitation and for the

---

[4] Prophetic trials explain how a drug would be administered and how a patient given that drug should be monitored in a clinical trial. Prophetic trials are not clinical trials that are performed; they are merely described on paper. Prophetic trials are sometimes used in patent applications because clinical trials are expensive and time consuming.

claimed 0.5 mg daily dose or (2) anticipation. HEC appeals the district court's findings as to written description for the 0.5 mg daily dose and no-loading-dose limitations.

With respect to the written description for the claimed 0.5 mg daily dose, the district court found that a skilled artisan would understand that the inventors possessed a 0.5 mg daily dose based on one of the successful doses in the EAE experiment results, 0.3 mg/kg weekly. The court credited the testimony of two of Novartis's expert witnesses, Dr. Lawrence Steinman, M.D., and Dr. William Jusko, Ph.D., to make the leap from a 0.3 mg/kg weekly rat dosage to a 0.5 mg daily human dosage. The court noted that the 0.5 mg daily dose is also illustrated in the Prophetic Trial. The district court concluded that there was sufficient written description for the 0.5 mg daily dosage limitation.

With respect to the written description for the "absent an immediately preceding loading dose" limitation, the district court again found sufficient written description in the EAE model and the Prophetic Trial. Neither the Prophetic Trial nor the EAE model recite a loading dose. 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 (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 (citing J.A. 23334–35 (Tr. 756:16–757:8); J.A. 23441–42 (Tr. 863:22–864:18)). Similarly, the district court found that the "EAE example discloses a dosing regimen which does not involve a loading dose." J.A. 27 (citing J.A. 23345 (Tr. 767:3–5); J.A. 22793 (Tr. 215:16–21)). 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. 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," and, thus, the patent provides sufficient written description of the negative limitation. J.A. 37–38.

HEC appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

II. DISCUSSION

On appeal, HEC challenges the district court's decisions concerning the '405 patent's written description of the 0.5 mg daily dose limitation and the no-loading-dose negative limitation. "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 Lab'ys, Inc.*, 745 F.3d 1180, 1190 (Fed. Cir. 2014)). Under the clear error standard, we will not overturn the district court's factual finding unless we have a "'definite and firm conviction' that a mistake has been made." *Nuvo Pharms. (Ireland) Designated Activity Co. v. Dr. Reddy's Lab'ys Inc.*, 923 F.3d 1368, 1376 (Fed. Cir. 2019) (quoting *Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365, 1374 (Fed. Cir. 2008)).

The written description requirement is found in section 112 of the patent statute, which provides that the patent's specification must contain "a written description of the invention, and of the manner and process of making and using it."[5] 35 U.S.C. § 112(a). 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

[5] 35 U.S.C. § 112(a) also contains the separate "enablement" requirement, which is not at issue in this appeal.

specification from the perspective of a person of ordinary skill in the art." *Id*.

HEC challenges the district court's decisions concerning the '405 patent's written description of two limitations: the 0.5 mg daily dose limitation and the no-loading-dose negative limitation.

Despite arguing that the inventors did not possess the claimed subject matter in 2006, HEC bases its arguments, not on the 2006 priority application's written description, but on the '405 patent's specification—leaving it to this court to independently search the 2006 priority application for written description of the claims. HEC's confusion is ultimately of no moment, as we find that the claims have adequate written description support in portions of the '405 specification which also appear in the 2006 priority application.[6]

A. Written Description for the Dosage Limitation

HEC argues that, as of the 2006 priority date, the inventors did not possess a 0.5 mg daily dose of fingolimod. It argues that, as of that date, 0.5 mg/day was considered too low to be effective to treat RRMS. It describes Novartis's calculation of the 0.5 mg/day human dose as derived

---

[6] Both parties wrongly assume that, if the 2006 priority application lacks sufficient written description of the '405 patent's claims, those claims are invalid. If the 2006 priority application lacks sufficient written description for the '405 patent's claims, the '405 patent's claims are not automatically rendered invalid; they are merely deprived of the 2006 priority date. *See* 35 U.S.C. § 119; s*ee also Paice LLC v. Ford Motor Co.*, 881 F.3d 894, 906 (Fed. Cir. 2018) ("For claims to be entitled to a priority date of an earlier-filed application, the application must provide adequate written description support for the later-claimed limitations.").

from the lowest disclosed dose in the rat EAE model described in the specification as "undisclosed mathematical sleights of hand." Appellant's Br. 7. And it argues that the Prophetic Trial, which lists a 0.5 mg daily dose along with two other dosages, does not provide sufficient written description of the 0.5 mg dose. Finally, it asserts that "blaze marks" directing a skilled artisan to the 0.5 mg daily dose are absent from the '405 patent.

We do not find HEC's arguments convincing. The Prophetic Trial and the EAE model provide sufficient written description to show that, as of the priority date, the inventors possessed a 0.5 daily fingolimod dosage as claimed in the '405 patent. The Prophetic Trial describes dosing RRMS patients with fingolimod hydrochloride at daily dosages of 0.5, 1.25, or 2.5 mg. '405 patent col. 11 ll. 8–16. The Prophetic Trial's disclosure of two other dosages does not detract from the written description of the claimed dose. Nor do disclosures of dosage ranges in other areas of the specification lead away from the claimed dose.

The rat EAE model describes additional information which provides further written description for the 0.5 mg/day limitation. The EAE model describes a dosage of 0.3 mg/kg per week as effective to "fully block[] disease-associated angiogenesis and completely inhibit[] the relapse phases." '405 patent col. 10 ll. 64–col. 11 ll. 2. The district court credited the testimonies of Dr. Steinman and Dr. Jusko to arrive at the claimed 0.5 mg/day human dosage from the EAE experiment's 0.3 mg/kg per week rat dosage. Those experts both testified that a skilled artisan would have converted the lowest daily rat dose described in the EAE experiment (0.3 mg/kg weekly) to a daily dose (0.042 mg/kg daily). J.A. 24 (citing J.A. 23325–26 (Tr. 747:6–748:19); J.A. 23443 (Tr. 865:12–24); J.A. 23482 (Tr. 904:2–18)). The district court found, again based on expert testimony, that a skilled artisan "would immediately recognize that 0.3 mg/kg weekly (0.042 mg/kg daily) in rats" is approximately 60% lower "than the lowest known effective

dose in the prior art (0.1 mg/kg daily)." J.A. 24–25 (citing J.A. 23440–41 (Tr. 862:25–863:21)). It found that a skilled artisan "would understand that the EAE results in the '405 Patent therefore demonstrate that a proportionally lower dose (again, roughly 60% lower) could be effective in humans." J.A. 25 (citing J.A. 23443–45 (Tr. 865:4–867:4); J.A. 23480–85 (Tr. 902:17–907:8)). It further found that a skilled artisan "would understand that the inventors translated the lowest dose that had ever been seen as effective from their EAE experiment (0.3 mg/kg once per week) to the 0.5 dose." J.A. 25 (citing J.A. 23356–57 (Tr. 778:25–779:14)).

HEC attacks the expert testimony underlying the district court's determination that the EAE experiment describes a 0.5 mg daily human dose as "undisclosed mathematical sleights of hand." Appellant's Br. 7. We disagree. A "disclosure need not recite the claimed invention *in haec verba*." *Ariad*, 598 F.3d at 1352. The disclosure need only "clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed." *Id.* at 1351. To accept HEC's argument would require us to ignore the perspective of the person of ordinary skill in the art and require literal description of every limitation, in violation of our precedent. We find no clear error in the district court's reliance on expert testimony in finding description of the 0.5 mg daily human dose in the EAE experiment results.

We also reject HEC's argument that the '405 patent does not have necessary "blaze marks" pointing to the 0.5 mg daily dose. "Blaze marks" directing an investigator of ordinary skill in the art to the claimed species from among a forest of disclosed options are not necessary in this case. In cases where the specification describes a broad genus and the claims are directed to a single species or a narrow subgenus, we have held that the specification must contain "'blaze marks' that would lead an ordinarily skilled investigator toward such a species among a slew of competing

possibilities." *Novozymes v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013).

"Blaze marks" are not necessary where the claimed species is expressly described in the specification, as the 0.5 mg daily dosage is here. *See, e.g.*, *Snitzer v. Etzel,* 465 F.2d 899, 902 (C.C.P.A. 1972) (finding that interference counts directed to the activation of a glass laser with trivalent ytterbium ions were adequately described by a specification listing fourteen materials which may be used as active laser ingredients, including trivalent ytterbium, and noting that "there would seem to be little doubt that the literal description of a species provides the requisite legal foundation for claiming that species"). The '405 patent does not contain the laundry-list-type disclosures that we have found require guidance to direct a skilled artisan to the claimed species—it contains the Prophetic Trial listing three doses, 0.5, 1.25, and 2.5 mg/day. While other sections of the specification disclose larger ranges of potential doses for S1P receptor modulators, e.g., 0.1 to 100 mg/day doses, those disclosures do not diminish the literal description of the 0.5 mg/day dose in the Prophetic Trial. All described dose ranges include the 0.5 mg/day dose. And smaller dosage ranges, such as 0.5–30 mg/day, are disclosed for fingolimod hydrochloride. Even if blaze marks were required in this case, the Prophetic Trial and 0.5–30 mg/day dosage range would provide a skilled artisan more than sufficient guidance to direct them to the claimed 0.5 mg/day dose.

Much of HEC's argument is directed to its assertion that no one, including the inventors, knew that a 0.5 mg/day dose would be effective as of the 2006 priority date. That argument fails for two reasons. First, efficacy is not a requirement of the claims. The claims require only administration of a 0.5 mg/day dose for, *inter alia*, treatment purposes. The district court found that the purpose limitations are adequately described, and HEC has not appealed that finding. Thus, cases such as *Nuvo Pharms.*, 923 F.3d 1368, in which this court found that claims directed to an

amount of uncoated PPI that is *effective* to raise the gastric pH to at least 3.5 were not adequately described by a specification that "provides nothing more than the mere claim that uncoated PPI might work" where skilled artisans "would not have thought it would work," are distinguishable. *See id.* at 1381. Second, as explained above, the EAE model provides evidence that the inventors knew that a 60% lower dose would be effective.

For these reasons, we find no clear error in the district court's holding that the 0.5 mg/day dosage limitation is adequately described. The district court's holding is supported by the specification and ample expert testimony interpreting that specification.

B. Written Description for the Negative Limitation

HEC argues that there is no written description of the negative limitation because the '405 specification contains no recitation of a loading dose "or its potential benefits or disadvantages at all." Appellant's Br. 40. It further argues that the district court's finding of written description of the negative limitation within the '405 specification contradicts the district court's finding that Kappos 2006, which is similarly silent as to loading doses, does not anticipate the claims. We find both arguments unavailing.

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). We are aware of no case that suggests otherwise. And, while HEC asserts that "[i]t is well-settled law that silence alone cannot serve as a basis for" a negative limitation, Appellant's Br. 41, HEC identifies no case that actually supports that proposition. To the contrary, we repeatedly have resisted imposition of heightened written description standards for negative limitations, such as that urged by HEC.

For example, in *Santarus, Inc. v. Par Pharmaceutical, Inc.*, 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.* We explained that "[n]egative claim limitations are adequately supported when the specification describes a reason to exclude the relevant limitation." *Id.* We did not hold that a specification *must* describe a reason to exclude a negative limitation. 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.

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 antiinfectives or antibiotics." *Id.* (citation and quotation marks omitted). We did not require that the

specification describe a reason to exclude acriflavine specifically, but, rather, 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)). 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 CS, 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). 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.* at1348–49.

Similarly, in *Erfindergemeinschaft Uropep GBR v. Eli Lilly & Co.*, Judge Bryson, sitting by designation in the Eastern District of Texas, explained that the law does not require that the disclosure explain a negative limitation. 276 F. Supp. 3d 629, 657–58 (E.D. Tex. 2017), *aff'd*, 739 F. App'x 643 (Fed. Cir. 2018). Judge Bryson explained, citing *Bimeda*, that "[w]hat is prohibited is a negative limitation that is contrary to the thrust of the invention." *Id.* at 658. He noted that "a patentee can choose to claim any particular embodiments identified in the specification and exclude others, without explanation, as long as the claim does not indicate to persons of skill that it covers embodiments inconsistent with, and therefore unsupported by, the disclosure." *Id.*

In asserting that "silence alone cannot serve as a basis for" a negative limitation, Appellant's Br. 41, HEC attempts to create a new heightened written description standard for negative limitations. In doing so, it ignores a central tenet of our written description jurisprudence—that the disclosure must be read from the perspective of a

person of skill in the art—as well as precedent stating that the disclosure need not describe a limitation *in haec verba*. *See, e.g.*, *All Dental Prodx, LLC v. Advantage Dental Prod., Inc.*, 309 F.3d 774, 779 (Fed. Cir. 2002) ("[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." (citing *Eiselstein v. Frank*, 52 F.3d 1035, 1039 (Fed. Cir. 1995)); *see also Ariad*, 598 F.3d at 1351. 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").

The dissent notes that the Manual of Patent Examining Procedure ("MPEP")[7] states: "The mere absence of a positive recitation is not a basis for an exclusion." MPEP § 2173.05(i). As the dissent puts it—"silence alone is insufficient." Dissent at 4. Both the MPEP and the dissent are correct in their statement of the law: the "*mere absence* of a positive recitation" is not enough and "silence *alone* is insufficient." But the dissent, like HEC, ignores that it is how a skilled artisan reads a disclosure that matters. Written description may take any form, so long as a skilled artisan would read the disclosure as describing the claimed invention.

Our case law makes clear that "[c]ompliance with the written description requirement is essentially a fact-based

---

[7] The MPEP is not binding on this court but may be persuasive.

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)). The 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. 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.

HEC and the dissent urge us to elevate form over substance by creating 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. As we have several times before, we reject the invitation to create a heightened written description standard for negative limitations. As with all other limitations, the negative limitation here must be accompanied by an original disclosure which *conveys to a person of ordinary skill* that the inventor was in possession of the claimed invention. *See Ariad*, 598 F.3d at 1351. And, as in all other written description challenges, HEC was required to show by clear and convincing evidence that the negative limitation was not adequately described. The district court did not clearly err in finding that HEC failed to do so.

In determining that there is adequate written description of the negative limitation, the district court correctly, and quite carefully, conducted "an objective inquiry into the four corners of the specification from the perspective of

a person of ordinary skill in the art" as required by our precedent. *See Ariad*, 598 F.3d at 1351. We review the evidence cited by the district court below and discern no clear error in the court's analysis or conclusions.

The Prophetic Trial describes giving RRMS patients fingolimod hydrochloride "at a daily dosage of 0.5, 1.25 or 2.5 mg p.o." '405 patent col. 11 ll. 8–9. It further states that: "Initially patients receive treatment for 2 to 6 months." *Id.* col. 11 ll. 13–14. Dr. Steinman, one of Novartis's expert witnesses, testified from the perspective of a skilled artisan that, if the Prophetic Trial included a loading dose, the patent would explicitly state as much:

> "[T]here were two places where if there were going to be a loading dose, you would explicitly state it.
>
> . . . .
>
> So the first place one might explicitly say there was—there was a preceding loading dose is when you described the daily dosage, the reason being a loading dose would occur before the first daily dose.
>
> The second place is even more dramatic, because they say, "Initially patients received treatment for 2 to 6 months." So now they're really zooming in on Day 1, what is that treatment, it's a daily dose of 0.5.
>
> So there were two perfectly logical places that if there was going to be a loading dose, it would have been stated.
>
> . . . .
>
> That's where you would put it if you were going to give a loading dose.

J.A. 23343 (Tr. 765:2–25).

Similarly, Dr. Fred Lublin, Ph.D., another expert testifying for Novartis, testified that a person of skill in the art

"would have viewed the patent as a document, as a complete document, that should give you 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 (Tr. 213:6–15). Dr. Lublin testified that a "loading dose is a greater than normal dose that you give until you return to a maintenance dose" and a loading dose is "not a daily dose." J.A. 22792 (Tr. 214:1–9). He further testified that "[o]ne would expect in a patent that if there was going to be a loading dose, it would be specified." J.A. 22793 (Tr. 215:5–8). And a third expert testifying for Novartis, Dr. Jusko, similarly testified that, from the perspective of a person of skill in pharmacology, the Prophetic Trial has a "specified initial regimen that does not include a loading dose." J.A. 23442 (Tr. 864:14–16).

The district court credited this expert testimony, as well as the testimony from HEC's own expert, Dr. Paul Hoffman, M.D., who agreed that "a loading dose is a higher-than-therapeutic level dose, usually given . . . as the first dose." J.A. 23125 (Tr. 547:14–18); J.A. 27. Based on that evidence, the court concluded that the "absence of an immediately preceding loading dose from the specification, and from the Prophetic Trial, would tell a person of skill that loading doses are excluded from the invention." J.A. 26. We discern no clear error in that finding. The district court further noted that the rat EAE experiment does not describe a loading dose. J.A. 26. It again credited the testimony of multiple expert witnesses who testified that the EAE model did not include a loading dose. J.A. 26. Dr. Jusko, in response to a question about whether there are any loading doses in the EAE model, stated: "Not that I'm aware of." J.A. 22793 (Tr. 215:16–21). Dr. Steinman similarly testified that no loading dose was used in the EAE experiment. J.A. 23345 (Tr. 767:3–5). HEC's own expert witness, Dr. Hoffman, testified that the EAE model does not talk about a loading dose. J.A. 23209 (Tr. 631:18–22).

Based on both the specification's disclosure of the rat EAE model and the ample expert testimony providing evidence of how a person of ordinary skill would read that disclosure, the district court concluded that the "EAE example discloses a dosing regimen which does not involve a loading dose." J.A. 27. Finally, the district court noted that, while the patent "describes alternative dosing regimens, like 'intermittent dosing,' [it] does not describe loading doses." J.A. 27.

The district court concluded that the "EAE model and the Prophetic Trial . . . both indicate to a person of ordinary skill that the claimed invention did not include the administration of a loading dose." J.A. 37–38. We are not left with the "definite and firm conviction" that the district court made a mistake in coming to this conclusion. *See Nuvo Pharms.*, 923 F.3d at 1376 (quoting *Scanner Techs.*, 528 F.3d at 1374). To the contrary, the district court's conclusion appears wholly correct. To arrive at the opposite conclusion would require us to disregard the perspective of a person of skill in the art—something our precedent simply does not allow. *See Ariad*, 598 F.3d at 1351.

We also find unpersuasive HEC's argument that the district court's written description decision contradicts its determination that the '405 patent is not anticipated by Kappos 2006. HEC notes that neither Kappos 2006 nor the '405 patent's specification explicitly state that a loading dose should not be administered. But HEC's argument ignores the differences between the two district court findings and ignores the differences between the disclosures of Kappos 2006 and the '405 specification.

As a granted patent, the '405 patent is presumed valid. Thus, it is also presumed to have a complete written description. *See 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."). No such presumption

applies to disclosures of a prior art reference that is not itself a granted patent, such as Kappos 2006. Further, the perspective of a person of skill in the art is important in both the written description and the anticipation inquiries. And, in this case, the district court credited the testimony of two expert witnesses, Dr. Lublin and Dr. Steinman, who testified that a person of skill in the art would not presume that the Kappos 2006 abstract was complete. J.A. 30 (citing J.A. 22782 (Tr. 204:12–19) (Dr. Lublin testifying that abstracts "have to by design" leave out information describing clinical trials); J.A. 23475 (Tr. 897:1–5) (Dr. Steinman testifying that "an abstract, like a press release, like any kind of announcement, is inherently incomplete," while "a publication and a patent are presumed complete")). Thus, although neither the '405 specification nor Kappos 2006 include the phrase "loading dose," it was not clear error for the district court to find that a skilled artisan would read the specification as not including a loading dose and would read Kappos 2006 as silent on the presence or absence of a loading dose.

Differences between the '405 patent's specification and Kappos 2006 justify the district court's findings that the specification describes the absence of a loading dose while Kappos 2006 does not anticipate that negative limitation. The specification includes the Prophetic Trial, which the district court found "describes giving a 'daily dosage of 0.5 . . . mg' fingolimod to treat RRMS, started 'initially.'" J.A. 26. The district court found that, "[o]n this record, starting with a daily dose plainly implies that there is no loading dose." J.A. 27. Kappos 2006 consists of two paragraphs describing a planned clinical trial and, with respect to dosing, states only that "[a]pproximately 1.100 patients . . . are being randomised in a 1:1:1 ratio to once-daily fingolimod 1.25 mg, fingolimod 0.5 mg, or placebo, for up to 24 months." J.A. 24723–24. Kappos 2006 nowhere says that the daily fingolimod dosage should be "initially" administered. Thus, differences between Kappos 2006 and the '405

patent justify the district court's conclusions that Kappos 2006 does not anticipate the claims and the '405 specification adequately describes the claims.

The dissent takes umbrage with the district court's finding that the "Prophetic Trial describes giving a 'daily dosage of 0.5 . . . mg' fingolimod to treat RRMS, started 'initially'" because the '405 patent says "[i]nitially, patients receive treatment for 2 to 6 months." Dissent at 6–7; J.A. 26; '405 patent col. 11 ll. 13–14. The dissent would find that the "word 'initially' is not modifying the daily dosage; it is modifying the initial length of treatment in this example." Dissent at 6–7. The dissent, thus, would substitute its own factual findings for those of the district court. But, if the 2–6 month "initial" dose does not differ in any way from the previously described daily doses, the language, used in context, must exclude a loading dose. As we have already explained, the district court did not clearly err in finding that the "Prophetic Trial describes giving a 'daily dosage of 0.5 . . . mg' fingolimod to treat RRMS, started 'initially.'" J.A. 26. And 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 dissent also asserts that, on this record, the term "daily dose" would not convey to a skilled artisan that no loading dose should be used. Dissent at 7–8. But the district court's decision did not rely only on the term "daily dose." Rather, as noted above, the district court found that "*starting* with a daily dose plainly implies that there is no loading dose," as a loading dose is a larger-than-daily dose. J.A. 27 (emphasis added). We need not, and do not, go

further than the district court to make findings about the term "daily dose." The dissent's assertion to the contrary and allegation that we "tease[] an entirely new claim limitation out of an entirely common term, relegating the legal determination of a term's meaning to the backseat of an expert's post-hoc rationalization" is, frankly, baffling. *See* Dissent at 8.

Written description in this case, as in all cases, is a factual issue. In deciding that the district court did not clearly err in finding written description for the negative limitation in the '405 patent, we do not establish a new legal standard that silence is disclosure, as the dissent asserts. Instead, we merely hold that, on this record, the district court did not clearly err in finding that a skilled artisan would read the '405 patent's disclosure to describe the "absent an immediately preceding loading dose" negative limitation.

III. CONCLUSION

For the foregoing reasons, we affirm the district court's decision.

AFFIRMED

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.

MOORE, *Chief Judge*, dissenting.

The majority dramatically expands a patentee's ability to add, years after filing a patent application, negative claim limitations that have zero support in the written description. By doing so, it contradicts our well-established precedent and nullifies the Patent Office's guidance in the Manual of Patent Examining Procedure (MPEP). I would reverse the district court's finding that there exists written description support as it is inconsistent with our established precedent. Silence is not disclosure.

I

"The hallmark of written description is disclosure." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (en banc). The description in the specification must clearly allow a skilled artisan to recognize that the inventor invented what is claimed. *Id.* The '405 patent contains no written description support for the limitation "absent an immediately preceding loading dose regimen." This negative limitation was added in response to an obviousness rejection during prosecution of the '405 patent's co-pending parent application. J.A. 23892–94. Claim 1:

> 1. A method for reducing or preventing or alleviating relapses in Relapsing-Remitting multiple sclerosis in a subject in need thereof, comprising orally administering to said subject 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol, in free form or in a pharmaceutically acceptable salt form, at a daily dosage of 0.5 mg, *absent an immediately preceding loading dose regimen*.

There is no disclosure in the specification of preventing a loading dose. Loading doses—whether to be used or not—are never discussed. As the majority concedes, we have long held that silence cannot support a negative limitation; for if the specification is silent there is no evidence that the inventor actually possessed the invention. Maj. at 17 ("Both the MPEP and the dissent are correct in their statement of the law: the 'mere absence of a positive recitation' is not enough, and 'silence alone is insufficient.'"). "Negative claim limitations are adequately supported when the specification *describes a reason to exclude* the relevant limitation," such as by listing the disadvantages of some embodiment. *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1351 (Fed. Cir. 2012). In *Inphi Corp. v. Netlist, Inc.*, 805 F.3d 1350, 1356 (Fed. Cir. 2015), we explained that reciting alternative features of the patented invention may also suffice.[1] In *Nike, Inc. v. Adidas AG,* we again reiterated that the specification should indicate a reason to exclude. 812 F.3d 1326, 1348 (Fed. Cir. 2016). This law, our law, does not create a heightened standard for negative claim limitations; it simply requires some disclosure to demonstrate that the inventor was not, as in this case, ambivalent about loading doses.[2]

---

[1] *Erfindergemeinschaft Uropep GBR v. Eli Lilly & Co.*, 276 F. Supp. 3d 629, 657–59 (E.D. Tex. 2017), consistent with *Inphi*, holds that when a patent discloses many alternatives, the claims are permitted to claim only some and exclude others. The specification here does not disclose alternatives (some with and some without loading doses).

[2] *In re Bimeda Research & Development Ltd.*, 724 F.3d 1320, 1323–24 (Fed. Cir. 2013), does not help the majority at all. The court simply held that, when the patent repeatedly emphasizes that the invention was "without

Following our clear precedent, the Patent Office's MPEP provides the following guidance: "The mere absence of a positive recitation is not a basis for an exclusion," i.e., silence alone is insufficient. MPEP § 2173.05(i). That remains true even if it would have been obvious to a skilled artisan to exclude the undisclosed feature. *Rivera v. Int'l Trade Comm'n*, 857 F.3d 1315, 1322 (Fed. Cir. 2017) ("The knowledge of ordinary artisans may be used to inform what is actually in the specification, but not to teach limitations that are not in the specification, even if those limitations would be rendered obvious by the disclosure.").

Nowhere in the patent does it say a loading dose should not be administered. Nowhere does it discuss alternatives (including or not including a loading dose). Nowhere does it give advantages or disadvantages of including a loading dose. Indeed, it provides no reason to exclude a loading dose. Even Novartis' expert, Dr. Lublin, agreed:

> Q: Nothing in the text of the specification of the '405 patent discloses a rationale for the negative limitation prohibiting an immediately preceding loading dose, correct?
>
> A: I don't believe so.

J.A. 22872–73. And 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, Novartis' second physician expert, 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

---

using antibiotics," a claim which allows some antibiotics lacks written description support. *Id.*

dose"). The '405 patent provides nothing to signal to the public that the inventors possessed a treatment excluding a loading dose when a loading dose was a known possibility.

The patent is silent, eerily silent. Consistent with *Santarus, Inphi,* and *Nike*, there needed to be some discussion of loading doses in order to show that the inventors in fact invented this treatment method that is not just ambivalent to, but expressly excludes, a loading dose. This is not a heightened written description requirement; it is simply a written description requirement.

The district court relied on the disclosure's silence to support the negative loading dose limitation, reasoning that silence "would tell a person of skill that loading doses are excluded from the invention." J.A. 26 ¶ 61. We have rejected the notion that a skilled artisan's knowledge can speak for a mute specification. *See Rivera*, 857 F.3d at 1322. Here, the expert that the majority relies upon to supplement a silent disclosure concludes that a loading dose is excluded because the patent is silent on loading doses: "the patent [i]s a document, as a complete document, that should give you all the information you need to carry out the claims, and that information of having a loading dose is not there." Maj. at 19–20 (quoting J.A. 22791). If silence were sufficient then every later-added negative limitation would be supported as long as the patent makes no mention of it. This is a fundamental error of law.

Novartis explained its support for the no-loading-dose limitation as follows:

> Judge Linn: There is nothing in the patent that says treatment begins with the daily dose?
>
> Novartis: Ummm the prophetic example says treatment begins initially and treatment is the 0.5 mg daily dose so if that begins initially it excludes the possibility of a loading dose.

> ***
>
> Chief Judge Moore: The patent says "Initially, patients receive treatment for 2 to 6 months," and you believe I should construe that as initially there is no loading dose?
>
> Novartis: Yes, your honor a loading dose is excluded from that treatment.

Oral Argument at 35:30–37:13. The majority claims that the Prophetic Example in the specification describes "start[ing] 'initially'" by "giving a 'daily dose of 0.5 . . . mg.'" Maj. at 7; Maj. at 22 (same). This is a false and inaccurate quotation. The word "initially" does not precede or modify the daily dosage sentence; it follows it three full sentences later. To be clear, the patent does NOT say treatment begins initially with a daily dose. Here is the actual quote:

> 20 patients with relapsing-remitting MS receive said compound at a *daily* dosage of 0.5, 1.25 or 2.5 mg p.o. The general clinical state of the patient is investigated weekly by physical and laboratory examination. Disease state and changes in disease progression are assessed every 2 months by radiological examination (MRI) and physical examination. *Initially*, patients receive treatment for 2 to 6 months. Thereafter, they remain on treatment for as long as their disease does not progress and the drug is satisfactorily tolerated.

'405 patent at 11:8–16. The word "initially" is not some complex, scientific term in need of expert explanation. It is basic English. The word "initially" is not modifying the daily dosage; it is modifying the initial length of treatment

in this example.[3] To the extent that the district court reached a fact finding to the contrary, it is inconsistent with the straight-forward, quite clear language of the patent and therefore clearly erroneous.[4]

Novartis also claims that the use of the term "daily dosage" itself would convey to a skilled artisan that no loading dose should be used. This is not only unsupported by the record; it is contradicted at every turn. First, the claim already said "daily dosage" before the negative limitation was added. It was allowed only after the applicants added the no loading dose limitation. J.A. 23903 (Examiner's rejection in parent application); J.A. 23892–93 (Applicant Response in same); *see also* Novartis Br. 11–12. The applicants explained they added the no-loading-dose limitation "to specify that the [daily dosage] cannot immediately follow a loading dose regiment. Applicants have made these amendments to further distinguish their claims from the disclosure of [the prior art]." J.A. 23892.[5] If daily already meant no loading dose, then there would have been no reason for the claims to recite both a "daily dosage" and the negative loading dose limitation. The same logic applies to

---

[3] I note that even if the Prophetic Example were to be understood as not having included a loading dose that does not mean that loading doses must be prohibited (as the claims now require).

[4] Nothing about this analysis "substitute[s] . . . factual findings for those of the district court." Maj. at 23. Instead, it merely points out how it is *clear error* for the majority, district court, and Novartis to misquote the specification.

[5] Novartis stated during argument that this limitation was "added to *clarify* that the claim does not overlap with [the prior art]." Oral Argument at 21:34–41. This litigation claim cannot be reconciled with their own prosecution statements.

the specification, which only mentioned "daily dosage." This prosecution makes clear that neither the applicant nor the examiner believed that the use of the term "daily dosage" alone conveyed the absence of a loading dose.

There is no evidence that daily had a special meaning in the field of pharmacology. Daily is not a complex or complicated term of art that requires expert testimony to explain. The district court construed the claim term "daily dosage of 0.5 mg" to mean "the amount of drug that someone takes in a given day." J.A. 18670. Neither party argued the term excludes a loading dose. *Id.* And for good reason—it has a plain meaning, and the prosecution history shows it does not implicitly exclude a loading dose. Novartis backdoors a claim construction argument, arguing that "experts understood the patent's description of a 'daily dose' as exclusive of a loading dose," Novartis Br. 46, but it and the district court already defined daily dosage otherwise.

Rather than defend Novartis' reliance on the "daily dosage" language, the majority pivots to focus on the district court's statement that "*starting* with a daily dose plainly implies that there is no loading dose." Maj. at 23–24 (quoting J.A. 27). But that statement is just another example of the district court (and now the majority) rewriting the specification with expert testimony. The patent never says "starting with a daily dose," and the district court relied exclusively on expert testimony to support that finding. *See* J.A. 27 (citing J.A. 23344). But "[t]he knowledge of ordinary artisans may . . . not [be used] to teach limitations that are not in the specification[.]" *Rivera*, 857 F.3d at 1322. Novartis, and now the majority, teases an entirely new claim limitation out of an entirely common term, relegating the legal determination of a term's meaning to the backseat of an expert's post-hoc rationalization.

In fact, the district court found that a nearly identical disclosure in the prior art (Kappos 2006, a Novartis-supported study) did not anticipate because it failed to disclose the negative loading dose limitation. Kappos disclosed a study administering 0.5 mg fingolimod to RRMS patients "*once-daily* fingolimod for up to 24 months." J.A. 29–30 ¶ 72; J.A. 24724. The district court found Kappos 2006 did *not* meet the negative loading-dose limitation, reasoning that "[t]he failure to mention a loading dose does not . . . indicate that the dose was not present in the trial, but only that the presence or absence of a loading dose was not mentioned." J.A. 30 ¶ 74. A district court's "internally inconsistent factual findings," like those here, "are, by definition, clearly erroneous." *In re Sentinel Mgmt. Grp., Inc.*, 728 F.3d 660, 670 (7th Cir. 2013); *see also United States v. AT&T, Inc.*, 916 F.3d 1029, 1033 (D.C. Cir. 2019) (citing, e.g., *Anderson v. City of Bessemer, N.C.*, 470 U.S. 564, 575 (1985)) ("A finding may be clearly erroneous when it is illogical or implausible, [or] rests on internally inconsistent reasoning.").

The majority's attempts to distinguish Kappos 2006 from the '405 patent fall flat. Maj. at 21–23. To be sure, Kappos 2006 does not "say[] the daily fingolimod dosage should be 'initially' administered." *Id.* at 22–23. But neither does the '405 patent. The '405 patent uses the word initially to describe the *length of treatment*, not the *dosage*. And it is simply not correct that an issued patent is "presumed to have a complete written description." Maj. at 21. "The presumption of validity includes a presumption the patent complies with" the written description requirement. *Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1195 (Fed. Cir. 1999). But it does not require presuming an issued patent is "complete," which would mean silence presumptively supports a negative limitation in *every* case. That presumption is contrary to our long-standing precedent, which the majority recognizes

(*see* Maj. at 17), and a gross expansion of the presumption of validity.

This specification is ambivalent as to loading doses in a field where, by all expert accounts, loading doses of fingolimod were sometimes used to treat MS. The inventors do not get to claim as their invention something they did not disclose in the patent. There are no fact findings here to defer to—the patent is silent as to loading doses. The district court relied upon that silence: "The absence of an immediately preceding loading dose from the specification, and from the Prophetic Trial, would tell a person of skill that loading doses are excluded from the invention." J.A. 26 ¶ 61. This is not a finding of fact; it is a misunderstanding of the law. An inventor cannot satisfy the written description requirement through silence. And when the majority concludes otherwise, it creates a conflict with our long-standing, uniformly-applied precedent including *Santarus*, *Inphi*, and *Nike*. While the negative limitation need not be recited in the specification *in haec verba*, there must be something in the specification that conveys to a skilled artisan that the inventor intended the exclusion: disadvantages, alternatives, inconsistencies, just something. This specification is entirely silent and ambivalent about loading doses. These inventors did not disclose treatment that must exclude a loading dose, and the district court's finding to the contrary is clearly erroneous. After this case, negative limitations are supported by a specification that simply never mentions them.

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 15-1328 **September Term, 2017**

EPA-80FR42870

Filed On: January 26, 2018

Mexichem Fluor, Inc.,

Petitioner

v.

Environmental Protection Agency,

Respondent

Chemours Company FC, LLC, et al.,
Intervenors

Consolidated with 15-1329

BEFORE: Brown*, Kavanaugh, and Wilkins, Circuit Judges

O R D E R

Upon consideration of the petitions of Natural Resources Defense Council and the Industry Intervenor-Respondents for panel rehearing and the joint response thereto; the motion of rehearing petitioners for leave to file a joint reply and the lodged joint reply; the motions for invitation to file brief of Administrative Law Professors and the States as amici curiae in support of the petitions for panel rehearing and the lodged briefs; the vote of Circuit Judge Kavanaugh to deny the petitions; and the vote of Circuit Judge Wilkins to grant the petitions, it is

ORDERED that the motion for leave and the motions for invitation to file be granted. The Clerk is directed to file the lodged documents. It is

FURTHER ORDERED that the petitions be denied as the current panel is equally divided.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

BY: /s/
Michael C. McGrail
Deputy Clerk

*Circuit Judge Brown was a member of the panel but retired prior to the filing of the petitions.

UNITED STATES COURT OF APPEALS
FOR THE
SECOND CIRCUIT

At a Stated Term of the United States Court of Appeals for the Second Circuit, held at the Thurgood Marshall United States Courthouse, 40 Foley Square, in the City of New York, on the 10th day of April, two thousand twenty,

Before: Amalya L. Kearse,
Richard J. Sullivan,

Circuit Judges.*

United States of America,

Appellee,

v.

David Blaszczak, Theodore Huber, Robert Olan, Christopher Worrall,

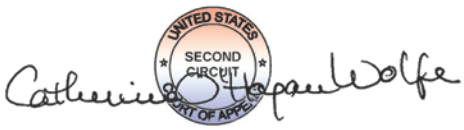
Defendants-Appellants.

ORDER
Docket No. 18-2811(L),
18-2825(CON), 18-2867(CON),
18-2878(CON)

Appellant, David Blaszczak, having filed a petition for panel rehearing and the panel that determined the appeal having considered the request,

IT IS HEREBY ORDERED that the petition is DENIED.

For The Court:
Catherine O'Hagan Wolfe,
Clerk of Court



*Judge Christopher F. Droney, who was originally part of the panel assigned to hear this case, retired from the Court effective January 1, 2020.

FILED: April 22, 2011

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 09-1021 (L)
(8:06-cv-02266-AW)

SHANE FELDMAN; BRIAN KELLY; PAUL SINGLETON

Plaintiffs - Appellees

v.

PRO FOOTBALL, INCORPORATED; WFI STADIUM, INCORPORATED

Defendants - Appellants

No. 09-1023
(8:06-cv-02266-AW)

SHANE FELDMAN; BRIAN KELLY; PAUL SINGLETON

Plaintiffs - Appellants

v.

PRO FOOTBALL, INCORPORATED; WFI STADIUM, INCORPORATED

Defendants - Appellees

O R D E R

The court denies the petition for rehearing and rehearing en banc. No judge requested a poll under Fed. R. App. P. 35 on the petition for rehearing en banc.

Entered at the direction of the panel: Judge Davis and Chief District Judge Beaty. Judge Michael participated in the decision of this case, but passed away before consideration of the petition for rehearing and petition for rehearing en banc.

For the Court

/s/ Patricia S. Connor, Clerk

United States Court of Appeals

FIFTH CIRCUIT
OFFICE OF THE CLERK

LYLE W. CAYCE
CLERK

TEL. 504-310-7700
600 S. MAESTRI PLACE
NEW ORLEANS, LA 70130

August 04, 2011

MEMORANDUM TO COUNSEL OR PARTIES LISTED BELOW:

No. 11-10086 USA v. Armando Portillo-Munoz
USDC No. 2:10-CR-42-1

Enclosed is an order entered in this case.

Sincerely,

LYLE W. CAYCE, Clerk

By: Madeline Chigoy
Madeline K. Chigoy, Deputy Clerk
504-310-7691

Mr. Jerry Van Beard
Mr. Lee P. Gelernt
Mr. James Wesley Hendrix
Mr. Kevin Joel Page
Ms. Cecillia Derphine Wang

IN THE UNITED STATES COURT OF APPEALS

FOR THE FIFTH CIRCUIT

No. 11-10086

UNITED STATES OF AMERICA,

Plaintiff - Appellee

v.

ARMANDO PORTILLO-MUNOZ, also known as Armando Portillo Munoz,

Defendant - Appellant

Appeal from the United States District Court for the Northern District of Texas, Amarillo

ON PETITION FOR REHEARING EN BANC

(Opinion 6/30/11, 5 Cir., _____, _____, F.3d _____)

Before GARWOOD, GARZA, and DENNIS, Circuit Judges.

PER CURIAM:

(✓) Treating the Petition for Rehearing En Banc as a Petition for Panel Rehearing, the Petition for Panel Rehearing is DENIED. No member of the panel nor judge in regular active service of the court having requested that the court be polled on Rehearing En Banc (FED. R. APP. P. and 5TH CIR. R. 35), the Petition for Rehearing En Banc is DENIED.

( ) Treating the Petition for Rehearing En Banc as a Petition for Panel Rehearing, the Petition for Panel Rehearing is DENIED. The court

having been polled at the request of one of the members of the court and a majority of the judges who are in regular active service and not disqualified not having voted in favor (FED. R. APP. P. and 5TH CIR. R. 35), the Petition for Rehearing En Banc is DENIED.

ENTERED FOR THE COURT:

United States Circuit Judge

*On account of his death on July 14, 2011, Judge Garwood did not participate in this decision.

Nos. 11-5773/5793

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

FILED
Oct 25, 2013
DEBORAH S. HUNT, Clerk

MARTIN COUNTY COAL CORPORATION,

Plaintiff-Appellant/Cross-Appellee,

v.

UNIVERSAL UNDERWRITERS INSURANCE COMPANY,

Defendant-Appellee/Cross-Appellant.

O R D E R

BEFORE: KEITH and ROGERS, Circuit Judges.*

The court having received a petition for rehearing en banc, and the petition having been circulated not only to the original panel members but also to all other active judges of this court, and no judge of this court having requested a vote on the suggestion for rehearing en banc, the petition for rehearing has been referred to the original panel.

The panel has further reviewed the petition for rehearing and concludes that the issues raised in the petition were fully considered upon the original submission and decision of the cases. Accordingly, the petition is denied. Judge Rogers would grant rehearing for the reasons stated in his dissent.

ENTERED BY ORDER OF THE COURT

Deborah S. Hunt, Clerk

* Hon. Boyce F. Martin, Jr., who was a member of the panel rendering a decision in this appeal, retired on August 16, 2013.

United States Court of Appeals

For the Seventh Circuit
Chicago, Illinois 60604

October 19, 2020

Before

MICHAEL S. KANNE, *Circuit Judge*

ILANA D. ROVNER, *Circuit Judge*[*]

No. 20-1041

CHRISTEL VAN DYKE,
Plaintiff-Appellant,

v.

VILLAGE OF ALSIP, et al.,
Defendants-Appellees.

Appeal from the United States District Court for the Northern District of Illinois, Eastern Division.

No. 18 C 6112

Virginia M. Kendall,
Judge.

O R D E R

On consideration of the petition for rehearing *en banc* filed on September 16, 2020, no judge in active service has requested a vote on the petition for rehearing *en banc* and all members of the original panel have voted to deny rehearing.

Accordingly, IT IS ORDERED that the petition for rehearing is DENIED.

[*] Circuit Judge Barrett was a member of the panel when this case was decided on September 2, 2020; however, she did not participate in the consideration of the petition for rehearing. The petition is resolved by a quorum of the panel pursuant to 28 U.S.C. §46(d).

UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

No. 02-2462

Reeder-Simco GMC, Inc.,	*	
	*	
Appellee,	*	
	*	Order Denying Petition for
vs.	*	Rehearing and for Rehearing
	*	En Banc
Volvo GM Heavy Truck Corporation, etc.,	*	
	*	
	*	
Appellant.	*	

The motion by the Truck Manufacturers Association to file an amicus brief has been considered by the court and is denied.

The petition for rehearing en banc is denied. The petition for rehearing by the panel is also denied.

Judge Gruender would grant the petition for rehearing en banc.

Judge Hansen would grant the petition for panel rehearing.

(5128-010199)

October 6, 2004

Order Entered at the Direction of the Court:

Clerk, U.S. Court of Appeals, Eighth Circuit

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 12-10793-BB

FLUOR INTERCONTINENTAL INC.,

Plaintiff,

IAP WORLDWIDE SERVICES INC.,
READINESS MANAGEMENT SUPPORT LC,

Defendants,

IAP WORLDWIDE SERVICES INC.,
READINESS MANAGEMENT SUPPORT LC,

Third Party Plaintiffs - Appellees
Cross Appellants,

versus

JOHNSON CONTROLS, INC.,

Third Party Defendant - Appellant
Cross Appellee.

Appeal from the United States District Court
for the Northern District of Florida

ON PETITION(S) FOR REHEARING AND PETITION(S) FOR REHEARING EN BANC

BEFORE: JORDAN and RIPPLE,* Circuit Judges**

PER CURIAM:

The Petition(s) for Rehearing are DENIED and no Judge in regular active service on the Court having requested that the Court be polled on rehearing en banc (Rule 35, Federal Rules of Appellate Procedure), the Petition(s) for Rehearing En Banc are DENIED.

ENTERED FOR THE COURT:

/S/ ADALBERTO JORDAN
UNITED STATES CIRCUIT JUDGE

---

*Honorable Kenneth F. Ripple, United States Circuit Judge for the Seventh Circuit, sitting by designation.

** This order is being entered by a quorum pursuant to 28 U.S.C. §46(d) due to Judge Barkett's retirement on September 30, 2013.