2021-1070

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. REDDYS LABORATORIES, INC., DR. REDDYS LABORATORIES, LTD., EMCURE PHARMACEUTICALS, HERITAGE PHARMACEUTICALS INC., GLENMARK PHARMACEUTICALS INC., USA, GLENMARK PHARMACEUTICALS LIMITED, HETERO USA INC., HETERO LABS LIMITED UNIT-V, HETERO

(For Continuation of Caption See Inside Cover)

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

APPELLANTS' RESPONSE TO PETITION FOR PANEL REHEARING AND REHEARING EN BANC

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Defendants

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

Defendants-Appellants

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 2021-1070

Short Case Caption Novartis Pharmaceuticals v. Accord Healthcare Inc.

Filing Party/Entity HEC Pharm Co., Ltd., HEC Pharm USA Inc.

Instructions: Complete each section of the form. In answering items 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance. **Please enter only one item per box; attach additional pages as needed and check the relevant box**. Counsel must immediately file an amended Certificate of Interest if information changes. Fed. Cir. R. 47.4(b).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 08/17/2022

Signature: /s/ Paul J. Skiermont

Name: Paul J. Skiermont

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	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. ☑ None/Not Applicable	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. ☐ None/Not Applicable
HEC Pharm Co., Ltd.		HEC Pharm Group
HEC Pharm USA Inc.		HEC Pharm Co. Ltd.

☐ Additional pages attached

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. Fed. Cir. R. 47.4(a)(4).

☐ None/Not Applicable ☐ Additional pages attached

Steven J. Udick	Skiermont Derby LLP	
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Stamatios Stamoulis	Stamoulis & Weinblatt LLC	

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. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

☐ None/Not Applicable ☐ Additional pages attached

1:20-cv-00133-LPS	Novartis Pharm. Corp. v. Apotex Inc. et al.	

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). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable ☐ Additional pages attached

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TABLE OF ABBREVIATIONS

Abbreviation	Full Term
(xx:yy-zz) (xxxxx:yy-zz)	If this format cites to a patent it refers to column xx, lines yy-zz. If this format is citing to a transcript including trial transcript it refers to page xxxxx, lines yy-zz.
cl.xx	Claim no.xx [in cited patent]
Appx	Joint Appendix (cited by this Court as "JA")
Add.	Addendum filed by Novartis on July 21, 2022 (consisting of the Rehearing Decision and Rehearing Dissent dated June 21, 2022 (Dkt. 59))
SA	Supplemental Addendum filed by Novartis on July 21, 2022 (Dkt. 60-2) (consisting of Vacated Panel Decision and various Orders from other courts and matters).
'405 patent	U.S. Patent No. 9,187,405
ANDA	Abbreviated New Drug Application
Argentum IPR	Petition for inter partes review brought against the '405 patent in the PTAB by other generics (not HEC). Appx13693-13759, Appx13827-13884. The PTAB's IPR decisions was appealed before this Court, resulting in an oral argument in front of a Federal Circuit panel (Lourie, J., Reyna, J., and Chief Judge Moore). Appx21937-21946. Ultimately this Court issued a limited opinion as to standing due to settlements post-argument between Novartis and certain generics.
FDA	United Stated Food & Drug Administration
Gilenya	Novartis' branded oral fingolimod used to treat RRMS

Abbreviation	Full Term
HEC or Appellants	HEC Pharm Co., Ltd. and HEC Pharm USA Inc.
Kappos 2006	Abstract published May/June 2006 announcing Phase III trial administering 0.5 mg, 1.25 mg and placebo oral fingolimod to RRMS patients. Appx24722-24724 (appearing at Appx24723-24724 – "P569")
Kovarik	Prior art disclosing administration of fingolimod with a loading dose and serving as a basis of rejection for the '405 patent application. Appx3652-3678.
Novartis	Novartis Pharmaceuticals Corporation
MS	Multiple Sclerosis
District Court Order	Order, Final Judgment, and Injunction (District Court Dkt. 780), entered on September 11, 2020 [Appx1-42]
POSA	Person of ordinary skill in the art
PTAB	Patent Trials & Appeals Board
RRMS	Relapsing Remitting Multiple Sclerosis
Rehearing Decision or Decision	This Court's June 21, 2022 majority decision on panel rehearing, invalidating the '405 patent (Moore, C.J.; Hughes, J.) and dissent (Linn, J.) (Dkt. 51), also filed in Novartis' Addendum accompanying its Petition
Vacated Panel Decision	This Court's January 3, 2022 majority decision (Linn, J., O'Malley, J.) and dissent (Moore, C.J.) (Dkt. 42), filed in Novartis' Supplemental Addendum at SA1-25)
Pet.	Novartis' Petition for Panel Rehearing or En Banc Review filed on July 21, 2022 (Dkt. 59) requesting review of this Court's Rehearing Decision

Abbreviation	Full Term
HEC's Petition	HEC's Petition for Panel Rehearing or En Banc Review filed on February 23, 2022 (Dkt. 46)
Dr. Hoffman	HEC's Expert
Drs. Steinman, Jusko and Lublin	Novartis' Experts

INTRODUCTION

On a Petition for Rehearing, and in view of the undisputed trial testimony from Novartis' own expert witnesses juxtaposed against settled law, this Court invalidated Novartis' '405 patent in its Rehearing Decision ("Decision") for failure to provide written description of a claim limitation added many years after the original disclosure. Tellingly, Novartis ignores the basis of this Court's Decision, arguing instead that the original panel opinion must stand, simply because a judge from the first panel retired and a new judge was appointed on rehearing.

The Petition ignores applicable provisions in the U.S. Code that instruct and empower federal appellate courts with the authority to conduct their business. These provisions require three-judge panels to hear and determine cases and controversies and plainly state this Court may determine by rule the number of judges, **not less than three**, who constitute a panel. *See* 28 U.S.C. § 46. Instead, Novartis tethers its Petition to a 36-year-old footnote in *dicta* from *Universal Restoration, Inc. v. United States*, 798 F.2d 1400, 1406 n.9 (Fed. Cir. 1986), addressing a rehearing decision from a Board of Contract Appeal—which has never been cited by any court—although it did draw a dissent limited solely to rejecting that footnote.

Dispositively, Novartis concedes (or at least ignores without rebuttal), that the Decision's findings of clear error are supported with meticulous record

citations - support that includes the '405 patent specification and Novartis' own experts' admissions collectively establishing insufficient written description by clear and convincing evidence as a matter of settled law:

> 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**[] J.A. 22792. . . [T]he **district court's reliance** on a misquotation "ferreted into trial testimony by Novartis' experts" **was clearly erroneous**. […]
>
> 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**. […]
>
> 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.

Add. 7-9, 10 (emphasis added).

Novartis' Petition cites the same district court findings and trial testimony as the Decision's findings above but does not address the Decision's reasoning that those citations do not support the district court. (Pet., *passim*.) Novartis' Petition should be denied.

BACKGROUND

The '405 patent claims recite orally administering 0.5 mg of fingolimod

daily, "absent an immediately preceding loading dose regimen." Appx24741-24742. Although the negative limitation appears in every claim (added by prosecution amendment years after filing), it is nowhere disclosed in either the priority application or specification.

Following a bench trial, the district court *confirmed* there was "no recitation of a loading dose in the specification" (Appx26(¶61)), and the specification "does not describe loading doses." Appx27(¶¶64-65). It also determined, contrary to these findings and well-settled law, ***that the very absence of the negative limitation itself served as disclosure of the negative claim limitation***. Appx37-38(¶24).

But those findings relied solely upon misquoting the specification and those same experts admitted that there was no concept of loading dose in the specification nor any textual hook upon which to tether it. The specification does not modify daily dosing with "[i]nitially." Appx24741(11:6-16).

The Decision held the district court clearly erred based on both the absence of any disclosure of loading doses in the specification and on Novartis' experts misquoting the specification and providing numerous dispositive admissions. Add.7-11.

The Decision found four categories of dispositive admissions.

(1) The Decision found Drs. Lublin and Steinman admitted there is no

disclosure to skilled persons in the specification of loading doses at all, and no disclosure to forbid them. *See* Lublin, Appx22780 (admitting nothing in specification "discloses a rationale for [] prohibiting an immediately preceding loading dose"), Appx22791 (admitting regarding the specification, "that information of having a loading dose is not there), Appx22871-22872 (admitting specification does not disclose any risks or side effects of fingolimod); Steinman, Appx23344-23345 (admitting after reading the entire specification from skilled persons perspective there is no disclosure of *prohibiting* loading doses).

(2) The Decision found all of Novartis' experts admitted that skilled persons understood loading doses had been used with fingolimod and MS treatments—and could envision using loading doses prior to the claimed dosage. *See* Jusko, Appx23475-23476 (admitting skilled persons would have considered loading doses preceding the claimed dosage for several reasons, including prior use of loading doses and fingolimod's long half-life); Steinman, Appx23347-23348 (admitting skilled person knew loading doses were used in MS treatments); Appx23348 (admitting fingolimod has a long half-life); Lublin, Appx22780 (admitting skilled person knew fingolimod and loading doses had been used in MS trials); Appx22794 (admitting skilled person would at times "want to use a loading dose").

(3) The Decision found the experts admitted their opinions were rooted in the legal error that the presumption of validity requires the skilled person to

assume the patent is a "complete" document—and thus never disclosing even the concept of loading doses *is somehow itself evidence* that forbidding them *was the invention*. *See* Lublin, Appx22791 (admitting basis of his opinion is that a skilled person would read the specification "as a complete document" and thus no discussion of loading doses is disclosure to forbid them); Jusko, Appx23474-23475 (admitting his opinion is based on assumption the patent is "presumed complete").

(4) The Decision showed clear error based on misquoting the specification, and admissions that the Decision's interpretation of that language is actually correct. *See* Lublin, Appx22792 (when asked what the specification sentence "Initially patients receive treatment for 2 to 6 months," means to the skilled person, admitting it means patients are "taking the dosing outlined in that first sentence continually for two to six months"); Steinman, Appx23334 (testifying about the same sentence above, admitting "what they're saying" is that "you follow the patient for a while, 2 to 6 months is spelled out here. And, thereafter you keep them on treatment as long as the disease []isn't progressing"; also admitting a loading dose would be given "before the initial treatment"); Appx23343 (admitting "a loading dose would occur before the first daily dose").

The Vacated Panel Decision adopted the district court's findings, including those that clearly misquoted the specification—ostensibly because correction would "substitute [a judge's] own factual findings for those of the district court"

(SA23) and held in error that the presumption of validity means that a patent is presumed complete (SA21).[1]

ARGUMENT

I. This Court May Lawfully Appoint A New Judge On Panel Rehearing

Novartis takes issue with this Court's assignment of a new panel judge following Judge O'Malley's retirement, and with vacating this Court's January opinion through panel rehearing rather than *en banc* review. Novartis asserts that appointing a judge on panel rehearing when a judge retires is not permitted, thus HEC's Petition should have been denied for polling the *en banc* court. Pet., 11. This argument fails.

First, the Rehearing dissent did not raise any objection to the procedure employed on rehearing here upon Judge O'Malley's retirement. *See* Add.14-22.

[1] Novartis suggests that because it prevailed in a preliminary injunction proceeding and an IPR proceeding, the trial judge must not have clearly erred. (Pet., 1-2, n.1.) This ignores that neither the preliminary injunction nor PTAB finding was reviewed by this Court. But there has been limited review in this Court pertinent to each. A January 2020 panel (Lourie, J., Reyna, J., Moore, C.J.) considered the referenced IPR and during oral argument deep skepticism was expressed: "this is a claim limitation and it isn't found in the [2006] application . . . it's not a question of heightened or lowered. It's just not there." Appx21941:1-6; Appx21942:1-11. Novartis promptly settled with every party with standing, avoiding a decision on this issue. And during this appeal, HEC filed a motion to stay district court orders resetting ANDA final approval and extinguishing its claim to Novartis' injunction bond. Dkt.9. HEC argued it was likely to succeed on its written description argument for the negative claim limitation. A Federal Circuit motion panel saw merit in HEC's argument and granted the stay. Dkt.21 (Dyk, J., Bryson, J., Taranto, J.).

Second, Congress has long-authorized and empowered all courts established by Act of Congress, including this Court, with authority to "prescribe rules for the conduct of their business" that are consistent with Acts of Congress and the rules of practice and procedure prescribed under section 2072. *See* 28 U.S.C. § 2071(a); 28 U.S.C. § 2072; 28 U.S.C. § 46; Fed R. App. P. 47.

In particular, Federal Circuit panels must have at least three judges. *See* 28 U.S.C. § 46(b) ("In each circuit the court may authorize the hearing and determination of cases and controversies by separate panels, ***each consisting of three judges*** . . . the Federal Circuit . . . may determine by rule the number of judges, ***not less than three***, who constitute a panel"); § 46(c) ("(the Federal Circuit may sit in panels of more than three judges if its rules so provide), unless a hearing or rehearing before the court in banc is ordered"); § 46(d) ("A majority of the number of judges authorized to constitute a court or panel thereof, as provided in paragraph (c), shall constitute a quorum").

Accordingly, this Court adopted rules. Fed. Cir. R. 47.2 requires that cases and controversies not heard *en banc* "will be heard and determined by a panel consisting of an odd number of at least three judges." Assigning a new judge to a panel when an original panel member is unavailable due to resignation is also codified in this Court. *See* Fed. Cir. R. 47.11.

Novartis contends Rule 47.11 does not apply to rehearing petitions (Pet., 10-

11). It cites the "submission" definition from this Court's I.O.P., comparing it to "resubmission" in Fed. R. App. P. 40(a)(4)(B). However, "resubmission" is inapposite, occurring only when the grant of panel rehearing restores the case to calendar "for reargument or resubmission." Fed. R. App. P. 40(a)(4)(B)). That did not happen here. Instead, panel rehearing "made a final disposition of the case without reargument." *See id*. 40(a)(4)(A).

Novartis' comparison is irrelevant. The case remained on appeal, which continues until the appeal is determined. *See* 28 U.S.C. § 46(a), (b). That does not happen until the judgment is final and the appellate court no longer retains jurisdiction for rehearing or to amend its judgment. This "case was still pending on appeal" when retirement resulted in replacement of an unavailable judge, "as [the] mandate had not yet issued." *See GPX Int'l Tire Corp. v. United States*, 678 F.3d 1308, 1312 (Fed. Cir. 2012) (citing Fed. R. App. P. 41 (b)-(c)); *see also Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 721 F.3d 1330, 1345–46 (Fed. Cir. 2013) (until the mandate issues the "case" "is still pending appeal").[2]

Even if this Court did not specifically invoke Rule 47.11, that is of no

[2] Novartis asserts HEC (and the Decision) failed to identify anything "overlooked or misapprehended by the [now-Vacated Decision]." (Pet., 6, 9-10.) Not so. *See* Dkt. 46 at xii, 1-2, 9-16 (HEC's Petition). The Decision agreed with HEC. *See* Add.4-7 (clear errors of law); Add.7-11 (clearly erroneous findings of fact).

moment. As established above the procedure employed here is unquestionably consistent with federal law, appellate rules and this Court's rules. *See* Fed. R. App. P. 47(b) (authorizing federal appellate courts to "regulate [their] practice ***in a particular case*** in any manner consistent with [federal and local rules]").

Finally, Novartis' claim (Pet., 9-10), that "virtually every circuit" rejects appointing a replacement judge for panel rehearing of a divided panel is unsupported. Novartis fails to cite Circuit rules governing a panel rehearing tie, and most of its cited "examples" are unsupportive:

First Circuit: Novartis does not cite any supporting rule or Order;

Second Circuit (SA36), Fourth Circuit (SA37-38) and Fifth Circuit (SA40-41): no Circuit rule is cited; the panel rehearing votes are not disclosed (indicating panel rehearing may have resolved by quorum);

Seventh Circuit (SA43): no Circuit rule is cited but the Order provides two remaining members "have voted to deny rehearing," suggesting quorum was met;

Ninth Circuit: Novartis admits (Pet., 9 n.2) a replacement judge is assigned when a judge becomes unavailable (consistent with this Court's procedure here);

Tenth Circuit (*Williams*, 583 F.3d 1254 (10th Cir. 2009)): Neither the Petition (nor *Williams*) cites a Circuit rule but the dissent disclosed a no vote for panel rehearing. *Id*. at 1256 n.1;

Eleventh Circuit (*Fluor*, SA45-46): no Circuit rule cited but the Order

provides it "is being entered by a quorum of the two remaining judges pursuant to 28 U.S.C. §46(d)."

This falls far short of "virtually every circuit."[3]

Novartis cites the Supreme Court's rehearing procedure. (Pet., 8-9.) Those procedures are neither relevant nor binding on this or any other Circuit. Novartis does not argue to the contrary, nor could it. *See* Fed. R. App. P. 47(a) (empowering Circuit courts to make rules governing their practice consistent with Acts of Congress and 28 U.S.C. §2072). Because the Supreme Court has neither panel or *en banc* rehearing, a Justice must change their mind for rehearing to occur.

Universal Restoration's footnote 9 (Pet. 11), is inapposite. The footnote is *dicta*: "the issue of the propriety of the rehearing is not controlling here." 798 F.2d

[3] In two Novartis' "examples" where appellate courts declined to resolve a tie, denying rehearing, the Supreme Court granted certiorari and reversed on the merits. *See Blaszczak v. United States*, 141 S.Ct. 1040 (2021); *Volvo Trucks N. Am., Inc. v. Reeder-Simco GMC, Inc.*, 126 S.Ct. 860 (2006). *Cf. Carver v. Lehman*, 558 F.3d 869, 878-79 (9th Cir. 2009) (replacing judges superior to quorums because it strengthens the quality of opinions, "better enabling them to stand the test of time, and engender the respect of thoughtful citizens for both the opinion, and the court that produced it"); *see also* Samuel P. Jordan, *Irregular Panels*, 60 Ala. L. Rev. 547, 550, 592-594 (2009) (advocating for more replacements of unavailable judges and fewer quorum decisions).

at 1406 n.9.[4] It is not directed to panel rehearing on Circuit Courts and did not comment on the permissibility of a replacement judge for panel hearing when the remaining judges are divided. The dissent is limited to rejecting footnote 9, because "[i]t is *dicta* unnecessary to the decision and is unsupported by any cited authority relevant to this case." *Id*. at 1407. No court has ever cited it.

Like the court decisions relied on in *Universal Restoration's* Claims Court decision (*see* FN4, *supra*), Ohio's Supreme Court recently affirmed the replacement of an unavailable judge on rehearing. *See Jezerinac v. Dioun*, 2022 WL 549097, No. 2020-0743, at *4, ¶22 (Ohio, Feb. 24, 2022) ("we have little difficulty concluding that the [appellate court below] acted within the bounds of the law"); *see also id*., *2-3, ¶¶13-14 (analyzing Ohio requirement nearly the same as those set forth in 28 U.S.C. § 46(b), Fed. Cir. R. 47.2 and 47.11; explaining that failure to replace a judge is "at odds with basic conceptions of procedural fairness.").

II. The Decision Applies Settled Law and Finds Clear Error

Novartis asserts the Decision creates a never-before applied "new rule" and

[4] All ALJs denied a motion to vacate the rehearing decision, including the dissenting judges. *See Universal Restoration*, 798 F.2d at 1405. The U.S. Claims Court rejected the argument that the rehearing decision was invalid due to the replacement judge, *see Universal Restoration, Inc. v. United States*, 8 Cl. Ct. 510, 513-514 (1985) (*rev'd on other grounds*), citing the ASBCA's and others prescribed rules as permitting a replacement judge on rehearing.

"inflexible heightened standard" for written description that "conflicts with circuit precedent" imposing "a rigid *per se* rule." (Pet., 2-3, 6, 12-14.) Not so. The Decision creates no new rule or standard, and is fully consistent with precedent, holding:

> 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.

Add.12.

It reaffirmed settled law that inherent disclosure can satisfy written description, even where the disclosure is silent, when it is necessarily present to skilled persons. Add.6. Here, there was no relevant disclosure.

Novartis argues written description does not demand "any particular *form* of disclosure," and the specification need only convey disclosure to skilled persons, "regardless of *how* it conveys such information." (Pet., 12.) These statements require disclosure. The Decision held, based on the testimony, there was no

disclosure of an invention forbidding loading doses to skilled persons at all—not in *any form*. *See supra*, pp. 3-5; Add.7-11. Moreover, this Court *has found* certain "forms" of disclosure insufficient.

Specifically, this Court rejects disclosure conveying to skilled persons that the claimed invention is obvious from that disclosure, or one that leads to speculation as to what might have been invented but not disclosed. *See, e.g.*, *Univ. of Rochester v. G.D. Searle & Co. Inc.*, 358 F.3d 916, 925-27 (Fed. Cir. 2004) (written description deficient on the face of the specification despite contrary expert testimony); *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 2007) ("*all* the *limitations* must appear in the specification"; "speculat[ion] as to modifications that the inventor might have envisioned, but failed to disclose [is insufficient]"); *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010) (no requirement the disclosure recite claim "*in haec verba*, [but] a description that merely renders the invention obvious does not satisfy the requirement"); *id*. ("actual 'possession' or reduction to practice outside of the specification is not enough"; rather, "the *specification itself* that must demonstrate possession."); *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1347 (Fed. Cir. 2011) (holding written description can be evidenced "solely on the face of the patent specification"); *Nuvo Pharm. (Ireland) Designated Activity Co. v. Dr. Reddy's Labs. Inc.*, 923 F.3d 1368, 1381 n.4 (Fed. Cir. 2019) ("Dispositively, [the

proffered expert] testimony is irrelevant to the written description inquiry, because it does not point to any disclosure in the specification to which the testimony could relate").

Novartis' cite to §2163(II)(A)(3(b)) of the MPEP's reference to "implicitly" (Pet., 13-14) should be interpreted together with MPEP §2173.05(i), which provides "[t]he mere absence of a positive recitation is not basis for an exclusion." These provisions together establish that "implicit" disclosure does not include and is not satisfied by "the mere absence of a positive recitation."

The Decision confirms there must be disclosure to the skilled person in the specification, but even if there is not, adequate written description can exist if it is necessarily present to the skilled person. *See, e.g.*, *Martin v. Mayer*, 823 F.2d 500, 505 (Fed. Cir. 1987) (inherent disclosure asks "whether the application necessarily discloses that particular [claimed invention]"); *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159 (Fed. Cir. 1998) ("the missing descriptive matter must necessarily be present in the [original] application's specification such that one skilled in the art would recognize such a disclosure"); *TurboCare Div. of Demag Delaval Turbomachinery Corp. v. Gen. Elec. Co.*, 264 F.3d 1111, 1119 (Fed. Cir. 2001) ("the [claim limitation] must be actually or inherently disclosed; that the location may be obvious from the disclosure is not enough"); *PowerOasis, Inc. v. T-Mobile USA, Inc*., 522 F.3d 1299, 1309-1310 (Fed. Cir. 2008) (written description was

inadequate where there "is simply no disclosure in the Original Application of [the limitation]"); *Research Corp. Techs., Inc. v. Microsoft Corp.*, 627 F.3d 859, 870 (Fed. Cir. 2010) ("parent application must actually or inherently disclose the elements of the later-filed claims").

Novartis asserts the Decision "brush[ed] aside unrebutted expert testimony" as to how a skilled artisan would read the specification. (Pet., 3.) But Novartis does not rebut the Decision's detailed recitation of clear error from the district court's reliance on that very testimony. *Compare* Add.7-11; *with* Pet.4-5, 12-17.[5] As shown *supra*, pp. 3-5, the trial testimony directed to whether the specification discloses an invention to skilled persons that forbids loading doses utterly failed to show that a skilled person would discern from the specification an invention forbidding loading doses; instead the trial testimony consisted predominantly of four categories of admissions establishing the opposite. *See Alcon Research Ltd. v.*

[5] Novartis cites the district court's finding citing Dr. Hoffman's testimony about fingolimod risks and that skilled persons would not expect a fingolimod loading dose to be used for RRMS. Pet. 5 (citing Appx27, which cites Appx23126-23127, 23129). This is the third appellate brief from Novartis citing this testimony. However, none of the decisions from this Court has cited this testimony or the district court paragraph citing it. HEC noted these are citations to testimony directed to how a skilled person would interpret Kappos 2006 for purposes of anticipation. It is not testimony for how a skilled person would interpret the '405 specification. Novartis' experts admitted skilled persons would have considered loading doses. *See supra*, p. 4 (Category 2). With respect to the '405 specification, Dr. Hoffman testified without contradiction (Appx23118) that skilled persons would not find disclosure of an invention "avoiding loading doses" anywhere in the specification.

Barr Labs., Inc., 745 F.3d 1180, 1186 (Fed. Cir. 2014) ("a factual finding is clearly erroneous when, despite some supporting evidence, we are left with a definite and firm conviction that the district court was in error.").

As set forth *supra*, pp. 3-5, the trial testimony directed to the negative claim limitation consisted of four categories, and the Decision meticulously found that virtually all of the testimony the district court cited established insufficient written description for the negative claim limitation by clear and convincing evidence, and that the contrary district court findings resulted from clear errors. *Id*.

That cited testimony, the '405 patent, and its file history, encompass the trial record directed to the adequacy of written description for the "absent an immediately preceding loading dose" claim limitation. It establishes clearly and convincingly that there is no disclosure to skilled persons in the patent's specification of an invention that forbids an immediately preceding loading dose.

It's just not there.

CONCLUSION

Novartis' Petition should be denied.

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Respectfully submitted:

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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Case Number: 2021-1070

Short Case Caption: Novartis Pharmaceuticals v. Accord Healthcare Inc.

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