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-

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

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

DISCUSSION

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

A

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

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

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

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

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

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

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

marks and citation omitted)). When the specification is itself silent regarding a negative limitation, testimony from a skilled artisan as to possibilities or probabilities that the recited element would be excluded would not suffice, lest such testimony could effectively eliminate the written description requirement. If silence were generally sufficient, all negative limitations would be supported by a silent specification. If, however, a patent owner could establish that a particular limitation would always be understood by skilled artisans as being necessarily excluded from a particular claimed method or apparatus if that limitation is not mentioned, the written description requirement would be satisfied despite the specification's silence.

B

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

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

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

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

J.A. 22792 (emphasis added).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CONCLUSION

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

REVERSED

COSTS

No costs.

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v.

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

LINN, *Circuit Judge*, dissenting.

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

I

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

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

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

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

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

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

which is inconsistent with the disclosure is not adequately described.

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

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

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

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

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

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

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

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

II

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

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[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.