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. 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.,

(For Continuation of Caption See Inside Cover)

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

BRIEF OF *AMICI CURIAE* INTELLECTUAL PROPERTY LAW PROFESSORS IN SUPPORT OF NOVARTIS PHARMACEUTICALS CORPORATION'S PETITION FOR PANEL AND *EN BANC* REHEARING

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Defendants,

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

Defendants-Appellants.

CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rules 29(a) and 47.4, counsel for *amici curiae* certifies to the following:

1. Represented Entities. Fed. Cir. R. 47.4(a)(l). Provide the full names of all entities represented by undersigned counsel in this case.

See Attachment A.

2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2). 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.

3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3). 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.

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.

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).

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.l(b) (organizational victims in criminal cases) and 26.l(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

None.

Dated: August 4, 2022

/s/ Christopher E. Loh
Signature of counsel

Christopher E. Loh
Printed name of counsel

ATTACHMENT A TO CERTIFICATE OF INTEREST

Affiliation is provided for identification purposes only. All signatories are participating in their individual capacity, not on behalf of their institutions.

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STATEMENT OF INTEREST OF *AMICI CURIAE*

Amici curiae are intellectual property law professors. They have no personal interest in the outcome of this case or the patent at issue, U.S. Patent No. 9,187,405 ("'405 patent"). They submit this brief to highlight conflicts between the June 21, 2022 decision of the rehearing panel majority and existing Federal Circuit and Supreme Court precedent—as evidenced by the split between the June 21, 2022 second panel decision and the earlier January 3, 2022 decision in the same case. *Amici* respectfully urge the Court to grant Novartis's petition for rehearing *en banc* to address those conflicts.

Amici have authorized the undersigned to file this brief. This brief was not authored in whole or in part by any party's counsel. No person or entity other than *amici* or their counsel contributed financially to its preparation or submission. *Amici* have no stake in the parties or case outcome.

ARGUMENT

1. The Second Panel Decision Creates a New "Necessarily/Always" Written Description Standard

While the second panel decision states that it creates no new written description standard, that is incorrect. The decision states that written description exists ***only*** if there is express support or if "a particular limitation would ***always*** be understood by skilled artisans as being ***necessarily***" present. Slip op. at 7 (emphasis added). The decision explains that, "[w]hen the specification is itself

silent regarding a negative limitation, testimony from a skilled artisan as to possibilities or probabilities that the recited element would be excluded would not suffice, lest such testimony could effectively eliminate the written description requirement." *Id*. That rule forecloses reliance on testimony about how a person having ordinary skill in the art ("PHOSITA") would understand the text, structure and technological context of the specification. Although a negative claim limitation was at issue, the decision suggests that the new standard should apply equally to positive and negative limitations. Slip op. at 12 (emphasizing that the same standard applies "for positive limitations" as "for negative limitations").

The second panel decision's new standard for limitations other than those expressly in the written description is contrary to Federal Circuit precedent. As an initial matter, it erroneously places the burden of proving validity upon the owner of an issued patent. *Cf. Tech. Licensing Corp. v. Videotek, Inc*., 545 F.3d 1316, 1329 (Fed. Cir. 2008) (ultimate burden of proving invalidity by clear and convincing evidence rests with patent challenger). And the substance of the new standard is contrary to *Ariad Pharms., Inc. v. Eli Lilly & Co*., 598 F.3d 1336, 1351–52 (Fed. Cir. 2010) (*en banc*), wherein the *en banc* Federal Circuit established that written description does not require any "particular form of disclosure." On the specific matter of negative limitations, *Inphi Corp. v. Netlist,*

Inc., 805 F.3d 1350, 1356 (Fed. Cir. 2015) clarified that there is no "reason to [] articulate a new and heightened standard for negative claim limitations."

Decisions like *Ariad* and *Inphi* establish that the written description in a specification must be evaluated in its proper technological context, without wooden rules. While the Federal Circuit has held that written description can ***also*** be shown through inherent disclosure, in which a claim element not expressly disclosed in the specification is necessarily present, *e.g.*, *Cont'l Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268–69 (Fed. Cir. 1991), the Federal Circuit—until now—has never suggested that, absent *in haec verba* disclosure, the written description requirement can ***only*** be met through inherent disclosure, wherein the specification "necessarily" or "always" includes a positive limitation or excludes a negative one.

A good example of the Federal Circuit's flexible approach to written description is seen in *Pozen Inc. v. Par Pharm., Inc.*, 696 F.3d 1151 (Fed. Cir. 2012). There, claims to a drug's packaging and container were challenged on § 112 grounds because those ideas were nowhere in the specification. *Id.* at 1166. The district court nevertheless found that a PHOSITA "would know that medications are not simply handed out to patients. Rather, pharmaceutical products, like the claimed tablets, are routinely administered in containers or packages." *Pozen Inc. v. Par Pharm., Inc.*, 800 F. Supp. 2d 789, 821–22 (E.D.

Tex. 2011). This Court affirmed for lack of clear error. 696 F.3d at 1167. The same flexible approach should have yielded the same result in the present case.

But it did not. Instead, the second panel decision applied the sort of rigid rule the Supreme Court has repeatedly admonished against in patent law. In so doing, the decision jeopardizes the validity of thousands of issued patent claims and upsets expectations over how the written description requirement should apply to future claims.

2. The New Standard Deprives Patentees of the Ability to Limit Claims to Avoid the Prior Art

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

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

Consider the situation described in *In re Wertheim*, 541 F.2d 257, 263 (C.C.P.A. 1976), in which the applicant discovers during prosecution that the prior art covers part of the invention as originally claimed and described. The applicant should be able to narrow its original claims with a negative limitation to carve out

that aspect of the invention. Indeed, prior decisions have encouraged patentees to include such negative limitations—even if not specified in their written descriptions—so long as a PHOSITA reasonably would understand that the patentee possessed the narrowed invention. *E.g.*, *Union Oil Co. of Cal. v. Atl. Richfield Co.*, 208 F.3d 989, 1000 (Fed. Cir. 2000); *In re Johnson*, 558 F.2d 1008, 1018–19 (C.C.P.A. 1977). As the Federal Circuit's predecessor observed in *Wertheim*:

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

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

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

In depriving patent applicants of the option to rely on negative limitations, the new standard imperils meaningful patent protection for all inventions. This burden likely will fall heaviest upon pharmaceutical and biotechnology inventions, which often can address an array of diseases through the same mechanism of action. John Carroll, *One Drug, Many Uses*, 2 Biotech. Healthc. 56, 58–61 (2005). For example, fingolimod not only can be used to treat relapsing remitting multiple sclerosis ("RRMS"), as claimed in the patent at issue in this case, but also has utility in treating transplant rejection, viral myocarditis, and autoimmune disorders other than RRMS. U.S. Patent No. 8,324,283 at col. 12, ll. 19–37. To meet the new "necessarily/always" standard any time treatment-related prior art is cited during prosecution, specifications for drug patents would have to include every detail of every treatment protocol for every disease for which the drugs have been found useful, even if those details were already well-known in the art. Such a standard would be prohibitive and would endanger a significant percentage of drug patents.

Likewise, pharmaceutical and biotechnology patent applicants often must file broad genus claims at the start of each drug development cycle to cover all potential drug candidates that may later enter clinical trials. Dmitry Karshtedt *et al.*, *The Death of the Genus Claim*, 35 Harv. J. Law & Tech. 1, 14–15 (2021). The law should not limit the ability of these applicants to pare back the scope of their

original genus claims, including through the use of negative limitations, in order to avoid the prior art and to align patent scope with the subset of drug candidates ultimately selected for development.

The new standard thus would undermine the value of pharmaceutical and biotechnology patents and in turn undermine incentives to develop innovative new medicines. Patents are pivotal to protecting the multi-year and multi-billion dollar investments necessary to develop new products. *E.g.*, J.A. DiMasi *et al.*, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 24–25, 31 (2016) (estimating costs exceeding $1.395 billion for development of a pharmaceutical, and a synthesis-to-market approval timeline totaling more than 10 years); Jorge Mestre-Ferrandiz *et al*., *The R&D Cost of a New Medicine*, Off. Health Econ. (2012), (https://www.ohe.org/system/files/private/publications/380%20-%20R%26D%20Cost%20NME%20Mestre-Ferrandiz%202012.pdf?download=1) (similar). Absent the prospect of obtaining appropriate patent protection, most pharmaceutical and biotechnology companies would not be able to bear the time and cost associated with developing new medicines.

3. The Second Panel Decision Engaged in Improper Fact-Finding

Fed. R. Civ. P. 52(a)(6) states that a court of appeals "must not . . . set aside" a district court's "[f]indings of fact" unless they are "clearly erroneous." In *Teva*

Pharms. USA, Inc. v. Sandoz, Inc., 574 U.S. 318 (2015), the Supreme Court held that this rule constituted a "clear command," *id.* at 318, and criticized the Federal Circuit there for engaging in improper appellate fact-finding to overturn the district court's conclusion that a patent was valid based upon the testimony of the patentee's expert. *Id.* at 335–36.

This case presents an even more egregious case than *Teva* of improper appellate fact-finding. Here, the second panel's decision overturned both the district court's finding of patent validity and the January panel majority's affirmance of that finding—all of which were consistent with fact findings by four prior judges (three in a parallel IPR proceeding on the '405 patent, and then-District Judge Stark on a motion for a preliminary injunction). The second panel did so by treating the "plain text" of the specification as negating the ***unrebutted*** testimony of four experts as a matter of law. Slip op. at 8. Indeed, the sole decision the second panel cites to support its disregard of lower-court fact-finding is not about the written description requirement, but instead is about claim construction and *de novo* review. *Id.*, citing *Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys.*, 132 F.3d 701, 706 (Fed. Cir. 1997).

The second panel engaged in improper fact-finding, notwithstanding that the written description requirement has long been held to be a pure issue of fact addressed from the perspective of the PHOSITA. *Allergan, Inc. v. Sandoz Inc.*,

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

By failing to defer to the unrebutted fact-finding of four experts and the district court on that question, the second panel decision adds a further layer of unpredictability to an already intractable written description requirement. Decisions like these generate uncertainty over the value of existing patents and discourage incentives to seek future ones; fuel the perception of the Federal Circuit as an overactive and unpredictable court;[1] diminish the importance of expert

[1] *E.g.*, Andrew Karpan, *Fed. Circ. Reverses Initial Panel To Find Gilenya IP Invalid*, Law 360, June 21, 2022 (https://www.law360.com/articles/1504555?scroll=1&related=1) (describing how the second panel's "sudden about-face startled" patent practitioners); Kaitlin Farrell and Austin Keith, *Federal Circuit Rehearing Panel Vacates its January Decision and Reverses District Court Finding of Sufficient Written Description for Negative Claim Limitation*, J.D. Supra, July 6, 2022 (https://www.jdsupra.com/legalnews/federal-circuit-rehearing-panel-vacates-7497636/) (describing how the panel decisions here "expose discord among Federal Circuit Judges" and create uncertainty); Luke T. Shannon and Andrew M. Solomon, *Silence is Not Golden - Federal Circuit Invalidates Method of Treatment Patent for Lack of Written Description*, The National Law Review,

testimony in patent litigation; and undermine the independent authority of district courts to resolve questions of fact.

Last, the second panel decision contradicts the Federal Circuit's assurance that a patent specification need not teach, and "preferably omits," that which is already known in the art. *E.g.*, *Hybritech, Inc. v. Monoclonal Antibodies, Inc*., 802 F.2d 1367, 1384 (Fed. Cir. 1986). The decision ignores that written description—like enablement—requires consideration of the PHOSITA's knowledge of the art at the time the invention was made. *Ariad*, 598 F.3d at 1351; *Capon*, 418 F.3d at 1358. As the three Administrative Law Judges found in the above-mentioned parallel IPR proceeding, "the use of loading doses [according to both expert testimony and supporting evidence], 'are not today, and were not in June 2006, part of the accepted MS or RR-MS treatment protocols.'" *Apotex Inc. v. Novartis AG*, IPR2017-00854, 2018 WL 3414289 (P.T.A.B. July 11, 2018), at *10. A PHOSITA clearly would have known that a loading dose was ***not*** part of the '405 patent's claimed RRMS treatment method as of its 2006 invention date. Contrary to the approach taken by the second panel, the Federal Circuit repeatedly has allowed patentees to rely on prior art to demonstrate to a PHOSITA that the inventor had invented what was claimed. *E.g.*, *Falkner v. Inglis*, 448 F.3d 1357,

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June 24, 2022 (https://www.natlawreview.com/article/silence-not-golden-federal-circuit-invalidates-method-treatment-patent-lack-written) (noting how the second panel decision can be used to create uncertainty).

1366-68 (Fed. Cir. 2006); *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1285-87 (Fed. Cir. 2012); *Union Oil Co. of Cal.*, 208 F.3d at 999–1001. And because avoidance of loading doses was known in the art, the exclusion of a loading dose could not have been a novel or "essential element" of the invention for which written description support was particularly important. *Cf. Gentry Gallery, Inc. v. Berkline Corp*., 134 F.3d 1473, 1479–80 (Fed. Cir. 1998) (invalidating claims for lack of written description of "essential element"); *Capon*, 418 F.3d at 1358 (finding error in BPAI's requirement that written description specify prior art element unrelated to novelty of claimed invention). The written description inquiry here thus did not warrant any contrary, "plain text" fact-finding by the second panel.[2]

CONCLUSION

For the foregoing reasons, *amici* respectfully urge the Court to grant Novartis's petition for panel and *en banc* rehearing.

[2] To the extent the second panel majority did cite facts adduced at trial, its fact-finding was selective and clearly contrary to the prior art.

Respectfully submitted,

Dated: August 4, 2022

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APPENDIX

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PROOF OF SERVICE

The undersigned counsel for *amici curiae* certifies that, on August 4, 2022, the foregoing **BRIEF OF *AMICI CURIAE* INTELLECTUAL PROPERTY LAW PROFESSORS IN SUPPORT OF NOVARTIS PHARMACEUTICALS CORPORATION'S PETITION FOR PANEL AND *EN BANC* REHEARING** was filed with the Clerk of the United States Court of Appeals for the Federal Circuit via the CM/ECF system, which will send notice of such filing to all registered CM/ECF users.

Dated: August 4, 2022

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CERTIFICATE OF COMPLIANCE
WITH TYPE-VOLUME LIMITATIONS

The undersigned counsel for *amici curiae* certifies that the foregoing brief complies with the type-volume limitation of Fed. R. App. P. 32(a) and Fed. Cir. R. 35(g)(3). The brief contains 2550 words, excluding portions exempted by Fed. R. App. P. 32(f) and Fed. Cir. Rule 32(b). The undersigned counsel also certifies that this brief complies with the type-face requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6). The brief was prepared in Microsoft Word for Office 365 using a proportional 14-point Times New Roman type-face.

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