No. 22-671

In The Supreme Court of the United States

NOVARTIS PHARMACEUTICALS CORPORATION,
PETITIONER

v.

HEC PHARM CO., LTD., ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF FOR PETITIONER

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CORPORATE DISCLOSURE STATEMENT

The corporate disclosure statement included in the petition for a writ of certiorari remains accurate.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

TABLE OF AUTHORITIES—Continued

STATUTES

OTHER AUTHORITIES

TABLE OF AUTHORITIES—Continued

REPLY BRIEF FOR PETITIONER

HEC's response confirms the need for review. HEC concedes that multiple circuits would not have added a new judge and overturned an already-entered decision on "panel" rehearing. This issue—about both the finality of appellate decisions and a judge's power to participate—is too important to allow circuit-to-circuit variability. And these circumstances recur far more frequently than HEC pretends, with at least one new example since Novartis's petition. This Court should intervene now to bring the Federal and Ninth Circuits in line with the governing statute and principles of sound judicial administration.

On the patent-law ruling, HEC's "fact-bound" characterization backfires—the disputed factual issues here were for factfinders, not appellate judges. Multiple factfinders found against HEC. The second Federal Circuit panel reversed only because of its heightened legal standard, which HEC never even tries to square with 35 U.S.C. § 112(a).

Absent intervention, Novartis will be deprived of its patent covering Gilenya®, a groundbreaking multiple-sclerosis treatment that has benefited tens of thousands of patients. That success is why HEC sought to market a generic. After repeatedly losing on the facts, HEC prevailed only because the Federal Circuit departed—on both procedure and substance—from statutory text and longstanding principles. Both departures warrant review.

I. THIS COURT SHOULD REVIEW WHETHER DIFFERENTLY CONSTITUTED PANELS CAN REDECIDE ALREADY-ENTERED DECISIONS ON "PANEL" REHEARING

A. Text and Precedent Support Review

To defend adding a new judge for "panel" rehearing, HEC focuses on local rules. Opp. 11-12. That gets the analysis backwards. Local rules must be "consistent with Acts of Congress." 28 U.S.C. § 2071(a). The starting point for circuit judges' "power to participate" is thus what Congress, not the judges themselves, prescribed. *Yovino v. Rizo*, 139 S. Ct. 706, 709 (2019).

Congress prescribed that "[c]ases and controversies shall be heard and determined by a court or panel of not more than three judges, unless a hearing or rehearing before the court in banc is ordered." 28 U.S.C. § 46(c) (parenthetical omitted). That panel can grant relief only if "[a] majority of the number of judges authorized to constitute" it agrees. *Id.* § 46(d). Thus, once a three-judge panel has "determined" a case—which happens when the panel publicly enters its decision—Congress authorized only a majority of those three judges, or the en banc court, to alter that determination. *Id.* § 46(c), (d); *Yovino*, 139 S. Ct. at 708.

HEC never grapples with this plain reading. Instead, it complains Section 46 does not spell out in haec verba "what happens when" a judge "retires or dies" after decision entry. Opp. 12-14. But HEC omits

text when quoting paragraph (d), which specifies who "may legally transact judicial business." *Nguyen v. United States*, 539 U.S. 69, 82 n.14 (2003). Congress authorized only a majority of the panel "*as provided in paragraph (c)*" to transact business. 28 U.S.C. § 46(d) (emphasis added); *see* Opp. 12. Because paragraph (c) defines the panel as the judges who "determined" a given case, Congress did spell out what post-determination unavailability means—only a majority of the remaining panel members, or the en banc court, can act. *Id.* § 46(c), (d).

HEC is wrong to demand more from the text. In *United States v. American-Foreign Steamship Corp.*, Justice Harlan's dissent similarly complained that "nothing in 28 U.S.C. § 46(c)" explicitly "prevented" a judge who was active when a court granted en banc review from voting if he took senior status before the en banc decision's public entry. 363 U.S. 685, 691-93 (1960). Yet this Court held senior judges were "without power to participate" because Section 46's import was "plain enough." *Id.* at 688, 691. *Yovino* held similarly: although Section 46 never expressly recites the effect of a judge's passing before a decision's public entry, his participation was precluded by the interplay of paragraphs (c) and (d), combined with the settled understanding that cases are determined when decisions are publicly entered. 139 S. Ct. at 708-10.

This precedent applied the same rule that controls here—Congress made public entry the critical step, because that is when a case is "determined." As amici retired judges explain, the Federal and Ninth Circuits'

approach wrongly treats a public decision as preliminary, as "'only part way through its finalization process.'" Retired Judges 8-9 (quoting *Carver v. Lehman*, 558 F.3d 869, 878 (9th Cir. 2009)). But a decision's public entry marks when a case is "determined" and its three-judge panel fixed. HEC ignores this reasoning in asserting "*Yovino* and *American Steamship* merely confirm" retired judges cannot vote for rehearing. Opp. 13.

HEC claims this Court has endorsed the sweeping proposition that circuit courts have "'wide latitude of discretion' on questions of procedure." Opp. 14-15 (citation omitted). But what this Court actually held is narrower: Congress granted circuit courts discretion specifically to establish procedures for en banc review. *Western Pacific R.R. Corp. v. W. Pac. R.R. Co.*, 345 U.S. 247, 257-59 (1953). That conclusion followed from "an harmonious reading" of Section 46 and the "legislative background" on en banc procedures. *Ibid.*; *see Shenker v. Baltimore & Ohio R.R. Co.*, 374 U.S. 1, 4-5 (1963). Yet even so, *Western Pacific* rejected Ninth Circuit practices that undermined fairness and sound judicial administration. 345 U.S. at 259-68.

This Court should likewise reject the practice here—even setting aside Section 46. HEC never disputes this Court's supervisory authority to intervene. Opp. 14-15. Instead, HEC speculates the Federal Circuit applied its Rule 47.11, which allows the chief judge—the original dissenter here—to "secure" a new judge for "a panel that has heard oral argument or taken under submission any appeal,

petition, or motion." But that rule is inapplicable to rehearing petitions. Unlike some petitions, rehearing petitions are neither argued nor "taken under submission." Fed. R. App. P. (FRAP) 40(a)(2); Fed. Cir. I.O.P. #1(2). Once a panel publicly enters its decision, the appeal is no longer under submission; the panel would first have to grant rehearing before the appeal could be under "resubmission." FRAP 40(a)(4).

Even if local rules could be stretched to cover this situation, the question is too important to allow circuit-by-circuit variability. This is not a question of "administrative machinery" but of "fundamental requirements": the finality of already-entered decisions and who has power to redecide them. *See Western Pacific*, 345 U.S. at 250, 260.[1]

B. History and Circuit Division Are Clear

This Court interprets Section 46 to accord with longstanding judicial practice, as HEC never disputes. Yet HEC identifies no established practice supporting its interpretation. *Yovino*, 139 S. Ct. at 709-10 (relying on such absence to reverse). HEC dismisses this Court's rule requiring a majority member to concur in rehearing as "not govern[ing] the Federal Circuit." Opp. 13. But that rule reflects a century-plus of judicial practice, predating the circuit courts of appeals. Pet. 25-26.

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[1] Although HEC half-heartedly calls this issue "newly minted" (Opp. 10), Novartis pressed this principle at its first opportunity, citing Section 46 and many of the same authorities. C.A. Pet. 7-11.

Lacking historical support, HEC labels the assertion of a circuit split "frivolous." Opp. 4, 16-18. But HEC cannot back up its bluster. It concedes the essential fact: multiple circuits deny panel rehearing 1-1 without adding a new judge. Opp. 16-18. The outcome here would have been different in those circuits. That warrants intervention.

Nothing about HEC's quibbles over Novartis's examples suggests otherwise:

- HEC concedes the D.C., Sixth, and Eighth Circuits have denied panel rehearing 1-1 without appointing a new judge. Opp. 17.
- HEC concedes the Third Circuit requires concurring-judge support for rehearing but complains of no "on-point ruling." Opp. 18. *Ranke v. Sanofi-Synthelabo Inc.* is on point. 436 F.3d 197, 206 (3d Cir. 2006). Judge Ambro dissented from the panel decision, which then-Judge Alito had joined. *Ibid.* Without Justice Alito, the Third Circuit denied panel rehearing 1-1, noting "Judge Ambro voted for rehearing." *Id.*, No. 04-4514 (Feb. 28, 2006);[2] Retired Judges 12. HEC is just wrong that the "two remaining judges were in agreement." Opp. 18 n.7.
- HEC acknowledges then-Judge Gorsuch's statement that the Tenth Circuit would deny panel rehearing after a resignation left the panel "in a tie," though HEC claims not to know "what a 'tie' signifies." Opp. 17 & n.6.

[2] https://tinyurl.com/yckpdd56.

Instead, HEC cites an irrelevant 2-0 panel-rehearing denial. *Ibid.*

- Novartis explained the Second Circuit's similar practice. Pet. 24. HEC responds with two cases involving rehearing after unanimous two-judge-quorum decisions. Opp.16-17. But both accord with the principle that rehearing requires agreement from a "judge who concurred in the decision." *Ogden Corp. v. Travelers Indem.*, 924 F.2d 39, 43 (2d Cir. 1991). And the third judge was added to decide issues, first raised on rehearing, about the authority of two-judge panels. *Whitehall Tenants Corp. v. Whitehall Realty Co.*, 136 F.3d 230, 231-32 (2d Cir. 1998); *United States v. Desimone*, 140 F.3d 457, 458-59 (2d Cir. 1998).

- HEC dismisses orders from the Fourth, Fifth, Seventh, and Eleventh Circuits as "not show[ing] a split vote on the rehearing petition." Opp. 18. But those orders uniformly deny panel rehearing without adding a judge under the circumstances here: a divided panel decision followed by a majority member's unavailability. Pet. 24-25. HEC provides no counterexample—just the implausible inference that *none* of those dissenting judges favored rehearing. And former Fourth and Seventh Circuit judges (including the author of one of those divided decisions) have weighed in against the Federal and Ninth Circuits' approach. Retired Judges 8-14.

C. The Issue Is Important and Recurring

Almost every retirement, resignation, death, or elevation produces the circumstances HEC dismisses as purportedly "unusual" (Opp. 20): the unavailability for rehearing of a judge in a divided panel majority. For instance, when Fifth Circuit Judge Costa resigned, at least four rehearing petitions were pending or subsequently filed from divided decisions he joined. *E.g.*, *Crittindon v. LeBlanc*, No. 20-30304 (5th Cir. Jan. 31, 2023); *In re Silver State Holdings*, No. 21-10212 (5th Cir. Oct. 3, 2022). In two others, no petition was filed—but had Judge Costa resigned from the Federal or Ninth Circuits, the losing party likely would have taken the chance for a do-over.

In those circuits, the recurrence risk is high. HEC acknowledges the Ninth Circuit has long followed this practice and shows no signs of stopping. Opp. 16; *e.g.*, *United States v. Kyllo*, 190 F.3d 1041 (9th Cir. 1999) (newly formed panel granting "panel" rehearing and overturning decision). Since Novartis filed this petition, rehearing was sought from a divided decision that Judge Feinerman (sitting by designation) joined one day before resigning. *Smith v. Agdeppa*, 56 F.4th 1193 (9th Cir. 2022) (petition pending; response requested). Because he was sitting with the Ninth Circuit (instead of, say, the Seventh), that published decision is now subject to do-over. And Judge Watford's upcoming resignation may soon produce more examples.

The repeat risk is similar in the Federal Circuit. Twelve of that court's nineteen judges are eligible to

retire.[3] That makes it likely this situation will recur in a court that regularly decides cases, like this one, with significant financial and public consequences.

Given these stakes, review would be warranted regardless of recurrence. This Court granted review despite the "highly unusual" practice in *Nguyen* and despite being "aware of no cases" similar to *Yovino*. *Nguyen*, 539 U.S. at 73; *Yovino*, 139 S. Ct. at 709-10. Indeed, *Yovino* summarily reversed based on Section 46 and the same precedent pressed in Novartis's petition. *Contra* Opp. 21.

This Court's decisions reviewing compliance with Section 46 demonstrate this issue's importance. Whether an unauthorized judge participated in overturning an already-entered precedential decision goes to "the integrity as well as the public reputation of judicial proceedings." *Nguyen*, 539 U.S. at 83 n.17. HEC never disputes that the Federal and Ninth Circuits' approach risks undermining finality, increasing intra-circuit conflicts, and eroding public confidence in the judiciary. Pet. 27-29; Law Professors and Civil Procedure Scholars 9-15. Intervention is needed now.

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[3] https://cafc.uscourts.gov/home/the-court/judges/judge-biographies/.

II. THE PATENT QUESTION WARRANTS REVIEW

A. The Federal Circuit Has Added Atextual Requirements

HEC again avoids the statutory text when trying to defend the Federal Circuit's patent-law ruling. That text requires a "full," "clear," "concise," and "exact" "description of the invention," measured from the perspective of a "person skilled in the art." 35 U.S.C. § 112(a). The Federal Circuit imposed an additional, unwritten requirement: even when skilled artisans would understand a patent as implicitly describing the invention, the description is inadequate unless it *explicitly* or *necessarily* discloses every element of the invention. Pet. App. 7a-8a.

Here, that heightened requirement resulted in invalidation because Novartis's patent does not describe a fingolimod regimen that *explicitly* excludes a loading dose. Despite district court findings based on unrebutted testimony that, to skilled artisans, the patent explains a "dosing regimen (dosage, frequency, and length)" that "does not involve a loading dose" (Pet. App. 98-99a), the Federal Circuit deemed those findings legally insufficient absent evidence in the specification "*necessarily exclud[ing]* a loading dose." Pet. App. 12a-13a. Also deemed insufficient: findings of well-known risks from administering fingolimod with loading doses. Pet. App. 98a-99a.

Unable to connect the Federal Circuit's heightened requirement to any statutory text, HEC attempts to

defend it with the Federal Circuit's own precedent. Opp. 21-24. But if that court has departed from Section 112(a)'s text in previous decisions, that only underscores the need for review. *See Amgen Inc. v. Sanofi*, No. 21-757 (U.S.).

This Court has long applied Section 112(a) as a flexible standard that permits implicit descriptions understandable to skilled artisans. *Marconi Wireless Tel. Co. of Am. v. United States*, 320 U.S. 1 (1943); Pet. 31-33. Because the Federal Circuit's heightened legal standard cannot be reconciled with *Marconi*, HEC must alter the standard to try to defend it. Opp. 26. HEC says a description suffices if it "necessarily covered the later-amended claims." Opp. 26 (citing *Marconi*, 320 U.S. at 23-24). But had the Federal Circuit applied that standard, Novartis would still have a valid patent: the majority acknowledged evidence showing the patentee did not "intend[] there to be a loading dose" (Pet. App. 13a)—i.e., showing the patent described a dosing regimen that necessarily covers omitting a loading dose. HEC similarly says "the description could just as well embrace administering a loading dose as excluding one." Opp. 26. A description embracing either option necessarily covers both.

The Federal Circuit's predecessor also endorsed "implicit" descriptions. *In re Robins*, 429 F.2d 452, 456-57 (C.C.P.A. 1970). HEC says *Robins* merely recognizes "years of precedent" that "*explicitly* listing 'representative' examples 'may' provide a sufficient 'description.'" Opp. 26-27 (citation omitted; emphasis

by HEC). But that is what the district court found Novartis's patent described: representative examples, including animal testing and a human-clinical trial, that skilled persons would understand involve administering fingolimod without a loading dose. Pet. App. 98a-99a. The Federal Circuit held that insufficient under its heightened standard, contrary to "years of precedent."

Consistent with longstanding precedent, the Manual of Patent Examining Procedure (MPEP) instructs examiners that "express[ ], implicit[ ], and inherent[ ]" descriptions are each sufficient. Pet. 32-33. Without disagreeing, HEC dismisses the MPEP as "possess[ing] no precedential power." Opp. 27. But the MPEP contains the Patent and Trademark Office's "official interpretation of statutes." *Litton Sys., Inc. v. Whirlpool Corp.*, 728 F.2d 1423, 1439 (Fed. Cir. 1984). Every patent examiner applies its interpretations when issuing patents. *Ibid.* As amici explain, overriding the Office's understanding that implicit disclosure suffices would "upset[] settled expectations." IP Professors 5-9.

HEC insists the Federal Circuit imposed no heightened standard because the new majority said so. Opp. 24 (quoting Pet. App. 14a). But the majority's belief in the correctness of its decision does not prove correctness. And those statements refute HEC's argument that the four Federal Circuit judges here agreed on the legal standards. Opp. 21-25. The majority disclaimed applying a heightened standard only because the dissent (like the original majority) made that

accusation. Pet. App. 14a, 16a-18a, 48a-49a. That is a *legal* disagreement.

Review is warranted even under HEC's characterization. HEC says the competing decisions reflect a "fact-bound" dispute "turn[ing] on the intricacies of the expert testimony and the factual evidence presented in this case." Opp. 21, 29. But the "intricacies" of expert testimony and evidence are for the factfinder, especially in patent law "'where so much depends upon familiarity with specific scientific problems and principles not usually contained in the general storehouse of knowledge.'" *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 327-28 (2015). An appellate decision that rejects expert testimony for "conflict[ing]" with the appellate court's own reading of a patent's technical details contravenes ordinary procedural rules. *Contra* Opp. 28.

B. The Federal Circuit Is Threatening Innovation

Significant interests are at stake, as the petition and amici show. Pet. 37-40; IP Professors 6-9. Novartis did what patent law provides it should: narrowed its claims to avoid obtaining rights beyond what it invented. HEC just ignores Novartis's claims in arguing that the "patent bargain" requires "tell[ing] the public whether the invention includes the limitation or not." Opp. 23-25. A different statutory provision ensures the public knows which limitations an invention includes: 35 U.S.C. § 112*(b)* requires "claims particularly pointing out and distinctly claiming the subject matter" of

"the invention." There is no question Novartis complied with that requirement—its claims expressly exclude a loading dose.

The Federal Circuit's heightened standard undermines the very bargain HEC emphasizes. Applicants that upheld their end of the bargain by narrowing their claims during the back-and-forth with the patent examiner may end up without *any* patent protection unless they also have recited every variation of the invention in their original application. The results will be dramatic, wiping out the value of years of research, development, and investment in one fell swoop. HEC's response that Congress can deal with it ignores that the question is whether Congress already did. Opp. 29-30. This Court should decide that question.

Finally, HEC's opposition to this Court's holding the petition pending disposition in *Amgen* ignores Novartis's argument. Opp. 30. The question in *Amgen* involves the same statutory sentence and same concerns about limitations inconsistent with that sentence's text. Pet. 40.

CONCLUSION

The petition should be granted.

Respectfully submitted,

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