No. 22-_____

In The
Supreme Court of the United States

NOVARTIS PHARMACEUTICALS CORPORATION,
PETITIONER

v.

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

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether 28 U.S.C. § 46 and principles of sound judicial administration preclude a court of appeals from adding a new judge to form a new panel and redecide a case after an original three-judge panel has already decided the case and entered its judgment.

2. Whether 35 U.S.C. § 112 should be interpreted consistent with its plain text as requiring that a patent specification contain a "written description of the invention" in a form that need only be understandable to "any person skilled in the art," or whether the court of appeals properly read in a heightened requirement that allows it to deem the specification inadequate on *de novo* review and displaces the perspective of a person skilled in the art.

PARTIES TO THE PROCEEDING

All parties to the case in the court of appeals appear in the caption of this petition. Other defendants were parties in the district court but were not parties to the appeal.

CORPORATE DISCLOSURE STATEMENT

Novartis Pharmaceuticals Corporation is a wholly owned subsidiary of Novartis AG, and no other publicly traded company owns 10% or more of its stock.

STATEMENT OF RELATED PROCEEDINGS

This case arises from the following proceedings:

- *Novartis Pharmaceuticals Corporation v. Accord Healthcare Inc. et al.*, No. 1:18-cv-01043 (D. Del.) (final judgment and order of injunction entered September 11, 2020);
- *Novartis Pharmaceuticals Corporation v. Accord Healthcare, Inc. et al.*, No. 21-1070 (Fed. Cir.) (original opinion and judgment entered January 3, 2022, affirming district court judgment; new opinion and judgment entered June 21, 2022, granting panel rehearing and reversing district court judgment; and order entered September 20, 2022, denying panel rehearing and rehearing en banc).

STATEMENT OF RELATED PROCEEDINGS
—Continued

This Court previously denied Novartis's application for stay of the mandate, *Novartis Pharmaceuticals Corp. v. HEC Pharm Co., Ltd.*, No. 22A272 (order denying application entered Oct. 13, 2022).

In the trial court, the following cases were designated related cases:

- *Novartis Pharmaceuticals Corporation v. Apotex Inc. et al.*, No. 18-cv-01038 (D. Del.);
- *Novartis Pharmaceuticals Corporation v. Teva Pharmaceuticals USA, Inc. et al.*, No. 18-cv-01039 (D. Del.);
- *Novartis Pharmaceuticals Corporation v. Sun Pharmaceuticals Industries, Ltd. et al.*, No. 18-cv-01040 (D. Del.);
- *Novartis Pharmaceuticals Corporation v. Alembic Pharmaceuticals Limited et al.*, No. 1:20-cv-00074 (D. Del.);
- *Novartis Pharmaceuticals Corporation v. Mylan Pharmaceuticals, Inc.*, No. 1:19-cv-01118 (D. Del.);
- *Novartis Pharmaceuticals Corporation v. HEC Pharm Co., Ltd. et al.*, No. 1:20-cv-00133 (D. Del.);
- *Novartis Pharmaceuticals Corporation v. Alkem Laboratories Ltd. et al.*, No. 1:19-cv-01979 (D. Del.);

STATEMENT OF RELATED PROCEEDINGS
—Continued

- *Novartis Pharmaceuticals Corporation v. Handa Neuroscience, LLC et al.*, No. 1:21-cv-00645 (D. Del.);
- *Novartis Pharmaceuticals Corporation v. HEC Pharm Co., Ltd. et al.*, No. 1:21-cv-01530 (D. Del.);
- *Novartis Pharmaceuticals Corporation v. Dr. Reddys Laboratories, Inc. et al.*, No. 1:19-cv-02053 (D. Del.);
- *Novartis Pharmaceuticals Corporation v. Alembic Pharmaceuticals Limited et al.*, No. 1:20-cv-00074 (D. Del.).

There are no other directly related proceedings within the meaning of this Court's Rule 14.1(b)(iii).

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PETITION FOR A WRIT OF CERTIORARI

The Federal Circuit deepened a longstanding, lopsided divide on an important question of judicial authority and the sound administration of justice. The court of appeals' approach, shared only by the Ninth Circuit, flouts clear statutory text and basic norms that have stood for more than a century. And the outcome wrongly deprived Novartis of its patent on a groundbreaking new method for treating multiple sclerosis.

From the beginning, Congress has assigned the primary decision-making authority of the federal courts of appeals to panels of judges, usually three. Time and again, Congress has required that each case should be heard and determined by a panel. And it has provided that a decision by a majority of the judges on that panel is the final decision of the appellate court. The only exception Congress authorized—meant for extraordinary circumstances—is en banc review ordered by a majority of a circuit court's active judges.

Every circuit except the Ninth and (now) Federal Circuits follows this restriction. In the other circuits, once a panel publicly enters its decision, no new judge is added to redecide the case on purported "panel" rehearing. This Court's rules similarly prohibit a new Justice from casting the deciding vote for rehearing.

But in the Ninth and Federal Circuits, an already-entered decision can be overturned without en banc review and without any change of mind by a panel judge, by adding a new judge for "panel" rehearing.

That is what happened here. In a precedential decision (entered over a dissent) a three-judge panel affirmed a bench-trial verdict rejecting validity challenges to Novartis's patent. But after the authoring judge retired while a rehearing petition was pending, the Federal Circuit added a new judge. The altered panel entered a new precedential decision overturning the original panel's decision—with the original dissenter authoring, the newly added judge providing the decisive vote, and the remaining original-majority member dissenting.

This Court should bring the Federal and Ninth Circuits in line with the law and sound judicial practice. The circuit courts have the final word in the vast majority of federal cases. Allowing panel changes to overturn already-entered decisions undermines confidence in the judiciary. It creates an impression that circuit courts administer judge-specific justice, with outcomes depending not on the merits but on which judges are assigned to the panel. The finality of a panel decision should not turn on whether one judge leaves the judiciary after entry of that decision, much less on which circuit decided the case.

Independently, this Court's review is needed on the new panel's substantive ruling. "[O]nce again," the Federal Circuit has "impose[d] limitations on the Patent Act that are inconsistent with the Act's text." *Bilski v. Kappos*, 561 U.S. 593, 612 (2010). And once again, the Federal Circuit's addition to the Act "transforms" a "general principle into a rigid rule that

limits" the relevant inquiry. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007).

Here, the Patent Act's requirement for a "written description of the invention" is plainly stated in 35 U.S.C. § 112(a)—the same statutory provision this Court is considering in *Amgen Inc. v. Sanofi*, No. 21-757 (cert. granted Nov. 4, 2022). The text expressly requires a fact-specific inquiry, measuring the description's adequacy by the knowledge of a "person skilled in the art" related to the patent. 35 U.S.C. § 112(a). But the Federal Circuit here added a new, heightened requirement that displaces the perspective of persons skilled in the art and allows the court of appeals to substitute its views *de novo*.

Rather than the statute's flexible case-by-case approach, the Federal Circuit's new decision demands that a patent explicitly or necessarily describe the elements of a patent's claims. That heightened burden prevents factfinders from relying on descriptions that are implicit to skilled artisans in the relevant field based on their common knowledge. And it allows courts to invalidate patents even if skilled artisans would understand the description of the invention without such a disclosure.

The four Federal Circuit judges who heard this case divided two-to-two on whether the Patent Act imposes such a rigid requirement, entering two separate precedential decisions with opposite outcomes. This split within the court with nationwide jurisdiction over patent appeals demonstrates the

issue's importance—and the need for this Court's intervention.

Review should be granted. Indeed, as this Court has done in similar cases, the Federal Circuit's procedural approach warrants summary disposition.

ORDERS BELOW

The district court's final judgment and injunction order (Pet. App. 71a-76a) is unreported. Its post-trial findings of fact and conclusions of law (Pet. App. 77a-114a) are unreported. The Federal Circuit's original opinion affirming the district court (Pet. App. 27a-70a) is reported at 21 F.4th 1362 (2022). Its new opinion granting panel rehearing, vacating the original decision, and reversing the district court (Pet. App. 1a-26a) is reported at 38 F.4th 1013. The Federal Circuit's order denying panel rehearing and rehearing en banc of the new decision (Pet. App. 115a-17a) is unreported.

JURISDICTION

The court of appeals entered judgment on June 21, 2022 (Pet. App. 2a) and denied panel rehearing and rehearing en banc on September 20, 2022 (Pet. App. 116a). On December 8, 2022, the Chief Justice extended the time to petition for a writ of certiorari until January 18, 2023. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

28 U.S.C. § 46 and 35 U.S.C. § 112 are reproduced at Pet. App. 118a-20a.

STATEMENT OF THE CASE

A. Statutory Framework

1. Section 46's limits on judicial authority

Ever since creating the federal courts of appeals, Congress has vested the primary decision-making authority for hearing and determining cases and controversies in three-judge panels (formerly called divisions). Congress originally defined those courts as acting only through such three-judge panels: "there is hereby created in each circuit a circuit court of appeals, which shall consist of three judges." Evarts Act, ch. 517, § 2, 26 Stat. 826, 826 (1891). Congress created those courts without permanently assigning them any judges. *Comm'r v. Textile Mills Secs. Corp.*, 117 F.2d 62, 68-69 (3d Cir. 1940), *aff'd sub nom. Textile Mills Secs. Corp. v. Comm'r*, 314 U.S. 326 (1941). Instead, the circuit courts of appeals consisted at any given time of three judges drawn from three preexisting pools: the circuit justice of the Supreme Court; the circuit judges of the circuit courts (different from the circuit courts of appeals); and the district judges of the district courts. *Textile Mills*, 314 U.S. at 328-29; Evarts Act § 3, 26 Stat. at 826-27.

Only after Congress abolished the circuit courts did the circuit courts of appeals gain a permanent roster of judges. Judicial Code, ch. 231, §§ 116-118, 289, 36 Stat. 1087, 1131, 1167 (1911). Yet even then, and as the courts of appeals grew in size, it was understood the circuit courts of appeals would

primarily act through panels—"the ordinary complement of circuit judges would be three." *Textile Mills*, 314 U.S. at 331 n.10. The difficult question was not whether courts of appeals were restricted to hearing and deciding cases in panels of three judges, but whether those courts had authority in exceptional circumstances to hear or rehear such cases en banc. *Id.* at 332-35 (concluding Congress had allowed en banc sittings).

Congress cemented this default rule of three-judge panels when it revised the Judicial Code in 1948. Pub. L. No. 80-773, 62 Stat. 869. At that time, it relocated the provisions delineating courts of appeals' authority to hear and determine cases to 28 U.S.C. § 46. *Id.* at 871-72. Section 46(c) then prescribed:

> Cases and controversies shall be heard and determined by a court or division of not more than three judges, unless a hearing or rehearing before the court in banc is ordered by a majority of the circuit judges of the circuit who are in active service. A court in banc shall consist of all active circuit judges of the circuit.

Ibid. Paragraph (b) similarly authorized the use of "separate divisions" for "the hearing and determination of cases." *Ibid.* It defined divisions as "each consisting of three judges." *Ibid.* And paragraph (d) specified that it would take a majority of that assigned three-judge panel to act—"[a] majority of the number of judges authorized to constitute a court or division

thereof, as provided in paragraph (c), shall constitute a quorum." *Id.* at 871-72.

Congress thus ordered "[c]ases and controversies" to "be heard and determined" by "not more than three judges" and designated a majority of those judges a quorum. *Ibid.* Beyond that majority, Congress granted only "the court in banc" power to determine or redetermine a case. *Ibid.* In this way, Congress achieved a "dual purpose: to give express recognition" to the authority for en banc action, "while at the same time securing the tradition of three-judge courts against any further intrusion." *Western Pacific R.R. Corp. v. W. Pac. R.R. Co.*, 345 U.S. 247, 254-56 (1953).

Today, the core requirements of Section 46 remain unchanged: "[c]ases and controversies shall be heard and determined by a court or panel of not more than three judges" absent en banc review. 28 U.S.C. § 46(c). And "[a] majority of the number of judges authorized to constitute a court or panel thereof, as provided in paragraph (c), shall constitute a quorum." *Id.* at § 46(d).[1]

When Congress created the Federal Circuit, it likewise made panels of three judges the ordinary complement. Pub. L. No. 97-164, 96 Stat. 25, 25-26 (1982). And it applied the same statutory limit to the Federal Circuit that applies to the other circuits—once a controversy is "heard and determined" by a panel,

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[1] In every circuit except the Ninth, the en banc court consists of "all circuit judges in regular active service." 28 U.S.C. § 46(c); *see* Pub. L. No. 95-486, § 6, 92 Stat. 1633 (1978).

other judges may not hear or determine the same controversy "unless a hearing or rehearing before the court in banc is ordered." *Ibid*; 28 U.S.C. § 46(c).[2]

2. The Patent Act's requirement to describe the invention

This case also involves the interpretation of 35 U.S.C. § 112(a), the same statutory provision this Court is considering in *Amgen*. That statutory provision embodies a "carefully crafted bargain" at the heart of the patent system. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998). The Constitution empowers Congress to grant inventors "the exclusive right" to their discoveries for a limited time. U.S. Const., art. I, § 8, cl.8. But in return, Congress requires "the public disclosure" of those discoveries. *Pfaff*, 525 U.S. at 63. Public disclosure promotes further discoveries and ensures that, upon patent expiration, the public can practice the invention. *Ibid*.

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[2] Congress also allowed the Federal Circuit to "sit in panels of more than three judges if its rules so provide" (28 U.S.C. § 46(c)) based in part on the practice of its predecessor, the Court of Customs and Patent Appeals, which always heard cases en banc with five judges (G.S. Rich, *Thirty Years of this Judging Business*, 14 AIPLA Q.J. 139, 147-48 (1986)). But that provision does not apply here. *Compare* Pet. App. 1a-28a *with Martek Bioscis. Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1368 n.2 (Fed. Cir. 2009) (expressly invoking Section 46(c) and local rules to explain basis for five-judge panel); *see* Fed. Cir. R. 47.2(a) (requiring "an odd number of at least three judges").

Section 112 defines the inventor's half of this "quid pro quo." *Universal Oil Prods. Co. v. Globe Oil & Refin. Co.*, 322 U.S. 471, 484 (1944). It reads:

> (a) In General.—
>
> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

35 U.S.C. § 112(a). The Federal Circuit treats this provision as embodying an enablement requirement and a "separate" written-description requirement. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1340 (Fed. Cir. 2010) (en banc).

B. Proceedings Below

1. Novartis invented and patented the first oral treatment for relapsing-remitting multiple sclerosis

Relapsing-remitting multiple sclerosis (RRMS) is the most common form of multiple sclerosis, a potentially disabling autoimmune disorder. Researchers at Novartis discovered that fingolimod, a drug they had been investigating for kidney-transplant rejection, also held promise for treating RRMS. C.A. App. 23282-84. Through animal testing,

the researchers identified a previously undiscovered mechanism of action for fingolimod. C.A. App. 23217, 23444. They also discovered that a much lower dose of fingolimod could trigger that mechanism of action and help stop the disability "relapses" that multiple sclerosis generally induces. C.A. App. 24560; Pet. App. 96a.

Novartis was granted a patent for a method of treating RRMS by "orally administering" fingolimod "at a daily dosage of 0.5 mg, absent an immediately preceding loading dose regimen." C.A. App. 24741 (U.S. Patent No. 9,187,405; col.12:45-55). A loading dose is a "higher-than-daily dose usually given as the first dose." Pet. App. 3a (alteration omitted). The patent's specification describes several potential dosing regimes for fingolimod that could be used in clinical trials, including "a daily dosage of 0.5" mg. C.A. App. 24740-41 (col.10:35-col.11:16). It describes treating patients "[i]nitially" for "2 to 6 months" without suggesting any other initial treatment, such as a loading dose. C.A. App. 24741 (col.11:5-16). The patent also describes the inventors' animal studies that likewise used no loading dose. C.A. App. 24740-41.

Novartis markets the 0.5 mg daily dose of fingolimod under the brand name Gilenya. Gilenya was a breakthrough—the first-ever solid oral medication for RRMS.

2. Novartis's discovery attracted other companies, which tried and failed to invalidate Novartis's patent

Novartis's discovery attracted interest from HEC and others seeking to take advantage of Novartis's development efforts. Those companies sought FDA approval to market generic versions of Gilenya. C.A. App. 143-97.

Before the start of this federal-court action, several of those companies tried and failed to invalidate Novartis's patent through *inter partes* review by the Patent Trial and Appeal Board. C.A. App. 215. The companies argued that Novartis's original patent application failed to adequately describe the claimed method of administering fingolimod absent a loading dose because the specification never expressly uses a phrase such as "absent an immediately preceding loading dose." C.A. App. 209. The three administrative patent judges unanimously rejected that challenge on the facts, applying a preponderance of the evidence standard. *Apotex Inc. v. Novartis AG*, 2018 WL 3414289 (P.T.A.B. July 11, 2018), *appeal dismissed sub nom. Argentum Pharms. LLC v. Novartis Pharms. Corp.*, 956 F.3d 1374 (Fed. Cir. 2020), *cert. denied*, 141 S. Ct. 1685 (2021).

In this case, Novartis sued HEC and other companies for infringing all six claims of its patent. Pet. App. 4a. Based on an in-person evidentiary hearing and a "voluminous record," then-Chief Judge Stark of the District of Delaware (now a Federal

Circuit judge) granted a preliminary injunction preventing launch of generic copies of Gilenya. C.A. App. 18857–65. He held HEC "not at all likely to prevail at trial on invalidity," including on its written-description challenge to the no-loading-dose claim limitation. C.A. App. 18857–65. No generic company appealed the injunction.

This case was transferred to Judge Jordan of the Third Circuit, sitting by designation (and formerly a District of Delaware judge). Before trial, the claims against all but HEC were settled or stayed. Pet. App. 4a n.1. The four-day bench trial focused on HEC's attempts to prove invalidity by clear-and-convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011). Judge Jordan heard testimony from six experts and additional witnesses about the patent's no-loading-dose term. Focusing on the relevant person skilled in the art and citing admissions from HEC's own expert, he found the patent's description of an animal "example discloses a dosing regimen which does not involve a loading dose." Pet. App. 99a. He also credited expert testimony about the patent's detailed description of a "dosing regimen (dosage, frequency, and length)" for a human-clinical trial that "does not involve a loading dose"; those details "would tell a person of skill" familiar with multiple-sclerosis trials "that loading doses are excluded." Pet. App. 98a. Indeed, Novartis's evidence about how persons of skill in this field would read the patent's clinical-trial description was unrebutted—

HEC's expert conceded he was unqualified to opine on this key specification passage. C.A. App. 23317.

The district court also found it well-known in this field that increased doses of fingolimod carried increased risk, especially at the beginning of treatment when a loading dose would be given. Pet. App. 93a (citing C.A. App. 23126-27, 23129). With that background knowledge, the court found skilled artisans reading Novartis's patent "would not expect a loading dose to be used to treat RRMS with fingolimod." Pet. App. 99a. Based on all the evidence, the court found "[a] person of skill in the art would understand that the Patent describes a daily dosage of 0.5 mg of fingolimod without a preceding loading dose." Pet. App. 94a, 99a. Simply put, HEC failed on the facts to prove invalidity under the required clear-and-convincing evidence standard.

The district court entered judgment for Novartis on infringement and validity, enjoining HEC's generic launch. Pet. App. 71a-75a.

3. One three-judge panel of the Federal Circuit affirmed, only for a differently constituted three-judge panel to reverse

a. The Federal Circuit originally affirmed in a precedential decision written by Judge O'Malley and joined by Judge Linn, with Chief Judge Moore dissenting. Pet. App. 28a-68a.

The majority rejected HEC's attempt to impose a "new rule that a limitation which is not expressly recited in the disclosure is never adequately described, regardless of how a skilled artisan would read that disclosure." Pet. App. 48a. It also refused to apply a "heightened written description standard" to so-called "negative limitations," i.e., elements of a patent claim that recite matter not claimed (such as the requirement here to administer fingolimod without a loading dose). Pet. App. 42a-46a. Instead, the majority emphasized the written-description "requirement is essentially a fact-based inquiry," because "it is how a skilled artisan reads a disclosure that matters." Pet. App. 42a-48a. The majority thus applied the rule that "[w]ritten description may take any form, so long as a skilled artisan would read the disclosure as describing the claimed invention." Pet. App. 47a-48a.

Under those standards and giving due deference to the district court's factfinding, the majority found ample evidence to affirm. Pet. App. 49a-56a. The district court had "quite carefully" conducted an "'objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill.'" Pet. App. 49a-50a (citation omitted). The majority detailed testimony from Novartis's experts showing how skilled artisans would have understood the patent's description of both the animal study and the human-clinical trial as excluding a loading dose. Pet. App. 50a-56a. That testimony went unrebutted on key points. *Ibid.* The majority criticized the dissent's contrary view as "substitut[ing] its own

factual findings for those of the district court." Pet. App. 54a-55a.

Chief Judge Moore's dissent argued the specification was "silent as to loading doses" because it did not explicitly rule them out. Pet. App. 57a-68a. The dissent would have applied a rule making such a lack of explicit disclosure dispositive. Pet. App. 67a-68a. And it saw no "finding of fact" warranting deference but rather, in its view, "a misunderstanding of the law." Pet. App. 67a-68a.

b. After entry of this precedential decision, and following a three-week extension, HEC petitioned for rehearing on only its written-description challenge to the no-loading-dose limitation. One week after Novartis filed an expedited response, Judge O'Malley retired from the court. Three months later, a new panel of Chief Judge Moore (originally in dissent), Judge Linn (originally in the majority), and Judge Hughes (not previously on the panel) granted HEC's petition, vacated the prior precedential decision, and entered a new precedential decision reversing the district court.

Although the Federal Circuit's rules allow the chief judge to select a new panel member when a vacancy occurs on a panel after oral argument or submission, the rules do not address a vacancy after entry of a decision. *See* Fed. Cir. R. 47.11. Here, the court of appeals did not explain the change in panel membership or how Judge Hughes was selected. Nor did the new opinion identify any basis for granting

rehearing—for example, a point of law or fact that the original panel "overlooked or misapprehended." Fed. R. App. P. 40(a)(2).

The new decision was, in substance, the original dissent recast as a majority. The new majority held that a written description of the invention must be express, not implicit, and that silence "may often be dispositive" of invalidity. Pet. App. 5a-8a & n.2. In its view, the only viable alternative to an explicit description of every limitation of a claimed invention was if the "patent owner could establish" that the specification "inherently" discloses every limitation, which would require showing that the specification would "always" be read as "necessarily" disclosing all limitations. *Ibid.*

Under that standard, the new decision rejected the district court's factfinding because the evidence the district court cited did not "*necessarily exclude* a loading dose." Pet. App. 9a-14a (emphasis by court). It dismissed unrebutted expert testimony about what would be implicitly disclosed to skilled artisans from the patent's description of human-clinical-trial dosing because that testimony was "inconsistent with the plain text of the" patent as the new majority read it. Pet. App. 9a-10a, 12a.

Judge Linn dissented, adhering to the reasoning of the original precedential decision. Pet. App. 16a-26a. He criticized the new decision's "heightened written description standard" of "necessary exclusion." Pet. App. 16a-18a. He emphasized this heightened, rigid

standard conflicted with historical practice, which followed a flexible approach to assessing a patent's written description. Pet. App. 18a-26a.

c. The new decision prompted a wave of criticism. Commenters described the court's procedural approach as suggesting that the outcome of an appeal to the Federal Circuit depends on panel composition. *See*, *e.g.*, Eileen McDermott, "Novartis to Appeal CAFC's 'Unprecedented' U-Turn in Ruling on Multiple Sclerosis Drug Claims to SCOTUS," *IPWatchdog* (Sept. 21, 2022);[3] Dennis Crouch, "Decisions by the Court as an Institution; or by the Judge as a Human," *Patently-O* (Aug. 25, 2022);[4] Samantha Handler, "Generic Drugmakers Score Big in Rare Federal Circuit Reversal," *Bloomberg Law* (describing decision as "Patent Law Soap Opera") (June 23, 2022).[5] Commenters similarly warned about the "uncertainty" created by the court's interpretation of Section 112 and its refusal to defer to factfinders. Handler, *supra*.

Novartis sought rehearing, supported by several amici. Brief of *Amici Curiae* Law Professors and Civil

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[3] https://www.ipwatchdog.com/2022/09/21/novartis-appeal-cafcs-unprecedented-u-turn-ruling-multiple-sclerosis-drug-claims-scotus/.

[4] https://patentlyo.com/patent/2022/08/decisions-court-judge.html.

[5] https://news.bloomberglaw.com/us-law-week/generic-drugmakers-score-big-in-rare-federal-circuit-reversal?.

Procedure Scholars, C.A. Dkt. 72; Brief of *Amici Curiae* Intellectual Property Law Professors, C.A. Dkt. 73.

d. After denial of Novartis's rehearing petition (Pet. App. 115a-17a), the Federal Circuit and this Court denied Novartis's request to stay the mandate.

REASONS FOR GRANTING THE PETITION

I. IN ALLOWING A NEW PANEL TO REDECIDE THIS CASE, THE FEDERAL CIRCUIT EXCEEDED STATUTORY AUTHORITY AND DEEPENED AN ENTRENCHED AND LOPSIDED CIRCUIT CONFLICT

Allowing the outcome of an already-entered decision to be changed by a differently constituted panel conflicts with federal law and sound principles of judicial administration. This result would not have happened in any other circuit except the Ninth. This Court's intervention is needed to resolve this conflict and maintain confidence in the judicial system.

A. Section 46 Prohibits Adding Judges After Entry of a Decision Except Through the En Banc Process

Congress spoke plainly in Section 46: "[c]ases and controversies shall be heard and determined by a court or panel of not more than three judges." 28 U.S.C. § 46(c). That three-judge panel speaks for the entire court unless "hearing or rehearing before the court in banc is ordered by a majority of the circuit judges." *Ibid.*

For that three-judge panel to act, Congress required a majority of its members to agree. Referring back to the panel of judges assigned to hear and determine a case, Section 46(d) defines a quorum as "[a] majority" of the panel "as provided in paragraph (c)." 28 U.S.C. § 46(d). A quorum is the "'number of the members of the court as may legally transact judicial business.'" *Nguyen v. United States*, 539 U.S. 69, 82 n.14 (2003) (vacating Ninth Circuit decision for incorrectly applying the requirements of paragraphs (c) and (d)).

And the meaning of "heard and determined" in Section 46 is clear: "[a] case or controversy is 'determined' when it is decided" through entry of a public opinion and judgment. *United States v. American-Foreign Steamship Corp.*, 363 U.S. 685, 688 (1960). In *American-Foreign Steamship*, the question was whether a Second Circuit judge who was active when a court granted en banc review but had taken senior status before entry of the en banc decision could join in redeciding the case en banc. *Id.* at 685-87. Because the statute at the time allowed only an "active" judge to "hear[] and determine[]" a case en banc, the Court held that the judge must be "active" when the en banc decision was entered—"a retired circuit judge is without power to participate in an *en banc* Court of Appeals determination." *Id.* at 685-86, 691.

This Court applied that same interpretation to Section 46 in *Yovino v. Rizo*, 139 S. Ct. 706 (2019). There, Judge Reinhardt drafted a majority opinion for the en banc Ninth Circuit but passed away before "the

decision was filed." *Id.* at 707-08. Without Judge Reinhardt's vote, the remaining judges were evenly divided. *Id.* This Court summarily vacated the decision counting his vote because he was not a member of the court when the case was determined, i.e., when "the decision was 'filed,' entered on the docket, and released to the public." *Id.* at 708.

Taken together, these principles establish a clear rule. Under Section 46, once a three-judge panel has heard and determined an appeal, which occurs when those judges publicly enter their decision, the panel's decision can be altered in only two ways—either by a majority of the judges who entered the decision or through en banc review.

That rule also follows by negative implication from the statutory text. Section 46(c) specifically authorizes "rehearing before the court in banc" but says nothing about rehearing before a reconfigured panel. Given that omission, "[a]textual judicial supplementation" that allows a differently constituted panel to grant rehearing would be "particularly inappropriate." *Rotkiske v. Klemm*, 140 S. Ct. 355, 360-61 (2019) (rejecting atextual requirement where "Congress has shown that it knows how to adopt the omitted language").

As *American-Foreign Steamship*, *Yovino*, and *Nguyen* confirm, this Court has consistently granted review to ensure courts of appeals stay within Section 46's limits. Unless Section 46 authorizes a judge to decide a case, "'the decree in which he took part was

unlawful, and perhaps absolutely void, and should certainly be set aside or quashed by any court having authority to review it by appeal, error or *certiorari*.'" *Nguyen*, 539 U.S. at 79 (citation omitted).

That remedy is required here. A three-judge panel had already publicly entered its decision, and no quorum from that three-judge panel agreed to grant rehearing. Nor did a majority of the active judges on the Federal Circuit vote to grant rehearing en banc. Instead, a differently constituted panel redecided this case with a new judge. That second panel was unauthorized by Section 46, and its new decision "should certainly be set aside," thus reinstating the original panel decision. *Nguyen*, 539 U.S. at 79.

B. Well-Established Judicial Practice Reinforces Section 46's Plain Text and Shows the Federal Circuit Joined the Wrong Side of an Established Split

The conclusion that the new panel's decision was unauthorized by Section 46 accords with longstanding judicial practice. In *Yovino*, this Court began its analysis of Section 46 with "well-established" practice and what was "generally understood" about it. 139 S. Ct. at 708-09. Similarly, in *Moody v. Albemarle Paper Co.*, the Court explained it was "not at liberty to engraft upon the statute a meaning inconsistent with its historical limitations." 417 U.S. 622, 626 (1974). The Court thus refused to interpret Section 46 to allow senior judges who had participated at the panel stage to vote whether to grant en banc

rehearing. *Id.* at 622-23. Longstanding practice showed "the eligibility of senior judges for participation" in the en banc process "ha[d] been the exception." *Id.* at 626.

Two aspects of well-established judicial practice confirm the error in what happened here. First, from their inception, the circuit courts of appeals have been synonymous with three-judge panel decisions. Congress originally defined these courts as "consist[ing] of three judges." 26 Stat. at 826. When it later expanded these courts, the question was not whether panels of three remained "the ordinary complement," but whether that default precluded an en banc court from hearing and determining a case. *Textile Mills*, 314 U.S. at 332-35 & n.10; *supra* pp. 5-8 & n.2.

As this Court has already recognized, Congress captured that history in Section 46. The section "was motivated by a dual purpose: to give express recognition to the doctrine of *Textile Mills* [permitting en banc review], while at the same time securing the tradition of three-judge courts against any further intrusion." *Western Pacific*, 345 U.S. at 254, 256-57.

Second, outside of the en banc process, courts of appeals have long required that a majority of the *original* panel agree to grant panel rehearing of an already-entered decision. When a judge in the majority leaves a court after entry of a divided panel decision, the uniform practice in the circuits (other than the Ninth and now Federal) is to deny panel

rehearing without appointing a new judge. In *Williams v. Jones*, for example, Judge McConnell had joined the panel majority that reversed a district court decision; then-Judge Gorsuch dissented. 571 F.3d 1086 (10th Cir. 2009). After Judge McConnell left the court, the Tenth Circuit denied panel rehearing without appointing a new judge, with then-Judge Gorsuch voting to deny panel rehearing in part because "a vote among the remaining two panel members would likely result in a tie." *Williams v. Jones*, 583 F.3d 1254, 1256 n.1 (10th Cir. 2009).

Other courts deny panel rehearing in similar circumstances, expressly acknowledging a 1-1 tie. For example:

- *Mexichem Fluor, Inc. v. EPA*, No. 15-1328 (D.C. Cir. Jan. 26, 2018) (after Judge Brown retired, denying rehearing because remaining "panel is equally divided"); 866 F.3d 451 (2017) (panel decision with then-Judge Kavanaugh and Judge Brown in majority and Judge Wilkins partially dissenting);
- *Martin Cty. Coal Corp. v. Universal Underwriters Ins. Co.*, No. 11-5773 (6th Cir. Oct. 25, 2013) (after Judge Martin retired, two-judge panel denying rehearing despite dissent from Judge Rogers); 727 F.3d 589 (panel decision with Judges Keith and Martin in majority and Judge Rogers dissenting);
- *Reeder-Simco GMC, Inc. v. Volvo GM Heavy Truck Corp.*, No. 02-2462 (8th Cir. Oct. 6, 2004) (following death of Judge R. Arnold, two-judge

panel denying panel rehearing despite dissent from Judge Hansen); 374 F.3d 701 (panel decision with Judges Bye and R. Arnold in majority and Judge Hansen partially dissenting).

See C.A. Reh'g Supp. Add. SA35-46 (collecting same).

Others deny rehearing without recorded dissent. For example:

- *United States v. Blaszczak*, No. 18-2811 (2d Cir. Apr. 10, 2020) (after Judge Droney retired, two-judge panel denying panel rehearing); 947 F.3d 19 (2019) (panel decision with Judges Droney and Sullivan in majority and Judge Kearse dissenting);
- *Feldman v. Pro Football, Inc.*, No. 09-1021 (4th Cir. Apr. 22, 2011) (following Judge Michael's death, two-judge panel denying panel rehearing); 419 F. App'x 381 (panel decision with Judges Davis and Michael in majority and Judge Beaty partially dissenting);
- *United States v. Portillo-Munoz*, No.11-10086 (5th Cir. Aug. 4, 2011) (following Judge Garwood's death, two-judge panel denying panel rehearing); 643 F.3d 437 (panel decision with Judges Garwood and Garza in majority and Judge Dennis partially dissenting);
- *Van Dyke v. Vill. of Alsip*, No. 20-1041 (7th Cir. Oct. 19, 2020) (with then-Judge Barrett not participating, two-judge panel denying panel rehearing); 819 F. App'x 431

(panel decision with Judge Kanne and then-Judge Barrett in majority and Judge Rovner partially dissenting);

- *Fluor Intercont. Inc. v. IAP Servs. Inc.*, No. 12-10793 (11th Cir. Nov. 18, 2013) (after Judge Barkett's retirement, two-judge panel denying panel rehearing); 533 F. App'x 912 (panel decision with Judges Barkett and Ripple in majority and Judge Jordan dissenting).

See C.A. Reh'g Supp. Add. SA35-46 (collecting same).

The Third Circuit follows a similar practice, denying rehearing when no "judge who concurred in the decision" seeks rehearing. *E.g.*, *United States v. Safehouse*, 991 F.3d 503, 505 (3d Cir. 2021).

These practices predate the adoption of the Federal Rules of Appellate Procedure. W.S. Simkins, *Federal Practice* 1015, 1268-1270 (1923) (noting uniform practice of requiring a change of mind by a participating judge before granting rehearing, except for Ninth Circuit).

This Court, too, has long followed the rule that "a Justice who concurred" must vote for rehearing. Sup. Ct. R. 44.1. "[N]o reargument will be heard in any case after judgment is entered, unless some member of the court who concurred in the judgment afterwards doubts the correctness of his opinion." *Brown v. Aspden's Adm'rs*, 55 U.S. (14 How.) 25, 26-27 (1852). New Justices who join the Court after a case is decided thus generally do not vote on rehearing, even if their

vote would be "enough to change the decision" or create a majority. S. Shapiro et al., *Supreme Court Practice* 15-14 (11th ed. 2019); *see*, *e.g.*, *Hartigan v. Zbaraz*, 484 U.S. 171 (1987) (equally divided Court), *reh'g denied*, 484 U.S. 1082 (1988) (Kennedy, J., not participating); *Gundy v. United States*, 139 S. Ct. 2116 (4-1-3 decision), *reh'g denied*, 140 S. Ct. 579 (2019) (Kavanaugh, J., not participating); *Brown*, 55 U.S. at 27-28.

The underlying principles behind this Court's and the other circuits' well-established practice are the same—once a court publicly enters its decision, the composition of the court for that case is set, and new judges or justices may not be added to alter the outcome. They also reflect Justice Frankfurter's caution that "[r]ehearings are not a healthy step in the judicial process." *Western Pacific*, 345 U.S. at 270 (separate opinion).

The Ninth Circuit, long the sole outlier, has never reconciled its different approach with Section 46 or its predecessors. *See Carver v. Lehman*, 558 F.3d 869, 878-79 (9th Cir. 2009). Rather, just as with the practice this Court summarily rejected in *Yovino*, the Ninth Circuit simply assumed it had authority to add a new judge and change the outcome of a three-judge panel's decision if one of those judges left the judiciary. *Ibid.* The Federal Circuit apparently made the same assumption—despite contradicting views in its own precedent. *See Universal Restoration, Inc. v. United States*, 798 F.2d 1400, 1406 n.9 (Fed. Cir. 1986) (calling it "troubling" for a multi-member lower tribunal to

grant rehearing without "a member of the original majority * * * vot[ing] for the change").

C. This Issue Is Important and This Case Is an Ideal Vehicle for Addressing It

Ensuring uniform practice on this issue is important. As this Court has recognized when interpreting Section 46's limits on courts of appeals' authority, "in our federal judicial system these courts are the courts of last resort in the run of ordinary cases." *Textile Mills*, 314 U.S. at 335; *American-Foreign Steamship*, 363 U.S. at 691 (same). Public confidence in the judiciary thus depends on these courts staying within the limits Congress established.

Section 46 embodies important policies, not the least of which is "[f]inality of decision in the circuit courts of appeal." *Textile*, 314 U.S. at 335. The approach of the Federal and Ninth Circuits undermines finality. It encourages parties to treat rehearing as "an automatic, second appeal." *Western Pacific*, 345 U.S. at 258 ("difficult to believe that Congress intended to give" such a second chance).

Congress also intended Section 46 to reduce conflicts within the circuits by authorizing only the en banc court, and not some smaller complement of other judges, to overturn a panel's decision. *Textile*, 314 U.S. at 335. Yet rather than avoid intra-circuit conflict, the Federal and Ninth Circuits' approach promotes it. Here, the addition of a new judge created a two-to-two split about the correct interpretation of Section 112. Such conflicts undermine predictability in the law.

They also create an impression that the outcome of cases turns not on the merits, but on which judges decide them.

Even apart from Section 46, these important principles of finality, uniformity, and confidence in the courts warrant this Court's intervention as a matter of its authority over the lower courts. Such principles have led this Court to use its "general power to supervise the administration of justice in the federal courts." *Western Pacific*, 345 U.S. at 260. The same should happen here.

That is especially so because the two outliers are courts of great significance. The Federal Circuit has nationwide appellate jurisdiction over patent cases (28 U.S.C. § 1295(a)), which—like this one—often involve substantial economic interests and public consequences. Congress created that court because of the "unusually complex and technical" nature of patent cases and the importance of uniformity "throughout the country" on these issues. S. Rep. No. 97-275, at 7 (1981). And the Ninth Circuit has far and away the largest caseload of all the circuits, accounting for roughly a quarter of all regional-circuit appeals. USCourts.gov, *Federal Judicial Caseload Statistics 2022 Tables* (last visited Dec. 31, 2022).[6]

Neither court shows any sign of changing its approach without intervention. The Ninth Circuit's practice has continued unchanged for decades.

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[6] https://www.uscourts.gov/federal-judicial-caseload-statistics-2022-tables.

Compare Simkins 1015, 1268-1270 (explaining Ninth Circuit practice as of 1923), *with Carver*, 558 F.3d at 878-79 (reaffirming same practice in 2009). And no Federal Circuit judge dissented from the denial of Novartis's rehearing petition raising these complaints. Pet. App. 115a-117a.

Although these important principles warrant review regardless, the likelihood this issue will recur also favors review. As shown by the examples in Part I.B, *supra*, judges continue to leave the judiciary for various reasons, including "well short of retirement age." Madison Alder, "Ninth Circuit Judge Paul Watford to Resign, Leaving Vacancy," *Bloomberg Law* (Jan. 9, 2023).[7] And because about a quarter of all active and senior circuit judges are members of the Federal or Ninth Circuits, many of those vacancies will occur in one of these courts.

* * *

Either summarily or after plenary review, the Court should vacate the improper grant of panel rehearing and accompanying decision, thus reinstating the original panel decision.

II. THE FEDERAL CIRCUIT'S INTERPRETATION OF SECTION 112'S REQUIREMENT CONTRAVENES TEXT AND PRECEDENT

This Court's review is independently warranted because the four Federal Circuit judges who ruled on

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[7] https://www.bloomberglaw.com/bloomberglawnews/us-law-week/XB0RIL5S000000.

this case divided evenly over an important and recurring question about how to interpret the Patent Act's requirement that a patent contain a written description of the invention. The new majority's decision adds an atextual, rigid requirement that displaces the viewpoint of a skilled artisan and allows that court to engage in appellate factfinding of adjudicative facts, contrary to rules and precedent.

A. Section 112's Text Is Broad and Requires No Specific Kind of Description

Section 112's text establishes a simple requirement: to describe the invention. It states: "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains" to "make and use the same." 35 U.S.C. § 112(a).

That text neither requires nor precludes any specific form of description. Rather, it demands a fact-specific inquiry. The text measures whether the description is "full," "clear," "concise," and "exact" from the perspective of a "person skilled in the art to which [the invention] pertains." *Ibid.* What a skilled person understands varies depending on such factual questions as "the background science," "'the state of the art,'" and what particular words would have conveyed to a skilled person at a particular time in light of that background knowledge and state of the art. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*,

574 U.S. 318, 331-33 (2015) (discussing these factual inquiries in context of interpreting patent claims; citation omitted). And the relevant arts vary widely, because the description requirement applies to highly technical utility patents (like the pharmaceutical one here) and also to patents on plants and designs. 35 U.S.C. §§ 162, 171(c).

Consistent with the text, this Court has long interpreted Section 112 as embodying a flexible standard. "[I]t is enough if [the inventor] describes his method with sufficient clearness and precision to enable those skilled in the matter to understand what the process is, and if he points out some practicable way of putting it into operation." *The Telephone Cases*, 126 U.S. 1, 536 (1888). The point is to describe the invention sufficiently so that, "upon expiration of [the patent], the knowledge of the invention inures to the people, who are thus enabled without restriction to practice it." *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 187 (1933).

That flexible standard has thus been understood as permitting implicit disclosures of aspects of an invention, so long as the relevant skilled artisan would understand the disclosure. For example, in *Marconi Wireless Tel. Co. of Am. v. United States*, this Court affirmed a patentee's right to amend its patent to "ma[k]e explicit what was already implicit" in its original patent application. 320 U.S. 1, 34, 38 (1943) (holding that patentee's patent anticipated certain claims of Marconi's). The question there involved whether a patentee's original application had disclosed

tuning of antenna circuits, which was later expressly added to the patent by amendment. *Ibid.* The original application "nowhere state[d] in so many words that the antenna circuits should be tuned, nor [did] its specifications or drawings explicitly disclose any means" for doing so. *Ibid.* Nevertheless, after canvassing what was known to those skilled in the relevant art, this Court held the "principles which [the patentee] recognized in his application, the purpose which he sought to achieve, and certain passages in his specifications, show that he recognized, as they plainly suggest to those skilled in the art, the desirability of tuning the antenna circuits as well." *Id.* at 21-22, 34. Adding that express requirement was thus not a "departure from or improper addition to" the patent because the "idea of such tuning was at least implicit in his original application" all along. *Id*. at 34-36; *Hobbs v. Beach*, 180 U.S. 383, 395-97 (1901) (explaining rule against "any expansion of the original specification and claims").

The Court of Customs and Patent Appeals—whose decisions the Federal Circuit adopted as precedent—similarly interpreted Section 112, explaining a patent "may provide an implicit description" of the claimed invention. *In re Robins*, 429 F.2d 452, 456-47 (C.C.P.A. 1970); *see South Corp. v. United States*, 690 F.2d 1368, 1369 (Fed. Cir. 1982) (en banc) (adopting C.C.P.A. decisions). The Patent and Trademark Office likewise instructs its patent-application examiners to apply the same interpretation—an application adequately describes an invention when it "expressly, *implicitly*,

or inherently" describes "each claim limitation" of the invention to a person of skill in the field. Manual of Patent Examining Procedure (MPEP) § 2163(II)(A)(3)(b) (emphasis added).

B. The Federal Circuit Adopted an Atextual, Rigid Interpretation of Section 112 and Used It to Create a Patent-Specific Exception to Clear-Error Review

But here, the Federal Circuit layered on an atextual requirement that disrupts that settled law, calling into question all patents issued in reliance on it.

According to the second of the Federal Circuit's precedential decisions in this case, a patent's description of the invention generally must be express, not implicit. Pet. App. 5a-8a & n.2. The court held that a lack of express disclosure for every claim limitation "may often be dispositive" of patent invalidity. *Ibid.* And it allowed just one possible exception: if the "patent owner could establish" that a particular limitation would always be understood by skilled artisans as being "necessarily" present in what is expressly described in the specification. Pet. App. 7a-8a.

Section 112 nowhere adopts such a high bar. And this case shows how the Federal Circuit's new requirement creates a rigid rule that displaces the perspective of those of skill in the art. The original decision of the Federal Circuit faithfully applied Section 112's flexible standard for adequate

description, reviewing the district court's decision of this "essentially * * * fact-based inquiry" for clear error. Pet. App. 42a-56a. Under that flexible standard, the district court's findings about how skilled persons in this art would understand the patent's description were paramount. *Ibid.* That included findings—based on unrebutted expert testimony—about how skilled artisans would read a detailed clinical-trial description like the one in Novartis's patent, in which the omission of a loading dose would implicitly " 'tell a person of skill that loading doses are excluded.' " Pet. App. 49a-51a.

By contrast, the new decision adopted a heightened burden that precluded the district court from relying on such facts. Pet. App. 8a-14a. It imposed a universal rule, regardless of the art or background knowledge in the field, making a lack of explicit description generally "dispositive." Pet. App. 7a-10a. And in the absence of an explicit disclosure, it reduced Section 112's flexible standard to a single inquiry: whether the patent's description "*necessarily excluded* a loading dose." Pet. App. 12a-13a (emphasis by court). This case shows the problem with that rule—the new decision dismissed expert testimony that the specification's animal testing and clinical-trial description "discloses the absence of a loading dose" because none of that testimony purportedly rose to the level of necessarily excluding use of a loading dose. Pet. App. 7a-13a.

The Federal Circuit's "necessarily excluded" standard contradicts Congress's direction that issued patent claims "shall be presumed valid." 35 U.S.C. § 282. That presumption requires patent challengers to prove

invalidity by clear-and-convincing evidence. *Microsoft*, 564 U.S. at 95. Yet according to the Federal Circuit, a patent challenger needs merely to assert that a patent's description lacks an express disclosure of some aspect of the invention (even, as here, for a statement of what is *not* claimed). Pet. App. 7a-8a. The court's new rule then improperly shifts the burden to the "patent owner" to "establish" the "necessarily excluded" standard. Pet. App. 8a, 13a. Here, that allowed the appellate court to substitute its own views *de novo*.

This Court has consistently intervened to review the Federal Circuit's creation of similar atextual and rigid requirements, and it should do so here. *E.g.*, *KSR*, 550 U.S. at 407, 419, 428 (rejecting creation of similar rigid requirement for applying 35 U.S.C. § 103); *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 553 (2014) (reversing attorney-fees rule as "unduly rigid," contrary to 35 U.S.C. § 285); *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 579 U.S. 93, 104 (2016) (similar for enhanced-damages test under 35 U.S.C. § 284). As in those cases, the Federal Circuit's new requirement wrongly cabins the range of circumstances factfinders should consider. Under this rule, a patent would be invalid for inadequate description even if it were undisputed that persons of skill in a field would understand the patent to implicitly describe certain aspects of an invention—for example, because of well-understood background knowledge. That result contradicts Section 112's plain language and its focus

on what a patent conveys to a "person skilled in the art." 35 U.S.C. § 112(a).

Changing Section 112's understanding now would upset patent owners' settled expectations. Every patent in force today was issued under judicial decisions and Patent Office guidance expressly allowing implicit descriptions. *Supra* pp. 31-33; MPEP § 2163(II)(A)(3)(b) (8th ed. 2001). Patent applicants drafted their applications based on that understanding. Yet patent owners now face the prospect of having their property rights rescinded based on the Federal Circuit's newly announced "wooden" rule. Intellectual Property Law Professors Brief, C.A. Dkt. 73, at 2-4.

The Federal Circuit's interpretation would also make it harder for future applicants to protect their discoveries without lengthy disclosures detailing well-known minutiae in the relevant field, contrary to Congress's command for a "concise" description. 35 U.S.C. § 112(a). Because patent descriptions are directed to persons skilled in the art, they "preferably omit[] what is well known in the art," as the Federal Circuit once recognized. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986).

This Court's intervention is further warranted because the Federal Circuit's heightened requirement wrongly supplants Rule 52's deferential clear-error standard. *See*, *e.g.*, *Teva*, 574 U.S. at 333-36 (vacating for failure to apply clear-error review under Fed. R. Civ. P. 52); *Dennison Mfg. Co. v. Panduit Corp.*, 475

U.S. 809, 810-12 (1986) (summarily vacating decision for failing to cite or clearly apply Rule 52 to factual issues). "[C]lear error review is 'particularly' important where patent law is at issue because patent law is 'a field where so much depends upon familiarity with specific scientific problems and principles not usually contained in the general storehouse of knowledge and experience.'" *Teva*, 574 U.S. at 327-28. In *Teva* and *Dennison*, the factual findings merely underlay what was ultimately a legal question, such as claim construction and obviousness. Here, the ultimate question of compliance with Section 112 is itself factual, making the Federal Circuit's current interpretation even more problematic. Pet. App. 4a.

C. The Federal Circuit's Approach Threatens Innovation, and This Is an Ideal Case for Righting the Ship

The substantive patent-law question here is exceptionally important, as the history of this case confirms. For one, the issue was important enough to warrant two precedential opinions, each with an authored dissent. *Compare* Pet. App. 1a-26a *with* Pet. App. 27a-68a. The new panel considered the question sufficiently important to grant panel rehearing and vacate the original panel's opinion. Pet. App. 2a-3a. And the question has equally divided the members of the Federal Circuit who addressed it. Chief Judge Moore, joined by Judge Hughes, rejected implicit disclosure and required that each limitation be either explicitly disclosed or "necessarily" present in some explicit disclosure. Pet. App. 5a-8a & n.2. Judge Linn

and then-Judge O'Malley disagreed, explaining instead that "a showing of 'necessary exclusion' * * * is not and should not be a requirement in every case." Pet. App. 18a, 48a-49a.

This intra-circuit divide also confirms the need for this Court's intervention. Congress created the Federal Circuit and gave it exclusive appellate jurisdiction over patent cases to achieve "desirable uniformity" in patent law. *Markman v. Westview Instrs., Inc.*, 517 U.S. 370, 390 (1996). But the Federal Circuit has often been criticized for panel-dependent results produced by adoption of atextual requirements and refusal to defer to factfinders. *See* Intellectual Property Law Professors Brief, C.A. Dkt. 73, at 9-11. As scholars have explained, "[p]roper application of the written description doctrine is challenging" because "the Federal Circuit's development of the law surrounding the written description requirement has been turbulent" and "the contours of the legal test" are "ever-evolving." Aaron B. Rabinowitz, *Ending the Invalidity Shell Game: Stabilizing the Application of the Written Description Requirement in Patent Litigation*, 12 MINN. J.L. SCI. & TECH. 127, 148 (2011).

The effects of this uncertainty are especially acute for innovators in life sciences and biotechnology. It is no secret that innovations in these fields require immense investments of capital and long development times. D. Karshtedt, M.A. Lemley, & S.B. Seymore, *The Death of the Genus Claim*, 35 HARV. J.L. & TECH. 1, 63-65 (2021). These industries, perhaps more than any others, depend heavily on the promise of patent

protection to spur this innovation. *Ibid.* Yet by constantly moving the goal posts, the Federal Circuit has eroded that protection and reduced the incentives to innovate. *See* Brief of Intellectual Property Professors as *Amici Curiae* in Support of Petitioners, *Amgen*, No. 21-757, at 11-12 (making similar point about Federal Circuit's interpretation of "enablement" requirement under same statutory provision).

This case is an excellent vehicle for deciding this important statutory-interpretation question. The competing majority decisions show that the Federal Circuit's holding on the statutory-interpretation issue is dispositive. Indeed, under the correct legal standards—which permit implicit descriptions of an invention and require deference to factfinders—the evidence is wholly one-sided that a skilled artisan would read Novartis's patent to disclose administering fingolimod without a loading dose. *Supra* pp. 12-13. That evidence went unrebutted; HEC's expert conceded on direct examination that he was unqualified to opine on the patent's key passage. C.A. App. 23117.

Review is also warranted because the stakes are high. Then-Chief Judge Stark granted a preliminary injunction partly because of the "massive and immediate price erosion in the market for oral treatment of RRMS" that generic entry would cause. C.A. App. 18863. That massive erosion is well underway now that at least ten competitors, including HEC, have entered the market following the Federal

Circuit's invalidation of Novartis's patent. Only this Court's review can mitigate those effects.

If this Court does not summarily vacate on the first question or grant now on either question, it should at least hold this petition pending disposition of *Amgen*. As here, the question there involves the correct interpretation of Section 112 and whether the Federal Circuit "'impose[d] limitations on the Patent Act that are inconsistent with the Act's text.'" Petrs' Br. 1, No. 21-757 (citation omitted). And although *Amgen* concerns the Federal Circuit's "enablement" test and this case involves its "written description" test, both tests derive from the same Patent Act sentence. This Court's decision there will bear on—and could require rejection of—the rule the Federal Circuit announced here.

CONCLUSION

The Court should grant the petition and any other appropriate relief.

Respectfully submitted,

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