No. 22-671

In the Supreme Court of the United States

NOVARTIS PHARMACEUTICALS CORP., 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

BRIEF FOR RESPONDENTS IN OPPOSITION

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QUESTIONS PRESENTED

As a basic function of the patent bargain, the law has for centuries required patent specifications to "contain a written description of the invention" that is set out in "full, clear, concise, and exact terms." 35 U.S.C. § 112. In a 2-1 decision, the Federal Circuit held that Novartis's patent failed this requirement. The majority and dissent agreed on the legal standard. They simply disagreed on how to read the particular specification and interpret the particular evidence at issue.

The panel reached this outcome on rehearing; originally, the court upheld Novartis's patent. While respondents' petition for rehearing was pending, one judge on the original panel retired and, per the Federal Circuit's longstanding local rules, another was added to the panel in her place. The panel subsequently granted rehearing and ruled in favor of respondents.

The questions presented are:

1. Did the Federal Circuit act within its authority to govern its own internal operations when, upon one panel judge's retirement, it added another judge to the panel while a petition for rehearing was pending?

2. Did the Federal Circuit correctly conclude, on the particular facts of this case, that Novartis's patent specification failed § 112's written description requirement?

RULE 29.6 STATEMENT

Respondent HEC Pharm Co., Ltd.'s parent corporation is HEC Pharm Group. Respondent HEC Pharm USA Inc.'s parent corporation is HEC Pharm Co., Ltd. No publicly held company owns 10% or more of either respondent's (or their parents') stock.

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INTRODUCTION

After a close review of the underlying record, the Federal Circuit invalidated Novartis's patent because it lacked the "written description" of the "invention" that 35 U.S.C. § 112 requires. Its ruling is a fact-specific application of settled law—sufficiently settled that the majority and the dissent agreed on the legal standard. The Federal Circuit found that certain findings by the district court were clearly erroneous and that Novartis's trial experts had offered testimony that conflicted with the plain language of the patent specification. That specification, from 2006, does not describe the treatment method Novartis tried to patent years later, in 2014. The Federal Circuit's decision is both correct and, more to the point, not remotely certworthy.

Though the asserted patent should never have been granted, Novartis used it to stave off generic competition for years. Trying to squeeze every last dollar from its lucrative monopoly, Novartis unsuccessfully sought rehearing en banc and then a stay from the Federal Circuit. Then it sought a stay from this Court, also denied. Its petition for certiorari shares the same basic flaw as its earlier filings: Novartis cannot identify any legal error in the Federal Circuit's fact-bound inquiry, much less one of substantial importance that warrants this Court's review.

Not for lack of trying. Below, Novartis claimed (wrongly) that the Federal Circuit violated its own procedural rules. Then, in its application for a stay, Novartis linked this case closely to the then-pending petition in *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, No. 21-1566, arguing that the Court should grant review to address whether the statute contains a "written description" requirement at all. But the Court denied both the *Juno* petition and Novartis's stay application. So Novartis has dropped the untenable *Juno* argument and relegated any claim of patent law error to a fallback. It now claims instead that the composition of the Federal Circuit panel violated 28 U.S.C. § 46—a new argument it never made below or in its stay application.

Novartis's petition should be denied. The Federal Circuit followed its own rules and procedures when it designated a new judge to replace a retired one. Section 46 does not even speak to the issue Novartis complains of, much less require a panel reduced to two members to act when those members are evenly divided. No Federal Circuit judge—including the dissenter—suggested any procedural concern. As for Novartis's fallback patent-law question: this Court has repeatedly and correctly declined to review the Federal Circuit's written description jurisprudence. *See infra* 29-30. And Novartis offers no persuasive

reason for the Court to address a case-specific application of that standard where the panel split, not on the law, but on how to assess the evidence and district court's findings.

STATEMENT

I. Statutory Background

A. Court Administration

In 28 U.S.C. § 46, Congress adopted a basic framework for the "hearing and determination of cases" by the courts of appeals, *id.* § 46(b), but left nearly all the details for those courts to manage, *see id.* § 46(a) ("Circuit judges shall sit on the court and its panels in such order and at such times as the court directs."). Section 46 authorizes three-judge panels—except for the Federal Circuit, which may designate panels of "more than three judges." *Id.* § 46(c). Absent unusual circumstances, a majority of judges on a panel must be "judges of that court." *Id.* § 46(b). Congress also authorized "hearing or rehearing before the court in banc" when "ordered by a majority of the circuit judges of the circuit who are in regular active service." *Id.* § 46(c). A quorum is a "majority of the number of judges authorized to constitute a court or panel thereof." *Id.* § 46(d).

Although § 46 requires "at least three judges [on a panel] in the first instance," *Nguyen v. United States*, 539 U.S. 69, 82 (2003), it does not address what happens when one of those judges becomes unavailable before an appeal is finally decided. Relying on the quorum provision, courts have long followed the practice "that when one of the judges on a three-judge panel dies, retires, or resigns after an appeal is argued or is submitted for decision without argument, the other two judges on the panel may issue a decision if they agree." *Yovino v. Rizo*, 139 S. Ct. 706, 709 (2019); *see Murray v. Nat'l Broad. Co.*, 35 F.3d 45, 47 (2d Cir. 1994) (Congress anticipated "local rules

permitting the disposition of an appeal [when] … one of the three judges dies or becomes disabled and the remaining two agree on the disposition" (citing S. Rep. No. 97–275, 97th Cong., 2d Sess. 9)).

Novartis says that under § 46, once a panel is assigned, "other judges" may not participate in determining a matter except through en banc review. Pet. 7-8. Section 46 does not say that, nor does it say anything about panel rehearing, nor what happens if two remaining judges on a panel do not agree on disposition. Courts regularly appoint a replacement judge to a panel when one member has become unavailable. *See, e.g., United States v. Rosario*, 7 F.4th 65, 67 n.* (2d Cir. 2021); *Leonardo v. Crawford*, 646 F.3d 1157, 1158 n.* (9th Cir. 2011).

Beyond § 46's guardrails, the courts of appeals retain discretion to manage their "internal administration." *Shenker v. Baltimore & Ohio R.R. Co.*, 374 U.S. 1, 5 (1963); *see also W. Pac. R. Corp. v. W. Pac. R. Co.*, 345 U.S. 247, 250, 259, 267 (1953) (courts of appeals have discretion under § 46 to adopt "administrative machinery" for en banc hearings and no "particular procedure" is required). Consistent with its authority to "prescribe rules for the conduct of [its] business," 28 U.S.C. § 2071(a), the Federal Circuit adopted a local rule that governs when a panel member becomes unavailable while the panel has an "appeal, petition, or motion" "under submission," Federal Circuit Rule 47.11. The remaining judges may "determine the matter if they are in agreement." *Ibid.* If they are not in agreement, or one of the remaining judges so requests, another judge is designated to the panel. *Ibid.*

B. Written Description

The Federal Circuit invalidated Novartis's patent for lack of the adequate written description required by 35 U.S.C. § 112. Pet. App. 1a-15a. Section 112 requires a patent specification to "contain a written description of the

invention, and of the manner and process of making and using it" that is set out in "full, clear, concise, and exact terms." As the Federal Circuit has explained, the "requirement to describe one's invention is basic to patent law. . . . It is part of the *quid pro quo* of [obtaining] a patent." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1345 (Fed. Cir. 2010) (en banc); *accord Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002) (inventors must "describe their work" in "full, clear, concise, and exact terms"); *Biogen Int'l GMBH v. Mylan Pharms. Inc.*, 18 F.4th 1333, 1341 (Fed. Cir. 2021), *cert. denied*, 143 S. Ct. 112 (2022) ("written description" has been a "fixture" of patent law for over "two centuries").

II. Facts and Procedural History

A. The '405 Patent. Novartis sells fingolimod, brand-name Gilenya, a drug used to treat multiple sclerosis. The first fingolimod patents, issued to Japanese researchers at Mitsubishi, date back nearly 30 years. *See* U.S. Pat. Nos. 5,604,229; 6,004,565. Novartis licensed those patents from Mitsubishi, and when they expired, Novartis leveraged two invalid follow-on patents to continue to block generic competition with Gilenya. The first, U.S. Patent No. 8,324,283, was invalidated in 2015. *See Torrent Pharms. Ltd. v. Novartis Ag*, Nos. IPR2014-00784, IPR2015-00518, 2015 WL 5719630, at *2 (P.T.A.B. Sept. 24, 2015), *aff'd*, 853 F.3d 1316 (Fed. Cir. 2017).

The other is U.S. Patent No. 9,187,405, the patent the Federal Circuit held invalid below. Novartis filed the application that issued as the '405 patent in April 2014 claiming priority back to a foreign application filed in 2006. As relevant here, the asserted claims of the '405 patent purport to cover and exclude others from practicing a specific treatment method for fingolimod: "a daily dosage of 0.5

mg, absent an immediately preceding loading dose regimen." U.S. Patent No. 9,187,405 col. 12 l. 54-55; Pet. App. 31a. Because the '405 patent claims priority to the earlier 2006 application, its specification is identical to the 2006 specification. C.A. App. 25198, 25219. The 2006 priority date was critical for Novartis because by 2014 there was nothing innovative about this treatment—the FDA approved the 0.5 mg daily dose with no loading dose in 2010. C.A. App. 10. The upshot is that for the '405 patent to satisfy § 112's written description requirement, the 2006 specification must describe the claimed treatment method.

But on this critical question the 2006 specification falls short: it does not disclose a 0.5 mg dose of fingolimod as an effective treatment for multiple sclerosis, let alone disclose administering it without a loading dose. In fact, the 2006 specification does not describe any actual treatment of humans with fingolimod—at all.

Novartis nonetheless pursued the '405 patent in an undisguised effort to extend its lucrative Gilenya monopoly. Questionable priority claim to 2006 aside, Novartis had an even bigger problem. Prior art claiming priority to 2004 known as "Kovarik," together with other references, disclosed administering fingolimod in a 0.5 mg daily dose, but in the context of a loading dose. C.A. App. 23892-23894, 23900-23906, 03652. So years later, Novartis amended its claims to expressly *exclude* a loading dose. C.A. App. 23889-23894, 25259-25261. And Novartis readily admitted that its reason for doing so was to avoid the Kovarik prior art:

> Applicants have amended all pending claims (or the claims from which they depend) to specify that the stated daily dosage of 0.5 mg cannot immediately follow a loading dose regimen. Applicants have made

> these amendments to further distinguish their claims from the disclosure of Kovaric [sic].

C.A. App. 23892.

At no point did Novartis amend the 2006 specification to describe the treatment method it now claimed. Nor could it have done so while preserving its priority claim: Changing the specification would mean losing the 2006 priority date. That was a non-starter, because Novartis conceded that a 2010 study disclosed using a 0.5 mg dose of fingolimod *without* a loading dose. C.A. App. 00248 ("Patent Owner does not dispute that Kappos 2010 discloses each element of claims 1-6."). Novartis had to thread a needle: it needed to change its claims to avoid Kovarik, but needed to keep the 2006 priority date to maintain priority over Kappos, so it eked out the patent by amending the *claims* to exclude a loading dose, but leaving the *specification* as it had been written in 2006.

B. Procedural history. In 2018, Novartis sued HEC (and other generic drug companies poised to compete with Gilenya) for supposedly infringing the '405 patent. C.A. App. 00143-00197. This lawsuit followed years of other fingolimod patent litigation at the Patent Trial and Appeal Board and in federal court.

1. Novartis sought a preliminary injunction in the district court, on the ground that it stood to lose billions of dollars if generic manufacturers were allowed to market generic fingolimod. C.A. App. 18865. The district court granted the injunction, *ibid.*, thus blocking generic competition for Gilenya while the litigation continued. Novartis later settled with all defendants other than HEC.

Following a bench trial, the district court rejected HEC's written-description challenge and ruled in Novartis's favor. Pet. App. 94a-99a.

2. HEC appealed. Initially, a split panel of the Federal Circuit affirmed. Pet. App. 29a-56a. Chief Judge Moore dissented, concluding that nothing in the 2006 specification disclosed a method for treating multiple sclerosis with a 0.5 mg daily dose absent an initial loading dose. Pet. App. 57a-68a. As her opinion explained, Novartis's argument that the term "daily dosage" excluded a loading dose was "not only unsupported by the record," but rather "contradicted at every turn." Pet. App. 64a. Most importantly, the claims were allowed only *after* Novartis added the limitation excluding an initial loading dose, which it concededly did to overcome prior art. The "same logic" that applies to the claims applies to the specification: "If daily already meant no loading dose, then there would have been no reason for the claims to recite both a 'daily dosage' and the negative loading dose limitation." Pet. App. 64a-65a.

HEC petitioned for rehearing. While the petition was pending, Judge O'Malley—author of the majority opinion—retired and a new judge was assigned to replace her. The panel granted rehearing, vacated the initial panel decision, and issued an opinion reversing the district court. Pet. App. 2a-3a. Judge Linn, previously in the majority, now dissented.

The majority on rehearing held that the 2006 specification did not disclose what Novartis now claimed as its invention: administering 0.5 mg of fingolimod daily to treat multiple sclerosis *without a loading dose*. Pet. App. 2a-3a. Reiterating that "[d]isclosure is essential; it is 'the *quid pro quo* of the right to exclude,'" the majority applied the standard set forth in the Federal Circuit's 2010 en banc ruling in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010). Pet. App. 5a. The majority and dissent both looked to *Ariad* and agreed that *Ariad's* standard governs disclosure of a negative

limitation like this one. *See* Pet. App. 5a-6a (majority); 16a-18a (dissent).

In applying that standard to the facts of this case, the majority held that key findings of the district court were clearly erroneous. *E.g.*, Pet. App. 10a (agreeing with HEC that the district court relied on a "misquotation 'ferreted into trial testimony by Novartis' experts'"). Novartis argued, and the district court found (in error), that the specification disclosed giving a "daily dose" of 0.5 mg, starting "initially." Pet. App. 9a. But the "specification nowhere describes 'initially' administering a daily dosage." Pet. App. 9a. What was clear, after setting aside the district court's flawed findings, was that the specification is silent as to loading doses. It does not discuss them, explain them, or otherwise provide a rationale for excluding them.

And the prosecution history showed that merely disclosing a daily dose did not exclude a loading dose; if that were true, "there would have been no reason for the applicants to add the no-loading-dose limitation." Pet. App. 12a. The majority thus concluded that, because a person skilled in the art would not read the specification to necessarily exclude a loading dose, it does not satisfy § 112. Pet. App. 13a-14a. The "written description requirement cannot be met through simple disregard of the presence or absence of a limitation." Pet. App. 6a.

Although Judge Linn dissented on the merits, he did not object to or even comment on the designation of a third judge to replace Judge O'Malley.

3. Novartis petitioned for panel rehearing and rehearing en banc. It primarily argued that the designation of a new judge to replace Judge O'Malley violated the Federal Circuit's rules. C.A. Reh'g Pet. 7-11. On September 20, 2022, the Federal Circuit issued an order denying both panel and en banc rehearing. Pet. App. 116a-117a. There was no recorded dissent.

4. After the Federal Circuit refused to stay the mandate, Novartis filed an application for a stay with this Court. In seeking a stay, Novartis primarily argued that this case presented the same issue as *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, No. 21-1566 (pet. filed June 13, 2022; cert. denied Nov. 7, 2022): whether § 112 requires a written description at all. Novartis argued that the Court should either grant *Juno* and hold this case, or grant certiorari in this case to decide that question. Stay App. 2, 15-20. As a fallback, Novartis argued that the Court should grant review of this case to decide whether "implicit" disclosure satisfies § 112. Stay App. 20. Notably, as Novartis sought a stay to avoid what it deemed a "cascade of irreparable harms," Stay App. 30, it did not argue that the composition of the Federal Circuit panel was a certworthy issue.

The Court denied Novartis's stay application. No. 22A272, Order (Oct. 13, 2022). The Court denied the *Juno* petition a few weeks later.

REASONS FOR DENYING THE PETITION

I. Novartis's newly minted procedural question presented does not warrant this Court's review.

After telling this Court last fall that the decision below implicated two certworthy patent questions, Novartis now relegates substantive law to an afterthought and fronts its petition with a procedural question regarding 28 U.S.C. § 46. *Compare* Stay App. 16, *with* Pet. 1-2. But all three reasons Novartis offers in support of its new procedural question are meritless.

First, the Federal Circuit procedure at issue here violates no statute, rule, precedent, or uniformly accepted notion of fairness. Not one Federal Circuit judge—including the dissenting judge below—suggested any procedural impropriety. There is none.

Second, Novartis's assertion of a circuit split is frivolous. Novartis falsely describes a "uniform" practice of other circuits and, regardless, permissible variations in procedure do not constitute a circuit split. They merely reflect the basic architecture of our appellate system.

Finally, Novartis's claim of importance is hard to take seriously. It could hardly have picked a question that arises less frequently.

A. The practice that Novartis challenges unquestionably falls within the Federal Circuit's authority to govern its own procedure.

Nothing that happened below "conflicts with federal law." Pet. 18. The Federal Circuit followed its own local rules in appointing another judge to the panel when one of the original members retired. Fed. Cir. R. 47.11. That action did not violate any statute, rule, or precedent. Both Rule 47.11, and the application of that rule here, fall well within the Federal Circuit's discretion to "devise its own administrative machinery" and determine matters of procedure and court operations. *Shenker v. Baltimore & Ohio R.R. Co.*, 374 U.S. 1, 5 (1963); *see* 28 U.S.C. § 2071(a) (statutory authority for lower courts to "prescribe rules for the conduct of their business").

1. The Federal Circuit's rules provide for the designation of another judge when a panel member has become unavailable while "any appeal, petition, or motion" is pending and the remaining two judges are not in agreement. Fed. Cir. R. 47.11. That rule was followed here. Novartis's assertion that Rule 47.11 does "not address a vacancy after entry of a decision" is indefensible. Pet. 15. It expressly applies when "any . . . *petition* or motion" is "under submission," and here, the panel had a petition for rehearing under submission. Fed. Cir. R. 47.11

2. After ignoring the plain language of Rule 47.11, Novartis goes on to re-write 28 U.S.C. § 46. It claims the statute sets forth a "clear rule" that a panel may grant rehearing and revise a decision only if ordered by "a majority of the judges who entered the decision." Pet. 20. But § 46 says nothing of the kind. It says cases are ordinarily heard by three-judge panels:

> Cases and controversies shall be heard and determined by a court or panel of not more than three judges (except that the United States Court of Appeals for the Federal Circuit may sit in panels of more than three judges if its rules so provide), unless a hearing or rehearing before the court in banc is ordered ....

28 U.S.C. § 46(c). And it provides that a "quorum" is a "majority of the number of judges authorized to constitute a court or panel thereof." *Id.* § 46(d).

Section 46 doesn't speak to panel rehearing, or direct what happens when a member of a panel retires or dies before a matter is finally resolved. Novartis's supposed "clear rule" is pure invention.[1]

To begin with, Novartis protests that "four" judges "ruled on" the case. Pet. 29. That is not true; the initial opinion was vacated and the case was decided by a three-judge panel. But the "four" judge hyperbole is particularly ironic given that § 46 authorizes the Federal Circuit to sit in panels of "more than three judges." 28 U.S.C. § 46(c).

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[1] When Novartis petitioned for rehearing en banc below, it did not argue that the appointment of a third judge to the panel violated § 46. It cited § 46 in passing, but premised its argument for rehearing en banc on a supposed violation of the Federal Circuit's rules, not a statutory violation. C.A. Reh'g Pet. 11.

What Novartis really contends is that HEC's petition for rehearing should have been ruled on by a *two*-judge panel that was divided 1-1. But nothing in § 46 purports to require action by a 1-1 panel. And while this Court has held that "two judges constitute a quorum and are able to decide an appeal," that conclusion came with an important caveat—"provided, of course, that they agree." *Yovino v. Rizo*, 139 S. Ct. 706, 709 (2019). The two judges here did not agree.

In fact, both *Yovino* and Novartis's other main case, *United States v. American Foreign Steamship Corp.*, 363 U.S. 685 (1960), directly contravene its position. In *Yovino*, the Ninth Circuit counted a deceased judge's vote in deciding a case. 139 S. Ct. at 708. That has nothing to do with appointing a new judge while rehearing is pending. The problem in *Yovino* was counting the vote of someone who was "no longer a judge." *Id.* at 710. Same in *American Steamship*, only as to a retired judge who (under an old version of § 46) lacked the "power to participate" in en banc proceedings. 363 U.S. at 691.

Yovino and *American Steamship* merely confirm that once Judge O'Malley retired, she could not vote on the petition for rehearing. Yet Novartis in effect assumes Judge O'Malley would have voted to deny rehearing and wants to count that "vote" here. *See* Pet. 23. That is precisely what this Court's cases forbid.

Novartis also contends that the Federal Circuit should have followed this Court's rules, which provide that a petition for rehearing "will not be granted except by a majority of the Court, at the instance of a Justice who concurred in the judgment or decision." Sup. Ct. R. 44.1. But this Court is differently situated from the courts of appeals, because this Court always sits "en banc." More importantly, this Court's rules do not govern the Federal Circuit or limit its discretion to adopt its own rules.

Novartis, in short, can find no statute, case, or rule that requires a 1-1 panel to deny a petition for rehearing.

3. And because no authority requires that outcome, the Federal Circuit was free to adopt the procedure of its choosing. This Court has long recognized that § 46 grants the courts of appeals a "wide latitude of discretion" on questions of procedure. *W. Pac. R. Corp. v. W. Pac. R. Co.*, 345 U.S. 247, 259 (1953). In *Western Pacific*, for example, the Court deemed it "quite clear" that Congress gave the courts of appeals substantial leeway to adopt their own "administrative machinery" for en banc hearings. *Id.* at 250, 257.

The Court reaffirmed *Western Pacific* in *Shenker v. Baltimore & Ohio Railroad Co.*, 374 U.S. 1 (1963). There, the Third Circuit denied rehearing en banc even though four judges voted in favor and two against. *Id.* at 4. Two judges abstained. The Third Circuit's rules required an "absolute majority" of active judges to vote for en banc review. *Ibid.* The Court held that this procedure was "clearly within the scope of the court's discretion." *Id.* at 5. This Court accordingly declined to "involve it[self] unnecessarily in the internal administration of the Courts of Appeals." *Ibid.*[2]

The same is true here. Because no authority requires a particular procedure when a panel is divided 1-1 on a petition for rehearing, the courts of appeals have that same "wide latitude of discretion" to adopt their preferred "administrative machinery." *Western Pacific*, 345 U.S. at 250, 259. Appointing another judge to the panel, as the Federal Circuit did here, was permissible and consistent

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[2] This Court observed in *Western Pacific* an important check on any procedure adopted by a court of appeals: a majority of the court remains free to reconsider and change its procedures at any time. 345 U.S. at 261. Here, Novartis's petition for en banc review was denied with no objection noted.

with that court's rules. Fed. Cir. R. 47.11; *see also* Fed. Cir. IOP #12, Petitions for Panel Rehearing (eff. Mar. 1, 2022) (requiring "vote of the panel . . . to deny the petition"; no authority to deny petition where panel is evenly divided).[3]

4. Novartis's amici offer policy arguments for why, in their view, the Federal Circuit should have adopted a different rule. They say, for example, that designating a replacement judge is "one-sided" and inconsistent with "due process" because it can "benefit only the original losing party" with "no corresponding benefit to the prevailing party." Br. Civ. Profs. 13. That is true of any petition for rehearing—and for that matter, any appeal.

But like Novartis, amici identify nothing *requiring* a 1-1 panel to deny rehearing. *See, e.g.*, Br. Ret. Judges 10 (arguing, without citation, that "agreement of both remaining judges" is needed to order rehearing and request appointment of a third judge); Br. Civ. Profs. 4-5 (arguing that § 46(d) requires two-judge panel to decide rehearing petition, but relying on case where third judge was added to panel to decide rehearing petition (citing *United States v. Desimone*, 140 F.3d 457 (2d Cir. 1998)). Amici do not cite a single published decision from any court that so holds. And they ignore Federal Circuit Rule 47.11, which expressly authorizes the procedure followed here.

There is no basis for this Court to "impose a uniform rule," Br. Ret. Judges 14, where the governing statute and rules afford discretion to the courts of appeals to determine their procedures. The Federal Circuit's approach

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[3] https://cafc.uscourts.gov/home/rules-procedures-forms/internal-operating-procedures/. Novartis relies on a Federal Circuit "practice note" but a practice note is not a duly adopted rule or procedure. *See U.S. Philips Corp. v. Windmere Corp.*, 971 F.2d 728, 730 (Fed. Cir. 1992); *Pashun v. Dep't of Treasury*, 985 F.2d 585 (Fed. Cir. 1992) (practice note "advisory, not mandatory").

falls well within its authority to manage "the conduct of [its] business." 28 U.S.C. § 2071(a). Granting review would only involve this Court "unnecessarily" in the Federal Circuit's "internal administration." *Shenker*, 374 U.S. at 5.[4]

B. The assertion of a circuit split is frivolous.

Novartis and its amici insist all circuits other than the Federal Circuit and the Ninth Circuit follow a "uniform" practice and would not designate another judge to a panel to decide a petition for rehearing. But Novartis ignores decisions that undermine its claim of uniformity and draws unjustified inferences from silence. Regardless, the circuits have no obligation to act in lockstep on matters of procedure. That permissible variation is not a "split" but the expected result of allowing thirteen appellate courts to govern their own internal operations.

1. Novartis's claim of a discernible and uniform rule across 11 of the 13 circuits is demonstrably false:

- The Ninth and the Federal Circuits have published decisions in which a third judge was designated to decide a petition for rehearing, and the panel thereafter granted rehearing. *See Carver v. Lehman*, 558 F.3d 869, 878-79 (9th Cir. 2009); Pet. App. 1a-26a. As Novartis acknowledges, this has been the practice of the Ninth Circuit for a century, Pet. 26—although it rarely happens.
- The Second Circuit has published opinions (which Novartis ignores) in which one of the two

[4] Notably, no former Federal Circuit or Ninth Circuit judges joined the five former judges who appear as amici here. When the amici former judges served on the bench, they had a voice in determining their circuits' procedures—and, if the issue arose, could advocate for their preferred rule. But their brief does not demonstrate any need for this Court's review, because they have not shown that the Federal Circuit lacked authority to adopt its preferred rule.

remaining judges asked for a third judge to be designated to decide a petition for rehearing. In *United States v. Desimone*, 140 F.3d 457, 458 (2d Cir. 1998), then-Chief Judge Winter "designated [him]self" and authored a ruling denying panel rehearing. *Id.*; *see Whitehall Tenants Corp. v. Whitehall Realty Co.*, 136 F.3d 230 (2d Cir. 1998) (similar).[5]

- A Tenth Circuit case (which Novartis ignores) says that two panel judges may decide a petition for rehearing *if they agree*. *Cupps v. Pioneer Canal-Lake Hattie Irrigation District*, 955 F.3d 850, 850 n.** (10th Cir. 2020). It does not directly address what happens if they disagree.[6]
- Novartis proffers unpublished orders from three circuits that may reflect the denial of a petition for rehearing by a 1-1 panel. Pet. 23-24. But only the D.C. Circuit order says that expressly. C.A. Reh'g Supp. Add. SA35. Novartis infers that the votes of a retired (Sixth Circuit) and deceased (Eighth Circuit) judge were disregarded in the other two

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[5] Amici claim that circuit rules only permit the designation of a replacement judge before any decision issues, but the rules they cite do not say that. Br. Ret. Judges 9 & n.4. The Second Circuit's IOP applies anytime "[a]fter a matter has been assigned" to a panel. 2d Cir. IOP E(b). Eighth Circuit Rule 47E, like the Federal Circuit's, applies when a panel "has taken under submission any appeal, petition, or motion." Eleventh Circuit Rule 34-2 applies when a "panel has taken an appeal or matter under submission."

[6] Novartis cites *Williams v. Jones*, 583 F.3d 1254 (10th Cir. 2009), where then-Judge Gorsuch dissented from the denial of en banc review but did not dissent from the denial of panel rehearing. He noted that the standard for panel rehearing was not satisfied and further "because we have, sadly, lost a panel colleague to the academy, a vote among the remaining two panel members would likely result in a tie." *Id.* at 1256 & n.1. The opinion does not explain what a "tie" signifies.

matters, although the orders do not say that. *See id.* at 42 (order notes judge's retirement but further states that "the panel . . . reviewed the petition"); *id.* at 44 (no acknowledgement that Judge Arnold died a few days earlier).

- In six circuits (First, Third, Fourth, Fifth, Seventh, and Eleventh), neither party has identified any relevant ruling. For some, Novartis points to unpublished orders where two-judge panels denied rehearing and one of those judges had dissented *on the merits*. Pet. 24-25. But those orders do not show a split vote on the rehearing petition. C.A. Reh'g Supp. Add. SA36-41, 43, 45-46. The Third Circuit's procedure may require denial of a petition for rehearing if the panel is divided 1-1, but neither party has identified an on-point ruling. Third Circuit IOP 8.2, 8.3.

To sum up: unsurprisingly, in the majority of the circuits—seven—the issue has not come up. Three of the remaining circuits have published opinions in which a third judge was designated to decide a rehearing petition. The other three circuits have issued nonprecedential orders stating or suggesting that a petition for rehearing was denied where two remaining members were divided 1-1. Novartis and its amici do not identify *a single published opinion* that supports Novartis's position. There is no overwhelming consensus or "uniform" practice here.[7]

2. Nor does there have to be a uniform practice. Novartis's proposed rule—that another judge may never be designated to a panel in these circumstances—indeed has

[7] Amici cite two cases in which rehearing was denied by a two-judge panel after the elevation of the third judge to this Court. Br. Ret. Judges 12. In both of those cases, the two remaining judges were in agreement.

drawbacks. It would apply where the original decision was unanimous, but one of two remaining judges would vote to grant rehearing. It has unclear implications if two of the original three judges become unavailable. *See Knight First Amendment Inst. v. Biden*, No. 18-1691, 2021 WL 5548367, at *1 & n.* (2d Cir. May 26, 2021) (unpub.) (judge added to panel after one judge died and another retired). And it would prevent a two-judge panel from deciding that an issue raised on rehearing would be better decided by three judges. *See Desimone*, 140 F.3d at 458. All to say: absent a governing statute or rule, and given how rarely the situation arises, it is unsurprising that courts of appeals have not adopted a "uniform" procedure on this issue. There are reasons they might adopt one approach or another, and they retain the discretion to adopt an appropriate practice in the rare circumstance where it's needed.

This Court has never viewed that kind of permissible procedural variation as a circuit split. *See, e.g.*, *Western Pacific*, 345 U.S. at 267 (no "particular procedure" required); *Shenker*, 374 U.S. at 5 (Third Circuit's absolute majority rule "clearly within the scope of [its] discretion"). The lower courts have adopted varying procedures for en banc votes, oral argument, motion and screening panels, and even word limits. Such differences reflect local responses to local circumstances and in no way require this Court's review.

C. The question is unimportant and Novartis never raised it below.

Novartis's claim of importance is overblown, to say the least. Its complaint is that while a petition for panel rehearing was pending, one member of the original panel retired, another judge was appointed, and the panel thereafter granted rehearing, vacated its prior opinion, and issued a new one. To call these circumstances rare would be an understatement.

1. Novartis cites only one other similar case, and its amici found one more. Pet. 26 (citing *Carver*, 558 F.3d at 878-79); Br. Ret. Judges 9. That is, with 25,000 or more federal appeals decided every year, there are three examples of this practice that supposedly threatens the "sound administration of justice." Pet. 1.[8]

That's not surprising, because every step that led to this outcome is unusual. The starting point of a split panel decision is itself relatively rare—over 97% of decisions by the courts of appeals are unanimous. *See* Lee Epstein, William M. Landes & Richard A. Posner, *The Behavior of Federal Judges: A Theoretical and Empirical Study of Rational Choice* 265, 255-303 (Harvard Univ. Press 2013). Then, for this fact pattern to recur: (i) the losing party must petition for panel rehearing; (ii) a panel member who was in the majority must die or retire while the petition is pending; (iii) the two remaining panel members must disagree about the resolution of the petition and request appointment of a third judge; (iv) the third judge must conclude that the standard for rehearing is satisfied, vote to grant rehearing, and vote to change the outcome; and (v) despite (i)-(iv), there's no en banc review that supersedes the panel opinion. The odds of all of these things happening are exceedingly low.

There is no call for this Court to reach out and address a procedural issue that is "hen's teeth" rare. Speculation by Novartis and its amici about judicial retirements, *e.g.*, Pet. 29, falls far short of satisfying Rule 10's standard. Novartis offers no reason to believe that this issue will arise in more than a vanishingly small number of cases. That alone is grounds to deny the petition.

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[8] *See* Federal Judicial Caseload Statistics, 2013-2022, available at: https://www.uscourts.gov/statistics-reports/analysis-reports/federal-judicial-caseload-statistics.

2. Novartis's pattern of overreach continues with its suggestion that the Court summarily reverse. Pet. 29. Novartis has not identified a governing statute or rule or a published decision from *any* court that supports its position. There is no basis for this Court's intervention at all, much less a clear error warranting summary disposition.

Even if Novartis had identified some potential inconsistency with § 46—and it has not—this case would be an exceptionally poor vehicle to address it. Although it now claims the error is so obvious as to warrant summary reversal, Novartis did not even argue below that the Federal Circuit violated § 46, so that court had no opportunity to address that issue.

II. Novartis's fallback question presented is not remotely certworthy.

Novartis also poses a question about the merits of this patent dispute, but its search for a certworthy merits issue is futile. Novartis previously told this Court that "[t]he Federal Circuit's decision invalidating Novartis's Patent rested *entirely* on the [written-description] requirement at issue in *Juno*." Stay App. 17 (emphasis in original). Now that *Juno* has been denied, Novartis has dropped this argument. Instead it seeks review of the Federal Circuit's entirely correct, and more importantly, fact-bound, application of settled law. Its petition should be denied.

A. The Federal Circuit's application of settled law to the facts of this case does not warrant review.

To obtain a patent, the original patent specification must contain a "written description" of the claimed invention. 35 U.S.C. § 112(a). This pre-condition is important, because "[a] patent holder should know what he owns, and the public should know what he does not." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722,

731 (2002). It is also simple: it requires patentees to describe their inventions in "'full, clear, concise, and exact terms.'" *Ibid* (quoting 35 U.S.C. § 112). The majority and dissent below agreed on this critical premise (Pet. App. 5a-6a, 16a-18a); they simply read this particular specification differently.

Novartis says it invented a specific daily dosing regimen to treat RRMS *without first administering a loading dose*. According to Novartis in 2014, when it amended its patent claims to distinguish prior art that *included* a loading dose, the absence of the loading dose was what made its invention novel and thus patent-worthy. But given the written description requirement, these claims are valid only if the original 2006 specification actually describes that treatment method, including the absence of a loading dose. *E.g.*, *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1344 (Fed. Cir. 2013) (later-added claims "must find support sufficient to satisfy § 112 in the written description of the original priority application"). It doesn't. Novartis is forced to argue about expert testimony and "implicit" unwritten descriptions because it cannot accomplish the simple task § 112 requires: point to anything in the 2006 specification that describes the treatment method its 2014 patent claims.

1. A patent is "a fully integrated written instrument, consisting principally of a specification that concludes with the claims." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc) (cleaned up); *see also* 35 U.S.C. § 112(a)-(c). There is a "close kinship" between the specification and the claims: the claims define the scope of patent protection, but they must be interpreted in light of the specification. *Phillips*, 415 F.3d at 1316.

Section 112 dictates what a specification must contain:

> 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 . . . .

35 U.S.C. § 112, ¶ 1 (2006) (amended 2011).[9]

This Court and the Federal Circuit have long recognized that § 112 contains an independent "written description" requirement. *Ariad*, 598 F.3d at 1347; *Festo*, 535 U.S. at 736 ("[T]he patent application must *describe, enable, and set forth the best mode* of carrying out the invention." (emphasis added)). "[D]espite the enactment and revisions of numerous patent statutes since the Founding era," this "mandate for a written description as a prerequisite for patenting an invention has been a fixture of our laws for more than two centuries." *Biogen*, 18 F.4th at 1341.

The "essence" of the written description requirement is that "a patent applicant, as part of the bargain with the public, must describe his or her invention so that the public will know what it is and that he or she has truly made the claimed invention." *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1298 (Fed. Cir. 2014). Whether a skilled artisan could identify or envision the invention is irrelevant; the question is "'whether the application necessarily discloses'" it. *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (citation omitted). "[A]ll the limitations must appear in the specification." *Ibid.* And the specification must "show that

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[9] Novartis applied for its patent when the prior version of § 112 was in effect. The current version contains identical language.

the inventor actually invented the invention claimed." *Ariad*, 598 F.3d at 1351.

2. Against this backdrop, Novartis's assertion that the Federal Circuit "add[ed] an atextual, rigid requirement" to § 112 is wholly unconvincing. Pet. 30. The court imposed no new "heightened burden." Pet. 34. To the contrary, the Federal Circuit was clear that it was not "creat[ing] a heightened standard." Pet. App. 14a. Rather, it applied the long line of cases holding that while a specification need not use any magic words or come in any particular form, *Ariad*, 598 F.3d at 1352, it must "show that one is in possession of *the invention* by describing *the invention*, with all its claimed limitations," *Lockwood*, 107 F.3d at 1572 (cleaned up) (emphasis in original); Pet. App. 14a. Far from rigid, patentees can meet this requirement in multiple ways, including, in some instances, without explicit disclosure. Pet. App. 7a.

The Federal Circuit's application of that basic rule here tracks decades of well-established law. Its decisions recognize that "under a narrow set of circumstances, the written description requirement may be satisfied without an explicit disclosure if the claimed features are necessarily inherent in what is expressly described." *Nuvo Pharms. v. Dr. Reddy's Lab'ys Inc.*, 923 F.3d 1368, 1382-83 (Fed Cir. 2019); *see Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159 (Fed. Cir. 1998) ("[M]issing descriptive matter must *necessarily be present* in the . . . specification such that one skilled in the art would recognize such a disclosure." (emphasis added)); *Jepson v. Coleman*, 314 F.2d 533, 536 (C.C.P.A. 1963) ("It is not a question whether one skilled in the art *might* be able to construct the patentee's device from the teachings of the disclosure of the application. Rather, it is a question whether the application *necessarily discloses* that particular device." (emphasis added)).

But a disclosure cannot suffice where it could mean *either* the presence or absence of a given limitation; that would not tell the public whether the invention includes the limitation or not. *See, e.g.*, *Schriber-Schroth Co. v. Cleveland Trust Co., Chrysler Corp.*, 305 U.S. 47, 58-59 (1938) ("Even if those skilled in the art would have known that a piston . . . would work most effectively if the webs were laterally flexible rather than rigid, that was not the invention which [the inventor] described [in his specification]."); *Permutit Co. v. Graver Corp.*, 284 U.S. 52, 59 (1931) (rejecting reasoning adopted by circuit court that "it is not necessary that the patentee should expressly describe [the invention]," noting "[t]he absence" of a description "of a sand bed placed above the zeolites does not imply that the zeolite bed is to be unconfined"). Telling the public what is claimed is a fundamental tenant of the patent bargain. *Festo*, 535 U.S. at 731.

Here, the Federal Circuit looked at the evidence and concluded that the disclosure just as easily *in*cluded a loading dose as *ex*cluded it. *E.g.*, Pet. App. 10a; *see also Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1351 (Fed. Cir. 2012) (requiring complete disclosures for negative claim limitations); *Inphi Corp. v. Netlist, Inc.*, 805 F.3d 1350, 1356 (Fed. Cir. 2015) (same). Again, Novartis had to amend its proposed claims to expressly exclude a loading dose to distinguish prior art that did include a loading dose. Pet. App. 12a. Even its own expert "readily admitted" that the specification "discloses neither the presence nor absence of a loading dose." Pet. App. 10a. The disclosure thus did not suffice on the facts of this particular case.

3. Instead, and contrary to longstanding precedent, Novartis argues for a lower bar: that under § 112 an "implicit," unwritten description should suffice. That would

turn the law on its head. Neither of the two cases Novartis cites supports its position.

a. First, Novartis relies on a cherry-picked quote from a 90-year old decision of this Court stating that claims may be amended to "ma[k]e explicit what was already implicit" in the original patent application. Pet. 31 (quoting *Marconi Wireless Tel. Co. of Am. v. United States*, 320 U.S. 1, 34, 38 (1943)). *Marconi* is consistent with the Federal Circuit's requirement that claimed inventions must be either explicitly disclosed or inherent in the written description.

Marconi involved a fight over who first invented various methods of transmitting and receiving radio waves. 320 U.S. at 17-18. One patent covered "a four circuit wireless telegraph apparatus" with two closed circuits and two antenna circuits. *Id.* at 17. The original specification disclosed tuning "the entire transmitting and receiving 'apparatus.'" *Id.* at 23. Later, the claims were amended to clarify that the invention included tuning not just the two closed circuits, but also the two antenna circuits. *Id.* at 21-22. Because the original application described tuning "the entire . . . apparatus," it adequately disclosed tuning the two antenna circuits. *Id.* at 23-24 ("To say that by this reference to the tuning of sending and receiving apparatus he meant to confine his invention to the tuning of only some of the circuits in that apparatus is to read into his specifications a restriction which is plainly not there[.]").

The description in *Marconi* thus necessarily covered the later-amended claims. That is nothing like the situation here, where the description could just as well embrace administering a loading dose as excluding one.

Second, the passing reference in *In re Robins*, 429 F.2d 452, 456-57 (C.C.P.A. 1970), to an "implicit" description does not help Novartis either. The quote containing the phrase "implicit description" is dicta. *Robins* made

clear that the specification at issue contained an "explicit description," so whether "implicit description" was sufficient to meet the written description requirement was not at issue. *Ibid.* Moreover, *Robins* used the word "implicit" not with respect to disclosure writ large, as Novartis suggests, but rather consistent with years of precedent (and common practice) to explain that *explicitly* listing "representative" examples "may" provide a sufficient "description upon which to base generic claim language" concerning a broader chemical invention. *Ibid.* (distinguishing *In re Sus*, in which the court "found nothing in the way of express statements or examples in the specification that would teach one skilled in the art that" certain claimed subject matter was "properly within the subject matter which appellants considered to be their invention"). That type of description is not at issue here and does not support Novartis's new theory.

Out of case law, Novartis turns to the Manual of Patent Examining Procedure (MPEP). Pet. 32-33. As the dissenting judge below acknowledged, the MPEP possesses no precedential power. Pet. App. 22a n.1. Section 2163(II)(A)(3)(b) of the MPEP provides that "each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure," followed by a string cite of ostensibly supporting cases. The only one even mentioning "implicit" disclosure is *Robins*. But as explained, "implicit disclosure" was not at issue in *Robins*, and the case did not approve the type of unbounded "implicit disclosure" for which Novartis now advocates. Thus, even Novartis's non-binding secondary source does not support its position.

4. The utter dearth of authority to support Novartis's theory negates its related arguments. The Federal Circuit's decision will not "upset patent owners' settled expectations," Pet. 36, because the Federal Circuit has

never allowed "implicit disclosure" to satisfy the written description requirement. And there is no reason to expect that "future applicants" will have to write "lengthy disclosures" in light of the decision below. *Ibid.* Applicants face no greater task now than they always have to provide a "full" and "clear" written description of their invention.

Novartis also argues that the decision below displaces the roll of skilled artisans and "wrongly cabins" the evidence factfinders can consider in determining whether written description is satisfied. Pet. 35. Not so. Skilled artisans can—and in this very case did—interpret what is contained in "the four corners of the specification," but they cannot fill a "gap" in a silent specification or expand it "to teach limitations that are not in the specification." *Rivera v. Int'l Trade Comm'n*, 857 F.3d 1315, 1322 (Fed. Cir. 2017); *Lockwood*, 107 F.3d at 1572 ("While the meaning of terms, phrases, or diagrams in a disclosure is to be explained or interpreted from the vantage point of one skilled in the art, all the limitations must appear in the specification."). To hold otherwise would invite patentees to improperly expand their monopolies through the creative use of expert testimony. *Ibid.*

Here, Novartis tried to evade this settled rule using expert testimony. The Federal Circuit properly rejected that testimony because it conflicted with the specification and intrinsic record. Pet. App. 9a-14a. *See Lockwood*, 107 F.3d at 1572 (expert testimony "speculat[ing] as to modifications that the inventor might have envisioned" would improperly expand disclosure); *Rivera*, 857 F.3d at 1322 (adhering carefully to distinction between experts interpreting specification and impermissibly expanding it). And in fact, "Novartis's experts readily admitted" that the "specification discloses neither the presence nor absence of a loading dose," nor even "a rationale for the negative limitation." Pet. App. 10a. The Federal Circuit thus

properly considered the proffered testimony; it just happens that this testimony did not help Novartis here.

Novartis also suggests that the decision below wrongly shifts the burden of proof to patent owners and "supplants Rule 52's deferential clear-error standard." Pet. 36. The Federal Circuit did no such thing; it simply found, as courts of appeals often do, that the district court had clearly erred. The court walked carefully through the evidence and concluded that the district court relied on expert testimony that was inconsistent with the plain language of the 2006 specification and "a misquotation 'ferreted into trial testimony by Novartis' experts.'" Pet. App. 10a (citation omitted). It further found erroneous the district court's conclusion, which Novartis did not and could not defend, that the 2006 specification inherently disclosed the absence of a loading dose. Pet. App. 10a-11a. Novartis wrongly tries to re-cast this fact specific inquiry—which turns on the intricacies of the expert testimony and the factual evidence presented in this case—as a fight over the legal standard. But the kind of case specific error correction that Novartis seeks does not merit this Court's attention.

B. Novartis's remaining arguments lack merit.

Novartis's hodge-podge of unsupported policy arguments cannot justify this Court's review. To begin, its claimed "intra-circuit divide" is just a fancy way of saying the panel below was divided. Pet. 38. A split decision is not a reason to grant certiorari. And the Federal Circuit denied en banc review without any recorded dissent.

Novartis's accusation that the Federal Circuit is "constantly moving the goal posts" on the written description requirement is baffling. Pet. 39. The two-centuries-old rule is simple: describe the claimed invention. This Court has rejected every plea in the last 20 years to take up the issue, all of which offered the same unfounded assertions

about supposed harm to innovation. *See, e.g.*, *Biogen*, 143 S. Ct. 112 (2022) (Petition, 2022 WL 2181598, at *29-31); *Juno*, 143 S. Ct. 402 (2022) (Petition, 2022 WL 2834644, at *5-14); *Idenix Pharms. LLC v. Gilead Sciences, Inc.*, 141 S. Ct. 1234 (2021) (Petition, 2020 WL 5751271, at *28-35; *Amgen Inc. v. Sanofi*, 139 S. Ct. 787 (2019) (Petition, 2021 WL 5506421, at *29-32); *Janssen Biotech, Inc. v. Abbott Labs.*, 565 U.S. 1197 (2012) (Petition, 2011 WL 5548738, at *33-34). Congress, however—the proper entity to consider these policy arguments—has never revisited the written description doctrine, despite repeatedly amending the patent laws over the last sixty years, including in its major overhaul shortly after *Ariad* (the Leahy-Smith America Invents Act).

Finally, Novartis would like to keep this case alive "pending disposition of *Amgen*," Pet. 40, a case involving § 112's enablement requirement specifically in the context of genus claims, which the Court will hear on March 27, 2023. *See Amgen Inc. v. Sanofi*, No. 21-757. *Amgen* addresses an entirely different requirement of patent law and an entirely different type of patent. Novartis, tellingly, makes no effort to explain how the Court's decision in *Amgen* could possibly "require rejection of" the Federal Circuit's decision in this case. Pet. 40. Thus, the Court need not, and should not, hold this case while *Amgen* is pending.

CONCLUSION

The petition should be denied.

Respectfully submitted.

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