No. _____

In the Supreme Court of the United States

NOVARTIS PHARMACEUTICALS CORPORATION,

Applicant,

v.

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

Respondents.

On Application for Stay

EMERGENCY APPLICATION FOR A STAY OF MANDATE PENDING THE DISPOSITION OF A PETITION FOR A WRIT OF CERTIORARI

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September 28, 2022

RULE 29.6 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.

PARTIES TO THE PROCEEDING

All parties to the case in the court of appeals appear in the caption of this application. Various other companies were defendants in the district court, but were not parties to the appeal.

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To the Honorable John G. Roberts, Jr., Chief Justice of the United States and Circuit Justice for the Federal Circuit:

Pursuant to this Court's Rules 22 and 23, applicant Novartis Pharmaceuticals Corporation ("Novartis") respectfully requests that the Circuit Justice stay issuance of the mandate of the United States Court of Appeals for the Federal Circuit pending the filing and disposition of Novartis's petition for a writ of certiorari. The court of appeals denied a stay of mandate by a divided vote on Tuesday, September 27, 2022. Unless stayed, the mandate will issue the morning of Tuesday, October 4, pursuant to Fed. R. App. P. 41(b). Novartis requests that, if the Court is still considering this application at that time, the Circuit Justice grant an administrative stay to ensure that the mandate does not issue during the Court's consideration.

Novartis has submitted public and sealed appendices in support of this application.[1]

[1] The sealed appendix contains Novartis's highly confidential information regarding its business plans, financial information, and settlement agreements. The same document was filed under seal in the court of appeals, *see* App. F, at 2, and meets the standard for highly confidential information under the terms of the protective order entered by the district court. Novartis therefore requests that it be maintained under seal in this Court as well. Novartis is also submitting a redacted version of that appendix for the public record.

INTRODUCTION

Respondents HEC Pharm Co., Ltd. and HEC Pharm USA Inc. (together, "HEC") infringe a Novartis patent that they claim is invalid. The trial judge rejected their invalidity argument after a trial, and the Federal Circuit initially affirmed over a dissent. But then the Federal Circuit reversed itself on rehearing, for a single reason: the author of the opinion retired and was replaced by a new judge who agreed with the dissenter. The reconfigured panel held by a divided vote that Novartis's patent is invalid, based on a legal rule of the Federal Circuit's own creation. And the Federal Circuit is now insisting on issuing its mandate (again, by a divided vote); if not stayed, the mandate will dissolve the injunction Novartis obtained in the district court. Even recalling the mandate could come too late: HEC and a dozen or more other generics are able to launch infringing products upon issuance of the mandate, and the district court explicitly found that in this market damages would not be able to compensate Novartis for the ensuing infringement. This Court should stay the mandate to prevent irreparable harm to Novartis for the short period needed to consider this application and Novartis's petition.

The only basis for HEC's appeal, or the Federal Circuit's reversal, was circuit precedent reading an atextual requirement into the statute governing a patent's written description. The Federal Circuit requires that the original application show that the patent owner had "possession" of the claimed invention. The Court considered today a petition presenting the question whether the Federal Circuit has simply invented this requirement. *See* Pet., *Juno Therapeutics, Inc. v. Kite Pharma,*

Inc., No. 21-1566 (filed June 13, 2022) ("*Juno* Pet."). If this Court were to grant certiorari in that case and agree with Juno, it is indisputable that HEC's challenge would fail and Novartis's patent would be held valid. A grant in *Juno* means that Novartis has a likelihood of success.

But this case presents a certworthy question even if the Court does not grant the *Juno* petition. The Federal Circuit's reconfigured panel adopted a new legal rule for invalidating patents for lack of "possession" that this Court, the original panel, the Patent Office, and prior circuit precedent have all rejected. Novartis discovered the efficacy of a low (0.5 mg) daily dose of a multiple-sclerosis medication called fingolimod, which Novartis markets as Gilenya. Its patent application disclosed giving exactly that dose—without ever suggesting giving a higher "loading" dose first. The patent issued by the Patent Office claims giving exactly that dose—without any loading dose. The district court found, based on unrebutted expert evidence, that a skilled artisan reading the patent application would expect no loading dose. While the first panel agreed, over a dissent, that this disclosure met the "possession" requirement, the reconfigured Federal Circuit panel held, again over a dissent, that that is not good enough: the application needed to either *expressly say* "no loading dose" or else show that one is "necessarily" ruled out. Requiring patent applicants to explicitly say what their invention is *not* is an absurd extension of a supposed requirement to show "possession" *of the invention* at the time of filing. Given the obvious division within the Federal Circuit, including the even split between the four

Federal Circuit judges who heard this very case before and after rehearing, there is a substantial likelihood that this Court will review the issue and reverse.

Without a stay of mandate, that review will come too late to avoid irreparable harm to Novartis. The district court found that after the launch of even half a dozen generics, the price will irreparably erode—and the market for this product will shrink—in ways that could be impossible to calculate at an after-the-fact damages trial. Now issuing the mandate could lead 20 generics to enter. And following a generic entry of that magnitude, Novartis would no longer be able to sustain the patient-service program that it maintains for patients taking Gilenya. The irreparable harm to Novartis and to the public interest outweigh the impact of a stay on HEC's plans to launch its admittedly infringing product.

OPINIONS BELOW

Different divided panels of the Federal Circuit issued two different majority opinions in this case. The opinion to be reviewed (issued after the original author retired and a reconfigured panel changed the outcome) is reported at *Novartis Pharmaceuticals Corp. v. Accord Healthcare, Inc.*, 38 F.4th 1013 (Fed. Cir. 2022), and is attached as Appendix A. The original opinion was reported at *Novartis Pharmaceuticals Corp. v. Accord Healthcare, Inc.*, 21 F.4th 1362 (Fed. Cir. 2022), and is attached as Appendix B. The district court's findings of fact and conclusions of law finding the patent valid are unreported and attached as Appendix C. The district court's order granting Novartis's motion for a preliminary injunction is unreported and is attached as Appendix D. The Federal Circuit's orders denying Novartis's

petition for rehearing and its motion to stay the mandate are unreported and are attached as Appendix E and Appendix F, respectively.

STATEMENT

I. Novartis demonstrated, and the district court found, irreparable harm from a generic launch that would infringe Novartis's patent.

The Novartis patent at issue in this case—U.S. Patent No. 9,187,405 (the "Patent"), attached as Appendix G—involves a new method for treating relapsing-remitting multiple sclerosis ("RRMS") with a lower dose of fingolimod than previously thought necessary. It expires in June 2027.

The Patent's specification, which provides the required "written description of the invention," 35 U.S.C. § 112(a), describes several dosages of fingolimod that could be used in clinical trials in humans, including "a daily dosage of 0.5 [mg]." App. G, 10:35-11:16. The description of the "daily dosage of 0.5 [mg]" never suggests that a patient would ever receive any daily amount of fingolimod other than 0.5 mg. The Patent also describes *in vivo* animal studies conducted in rats, using a dosage that equates to 0.5 mg in a human. The rat study was also conducted without beginning with a higher dose.

The Patent then claims patent protection for the method of treatment described in the specification: a method of treating RRMS by "orally administering" fingolimod "at a daily dosage of 0.5 mg, absent an immediately preceding loading dose regimen." App. G, 12:49-55. A loading dose is a "higher-than-daily dose … usually given as the first dose." App. C, at 21-22. So the patented regimen consists of giving the "daily dosage of 0.5 [mg]," no less and no more.

Novartis markets the 0.5 mg daily dose of fingolimod under the brand name Gilenya. Gilenya was a breakthrough—the first-ever oral medication for RRMS. Gilenya is now one of Novartis's most successful products, with more than $1 billion of annual revenue. App. D, at 9. In 2018, Novartis asserted the Patent against more than 20 companies that had filed applications (Abbreviated New Drug Applications, or ANDAs) with the FDA seeking to market generic versions of Gilenya. C.A. App. 143-197. Novartis sought a preliminary injunction to prevent a launch by HEC and eight other ANDA filers in active litigation at that time.

After holding an in-person evidentiary hearing and considering what he described as a "voluminous record"—including deposition testimony, fact and expert declarations, and hundreds of documents—Chief Judge Stark (before his appointment to the Federal Circuit) granted the preliminary injunction. App. D. He first concluded that Novartis was likely to succeed on the merits of its claim: The generics had not contested their products would infringe the Patent, and Chief Judge Stark concluded that the generics were "not at all likely to prevail at trial on invalidity." App. D, at 2-3.

Chief Judge Stark also concluded that Novartis had carried its burden of showing that it would likely suffer irreparable harm absent a preliminary injunction from the at-risk launch of "one or more and up to six generic[]" competitors. App. D, at 7. That harm would be "immediate and substantial" and it could not "be remedied by money damages" after the fact. *Id.*

Chief Judge Stark identified three particular types of irreparable harm. First, at-risk launch would create "massive and immediate price erosion in the market for oral treatment of RRMS." *Id.* And "[a]fter what might be as long as a year of generic competition," Novartis would "not be able to raise the price back to where it is now, or to where it would have been … in the absence of defendants' at-risk infringement." *Id.* Novartis likely could not recover the damages from such post-judgment price erosion: They could be "impossible" to calculate and it was not clear that Novartis would be entitled to recover them from the generics even if they were calculable. *Id.*

Second, at-risk launch would also "condense[]" (*i.e.*, shrink) the overall market for fingolimod, driving patients to other RRMS treatments. *Id.* Fingolimod requires something called First Dose Observation, or FDO, which can be costly to provide. Novartis currently provides these services for free in many instances, but it would likely be unable to do so after a generic launch. Vellturo Declaration, attached as Appendix H, ¶¶ 42-43. Chief Judge Stark found that generic launch would impact the "availability of FDO," which would drive doctors to prescribe other treatments. App. D, at 7.

Third, Chief Judge Stark found that "Novartis will suffer an irreparable injury to its goodwill from an at-risk launch for reasons including that to try to make itself whole (or as whole as possible should it prevail at trial after an at-risk launch), Novartis would have to raise Gilenya prices back to the pre-infringement level." *Id.* If so, Novartis would be "unfairly" and "widely criticized, thereby suffering irreparable harm to its goodwill." *Id.*

Turning to "balance of harms and the public interest," Chief Judge Stark again concluded that each factor favored injunctive relief. App. D, at 9. With respect to the balance of harm, he explained that all defendants—not just HEC—stood "to lose the opportunity to earn on the order of $50 million collectively by not being able to compete over approximately the next year whereas Novartis will irreparably lose a market in which they sell approximately $1.8 billion of drugs [each] year." *Id.* That "balance clearly favors Novartis under the circumstances." *Id.* Finally, he noted the public "interest in protecting valid patent rights and in maintaining incentives for the massive investments required for drug development." *Id.* The court noted that although consumers would "benefit from lower prices," the decreased availability of support services might be a countervailing harm. *Id.*

No defendant, including HEC, appealed the preliminary injunction.

II. After a bench trial, the district court found that Novartis's Patent satisfies the Federal Circuit's "written description" requirement because the specification discloses what is claimed—a dosing regimen without a loading dose.

After the preliminary-injunction ruling, the case was transferred from Chief Judge Stark to Third Circuit Judge (and former District of Delaware judge) Kent A. Jordan, sitting by designation. Judge Jordan held a four-day bench trial focused on the Patent's validity. By the time of trial, all of the generics had settled other than HEC. Judge Jordan ultimately held—consistent with Chief Judge Stark's preliminary-injunction ruling—that the Patent is valid and would be infringed by HEC's marketing of its generic product. App. C, at 27.

One of HEC's arguments at the bench trial was that the Patent lacked adequate "written description" support for the claims. The statute requires that the patent include "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(a). The Federal Circuit has held that this provision includes two distinct requirements. First, the "written description" must "enable any person skilled in the art … to make and use the [invention]." *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Company*, 598 F.3d 1336, 1344 (Fed. Cir. 2010) (en banc). That is known as the "enablement" requirement. Second, the Federal Circuit held that the "written description of the invention" must *also* "reasonably convey[] to those skilled in the art that the inventor had possession of the claimed subject matter." *Id.* at 1351. That has come to be known as the "written description" or "possession" requirement.

Notably, HEC dropped any enablement argument by the time of trial. ECF 757, ¶ 103 (D. Del. May 8, 2020). The only arguments that it pursued through both trial and appeal were based on a supposed lack of written description.

Relevant here, HEC argued at trial that the Patent did not satisfy the written-description requirement as to the "no loading dose" limitation in the Patent's claims—*i.e.*, the requirement that the 0.5 mg daily dosage be given "absent an immediately preceding loading dose regimen." App. G, at 12:49-13:10. HEC argued that, because the Patent's specification did not *explicitly exclude* the use of a loading dose, the

Patent did not adequately disclose possession of the claimed method, 0.5 mg daily without a loading dose.

The district court rejected this argument. The specification describes how the inventors discovered the lower dose's efficacy through animal testing. App. G, at 10:32-11:2; C.A. App. 23217. Citing HEC's own expert, the district court found that the rat study discloses, to skilled artisans, a "dosing regimen which does not involve a loading dose." App. C, at 22 (citing C.A. App. 22793, C.A. App. 23209, C.A. App. 23345).

The specification also describes a prophetic clinical trial in which "20 patients with [RRMS] receive [fingolimod] at a daily dosage of 0.5, 1.25 or 2.5" mg; "[i]nitially patients receive treatment for 2 to 6 months." App. G, 11:8-14. Novartis presented expert evidence that a skilled artisan would read this description to preclude a loading dose. C.A. App. 22791-22793 (Lublin); C.A. App. 23342-23345 (Steinman); C.A. App. 23442 (Jusko). That evidence went unrebutted; HEC's expert conceded on direct examination that he was unqualified to opine on this key specification passage. C.A. App. 23117.

Based on that evidence, the district court found that this example "tells a person of skill that on day 1, treatment begins with a daily dose of 0.5 mg, not a loading dose." App. C, at 21 (citing C.A. App. 23343-23344). Because a "loading dose is necessarily a higher-than-daily dose[,]" "starting with a daily dose plainly implies that there is no loading dose." App. C, at 22. And relying on testimony about known risks of increased fingolimod dosing, the district court found that skilled artisans

"would not expect a loading dose to be used to treat RRMS with fingolimod." *Id.* (citing C.A. App. 23126-23127, C.A. App. 23129).

III. A Federal Circuit panel affirmed, over a dissent, in an opinion authored by Judge O'Malley.

The Federal Circuit initially affirmed in a precedential decision written by Judge O'Malley and joined by Judge Linn. *See* App. B. The panel rejected HEC's attempt—endorsed by the dissent—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." App. B, at 18. It also refused to apply "heightened written description standard[s]" only to "negative limitations," which the Federal Circuit had "several times" declined to do. *Id.* The panel emphasized that the written-description "requirement is essentially a fact-based inquiry," turning on each case's particulars, because "it is how a skilled artisan reads a disclosure that matters." App. B, at 17-18.

The panel found ample evidence to support the district court's "quite carefully" conducted "'objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill.'" App. B, at 18-19. Detailing testimony from Novartis's experts, the majority saw no clear error in the findings that skilled artisans would have understood the Patent's description of both the animal study and human-clinical trial to exclude a loading dose. App. B, at 18-21. Therefore, the limitation in the claims—giving a dose of 0.5 mg daily, without first giving a loading dose—was disclosed in the specification.

Chief Judge Moore dissented, arguing that the specification was "silen[t]" about a loading dose because it did not explicitly rule one out; in her view, that should have been dispositive. App. B (Dissent), at 3-5.

IV. After Judge O'Malley retired, a new three-judge panel granted rehearing and reversed, essentially adopting the prior dissent.

The Federal Circuit then reversed itself, solely because of a change in the panel's membership. HEC petitioned for rehearing on February 23, after being granted a three-week extension. On March 11, one week after Novartis filed an expedited response, Judge O'Malley retired from the court. Three months later, a 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 opinion, and entered a new precedential decision reversing the district court. The new opinion identified no 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)—and never noted the change in panel membership.[2]

The new decision was, in substance, the original dissent recast as a majority. The new majority held that disclosure generally must be express, not implicit, so that even for a "negative" limitation (a statement of what is *not* claimed), silence "may

[2] 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, but do not address a post-decision petition for rehearing. *See* Fed. Cir. R. 47.11. Here the chief judge was the dissenter from the original panel decision. The court of appeals did not explain how Judge Hughes was selected—whether by the chief judge (the dissenter from the original panel decision) or in some other way.

often be dispositive" of invalidity. App. A, at 6 & n.2, 12. It allowed just one possible exception: if the "patent owner could establish" that the specification "inherently," or "necessarily," discloses a limitation, "written description could be satisfied." App. A, at 6-7, 12. Despite the district court's factfinding that a skilled artisan would read the specification to teach daily dosing without a loading dose, the majority rejected such evidence, App. A, at 7, because the specification did not go further and "necessarily exclude a loading dose." App. A, at 11. The new majority insisted it was not creating "a heightened standard for negative claim limitations"—i.e., its requirement that each limitation be expressly disclosed or "necessarily be present in a disclosure" applies throughout written-description law. App. A, at 12.

Judge Linn dissented, adhering to the original majority opinion's reasoning and criticizing the new majority decision's "heightened written description standard" of "necessary exclusion." App. A (Dissent), at 2-3. Judge Linn wrote that this standard was inconsistent with Federal Circuit precedent, which "makes clear [that] the critical question in assessing written description support" for any limitation is not whether the limitation is recited "*in haec verba*," but whether the "written description reasonably convey[s] to those skilled in the art that the inventor 'had possession of the claimed subject matter as of the filing date.'" App. A (Dissent), at 3-6 (quoting *Ariad*, 598 F.3d at 1351). He wrote that the new majority decision conflicted with this rule, as well as with many of the court's other written-description decisions applying that rule. *Id.* (citing *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1351 (Fed. Cir. 2012), *In re Bimeda Research & Dev. Ltd.*, 724 F.3d 1320, 1324

(Fed. Cir. 2013), *Nike, Inc. v. Adidas AG*, 812 F.3d 1326, 1348 (Fed. Cir. 2016), and *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779 (Fed. Cir. 2002)). Judge Linn stated that "[w]hile a showing of 'necessary exclusion' would most certainly provide written description support for a negative [claim] limitation, it is not and should not be a requirement in every case," and yet that was precisely what the panel majority had held. App. A (Dissent), at 3.

The new decision prompted a wave of criticism,[3] in part because it is exceptionally rare for a court of appeals to reverse itself only because one member of the panel left the court and was replaced by a new judge who would have decided the case differently. While the Ninth Circuit has approved that practice, *Carver v. Lehman*, 558 F.3d 869, 878-79 (9th Cir. 2009), most courts of appeals refuse to appoint a new judge to resolve a 1-to-1 vote on a petition for panel rehearing. *See, e.g.*, *Williams v. Jones*, 583 F.3d 1254 (10th Cir. 2009) (panel rehearing denied after Judge McConnell resigned); Novartis C.A. Pet. for Reh'g En Banc 7-11 & Suppl. Addendum.

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[3] *See, e.g.*, Samantha Handler, "Generic Drugmakers Score Big in Rare Federal Circuit Reversal," *Bloomberg Law*, https://news.bloomberglaw.com/us-law-week/generic-drugmakers-score-big-in-rare-federal-circuit-reversal?context=article-related (June 23, 2022) (describing criticism of the procedural posture as a "rare sequence of events" that turned the case into a "Patent Law Soap Opera"); Eileen McDermott, "Novartis to Appeal CAFC's 'Unprecedented' U-Turn in Ruling on Multiple Sclerosis Drug Claims to SCOTUS," *IPWatchdog*, https://www.ipwatchdog.com/2022/09/21/novartis-appeal-cafcs-unprecedented-u-turn-ruling-multiple-sclerosis-drug-claims-scotus/ (Sept. 21, 2022) (describing criticism of the Federal Circuit's about-face as "procedural insanity" that suggests to the public that an appeal to the Federal Circuit is a "crapshoot" that depends on the composition of the panel).

Supported by a number of amici, Novartis sought rehearing en banc, which the court denied. App. E.

Novartis promptly sought a stay of mandate pending certiorari, which the panel denied without explanation. Judge Linn would have granted the stay. App. F.

REASONS FOR GRANTING THE STAY

The traditional stay factors all support granting a stay to enable relief to Novartis. *See Nken v. Holder*, 556 U.S. 418, 426-427 (2009); *Maryland v. King*, 567 U.S. 1301 (2012) (Roberts, C.J., in chambers). Novartis has a strong likelihood of success, both in obtaining a grant of certiorari and ultimately prevailing on the merits. This Court considered at today's conference another petition explaining in detail why this Court should take up and disapprove the Federal Circuit's atextual "possession" requirement. Even if the statute does contain such a requirement, the Federal Circuit is deeply divided on the question of whether a specification must expressly or necessarily disclose a claim limitation to satisfy the written-description requirement, as is evidenced by the dueling panel decisions in this very case. The district court already found in 2019 that Novartis would suffer significant irreparable harm if HEC were not restrained from infringing. The relevant facts have not changed; if anything, the threat of irreparable injury has grown, because today there are more than a dozen generics poised to enter the market if the mandate issues, and as many as 20 that could enter subsequently. That would cause Novartis massive irreparable harm that could not be remedied through money damages. Once that many generic fingolimod products enter the market, the price will permanently erode,

and fingolimod products will permanently lose market share to other RRMS therapies because Novartis will no longer be able to sustain the multimillion-dollar patient-support program that eases patients' transition to Gilenya.

I. Novartis is likely to prevail in this Court, either through a GVR or on the merits.

This case implicates two important questions of statutory interpretation that have divided the Federal Circuit. The first question is whether Section 112 actually requires that the written description show "possession" at all—a question this Court considered at conference *today* (September 28), in the petition for certiorari in *Juno*, No. 21-1566. If the Court grants that petition (or is likely to do so, *e.g.*, following a relist), then Novartis has a reasonable probability of prevailing in this Court (presumably by GVR) following the resolution of *Juno*. Second, even if *Juno* is denied, this case cleanly presents a second important question of federal law: whether Section 112 permits *implicit* disclosure that is clear enough to be understood by a skilled artisan (as the original panel held), or whether it instead requires *express* or *inherent* disclosure of every claim limitation (as the reconfigured panel held). The text of Section 112, this Court's precedent, and the Patent Office's governing manual all make clear that the original panel was right and the reconfigured panel was wrong.

A. Granting certiorari in *Juno* would alone suffice to establish a likelihood of success here.

1. The *Juno* petition—which, as noted, this Court considered at conference today, September 28—presents the question whether the "possession" requirement for written description even exists. By now the Court may well have determined

whether to grant certiorari in *Juno*. If the Court does so, there is at least a fair chance the Court will reverse; indeed, given the Federal Circuit's nationwide jurisdiction, this Court grants certiorari in Federal Circuit patent cases only when there is at least a fair chance of reversal.

It follows that a grant in *Juno* would mean at least a fair chance that Novartis will prevail through a GVR. The Federal Circuit's decision invalidating Novartis's Patent rested *entirely* on the possession requirement at issue in *Juno*. If this Court holds that there is no "possession" requirement, then the Federal Circuit's basis for declaring the Patent invalid would disappear.

2. Even if the *Juno* petition is relisted or otherwise deferred, or rejected on some case-specific vehicle ground, there is a reasonable chance this Court will grant review of the question it presents.

a. As the *Juno* petition explains (at 18-29), the statute's text says nothing about possession. It states, in pertinent part: "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).[4] The en banc Federal Circuit read the "enablement" phrase ("in such … terms as to enable") to modify only "the manner and process," not "written description." *Ariad*, 598 F.3d at 1344. From there, the Federal Circuit reasoned that "written description"

[4] Section 112 was amended in 2011 in immaterial ways, including by designating part of the statute as subsection (a). Like the courts below, this application uses that designation.

must be an independent requirement—separate from enablement—and it phrased the test as whether the specification "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date," *id.* at 1351. Whatever the boundaries of that requirement (a question that has repeatedly vexed the Federal Circuit), it goes beyond Section 112's explicit requirement: that the patent's written description enable an ordinary person of skill in the art to pick up the patent, read it, and make and use the invention.

The *Juno* petition sets forth reasons why this "possession" requirement conflicts with the statute's text and this Court's precedent. Section 112 requires that the written description show *enablement*;[5] the statutory text and this Court's case law allow for no separate "possession" requirement. *See Juno* Pet. 18-24; *Facebook, Inc. v. Duguid*, 141 S. Ct. 1163, 1170 (2021) ("[A] qualifying phrase separated from antecedents by a comma is evidence that the qualifier is supposed to apply to all the antecedents instead of only to the immediately preceding one." (quotations and brackets omitted)). The *Juno* petition also cites numerous decisions by this Court, over more than a century, indicating that Section 112(a) imposes only the textual requirement of enablement. *Juno* Pet. 24-29; *see also*, *e.g.*, *The Telephone Cases*, 126 U.S. 1, 535-36 (1888) ("[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

[5] It is undisputed that the Patent satisfies *that* requirement; as noted above, HEC dropped its enablement challenge before trial.

operation."); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 90 (2012) ("Section 112 requires only a 'written description of the invention … in such full, clear, concise, and exact terms as to enable any person skilled in the art … to *make and use* the same.'") (ellipses in original; quoting Section 112(a)).

b. The *Juno* petition also gives reasons (at 29-36) why the question whether there is a written-description requirement separate from enablement is an important issue warranting this Court's review. Federal courts across the country are deciding cases on the assumption that there *is* such a written-description requirement, and those courts will continue to strike down patent claims for lack of written description until this Court holds that there is no such requirement. The *Juno* petition identifies ways in which this imposes costs on innovation, particularly in the pharmaceutical and other life sciences fields, where describing the full scope of the invention to the level the Federal Circuit has required is particularly difficult. *See Juno* Pet. 31-32 (citing concerns from leading research hospitals about the harm of the Federal Circuit's rule to their lifesaving research).

c. As discussed, if the Court grants certiorari on this question (in *Juno* or another case), Novartis plainly has a likelihood of success on the merits in this case. Holding that Section 112 imposes no separate possession requirement would doom HEC's written-description challenge. The Court should therefore stay the mandate pending Novartis's petition for certiorari; at the very least, if this Court has not disposed of the *Juno* petition by the time this application is fully briefed, the Court

should stay the mandate long enough to determine how it will resolve the *Juno* petition.

B. The question whether implicit disclosure is sufficient to satisfy Section 112 is worthy of this Court's review, and the Court is likely to reject the Federal Circuit's rigid rule.

Even if this Court does not take up and reject the Federal Circuit's "possession" requirement outright, the Court is still likely to grant certiorari and reverse here, because this case presents an important question about the scope of the written-description requirement that has sharply divided the Federal Circuit. Specifically, it raises the question whether a patent's specification can show possession through "implicit" disclosure that, as a factual matter, informs a skilled artisan of the invention's scope, or whether it requires an express or "necessary" disclosure of every aspect of the invention. Until this case, *every possible authority* held that any disclosure understood by a skilled artisan would suffice. Two judges of the Federal Circuit agreed *in this case*. Two other judges disagreed. Only the happenstance of a retirement while the petition for panel rehearing was pending gave the second pair the chance to impose their view. This Court is likely to reverse that decision.

1. There is a reasonable probability that this Court will grant certiorari.

The question whether disclosure to a skilled artisan suffices implicates an intra-circuit split in the Federal Circuit, as well as a conflict between the Federal Circuit's case law and case law of this Court. That question is an important one, and this case presents a clean vehicle to decide it.

First, the panel majority has created a conflict with a long line of Federal Circuit cases holding that an invention need not be disclosed in any particular way as long as a skilled artisan can understand it. The Federal Circuit held in its en banc decision on the issue, in no uncertain terms, that "the description requirement does not demand *any particular form* of disclosure or that the specification recite the claimed invention *in haec verba*." *Ariad*, 598 F.3d at 1352 (citation omitted; emphasis added); *see also In re Robins*, 429 F.2d 452, 456-57 (C.C.P.A. 1970) (where there is no explicit description of a genus, description of representative compounds "may provide *an implicit description* upon which to base generic claim language") (emphasis added). Applying this rule, the Federal Circuit has emphasized that what matters is "what the specification shows" to a skilled artisan, even if the disclosure is not "a model of clarity." *All Dental Prodx*, 309 F.3d at 779. Thus, the court has upheld claims with "no mention of" claimed elements "anywhere in the patent specification," as long as a skilled artisan "would recognize upon reading the specification" that the claimed invention was "described in the specification, albeit not *in haec verba*." *Id.*

The initial Federal Circuit decision in this case faithfully applied this law and upheld Novartis's Patent. But the subsequent, post-rehearing decision brushed all of this law aside and created a new rule that ignores how the skilled artisan would understand the specification. The court rejected any reliance on "implicit disclosure," adding the parenthetical "(whatever that means)." App. A, at 6 n.2. Instead, according to the second Federal Circuit ruling, what matters is how *judges* read the specification. *Even if* a skilled artisan would understand the patent's disclosure—as

the factual findings here establish—the Federal Circuit will invalidate the patent for failing to meet its *own* standard for judicially-determined "clarity."

Second, the Federal Circuit's new rule also conflicts with this Court's limited analysis of the issue. As explained above, at pp. 18-19, this Court has never acknowledged a written-description requirement separate from enablement, and in fact it has repeatedly indicated that there is no such requirement. But to the extent this Court has addressed this issue at all, it has acknowledged that claims may be amended during the examination process to "ma[k]e explicit what was already implicit" in the specification as originally filed. *Marconi Wireless Tel. Co. of Am. v. United States*, 320 U.S. 1, 34 (1943). That is what Novartis did here, yet the panel majority in this case held *exactly the opposite*—that disclosure cannot be implicit and must be express or "necessary."

Third, this question is exceptionally important. By adopting a standard that requires that each limitation be necessarily present in the specification, the panel majority in this case rejected the settled expectations of patent owners and the established practices of the Patent Office. Implicit disclosure is good enough to satisfy the examination process, as the Patent Office's Manual of Patent Examining Procedure explicitly states: "[E]ach claim limitation must be expressly, *implicitly*, or inherently supported in the originally filed disclosure." MPEP § 2163(II)(A)(3)(b) (emphasis added). The Federal Circuit has demolished the middle third of that three-part standard and held that *only* "express" or "inherent" disclosure will do.

Moreover, as a group of intellectual property law professors explained to the Federal Circuit in their brief supporting Novartis's petition for rehearing, the Federal Circuit's new rule in this case "deprive[s] patentees of the ability to limit claims to avoid the prior art through negative limitations," thereby "imperil[ing] meaningful patent protection for all inventors," and in particular inventors in the pharmaceutical and biotechnology space. Brief of *Amici Curiae* Intellectual Property Law Professors in Support of Novartis Pharmaceuticals Corporation's Petition for Panel and *En Banc* Rehearing, C.A. Dkt. 73, at 4-7. This is because pharmaceutical and biotechnology inventions often address an array of diseases through the same mechanism of action. *Id.* at 6. For example, fingolimod not only can be used to treat RRMS, as claimed in the Patent at issue in this case, but also has been used to treat transplant rejection, viral myocarditis, and other autoimmune disorders. *Id.* To meet the Federal Circuit's "necessarily present" standard, a drug patent's specification will have to include every detail of every treatment protocol for every disease for which the drugs have been found useful, even if those details were already well-known at the time. As amici explain, this standard "endanger[s] a significant percentage of drug patents." *Id.* at 6.

The history of this case below also indicates the importance of this issue. Each panel opinion drew a dissent, and the new panel considered the question sufficiently important to grant panel rehearing and vacate the original panel's opinion. 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 disclosed either explicitly or "inherently"—meaning that each limitation must be "necessarily" present in some explicit disclosure. App. A, at 6-7, 12. Judge Linn and then-Judge O'Malley, on the other hand, explained why "a showing of 'necessary exclusion' … is not and should not be a requirement in every case." App. A (Dissent), at 3; *see also* App. B, at 18 ("[T]he MPEP … correctly states that no specific form of disclosure is required and provides for implicit written description."). In addition to highlighting the importance of the issue, this history also raises concerns that future written-description decisions will be panel-dependent. *See* Brief of *Amici Curiae* Law Professors and Civil Procedure Scholars in Support of Petition for Panel and *En Banc* Rehearing, C.A. Dkt. 72, at 9-11.

Although the purpose of the Federal Circuit is to achieve "desirable uniformity" in cases involving patent law, *Markman*, 517 U.S. at 390, the decision in this case only increases the substantial uncertainty that already existed regarding written description. As commentators 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 for written description 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). Because "predictability and stability are of prime importance" in matters affecting "property rights," *Landgraf v. USI Film Prods.*, 511 U.S. 244, 271 (1994),

there is a reasonable probability this Court will grant certiorari to restore uniformity, predictability, and stability in this important area of law.

Fourth, this case is an excellent vehicle to decide the important statutory-interpretation questions it presents. There is no issue in the case other than written description, as that is the only argument HEC pursued through trial and appeal. Moreover, the Federal Circuit's holding is case-dispositive; there is no factual dispute that would prevent this Court from resolving the legal questions. For example, if "implicit" disclosure is permitted, then the district court did not clearly err in finding written-description support for the no-loading-dose limitation. Indeed, the evidence that a skilled artisan would read Novartis's specification to disclose administering fingolimod without a loading dose was entirely one-sided. *See* C.A. App. 22791-22793, 23342-23345, 23442. That evidence went *unrebutted*; HEC's expert conceded on direct examination that he was unqualified to opine on the key passage. C.A. App. 23117.

2. There is a fair prospect of reversal.

If this Court grants the petition, Novartis is likely to prevail. As already explained, the arguments supporting Novartis's position that implicit disclosure is permissible are well grounded in the text of the statute, precedent of this Court, and the MPEP. And they have already persuaded two judges of the Federal Circuit, as well as then-Chief Judge Stark (now on the Federal Circuit himself) at the preliminary-injunction stage and Circuit Judge Jordan after a full bench trial. For the same reasons, there is a fair prospect that they will persuade a majority of this Court as well.

Moreover, the new panel majority's conclusion that the specification—absent implicit disclosure—is silent as a matter of law led it to dismiss the unrebutted "expert testimony that the specification discloses the absence of a loading dose." App. A, at 10-11; C.A. App. 23344-23345 (Steinman); *see* C.A. App. 23117 (HEC expert declining to testify about key paragraph on ground that he lacks relevant "expert[ise]"). That approach transforms an intensely factual question—what the specification "reasonably conveys" to skilled artisans, *Ariad*, 598 F.3d at 1351-52—into a predominantly legal one—whether the specification "necessarily" discloses the limitation to a judge's standard of clarity. This Court has not hesitated to reverse when it has concluded that the Federal Circuit has replaced the district court's fact-finding with its own legal judgment. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 324 (2015) ("[W]hen reviewing the findings of a district court sitting without a jury, appellate courts must constantly have in mind that their function is not to decide factual issues *de novo*." (internal quotation marks omitted)); *accord, e.g.*, *Halo Electronics, Inc. v. Pulse Electronics, Inc.*, 579 U.S. 93, 107 (2016).

II. Generic launch would inflict a significant and irreparable harm on Novartis.

The district court's order granting Novartis a preliminary injunction found that Novartis would suffer irreparable harm from generic launch. That decision—reached on a substantial evidentiary record and after an in-person hearing—was correct, and the Federal Circuit majority did not question it in its opinion or its unexplained order denying a stay of mandate. It is well recognized that "irreversible harm" includes a monetary loss that "cannot be recouped." *Philip Morris USA Inc. v.*

Scott, 561 U.S. 1301, 1305 (2010) (Scalia, J., in chambers); *see also Ala. Ass'n of Realtors v. DHS*, 141 S. Ct. 2485, 2489 (2021) (finding irreparable harm when there was "no guarantee of eventual recovery"). There is ample evidence here that in the event of a generic launch, Novartis will not only suffer monetary loss, but be unable to be made whole even if it were ultimately to prevail before this Court.

First, as the district court found at the preliminary-injunction stage, a launch by generics would cause "massive and immediate price erosion" for Novartis. App. D, at 7. At that time the district court was considering a possible at-risk launch by "up to six generics." *Id.* Now there are at least *twenty* other generic applicants. App. H, ¶¶ 20-21, 30-31. Twelve companies (including HEC) have final FDA approval to launch generic versions of Gilenya, and four have tentative FDA approval, which could rapidly be converted to final approval once the mandate issues. App. H, ¶ 20. Thus, the resulting price erosion would be even more significant now than when the district court granted a preliminary injunction in this case. App. H, ¶¶ 37-40.

That price erosion could not be undone by a subsequent order that forced the generics off the market. As the district court found, "Novartis will not be able to raise the price back to where it is now, or to where it would have been … in the absence of defendants' at-risk infringement." App. D, at 7. That is due to contractual restraints limiting price increases, the damage to important customer relationships price increases would cause, and Novartis's decreasing bargaining power due to the increased number of RRMS therapies. App. H, ¶¶ 36, 39-40, 51. Thus, the harm to

Novartis will last not only throughout the proceedings in this Court, but also into the future.

Nor could Novartis recover its losses from this price erosion through a subsequent damages award. As the district court explained in this case, even if "the amount of past damages" could, "with some difficulty, … be calculated," calculating "future damages" from the price erosion—*i.e.*, damages that post-date the judgment—"may be impossible," and would be resisted by HEC in any event. App. D, at 7 (ellipsis in original). Among other reasons, the increased number of RRMS therapies that are available would make it extremely difficult to identity what portion of the price erosion was due to HEC's infringement versus other market factors. App. H, ¶ 39.

Second, unique features of fingolimod treatment are likely to lead the fingolimod market to irreversibly contract upon generic launch. As the district court recognized, both new fingolimod patients and patients restarting fingolimod after a break must undergo six hours of costly medical monitoring after their first dose, as well as electrocardiograms and other tests. App. D, at 7; App. H, ¶¶ 14-15. Novartis currently provides many of these services for free, often in the patient's home; Novartis spends many millions of dollars per year on its patient support program. App. H, ¶¶ 18-19, 41-42. In the event of a generic launch, as the district court found, Novartis would no longer be able to support patients entering into the program. App. D, at 7; App. H, ¶¶ 41-43, 56-57. And the generics will not offer such support services. As the district court found, the result will be fewer fingolimod patients: without the support program, patients will shift to other RRMS therapies that do not require

multiple tests and medical observation at the outset. App. H, ¶¶ 44-46. Indeed, there are even more such competing RRMS therapies on the market today than when the district court identified this irreparable market contraction—meaning that the market for fingolimod is even *more* likely to contract today, to a degree that would be difficult to quantify.

The result is that Gilenya would lose market share in the event of a generic launch, and Novartis would not be able to recover that market share for Gilenya if it prevails in this Court. App. H, ¶¶ 47-48. Nor would Novartis be able to recover for the loss of the substantial goodwill that it has built up through its successful development of Gilenya and its patient-support programs, or the reputational harm that the discontinuation of those programs would likely cause. App. D, at 7; App. H, ¶ 50.

This case therefore differs substantially from *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 572 U.S. 1301 (2014) (Roberts, C.J., in chambers). There, the district court made no factual finding of irreparable harm, and the Chief Justice concluded that the patent owner would not suffer irreparable harm because it could "recover damages from respondents for past patent infringement." *Id.* at 1301. Here, by contrast, the district court has already found that such a damages award would be insufficient, as it would not compensate Novartis for the *future* damage caused by contraction of the fingolimod market combined with irreversible price erosion. A district court's finding that the patentee cannot protect its "right to *exclude* through monetary remedies" is entitled to considerable weight. *eBay Inc. v. Mercexchange,*

LLC, 547 U.S. 388, 394-95 (2006) (Roberts, C.J., concurring). The market in this case also differs materially from *Teva*. Most notably, in *Teva* there were only two generic products at issue, and neither of them had FDA approval. Here, there could be a dozen generics immediately and *twenty* generics before long. That "exceptionally large" number of generics, App. H, ¶ 21, combined with market complications from other, new RRMS therapies, would make the damages calculation here particularly complicated. App. H, ¶¶ 39-40.

The cascade of irreparable harms described above would be triggered immediately by the issuance of the Federal Circuit mandate. App. H, ¶ 20. Even if this Court were to order the mandate recalled sometime later, the harm would be irreversible. Only a stay pending certiorari can avert it.

III. The balance of equities and public interest also favor a stay.

By contrast, any harm to HEC from a stay would be comparatively minimal. As the district court found in 2019, *all defendants combined* stood "to lose the opportunity to earn on the order of $50 million collectively by not being able to compete over approximately the next year," an amount that paled in comparison to Novartis's irreparable loss of "a market in which they sell approximately $1.8 billion of drugs [each] year." App. D, at 9. That is it. And nothing material has changed. App. H, ¶¶ 54-55. Equity strongly favors a stay where, as here, HEC's claim to harm is limited "to the difference between what [money] they would receive" if a stay is denied, but the other side faces a harm far greater in scope and far harder to quantify or remedy. *See NCAA v. Bd. of Regents of Univ. of Okla.*, 463 U.S. 1311, 1312-13 (1983) (White, J., in chambers). Any harm to HEC could be mitigated, if necessary,

by allowing Novartis to post a reasonable bond and directing the district court to determine its adequacy. *See, e.g., California v. Am. Stores Co.*, 492 U.S. 1301 (1989) (O'Connor, J., in chambers).

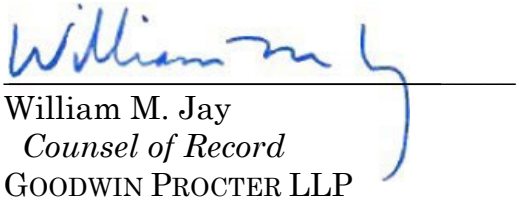
The public interest also tips in Novartis' favor. As the district court found, in "this particular market," and given the unique requirements of fingolimod treatment, patients would face additional harm: the loss of the support services for monitoring patients initially taking or restarting fingolimod. App. D, at 9. Novartis would be unable to support spending further multimillion-dollar sums on providing in-home doctor visits and medical tests to facilitate patients' transition to (or resumption of) fingolimod therapy, because many of those patients would be automatically switched to generic versions. The generic manufacturers facing intense price competition will have no incentive to provide similar support. *See* App. H, ¶¶ 56-57. And as the district court found, payors' interest in lower prices balances against the public interest in "protecting valid patent rights and in maintaining incentives for the massive investments required for drug development." App. D, at 9.

CONCLUSION

For all of these reasons, Novartis respectfully requests that the Court stay issuance of the mandate of the Federal Circuit pending the filing and disposition of Novartis's petition for a writ of certiorari and, if Novartis's petition for a writ of certiorari is granted, until the sending down of the judgment of this Court.

Should the Court determine that it needs additional time to consider the application before the mandate issues, Novartis respectfully requests that the Court enter an administrative stay pending disposition of this application.

Respectfully submitted,



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