No. 22A272

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

RESPONDENTS' OPPOSITION TO EMERGENCY APPLICATION FOR A STAY OF MANDATE PENDING THE DISPOSITION OF A PETITION FOR A WRIT OF CERTIORARI

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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 its parent's) stock.

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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 the Circuit Justice's September 29, 2022 order requesting a response, respondents HEC Pharm Co., Ltd. and HEC Pharm USA Inc. respectfully submit this opposition to applicant Novartis Pharmaceuticals Corporation's request to stay issuance of the Federal Circuit's mandate pending the filing and disposition of Novartis's petition for a writ of certiorari. HEC submits public and sealed versions of this opposition and its supporting appendix. The opposition and appendix reference information that Novartis has designated highly confidential, was sealed in the courts below, and that Novartis asked this Court to maintain under seal in connection with its stay application. HEC accordingly requests that the unredacted versions of its opposition and appendix be sealed as well.

Absent the interim order staying the mandate pending further order of the Circuit Justice or Court, the mandate would have issued yesterday (October 4). HEC respectfully requests that the Circuit Justice deny Novartis's stay application so that the mandate may now issue.

INTRODUCTION

Novartis seeks to enforce a patent that involves administering a 0.5 mg daily dose of a drug called fingolimod, which it markets as Gilenya. Novartis did not invent fingolimod. Nor did it discover that fingolimod could treat multiple sclerosis. It even balked at the FDA's suggestion to test a 0.5 mg daily dose of the drug. The patent's only purported innovation was administering 0.5 mg *without a loading dose*. But nowhere in the patent specification did Novartis disclose this critical limitation. The Federal Circuit thus held the patent invalid for failing to mention (much less describe) the purported invention.[1]

Today, Novartis makes $3.8 million *per day* on Gilenya in the United States alone, charging at least 10 to 20 times what its generic competitors would. And though the patent does not expire until 2027, [redacted]. That is because Novartis has [redacted] "to launch a generic version of 0.5 mg Gilenya on an agreed-upon date [redacted] that is prior to the expiration of the dosage regimen patent." Novartis 2021 Annual Report 41 (https://bit.ly/2vaGkQ1); *see also* Novartis, *2022 Q2 Results Presentation & Transcript*, Q&A (https://bit.ly/3V2aBLq) (CEO explaining "generics entering in 2024").

It is accordingly little wonder that Novartis seeks to stay the Federal Circuit's mandate. If Novartis can continue to restrain generic competition even for the months it will take until its petition is denied, it will have squeezed virtually every last dollar from its

[1] "A loading dose is a 'higher-than-daily dose . . . usually given as the first dose.'" Opinion 3 ("Op."). Citations to the decision below are to Novartis's Appendix A and take the form "Op." or "Dissent" followed by the page number of the decision (not the ECF numbering).

monopoly pricing of Gilenya. [redacted]

Novartis's request for this extraordinary relief should be denied. The Federal Circuit invalidated its patent based on the centuries-old requirement, now codified in 35 U.S.C. § 112(a), that a patent's specification must actually describe the invention it claims. That, of course, is a core tenet of the patent bargain: limited monopoly in exchange for full description. And as this Court, the Federal Circuit, and the Government have all explained, "the patent laws have always required a complete and exact description of the invention."[2]

Novartis's specification flunks that requirement because it discloses absolutely nothing about the absence of a loading dose. Novartis now calls it "absurd" for the Federal Circuit to require them to "say what their invention is *not*." Br. 3. But what the Federal Circuit required was for Novartis to say what its invention *is*. Novartis could only get its patent by adding the no-loading-dose limitation. Like "paint without priming the wall" or "wax without washing the car," the negative limitation is *the central thing Novartis claims to have invented*. It therefore had to be described in the specification. Under a straightforward application of the "written description" requirement, Novartis's patent fails spectacularly.

There is little chance Novartis convinces this Court to overturn that result under either of the two questions its forthcoming petition will present. The first is whether Section

[2] Br. for U.S. as Amicus Curiae, *Ariad Pharms., Inc. v. Eli Lilly & Co.*, No. 2008-1248, 2009 WL 4832140, at *4 (Fed. Cir. Nov. 19, 2009) (cleaned up); *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 112-13 (1853) (patentee cannot obtain "an exclusive right" over something "which he has not described and indeed had not invented"); *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1344 (Fed. Cir. 2010) (en banc).

112 contains a "written description" requirement at all (i.e., the question presented in *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, No. 21-1566 (petition pending)). The Court has denied certiorari on five petitions presenting this question, and it is likely to do the same in *Juno*. But even if the Court were to grant *Juno*, that wouldn't be enough to show a likelihood of success here. *See, e.g.*, *Biogen Int'l GmbH v. Mylan Pharms. Inc.*, No. 21-1567 (U.S. cert. denied Oct. 3, 2022) (presenting Section 112 question that *Juno* would resolve).

Novartis's fallback question presented—"whether implicit disclosure is sufficient to satisfy Section 112" (Br. 20)—is even less certworthy. Although the decision below was 2-1, the majority and dissent *agreed* on the legal standard; they simply disagreed on the "fact-based inquiry" (Dissent 2) of how to apply it. This Court is unlikely to wade into that case-specific, fact-bound dispute. And because the purported legal question presented by Novartis isn't even outcome determinative here, there is surely no fair prospect of reversal.

Merits aside, Novartis's application should be denied because it cannot show irreparable harm. Its application rests entirely on the specter of three categories of "incalculable" future injuries (irreversible price erosion, market shrinkage, and lost goodwill) caused by the immediate market entry of generic fingolimod products. But such injuries are readily compensable through money damages. And in any event, no such injuries could occur here [redacted] *See* Respondents' Appendix A, Decl. of Ivan T. Hofmann ¶¶ 14, 17 ("Hofmann Decl.").

Of course, any losses suffered by Novartis while this appeal is pending—as Novartis effectively concedes—can be easily remedied with money damages. And as the Circuit

Justice previously recognized on virtually identical facts, the ability to pursue such damages undermines any claim of irreparable harm. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 572 U.S. 1301, 1301 (2014) (Roberts, C.J., in chambers).

The converse, however, is not true. If Novartis does not prevail in this Court, it will improperly extract $3.8 million from payors and patients *every day its requested stay remains in effect*. And not one penny of those improper monopoly revenues will be recoverable from Novartis *by anyone*. That, respondents submit, must be dispositive in any balancing of the equities. Novartis's application for a stay should be denied.

STATEMENT

I. Factual History

A. Novartis earns $1.4 billion a year from its U.S. sales of fingolimod, sold as Gilenya, a drug used to treat relapsing-remitting multiple sclerosis. Hofmann Decl. ¶ 53. Fingolimod was first synthesized in 1992 by Japanese researchers at Mitsubishi. Kunitomo Adachi & Kenji Chiba, *FTY720 Story*, Perspect. Medicin. Chem. 2007: 1: 11-23; *see* U.S. Pat. Nos. 5,604,229; 6,004,565. Today, nearly 30 years after the first U.S. patent application was filed for fingolimod, it is widely acknowledged that Novartis has used every trick in the book—including term extensions, double-patenting, and even illegal kickbacks—to maintain its monopoly and high prices.[3]

[3] *See, e.g.*, *Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367, 1373 (Fed. Cir. 2018) (explaining Novartis's double-patenting and agreeing that Novartis could extend the term of the '229 patent even though doing so effectively extended the '565 patent beyond its expiration date); U.S. Dep't of Justice, *Novartis Agrees to Pay Over $51 Million to Resolve Allegations that It Paid Kickbacks Through Co-Pay Foundations* (July 1, 2020) (https://www.justice.gov/usao-ma/pr/novartis-agrees-pay-over-51-million-resolve-allegations-it-paid-kickbacks-through-co-pay).

Even though fingolimod itself is no longer under patent, Novartis has blocked generic competition with Gilenya for years by asserting two invalid follow-on patents. The first is U.S. Patent No. 8,324,283, in which Novartis tried and failed to repackage an earlier fingolimod patent to get a longer exclusivity period. In 2015, the Patent Trial and Appeal Board cancelled all claims of the '283 patent as obvious—largely based on the teachings of the earlier '565 patent. *See Torrent Pharms. Ltd. v. Novartis Ag*, Nos. IPR2014-00784, IPR2015-00518, 2015 WL 5719630, at *2 (P.T.A.B. Sept. 24, 2015). The Federal Circuit affirmed. *Novartis AG v. Torrent Pharms. Ltd.*, 853 F.3d 1316, 1318 (Fed. Cir. 2017).

The other follow-on patent that Novartis has used to block generic competition is U.S. Patent No. 9,187,405, the method patent at issue in this litigation. In 2018, the year after it lost the '283 patent at the Federal Circuit, Novartis sued the generic drug companies poised to compete with Gilenya for supposedly infringing the '405 patent. Appx142.[4] After four additional years of litigation, the Federal Circuit—in the decision below—found the '405 patent to be invalid. But during the course of this litigation alone, Novartis was nonetheless able to earn roughly $6 billion from its monopoly sales of Gilenya.

B. This is, in short, not a story of a pharmaceutical company rightly profiting from a major breakthrough, but a story of how low-quality patents and aggressive litigation can keep affordable generic drugs off the market for years. And as the factual record and decision below show, there's no doubt that the '405 patent deserves the "low-quality" label:

Novartis filed its application for what issued as the '405 patent in April 2014, claiming priority to an earlier foreign application filed in 2006. Appx25198, Appx25219. The

[4] Citations to the Joint Appendix below (C.A. Dkt. Nos. 25-26) take the form "Appx__."

specification for the '405 patent is identical to the 2006 foreign patent application. Make no mistake, Novartis needs that 2006 priority date because by 2014, there was nothing novel about the method it claimed. The FDA had approved that exact same drug treatment (0.5 mg daily with no loading dose) years earlier, in 2010. Appx10. Thus, if the claims in the '405 patent are to meet Section 112's written description requirement, then such description had to be in the 2006 specification.

But the 2006 specification does not disclose a 0.5 mg dose of fingolimod as an effective treatment for multiple sclerosis, let alone administering it without a loading dose. All it contains is a brief description of a hypothetical clinical trial that could potentially investigate a range of doses. Appx247440-741. And the reason is quite simple. At that time, no human had ever been orally administered a 0.5 mg dose of fingolimod, a dose then considered too low to be effective. Indeed, when the FDA asked that the 0.5 mg dose be added to a Phase III clinical trial, Novartis's investigators balked, believing it was a "bad idea." Appx22712 (134:1-21), Appx22716-19.

Nonetheless, in applying for the '405 patent, Novartis attempted to rely on the 2006 specification. Given that nobody had ever been treated with a 0.5 mg dose in 2006, Novartis's reliance on the 2006 specification was suspect. But Novartis had a bigger problem. Prior art known as "Kovarik," together with other references, had already disclosed administering fingolimod in a 0.5 mg daily dose, but in the context of a loading dose. Appx23892-23894, Appx23900-23906. So Novartis amended its claims to expressly *exclude* a loading dose. Appx23889-23891. Appx25259. 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 Kovarik.

Appx23892.

At no point, however, did Novartis amend the 2006 specification—which, of course, said nothing about a loading dose (or indeed *any* effective human dosing parameters). The reason for that is telling. Changing the specification would mean losing the 2006 priority date. But that was a non-starter for Novartis, who conceded that a 2010 study—authored by Kappos and published years before Novartis included the new limitation in its claims—disclosed using a 0.5 mg dose of fingolimod *without* a loading dose. Appx00248 ("Patent Owner does not dispute that Kappos 2010 discloses each element of claims 1-6."). Thus, if Novartis lost its 2006 priority date, it had no path forward on the '405 patent at all. So it eked out the patent by leaving the specification as it had been written in 2006.

C. Despite its tenuous origins (and presently invalidated status), the '405 patent has proven incredibly lucrative to Novartis. Public sources show Novartis charges over $300 per pill (the daily dose) for Gilenya, meaning an annual course of treatment costs over $110,000. *See, e.g.*, Drugs.com, *How much does Gilenya cost?* (https://www.drugs.com/medical-answers/gilenya-cost-3538874/) (last updated April 18, 2022). It makes $3.8 million in revenue *every day* in the U.S. alone. And it can only charge that much because it has a monopoly: no generic version is on the market. According to Novartis's calculations, generic competitors would offer the drug at *less than a thirtieth* of the price Novartis is charging. App. D at 9 (noting $50 million total expected revenue for all generics, compared to Novartis's $1.8 billion).

The Gilenya monopoly, however, is ending soon. As Novartis's CEO recently emphasized to investors in downplaying the importance of this appeal, generics will be entering the market in 2024 regardless of the outcome of this litigation:

> *Question*: "So just one on Gilenya. . . . [Y]ou said you're going to petition. . . . Does that prevent a [generic] launch happening in the intervening time frame?"
>
> *Answer*: "We would expect to get a response from the court in the coming months. [But] we guided to generics entering in 2024. So really, what we look at here is, between now and that time line, when exactly the entry might happen. . . . So from a midterm growth standpoint, this is not having a significant bearing."

Novartis, *2022 Q2 Results Presentation & Transcript*, Q&A (https://bit.ly/3V2aBLq).

[redacted] And in the meantime, it will try to hold onto its Gilenya monopoly for as long as it possibly can—after all, every day it keeps generics out is another $3.8 million in its pockets.

II. Procedural History

A. HEC and other generic manufacturers filed for approval of generic fingolimod in September 2014. Appx140-190. Novartis responded by suing generic manufacturers on a different patent, the '229 patent. Novartis also tried, and failed, to defend its '283 patent at the PTAB. But when the '405 patent issued in 2015, Novartis sat on it. [redacted] Generic competitors acted first, seeking PTAB review of the '405 patent in 2017. All told, Novartis waited three more years (until after PTAB proceedings had concluded) to file this 2018 lawsuit alleging infringement of the '405 patent.

Novartis sought a preliminary injunction in the district court, on the grounds that it stood to lose billions of dollars if generic manufacturers were allowed to market a low-cost version of the drug. Appx18865. 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. [redacted]

Novartis and HEC's dispute proceeded to a bench trial. The district court rejected HEC's Section 112 challenge and ruled in Novartis's favor. Appx1-3, Appx6-42.

B. HEC appealed, arguing that the district court's decision on adequate written description should be reversed. Initially, a split panel of the Federal Circuit affirmed. *See* App. B. 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. 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." App. B (Dissent) at 7. 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." *Id.* at 7-8.

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. *See* App. A. 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*. Op. 2-3. 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). Op. 4. Indeed, the majority, dissent, and both parties agreed that the *Ariad* standard controlled. *E.g.*, Op. 12; Dissent 2. The majority and dissent also agreed that the same standard governs disclosure of a negative limitation like this one. *E.g.*, Op. 12; Dissent 2.

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.*, Op. 8 (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." Op. 7. But the "specification nowhere describes 'initially' administering a daily dosage." Op. 7. 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." Op. 10. The majority thus concluded that, because a person

skilled in the art would not read the specification to exclude a loading dose, it does not satisfy Section 112. Op. 12. The "written description requirement cannot be met through simple disregard of the presence or absence of a limitation." Op. 5-6.

C. Novartis petitioned for panel rehearing and rehearing en banc. It devoted much of its petition to complaining about the change in panel composition following Judge O'Malley's retirement—an odd procedural argument that it has now dropped. On September 20, 2022, the Federal Circuit issued an order denying both panel and en banc rehearing. App. E. Novartis then moved for a stay of the mandate pending the filing of a petition for certiorari, which the Federal Circuit denied on September 27. App. F. In the normal course, the mandate would have issued seven days later (yesterday, October 4). Fed. R. App. P. 41(b) ("mandate must issue . . . 7 days after entry of an order denying a timely . . . motion for stay of mandate"). This application followed.

REASONS THE STAY SHOULD BE DENIED

This Court grants a stay pending appeal "only in extraordinary circumstances," *Graves v. Barnes*, 405 U.S. 1201, 1203 (1972) (Powell, J., in chambers), and only where the applicant carries a "heavy burden," *Williams v. Zbaraz*, 442 U.S. 1309, 1311 (1979) (Stevens, J., in chambers) (citation omitted). To obtain a stay pending a petition for certiorari, the applicant must show: (1) "a 'reasonable probability' that four Justices will consider the issue sufficiently meritorious to grant certiorari"; (2) "a fair prospect that a majority of the Court will conclude that the decision below was erroneous"; and (3) "irreparable harm is likely to result from the denial of a stay." *Corsetti v. Massachusetts*, 458 U.S. 1306, 1306-07 (1982) (Brennan, J., in chambers) (citation omitted). The Court also weighs "whether issuance of the stay will substantially injure the other parties interested in the proceeding" and "where

the public interest lies." *Nken v. Holder*, 556 U.S. 418, 434 (2009) (citation omitted). Here, each of these factors weighs against the granting of a stay.

I. Novartis cannot show a "reasonable probability" that this Court will grant its forthcoming petition for certiorari.

Novartis's first burden is to establish a reasonable probability that this Court will grant certiorari. But the Court is unlikely to review either of the two questions Novartis says its forthcoming petition will present. The first is the same question presented in *Juno*—whether Section 112 contains a written description requirement. The Court has five times before denied certiorari on this question; it will likely do so here as well. And Novartis's fallback question—"whether implicit disclosure is sufficient to satisfy Section 112" (Br. 20)—is even less certworthy. Novartis cites no decision (of this Court or the Federal Circuit) that has ever adopted its view. The majority and dissent below in fact agreed on the legal standard; they were divided over the "fact-based inquiry" (Dissent 2) into how to apply that standard here. Novartis thus dresses up a request for error correction as a fight over the legal standard. This Court does not grant certiorari when a case presents a fact-specific conflict or "has few if any ramifications beyond the instant case." *Bartlett v. Stephenson*, 535 U.S. 1301, 1304 (2002) (Rehnquist, J., in chambers).

A. This Court has consistently declined to review the *Juno* question presented, which Novartis claims will be its lead question.

What Novartis derides (at 2) as an "atextual requirement" to "show that the patent owner had 'possession' of the claimed invention" is in fact a fundamental principle that has been deeply embedded in patent law for centuries. Put simply, in addition to "enabl[ing]" a person skilled in the art to make and use the invention, a patent must provide a "written description" of the invention being claimed. *See* 35 U.S.C. § 112(a). The Federal Circuit (and

this Court), have used the shorthand "possession" because that is the point of the written description requirement: you have to tell the world what you created and describe it with enough detail to show you actually invented it. *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 433-434 (1822) (besides "enable[ment]," the "other object of the specification is, to put the public in possession of what the party claims as his own invention"). As this Court put it in 1853: a patentee cannot obtain "an exclusive right" over something "which he has not described and indeed had not invented." *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 112-13 (1853). That would frustrate the essential quid pro quo of patent law.

The en banc Federal Circuit, consistent with the age-old authority of this Court, reaffirmed the separate "written description" requirement over a decade ago. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc). The United States endorsed that holding. Br. for U.S. as Amicus Curiae on Rehearing En Banc in Support of Respondent, *Ariad*, No. 2008-1248, 2009 WL 4832140, at *4 (Fed. Cir. Nov. 19, 2009) ("the patent laws have always required a complete and exact description of the invention" separate from enablement) (formatting cleaned up). And both before and after *Ariad*, Congress has declined to repudiate the settled judicial understanding that Section 112 carries a separate written description requirement.

It is therefore little wonder that this Court has rejected each of the many petitions—both before and after *Ariad*—it has seen on this issue. *See Idenix Pharms. LLC v. Gilead Sciences, Inc.*, 141 S. Ct. 1234 (2021); *Amgen Inc. v. Sanofi*, 139 S. Ct. 787 (2019); *Janssen Biotech, Inc. v. Abbott Labs.*, 565 U.S. 1197 (2012); *Chiron Corp. v. Genentech, Inc.*, 543 U.S. 1050 (2005); *Univ. of Rochester v. G.D. Searle & Co.*, 543 U.S. 1015 (2004). As the *Juno*

respondents ably explain, the pending petition in *Juno* should be no different. *See generally* Br. in Opp., *Juno*, No. 21-1566 (U.S. Aug. 24, 2022). And if the *Juno* petition is denied, marking the sixth time this Court has declined review in the last 20 years, Novartis cannot establish a reasonable probability that its petition on this question will be granted either.

But even a grant in *Juno* is not enough to show a fair prospect that Novartis's forthcoming petition will be held or granted. On Monday (October 3), the Court denied certiorari in *Biogen*—another Section 112 case involving a different multiple sclerosis drug that was in essentially the same posture as this case. *Biogen*, No. 21-1567. The petitioners there argued, as Novartis does here, that although "35 U.S.C. § 112 requires only 'a written description of the invention,'" the Federal Circuit "imposed additional requirements not found in the statute." *Biogen* Pet. Reply 1; *see also Biogen* Pet. i. As here, the question presented would arguably be resolved if the Court were to grant certiorari and reverse in *Juno*. Yet the Court denied the *Biogen* petition even as it relisted *Juno* for consideration at a future conference.

B. The fallback question to be presented by Novartis's petition is not remotely certworthy.

Novartis says that even aside from the *Juno* question, this Court is likely to grant certiorari based on the "question whether implicit disclosure is sufficient to satisfy Section 112." Br. 20. It says this question "has sharply divided the Federal Circuit" and that "*every possible authority*" has agreed with its view. *Ibid.* (emphasis in original). But Novartis does not cite a single decision of the Federal Circuit reaching that holding. *See* Op. 6 n.2. In reality, its focus on implicit disclosure is an attempt to obscure that the decision below is

nothing more than a narrow, fact-bound decision about how to apply a well-settled legal standard to the particular circumstances of this case.[5]

1. By seizing on the word "implicit" (at 12, 16, 20, 21, 22, 23, 24, 25, 26), Novartis attempts to cast the decision below as turning on a dispute over the legal standard. But the majority and dissent both applied the Federal Circuit's en banc decision in *Ariad* and both agreed that a "disclosure must only 'reasonably convey to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.'" Op. 12 (quoting *Ariad*, 598 F.3d at 1351 (brackets omitted)); Dissent 2 (same). Both agreed the standard is the same for negative limitations, that a disclosure need not set forth a limitation verbatim as long as the substance is described, and that a limitation may be inherent in the disclosure.

Novartis can only suggest a conflict over the legal standard by ignoring what the majority and the dissent actually say. In the portion of its stay application discussing the supposed "conflict with a long line of Federal Circuit cases" (at 21-22), Novartis quotes a total of five words (from a single footnote) of the decision. The rest is its own invention.

Novartis argues, for example, that "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." Br. 21. But the majority stated the *very* rule (citing the *very* passage from the *very* case) that Novartis claims it rejected:

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[5] Although *In re Robins*, 429 F.2d 452, 456-57 (C.C.P.A. 1970), mentioned the idea of "implicit description," that case in fact involved an adequate "*explicit* description." (emphasis added). And in any event, *Robins* only used the word "implicit" to mean that a written description may be found adequate if it provides "representative [examples] . . . upon which to base generic claim language." *Id.* at 457. That is fully consistent with the *Ariad* standard applied below and nothing like the '405 patent's specification. Tellingly, neither Novartis nor the dissent cited *Robins* below.

> We do not today create a heightened standard for negative claim limitations. Just as disclosure is the "hallmark of written description" for positive limitations, *Ariad*, 598 F.3d at 1351, so too for negative limitations. That disclosure "need not rise to the level of disclaimer." *Santarus*, 694 F.3d at 1351. Nor must it use the same words as the claims. *Lockwood*, 107 F.3d at 1572 ("[T]he exact terms need not be used *in haec verba*." (citing *Eiselstein v. Frank*, 52 F.3d 1035, 1038 (Fed. Cir. 1995))). Rather, as with positive limitations, the disclosure must only "reasonably convey[ ] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad*, 598 F.3d at 1351.

Op. 12 (alterations in original). Even the dissent readily acknowledged that the majority "ultimately recogniz[ed] that the standard for negative limitations is the same as for any other limitation." Dissent 2.[6]

The majority and dissent also agreed that, sometimes, failing to mention something is enough to exclude it, if that's what a person skilled in the art would understand the absence to mean. *E.g.*, Op. 12; Dissent 2. Their disagreement was over the "fact-based inquiry" into what the '405 patent specification's silence as to a loading dose meant *in this case*. *Compare, e.g.*, Op. 12 ("While silence will not generally suffice to support a negative claim limitation, there may be circumstances in which it can be established that a skilled artisan would understand a negative limitation to necessarily be present in a disclosure. This is not such a case."), *with* Dissent 2 ("Our case law makes clear that '[c]ompliance with the written description requirement is essentially a fact-based inquiry that will necessarily vary depending on the nature of the invention claimed.'") (citation omitted).

[6] Judge Linn went on to say that despite articulating the correct legal standard, the majority "nonetheless applies a heightened written description standard *to the facts of this case*." Dissent 2 (emphasis added). Acknowledging that Judge Linn was disputing the "appli[cation]" of a correct legal standard "to the facts of this case," Novartis does not contend his statement demonstrates a conflict over the legal standard. *See* Br. 20-26.

The majority concluded that because Novartis itself, in order to avoid prior art, amended its claims to make this distinction, silence plainly was not enough. Op. 10. It also found important that "all the experts agreed that loading doses are sometimes given to MS patients," and that "there is intrinsic evidence that a skilled artisan would *not* understand reciting a daily dosage regimen without mentioning a loading dose to exclude a loading dose." Op. 11. The dissent read the expert testimony and prosecution history differently, spending nearly half its opinion explaining why it would have accepted Novartis's view of the evidence. Dissent 7-10. But either way, what matters are the facts of this case and the science in this particular area, not any broader legal principle.

While the answer to this question is obviously of great importance to the parties in this case—as well as the patients who stand to pay many times less for their medication—the question does not come close to meriting this Court's attention. What Novartis seeks is pure error correction on a case-specific application of settled legal principles.

2. Novartis's single-paragraph search for a conflict with this Court's cases on the concept of "implicit disclosure" likewise fails. Br. 22. It cherry-picks a quote from a 90-year-old decision of this Court, stating that claims may be amended to "make explicit what was already implicit" in the original specification. *Ibid.* (quoting *Marconi Wireless Tel. Co. of Am. v. United States*, 320 U.S. 1, 34 (1943)). But in context, it is clear that *Marconi* fits neatly with the Federal Circuit authority relied on by both the panel majority and dissent.

The patent at issue in *Marconi* involved radio devices. *E.g.*, 320 U.S. at 17-18. The patent application disclosed a new method of tuning the transmitter and receiver. *Id.* at 17-21. Later, the claims were amended to clarify that this included tuning the antenna. *Id.* at

21-22. This Court found that the specification as originally filed adequately disclosed that limitation because it comprehensively discussed the importance of tuning *all* aspects of the system, which necessarily included the antenna. *Id.* at 21-23, 34.

That is directly analogous to numerous decisions of the Federal Circuit, including the very cases on which the majority relied. Where the specification discloses the relevant element and demonstrates it was part of what the inventor conceived, the specification is adequate; setting forth every detail verbatim is not necessary. Op. 4-6 (collecting cases) ("The common denominator of these examples is disclosure of the element."); Dissent 4-7 (similar). The point is merely to describe the invention in enough detail to notify the public and show you actually invented it. *Ariad*, 598 F.3d at 1352; *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 112-13 (1853) (inventor cannot obtain "an exclusive right" over something "which he has not described and indeed had not invented"). That avoids, as happened here, attempting to claim an earlier priority date for something that was only discovered (and added to the patent) later.[7]

3. Even if Novartis's fallback question were otherwise certworthy (it's not), this case is an unsuitable vehicle to address it. First, the panel majority found that Novartis "d[id] not defend" the argument "that the specification's disclosure of a daily dosage combined

[7] This is the same reason to disregard Novartis's policy arguments (at 22-24). Nothing about the decision below "deprives patentees of the ability to limit claims to avoid prior art through negative limitations." Br. 23 (brackets omitted). When Novartis realized that it needed to exclude a loading dose to avoid prior art, it could have amended its specification, just as it amended its claims. But Novartis didn't want to lose its priority date, so it left the specification as is. Patentees have long been able to "avoid prior art through negative limitations," *e.g.*, *In re Johnson*, 558 F.2d 1008, 1017-19 (C.C.P.A. 1977), and they still can. What they cannot do is back-date a material change in their invention in order to claim a monopoly over something they did not discover until years later.

with its silence regarding a loading dose would 'tell a person of skill that loading doses are excluded from the invention.'" Op. 9.

Second, the panel only mentioned the concept of "implicit disclosure" in a passing footnote remarking on its utter lack of foundation in the case law, *id.* at 6 n.2—underscoring that the fight wasn't over implicit disclosure as a legal standard, but how to treat the specification's silence in the fact-specific context of this case. Novartis's fallback question, accordingly, was hardly "pressed or passed upon below" in a manner that warrants a grant of certiorari. *United States v. Williams*, 504 U.S. 36, 41 (1992) (citation omitted). And to the extent it was, this would mark the first time the Federal Circuit has addressed it. Before any percolation whatsoever, this Court's review is premature.

Finally, Novartis's fallback question is simply not outcome determinative. Novartis proposes a rule that silence in the specification satisfies Section 112 as long as a "skilled artisan" would "implicitly" understand silence to mean exclusion. Br. 20-21. But the panel majority below clearly held that Novartis could not satisfy that rule. *See, e.g.*, Op. 11 ("[T]here is intrinsic evidence that a skilled artisan would not understand reciting a daily dosage regimen without mentioning a loading dose to exclude a loading dose."); *ibid.* ("all the experts agreed that loading doses are sometimes given to MS patients").

II. Novartis cannot show a "fair prospect" that a majority of this Court will reverse the decision below.

In addition to showing a reasonable probability that the Court will grant certiorari, Novartis must establish a fair prospect that it will prevail on the merits. *Corsetti*, 458 U.S. at 1306-1307. It has not and cannot do so.

A. As respondents in *Juno* and the United States have explained, the position urged by petitioners there (and Novartis here) is baseless.

The arguments about Section 112's written description requirement are well-ventilated and do not bear further repetition here. *See generally* Br. for U.S. as Amicus Curiae, *Ariad*, No. 2008-1248, 2009 WL 4832140 (Fed. Cir. Nov. 19, 2009); Br. in Opp., *Juno*, No. 21-1566 (U.S. Aug. 24, 2022). Suffice to say, if the Court grants certiorari in *Juno*, it can only be to declare once and for all that Section 112 embodies a separate written description requirement. As the Government explained in *Ariad*, such a requirement has "always" been part of patent law in this country. 2009 WL 4832140, at *4; *e.g.*, *O'Reilly*, 56 U.S. (15 How.) at 112-13. And for good reason: allowing patentees to obtain a monopoly over more than they have actually invented and disclosed to the public would undermine the central bargain of the Patent Act. *See* U.S. Amicus Br., 2009 WL 4832140, at *17. That is what the written description requirement prevents. There is accordingly no fair prospect of reversal on the *Juno* question.

B. Even if this Court agreed to review Novartis's fallback question and adopted its legal position, it would need to affirm the decision below.

Even more clearly, Novartis has not and cannot show a fair prospect of reversal on its fallback question presented. Novartis says it seeks a holding from this Court that a patent application satisfies Section 112 as long as a "skilled artisan" would "implicitly" understand the claimed invention. Br. 20-21. But Novartis's own actions show that it would lose under that rule. *Not* administering a loading dose is an express part of the method that Novartis claimed to invent. Appx24741. As the prosecution history details, Novartis in 2014 "amended all pending claims . . . to specify that the stated daily dosage of 0.5 mg cannot immediately follow a loading dose regimen" and did so precisely "to further distinguish

their claims from" the prior art. Appx23892. In other words, the prior art disclosed the 0.5 mg dosage, but in the context of a loading dose. Novartis thus did not merely claim a method of administering a daily 0.5 mg dose. Its method comprises administering that daily dose *and* necessarily excluding a loading dose. Like "paint without priming the wall" or "wax without washing the car," the absence of the loading dose is a crucial part of the invention Novartis ultimately claimed.

That limitation—the necessary absence of a loading dose—is not disclosed (implicitly or otherwise) by the 2006 specification. Op. 7-12. The specification does not describe any disadvantage of a loading dose or any reason for excluding it. *Id.* at 5, 7-12. It does not use different words to describe the concept of loading doses in substance. *Ibid*. It just says nothing. That silence cannot be construed as an adequate disclosure:

First, Novartis is bound by its own actions during prosecution. If disclosing only a daily dose were sufficient to also disclose *excluding* a loading dose, then Novartis would not have needed to amend its claims to add the negative limitation. That is what the majority correctly concluded below. Op. 10 ("the disclosure of a daily dosage cannot amount to a disclosure that there can be no loading dose, because such a finding is at odds with the prosecution history"). Novartis's assertion of silent but "implicit" disclosure is contradicted by the very patent claims it desperately wants to save.

Second, even aside from the prosecution history, there is no credible evidence in this record that a skilled artisan would have understood Novartis's invention to exclude a loading dose. All of the evidence is to the contrary. As the majority explained, the record shows (and the experts agreed) that loading doses are used both with this drug and in the

field of treating multiple sclerosis patients. Op. 11. To support its exclusion of loading doses, Novartis relied on other expert testimony, but that testimony conflicted with the "plain text of the specification." Op. 8. The Federal Circuit correctly refused to allow Novartis to expand the specification through after-the-fact evidence contradicted by the patent itself.

At bottom, this case is quite simple: Novartis attached new claims to an old specification in the hopes that something would stick, because the potential upside was enormous—billions in annual revenues selling a drug it didn't even invent. The specification doesn't exclude loading doses because Novartis had not, in 2006, invented any method "for reducing or preventing or alleviating relapses in Relapsing-Remitting multiple sclerosis" by administering fingolimod at 0.5 mg daily, Appx24741, much less invented the specific method claimed in the '405 patent. Thus, even if this Court were to grant review, Novartis cannot show that the 2006 specification supports the claims it came up with years later.

III. Novartis cannot show that it will suffer any irreparable harm if a stay is denied and the decision below is later reversed.

Merits aside, the application for a stay should also be denied because Novartis cannot show any possible risk of irreparable harm. Indeed, "[a]n applicant's likelihood of success on the merits need not [even] be considered . . . if the applicant fails to show irreparable injury from the denial of the stay." *Ruckelshaus v. Monsanto Co.*, 463 U.S. 1315, 1317 (1983) (Blackmun, J., in chambers).

A. To justify a stay, Novartis must establish a likelihood of irreparable harm on the record that exists *today*. As members of this Court have often explained, an "applicant must demonstrate . . . a likelihood that 'irreparable harm will result *from the denial of a stay.*'" *Conkright v. Frommert*, 556 U.S. 1401, 1402 (2009) (Ginsburg, J., in chambers) (emphasis

added) (citation and brackets omitted); *see also Rubin v. United States*, 524 U.S. 1301, 1301 (1998) (Rehnquist, C.J., in chambers) ("An applicant for stay first must show irreparable harm *if a stay is denied.*") (emphasis added).

In its application, however, Novartis relies largely on pre-trial district court findings from well over three years ago that have little, if any, continuing relevance. To be sure, Novartis implicitly acknowledges its burden to show *present* irreparable harm by submitting an updated declaration from an expert witnesses who provided testimony in 2019. App. H. But none of the potential injuries discussed in that updated declaration can possibly constitute irreparable harm. Rather, each could easily be compensated by a damages award. *See* Hofmann Decl. ¶¶ 14, 17-19, 21, 25-26, 48-50; *see also Sampson v. Murray*, 415 U.S. 61, 90 (1974) ("'The key word in this consideration is irreparable. Mere injuries, however, substantial, in terms of money, time and energy necessarily expended in the absence of a stay, are not enough.'") (citation omitted).

B.1. The central premise of Novartis's position is that permanent *future* price erosion caused by generics entering the market will be incalculable and unrecoverable. Br. 27-29. Novartis paints a picture of undeniable yet impossible-to-calculate losses stretching out into the unknowable future, presumably until its patent expires in 2027. Br. 5 (noting patent expires in 2027); Br. 29 ("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") (emphasis in original).

But generics will enter the market [redacted]

[redacted] *E.g.* Hofmann Decl. ¶¶ 14, 17, 27-28; Novartis, *2022 Q2 Results Presentation & Transcript*, Q&A (https://bit.ly/3V2aBLq) (CEO of Novartis explaining to investors that "generics [are] entering in 2024"); *see also* Novartis 2021 Annual Report 41 ("Under the confidential terms of terms of these settlements, these ANDA filers will be able to launch a generic version of 0.5 mg Gilenya on an agreed-upon date that is prior to the expiration of the dosage regimen patent.").

a. By the time this Court could reverse the decision below, any price erosion or market contraction caused by the entry of generics will necessarily happen anyway. Thus, in the unlikely event that Novartis obtained reversal, it could be made whole through an award of damages for past infringement—a number that would be both determinable and recoverable. Hofmann Decl. ¶¶ 48-50. [redacted] *see* Novartis, *2022 Q2 Results Presentation & Transcript*, Slide 23 (https://bit.ly/3V2aBLq) (noting "key assumption" in Novartis financial projections "that no Gilenya® . . . generics enter in the US").

Accordingly, the extraordinary relief of a stay is unwarranted. *Merck & Cie v. Watson Lab'ys, Inc.*, 136 S. Ct. 2442 (2016) (denying stay application where generic entry would occur regardless of case's outcome even though Merck argued that generic competition would cause irreparable harm) (Roberts, C.J., in chambers); *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 572 U.S. 1301 (2014) (denying motion for stay of mandate even after Court *granted* certiorari explaining "should Teva prevail in this Court and its patent be held valid, Teva will be able to recover damages from respondents for past patent infringement") (Roberts, C.J., in chambers); *Pfizer Inc. v. Apotex, Inc.*, No. 06A1131 (June

6, 2007) (Stevens, J., denial without opinion) (denying stay application in case where Pfizer argued that competition from generics would cause irreparable harm).[8]

b. The imminent generic launch equally undermines Novartis's argument that it will lose goodwill from lowering and then, if it wins here, raising its prices again to pre-mandate levels. *See* Br. 29; App. H ¶ 51. To put Novartis's argument more plainly: it is worried that once the public sees just how much less the generics cost, they will be outraged if Novartis later tries to re-establish its monopoly pricing. The loss of goodwill predicted by Novartis is speculative and, based on empirical evidence, unlikely to occur. *See* Hofmann Decl. ¶¶ 40-44 (noting Novartis's goodwill concerns are not supported by historical examples). But more importantly, [redacted] generic launch renders this supposed harm illusory: [redacted]

c. Novartis likewise cannot establish irreparable harm based on the prospect of patients transitioning to other multiple sclerosis therapies after a generic launch. Br. 28-29. [redacted]

[8] *See also, e.g.*, *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 566 F.3d 999, 1010 (Fed. Cir. 2009) (affirming finding of no irreparable harm from "price erosion, loss of market share, [and] loss of profits" due to generic entry because "the plaintiffs had not shown that the defendants were unable to respond in money damages"); *Eli Lilly & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1578-79 (Fed. Cir. 1996) (affirming denial of preliminary injunction against generic manufacturer where "calculating lost profits would be a relatively simple task"); *King Pharms., Inc. v. Sandoz, Inc.*, No. CIVA085974GEBDEA, 2010 WL 1957640, at *5 (D.N.J. May 17, 2010) (collecting cases finding loss of "market share and price erosion do not amount to irreparable harm" in patent cases).

[redacted] That much a stay would accomplish, but little else.[9]

In short, by the time Novartis could obtain reversal of the Federal Circuit's decision, there will be no more future harm for it to suffer. And any losses Novartis incurs in the meantime can be remedied by damages. The real purpose of its stay application is to run out the clock to [redacted] so that it can squeeze every drop out of its monopoly pricing whether or not it ultimately prevails before this Court. Even if its petition is denied, staying the Federal Circuit's mandate in the interim could plausibly buy Novartis six-plus months of unjustified monopoly profits. [redacted] And of course, *nobody* will be able to recover those billions from Novartis should it ultimately lose. *See infra* Part IV.

[9] Novartis also says a generic launch [redacted] on which it "spends many millions of dollars per year." Br. 28. Harm to patients is addressed below in Part IV, but suffice to say: it is better for patients to save 95% or more on their medication, even if they, or payors, must cover other support services. [redacted]

2. These arguments should come as no surprise to Novartis. It made the exact same points (through its wholly owned subsidiary Sandoz) in successfully opposing the brand-name pharmaceutical manufacturer's stay request in *Teva*. *See* Resps. Joint Opp. to 2d App. to Recall and Stay Mandate, *Teva*, No. 13A1003 (U.S. Apr. 14, 2014) ("Sandoz Opp.").

Like Novartis here, Teva had prevailed at trial—but its patent was held invalid on appeal. Like Novartis here, Teva applied for a stay of the Federal Circuit's mandate after it issued (No. 13A458). Teva also, however, reapplied for a stay after this Court granted certiorari (No. 13A1003). Both times Teva argued that generic market entry would cause it irreparable injury. And both times its application was denied, because Teva had not shown "a likelihood of irreparable harm from denial of a stay." *Teva*, 572 U.S. at 1301. If Teva "prevail[ed] in this Court," it could "recover damages from [the generic defendants] for past patent infringement." *Ibid.* And "[g]iven the availability of that remedy, the extraordinary relief that [Teva sought was] unwarranted." *Id.* at 1302.

Far from "differ[ing] substantially" (Br. 29), the relevant facts of *Teva* could not be more similar to those here:

Sandoz's arguments in *Teva*:	**This case:**
• Argued a stay was inappropriate "during the 15-month period" before generics could enter the market anyway. Sandoz Opp. 1.	• [redacted]

• Argued damages were adequate and determinable where "Teva has publicly quantified its expected losses from generic competition" in the interim. Sandoz Opp. 27.	• Novartis has both publicly quantified its expected losses from generic competition [redacted] Novartis, *2022 Q2 Results Presentation & Transcript*, Slide 23 (https://bit.ly/3V2aBLq).
• Argued that because the case involved only "reduced revenue . . . during a period of just over a year," a court could "calculate an appropriate damages award to compensate it for any lost revenue due to generic competition during that finite period." Sandoz Opp. 27.	• The prospect of lost revenue spans a similarly short period, and a court could calculate damages from generic competition during that finite period. Hofmann Decl. ¶¶ 48-50.
• [redacted]	• [redacted]
• Argued a stay should be denied because "[a]s a practical matter, an injunction or stay delaying competition would decide this litigation for Teva" by allowing it to run out the clock. Sandoz Opp. 32.	• As a practical matter, a stay is just as good as a win on the merits for Novartis. Either way, it only needs to run out the clock [redacted]

The circumstances here and in *Teva* are virtually indistinguishable. And the very arguments Sandoz pressed in successfully opposing a stay in that case demonstrate why a stay is equally inappropriate here. Novartis has failed to demonstrate irreparable harm.

IV. The public will suffer manifest irreparable harm if a stay is granted and the decision below ultimately stands.

If the mandate is stayed and this Court denies certiorari (or grants and affirms the Federal Circuit), the irreparable harm to the public, namely payors and patients, will be manifest and staggering.

Third-party payors, such as Medicare and Medicaid—who already have paid Novartis billions in net sales related to Gilenya resulting from monopoly pricing from an invalid patent—[redacted] *See* Decl. of Christopher Vellturo, Ph.d. in Support of Novartis's Mot. for Preliminary Injunction, *Novartis Pharms. Corp. v. Accord Healthcare Inc.*, C.A. No. 18-1043-LPS (D. Del.) Dkt. No. 363 ¶ 47[redacted] Hofmann Decl. ¶ 56. Unlike Novartis—who *would* be able to recover monetary damages if the Federal Circuit's invalidity holding is reversed—those payers will *never* be able to recover anything from Novartis for its artificial extension of monopoly prices. That is the paradigmatic example of an injury that is irreparable.

In addition to the irreparable and enormous injury to payors, there will be a separate irreparable injury to many multiple-sclerosis patients. Public sources show that a single daily dose of Gilenya costs approximately $300, or $9,000 for a month's supply, or approximately $110,000 for a year's supply. *See, e.g.*, Drugs.com, *How much does Gilenya cost?* (https://www.drugs.com/medical-answers/gilenya-cost-3538874/) (last updated April 18, 2022). The price has more than doubled since it came on the market at the already high price of $4,000 a month, or $48,000 each year. Jeri Burthcell, *Should Multiple Sclerosis Drugs Cost $62,000 a Year?*, Healthline (Jan. 16, 2019) (https://www.healthline.com/health-

news/ms-why-are-ms-drug-prices-so-high-071913) (evaluating price of multiple sclerosis drugs including Gilenya). For many patients, especially those who are uninsured, this price is simply too high, and they will continue to be denied access to this drug and its benefits—a reduction in the number and severity of multiple sclerosis relapses a patient experiences. For those patients who must pay all or a portion of the astronomical cost of Gilenya, like payors, they too will suffer irreparable financial losses with no path for recovery. Novartis will never repay the patients that have and will, if the stay is granted, pay uncountable sums only because an invalid patent imposed an undeserved monopoly on the market.

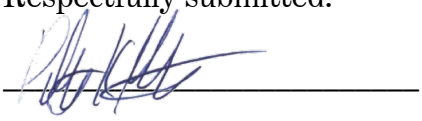
It is for these reasons that courts have long recognized the significant public "interest in receiving generic competition to brand-name drugs as soon as possible." *ViroPharma, Inc. v. Hamburg*, 898 F. Supp. 2d 1, 29 (D.D.C. 2012) (citation omitted). Congress passed the Drug Price Competition & Patent Term Restoration Act (better known as Hatch-Waxman) specifically to "speed the introduction of low-cost generic drugs to market," reduce drug prices, and make drugs more accessible to the public. *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012); *id.* at 426 (Sotomayor, J., concurring); *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 142 (2013) (Congress adopted "abbreviated procedures" for generics to obtain FDA approval to increase "drug competition"). A delay in bringing a generic drug to market is thus "against the public interest in reduced [drug] prices." *Biovail Corp. v. U.S. Food & Drug Admin.*, 448 F. Supp. 2d 154, 166 (D.D.C. 2006) (citation omitted). And, in circumstances like these, there is a separate "public interest in ensuring that competition is restored to a market that has been [unfairly] subject to a . . .

restraint on competition." *United States v. Alex Brown & Sons, Inc.*, 963 F. Supp. 235, 242 (S.D.N.Y. 1997), *aff'd sub nom. United States v. Bleznak*, 153 F.3d 16 (2d Cir. 1998).

CONCLUSION

Respondents respectfully request that Novartis's stay application be denied without delay so that the mandate may issue in as close to the ordinary course as is now possible.

Respectfully submitted.



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