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

REPLY IN SUPPORT OF EMERGENCY APPLICATION FOR A STAY OF MANDATE PENDING THE DISPOSITION OF A PETITION FOR A WRIT OF CERTIORARI (REDACTED)

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INTRODUCTION

Gilenya has been a breakthrough for patients: the first-ever oral and daily medication for relapsing-remitting multiple sclerosis (RRMS)—a breakthrough that was only possible due to the innovative dosing regimen that Novartis described in the patent application and claimed in the patent at issue. HEC's attempt to spin a contrary narrative and cast Novartis's stay application as a last-ditch effort to postpone the invalidation of a "low-quality" patent ignores the inconvenient fact that HEC repeatedly *lost* on its written-description argument below. HEC lost before then-Chief Judge Stark, who granted Novartis a preliminary injunction, finding that HEC was "not at all likely to prevail." HEC lost again on the merits before Circuit Judge Jordan, sitting by designation. He found, after a four-day bench trial, that the patent's written description *did* disclose to a skilled artisan the 0.5 mg dose of fingolimod to treat RRMS, with no loading dose. (For good measure, he also squarely rejected the alternative version of history that HEC peddles throughout its opposition; HEC simply disregards historical findings that it did not even *appeal*.) And HEC lost a third time before the Federal Circuit, which upheld Judge Jordan's findings in its initial published opinion authored by Judge O'Malley.

It was only Judge O'Malley's retirement that saved HEC: Her retirement led to a new judge being drawn and an about-face on panel rehearing, one that was unprecedented at the Federal Circuit and would not have happened in almost any other circuit (or in this Court, *see* Sup. Ct. R. 44.1). Two divided opinions reaching opposite conclusions make clear that the choice of legal rule was outcome-

determinative here. This Court is likely to reverse that erroneous legal rule, and it should act now to halt the irreparable harm to Novartis that will otherwise occur during the Court's review.

First, if the Court grants certiorari in *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, No. 21-1566, that necessarily establishes a likelihood of success here. This Court would grant a patent-law petition from the Federal Circuit only if there were at least a fair chance of reversal. And if this Court accepts Juno's argument, that indisputably would wipe out HEC's sole remaining challenge to Novartis's patent.

Moreover, even if the Court denies certiorari in *Juno*, this Court is likely to grant certiorari in this case and reverse the Federal Circuit's holding that an implicit disclosure, allowing a skilled artisan to recognize the relevant element, is not good enough to show possession of an invention. The extraordinary procedure here highlights that the Federal Circuit itself is clearly divided on the issue. And while HEC tries to obscure the clarity of that holding, there was nothing fact-bound about the Federal Circuit's decision. It adopted a new *legal* rule that allowed it to brush aside detailed factfinding by the district court as to how a skilled artisan would understand the patent. Instead, the Federal Circuit now relies on judges' *de novo* determination of what a patent explicitly or "inherently" discloses. That decision was both wrong and important, and warrants review by this Court.

Absent a stay, Novartis will suffer irreparable harm during the time it takes this Court to grant certiorari and reverse. Irreparable harm from generic launch was extensively litigated at the district court, and the district court found that generic

entry would lead to irreparable harm through at least price erosion and market contraction that could not be reversed or remedied if generics were subsequently ordered off of the market. HEC's response boils down to basically one argument: [redacted], this Court's decision could not come in time to force generics off the market, allegedly eliminating the risk of incalculable damages. But the premise of that argument is wrong: This Court will almost certainly resolve this case this Term [redacted] Novartis would face precisely the difficulties the district court identified in either reversing or remedying the harms from generic entry. This case is thus fundamentally different from *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 572 U.S. 1301 (2014) (Roberts, C.J., in chambers), which involved no district court finding of irreparable harm through irreversible and irremediable price erosion and market contraction.

This Court should stay the mandate.

ARGUMENT

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

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

The Court has relisted *Juno* for conference today (October 7) and may well have made a decision on the petition by the time of this filing. If this Court grants certiorari in *Juno*, then Novartis has a likelihood of success on its petition, too. HEC's arguments to the contrary are meritless.

First, if the Court grants the *Juno* petition and rejects the "possession" requirement on which HEC prevailed below, HEC's challenge to Novartis's patent necessarily fails. HEC gives no reason why the Court would not then GVR in this case, with the outcome on remand foreordained. And there is no such reason: if there is no possession requirement, HEC has no case.

Instead, HEC seems to argue (Opp. 14) that the Court has already decided not to hold other petitions for *Juno*. HEC bases that supposition on the Court's denial of the petition in *Biogen International GmbH v. Mylan Pharmaceuticals Inc.*, No. 21-1567. But the *Biogen* petition did not ask this Court to decide the question whether Section 112(a) contains a "possession" requirement. The *Biogen* petition instead took as a given that a "possession" requirement exists; it asked this Court to decide whether the Federal Circuit was correct to demand, as part of that requirement, that "the specification … disclose data that demonstrates the claimed invention is 'effective' and emphasize the claimed invention by singling it out and describing it more than once." Pet. for Cert. at i, *Biogen, supra*. And neither the *Biogen* petition (filed the day after the *Juno* petition) nor the reply asked the Court to hold the petition pending a decision on *Juno*.

Second, HEC argues that even if the Court grants certiorari in *Juno*, there still will not be even a fair prospect of reversal. Opp. 20. That is a remarkable contention: 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. Novartis explained as much in its application (at 17), and HEC has no explanation

for why this Court would grant certiorari to issue a slam-dunk affirmance. Nor does HEC even try to reconcile the Federal Circuit's possession requirement with the text of the statute.

To the extent the Court has not yet decided whether to grant the *Juno* petition, this Court should continue its stay of the mandate in this case at least until the Court makes a decision on that petition. And even if the Court were to deny certiorari in *Juno* on case-specific grounds (and none is apparent from the certiorari briefing), this case presents an excellent vehicle to grant and hear the same question presented in *Juno*.

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.

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

Patents are directed to skilled artisans who are familiar with and can appreciate nuances in the written description of the technology at hand. If a "possession" requirement exists, this case presents the important question of how possession must be shown, and to whom: To a skilled artisan, through disclosure that may be implicit in that it draws on the skilled artisan's background knowledge and understanding? Or to federal judges, in terms that must meet the heightened standard of express or "necessary" disclosure as a matter of law? The first panel decision chose the former; the second chose the latter, creating a split within the Federal Circuit and serious tension with a decision of this Court. *See* Stay Appl. 20-

25. HEC's arguments as to why this question is not worthy of this Court's review are unconvincing.

First, HEC is wrong that the decision below raises no question of law simply because the majority and the dissent both recited the *Ariad* standard. *See* Opp. 15-17. Although the majority recited that standard, it *also* held that a limitation must "necessarily be present in a disclosure" to be disclosed, App. A, at 12, or, for a negative limitation, "necessarily excluded," App. A, at 7. The majority also held that implicit disclosure is not sufficient. App. A, at 6 n.2. In dissent, Judge Linn criticized the majority for reciting the correct standard, but then "appl[ying] a heightened written description standard to the facts of this case in requiring … a showing that the negative limitation in question was 'necessarily excluded.'" App. A (Dissent), at 2. He would have held that "implicit written description" is sufficient, as the original panel did. App. A (Dissent), at 6-7.[1] The disagreement between the majority and dissent is clear, and it regards the law, not the facts. That is the point of Judge Linn's reference to the majority's having "applie[d] a heightened written description standard to the facts of this case," *see* App. A (Dissent), at 2; Opp. 16 n.6, which HEC misreads—the debate is about the "heightened standard," not its application.

Second, HEC argues that there is no real conflict with this Court's precedent. Opp. 17. But the Court's limited case law on the issue of implicit disclosure reflects the fact that this Court has never endorsed a "possession" requirement *at all*. What

[1] HEC is therefore wrong (Opp. 19) that the question whether implicit disclosure is permitted was not "passed upon below." The majority rejected implicit disclosure, and the dissent embraced implicit disclosure.

little it has said, though, indicates that Novartis's written description was more than adequate. Novartis amended its claims during prosecution merely to make "explicit what was already implicit" in the specification—precisely what this Court held in *Marconi Wireless Tel. Co. of Am. v. United States*, 320 U.S. 1, 34 (1943), was allowed. HEC argues that *Marconi* is entirely consistent with the decision below because "[t]he point" of both decisions is that it is sufficient "merely to describe the invention in enough detail to notify the public and show you actually invented it." Opp. 18. But the decision below requires far more than that. It requires that all limitations either be expressly stated or be "necessarily" present in the specification—even if a skilled artisan would have no trouble discerning the invention, fully satisfying any public-notice or disclosure obligation. And it is there that the decision splits with *Marconi*.

Third, HEC argues (Opp. 18 n.7) that the panel's decision in this case implicates no policy concerns, because patentees can amend their specifications whenever they want to make their claims more explicit. That is no response at all. As HEC acknowledges elsewhere (*e.g.*, Opp. 7), amending the specification means losing the original priority date—potentially letting a later inventor's work invalidate the patent. Amending the patent claims during prosecution is entirely routine; HEC's suggestion that to do so should mean sacrificing the priority date "would let form triumph over substance, substantially eliminating the right of an applicant to retreat to an otherwise patentable species merely because he erroneously thought he was first with the genus when he filed." *In re Wertheim*, 541 F.2d 257, 263 (C.C.P.A. 1976). As *amici* explained below, the process of amending the claims attached to a

single specification is an especially important tool in the pharmaceutical and biotechnology industries, where inventions "often can address an array of diseases through the same mechanism of action." 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 6. HEC's standard—and the standard the panel majority applied below—would require the original application for every drug patent "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 in the art," or risk losing the priority date entirely. *Ibid.* Novartis raised this point in its application (at 23), and yet HEC has no answer.[2]

Fourth, HEC's various vehicle objections (Opp. 18-19) are make-weights. Given the unusual procedural history of this case, the legal issue could not be more obviously outcome-determinative. The original panel applied the *Ariad* standard, allowing for implicit disclosure, and it held for Novartis. The reconfigured panel rejected implicit disclosure and required express or "necessary" disclosure, and it held for HEC. Different rule, different outcome.

There also is no question of waiver. *See* Opp. 18-19. Novartis argued in its merits brief before the Federal Circuit that "the law does not require the disclosure

[2] HEC claims with no citation that Novartis is trying to "back-date" a material change in its invention to "claim a monopoly over something they did not discover until years later." Opp. 18 n.7. But Novartis *did* discover the invention as of the priority date, and described it in the specification then, as the district court and two judges of the Federal Circuit held.

to be inherent or necessary: The written description requirement may equally be satisfied by implicit disclosure." Novartis C.A. Br. 50. And it further argued that this standard was satisfied here, because the specification's description of a daily dose coupled with its silence regarding a loading dose would have disclosed to a person of skill that loading doses are excluded from the invention. *See id.* at 43-44 ("starting with a daily dose plainly implies that there is no loading dose"); *see also* Novartis Resp. to HEC Pet. for Reh'g 1 ("a person of skill would read this specification as *not* silent"). The original panel opinion affirmed the relevant factual findings, refuting HEC's suggestion that Novartis mounted no defense on appeal.

HEC finally argues (Opp. 19) that this Court should let the erroneous rule percolate. But the Federal Circuit has reversed its own precedential decision and adopted the opposite legal rule, which is now binding on future panels, in the sole court with appellate jurisdiction over patent cases. Four Federal Circuit judges have already weighed in and have split 2-2, resulting in two decisions with two opposite outcomes. The time for review is now.

2. There is a fair prospect of reversal.

If this Court grants certiorari, Novartis is likely to prevail, because Novartis's position that implicit disclosure to a skilled artisan is permissible is well grounded in the text of the statute, the precedent of this Court, and the procedure that the Patent Office uses to examine patents for written description. *See* Stay Appl. 25-26. HEC does not defend the Federal Circuit's legal rule *at all*. Perhaps most notably, HEC completely ignores the Patent Office's express understanding that a patent *can* satisfy written description using precisely the type of "implicit[]" disclosure to a

skilled artisan that the Federal Circuit rejected as categorically insufficient—a view on which patent applicants have long relied. Stay Appl. 22. Rather than defend the Federal Circuit's rule, HEC argues only that Novartis would "lose under [the] rule" it advocates. Opp. 20-22. That is doubly wrong.

First, HEC relies on a skewed version of the facts to argue that Novartis cannot ultimately succeed under a legal standard permitting implicit disclosure (presumably on remand to the Federal Circuit). But every judge that has applied that standard to the facts of this case has held for Novartis already, and for good reason; Novartis's evidence on the issue was entirely unrebutted. *See* Stay Appl. 25. HEC's contrary claim—that "there is no credible evidence in this record" that a skilled artisan would have understood Novartis's invention to exclude a loading dose, Opp. 21-22—simply assumes away the testimony about how skilled artisans would read the disclosure. The second panel majority held otherwise only by jettisoning the clear-error standard and replacing the district court's factfinding with its own legal judgment, which is impermissible. *See* Stay Appl. 26.

HEC's backup argument, that Novartis is somehow estopped from defending the adequacy of the specification just because it amended its claim during prosecution (Opp. 22), is meritless. As the dissent below correctly explained, "Novartis, in adding the no-load limitation[,] was doing no more than what applicants regularly do to secure allowance in making explicit that which was implicit prior to the amendment. There is no basis to read more into the prosecution history …." App. A (Dissent), at 9. Even if the patent examiner had not asked Novartis to amend its

claims to make the point explicit, Novartis may well have successfully argued for a claim construction that excluded a loading dose.[3]

Second, HEC's argument is irrelevant in any event, because for the purposes of a stay *pending certiorari* Novartis need not show more than that it will prevail in this Court on the question presented. *See Conkright v. Frommert*, 556 U.S. 1401, 1402 (2009) (Ginsburg, J., in chambers) (requiring "a fair prospect that a majority of th[is] Court will conclude that the decision below was erroneous"). The Circuit Justice need not *also* predict how a panel of circuit judges might later decide the case once the case is remanded for reconsideration under the correct standard. *See John Doe Agency v. John Doe Corp.*, 488 U.S. 1306, 1308 (1989) (Marshall, J., in chambers) (stating that a Circuit Justice must attempt to predict "the final outcome of the case *in this Court*") (emphasis added); *see also Nat'l Farmers Union Ins. Co. v. Crow Tribe of Indians*, 468 U.S. 1315, 1315-16, 1321 (1984) (Rehnquist, J., in chambers) (granting a stay based in part on the "reasonable probability for at least partial success on the merits" of a justiciability issue, while expressing "no opinion" about whether, if this Court reversed the court of appeals' holding of nonjusticiability, "applicants would necessarily prevail" on the merits). Novartis has amply shown that the Federal Circuit's legal rule is wrong.

[3] Patent examiners read claims more broadly than a court would, precisely because claims can be clarified during prosecution to resolve ambiguities. *Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 280-81 (2016).

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

HEC cannot just wipe the slate clean on irreparable harm: The district court already found, after reviewing a "voluminous record" and conducting an in-person hearing, that Novartis would suffer irreparable harm from a generic launch. Among other things, Novartis would suffer significant monetary losses through price erosion and market contraction that it could not recoup through a subsequent damages award. App. D, at 1, 7-9. The determination that a patentee cannot adequately "protect[] [its] right to *exclude* through monetary remedies" generally lies "within the equitable discretion of the district court[]," and it is entitled to considerable weight on appeal. *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 394-95 (2006) (Roberts, C.J., concurring).

HEC disputes neither that "irreversible harm" includes a monetary loss that "cannot be recouped," *Philip Morris USA Inc. v. Scott*, 561 U.S. 1301, 1304 (2010) (Scalia, J., in chambers), nor that the district court found that generic launch would lead to such irreparable harms based on the specific details of the RRMS market generally and the fingolimod market in particular. Yet HEC asks the Court to completely ignore the district court's findings simply because they are from "well over three years ago." Opp. 23. Time alone, however, does not make Novartis's harm from generic launch any less irreparable. Novartis's expert from the district court has updated his evidence to address present-day conditions; HEC, by contrast, never explains *why* Novartis would have suffered irreparable harm from generic launch three years ago, but would suffer no such harm today. That is because there is no

possible explanation. Indeed, if anything the case for irreparable harm is stronger today. While Novartis faced the prospect that "up to six generics" would launch three years ago, App. D, at 7, there are now at least *twelve* generics poised to launch immediately, with many more likely to follow in short order.[4] There are also an increasing number of RRMS therapies, further complicating any attempt to calculate Novartis's lost-profit damages. App. H, ¶¶ 36, 39-40, 51.

HEC's only attempt to explain why the district court's findings are no longer valid is its repeated emphasis on the fact that [redacted] Absent a stay, HEC and the other generics could launch *immediately*, which would still lead to precisely the irreparable harm from price erosion and market contraction on which the district court's findings depended.

Take market contraction, as to which HEC offers no response. The district court found that generic launch would irreparably harm Novartis by driving some Gilenya patients to one of the increasingly large number of other RRMS therapies, shrinking the fingolimod market in irreversible ways. App. D, at 7; *see also* App. H, ¶¶ 44-48. Novartis's patient-support efforts have expanded the fingolimod market by easing new patients' transition to (or resumption of) that therapy. Patients taking

[4] Indeed, one generic company has asserted a right to launch without awaiting the mandate. The district court is receiving briefing on that dispute. No. 1:18-cv-01043-KAJ, ECF No. 820 (D. Del. filed Oct. 5, 2022).

generics will face the same first-dose observation requirements. And without those patient-support efforts—which HEC does not claim it or other generics will replace—patients will indisputably switch to other therapies.[5] HEC disputes neither that generic entry would shrink the fingolimod market nor that this market contraction could not be reversed if generics were subsequently ordered off the market. HEC's failure to contest these key facts is alone sufficient to establish irreparable harm.

As for price, the district court found that generic launch would lead to a "massive and immediate price erosion." App. D, at 7. Prices would not return to current levels even if this Court were to reverse, making calculating past damages during the period of infringement "difficult[]," and future damages from price erosion after the generics were forced to leave the market likely "impossible." *Id.* HEC addresses only the second point, claiming (at 23-26) that, [redacted] there would be no future damages because, "[redacted]." HEC ignores the difficulty the district court identified in even calculating *past* damages given the complexities of the fingolimod and RRMS markets.

Again, HEC is also simply wrong about the timing. If this Court were to grant and reverse in *Juno*—and hence set aside the decision in this case through GVR—it

[5] HEC's only attempt to address this issue is a footnote in which it suggests that patients themselves, or their insurers, will pay for the services that Novartis currently offers, including home visits by a physician to carry out first-dose observation. That completely unsupported suggestion is directly at odds with the district court's factual finding about market contraction.

would do so this Term [redacted] Even if the Court did not grant in *Juno*, a decision on the implicit-disclosure issue could come this Term so long as this Court granted Novartis's petition by January.[6] The district court's finding that Novartis could not reverse or recover the significant but lingering effects of price erosion applies fully to that significant period of time.[7]

HEC's discussion (Opp. 25-26) of Novartis's purported attempts to transition Gilenya patients to Kesimpta is just a distraction. Gilenya is a highly respected, important therapy for patients suffering from RRMS. Even accepting that Novartis is currently starting to plan for patients' shift away from fingolimod [redacted], that says nothing about whether Novartis will suffer irreparable harm if patients shift away from fingolimod after generic entry *now*. If generics enter now, and the fingolimod market contracts, Novartis will immediately lose customers to other RRMS therapies that, absent generic entry, Novartis could have retained [redacted]. Absent a stay, Novartis could not retain those customers even if this Court were to reverse the decision below in the spring of 2023. And

[6] If this Court were to grant a stay but not grant the *Juno* petition, Novartis would commit to filing its petition for a writ of certiorari by November 7, which should allow this Court to grant certiorari in time to set the case for argument this Term. (If the Court grants certiorari in *Juno*, the timing of Novartis's petition is likely to be immaterial.)

[7] For similar reasons, HEC's argument (at 28) that "a stay is just as good as a win on the merits for Novartis" is absurd. If this Court were to deny Novartis's petition, it would do so [redacted]. And as already explained, note 6, *supra*, Novartis would work to limit the duration of any stay by filing its petition in time to be heard this Term. If Novartis prevails, HEC would be unable to launch before 2027.

calculating the precise damages from that irreversible market contraction would be next to impossible.

HEC's table (Opp. 27-28) that purports to compare this case to *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 572 U.S. 1301 (2014) (Roberts, C.J., in chambers), simply ignores the significant differences between the two cases. The parties in *Teva* were writing on a clean slate in this Court—there were no district-court findings of irreparable harm. And the district court's findings in this case rested on specific facts that are materially different. In *Teva*, there were only two generic products at issue, neither of which could imminently launch because neither had FDA approval. Here, by contrast, a dozen generics could launch immediately, and twenty generics could launch before too long. HEC also identifies no facts in *Teva* analogous to the district court's findings in this case that generic launch would irreversibly contract the fingolimod market or that damages from price erosion would be difficult, if not impossible, to calculate. Ultimately, whether generic launch will lead to irreparable harm necessarily depends on the specific facts and market conditions in each case. HEC's table simply shows that Sandoz argued that damages would be an adequate remedy on the facts there; here the district court found that damages would *not* be adequate.

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

HEC does not even try to argue the balance of equities, recognizing that the immediate harm to Novartis far outweighs the potential harm to HEC. Instead, it asks the Court to deny a stay because the public will pay less for fingolimod after generic entry. But allowing infringing products onto the market will almost always

lead to lower prices. As the Framers recognized, patent protection "promote[s] the Progress of Science and useful Arts." U.S. Const., Art. I, § 8, cl. 8. Although a valid patent grants the patentee market exclusivity for a set period, that is a necessary tradeoff to "encourage innovation." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989). Courts thus impose injunctions "in the vast majority of patent cases"—even though those injunctions will always mean that consumers may have fewer options during the patent's term. *eBay*, 547 U.S. at 395 (Roberts, C.J., concurring). Indeed, the Federal Circuit has repeatedly held that the "significant public interest in encouraging investment in drug development and protecting the exclusionary rights conveyed in valid pharmaceutical patents" outweighs the public's interest in generic drugs, even where the need for a generic is particularly high. *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383-84 (Fed. Cir. 2006).

That is precisely the case here, despite HEC's attempt to gin up a contrary narrative that completely disregards the district court's findings of fact, including findings that HEC never even appealed (*e.g.*, Opp. 4-7). Novartis developed the first-ever solid oral therapy for multiple sclerosis. It did so at a lower dosage than experts had previously thought necessary. App. C, at 5, 19-22, 26.[8] That breakthrough therapy has helped countless RRMS patients. That is the interest patent protection

[8] *See also Apotex Inc. v. Novartis AG*, No. IPR2017-00854, 2018 WL 3414289, at *17 (P.T.A.B. July 11, 2018) (rejecting obviousness challenge to the '405 patent and finding that "one of ordinary skill in the art would have been dissuaded from administering 0.5 mg daily dosages of fingolimod for the treatment of RRMS"), *appeal dismissed*, 956 F.3d 1374 (Fed. Cir. 2020), *cert. denied*, 141 S. Ct. 1685 (2021).

serves: ensuring that innovative companies can recoup the investments they make in developing therapies like this.

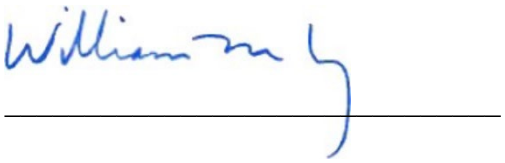
HEC's contrary public-interest argument rests on the assumption that *the patent is invalid*. HEC at times makes that assumption explicit. *E.g.*, Opp. 29 (arguing that a stay is inappropriate because payors are paying "monopoly pricing from an invalid patent"). And the two cases HEC cites (at 30) that found a public interest in generic competition are both cases in which the party seeking to keep the generic off the market had *not* shown a likelihood of success on the merits. *ViroPharma, Inc. v. Hamburg*, 898 F. Supp. 2d 1, 29 (D.D.C. 2012) (noting that "the public interest factor is inextricably linked with the merits of the case," and that the plaintiff was "not likely to establish that" the FDA erred in approving a generic application (quotation marks omitted)); *Biovail Corp. v. U.S. Food & Drug Admin.*, 448 F. Supp. 2d 154, 166 (D.D.C. 2006).

For the reasons discussed above, this Court is likely to hold that Novartis's patent is *not* invalid—as then-Chief Judge Stark, Circuit Judge Jordan, and the initial Federal Circuit panel all previously held. The public interest therefore supports Novartis, not HEC.

CONCLUSION

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.

Respectfully submitted,



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