No. 21-202

IN THE
Supreme Court of the United States

MYLAN LABORATORIES LTD.,

Petitioner,

v.

JANSSEN PHARMACEUTICA, N.V.,

and

ANDREW HIRSHFELD, Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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INTERESTS OF *AMICUS CURIAE*[1]

The Association for Accessible Medicines (AAM) is a nonprofit, voluntary association representing manufacturers and distributors of generic and biosimilar medicines and bulk active pharmaceutical chemicals, as well as suppliers of other goods and services to the generic pharmaceutical industry. AAM's members provide patients with access to safe and effective generic and biosimilar medicines at affordable prices. AAM's core mission is to improve the lives of patients by providing timely access to safe, effective, and affordable prescription medicines. Generic drugs constitute 90% of all prescriptions dispensed in the United States, yet generics account for only 20% of total drug spending. AAM regularly participates in litigation as *amicus curiae*.

AAM and its members have a significant interest in the questions presented and in the availability of the *inter partes* review (IPR) process. AAM's members depend on fair and prompt adjudication of patent claims that seek to block their efforts to bring lower-cost medicines to patients. The IPR process is thus essential to the work of AAM's members and to the patients who depend on generic and biosimilar medicines.

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[1] Pursuant to this Court's Rule 37.6, counsel for *amicus curiae* certifies that this brief was not authored in whole or in part by counsel for any party and that no person or entity other than *amicus curiae*, its members, or its counsel has made a monetary contribution intended to fund the preparation or submission of this brief. All parties received timely notice of and have consented to the filing of this brief.

INTRODUCTION AND SUMMARY OF ARGUMENT

Inter partes review (IPR) is an essential tool for quickly and efficiently eliminating invalid patents. Perhaps no one benefits more from IPR than the patients who depend on generic and biosimilar medications. Branded drug manufacturers often seek to extend their monopolies by filing multiple additional patent applications intended to keep affordable generic and biosimilar medicines off the market. AAM's members rely on IPR to root out those invalid, non-innovative drug patents and permit patients to access safe and less expensive generic and biosimilar medicines without undue delay. Thanks to successful IPR proceedings, generic and biosimilar alternatives used to treat diseases such as Alzheimer's, Parkinson's, and prostate cancer have reached the market far more quickly than they otherwise would have through litigation. *See, e.g.*, *Sanofi-Avenis U.S. LLC v. Mylan GmbH*, No. 17-cv-9105, 2020 WL 1151191, at *32, *38 (D.N.J. Mar. 9, 2020), appeal docketed, No. 21-1262 (Fed. Cir. Nov. 19, 2020).

The IPR process Congress adopted allows the Patent and Trademark Office (PTO) to address and eliminate invalid patents in a prompt and efficient manner. Yet the IPR system has been weakened by a series of rules adopted by the Patent Trial and Appeal Board ("Board") that make the IPR process more difficult than what Congress intended. This Court has already invalidated some of those rules in prior decisions. *See, e.g.*, *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348 (2018).

This petition presents the validity of another rule, the *NHK-Fintiv* Rule (or "Rule"), that has been detrimental to the IPR process, and, in particular, to IPRs brought by generic and biosimilar manufacturers. As Mylan has explained, the *NHK-Fintiv* Rule directs the Board to assess the progress of any parallel patent infringement litigation and deny institution of an otherwise timely-filed IPR if the Board deems litigation the more efficient route for resolving the validity of the patent claims.

The Rule plainly exceeds the Board's authority. Congress's express judgment was to permit IPR petitions notwithstanding parallel litigation so long as the petition for IPR is filed within one year of a complaint alleging infringement. *See* 35 U.S.C. § 315(b). The Rule supersedes that judgment by imposing timing limitations that Congress did not adopt. The result is a through-the-looking-glass world in which the Board refuses to institute proceedings that meet the criteria for institution that Congress *did* impose — a petition raising a claim of invalidity that is likely to succeed and filed within a year of the initiation of litigation — based on criteria that Congress *did not* impose. The Federal Circuit nonetheless held that decisions based on the Rule are unreviewable. But this Court's precedents have carefully and consistently explained that an institution decision is not shielded from review where the Board exceeds its statutory authority.

Indeed, any other conclusion would be absurd. Consider if the Director adopted a per se rule requiring the denial of any petition where an infringement action

concerning the same patent had been filed. Such a rule would obviously violate § 315(b), which expressly envisions that petitions may be filed up to one year after the filing of an infringement action. Yet under the Federal Circuit's logic, the decision would be unreviewable, no matter how obviously the rule exceeded the Director's statutory authority. That cannot be the law. The Court should grant review to reaffirm that the Board is not free to impose hurdles on IPR that Congress rejected.

Review is particularly critical here because the Rule is especially problematic in the context of IPRs brought by generic and biosimilar manufacturers. As explained below, specific facets of pharmaceutical IPRs and litigation mean that the Rule will frequently bar IPR petitions by generic and biosimilar manufacturers. Branded manufacturers routinely seek to extend their monopoly power by obtaining numerous patents—sometimes amounting to hundreds of patents for a single brand-name drug. These so-called patent estates make it difficult for a generic or biosimilar manufacturer to file an IPR until the branded manufacturer has sued for infringement and identified the patents and specific claims it actually intends to assert. While waiting to bring the IPR results in a far more efficient presentation of the issues, because the IPR is limited to the patents and claims that really matter, the Rule treats the fact that the IPR trails the litigation as a reason to deny the petition. In other words, the Rule rewards the patent holder for obtaining numerous invalid patents when the very purpose of IPR is to provide an efficient method for invalidating those patents.

Worse still, multiple generic manufacturers will often file abbreviated new drug applications (ANDAs) referencing the same branded drug at different times. If the Board dismisses IPR petitions based on litigation between *other* parties—as it did here—late-filing drug manufacturers could find themselves with *no* legal recourse. And without IPR to efficiently winnow down the potentially dozens of patents at issue in these lawsuits, branded drug manufacturers will have little incentive to settle these cases.

These and other features typical of Hatch-Waxman litigation make the Rule a death knell for IPR for generic and biosimilar manufacturers. And the ultimate loser under the Rule is the American public, who will be denied access to low-cost generic and biosimilar medicines in situations where, by definition, there is reason to think they are being blocked by an invalid patent.

This Court should reject the Federal Circuit's abdication of appellate review and reaffirm that, consistent with the strong presumption of judicial review of agency action, a forum remains to challenge extra-statutory actions by the Board in denying IPR institution.

ARGUMENT

I. *Inter Partes* Review Is Essential for Enabling Patient Access to Affordable Generic and Biosimilar Medicines.

Amicus—and the public—have an interest in ensuring that only valid patents are granted. No one—except an illegitimate patent-holder—benefits from the monopoly power that patents afford. Unfortunately, the PTO frequently issues patents that never should have been granted. *See* Michael D. Frakes & Melissa F. Wasserman, *Does the U.S. Patent and Trademark Office Grant Too Many Bad Patents?: Evidence from a Quasi-Experiment*, 67 Stan. L. Rev. 613, 615, 676 (2015) (describing consensus that PTO issues "too many invalid patents" and concluding that PTO "is in fact biased toward granting patents"). A recent study found that federal courts reviewing patent challenges hold the patent invalid 43% of the time. John R. Allison et al., *Understanding the Realities of Modern Patent Litigation*, 92 Tex. L. Rev. 1769, 1801 (2014).

Congress recognized this over-patenting reality in the America Invents Act (AIA) in 2011. The AIA overhauled the IPR process, concluding that existing mechanisms for reexamining patents were "too lengthy and unwieldy" to serve their stated goals, 157 Cong. Rec. 12992 (2011) (statement of Sen. Leahy), and that "questionable patents are too easily obtained and are too difficult to challenge," H.R. Rep. No. 112-98, pt. 1, at 39 (2011), *as reprinted in* 2011 U.S.C.C.A.N. 67, 69. As then-Senator Sessions explained, the goal of the AIA was to "allow invalid patents that were mistakenly

issued by the PTO to be fixed early in their life, before they disrupt an entire industry or result in expensive litigation." 157 Cong. Rec. at 3375 (2011) (statement of Sen. Sessions); *see also id.* at 2844 (statement of Sen. Klobuchar) ("The legislation also provides a modernized, streamlined mechanism for third parties who want to challenge recently issued, low-quality patents that should never have been issued in the first place.").

IPR has been particularly important for ensuring that generic and biosimilar medications are not blocked by invalid patents. The public benefits greatly from access to lower-cost generic and biosimilar medicines. Generics account for 90% of prescriptions dispensed in the United States, but only 20% of total drug costs. Ass'n for Accessible Meds., *Securing Our Access & Savings: 2020 Generic Drug & Biosimilars Access & Savings in the U.S. Report* 16 (2020), https://accessiblemeds.org/sites/default/files/2020-09/AAM-2020-Generics-Biosimilars-Access-Savings-Report-US-Web.pdf. In total, generic medicines generated $313 billion in savings for the American healthcare system in 2019, and $2.2 trillion in savings over the last decade. *Id.* at 16, 18. In 2019 alone, generic medicines saved the Medicaid system $48.5 billion and the Medicare system $96 billion. *Id.* at 17.

Yet generic and biosimilar medicines are frequently blocked by invalid patent claims held by branded drug manufacturers. *See, e.g., BTG Int'l Ltd. v. Amneal Pharms. LLC*, 923 F.3d 1063, 1066-67 (Fed. Cir. 2019) (finding Zytiga patent invalid); *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 518 F.3d 1353, 1356 (Fed. Cir. 2008)

(finding Celebrex patent invalid); *Sanofi-Avenis*, 2020 WL 1151191, at *1 (finding insulin patent invalid). While the generic and biosimilar manufacturers were ultimately successful, the months spent litigating the patents constituted time in which affordable, life-saving generic and biosimilars were not available to patients.

Brand-name drug companies also use dubious patents to continually delay the entry of more affordable biosimilar medicines. Many medications have dozens of patents—and some even have over a hundred. *See, e.g.*, Susannah Luthi, *AbbVie Sued over Humira 'Patent Thicket,'* Modern Healthcare (Mar. 19, 2019), https://www.modernhealthcare.com/politics-policy/abbvie-sued-over-humira-patent-thicket (noting 136 patents on best-selling rheumatoid arthritis drug Humira, most filed within several years of the expiration of the original patent); *accord* Biosimilars Council, *Failure to Launch: Patent Abuse Blocks Access to Biosimilars for America's Patients* 8 (June 2019), https://www.biosimilarscouncil.org/wp-content/uploads/2019/06/Biosimilars-Council-White-Paper-Failure-to-Launch-June-2019.pdf (highlighting that, absent settlements, late-stage patents would have extended patent protection for Humira over 30 years after its approval).

By allowing speedier resolution of patent validity, *inter partes* review avoids unnecessary delays and furthers the Congressional goal of ensuring that the patent monopoly on brand-name medicines be of limited duration, thus bringing more affordable treatment options to patients sooner.

II. The Director's Extra-Statutory Non-Institution Decision Is, and Must Be, Reviewable.

In the proceedings below, Mylan filed a petition for IPR review challenging the validity of one of Janssen's patents. Although Mylan indisputably filed its petition within six months of being sued for infringement by Janssen—*i.e.*, well within the one-year deadline set by Congress in § 315—the Board denied the petition under the *NHK-Fintiv* Rule. In its order denying Mylan's petition, the Board cited not only the progress of the Mylan-Janssen infringement litigation, but also the progress of a suit brought by Janssen against another generic manufacturer, Teva, concerning the same patents. Mylan appealed the denial to the Federal Circuit, which dismissed on the ground that the determination was unreviewable.

The Federal Circuit's conclusion that a non-institution decision relying on the *NHK-Fintiv* Rule is unreviewable stacks legal error upon legal error. The Rule itself exceeds the Board's statutory authority, and nothing bars the Federal Circuit from addressing that error.

The Federal Circuit claimed that its hands were tied by § 314(d), which provides that "[t]he determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable." 35 U.S.C. § 314(d). But the only criterion for instituting review "under" § 314 is whether the Director determines "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the

claims challenged in the petition." *Id.* § 314(a). Moreover, Congress expressly set out when an IPR petition is untimely in the face of parallel infringement litigation: IPR "may not be instituted if the petition ... is filed more than 1 year after the date on which the petitioner … is served with" the infringement complaint. *Id.* § 315(b).

Against that statutory backdrop, this Court's precedents make clear that a challenge to the application of the Rule is not an unreviewable challenge to an institution determination under § 314, but a traditionally reviewable challenge contending that the Board has exceeded its statutory authority. As this Court explained in a recent decision addressing § 314(d), the provision "precludes judicial review only of the Director's initial determination under § 314(a) that 'there is a "reasonable likelihood" that the claims are unpatentable on the grounds asserted.'" *SAS*, 138 S. Ct. at 1359 (quoting *Cuozzo v. Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016)). Conversely, § 314(d) does not bar a challenge—like the challenge at issue here—contending that the Director has "exceeded his statutory authority" altogether. *Id.*; *see also Cuozzo v. Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2141-42 (2016) (holding that § 314(d) does not foreclose review of agency actions that were "contrary to constitutional right, in excess of statutory jurisdiction, or arbitrary and capricious" (quotation marks and alteration omitted)).

Thus, in *SAS*, this Court reversed the Federal Circuit's determination that there could be no judicial review of the Director's decision to institute an IPR for

some, but not all, of the claims presented in a petition. The Court explained that Congress had expressly required the Director to issue a written decision for "any patent claim challenged by the petitioner," so long as the Director determined that "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." *SAS*, 138 S. Ct. at 1353-54 (quotation marks omitted). The Director was not free to ignore the statutory constraints on his institution decisions, and his failure to stay within his statutory authority was reviewable. *Id.* at 1359.

A challenge contending the *NHK-Fintiv* Rule exceeds the Director's authority is therefore reviewable for the same reasons. Any other conclusion would be irreconcilable with the text and structure of the relevant IPR provisions, with this Court's precedent, and with common sense. Indeed, following Janssen's logic, the PTAB could deny institution of any petition based on parallel litigation—even a petition filed one day after litigation commenced—and the petitioner would have no recourse whatsoever. This is clearly not what is contemplated in the AIA.

III. The Rule Is Particularly Harmful in the Context of Pharmaceutical Infringement Litigation.

The question presented has particular importance to AAM and patients because the Rule is especially harmful to IPRs brought by generic and biosimilar manufacturers.

First, as a general matter, the sheer number of patents and claims (however unwarranted) that branded manufacturers obtain to maintain monopoly power over a given drug make it highly inefficient to file an IPR petition before infringement litigation has begun. This fact alone weighs against allowing an IPR to proceed under the Rule. For biosimilar drugs in particular, there are often dozens of patents that could potentially be asserted for any one drug. Given that each patent requires its own IPR petition, filing dozens of petitions to address every potential patent that could be asserted from these patent "thickets" is expensive and wasteful. Biosimilar manufacturers accordingly may choose to wait until the branded manufacturer brings suit and identifies which patents and claims it actually will assert; those patents and claims in dispute then become the subject of the IPRs. And because IPRs in pharmaceutical cases tend to be complex and involve multiple patents, it is not uncommon for the generic or biosimilar manufacturer to need 5 or 6 months to prepare the petition after the infringement suit is filed.

This process results in an IPR petition that is properly focused on the patents and claims that really matter, saving the parties and the Board effort and time. But under the Rule, that pragmatic and cost-effective

practice is penalized, as the *NHK-Fintiv* factors counsel against granting the petition. The Rule instead pressures generic and biosimilar manufacturers to petition for IPR *before* litigation commences, or at the very latest immediately thereafter. These manufacturers would therefore need to invest in preparing complicated and lengthy IPRs before knowing the relevant patents, potentially wasting both the manufacturers' time and the Board's energies. A Rule that *rewards* litigants for obtaining numerous invalid patents as part of the very process that is supposed to weed out those patents should not be allowed to stand.

Second, other features of pharmaceutical litigation also cause the Rule to weigh heavily against granting IPR petitions. A generic manufacturer seeking to enter the market must first file a marketing application which makes a certification regarding brand-name patents claiming the brand-name drug. *See, e.g.*, 21 U.S.C. § 355(j). Litigation generally follows within 45 days thereafter. 35 U.S.C. § 271(e)(2)(A). Upon suit by the patent-holder, federal law immediately imposes a 30-month stay on the generic drug's approval to allow any infringement issues to be resolved.

Litigation schedules are often structured to conclude within that 30-month period, to avoid the need for further injunctive relief. Courts generally strive to conduct trial around the 24th month of the stay, to enable them to render a judgment in time. Conversely, under the IPR rules, a party has 12 months from being sued for infringement to file the petition, and the Board has 18 months to resolve it. 35 U.S.C. §§ 315(b), 316(a)(11). It is thus typical for a trial date to be set

ahead of the Board's projected statutory deadline for a final written decision (24 months in the district court, compared to the 30 months for the IPR decision). The Rule's concern with relative dates of resolution will thus by definition weigh in favor of dismissal of almost all ANDA cases.

Moreover, many courts are reluctant to stay proceedings before IPR has been granted because of the 30-month stay on FDA approval. *See, e.g.*, Order at 1, *Allergan Inc. v. Deva Holding A.S.*, No. 16-CV-01447 (E.D. Tex. July 28, 2017), ECF No. 31 ("[B]ecause this is an ANDA lawsuit, a stay could postpone district court proceedings until after the expiration of the 30-month regulatory stay. While this is not necessarily unduly prejudicial to Allergan in light of the nature and purpose of the 30-month stay, postponing the district court action could require costly preliminary injunction proceedings, wasting both the Court's and the parties' resources."); Order at 2 n.3, *AstraZeneca AB v. Aurobindo Pharma Ltd.*, No. 14-cv-664 (D. Del. Aug. 23, 2016), ECF No. 346 (denying stay pending IPR, in part, because "the 30-month stay of FDA approval will expire for most defendants' ANDAs before [the statutory deadline]"). The likelihood of a stay, which is the first factor in the *NHK-Fintiv* analysis, will therefore also weigh against instituting IPR in many pharmaceutical cases. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, 2020 WL 2126495, at *2 (PTAB Mar. 20, 2020).

Congress did not create a Hatch-Waxman exception to the IPR regime, yet the Rule effectively treats Hatch-Waxman litigation as superseding the IPR process. In

so doing, the Rule exceeds the Director's statutory authority.

Third, all of these issues are exacerbated by the fact that a generic manufacturer's IPR may be dismissed under the Rule due to litigation between *another* generic manufacturer and the branded manufacturer. The Board's decision below shows that in applying the Rule, the Board will look to the progress of *other* litigation involving the same patents, even if different grounds for invalidity are presented. *See* Mylan Pet. App. 25a-41a. Below, Mylan's petition was denied under the Rule in large part due to the status of Teva's litigation with Janssen concerning the same patents. This will be a persistent problem for generic and biosimilar manufacturers, where multiple manufacturers may challenge the same patents but may file their ANDAs at different times.

Those who file ANDAs later will be prejudiced by application of the Rule. First, these second-filers will almost always be unable to avail themselves of IPR, where they can put on their best case. Instead, thanks to an earlier trial date for a different ANDA filer, the Board will apply the Rule and deny institution. The second-filer will therefore be forced to wait and see the outcome of an unrelated proceeding with an unrelated infringement defendant. Depending on the patents at issue in that parallel litigation, the first-filer may not have an incentive to litigate the patents relevant to the second-filer as vigorously as the second-filer itself would. Because that second-filer cannot exert influence over the trial strategy of the other defendants, that filer

may end up wholly without a remedy if the first-filer does not succeed.

Moreover, the second-filer deprived of IPR and forced to wait months for the first-filer to go to trial will often see the parties settle without judgment on the merits. At best, then, the second-filer will file an IPR months later than it otherwise would have; at worst, the one-year statutory period may have run, leaving the second-filer with no recourse. This shows not only the harm to the second-filer, but also the senselessness of applying the Rule in this context—if there were *any* justification for declining to institute IPR here, it would be because a judgment on the merits was forthcoming. But these cases often conclude *without* a judgment on the merits, as this case itself illustrates. IPR therefore remains a useful and necessary tool for resolving the validity of these patents.

Fourth, particularly in biosimilar litigation where there is no statutory 30-month stay, trial dates can be uncertain and are subject to change. Although a trial may be scheduled for a date that would cause the Board to apply the Rule and dismiss the IPR, the trial may not actually proceed as scheduled. The complexity of these cases, and the possibility of additional patents being asserted throughout the litigation, means that the trial and ultimate resolution of the litigation may in reality occur much later than a decision would have been made in the IPR. The Rule therefore invites gamesmanship in these complex biosimilar cases. The patentee could push for an early trial date to ensure an IPR is dismissed under the Rule and then turn around and add additional

patents to the case to argue for a delay in trial, and therefore in the biosimilar drug's being brought to market.

Fifth, and finally, by making the IPR process more difficult, the Rule weakens a major tool for obtaining settlements. The availability of IPR to winnow down patent "thickets" and streamline the issues for resolution gives generic and biosimilar manufacturers a powerful tool against branded manufacturers, which can in turn drive settlement agreements. Settlements are good not only for the manufacturers, but also for patients. Drug prices would skyrocket if every infringement case went to trial. Patent settlements, and therefore IPR, are vital to the health of the American healthcare system. The quick and predictable timeline and the specialized bench of patent practitioners make IPR a crucial tool in the patent litigation process. They supplement, rather than duplicate, district court litigation, and they facilitate settlement of that litigation. The *NHK-Fintiv* Rule, however, puts a heavy thumb on the scale in favor of litigation, therefore harming consumers who rely on generics and biosimilars for affordable care.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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