

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 Intel-
lectual 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

REPLY BRIEF FOR PETITIONER

DEEPRO R. MUKERJEE
LANCE A. SODERSTROM
KATTEN MUCHIN
ROSENMAN LLP
575 Madison Avenue
New York, NY 10022

ROBERT T. SMITH
Counsel of Record
ERIC T. WERLINGER
RAJESH R. SRINIVASAN
ANDREW J. PECORARO
KATTEN MUCHIN
ROSENMAN LLP
2900 K Street, NW
Washington, DC 20007
robert.smith1@katten.com
202-625-3500

Counsel for Petitioner

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REPLY ARGUMENT

Respondents do not dispute that Mylan's appeal falls within the plain language of 28 U.S.C. § 1295(a)(4)(A). The denial of Mylan's request for institution was unquestionably a "decision" of "the Patent Trial and Appeal Board of the United States Patent and Trademark Office with respect to . . . inter partes review" (IPR). 28 U.S.C. § 1295(a)(4)(A).

Instead, Respondents argue that, in addition to § 1295's clear grant of appellate jurisdiction, the Patent Act must also provide Mylan with explicit authorization to appeal. U.S. Br. 11, 13-14; Janssen Br. 12-13. And, they argue, even if Mylan had such authorization, its appeal is barred by 35 U.S.C. § 314(d). U.S. Br. 15-19; Janssen Br. 8-9.

Neither argument is correct. Section 1295 confers a complete right to appeal adverse decisions of the Board. And, in any event, this Court held in *SAS* that the Administrative Procedure Act (APA) authorizes an aggrieved party to seek review of a decision where the Board "engage[s] in "shenanigans" by exceeding its statutory bounds." *SAS Inst. Inc. v. Iancu*, 138 S.Ct. 1348, 1359 (2018). Importantly, *SAS* makes clear that § 314(d) is no impediment to judicial review because it "does not 'enable the agency to act outside its statutory limits.'" *Id.* (quoting *Cuozzo Speed Techs., LLC v. Lee*, 136 S.Ct. 2131, 2141 (2016)).

There is no question the Director and the Board exceeded statutory bounds here. Through the America Invents Act (AIA), Congress commanded the Director to promulgate regulations "setting forth the standards for the showing of sufficient grounds to

institute a review under section 314(a),” 35 U.S.C. § 316(a)(2), and governing “the relationship of such review to other proceedings under this title,” *id.* § 316(a)(4). But, instead of doing so, the Director designated two decisions of the Board as precedential: *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, 2020 WL 2126495 (P.T.A.B. Mar. 20, 2020); and *NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, 2018 WL 4373643 (P.T.A.B. Sept. 12, 2018). Those decisions reflect policy judgments that clash with Congress’s deliberate structuring of the IPR process. *NHK-Fintiv* focuses on parallel litigation and relegates the merits of an IPR petition to one catch-all factor of a six-part test. The AIA, in contrast, contemplates parallel litigation and still prioritizes IPR where “there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a).

The Board never determined whether Mylan is reasonably likely to prevail on the merits. It dismissed Mylan’s timely IPR petition based *solely* on the existence of parallel litigation, which the Board deemed dispositive under *NHK-Fintiv*. Pet.App.42a-43a.

Respondents offer various arguments why *SAS* does not govern, but they are mistaken. More to the point, the debate over *SAS*’s application only underscores the need for this Court’s review—particularly where, as here, the importance of the issues presented is unquestioned. The petition for a writ of certiorari should be granted.

I. The Decision Below Conflicts with this Court’s Decision in SAS.

A. Both § 1295 and the Administrative Procedure Act Provide the Appeal Right that Respondents Claim is Missing Here.

Respondents argue that, through the Patent Act, Congress split the atom of appellate jurisdiction: The Federal Circuit was endowed with “exclusive jurisdiction” under 28 U.S.C. § 1295 but only of those appeals “separately authorized by the Patent Act.” U.S. Br. 13; *see* Janssen Br. 12-13.

But the Patent Act does not support this dichotomy. If the government were correct, then litigants would not be able to appeal district court decisions in infringement actions. Outside of § 1295(a)(1), no provision of the Patent Act authorizes those appeals. Similarly, outside of § 1295(a)(4)(C), no statute provides a right to appeal from district court proceedings under 35 U.S.C. §§ 145, 146, or 154(b). Yet the validity of these appeals is unquestioned. *E.g.*, *Traxcell Techs., LLC v. Sprint Commc’ns Co.*, 15 F.4th 1121, 1127 (Fed. Cir. 2021) (infringement appeal); *Chudik v. Hirshfeld*, 987 F.3d 1033, 1038-39 (Fed. Cir. 2021) (§ 154(b) appeal); *Troy v. Samson Mfg. Corp.*, 758 F.3d 1322, 1324 (Fed. Cir. 2014) (§ 146 appeal); *Mazzari v. Rogan*, 323 F.3d 1000, 1003 (Fed. Cir. 2003) (§ 145 appeal).

In any event, even if separate authorization were required, the APA provides it. As this Court recognized in *SAS*, “[i]f a party believes the Patent Office has engaged in “shenanigans” by exceeding its statutory bounds, judicial review remains available consistent with the [APA].” 138 S.Ct. at 1359; *see also*

Arthrex, Inc. v. Smith & Nephew, Inc., 880 F.3d 1345, 1348-49 (Fed. Cir. 2018) (concluding that the combination of § 1295(a)(4)(A) and the APA provides a right to appeal even where the Board failed to issue a “final written decision” under 35 U.S.C. § 319).¹

The Federal Circuit plainly had jurisdiction here. Section 1295(a)(4)(A) conferred upon Mylan a stand-alone right to appeal, and the APA confirms Mylan’s right to seek judicial review of the Board’s denial of IPR where, as here, the Board exceeded its statutory bounds. *SAS*, 138 S.Ct. at 1359.

B. SAS Rejected Respondents’ Construction of § 314(d), and that Decision is Not Distinguishable.

As a fallback, Respondents argue that § 314(d) stripped the Federal Circuit of whatever jurisdiction that § 1295(a)(4)(A) confers. But to reach this result, Respondents would read *SAS* out of existence.

In *SAS*, this Court held that, where the Board “exceeded [its] statutory authority” under the AIA,

¹ Respondents attempt to distinguish *Arthrex* because it did not address § 314(d)’s appeal bar. U.S. Br. 14-15; Janssen Br. 20 n.2. But there is no question *Arthrex* is one side of an intra-circuit dispute on Respondents’ *antecedent* claim—that, in addition to § 1295(a)(4)(A), the Patent Act must separately authorize an appeal. *See* Pet. 30-31. Whereas *Arthrex* held, consistent with *SAS*, that § 1295(a)(4)(A) and the APA combine to provide a right to appeal even where the Board fails to issue a “final written decision” under § 319, 880 F.3d at 1349, other panels have held that the Patent Act must separately authorize all appeals from the Board. *See* U.S. Br. 13 (citing *GTNX, Inc. v. INTTRA, Inc.*, 789 F.3d 1309, 1312 (Fed. Cir. 2015); *St. Jude Med., Cardiology Div., Inc. v. Volcano Corp.*, 749 F.3d 1373, 1376 (Fed. Cir. 2014)).

“nothing in § 314(d) . . . withdraws” a court’s “power to ensure that an inter partes review proceeds in accordance with the law’s demands.” 138 S.Ct. at 1359. The Court reached this result, in part, because § 314(d)’s appeal bar is limited to a “determination by the [Board] whether to institute an inter partes review under this section”—namely, under § 314. *Id.* (quoting 35 U.S.C. § 314(d)). Given the strong presumption in favor of judicial review and the statute’s text, the Court “concluded that § 314(d) precludes judicial review only of the [Board’s] ‘initial determination’ under § 314(a) that ‘there is a “reasonable likelihood” that the claims are unpatentable on the grounds asserted’ and review is therefore justified.” *Id.* (quoting *Cuozzo*, 136 S.Ct. at 2140).

Based on that reading of § 314(d), the Court saw no impediment to reviewing the Board’s refusal to institute IPR on all claims challenged by SAS. *Id.* SAS contended that the Board “exceeded [its] statutory authority by limiting the review to fewer than all of the claims SAS challenged.” *Id.* In contrast, Congress commanded the Board: “[i]f an inter partes review is instituted and not dismissed under this chapter, the [Board] *shall issue* a final written decision with respect to the patentability of *any patent claim challenged by the petitioner.*” *Id.* at 1354 (quoting 35 U.S.C. § 318(a)). Thus, § 314(d) did not preclude the Court from reviewing the Board’s “‘partial institution’ practice.” *Id.* at 1359.

Reading the decision differently, Respondents argue that the Court was “exercising the authority to review [a] final written decision[]” under § 319. U.S. Br. 18; Janssen Br. 13, 15. But that reading makes no sense procedurally or substantively.

In *SAS*, the petitioner did not challenge the Board’s final written decision of the claims that the Board had reviewed. 138 S.Ct. at 1359. Rather, the petitioner challenged “the remaining claims on which the [Board] had refused review” altogether. *Id.* at 1354.

And this Court did not invoke its authority under § 319 to review the Board’s action. Rather, it relied upon catch-all authority under “the Administrative Procedure Act” to review the Board’s failure to institute on all claims. *Id.* at 1359. Indeed, the Court would have had no need to invoke the APA if, as Respondents contend, it relied on § 319.

C. Respondents’ Reading of *Thryv* Would Turn that Decision on Its Head and Only Underscores the Need for Review.

Respondents argue that this Court’s decision in *Thryv, Inc. v. Click-to-Call Technologies, LP*, 140 S.Ct. 1367 (2020), effectively overruled *SAS* and prevents review here. U.S. Br. 15-19; Janssen Br. 15-17. But that is not so. And even if those decisions were irreconcilable, that would support this Court’s review.

In *Thryv*, the Court held that § 314(d)’s appeal bar prevented judicial review of the Board’s interpretation and application of § 315(b). 140 S.Ct. at 1373-74. The Board had held that dismissal without prejudice did not trigger § 315(b)’s bar on the institution of a petition filed more than one year after an IPR petitioner is served with an infringement complaint. *Id.* at 1371. In rejecting review, this Court held that § 314(d)’s bar applies to “questions that are closely tied to the application and interpretation of statutes

related to the Patent Office’s decision to initiate inter partes review.” *Id.* at 1373.

But Mylan’s challenge is not to the application and interpretation of statutes related to the Patent Office’s decision to initiate IPR. As in *SAS*, Mylan contends that the Patent Office ignored the AIA entirely—and also violated the APA. The Director has used two Board decisions as a substitute for Congress’s command to promulgate regulations through notice-and-comment rulemaking. 35 U.S.C. § 316(a). And the Board refused to initiate IPR—not based on any institution statute—but by assigning dispositive weight to the existence of parallel litigation under *NHK-Fintiv*, Pet.App.42a-43a.

Respondents argue that this Court has never drawn a distinction between misapplying a statute—which is not reviewable under § 314(d)—and ignoring a statute altogether—which is reviewable. U.S. Br. 18; Janssen Br. 16-17. But they are mistaken.

To start, the difference between misapplying and ignoring a statutory command reconciles the holdings in *Thryv* and *SAS*. The respondent in *Thryv* complained about how the Board calculated the start of the statute’s one-year clock, 140 S.Ct. at 1371, which “raise[d] ‘an ordinary dispute about the application of an institution-related statute,’ *id.* at 1373 (quoting *Cuozzo*, 136 S.Ct. at 2139). In contrast, the petitioner in *SAS* complained that the Board disregarded § 318(a) altogether when it refused to institute IPR on all claims that the petitioner had challenged. 138 S.Ct. at 1359.

Moreover, this Court drew the same distinction—between misapplication and ignorance—in *Lindahl*

v. *Office of Personnel Management*, 470 U.S. 768 (1985), a decision on which *Cuozzo* relies, 136 S.Ct. at 2141. In *Lindahl*, the Court held that a statute that barred review of “[q]uestions of dependency and disability” applied only to the agency’s “factual underpinnings” in “disability determinations.” 470 U.S. at 791. But the bar did not stop a court from reviewing the agency’s “substantial departure from important procedural rights” secured by statute. *Id.*

Respondents’ view also ignores a key difference between this case and *Thryv*. In *Thryv*, the Court was concerned about allowing parties to assert claims that institution was improper to “unwind the agency’s merits decision” invalidating a patent. 140 S.Ct. at 1374. But here, Respondents claim the opposite—that *Thryv* requires this Court to “leav[e] bad patents enforceable,” *id.*, by foreclosing review of the Board’s refusal to institute IPR on grounds nowhere tied to an institution statute.

There is no merit to Respondents’ contention that *Thryv* effectively overruled *SAS*. But even if there were, that would further support this Court’s need to clarify the scope of § 314(d).

II. The *NHK-Fintiv* Rule Violates the America Invents Act and the Administrative Procedure Act.

Respondents offer no compelling defense of *NHK-Fintiv*—and for good reason. That rule fails substantively and procedurally under the AIA and APA.

Through the AIA, Congress commanded the Director to promulgate regulations “setting forth the standards for the showing of sufficient grounds to

institute a review under section 314(a),” 35 U.S.C. § 316(a)(2), and governing “the relationship of such review to other proceedings under this title,” *id.* § 316(a)(4). Neither Respondent defends the Director’s failure to do so. And that failure violates the AIA’s and APA’s requirements of notice-and-comment rulemaking. Pet. 26-29.

In addition, the AIA defines what constitutes a timely filed petition. Section 315(b) provides that IPR is barred where the petition is filed “more than 1 year after the petitioner is served with a complaint alleging infringement of the patent.” Yet, the Board has used *NHK-Fintiv* to substitute its judgment of what constitutes a timely filed petition for that of Congress—denying review even when a petition is filed less than a month after the petitioner was served with an infringement complaint. Pet. 22-26.

III. Respondents Have Identified No Legitimate Reason for Declining to Resolve the Important Questions Raised by the Petition.

The proper interpretation of § 314(d) is an exceptionally important question that merits this Court’s review.

Confusion about the scope of § 314(d) has already required three decisions of this Court in the past five years. *Thryv*, 140 S.Ct. 1367; *SAS*, 138 S.Ct. 1348; *Cuozzo*, 136 S.Ct. 2131. Yet, as Justice Gorsuch observed, substantial uncertainty remains about how to apply that provision. *Thryv*, 140 S.Ct. at 1387 (Gorsuch, J., dissenting). Since *Thryv*, the Federal Circuit continues to wrestle with whether § 314(d) forecloses review of “matters addressed in an IPR

that are not directly related to the ultimate patentability decisions the Board renders in a final written decision.” *Uniloc 2017 LLC v. Facebook Inc.*, 989 F.3d 1018, 1024-27 (Fed. Cir. 2021).

Meanwhile, the Board’s reliance on *NHK-Fintiv*’s non-statutory factors threatens the system Congress enacted to weed out junk patents. Plaintiffs are concentrating patent cases in a handful of districts known for setting quick trial dates, hoping to persuade the Board to deny IPR. Br. of *Amicus Curiae* Intel Corp. in Support of Petitioner at 20-21 (number of patent infringement suits in the Western District of Texas has grown 845% between 2018 and 2020).

District courts are contributing to this gamesmanship by setting unrealistic trial dates that, for at least one district judge, are intentionally designed to evade IPR. Ltr. from Sens. Patrick Leahy & Thom Tillis to Chief Justice Roberts, U.S. Supreme Court (Nov. 2, 2021), <https://tinyurl.com/ynf445h9>. And in denying institution under *NHK-Fintiv*, the Board accepts these unrealistic dates at “face value”—absent compelling evidence to the contrary. *Samsung Elec. Co. v. Ancora Techs., Inc.*, No. IPR2020-01184, 2021 WL 42429, at *5 (P.T.A.B. Jan. 5, 2021). As a result, these types of “shenanigans” will continue unchecked absent this Court’s intervention.

Rather than find any defect in Mylan’s petition, Respondents argue that this Court should decline review primarily because the Director *might* one day promulgate regulations adopting *NHK-Fintiv*’s non-statutory factors. U.S. Br. 20; Janssen Br. 20-21. But the action cited by Respondents is not a proposed rule; it is merely a *solicitation* whether the Director

should one day propose rules codifying the *NHK-Fintiv* factors. 85 Fed. Reg. 66,502 (Oct. 20, 2020).

Tellingly, the Director has not taken any action in the year since he received comments in response to this solicitation. Nor has he acted despite Congress’s command—more than a decade ago—to promulgate regulations governing institution. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, 302 (2011) (codified at 35 U.S.C. § 316). That’s because the Director has no incentive to do so.

As it stands now, the Director has successfully evaded any judicial review of *NHK-Fintiv* by asserting that § 314(d) prevents such review in appeals from Board decisions, Pet. 32, and in direct challenges in district court, *Apple Inc. v. Iancu*, No. 5:20-cv-6128, 2021 WL 5232241 (N.D. Cal. Nov. 10, 2021). Indeed, a court just refused to consider a procedural and substantive challenge to the merits of *NHK-Fintiv* on the ground that § 314(d)’s *appeal bar* forecloses judicial review even in an action brought under the APA in *district court*. *Id.* at *5-6.

Respondents do not seriously dispute that this petition is an excellent vehicle to resolve the questions presented. The Board relied exclusively on *NHK-Fintiv*’s non-statutory factors to deny Mylan’s IPR petition. Pet.App.42a-43a. It did not find that Mylan failed to show “a reasonable likelihood” of “prevail[ing] with respect to at least 1 of the claims challenged” in the petition, 35 U.S.C. § 314(a), or that the petition was untimely under the AIA, *id.* § 315(b).²

² Janssen faults Mylan for not seeking rehearing en banc. Janssen Br. 20. But the Federal Circuit has denied three petitions raising the same issue, Pet. 31, including one *after* the

Nor do Respondents dispute the importance of the questions presented. Between this petition and Apple’s, *Apple Inc. v. Optis Cellular Tech., LLC*, No. 21-118 (U.S.), there has been a groundswell of *amici* support for this Court to intervene—both to clarify the scope of § 314(d) and to salvage the IPR process. As it stands now, the Patent Office claims the unchecked authority to reject IPR—even for reasons plainly contrary to the AIA. And opportunistic plaintiffs, along with a handful of judges, have exploited the non-statutory factors employed by the Board to keep patent cases in district courts—at the expense of the quick and efficient system that Congress enacted to invalidate junk patents.

CONCLUSION

The petition should be granted.

Respectfully submitted.

DEEPRO R. MUKERJEE
LANCE A. SODERSTROM
KATTEN MUCHIN
ROSENMAN LLP
575 Madison Avenue
New York, NY 10022

ROBERT T. SMITH
Counsel of Record
ERIC T. WERLINGER
RAJESH R. SRINIVASAN
ANDREW J. PECORARO
KATTEN MUCHIN
ROSENMAN LLP
2900 K Street, NW
Washington, DC 20007

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precedential order was issued in this case. *Intel Corp. v. VLSI Tech. LLC*, No. 21-1614 (Fed. Cir. Aug. 26, 2021) (Dkt. No. 33). Thus, Janssen’s claim—that the “full Federal Circuit” has not had “an opportunity to weigh in first,” Janssen Br. 20—is disingenuous.