No. 21-202

In the Supreme Court of the United States

MYLAN LABORATORIES LTD., PETITIONER

v.

JANSSEN PHARMACEUTICA, N.V., ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENT IN OPPOSITION

ELIZABETH B. PRELOGAR
Solicitor General
Counsel of Record
BRIAN M. BOYNTON
Acting Assistant Attorney General
SCOTT R. MCINTOSH
WEILI J. SHAW
Attorneys

Department of Justice
Washington, D.C. 20530-0001
SupremeCtBriefs@usdoj.gov
(202) 514-2217

QUESTION PRESENTED

In the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284, Congress authorized the United States Patent and Trademark Office (USPTO) to reconsider the patentability of an issued patent at the request of a third party through an administrative process called inter partes review. Under procedures established by the AIA, the USPTO first decides whether to institute review of the challenged patent claims. If it grants review, the USPTO conducts a trial and ordinarily issues a final written decision regarding patentability. The AIA authorizes a party to the inter partes review to appeal the agency's "final written decision with respect to the patentability" of the challenged patent claims, which is issued "[i]f an inter partes review is instituted and not dismissed." 35 U.S.C. 318(a), 319. The Act provides that the agency's determination whether to institute an inter partes review is "final and nonappealable." 35 U.S.C. 314(d). The question presented is as follows:

Whether petitioner may appeal the USPTO's denial of its petition for inter partes review on the grounds that, in determining whether to institute inter partes review, the agency considered factors that are inconsistent with the AIA and were adopted in a procedurally flawed manner.

ADDITIONAL RELATED PROCEEDINGS

United States Court of Appeals (Fed. Cir.):

Mylan Labs. Ltd. v. *Janssen Pharmaceutica, N.V.*, No. 2021-1071 (Mar. 12, 2021)

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases:

Cases—Continued: Page

Statutes and regulations:

Statutes and regulations—Continued: Page

Miscellaneous:

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-16a) is published in the Federal Reporter at 989 F.3d 1375. The decision of the Patent Trial and Appeal Board (Pet. App. 17a-44a) is not published but is available at 2020 WL 5580472.

JURISDICTION

The judgment of the court of appeals was entered on March 12, 2021. By orders dated March 19, 2020, and July 19, 2021, this Court extended the time within which to file any petition for a writ of certiorari due on or after March 19, 2020, to 150 days from the date of the lower-court judgment, order denying discretionary review, or order denying a timely petition for rehearing, as long as that judgment or order was issued before July 19, 2021. The petition for a writ of certiorari was filed on August

9, 2021. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. a. The Patent Act of 1952 (Patent Act), 35 U.S.C. 1 *et seq.*, charges the U.S. Patent and Trademark Office (USPTO) with examining applications for patents, and it directs the USPTO to issue a patent if the statutory criteria are satisfied. 35 U.S.C. 131. Federal law has long authorized the USPTO to reconsider the patentability of the inventions claimed in issued patents. In the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284, Congress substantially expanded those procedures, in an effort to "establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs." H.R. Rep. No. 98, 112th Cong., 1st Sess. Pt. 1, at 39-40 (2011); see *Oil States Energy Servs., LLC* v. *Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1370 (2018); *Cuozzo Speed Techs., LLC* v. *Lee*, 136 S. Ct. 2131, 2137-2138 (2016).

The AIA established several new procedures, to be conducted before the USPTO's Patent Trial and Appeal Board (Board), through which third parties may challenge the patentability of claims in issued patents. For challenges to patentability brought within nine months after the disputed patent was issued, the AIA established a procedure known as post-grant review, which allows challenges to patentability on any ground that could be asserted as a defense to a claim of infringement. 35 U.S.C. 321(b) and (c); see 35 U.S.C. 321-329. For challenges brought after that nine-month period, the AIA established inter partes review, which is limited to challenges "that could be raised under section 102 or 103" (*i.e.*, anticipation or obviousness challenges)

and that are based on "prior art consisting of patents or printed publications." 35 U.S.C. 311(b) and (c); see 35 U.S.C. 311-319. This case concerns inter partes review.

b. Under the AIA, inter partes review proceeds in two phases. When a petition for inter partes review is filed, the Director of the USPTO first must determine whether to institute a review. 35 U.S.C. 314. The institution decision is made on the basis of the petition and any response that the patent owner files. The decision must be made within three months after the agency receives the patent owner's response or, if no response is filed, "the last date on which such response may be filed." 35 U.S.C. 314(b)(2).

The AIA imposes several prerequisites for instituting an inter partes review. The Director may not institute review unless he finds "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). Inter partes review also "may not be instituted" if (1) "before the date on which the petition for such a review is filed, the petitioner or real party in interest filed a civil action challenging the validity of a claim of the patent"; or (2) "the petition requesting the proceeding is filed more than 1 year after the date on which the petitioner, real party in interest, or privy of the petitioner is served with a complaint alleging infringement of the patent." 35 U.S.C. 315(a)(1) and (b).

Even if the petition meets these requirements, the AIA contains "no mandate to institute review." *Cuozzo*, 136 S. Ct. at 2140; see *SAS Inst. Inc.* v. *Iancu*, 138 S. Ct. 1348, 1356 (2018). Instead, "Congress has committed the decision to institute inter partes review to the Director's unreviewable discretion." *United States* v. *Arthrex, Inc.*, 141 S. Ct. 1970, 1977 (2021). Consistent with

that approach, the AIA provides that the determination "whether to institute an inter partes review" is "final and nonappealable." 35 U.S.C. 314(d).

If the Director elects to institute inter partes review, the Board conducts a trial-like proceeding to determine the patentability of the claims at issue. See 35 U.S.C. 316; 37 C.F.R. Pt. 42, Subpt. A. During this second phase, both parties are entitled to take limited discovery, 35 U.S.C. 316(a)(5); to file affidavits and declarations, 35 U.S.C. 316(a)(8); to request an oral hearing, 35 U.S.C. 316(a)(10); and to file written memoranda, 35 U.S.C. 316(a)(8) and (13). At the end of the proceeding (unless the matter has been dismissed), the Board must "issue a final written decision with respect to the patentability of any patent claim challenged by the petitioner." 35 U.S.C. 318(a). A party aggrieved by the Board's final written decision may appeal that decision to the Federal Circuit. 35 U.S.C. 141(c), 319.

c. The Director has delegated to the Board the responsibility to determine, when a petition for inter partes review is filed, whether a review should be instituted. 37 C.F.R. 42.4(a). The Director is "responsible for providing policy direction and management supervision for the Office," 35 U.S.C. 3(a)(2), and has used several mechanisms to guide the Board regarding the proper exercise of its delegated authority to institute inter partes reviews. *Inter alia*, the Director may designate as precedential particular Board opinions concerning whether to institute inter partes review, thus making those opinions "binding Board authority in subsequent matters involving similar facts or issues." Patent Trial and Appeal Board, *Standard Operating Procedure 2 (Revision 10)*, at 8-11 (Sept. 20, 2018),

https://go.usa.gov/xwXem. At issue here is the Director's designation as precedential of two Board decisions that identify criteria for determining whether to institute inter partes review when parallel proceedings involving the same patent and the same or similar issues are pending in district court. See *NHK Spring Co.* v. *Intri-Plex Techs., Inc.*, No. IPR2018-752, 2018 WL 4373643 (PTAB Sept. 12, 2018); and *Apple Inc.* v. *Fintiv, Inc.*, No. IPR2020-19, 2020 WL 2126495 (PTAB Mar. 20, 2020).

In *NHK*, the Board noted that efficiency weighed in favor of denying review when a "district court proceeding will analyze the same issues and will be resolved before any trial on the [inter partes review p]etition concludes." 2018 WL 4373643, at *7. The Board expanded on *NHK* in *Fintiv*, explaining that "an early trial date" is one "non-dispositive factor[]" that "should be weighed as part of a 'balanced assessment of all relevant circumstances of the case, including the merits,'" in determining whether to institute review. 2020 WL 2126495, at *2. The Board in *Fintiv* identified six factors the Board had previously considered "relat[ing] to whether efficiency, fairness, and the merits support the exercise of authority to deny institution in view of an earlier trial date in the parallel proceeding":

> 1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;
>
> 2. proximity of the court's trial date to the Board's projected statutory deadline for a final written decision;
>
> 3. investment in the parallel proceeding by the court and the parties;

> 4. overlap between issues raised in the petition and in the parallel proceeding;
>
> 5. whether the petitioner and the defendant in the parallel proceeding are the same party; and
>
> 6. other circumstances that impact the Board's exercise of discretion, including the merits.

Id. at *2-*3. "[I]n evaluating the factors," the decision in *Fintiv* explained, "the Board takes a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review." *Id.* at *3.

2. In January 2018, the private respondent in this case, Janssen Pharmaceutica, N.V., filed suit against Teva Pharmaceuticals, a generic pharmaceutical company, for infringing a Janssen patent related to the drug paliperidone palmitate. *Janssen Pharm., Inc.* v. *Teva Pharm. USA, Inc.*, No. 18-cv-734 (D.N.J. filed Jan. 17, 2018); Pet. App. 20a. The only issue for trial in that case was the validity of claims 1-21 of Janssen's patent. Pet. App. 26a. In August 2019, Janssen filed suit against petitioner, alleging infringement of the same patent, after petitioner filed an abbreviated new drug application for paliperidone palmitate. *Janssen Pharm., Inc.* v. *Mylan Labs. Ltd.*, No. 19-cv-16484 (D.N.J. filed Aug. 8, 2019). The principal issue in the litigation was again the validity of claims 1-21. Pet. App. 27a.

In February 2020, petitioner filed a petition for inter partes review of Janssen's patent. *Mylan Labs.* v. *Janssen Pharmaceutica NV*, No. IPR2020-440, Paper 3 (PTAB Feb. 07, 2020). As it had in the infringement litigation, petitioner argued that claims 1-21 of Janssen's patent were invalid. Pet. App. 18a. In September 2020, the Board denied inter partes review after considering the *Fintiv* factors. See *id.* at 17a-43a.

The Board noted that, at the time, "[t]he *Teva* litigation [wa]s scheduled to begin trial later th[at] month, * * * a year prior to the deadline for a final written decision" if the Board instituted an inter partes review. Pet. App. 31a. It observed that "[t]he *Teva* litigation [wa]s trial-ready, representing a very considerable investment by both parties." *Id.* at 33a. And it noted that the parties in the *Mylan* litigation had proposed a trial in June 2021, also "before the mandatory deadline for the Final Written Decision in th[e] proposed *inter partes* review." *Id.* at 32a. The Board observed that fact discovery was already ongoing in *Mylan*, and it found "a reasonable likelihood that * * * the district court and the parties w[ould] have invested significant resources in assessing the validity of the challenged patent well before the Board would issue a Final Written Decision." *Id.* at 36a; see *id.* at 33a-34a.

The Board observed that the *Mylan* litigation involved the same parties as the inter partes review petition and, although *Teva* did not, "the issues in both the *Teva* and *Mylan* litigations are substantially the same as those raised in the Petition." Pet. App. 41a. "[T]he validity of claims 1–21," it further noted, is "central to both the *Teva* and *Mylan* litigations, and is, in fact, the *only* issue in at least the former case." *Id.* at 39a. After considering these and other factors, the Board found that "the balance of the factors favor the exercise of our discretion to deny the Petition for institution of *inter partes* review." *Id.* at 43a.

A month later, in October 2020, the district court conducted a bench trial in *Teva*. See *Teva*, No. 18-cv-734, D. Ct. Docs. 135-149, 151 (D.N.J.). In *Mylan*, the parties agreed, in light of the *Teva* trial, to stay the district court proceedings pending the outcome of the *Teva*

litigation. See Pet. 12; *Mylan*, No. 19-cv-16484, D. Ct. Doc. 62 (D.N.J. filed Oct. 23, 2020).

3. Petitioner appealed the Board's non-institution decision to the Federal Circuit and sought, in the alternative, a writ of mandamus. Pet. App. 3a. Petitioner argued that the *Fintiv* factors (1) are inconsistent with 35 U.S.C. 315(b), which prohibits institution when a petition is filed more than one year after an infringement suit; (2) were invalidly adopted without notice-and-comment rulemaking; and (3) violate procedural and substantive due process. Pet. App. 12a, 15a. The Federal Circuit dismissed the appeal and denied the request for mandamus. *Id.* at 1a-16a.

The court of appeals first explained that "no statute grants [it] jurisdiction over appeals from decisions denying institution." Pet. App. 5a. The court acknowledged that, standing alone, the grant of jurisdiction in 35 U.S.C. 1295(a)(4) over "'an appeal from a decision of [the Board] with respect . . . inter partes review,'" could "perhaps" be read to reach a non-institution decision. Pet. App. 6a (quoting 35 U.S.C. 1295(a)(4)). The court explained, however, that 35 U.S.C. 314(d) "dispels any such notion." Pet. App. 6a. Section 314(d) provides that "[t]he determination by the Director whether to institute an inter partes review under this section shall be final and non-appealable." 35 U.S.C. 314(d). That language, the court of appeals concluded, "bars" any "direct appeal from a decision denying institution." Pet. App. 7a.

The court of appeals also denied petitioner's request for mandamus relief. Pet. App. 8a-16a. Because an appeal of a final written decision in an inter partes review would fall within the court's exclusive jurisdiction, and

because Section 314(d) is "silent with respect to mandamus," the court concluded that judicial review of a decision denying institution "is available in extraordinary circumstances by petition for mandamus." *Id.* at 8a, 10a; see *id.* at 8a-12a. The court emphasized, however, that mandamus relief is a "drastic and extraordinary remedy" that requires, among other things, a "clear and indisputable" right to relief. *Id.* at 12a-13a (quoting *Cheney* v. *United States Dist. Court*, 542 U.S. 367, 380 (2004)). The court held that petitioner "lacks a clear and indisputable right to review of the Patent Office's determination to apply the *Fintiv* factors or the Patent Office's choice to apply them in this case through adjudication rather than notice-and-comment rulemaking." *Id.* at 14a. It further held that petitioner had "fail[ed] to state a colorable" due process claim because it had not "identif[ied] a[ny] deprivation of 'life, liberty, [or] property.'" *Id.* at 15a (second set of brackets in original; citation omitted).

ARGUMENT

Petitioner argues (Pet. 14-21) that the court of appeals should have exercised jurisdiction over petitioner's appeal from the USPTO's decision declining to institute inter partes review. Under the AIA, however, it is "the final written decision of the [Board] under section 318(a)" that is subject to appeal. 35 U.S.C. 319. And under Section 318(a), the Board issues a "final written decision" only "[i]f an inter partes review is instituted and not dismissed." 35 U.S.C. 318(a). By contrast, "[t]he determination by the Director whether to institute an inter partes review" is "final and nonappealable." 35 U.S.C. 314(d). The court thus correctly dismissed petitioner's appeal of the Board's determination not to institute inter partes review in this case. This

Court has previously denied review of a similar question, see *Arris Int'l Ltd.* v. *Chanbond, LLC*, 140 S. Ct. 2716 (2020), and the same result is warranted here.*

Petitioner further contends (Pet. 21-29) that the *Fintiv* factors that the Board considered in declining to institute review are unlawful. Because the court of appeals correctly held that it lacked jurisdiction over petitioner's appeal, and petitioner has not challenged the court's denial of mandamus relief, this case presents no opportunity to address those arguments. In any event, this case would be a poor vehicle to consider the questions presented, given that the agency has sought public input on and is currently considering whether to modify the *Fintiv* factors. The petition for a writ of certiorari should be denied.

1. a. The court of appeals correctly dismissed petitioner's appeal of the USPTO's decision declining to institute inter partes review. As explained, inter partes review proceeds in two phases—institution and trial. "A party dissatisfied with the final written decision of the [Board] * * * may appeal the decision pursuant to sections 141 through 144." 35 U.S.C. 319. Sections 141 through 144 establish the procedures for appeals from the USPTO to the Federal Circuit. 35 U.S.C. 141-144. Section 141(c) states that "[a] party to an inter partes review * * * who is dissatisfied with the final written decision of the [Board] under section 318(a) * * * may appeal the Board's decision only to the United States Court of Appeals for the Federal Circuit." 35 U.S.C. 141(c).

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* Another petition for a writ of certiorari presenting a similar question is currently pending before this Court in *Apple Inc.* v. *Optis Cellular Technology, LLC*, No. 21-118 (filed July 26, 2021).

Section 318(a) in turn provides that, "[i]f an inter partes review is instituted and not dismissed[,] * * * the [Board] shall issue a final written decision with respect to the patentability" of the challenged patent claims. 35 U.S.C. 318(a). A USPTO decision *not* to institute an inter partes review at the initial stage of the process is not a "final written decision * * * under section 318(a)," 35 U.S.C. 319, and therefore is not appealable under Sections 319 and 141(c). "[T]he statutory provisions addressing *inter partes* review contain no authorization to appeal a non-institution decision" to the Federal Circuit or to any other court. *St. Jude Med., Cardiology Div., Inc.* v. *Volcano Corp.*, 749 F.3d 1373, 1375 (Fed. Cir. 2014). Section 314(d) reinforces that conclusion, providing 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).

b. Congress's decision not to authorize appeals from non-institution decisions reflects the role of such decisions in the statutory scheme. The inter partes review process gives the USPTO "significant power to revisit and revise earlier patent grants." *Cuozzo Speed Techs., LLC* v. *Lee*, 136 S. Ct. 2131, 2139-2140 (2016). A final written decision regarding patentability can invalidate a patent owner's claims or estop a petitioner from challenging those claims in future proceedings. See 35 U.S.C. 318(b) (authorizing the USPTO to amend or cancel patent claims "[i]f * * * [the Board] issues a final written decision" under Section 318(a)); 35 U.S.C. 315(e)(1) (providing that a "petitioner in an inter partes review * * * that results in a final written decision under section 318(a)" is estopped from raising certain is-

sues in future USPTO or judicial proceedings). By contrast, if the USPTO declines to institute an inter partes review, its decision does not alter the rights of any private party. Instead, a non-institution decision leaves the patent owner's claims undisturbed and leaves the petitioner free to challenge the validity of a patent through the same mechanisms—such as petitioning for ex parte reexamination by the agency, seeking a declaratory judgment from a district court, or asserting unpatentability as an affirmative defense in a patent-infringement suit—that it could have invoked before the non-institution decision was made. See *Cuozzo*, 136 S. Ct. at 2153 (Alito, J., concurring in part and dissenting in part).

Congress had sound reasons for distinguishing, for purposes of appeal rights, between the Board's final written decisions on questions of patentability and its decisions not to institute inter partes review. "[W]hen an agency refuses to act it generally does not exercise its coercive power over an individual's liberty or property rights, and thus does not infringe upon areas that courts often are called upon to protect." *Heckler* v. *Chaney*, 470 U.S. 821, 832 (1985) (emphasis omitted); see *ibid.* ("[A]n agency's refusal to institute proceedings shares to some extent the characteristics of the decision of a prosecutor in the Executive Branch not to indict—a decision which has long been regarded as the special province of the Executive Branch."). Accordingly, "Congress has committed the decision to institute inter partes review to the Director's unreviewable discretion." *United States* v. *Arthrex, Inc.*, 141 S. Ct. 1970, 1977 (2021); see *Cuozzo*, 136 S. Ct. at 2140 ("[T]he agency's decision to deny a petition [for inter partes review] is a matter committed to [its] discretion.").

c. Petitioner contends (Pet. 16-23) that the court of appeals erred in dismissing petitioner's appeal of the Board's non-institution decisions because 28 U.S.C. 1295(a)(4)(A) vested the court with jurisdiction to review such decisions and Section 314(d) does not withdraw that jurisdiction over petitioner's appeal. Petitioner asserts that Section 314(d) bars appeals only from institution decisions that are "consistent with [Section 314 itself] and the law more generally." Pet. 18. Petitioner argues (Pet. 21) that, because it asserts that the USPTO exceeded its statutory authority by relying on the *Fintiv* factors in declining to institute inter partes review, its appeal of that determination can proceed. That is wrong.

Most fundamentally, regardless of the scope of Section 314(d), Section 1295(a)(4)(A) does not provide petitioner a right to appeal the Board's non-institution decision. Section 1295 grants the Federal Circuit "exclusive jurisdiction" over an "appeal from a decision of * * * [the Board] with respect to a patent application, derivation proceeding, reexamination, post-grant review, or inter partes review under title 35." 28 U.S.C. 1295(a)(4)(A). That provision addresses jurisdiction but does not confer a right to appeal. It "is most naturally read" to grant the Federal Circuit exclusive jurisdiction over whatever appeals are separately authorized by the Patent Act, including appeals of the Board's final written decisions in inter partes reviews as authorized by Sections 319 and 141(c). *St. Jude*, 749 F.3d at 1376; see *GTNX, Inc.* v. *INTTRA, Inc.*, 789 F.3d 1309, 1312 (Fed. Cir. 2015) (concluding that a Board decision vacating an institution decision was "outside 28 U.S.C. § 1295(a)(4)(A)").

Because no provision of the Patent Act authorizes an appeal of the USPTO's decision not to institute an inter partes review, Section 1295(a)(4)(A) does not grant the Federal Circuit jurisdiction over such an appeal. And because no statute vests the Federal Circuit with jurisdiction over petitioner's appeal in the first instance, there is no jurisdiction for Section 314(d) to "withdraw[]" (Pet. 14). In *Cuozzo*, 136 S. Ct. at 2141, and *Thryv, Inc.* v. *Click-to-Call Technologies, LP*, 140 S. Ct. 1367, 1373 (2020), the Court left open the possibility that in exceptional circumstances, challenges to the Board's institution decisions might be cognizable in appeals from the Board's final written decisions on patentability, notwithstanding Section 314(d)'s general bar. But the Court in *Cuozzo* explained that Section 314(d)'s preclusion of review is "superfluous" as applied to the USPTO's decision "to deny a petition" for inter partes review. 136 S. Ct. at 2140; see *St. Jude*, 749 F.3d at 1376.

Contrary to petitioner's contention, the court of appeals has not, at any time, "authoritatively rejected that view." Pet. 31 (citing *Arthrex, Inc.* v. *Smith & Nephew, Inc.*, 880 F.3d 1345 (Fed. Cir. 2018)). *Arthrex* did not involve a non-institution decision. In that case, the patent owner responded to a petition for inter partes review by disclaiming all of the challenged patent claims. *Id.* at 1347; see 35 U.S.C. 253(a). Rather than declining on that basis to institute inter partes review under 37 C.F.R. 42.71(a), the Board entered a final judgment against the patent owner under 37 C.F.R. 42.73. *Arthrex*, 880 F.3d at 1347. As a result, estoppel attached to the Board's decision, precluding the patent owner "from taking action inconsistent with the adverse judgment" in its three pending patent continuation applications. *Ibid.* (citation omitted).

The Federal Circuit held that, at least taken together, Section 1295 and the Administrative Procedure Act (APA), 5 U.S.C. 701 *et seq.*, gave the patent owner a right to appeal "a final decision that disposes of an [inter partes review] proceeding in the form of an adverse judgment." *Arthrex*, 880 F.3d at 1349; see *id.* at 1348 n.1 ("We need not decide whether the right to appeal comes directly from § 1295 or in conjunction with § 704 of the APA."); see 5 U.S.C. 701-706 (authorizing judicial review of certain final agency actions in suits brought by aggrieved persons). The court in *Arthrex* distinguished *St. Jude* on the ground that *St. Jude* "did not involve a similar situation" and did not address "the availability of appeal of final adverse judgment decisions." *Arthrex*, 880 F.3d at 1349. The court of appeals reiterated that distinction here. See Pet. App. 6a n.3 ("*Arthrex*'s holding that an adverse judgment under 37 C.F.R. § 42.73(b) is appealable pursuant to § 1295 does not conflict with *St. Jude*'s holding that non-institution decisions are nonappealable.").

d. In any event, there is no merit to petitioner's contention that Section 314(d) bars only appeals from institution determinations that are consistent with Section 314 "and the law more generally." Pet. 18. In *Cuozzo* and *Thryv*, this Court strongly suggested that Section 314(d) is most naturally read to bar *any* contention that the USPTO erred in determining whether to institute inter partes review. In *Cuozzo*, the Court explained that "Cuozzo's contention that the Patent Office unlawfully initiated" an inter partes review was "not appealable" because "that is what § 314(d) says": "the 'determination by the [Patent Office] whether to institute an inter partes review under this section shall be *final and*

nonappealable.'" 136 S. Ct. at 2139 (brackets and emphasis in original). And in *Thryv*, the Court likewise recognized that Section 314(d) "indicates that a party generally cannot contend on appeal that the agency should have refused 'to institute an inter partes review.'" 140 S. Ct. at 1373. In each of those cases, the challenger argued that the Board's institution decision was inconsistent with "the law" (Pet. 18), and yet in each case the Court found that Section 314(d) precluded consideration of that contention on appeal.

To be sure, the particular challenges in *Cuozzo* and *Thryv* concerned statutory provisions closely related to the USPTO's institution decision. The Court therefore found it unnecessary to decide whether Section 314(d) would also bar review of challenges premised "on other less closely related statutes, or that present other questions of interpretation that reach, in terms of scope and impact, well beyond" the statutes governing the institution decision. *Cuozzo*, 136 S. Ct. at 2141; see *Thryv*, 140 S. Ct. at 1373. But even if Section 314(d) were limited to challenges based on statutes closely related to the USPTO's institution decision, petitioner's own appeal would be precluded. Petitioner contends (Pet. 21-29) that the Director erred by considering the *Fintiv* factors in denying institution. The *Fintiv* factors merely represent the Director's instruction to the Board to consider certain non-exclusive factors when exercising its delegated discretion to grant or deny institution. See pp. 5-6, *supra*. In arguing that the Board lacks authority to consider these factors, petitioner raises challenges "closely tied" to the statutory provisions that govern the Director's institution decisions.

More specifically, petitioner contends (Pet. 22-23) that the *Fintiv* factors are inconsistent with 35 U.S.C.

315(b) because they direct the Board in some circumstances to treat pending infringement litigation as relevant to the institution decision even though the litigation does not trigger Section 315(b)'s time bar. But Section 315(b)'s purpose and effect is to specify litigation-related circumstances in which "[a]n inter partes review may not be instituted." 35 U.S.C. 315(b). In concluding that Section 315(b) does not preclude the USPTO from considering additional litigation-related circumstances in determining whether institution is warranted in particular cases (see pp. 18-19, *infra*), the agency was construing a statute "closely related" to the USPTO's institution decisions.

This Court therefore "need not venture beyond" its holdings in *Cuozzo* and *Thryv* to conclude that Section 314(d) bars petitioner's appeal here. *Thryv*, 140 S. Ct. at 1373. And petitioner cannot evade this result by arguing (Pet. 26-29) that the Director's adoption of the *Fintiv* factors was procedurally infirm. "At bottom, [petitioner] is challenging whether the Board has authority to consider the status of parallel district court proceedings as part of its decision under § 314(a) in deciding whether to deny institution." *In re Cisco Sys. Inc.*, 834 Fed. Appx. 571, 573 (Fed. Cir. 2020). "Such challenges, both procedural and substantive, rank as questions closely tied to the application and interpretation of statutes relating to the Patent Office's decision whether to initiate review." *Ibid.*

This Court's decision in *SAS Institute Inc.* v. *Iancu*, 138 S. Ct. 1348 (2018), is not to the contrary. Petitioner cites (Pet. 16) the Court's statement in *SAS Institute* that Section 314(d) neither prevents courts from setting aside USPTO decisions that are issued "'in excess of statutory jurisdiction'" nor "withdraws [this Court's]

power to ensure that an inter partes review proceeds in accordance with the law's demands." 138 S. Ct. at 1359. Petitioner characterizes the Court's decision as reviewing and rejecting the Board's "partial institution" determination. Pet. 16 (citation omitted). But, in fact, those statements concerned, and the Court was exercising, the authority to review final written decisions in inter partes review and to ensure that, where an inter partes review was instituted, those proceedings were conducted within "statutory bounds." *SAS Institute*, 138 S. Ct. at 1359. As the Court later recognized in *Thryv*, that holding is "inapplicable" where, as here, a petitioner's appeal "challenges not the manner in which the agency's review 'proceed[ed]' once instituted, but whether the agency should have instituted review at all." 140 S. Ct. at 1376.

Finally, petitioner attempts (Pet. 17) to distinguish *Thryv* on the ground that that "there is a difference between *misapplying* the statute and *ignoring* the statute altogether." Such a distinction finds no footing in the text of Section 314(d) or in this Court's decisions. And, contrary to petitioner's assertion (Pet. 18), the USPTO did not "ignore[] congressional [l]imitations on the Director's discretion" not to institute inter partes review. In *Fintiv*, the Board acknowledged the petitioner's argument that "declining to institute" an inter partes review "would 'essentially render nugatory' the one-year filing period of § 315(b)." 2020 WL 2126495, at *2 (citation omitted). The agency simply disagreed. See *id.* at *5 ("[N]otwithstanding that a defendant has one year to file a petition, it may impose unfair costs to a patent owner if the petitioner, faced with the prospect of a looming trial date, waits until the district court trial has progressed significantly before filing a petition at the

Office.") (footnote omitted). Accordingly, like the challengers in *Cuozzo* and *Thryv*, petitioner is contesting the Director's interpretation of a statutory provision that defines the scope of his authority to institute an inter partes review. But like the determinations at issue in those cases, "Congress entrusted th[at] institution decision to the agency." *Thryv*, 140 S. Ct. at 1376.

2. Petitioner separately asks (Pet. 21-29) the Court to consider the merits of its challenges to the *Fintiv* factors. Because the court of appeals concluded that it lacked jurisdiction over petitioner's appeal, it declined to address the merits of petitioner's challenge except to note that petitioner had failed to demonstrate the "clear and indisputable right to relief" that the mandamus standard requires. Pet. App. 14a. Because the court's jurisdictional holding was correct and petitioner does not renew its request for mandamus, this case presents no occasion for this Court to address the merits. Even if this Court granted certiorari and ultimately concluded that the court of appeals erred in its jurisdictional analysis, the proper course would be to remand for the court of appeals to consider petitioner's arguments on the merits, not for this Court to consider them in the first instance. See *Brownback* v. *King*, 141 S. Ct. 740, 747 n.4 (2021) ("[W]e are a court of review, not of first view.") (citation omitted).

In any event, petitioner's challenges to the *Fintiv* factors are unpersuasive. Contrary to petitioner's contention (Pet. 21-26), Section 315(b) speaks only to when an inter partes review "may *not* be instituted," not when it *must* be. 35 U.S.C. 315(b) (emphasis added); see *Cuozzo*, 136 S. Ct. at 2140 (recognizing that the AIA imposes "no mandate to institute review"). And petitioner's suggestion (Pet. 26-29) that the Director was

required to undertake notice-and-comment rulemaking to adopt criteria for future institution decisions is inconsistent with this Court's repeated recognition that such procedures are not required for "statements issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power." *Lincoln* v. *Vigil*, 508 U.S. 182, 197 (1993) (quoting *Chrysler Corp.* v. *Brown*, 441 U.S. 281, 302 n.31 (1979)).

3. Finally, even if the questions presented otherwise warranted this Court's review, this case would be a poor vehicle for considering them. Petitioner and its amici argue that the *Fintiv* factors were adopted without sufficient public notice and comment and have caused various adverse effects on the inter partes review process. See Pet. 32-35. The USPTO is currently soliciting and considering public comments on the *Fintiv* factors, however, and it will determine whether those factors should be modified based on public input and the agency's "broad experience as it relates to considerations for instituting" AIA proceedings. 85 Fed. Reg. 66,502, 66,503 (Oct. 20, 2020). In particular, the Director requested public comments on, *inter alia*, (1) whether the agency should "promulgate a rule with a case-specific analysis, such as generally outlined in *Fintiv* and its progeny, for deciding whether to institute" an inter partes review while parallel district court proceedings are pending; (2) whether the agency should instead adopt a bright-line rule for dealing with such circumstances; and (3) whether there are "any other modifications [it] should make in its approach." *Id.* at 66,506. Particularly in light of that pending agency pro-

cess, petitioner's and its amici's disapproval of the Office's current approach cannot justify this Court's intervention here.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

ELIZABETH B. PRELOGAR
Solicitor General
BRIAN M. BOYNTON
Acting Assistant Attorney General
SCOTT R. MCINTOSH
WEILI J. SHAW
Attorneys

NOVEMBER 2021