

No. 21-202

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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*

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**BRIEF IN OPPOSITION**

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## **QUESTION PRESENTED**

Whether 35 U.S.C. § 314(d) bars an appeal of a decision, committed to the discretion of the Director of the U.S. Patent and Trademark Office, denying institution of inter partes review in view of co-pending district court litigation and related factors.

## **CORPORATE DISCLOSURE STATEMENT**

Respondent Janssen Pharmaceutica NV is an indirectly wholly owned subsidiary of Johnson & Johnson, a publicly traded corporation. No publicly held corporation owns 10% or more of the stock of Johnson & Johnson.

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## INTRODUCTION

Section 314(d) of the Leahy-Smith American Invents Act (AIA) states, in no uncertain terms, that “[t]he determination by the Director” of the U.S. Patent and Trademark Office (PTO) “whether to institute an inter partes review under this section shall be final and nonappealable.” Decisions *denying* institution fall comfortably within that broadly worded appeal bar. That plain-text conclusion makes perfect sense under the scheme Congress created: there is no mandate to institute inter partes review even when statutory prerequisites are met, and the institution decision is ultimately committed to the PTO’s discretion. This Court’s precedents also compel that conclusion, rather than provide for the exceptions that Petitioner Mylan Laboratories seeks. And were there any doubt, this case would not be an appropriate vehicle for resolving the threshold jurisdictional question presented—much less Mylan’s merits challenge to the “*NHK-Fintiv*” factors, which (i) the Federal Circuit did not even reach, (ii) remain the subject of an ongoing PTO rulemaking proceeding and pending legislation, and (iii) are currently being challenged in a separate district court proceeding. Accordingly, this Court’s review is not warranted.

## STATEMENT

### A. Legal Framework

1. In 2011, Congress through the AIA created inter partes review, which “allows third parties to challenge patent claims on grounds of invalidity specified by statute.” *Thryv, Inc. v. Click-to-Call*

*Techs., LP*, 140 S. Ct. 1367, 1370 (2020). “For inter partes review to proceed, the agency must agree to institute review.” *Id.* (citing 35 U.S.C. § 314). The AIA specifies that “[t]he Director shall determine whether to institute an inter partes review \*\*\* pursuant to a petition” and any “preliminary response.” 35 U.S.C. § 314(b). The Director, in turn, has delegated institution authority to the Patent Trial and Appeal Board. 37 C.F.R. § 42.4(a).

Among other prerequisites for institution, the AIA provides that “[t]he Director may not authorize an inter partes review to be instituted unless the Director determines \*\*\* that 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). In addition, “[a]n inter partes review may not be instituted if 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(b).

At bottom, though, “the agency’s decision to deny a petition is a matter committed to the Patent Office’s discretion.” *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016). In a provision entitled “No Appeal,” the AIA states 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).

Where the PTO *does* “elect[] to institute inter partes review, the Board conducts a proceeding to evaluate the challenged claims’ validity.” *Thryv*, 140 S. Ct. at 1371. “At the conclusion of the proceeding—

if review ‘is instituted and not dismissed’—the Board ‘issue[s] a final written decision with respect to the patentability of the challenged claims.’ *Id.* (alteration in original) (quoting 35 U.S.C. § 318(a)). In contrast to an institution decision, “[a] party dissatisfied with the final written decision \*\*\* under section 318(a) may appeal the decision” to the Federal Circuit. 35 U.S.C. § 319.

2. In a series of Board decisions, the PTO has identified “factors relevant to the Board’s decision on whether to apply its discretion under 35 U.S.C. § 314(a) to deny institution.” *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, 2020 WL 2126495, at \*1, \*2 n.5 (P.T.A.B. Mar. 20, 2020). Where the validity of the patent at issue is also being challenged in parallel district court litigation, and “the patent owner raises an argument for discretionary denial [of inter partes review] \*\*\* due to an earlier trial date [in district court],” six factors may be relevant:

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. Those “non-dispositive” factors—often referred to as the “*NHK-Fintiv*” factors—“relate to whether efficiency, fairness, and the merits support the exercise of authority to deny institution.” *Id.* at \*2-\*3. The PTO is currently considering whether to codify the *NHK-Fintiv* factors through notice-and-comment rulemaking. *See* Request for Comments on Discretion To Institute Trials Before the Patent Trial and Appeal Board, 85 Fed. Reg. 66,502, 66,502-66,505 (Oct. 20, 2020).

## **B. Procedural History**

1. After Janssen brought suits in district court asserting U.S. Patent No. 9,439,906 (“the ’906 patent”) against Mylan and other companies, Mylan petitioned the PTO to institute inter partes review. Pet. App. 3a. Guided by the *NHK-Fintiv* factors, the Board “exercise[d] [its] discretion under § 314(a) to deny institution.” *Id.* at 18a. As the Board explained at length, institution of inter partes review would be an inefficient use of Board resources in view of well-progressed, co-pending litigations in which Mylan itself and Teva Pharmaceuticals USA, Inc. had challenged the validity of the same patent. *Id.* at 25a-43a (discussing *Janssen Pharms., Inc. v. Teva Pharms. USA, Inc.*, No. 2:18-cv-734 (D.N.J.), and *Janssen*

*Pharms., Inc. v. Mylan Labs. Ltd.*, No. 2:19-cv-16484 (D.N.J.); *id.* at 4a.<sup>1</sup>

2. Mylan appealed the Board’s non-institution decision to the Federal Circuit, identifying two issues. First, without mentioning its own parallel litigation with Janssen, Mylan questioned whether “the Board’s determination to deny institution under 35 U.S.C. § 314(a) of the *inter partes* review \*\*\* based on the timing of a separate [Teva] district-court litigation to which [Mylan] is not a party, undermines [Mylan’s] constitutional and other due process rights.” Notice of Appeal 1, No. 21-1071 (Fed. Cir.), ECF No. 1-2. Second, Mylan questioned whether “the Board’s continued adoption and application of non-statutory institution standards through *ad hoc* proceedings lie in contrast to congressional intent.” *Id.*

Before briefing on the merits, Janssen moved to dismiss the appeal for lack of jurisdiction. The PTO Director intervened in support of dismissal. Mylan countered that the Federal Circuit decisions finding section 314(d) to bar non-institution appeals were either unpublished, no longer good law, or distinguishable because Mylan was bringing a constitutional challenge. After ordering that the parties be prepared to address mandamus jurisdiction, the Federal Circuit held oral argument on the fully

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<sup>1</sup> On October 8, 2021, after a two-week bench trial last fall and closing arguments this spring, the district court rejected all of Teva’s invalidity challenges to the patent at issue. *Teva*, No. 2:18-cv-734 (D.N.J.), ECF No. 267. Mylan’s own district court litigation involving substantially similar invalidity challenges to the same patent was stayed pending the outcome of the *Teva* case.

briefed motion. It then issued a unanimous precedential decision dismissing the appeal under section 314(d) and denying mandamus relief.

With respect to the appeal, the Federal Circuit held that although 28 U.S.C. § 1295(a)(4) provides a “general grant of jurisdiction” over “an appeal from a decision \*\*\* ‘with respect to \*\*\* inter partes review,’” the “more specific” language of section 314(d) “dispels” the notion that section 1295(a)(4) “reach[es] an appeal from a decision denying institution.” Pet. App. 5a-6a (second ellipsis in original) (emphasis omitted). The Federal Circuit also noted that “[w]hen the Supreme Court [had] discussed decisions denying institution, \*\*\* it suggested such decisions are unreviewable” and “committed to agency discretion.” *Id.* at 7a (quoting *Cuozzo*, 136 S. Ct. at 2140). The Federal Circuit further observed that neither section 319 (limited to appeals of “final written decisions under section 318(a)”) nor the Administrative Procedure Act (which “is not a jurisdiction-conferring statute”) supported Mylan’s appeal from a non-institution decision. *Id.* at 7a-8a. Thus, with “no statute confer[ring] jurisdiction over appeals from decisions denying institution,” the Federal Circuit granted Janssen’s motion to dismiss. *Id.* at 8a.

At the same time, the Federal Circuit determined that “judicial review is available in extraordinary circumstances by petition for mandamus” because “[a] decision denying institution prevents the Board from issuing any final decision that falls within [its] direct appellate jurisdiction.” Pet. App. 8a-12a. In this case, however, Mylan did not satisfy the standard for mandamus relief. In analyzing Mylan’s statutory

claims, the Federal Circuit again emphasized that “[t]he Director is permitted, but never compelled, to institute an IPR,” and that “no petitioner has a right to such institution.” *Id.* at 13a-15a. In analyzing Mylan’s constitutional claim, the Federal Circuit observed that Mylan had not identified a constitutionally cognizable right of which it was deprived, and, in any event, would “not be bound by the Teva litigation” and remained “free to litigate the ’906 patent claims’ validity in its own district court case.” *Id.* at 15a.

Mylan did not seek rehearing before the Federal Circuit.

#### **REASONS FOR DENYING THE PETITION**

The Federal Circuit’s conclusion that section 314(d) precludes Mylan’s appeal from a decision denying institution of inter partes review is dictated by the statute’s text, as confirmed by this Court on more than one occasion. Accordingly, there is no reason for this Court to intervene—especially in light of a pending PTO rulemaking proceeding implicating the *NHK-Fintiv* factors, pending legislation seeking to limit their application, and ongoing district court litigation challenging those factors on the same grounds that Mylan raises. The petition should be denied.

**I. DISMISSAL OF MYLAN'S NON-  
INSTITUTION APPEAL FOLLOWS FROM  
THE PLAIN LANGUAGE OF THE AIA AND  
THIS COURT'S PRECEDENTS**

**A. As This Court's Precedents Dictate,  
Section 314(d) Expressly Precludes  
Mylan's Appeal**

Section 314(d) of the AIA plainly bars Mylan's appeal of "the Board's determination to deny institution under 35 U.S.C. § 314(a)." Notice of Appeal 1, No. 21-1071 (Fed. Cir.), ECF No. 1-2. After all, "that is what § 314(d) says. It states that the 'determination by the [Patent Office] whether to institute an inter partes review under this section shall be *final* and *non-appealable*.'" *Cuozzo*, 136 S. Ct. at 2139 (alteration in original) (quoting 35 U.S.C. § 314(d)). Because "Congress has told the Patent Office to determine whether inter partes review should proceed, and it has made the agency's decision 'final' and 'nonappealable,'" the "conclusion that courts may not revisit this initial determination gives effect to this statutory command." *Id.* at 2141 (emphasis omitted). That statutory command also "preclud[es] review of the Patent Office's institution decisions with sufficient clarity to overcome the strong presumption in favor of judicial review." *Thryv*, 140 S. Ct. at 1373 (alteration in original) (internal quotation marks omitted).

Beyond section 314(d)'s text, several "features" of the statutory scheme "point in favor of precluding review of the Patent Office's institution decisions." *Cuozzo*, 136 S. Ct. at 2141 (emphasizing section 314(d)'s "place in the overall statutory scheme, its role alongside the Administrative Procedure Act, the prior

interpretation of similar patent statutes, and Congress' purpose in crafting inter partes review"). In particular, section 319 works in tandem with section 314(d) to "limit[] appellate review to the 'final written decision'" issued under section 318(a). *Id.* at 2140; *see also* 35 U.S.C. § 141(c) ("A party to an inter partes review \*\*\* who is dissatisfied with the final written decision of the Patent Trial and Appeal Board *under section 318(a)* \*\*\* may appeal the Board's decision only to the United States Court of Appeals for the Federal Circuit.") (emphasis added). Section 318(a), in turn, makes clear that a "final written decision" on "the patentability of any patent claim challenged by the petitioner" will issue only "if an inter partes review is instituted." 35 U.S.C. § 318(a). The institution decision, of course, is a distinct determination made under section 314 that authorizes the Board to "commence" and "conduct" the review that culminates in the final written decision. *Id.* §§ 314(c), 316(c).

The AIA's appeal provisions thus reflect Congress's decision to "separate[] the Director's decision to 'institute' the review, § 314, on one hand, from the Board's 'conduct' of the review 'instituted' by the Director, § 316(c), and the Board's subsequent 'written decision,' § 318, on the other." *St. Jude Med., Cardiology Div., Inc. v. Volcano Corp.*, 749 F.3d 1373, 1375 (Fed. Cir. 2014). In other words, "[t]he statute \*\*\* establishes a two-step procedure for *inter partes* review: the Director's decision whether to institute a proceeding, followed (if the proceeding is instituted) by the Board's conduct of the proceeding and decision with respect to patentability." *Id.* at 1375-1376. The corresponding appeal provisions "provide[] for an

appeal to [the Federal Circuit] only of the Board’s decision at the second step, not the Director’s decision at the first step.” *Id.* at 1376.

The discretionary nature of the institution decision reinforces that straightforward reading of the statutory scheme. Although section 314(a) sets a “reasonable likelihood” standard for institution, it imposes “no mandate to institute review” even when that standard is met. *Cuozzo*, 136 S. Ct. at 2140; *see id.* at 2153 (Alito, J., concurring in part and dissenting in part) (“I agree that one can infer from the statutory scheme that the Patent Office has discretion to deny inter partes review even if a challenger satisfies the threshold requirements for review.”). Instead, it limits the Director’s discretion to *grant* (not *deny*) institution of inter partes review. *See* 35 U.S.C. § 314(a) (providing that “Director may not authorize an inter partes review to be instituted *unless*” standard is met) (emphasis added).

Consequently, as this Court has acknowledged repeatedly, the “decision to deny a[n] [inter partes review] petition is a matter committed to the Patent Office’s discretion.” *Cuozzo*, 136 S. Ct. at 2140; *see United States v. Arthrex*, 141 S. Ct. 1970, 1977 (2021) (“Congress has committed the decision to institute inter partes review to the Director’s unreviewable discretion.”); *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1356 (2018) (“[Section] 314(a) invests the Director with discretion on the question whether to institute review[.]”) (emphasis omitted); *Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC*, 138 S. Ct. 1365, 1378 n.5 (2018) (“[T]he decision to institute review is made by the Director and committed to his

unreviewable discretion.”). Such discretionary agency decisionmaking is well understood to fall outside the scope of judicial review. *See Cuozzo*, 136 S. Ct. at 2140 (citing 5 U.S.C. § 701(a)(2)). And to the extent the denial of institution might be viewed as final agency action appealable under the Administrative Procedure Act, even the *Cuozzo* dissent (which read section 314(d) to prevent interlocutory appeals of affirmative decisions to institute) embraced the conclusion that section 314(d) would serve the “clarifying role” of “prevent[ing] an appeal from a decision *not* to institute inter partes review.” *Id.* at 2153 (Alito, J., concurring in part and dissenting in part).

It is not “surprising that Congress would design such a scheme” that “leaves no apparent avenue (short of mandamus, at least) for judicial review of decisions *not* to institute inter partes review.” 136 S. Ct. at 2153 n.6 (Alito, J., concurring in part and dissenting in part). As Justice Alito explained (despite proposing a less categorical interpretation of section 314(d)’s appeal bar than adopted by the majority):

A patent challenger does not have nearly as much to lose from an erroneous *denial* of inter partes review as a patent owner stands to lose from an erroneous *grant* of inter partes review. Although such a challenger loses some of the advantages of inter partes review (such as \*\*\* a lower burden of proof), it remains free to challenge the patent’s validity in litigation. A patent owner, on the other hand, risks the destruction of a valuable property right.

*Id.*

The foregoing easily disposes of Mylan's appeal, which challenges the PTO's non-institution decision, for lack of appellate jurisdiction.

**B. Mylan Cannot Overcome The Statutory Appeal Bar**

Mylan admits that "Congress gave the Director discretion to determine whether to institute IPR under § 314(a)" and that "[t]he Director's discretion to institute (or not institute) IPR is typically unreviewable." Pet. 7-8. Mylan nonetheless reads the statutory scheme and this Court's precedents to allow an appeal in this case. That reasoning fails in every respect.

*1. Mylan misreads section 1295(a)(4)(A) and SAS Institute.*

**a.** The only statutory provision that Mylan identifies as supporting Federal Circuit jurisdiction over non-institution appeals is 28 U.S.C. § 1295(a)(4)(A). Under that provision, the Federal Circuit has exclusive jurisdiction "of an appeal from a decision of \*\*\* the Patent Trial and Appeal Board of the United States Patent Trademark Office with respect to \*\*\* inter partes review under title 35." *Id.* As an initial matter, whether that provision is "perhaps broad enough to reach an appeal from a decision denying institution" is far from a given and a question the Federal Circuit did not resolve. Pet. App. 6a; *see* Amicus Br. of Jeremy C. Doerre 2-16 (arguing that section 1295(a)(4)(A)'s reference to a decision of the "Board" does not encompass the institution decision that Congress assigned to the Director (even though delegated by regulation to the Board), and that

a contrary reading would raise constitutional concerns).

In any event, whatever the precise scope of section 1295(a)(4)(A) standing alone, this Court “do[es] not \*\*\* construe statutory phrases in isolation; [it] read[s] statutes as a whole.” *Samantar v. Yousuf*, 560 U.S. 305, 319 (2010) (ellipsis in original); see *Deal v. United States*, 508 U.S. 129, 132 (1993) (reiterating “fundamental principle of statutory construction (and, indeed, of language itself) that the meaning of a word cannot be determined in isolation, but must be drawn from the context in which it is used”). In that regard, “[i]t is a commonplace of statutory construction that the specific governs the general.” Pet. App. 6a (quoting *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384 (1992)).

Notably, Mylan offers no answer to the Federal Circuit’s conclusion that “§ 314(d), the more specific statute, dispels any \*\*\* notion” that section 1295(a)(4) is “perhaps broad enough to reach an appeal from a decision denying institution.” Pet. App. 6a. When the statutory provisions are read together, “[s]ection 314(d) prevents ‘appeal’ from a decision denying institution,” and “[w]ithout the ability to ‘appeal,’ parties cannot make use of § 1295(a)(4)’s jurisdictional grant.” *Id.* That explains why this Court’s decisions in *Cuozzo*, *SAS Institute*, and *Thryv* focus on section 314(d) (and its interplay with section 319’s “final written decision” appeal authorization) without once mentioning section 1295(a)(4)(A). It also explains why Mylan itself devotes the bulk of its jurisdictional argument (Pet. 15-21) to overcoming the “impediment” of section 314(d).

b. Mylan insists (Pet. 17) that this Court has created an “*ultra vires* exception to § 314(d)” that permits non-institution appeals. But this Court has had no opportunity to articulate such an atextual exception. As the Federal Circuit observed, “[e]very relevant Supreme Court case involved an appeal from a final written decision—not an institution decision.” Pet. App. 7a. Mylan accuses the Federal Circuit of using that indisputable reality as a means to “brush[] aside this Court’s limits on the scope of § 314(d).” Pet. 18-21. But the Federal Circuit had no need to avoid any of this Court’s explications of section 314(d) because they do not help Mylan.

In the context of reviewing a final written decision, *Cuozzo* held that section 314(d) bars judicial review “of questions that are closely tied to the application and interpretation of statutes related to the Patent Office’s decision to initiate inter partes review.” 136 S. Ct. at 2141. Although the Court “d[id] not categorically preclude review of a final decision where a petition fails to give ‘sufficient notice’ such that there is a due process problem with the entire proceeding,” that caveat by its terms refers to a “review of a final decision” following a grant of institution. *Id.* Likewise, in the situation where review might be available when the Board “act[s] outside its statutory limits by, for example, canceling a patent claim for ‘indefiniteness under § 112’ in inter partes review,” *id.*, such a cancellation of claims could occur only in the final written decision when the Board actually passes upon “the patentability of any patent claim challenged by the petitioner,” 35 U.S.C. § 318(a).

Confirming as much, the Court wrapped up that discussion by stating that “[s]uch ‘shenanigans’ may be properly reviewable *in the context of § 319 and under the Administrative Procedure Act.*” 136 S. Ct. at 2142 (emphases added). But as explained above (p. 9, *supra*), section 319 permits appeals only from a “final written decision” following a grant of institution; the denial of institution never results in appellate review “in the context of § 319.” 136 S. Ct. at 2142. The same is true of review under the Administrative Procedure Act; the denial of institution would be “a matter committed to the Patent Office’s discretion,” thus rendering such review unavailable. *Id.* (citing 5 U.S.C. § 701(a)(2)); *see also id.* at 2153 & n.6 (Alito, J., concurring in part and dissenting in part).

*SAS Institute* does not support an “*ultra vires* exception” for non-institution decisions either. In that case, the Court took up an appeal following a grant of institution and held that, once it granted institution, the PTO could not pick and choose which patent claims to review. *See* 138 S. Ct. at 1353 (“The agency cannot curate the claims at issue but must decide them all.”). Critically, the Court grounded that “clear answer” in a statute that governs final written decisions: “the Patent Office must ‘issue a final written decision with respect to the patentability of *any* patent claim challenged by the petitioner.’” *Id.* (quoting 35 U.S.C. § 318(a)).

Mylan offers a more expansive reading of *SAS Institute*, based on the Court’s statement that “nothing in § 314(d) or *Cuozzo* withdraws our power to ensure that an inter partes review proceeds in accordance with the law’s demands.” 138 S. Ct. at 1359. But this

Court in *Thryv* squarely rejected the suggestion that *SAS Institute* opened the door to challenging institution decisions—let alone non-institution decisions—as unlawful on appeal. *Thryv* concerned a challenge to a decision to *grant* institution of inter partes review after the one-year time limit set forth in section 315(b). In finding such an appeal barred by section 314(d), the Court explained that *SAS Institute*’s “reviewability holding is inapplicable here, for Click-to-Call’s appeal challenges not the manner in which the agency’s review ‘proceeds’ once instituted, but whether the agency should have instituted review at all.” 140 S. Ct. at 1376.

*Thryv*’s reasoning is even easier to apply here. In appealing from the *denial* of institution, Mylan by definition cannot be pursuing a (permissible) challenge to “the manner in which the agency’s review ‘proceeds’ once instituted.” 140 S. Ct. at 1376. To the contrary, Mylan is unmistakably pursuing a (precluded) challenge to “whether the agency should have instituted review at all.” *Id.* It is therefore anything but “impossible” (Pet. 19) to explain how the decision below fits with *SAS Institute*. *Thryv* does just that.

Mylan is thus left to surmise that after *Thryv* a party may still appeal a non-institution decision that “*ignor[es]* [a] statute” governing institution even though it may not appeal a non-institution decision that “*misappl[ies]* [such a] statute.” Pet. 17. That distinction appears nowhere in *Thryv*. For good reason: in either scenario, the complaint is that the institution decision itself is unlawful because the PTO “acted in excess of the boundaries placed on it.” *Id.*

That is precisely what *Thryv* held section 314(d) to prohibit. See 140 S. Ct. at 1376 (disagreeing with Click-to-Call’s “doubts that Congress would have limited the agency’s institution authority in § 315(b) without ensuring judicial supervision”).

2. *Mylan’s yet-to-be-adjudicated substantive and procedural attacks on the Director’s discretion lack merit.*

Despite the fact that the decision below held on a threshold motion to dismiss that Mylan’s appeal must be dismissed for lack of jurisdiction, Mylan invites this Court to resolve the merits of whether “the *NHK-Fintiv* Rule substantively and procedurally [is] unlawful.” Pet. ii. That invitation is highly imprudent. The Federal Circuit did not reach those issues, and this Court is “a court of review, not of first view.” *Cutter v. Wilkinson*, 544 U.S. 709, 718 n.7 (2005).

Beyond that threshold obstacle, Mylan’s substantive challenge to the *NHK-Fintiv* factors is bound up with the statutory provisions governing initiation of inter partes review. It thus runs headlong into this Court’s statement that section 314(d) bars review of questions “closely tied to the application and interpretation of statutes related to the Patent Office’s decision to initiate inter partes review.” *Cuozzo*, 136 S. Ct. at 2141. That is true even if, contrary to all indications (see pp. 8-17, *supra*), Congress or this Court contemplated appellate jurisdiction over some hypothetical subset of non-institution decisions.

In any event, Mylan is wrong that the *NHK-Fintiv* factors “allow[] the Director to substitute his

judgment of what constitutes a timely filed petition \*\*\* for that of Congress.” Pet. 23-26. The Director is not finding that an inter partes review petition is untimely; rather, the Director is exercising discretion as to how best to use Board resources. Neither section 315(b), nor any of the other cited statutory provisions, eliminates the exercise of discretion to deny an institution petition that meets all of the statutory prerequisites, for there is “no mandate to institute review.” *Cuozzo*, 136 S. Ct. at 2140; *see pp.* 10-11, *supra*; *see also* 35 U.S.C. § 315(a)(1) (providing condition that institution may not be granted if civil action challenging validity of a patent claim filed previously by petitioner or real party interest); 35 U.S.C. § 315(a)(2) (providing for stay in *district court*); *id.* § 325(d) (providing for manner in which Director should consider related PTO proceedings); Amicus Br. of Intel, Corp. 10-11 (conceding that section 315(b) “does not prohibit the PTAB from denying institution even of timely filed petitions”).

Mylan’s notice-and-comment rulemaking challenge fares no better. The *NHK-Fintiv* factors are a general statement of policy excepted from notice-and-comment rulemaking. 5 U.S.C. § 553(b)(3)(A); *see* PTO Summ. J. Opp’n 21-23, *Apple Inc. v. Iancu*, No. 5:20-cv-6128 (N.D. Cal.), ECF No. 91. They do not impose any rights or obligations on parties and leave the Director free to exercise discretion, while guided by a consistent framework. *See, e.g., Clarian Health West, LLC v. Hargan*, 878 F.3d 346, 357-359 (D.C. Cir. 2017) (upholding criteria used to determine whether Medicare payments are subject to reconciliation because criteria “merely explain[] how the agency will

enforce a statute or regulation—in other words, how it will exercise its broad enforcement discretion,” and emphasizing that “[i]f the agency so chooses, it may forego notice-and-comment procedures and announce through a policy statement its intentions for future adjudications”). Contrary to Mylan’s characterization (Pet. 9), it is *not* the case that institution is automatically denied once a certain number of factors have been satisfied. *See, e.g., Fintiv*, 2020 WL 2126495, at \*2-\*3 & n.5 (describing “holistic view” of “non-dispositive factors” and “balanced assessment of all relevant circumstances” rather than “bright-line rule”).

## **II. REVIEW OF THE QUESTIONS PRESENTED IS UNWARRANTED, PARTICULARLY AT THIS TIME**

Unsurprisingly, in the near decade since the inception of inter partes review, neither this Court nor the Federal Circuit has *ever* exercised appellate jurisdiction over a case in which the PTO declined to institute. This case presents no reason to break from that established precedent and practice. To the contrary, several reasons counsel against accepting review of the questions presented at this time (if ever).

*First*, further percolation is warranted. To quote Mylan, “[n]o court has addressed the merits of the *NHK-Fintiv* Rule.” Pet. 32. Neither should this Court in the first instance. *See* p. 17, *supra*.

As to the jurisdictional question presented, in briefing below, Mylan underscored that the Federal Circuit’s existing decisions enforcing the section 314(d) appeal bar had been non-precedential or

distinguishable because they did not involve a constitutional claim. See Mylan Opp’n 16-17, No. 21-1071 (Fed. Cir.), ECF No. 16. Mylan could have, but did not, seek rehearing of the precedential decision below. Because “[a] petition for rehearing en banc is rarely appropriate if the appeal was the subject of a nonprecedential opinion by the panel of judges that heard it,” Practice Notes to Rule 35, Federal Circuit Rules of Practice (2021), this case was the first meaningful opportunity to seek en banc review on the jurisdictional question. This Court should permit the full Federal Circuit an opportunity to weigh in first.<sup>2</sup>

*Second*, the questions presented would be litigated against an uncertain and potentially shifting landscape. Although not required by law to do so, the PTO has initiated notice-and-comment rulemaking on

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<sup>2</sup> Mylan notes that the en banc Federal Circuit previously declined to wade into a (supposed) conflict with the decision in *Arthrex, Inc. v. Smith & Nephew, Inc.*, which held that an adverse judgment under 37 C.F.R. § 42.73(b) that disposes of an inter partes review proceeding is appealable as a final decision. 880 F.3d 1345 (Fed. Cir. 2018). But the Federal Circuit has consistently explained (including in the decision below) that *Arthrex* is distinguishable because it did not concern a non-institution appeal. 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.”); see also *ARRIS Int’l PLC v. ChanBond, LLC*, 773 F. App’x 605, 606 (Fed. Cir. 2018) (“*Arthrex* distinguished *St. Jude*, stating that ‘*St. Jude* did not involve a similar situation, and the availability of appeal of final adverse judgment decisions was not directly addressed in that case.’”). Indeed, *Arthrex* itself acknowledged that “[t]here [wa]s no contention that the statutory appeal-bar provision applies.” 880 F.3d at 1348.

the discretionary factors governing institution of inter partes review. The PTO has received over 800 comments in response to a request for public input “on considerations for instituting trials before the Office under the [AIA],” as it weighs “codification of its current policies and practices”—including use of the *NHK-Fintiv* factors. 85 Fed. Reg. at 66,502-66,505. That proceeding has not yet concluded.

At the same time, Congress is considering a bill relating to the *NHK-Fintiv* factors. Restoring the America Invents Act, S. 2891, 117th Cong. § 2(3) (2021). If enacted, such legislation would moot the question presented.

Further complicating the situation, a motion for summary judgment challenging the *NHK-Fintiv* factors on the same grounds as Mylan is ripe for resolution in federal district court. *See Apple Inc. v. Iancu*, No. 5:20-cv-6128 (N.D. Cal.). If that court (or another court) ultimately opines on the PTO’s use of the *NHK-Fintiv* factors, as other like-minded challengers seek, then the issue will not have “evaded judicial review.” Pet. 32. Accordingly, developments in either the pending rulemaking proceeding or the pending district court challenge could materially impact—if not outright obviate—this Court’s review.

*Third*, Mylan does not seek review of the Federal Circuit’s mandamus reasoning. Pet. App. 8a-15a. That undermines Mylan’s proclamation that the Federal Circuit “effectively handed the Director and the Board *carte blanche* to deny IPR petitions for any random (and potentially unlawful) reason they can dream up.” Pet. 29. Should the PTO “categorically refuse to hear certain kinds of cases (*e.g.*,

pharmaceutical patents) in the name of conserving scarce resources” or “engage in outright arbitrary behavior by denying petitions based upon a lottery, coin flips, or drawing names out of a hat,” *id.* at 29-30, this Court will have ample opportunity to police such conduct (assuming the Federal Circuit somehow does not do so through mandamus review).

Mylan’s appeal, by contrast, does not come close to implicating such farfetched hypotheticals. The denial of institution for reasons of administrative efficiency, taking into account the progression of parallel district court litigation involving Mylan itself, does not require a court to “explore the outer contours” of discretion. Pet. App. 13a-15a. And Mylan does not provide any reason to second-guess the Federal Circuit’s conclusion that Mylan “fail[ed] to state a colorable claim for constitutional relief,” when it could not identify the deprivation of a relevant right (including to inter partes review) and remains free to challenge the validity of the ’906 patent claims in its ongoing district court litigation with Janssen. *Id.* at 15a.

**CONCLUSION**

For the foregoing reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted.

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