IN THE

Supreme Court of the United States

MYLAN LABORATORIES LTD.,

Petitioner,

v.

JANSSEN PHARMACEUTICA, N.V.,

and

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

Patent and Trademark Office.

Respondents.

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

PETITION FOR A WRIT OF CERTIORARI

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

KATTEN MUCHIN

ROSENMAN LLP

2900 K Street, NW

Washington, DC 20007

robert.smith1@katten.com

202-625-3500

Counsel for Petitioner

QUESTIONS PRESENTED

The Director of the U.S. Patent and Trademark Office (acting through the Patent Trial and Appeals Board) has created a six-factor test known as the *NHK-Fintiv* Rule to determine whether to institute *inter partes* review in light of parallel infringement litigation pending in district court. Under *NHK-Fintiv*, the Board may deny a petition if it believes that the parallel litigation has may proceed too far for IPR to be of any efficient use. That is true even if the IPR petition is timely filed within one year of the petitioner being served with a patent-infringement complaint, 35 U.S.C. § 315(b), and otherwise complies with Congress's express limitations related to co-pending litigation in other fora.

The practical import of the *NHK-Fintiv* Rule is that it allows the Director to truncate the explicit time limit created by Congress. Indeed, the Board has wielded the *NHK-Fintiv* Rule to terminate scores of timely filed petitions since March 2020. Worse, this "rule" is not the product of a formal rulemaking, despite Congress's command that the Director "prescribe regulations" setting forth the standards and rules governing the institution of IPR. 35 U.S.C. § 316(a). *NHK-Fintiv* is instead a creature of two precedential Board decisions from which it takes its name. It has never faced public comment, let alone judicial review.

In this case, Petitioner appealed non-institution of its IPR petition under *NHK-Fintiv* because the rule exceeds the substantive and procedural limitations placed on the Director's authority by Congress. Notwithstanding the general prohibition on appellate

review of IPR institution decisions, 35 U.S.C. § 314(d), review is available to rein in the Director's overreach, *SAS Inst. Inc.* v. *Iancu*, 138 S. Ct. 1348, 1359 (2018).

The Federal Circuit refused to hear the appeal. But instead of deciding whether this case fell within the scope of *SAS*'s exception to the appellate bar, it construed § 314(d) as establishing a categorical rule that *all* non-institution decisions are nonappealable—in direct conflict with *SAS*. In light of this, the panel below said it had no jurisdiction under 28 U.S.C. § 1295(a)(4)(A), which otherwise provides the Federal Circuit authority to review an "appeal" from a "decision" of the Board "with respect to ... *interpartes* review."

The questions presented are:

- 1. Does 35 U.S.C. § 314(d) categorically preclude appeal of all decisions not to institute *inter partes* review?
- 2. Is the *NHK-Fintiv* Rule substantively and procedurally unlawful?

PARTIES TO THE PROCEEDING BELOW AND RULE 29.6 STATEMENT

Petitioner Mylan Laboratories Ltd., the Appellant below, is a subsidiary of Mylan, Inc., which in turn is a wholly owned subsidiary of Viatris Inc. Viatris has no parent company, and no publicly held company owns 10% or more of its stock.

Respondents are: Janssen Pharmaceutica, N.V., the Appellee below; and Andrew Hirshfeld, in his capacity performing the functions and duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, the Intervenor below.

TABLE OF CONTENTS

Que	estio	ns Presented	.i
Par		to the Proceeding Below Rule 29.6 Statementi	ii
Tab	le of	f Authorities	⁄i
Inti	odu	ction	1
Opi	nion	ns Below	4
Jur	isdio	etion	4
Sta	tuto	ry Provisions Involved	5
Sta	teme	ent	5
		s for Granting the Writ1	
I.	The	e Decision Below Is Erroneous and afficts With This Court's Precedent1	4
	A.	The Federal Circuit Had Jurisdiction to Hear This Case1	4
	В.	The NHK-Fintiv Rule Exceeds the Authority that Congress Delegated to the Director	1
II.		e Questions Presented Are Exceptionally portant2	9
	A.	The Federal Circuit's Misapplication of § 314(d) Severely Limits the Ability to Challenge Misconduct by the Director and Has Created Confusion Regarding Appellate Jurisdiction over IPRs	9
	В.	The NHK-Fintiv Rule Has Evaded Judicial Review and Continues to Disrupt the IPR System	2
Cor	clus	·	5

Appendix A: Order of the U.S. Court of Appeals for the Federal Circuit (Mar. 12, 2021)1	a
Appendix B: Decision of the U.S. Patent and Trade Mark Office, Patent Trial and Appeal Board (Sept. 16, 2020)178	a
Appendix C: Statutory Provisions Involved	
28 U.S.C. § 1295(a)(4)(A)45	a
35 U.S.C. § 314(a), (d)46	a
35 U.S.C. § 315(b)46	a
35 U.S.C. § 316(a)(2), (4)478	

TABLE OF AUTHORITIES

CASES: Aqua Prods., Inc. v. Matal, 872 F.3d 1290 (Fed. Cir. 2017)27 Arthrex, Inc. v. Smith & Nephew, Inc., 880 F.3d 1345 (Fed. Cir. 2018)31 Cisco Sys. Inc. v. Ramot at Tel Aviv *Univ. Ltd.*, 834 F. App'x 571 (Fed. Cir. 2020)32 City of Arlington v. FCC, 569 U.S. 290 (2013)......22, 24 Click-To-Call Techs., LP v. Ingenio, Inc., 899 F.3d 1321 (Fed. Cir. 2018)20 Cuozzo Speed Techs., LLC v. Lee, 136 S. Ct. 2131 (2016)......passim Dep't of Comm. v. New York, 139 S. Ct. 2551 (2019)......22 Holmberg v. Armbrecht, 327 U.S. 392 (1946)......23 In re Cuozzo Speed Techs., LLC, 793 F.3d 1268 (Fed. Cir. 2015)20 In re Dominion Dealer Sols., LLC, 749 F.3d 1379 (Fed. Cir. 2014)30 In re Power Integrations, Inc., 899 F.3d 1316 (Fed. Cir. 2018)30 Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd., 821 F.3d 1359 (Fed. Cir. 2016)6

Kisor v. Wilkie,
139 S. Ct. 2400 (2019)26
La. Pub. Serv. Comm'n v. FCC, 476 U.S. 355 (1986)21
Leedom v. Kyne, 358 U.S. 184 (1958)17
Lincoln v. Vigil, 508 U.S. 182 (1993)20
<i>Microsoft Corp.</i> v. <i>i4i Ltd. P'ship</i> , 564 U.S. 91 (2011)6
Perez v. Mortg. Bankers Ass'n, 575 U.S. 92 (2015)27
Petrella v. Metro-Goldwyn-Mayer, Inc., 572 U.S. 663 (2014)23, 24
SAS Inst., Inc. v. ComplementSoft, LLC, 825 F.3d 1341 (Fed. Cir. 2016)20
SAS Institute Inc. v. Iancu, 138 S. Ct. 1348 (2018)passim
SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC,
137 S. Ct. 954 (2017)23
SEC v. Chenery Corp., 332 U.S. 194 (1947)28
St. Jude Med., Cardiology Div., Inc. v. Volcano Corp., 749 F.3d 1373 (Fed. Cir. 2014)31
Thryv, Inc. v. Click-To-Call Techs., LP, 140 S. Ct. 1367 (2020)17, 18, 19, 20
United States v. Arthrex, Inc., 141 S. Ct. 1970 (2021)

US Inventor Inc. v. Hirshfeld, No. 21-CV-00047, 2021 WL 2936385 (E.D. Tex. July 13, 2021)	33
Weyerhaeuser Co. v. U.S. Fish & Wildlife Serv.,	
139 S. Ct. 361 (2018)	20
STATUTES AND LEGISLATIVE MATERIALS:	
5 U.S.C. § 551(4)	10, 27
5 U.S.C. § 553	26
5 U.S.C. § 553(b)	26
5 U.S.C. § 553(c)	26, 28
5 U.S.C. § 701(a)(2)	20
28 U.S.C. § 1254(1)	5
28 U.S.C. § 1295(a)(4)(A)	passim
35 U.S.C. § 2(b)(2)(B)	26, 27
35 U.S.C. § 141(c)	31
35 U.S.C. § 311(a)	6
35 U.S.C. § 311(b)	5, 6
35 U.S.C. § 311(c)	22
35 U.S.C. § 312(a)	23
35 U.S.C. § 312(a)(3)	6
35 U.S.C. § 313	7
35 U.S.C. § 314(a)	passim
35 U.S.C. § 314(b)	5
35 U.S.C. § 314(d)	passim
35 U.S.C. § 315(a)(1)	22. 25

35 U.S.C. § 315(a)(2)	25
35 U.S.C. § 315(b)	1, 7, 22, 25
35 U.S.C. § 315(d)	25
35 U.S.C. § 316(a)	1, 8, 27, 28
35 U.S.C. § 316(a)(2)	
35 U.S.C. § 316(a)(4)	
35 U.S.C. § 316(a)(11)	5
35 U.S.C. § 316(e)	6
35 U.S.C. § 318(a)	22, 31
35 U.S.C. § 319	19, 20
35 U.S.C. § 325(d)	25
Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011)	5
America Invents Act, H.R. 1249, 112th Cong. (introduced Mar. 30, 2011)	23
Patent Reform Act of 2011, S. 23, 112th Cong. (introduced Jan. 25, 2011)	23
Patent Reform Act of 2011, S. 23, 112th Cong. (reported Feb. 3, 2011)	23
H.R. Rep. No. 112-98 (2011)	5
REGULATIONS AND AGENCY MATERIALS:	
37 C.F.R. § 42.4(a)	6, 7
77 Fed. Reg. 48612 (Aug. 14, 2012)	8
77 Fed. Reg. 48680 (Aug. 14, 2012)	8
83 Fed. Reg. 51340 (Oct. 11 2018)	8

PTAB DECISIONS: Apple Inc. v. Fintiv, Inc., IPR2020-00019, 2020 WL 2126495 Mylan Labs. v. Janssen Pharmaceutica NV, IPR2020-00440 (PTAB Feb, 07, 2020)......10, 11, 12 NHK Spring Co. v. Intri-Plex Techs., Inc., IPR2018-00752, 2018 WL Philip Morris Prod., S.A. v. Rai Strategic Holdings, Inc., No. IPR2020-00921, 2020 WL 6750120 (PTAB Nov. 16, 2020)......24 OTHER AUTHORITIES: J. Jonas Anderson & Paul Gugliuzza, Federal Judge Seeks Patent Cases, Judge Albright Now Oversees 20% of New US Patent Cases (Mar. 10, 2021), https://www.law360.com/ articles/1361071/judge-albright-nowoversees-20-of-new-us-patent-case......35 Mapping the Contours of PTAB Discretionary Denials In 2020 (Dec. 15, 2020), https://www.law360.com/ articles/1335699/mapping-the-contoursof-ptab-discretionary-denials-in-202......34 Patent Trial and Appeal Board, Standard Operating Procedure 2

Unified Patents, Portal, https://bit.ly/3fCDI5b (last visited Aug. 5, 2021)33
Unified Patents, PTAB Discretionary Denials Up 60%+ in 2020: Fueled Entirely by 314(a) Denials (Jan. 5, 2021), https://www.unifiedpatents. com/insights/2020-ptab- discretionary-denials-report
DOCKETED CASES:
Apple Inc. v. Iancu, No. 20-cv-6128 (N.D. Cal.)33
Apple Inc. v. Maxell, Ltd., Nos. 20-2132, -2211-2213, 21-1033 (Fed. Cir.)
Apple Inc. v. Optis Cellular Tech., LLC, Nos. 21-1043, -1044, -1046 (Fed. Cir.)31, 32
Apple v. Optis Cellular Tech., LLC, No. 21-118 (U.S.)
Google LLC v. Uniloc 2017 LLC, No. 20-2040 (Fed. Cir.)32
Intel Corp. v. VLSI Tech. LLC, Nos. 21-1614, -1616-1617, -1673- 1677, -1738-1741 (Fed. Cir.)31, 32
Janssen Pharm., Inc. v. Mylan Labs. Ltd., No. 19-cv-16484 (D.N.J.)10, 11
Janssen Pharm., Inc. v. Teva Pharm. USA, Inc., No. 18-cv-00734 (D.N.J.)10, 12

INTRODUCTION

This petition presents important questions about the judiciary's ability to oversee the administrative state and the limits of agency discretion. Back in May 2020, the PTO designated two Board decisions as "precedential." Through this internal administrative maneuvering, the *NHK-Fintiv* Rule was born—a multi-factor test that asks whether, separate and apart from the merits, institution of *inter partes* review should be denied because it would be "an inefficient use of Board resources in light of the 'advance state' of parallel district court litigation" involving the same patent claims. Apple Inc. v. Fintiv, Inc., IPR2020-00019, 2020 WL 2126495, at *1 (PTAB Mar. 20, 2020) (quoting NHK Spring Co. v. Intri-Plex Techs., Inc., IPR2018-00752, 2018 WL 4373643, at *7 (PTAB Sept. 12, 2018)). The rule did not face public comment. Nor has it been reviewed on the merits by a federal court. And if the Director has his way, it never will.

The NHK-Fintiv Rule is unlawful. Substantively, the rule renders Congress's one-year period for seeking IPR illusory. 35 U.S.C. § 315(b). It allows the Board to reject a timely filed IPR petition as "too late" to be of any utility, based upon the Board's assessment of the then-existing trial schedule in copending litigation—schedules that oftentimes are extended. Procedurally, the Director violated Congress's command to promulgate substantive rules establishing standards for instituting *inter partes* review. 35 U.S.C. § 316(a). He instead created the rule by fiat, slapping labels of precedential on Board decisions months (in the case of *Fintiv*) and years (in the case of *NHK*) after they were issued.

Despite its short life, *NHK-Fintiv* has resulted in chaos. Numerous timely filed IPR petitions have been denied due to little more than an aggressive (and oftentimes unrealistic) district-court scheduling order. Worse, the rule has encouraged plaintiffs to seek out courts that boast break-neck trial schedules in patent cases, hoping that filing in these jurisdictions will minimize the chance of facing IPR. Particularly in light of the lack of public input, the patent community is understandably upset about the *NHK-Fintiv* Rule and has raised a slew of challenges against it. This is one such case.

Mylan sought review by the Federal Circuit after the Board denied its IPR petition against Janssen using the NHK-Fintiv Rule. Mylan invoked 28 U.S.C. § 1295(a)(4)(A), which vests the Federal Circuit with jurisdiction to review an "appeal" from a "decision" of the Board "with respect to ... inter partes review." The Federal Circuit held that 35 U.S.C. § 314(d) withdrew its jurisdiction, but that holding conflicted with decisions of this Court. In SAS Institute Inc. v. *Iancu*, for example, this Court held that § 314(d) is no impediment where the Board "exceed[s] its statutory bounds," and "judicial review remains available consistent with the Administrative Procedure Act, which directs courts to set aside agency action 'not in accordance with law or in excess of statutory jurisdiction, authority, or limitations." 138 S. Ct. 1348, 1359 (2018) (quoting Cuozzo Speed Techs., LLC v. Lee, 136 S. Ct. 2131, 2141 (2016)). Such is the case here. No amount of discretion allows an agency to ignore congressional limits on its power, enact rules in a congressionally forbidden manner, or violate the

Constitution. That is exactly what the Director did with *NHK-Fintiv* Rule.

The Federal Circuit distinguished Cuozzo and SAS because both involved "an appeal from a final an institution decision." decision—not Pet.App.7a. But that distinction has no support in the text of § 314(d) and clashes with this Court's precedent. In SAS, this Court reviewed the Board's decision not to institute review on all claims in an IPR petition. 138 S. Ct. at 1359. The Court held that "the statute forbids [t]his partial institution practice," and it rejected the Director's contention that § 314(d) precluded "judicial review of any legal question bearing on the institution of *inter partes* review." Id. Instead, relying on Cuozzo, the Court held that § 314(d) does not bar judicial review of a noninstitution decision when the Director has "exceed[ed] [his] statutory bounds." Id.

Had the Federal Circuit engaged the substance of those decisions, it would have readily concluded that this case presents an instance of "shenanigans" that falls outside the scope of § 314(d). *Id.* But it did not. Unfortunately, the Federal Circuit has repeated this error in multiple *NHK-Fintiv* appeals, dooming a number of litigants to the same fate as Mylan.

All that is bad enough. But what makes this case particularly disturbing is how it fits within the Director's broader approach to defending *NHK-Fintiv*. In the raft of litigation filed in the wake of *NHK-Fintiv*, the Director has maintained that no federal court has jurisdiction to touch the rule. As he sees things, the *NHK-Fintiv* Rule is an exercise of his absolute discretion to deny institution of *inter partes* review for any reason the Board can think up. So in

direct challenges from non-institution, the Director asserts the Federal Circuit lacks subject-matter jurisdiction under 28 U.S.C. § 1295(a)(4)(A), in light of § 314(d). And in district-court suits brought under the Administrative Procedure Act, the Director claims the plaintiffs lack standing to challenge the rule. In essence, the Director has said to patent community and the courts: "Heads, I win; tails, you lose."

Review by this Court is critical. Indeed, another litigant in Mylan's position recently petitioned this Court for review, *Apple, Inc.* v. *Optis Cellular Tech., LLC*, No. 21-118 (filed July 26, 2021)—underscoring the urgent need for this Court's intervention. The Director has used the unlawful *NHK-Fintiv* Rule to cull scores of IPR petitions in its short life. And given the Federal Circuit's failure to apply this Court's precedent properly, the practice will continue unabated and without recourse for aggrieved parties unless this Court steps in.

OPINIONS BELOW

The opinion of the court of appeals (Pet.App.1a-16a) is reported at 989 F.3d 1375 (Fed. Cir. 2021). The Board's decision denying institution of *interpartes review* (Pet.App.17a-44a) is not reported but available at 2020 WL 5580472 (PTAB Sept. 16, 2020).

JURISDICTION

The judgment of the court of appeals was entered on March 12, 2021. Pet.App.16a. By a general order of this Court dated March 19, 2020, which was modified by an order dated July 19, 2021, the time for fil-

ing this petition was extended to 150 days from the date of the lower-court judgment. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The relevant statutory provisions are reprinted in the appendix to this petition. Pet.App.45a-47a.

STATEMENT

A. Background

1. Congress introduced IPR as part of the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284 (2011). It intended IPR to provide a "quick and cost effective alternative[] to litigation" and to "improve patent quality and restore confidence in the presumption of validity that comes with issued patents in court." H.R. Rep. No. 112-98, pt. 1, at 45, 48 (2011). IPR replaced the former system of *inter partes* reexamination. *See Cuozzo*, 136 S. Ct. at 2137. IPR is "a second look at an earlier administrative grant of a patent." *Id.* at 2144. The AIA also created the Patent Trial and Appeal Board within the Patent and Trademark Office. *Id.* at 2137.

IPR has a number of benefits for patent challengers over district-court litigation. It is limited in scope and follows a statutorily prescribed schedule, which means it is usually quicker and cheaper than district-court litigation. 35 U.S.C. §§ 311(b) (limiting IPR to novelty and obviousness challenges); 314(b) (time limit for deciding to institute IPR); 316(a)(11) (time limit for issuing a final written decision). It requires a lower burden of proof for invalidity—a preponderance of the evidence, as opposed to clear and

convincing evidence. Compare 35 U.S.C. § 316(e), with Microsoft Corp. v. i4i Ltd. P'ship, 564 U.S. 91, 95 (2011). And the case is heard by a panel of administrative patent judges, all of whom have a technical background. See United States v. Arthrex, Inc., 141 S. Ct. 1970, 1977 (2021).

IPR is a two-step process consisting of institution and trial. This case involves the first step of the process. Any person other than the patent owner can file a petition for IPR. 35 U.S.C. § 311(a). Preparing an IPR petition is no small undertaking. The would-be patent challenger must identify, "in writing and with particularity, each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim." Id. § 312(a)(3). The petition must include "copies of patents and printed publications that the petitioner relies upon in support of the petition, id. § 312(a)(3)(A), as well as "affidavits or declarations of supporting evidence and opinions, if the petitioner relies on expert opinions," id. § 312(a)(3)(B). PTO regulations echo this requirement: a petition must contain "[a] full statement of the reasons for the relief requested, including a detailed explanation of the significance of the evidence including material facts, and the governing law, rules, and precedent." 37 C.F.R. § 42.22(a)(2).

Arguments and evidence not presented in the petition are deemed waived. *Intelligent Bio-Sys.*, *Inc.* v. *Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016). That means a petitioner must make its full case-in-chief in its IPR petition. It must formulate its invalidity arguments, marshal the prior art supporting its position, retain experts, and help pre-

pare often-times lengthy declarations. A litigant thus cannot put together a filing overnight. And the patent owner has "the right to file a preliminary response to the petition" containing "reasons why no *inter partes* review should be instituted based upon the failure of the petition to meet any requirement of this chapter." 35 U.S.C. § 313.

The Director may institute review if he concludes that "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." *Id.* § 314(a). The Director has delegated his statutory discretion to the Board, which considers IPR petitions in three-member panels typically comprised of three administrative patent judges. 37 C.F.R. § 42.4(a); *Arthrex, Inc.*, 141 S. Ct. at 1977.

Congress gave the Director discretion to determine whether to institute IPR under § 314(a). But it also placed a number of statutory limitations on that discretion. Two are important here:

First, Congress instructed that IPR "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). This provision reflects Congress's attempt to balance two competing needs. On one hand, many petitioners will not seek IPR until after they have been sued for infringement, so it is necessary to give them a reasonable amount of time after they have been served with a complaint to put together an IPR petition. On the other hand, parallel litigation can be a source of inefficiency, disruption, and potentially abuse, so would-

be petitioners need to act expeditiously if they wish to seek *inter partes* review. Congress settled on one year as an appropriate period in light of these concerns.

Second, Congress commanded the Director to "prescribe regulations" governing various aspects of the IPR process. 35 U.S.C. § 316(a). This includes regulations "setting forth the standards for the showing of sufficient grounds to institute a review under section 314(a)," as well as "establishing and governing inter partes review under this chapter and the relationship of such review to other proceedings under this title." Id. § 316(a)(2), (4). This reflects Congress's typical approach to administrative law: it lays out key boundaries on the agency's power in the statute, while leaving other details to be formed by the agency itself through the rulemaking process. The Director has previously established a number of rules related to IPR through notice-and-comment rulemaking. E.g., 77 Fed. Reg. 48,612 (Aug. 14, 2012); 77 Fed. Reg. 48,680 (Aug. 14, 2012); 83 Fed. Reg. 51,340 (Oct. 11, 2018).

2. The Director's discretion to institute (or not institute) IPR is typically unreviewable. In a provision entitled "No Appeal," Congress provided that the "determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable." 35 U.S.C. § 314(d). But as this Court has previously held, the AIA's appellate bar does not amount to an unchecked grant of power to the Director over institution decisions. To the contrary, § 314(d) does not preclude review where the Director has acted "outside [his] statutory limits."

SAS, 138 S. Ct. at 1359 (quoting *Cuozzo*, 136 S. Ct. at 2141).

- 3. Under the *NHK-Fintiv* Rule, the Board will consider the "advanced state of the district court proceeding" when deciding whether to deny instituting IPR. *Fintiv*, *Inc.*, 2020 WL 2126495, at *2. To determine the "state" of the district-court litigation, the PTAB applies a six-factor analysis that looks at:
 - (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.

If the Board decides that the first five factors weigh in favor of denial, it will reject the petition without addressing the merits—the lone factor that Congress articulated under 35 U.S.C. § 314(a) for granting a petition. All the more troubling, the Board will deny a petition under *NHK-Fintiv* even if it is filed within the one-year window for seeking IPR.

In May 2020—nearly two months after *Fintiv* was issued and almost two years after *NHK* was rendered—the Director designated both *NHK* and *Fintiv* "precedential." This after-the-fact maneuvering made these decisions "binding" on the Board "in subsequent matters involving similar facts or issues." Patent Trial and Appeal Board, Standard Operating Procedure 2 (Rev. 10) ("SOP-2"), at 11 (Sept. 20, 2018). By doing so, the Director adopted those decisions as a "rule"—"an agency statement of general or particular applicability and future effect." 5 U.S.C. § 551(4). The designation process is done behind closed doors at the PTO, and the public is given neither notice nor an opportunity for comment. SOP-2 at 8-11.

B. Procedural History

1. Mylan filed an abbreviated new drug application and Paragraph IV certification for paliperidone palmitate in 2019. Janssen sued Mylan several months later. Janssen Pharm., Inc. v. Mylan Labs. Ltd., No. 19-cv-16484 (D.N.J. filed Aug. 8, 2019). By this time, Janssen had already sued another generic pharmaceutical company (Teva) and litigated the atissue patent for over a year. Janssen Pharm., Inc. v. Teva Pharm. USA, Inc., No. 18-cv-00734 (D.N.J. filed Jan. 17, 2018). On February 7, 2020—less than six months after Janssen filed suit—Mylan petitioned for IPR. Mylan Labs. v. Janssen Pharmaceutica NV, IPR2020-00440 (hereinafter "Mylan IPR"), Paper 3 (PTAB Feb. 07, 2020).

About a month after Mylan filed its petition, the Board issued its decision in *Fintiv*, and soon thereafter made both it and *NHK* precedential. Janssen

then urged the Board to deny Mylan's petition in light of the supposed advanced state of district-court litigation involving the at-issue patent. Mylan IPR, Paper 8, at 6-20 (PTAB Jun. 19, 2020).

Originally, Janssen tried to argue that IPR would be a waste because the Mylan litigation was too far along. *Id.* at 6-11; *see also id.* at 11-16. But that argument was not persuasive because trial was not scheduled in the Mylan litigation, no depositions had been taken, and the district court would have taken no material action in the case by the time of institution. Mylan IPR, Paper 16, at 1-2 (PTAB July 20, 2020). So in a sur-reply, Janssen argued that the Board should deny Mylan's petition because trial in the Teva litigation was "imminent." Mylan IPR, Paper 14, at 1 (PTAB July 17, 2020).

2. The Board sided with Janssen. It concluded that granting Mylan's petition would be inefficient in light of co-pending district-court litigation on the atissue patent. Pet.App.43a. Though it cited to both the Mylan and the Teva litigations as bases for its decision, the Board focused on the state of the Teva litigation. Pet.App.25a-41a. It factored the Teva litigation into all five of the main *NHK-Fintiv* factors, and it placed particular emphasis on the fact that Teva was (at the time) scheduled to go to trial at the end of September 2020. Pet.App.27a, 30a-31a, 33a, 34a-35a, 36a.

Of the Mylan litigation, the Board could only surmise that there was a "reasonable likelihood" that trial might occur before it could render a final written decision (at the time, and to this day, trial had not been set). Pet.App.36a. It also gave no weight to the fact that the "defendant in the *Teva* litigation is,

self-evidently, an unrelated party" to Mylan, concluding that it was good enough that the same patent and similar arguments were presented in Teva's case. Pet.App.39a-40a. Finally, the PTAB did not delve into the merits of the case, deeming the sixth *NHK-Fintiv* factor neutral. Pet.App.42a.

Meanwhile, the district court has still not rendered a decision in the *Teva* litigation. The case did not go to trial until mid-October 2020. And closing arguments were not held until March 2021. *See Janssen Pharm., Inc.* v. *Teva Pharm. USA, Inc.*, No. 18-cv-00734, ECF No. 151 (D.N.J. Oct. 30, 2020). Mylan's district-court litigation against Janssen is presently stayed pending the outcome of the Teva litigation.

3. Mylan appealed to the Federal Circuit. Janssen moved to dismiss the appeal for want of jurisdiction, arguing principally that § 314(d) barred the appeal because the *NHK-Fintiv* Rule is an appropriate exercise of the Director's discretion under § 314(a) and, in any event, the Federal Circuit lacked jurisdiction over a non-institution decision. The Director intervened and amplified the latter point.

In a precedential decision, the panel below dismissed Mylan's appeal. It concluded that it lacked jurisdiction because § 314(d) establishes a categorical bar on non-institution decisions. Pet.App.5a-8a. Because of this, the panel found there was no "appeal" over which to assert jurisdiction pursuant to § 1295(a)(4)(A). *Id.* The court never engaged the substance of *Cuozzo* and its progeny. Instead, the panel said that these cases apply only to "an appeal from a final written decision—not an institution decision." Pet.App.7a.

The panel concluded that it had jurisdiction to alternative request for mandamus. Pet.App.12a, but it ultimately refused to grant any relief. Notably, the panel held that, "[w]hen a mandamus petition challenges a decision denying institution, the mandamus standard will be especially difficult to satisfy." Pet.App.13a. And it stated that "it is difficult to imagine a mandamus petition that challenges a denial of institution and identifies a clear and indisputable right to relief," because, in the panel's view, the Director had virtually unfettered discretion to deny review. Pet.App.14a-15a. Though the panel left the door cracked ajar to future mandamus relief, it observed that the extraordinary writ is a functionally useless device in the context of a noninstitution decision.

REASONS FOR GRANTING THE WRIT

Review of the *NHK-Fintiv* Rule is of extreme importance to the patent community. Since it was formalized in May 2020, the Board has used the rule to procedurally terminate over one hundred IPR petitions, and it has spawned a flurry of litigation—mostly in the Federal Circuit. The decision below erects a massive jurisdictional roadblock to judicial review of the *NHK-Fintiv* Rule and other *ultra vires* conduct by the Director.

In holding that it did not have jurisdiction to consider the Rule, the Federal Circuit departed from this Court's precedent. Contrary to SAS and Cuozzo, the Federal Circuit held that § 314(d) bars all judicial review of "decisions denying institution," Pet.App.3a—even if the Director "act[s] outside [his] statutory limits," SAS, 138 S. Ct. at 1359. In so hold-

ing, the Federal Circuit cast aside *SAS* as involving "an appeal from a final written decision—not an institution decision." Pet.App.7a. But *SAS* reviewed the Director's decision to partially not institute IPR, and it rejected the Director's contention that § 314(d) barred this Court's review of that practice. 138 S. Ct. at 1359. If *SAS* did not implicate § 314(d), this Court would have said so. Instead, this Court held that § 314(d) does not bar judicial review where, as there—and here—the Director denies institution on a ground "the statute forbids." *Id*.

I. The Decision Below Is Erroneous and Conflicts With This Court's Precedent.

A. The Federal Circuit Had Jurisdiction to Hear This Case.

The Federal Circuit has jurisdiction under 28 U.S.C. § 1295(a)(4)(A) to review a final "decision" of the Board "with respect to ... inter partes review." That grant of authority is broad enough to encompass Mylan's appeal, which challenges the substantive and procedural lawfulness of the *NHK-Fintiv* Rule used by the Board to deny its IPR petition. *See infra* Section I.B. (explaining why the *NHK-Fintiv* Rule is unlawful). Even the panel below acknowledged the "language in § 1295(a)(4) seems ... broad enough to reach an appeal from a decision denying institution" standing alone. Pet.App.6a.

Nothing in 35 U.S.C. § 314(d) withdraws that jurisdiction. The Board relied exclusively upon the *NHK-Fintiv* Rule to reject Mylan's IPR petition and made no assessment of the merits of patentability. So Mylan's appeal presented a clean question of

whether the Board exceeded the statutory discretion granted to the Director under the AIA, which is appealable according to the applicable statutory text of 35 U.S.C. § 314(d) and this Court's precedent. The Federal Circuit's decision to the contrary is wrong.

1. Congress delegated discretion to the Director to determine whether to institute IPR. 35 U.S.C. § 314(a). When exercised within the confines of his congressionally vested authority, the Director's discretion whether to institute IPR is unreviewable on appeal. 35 U.S.C. § 314(d). As this Court explained in Cuozzo, § 314(d) "bar[s] judicial review" or "mine-run claim[s]" that challenge the Director's determination under § 314(a) that "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged." 136 S. Ct. at 2136, 2142. The "legal dispute" in *Cuozzo* was "an ordinary dispute about the application of certain relevant patent statutes concerning the Patent Office's decision to institute inter partes review." Id. at 2139 (challenging the Board's determination that the IPR petition had been pled "with particularity" pursuant to § 312).

But the Court in *Cuozzo* did not construe § 314(d) as a complete jurisdictional blackout of review over all institution-phase errors. It "emphasize[d]" that its "interpretation [of § 314(d)] applies where the grounds for attacking the decision to institute *interpartes* review consist of questions that are closely tied to the application and interpretation of statutes related to the Patent Office's decision to initiate *interpartes* review." *Id.* at 2141. It did not "decide the precise effect of § 314(d) on appeals that implicate constitutional questions, that depend on other less close-

ly related statutes, or that present other questions of interpretation that reach, in terms of scope and impact, well beyond 'this section." *Id.* That came later in *SAS*.

Relying on *Cuozzo*, the Court in SAS held that, if a party challenges a decision of the Board as "exceeding its statutory bounds, judicial review remains available consistent with the Administrative Procedure Act, which directs courts to set aside agency action 'not in accordance with law' or 'in excess of statutory jurisdiction, authority, or limitations." SAS *Inst. Inc.*, 138 S. Ct. at 1359 (quoting *Cuozzo*, 136 S. Ct. at 2141). Such was the case in SAS itself. The challenger in SAS petitioned for review of over a dozen patent claims, but the Board "instituted review on only some" of them. Id. at 1354. It "denied review on the rest" pursuant to a "regulation that purported to recognize a power of 'partial institution." Id. The Court struck the rule down as unlawful because it contravened the AIA. Id. at 1355-59.

SAS's holding is consistent with the text of § 314(d) itself, which strips jurisdiction only where the Director has exercised his discretion "under this section"—namely, § 314 and related provisions. Section 314(d) is not a bar when the Director exceeds his authority under law. This Court said as much in SAS. When the Director invoked § 314(d) to prevent review of the unlawful partial-institution rule, this Court observed that the statute "does not enable the agency to act outside its statutory limits." 138 S. Ct. at 1359 (internal quotation marks omitted). Nothing in § 314(d) or Cuozzo "withdraws [the Court's] power to ensure that an inter partes review proceeds in accordance with the law's demands." Id.

The Court's recent decision in Thryv v. Click-To-Call Technologies, LP fits squarely within this framework. The issue in Thryv concerned the Board's application of the statutory prerequisites for initiating IPR—namely, when the statutory clock starts for the one-year time bar. 140 S. Ct. 1367, 1373 (2020). Critically, neither party in *Thryv* questioned whether the time bar applied to the case; rather the patentee just disagreed with the decision of when the one-year clock started to run. Id. But in SAS, the Board completely ignored the statute and acted in excess of the boundaries placed on it by Congress. Put another way, there is a difference between misapplying the statute and *ignoring* the statute altogether. The appellate bar stops aggrieved parties from challenging the former. The latter is fair game for the courts.

The rule carved out by *Cuozzo*, *SAS*, and *Thryv* accords with first principles of federal jurisdiction and administrative law. There is a "strong presumption' in favor of judicial review" that this Court applies when it "interpret[s] statutes, including statutes that may limit or preclude review." *Cuozzo*, 136 S. Ct. at 2140; *SAS*, 138 S. Ct. at 1359 (observing limits on § 314(d) in light of the presumption). Similarly, this Court has expressed reluctance to eliminate judicial review of agency action that exceeds congressional limits on the agency's power to act. *Leedom* v. *Kyne*, 358 U.S. 184, 187-89 (1958).

Mylan's challenge to the *NHK-Fintiv* Rule fits neatly within the statutory text and the *ultra vires* exception to § 314(d). Unlike in *Cuozzo*, Mylan is not challenging the Board's determination whether there is a reasonable likelihood that at least one of its invalidity arguments would prevail on the merits. And

unlike in *Thryv*, Mylan is not challenging the Board's application of a statutory prerequisite to instituting IPR. Rather, as explained in detail below, Mylan's argument is that that Board altogether ignored congressional imitations on the Director's discretion. *See infra* Section I.B. *Cuozzo* and *SAS* make clear arguments like this are reviewable on appeal notwithstanding § 314(d).

2. The Federal Circuit did not try to apply *Cuozzo* and its progeny to this case. It instead read § 314(d) to categorically foreclose appeal of all noninstitution decisions. Pet.App.6a. ("Section 314(d) prevents 'appeal' from a decision denying institution."). It brushed aside this Court's limits on the scope of § 314(d) by concluding they apply only to "an appeal from a final written decision—not an institution decision." Pet.App.7a. Because the Federal Circuit decided there was "no appeal" of a noninstitution decision, it held that it lacked jurisdiction under 28 U.S.C. § 1295(a)(4)(A). Pet.App.6a-8a.

The distinction drawn by the Federal Circuit is unmoored from the statutory text of § 314(d) and atodds with this Court's decision in SAS. Section § 314(d) applies to "determination[s] ... whether to institute" made "under this section." (Emphasis added.) The text is agnostic as to whether the Director's "determination" is institution, partial institution, or non-institution The provision applies all the same, which means this Court's decisions construing the provision apply, too, and those decisions limit the bar to the Director's actions taken consistent with "this section" and the law more generally. By finding a non-existent distinction in § 314(d), the Federal Circuit committed a sin this Court warned against in

Cuozzo: it "reads into [§ 314(d)] ... a limitation ... that the language nowhere mentions and that is unnecessary." 136 S. Ct. at 2140.

It is also impossible to square the decision below with the outcome in SAS. There, the Court reviewed (and overturned) a partial non-institution decision. 138 S. Ct. at 1359. The Court held that "the statute forbids [t]his partial institution practice." Id. In so holding, the Court expressly rejected the Director's contention that § 314(d) precluded "judicial review of any legal question bearing on the institution of *inter* partes review." Id. Because "SAS contend[ed] that the Director exceeded his statutory authority by limiting the review to fewer than all of the claims SAS challenged," this Court concluded it had power to review and correct the Director's overreach: "nothing in § 314(d) or *Cuozzo* withdraws our power to ensure that an *inter partes* review proceeds in accordance with the law's demands." *Id*.

Likewise, the fact that SAS proceeded to a partial final written decision is irrelevant to the operation of § 314(d). Cuozzo and Thryv both proceeded to final written decisions. Yet the Court still applied § 314(d) with full force because the issues presented in those cases fell within the prohibitive scope of the provision. Indeed, the Court in Cuozzo considered and rejected a reading of § 314(d) that hinged upon whether the Board issues a final written decision, concluding that Congress did not intend to make this atextual distinction. 136 S. Ct. at 2140.

The Federal Circuit tried to smooth over this issue by asserting that 35 U.S.C. § 319—not 28 U.S.C. § 1295(a)(4)(A)—provided the jurisdictional basis for *Cuozzo*, *SAS*, and *Thryv*. Pet.App.7a. That is incor-

The Federal Circuit itself invoked rect. § 1295(a)(4)(A) as the basis for its jurisdiction in all three cases. In re Cuozzo Speed Techs., LLC, 793 F.3d 1268, 1272 (Fed. Cir. 2015); SAS Inst., Inc. v. ComplementSoft, LLC, 825 F.3d 1341, 1347 (Fed. Cir. 2016); Click-To-Call Techs., LP v. Ingenio, Inc., 899 F.3d 1321, 1328 (Fed. Cir. 2018). And in any event, § 319 does not speak in jurisdictional language; it is a basic sign-posting provision that alerts parties when the agency process has reached a point where an appeal may be taken.

Nor does the discretion to institute review under § 314(a) make this case unreviewable under 5 U.S.C. § 701(a)(2). Pet.App.7a-8a. This Court has read the exception in § 701(a)(2) "quite narrowly, restricting it to 'those rare circumstances where the relevant statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion." Weyerhaeuser Co. v. U.S. Fish & Wildlife Serv., 139 S. Ct. 361, 370 (2018) (quoting Lincoln v. Vigil, 508 U.S. 182, 191 (1993)). As discussed below, there are "meaningful"—indeed, clear—standards laid out by Congress against which to judge the purported exercise of the Director's discretion.

Simply put, the institution/non-institution distinction drawn by Federal Circuit is cut from whole cloth. It is nowhere supported in the text of § 314(d) and is fundamentally at odds with this Court's decisions construing the statute.

Had the court below faithfully applied the statutory text and this Court's binding case law, it would have concluded that § 314(d) is not an impediment to its jurisdiction. Mylan is not challenging the Direc-

tor's determination on the merits of its petition, nor "the application and interpretation of statutes related to the Patent Office's decision to initiate inter partes review." Cuozzo, 136 S. Ct. at 2141. Mylan claims instead that the Director has not exercised discretion under "this section," 35 U.S.C. § 314(d) specifically, that he has "exceed[ed] [his] statutory bounds" by using the NHK-Fintiv Rule to dismiss Mylan's petition. SAS, 138 S. Ct. at 1359. In these circumstances, "judicial review remains available consistent with the Administrative Procedure Act, which directs courts to set aside agency action 'not in accordance with law or in excess of statutory jurisdiction, authority, or limitations." Id. (quoting Cuozzo, 136 S. Ct. at 2141). As a result, the Federal Circuit plainly had jurisdiction under the catch-all provided by 28 U.S.C. § 1295(a)(4)(A), which authorizes that court to review an "appeal" from a "decision" of the Board "with respect to ... inter partes review."

B. The *NHK-Fintiv* Rule Exceeds the Authority that Congress Delegated to the Director.

Section 314(d) forbids appellate review only when the Director lawfully exercises his discretion under § 314(a), but the *NHK-Fintiv* Rule is not a lawful exercise of the Director's discretion. Congress placed both substantive and procedural limits on the Director's authority under § 314(a). The *NHK-Fintiv* Rule exceeds both.

1. Agencies are creatures of Congress. "[A]n agency literally has no power to act ... unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n* v. *FCC*, 476 U.S. 355, 374 (1986). A corollary

of this proposition is that Congress can limit or condition whatever power it decides to bestow upon an agency. "Both their power to act and how they are to act is authoritatively prescribed by Congress[.]" City of Arlington v. FCC, 569 U.S. 290, 297 (2013) (emphasis added). When agencies act outside the boundaries set by Congress, "what they do is ultra vires." Id.

Here, Congress allows the Director to "authorize an *inter partes* review to be instituted" if he "determines that the information presented in the petition" shows "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). Congress gave the Director discretion, to be sure. But it "d[id] not leave his discretion unbounded." *Dep't of Comm.* v. *New York*, 139 S. Ct. 2551, 2568 (2019). Far from it, the AIA contains a number of conditions on the Director's discretion.

For example, Congress made institution an all-ornothing proposition. The Director cannot partially institute review on fewer than all the claims challenged in the petition. 35 U.S.C. §§ 314(a), 318(a); SAS, 138 S. Ct. at 1354. Additionally, the statute says an IPR petition cannot be filed (and thus cannot be considered) until 9 months after the patent is granted or post-grant review is completed. 35 U.S.C. § 311(c). And IPR cannot be instituted if the petitioner previously filed a civil action challenging the validity of a claim of the patent in issue. *Id.* § 315(a)(1).

The one-year time bar established by § 315(b) is no less a congressional limit on the Director's discretion than any of these other provisions. It reflects a deliberate policy choice by Congress to balance the petitioner's need for time to marshal its evidence and prepare a document that complies with the requirements of § 312(a), with the need for patent litigation in district court to move forward efficiently and without undue delay. Indeed, statutorily defined time limits inherently "take[] account of delay." *Petrella* v. Metro-Goldwyn-Mayer, Inc., 572 U.S. 663, (2014). For this reason, the Court has repeatedly frowned on efforts to truncate congressionally mandated limitations periods using equitable or judgemade rules. Id. at 679 ("[I]n face of a statute of limitations enacted by Congress, laches cannot be invoked to bar legal relief[.]"); see also SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC, 137 S. Ct. 954, 959-960 (2017); Holmberg v. Armbrecht, 327 U.S. 392, 395 (1946). This concern is particularly salient in this case, given that Congress considered—and rejected—shorter time limits on filing for IPR.1

The problem with the *NHK-Fintiv* Rule is that it allows the Director to substitute his judgment of what constitutes a timely filed petition (which is subject to change case-to-case) for that of Congress. In the Director's judgment, a petition may be untimely if it is filed "six months before the statutory deadline," as was the case here. Pet.App.34a. If a parallel infringement suit is pending in an exceptionally fast court, the Director may deem the petition too late if it is filed *less than one month* after service of the

Patent Reform Act of 2011, S. 23, 112th Cong. § 315(b) (introduced Jan. 25, 2011) (three months); Patent Reform Act of 2011, S. 23, 112th Cong. § 315(b) (reported Feb. 3, 2011) (six months); America Invents Act, H.R. 1249, 112th Cong. § 315(b) (introduced Mar. 30, 2011) (nine months).

complaint. *Philip Morris Prod.*, S.A. v. Rai Strategic Holdings, Inc., No. IPR2020-00921, 2020 WL 6750120, at *7 (PTAB Nov. 16, 2020). Outcomes like this cannot be reconciled with the one-year time bar enacted by Congress.²

The Director does this all in the name of "efficiency," "fairness," and avoiding "duplication of efforts" in light of parallel proceedings. Fintiv Inc., 2020 WL 2126495, at *2-3. Those may well be laudable goals in theory, but the problem is that Congress already made a determination of what it thought to be efficient and fair when it comes to the timing of IPR. That judgment is baked into § 315(b). Petrella, 572 U.S. at 677. No amount of discretion allows the Director to overrule Congress's judgment; "how [the Director is] to act" in this regard "is authoritatively prescribed by Congress[.]" City of Arlington, 569 U.S. at 297.

Importantly, Congress had parallel proceedings in mind when it crafted the AIA. That is clear from the fact that service of an infringement complaint is the trigger point for starting the clock. 35 U.S.C. § 315(b). Congress recognized that IPR would often overlap with an infringement action pending in district court, and it was okay with that so long as an

Also troubling is the fact that the "clock" might start running in the Director's mind long before a petitioner is even sued for patent infringement. Here, the main reason the Board denied Mylan's petition was because litigation involving Teva—a third party and commercial rival over whom Mylan has no control—had allegedly progressed too far for Mylan's IPR to be worthwhile. Pet.App.27a-36a. This, too, undermines Congress's judgment as to when it is reasonable for the petitioner (not an unrelated third party) to take action.

IPR petition was filed within the statutory limitations period.

Congress passed other regulations on parallel proceedings in addition to the one-year time limit. It prohibited the Director from instituting review if the petitioner previously "filed a civil action challenging the validity of a claim of the patent." Id. § 315(a)(1). And if a petitioner files such a civil suit after petitioning for IPR, Congress decided that suit will be "automatically stayed" until the patent owner either asks for the stay to be lifted or files its own claims for patent infringement, or if the petitioner dismisses the action. Id. § 315(a)(2). It also gave the Director discretion to deny a petition if "the same or substantially the same prior art or arguments previously were presented" to the PTO in other proceedings. *Id*. § 325(d). And it gave the Director discretion on how to handle overlap between IPR and other proceedings in the PTO, including "stay, transfer, consolidation, or termination of any such matter or proceeding." Id. § 315(d).

Plainly, Congress considered the "efficiency" and "fairness" of IPR in the face of co-pending proceedings, and it created a number of statutory provisions regulating the interplay between IPR and proceedings in other fora, including the one-year time bar. The Director cannot wield his discretion under § 314(a) to override Congress's policy decisions with the *NHK-Fintiv* Rule. Indeed, it would have made little sense for Congress to direct how IPR and overlapping proceedings should be managed "if, in truth, the Director enjoyed the discretion" to deny IPR petitions based on parallel litigation, as he claims he may. *SAS*, 138 S. Ct. at 1356. The truth of the matter

is that Congress has already struck what it believes to be the right balance between IPR and parallel proceedings, and that balance is reflected in the text of the AIA. "Where a statute's language carries a plain meaning," the Director's duty "is to follow its commands as written, not to supplant those commands with others it may prefer." *SAS*, 138 S. Ct. at 1355.

2. The NHK-Fintiv Rule is procedurally defective, too. The Director created the rule by labeling two decisions of the Board "precedential" many months after they were issued. This process does not reflect lawful rulemaking—whether by notice-and-comment rulemaking or policymaking by adjudication.

It is textbook administrative law that the APA "mandates that an agency use notice-and-comment procedures before issuing legislative rules." Kisor v. Wilkie, 139 S. Ct. 2400, 2420 (2019) (citing 5 U.S.C. § 553(b), (c)). The AIA provides that the Director "shall prescribe regulations ... setting forth the standards for the showing of sufficient grounds to institute a review under section 314(a)," and "establishing and governing inter partes review under this chapter and the relationship of such review to other proceedings under this title." 35 U.S.C. § 316(a)(2), (4). The contemplated regulations do not merely "advise the public" as to how the Director will exercise his power, but instead "bind private parties" who participate in the IPR process. Kisor, 139 S. Ct. at 2420. They accordingly must be promulgated using "notice-and-comment procedures" under § 553 of the APA. Id.; see also 35 U.S.C. § 2(b)(2)(B) (stating the PTO may establish regulations, "which ... shall be made in accordance with section 553 of title 5"). Indeed, the Director has previously used notice-and-comment rulemaking to promulgate regulations under § 316(a). See supra p. 8.

The NHK-Fintiv Rule likewise should have been promulgated using the notice-and-comment procedure. It is "an agency statement of general or particular applicability and future effect." 5 U.S.C. § 551(4) (defining "rule"). And it is not a mere policy statement. By designating NHK and Fintiv "precedential," the Director made their standard "binding" on the Board "in subsequent matters involving similar facts or issues." SOP-2 at 11. The NHK-Fintiv Rule therefore has the "force and effect of law" and constitutes a substantive rule. Perez v. Mortg. Bankers Ass'n, 575 U.S. 92, 96 (2015).

Adopting the *NHK-Fintiv* Rule through the "precedential" designation process violated the AIA's and APA's notice-and-comment requirements. The designation of *NHK* and *Fintiv* as precedential was entirely internal, involving (at most) only the recommendations of entities within the PTO. SOP-2 at 7. There was no opportunity for public comment and no consideration by the Director of any public input. *Aqua Prods., Inc.* v. *Matal*, 872 F.3d 1290, 1331-1332 (Fed. Cir. 2017) (Moore, J., concurring) ("precedential Board decisions are not subject to notice and comment").

By creating *NHK-Fintiv* in this closed-door manner, the Director thwarted the entire purpose of notice-and comment rulemaking, which is to "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments." 5 U.S.C. § 553(c). The agency "must consider and respond to significant comments

received during the period for public comment." *Perez*, 575 U.S. at 96. Had the public been given a chance to weigh in, they could have identified the rule's many defects, and the Director would have had to alter the rule to address those defects or else provide a reasoned explanation for refusing to do so.

NHK-Fintiv cannot be defended as a rule adopted through adjudication. See SEC v. Chenery Corp., 332 U.S. 194, 203 (1947). Indeed, it was not adopted through a binding adjudication at all. The NHK-Fintiv Rule only became binding ("precedential") based upon the Director's say-so months (and years) after the decisions were rendered. See SOP-2 at 10-11. Importantly, the process employed by the Director here lacks the procedural protections that a true adjudicative rulemaking would have. Neither the litigants nor the public had an opportunity to weigh in on the Director's post hoc decision to make NHK and Fintiv precedential.

All the more troubling, there was no opportunity for judicial review. By stamping *NHK* and *Fintiv* "precedential," and then invoking the appellate bar to preclude review of the resulting standard, the Director has prevented review of the legality of the *NHK-Fintiv* Rule that would have occurred in the normal course had he engaged in formal rulemaking—and that's on top of Congress's command that the Director "shall" promulgate rules through notice and comment governing these procedures. 35 U.S.C. § 316(a).

The requirements of formal rulemaking are meant to prevent administrative tyranny. The requirement for notice and public comment create transparency and allows for participation by interested stakeholders in the rulemaking process. Opportunity for judicial review prevents unelected bureaucrats from usurping the courts' power to say what the law is. The process used to promulgate the *NHK-Fintiv* Rule circumvents all of these protections. It is procedurally unlawful.

II. THE QUESTIONS PRESENTED ARE EXCEPTIONALLY IMPORTANT.

The issues presented here are extremely important. The Federal Circuit's jurisdictional ruling slams the door shut on the best (and perhaps only) avenue for reviewing the *NHK-Fintiv* Rule and other types of overreach like it. Particularly in light of the Director's aggressive use of the *NHK-Fintiv* Rule to deny IPR petitions, immediate correction by this Court is required.

A. The Federal Circuit's Misapplication of § 314(d) Severely Limits the Ability to Challenge Misconduct by the Director and Has Created Confusion Regarding Appellate Jurisdiction over IPRs.

The Federal Circuit's flawed jurisdictional ruling warrants this Court's intervention. By construing § 314(d) to categorically foreclose review of non-institution decisions, the court below effectively handed the Director and the Board carte blanche to deny IPR petitions for any random (and potentially unlawful) reason they can dream up. The Board could categorically refuse to hear certain kinds of cases (e.g., pharmaceutical patents) in the name of conserving scarce resources for other types of cases that are of greater interest to the Director. Or it

could engage in outright arbitrary behavior by denying petitions based upon a lottery, coin flips, or drawing names out of a hat. The fact that the Director has discretion to determine whether to institute review does not mean that he can wield that discretion in an arbitrary or discriminatory manner. Yet the decision below renders courts powerless to police conduct well outside the boundaries of the Director's discretion.

To be sure, the panel left the door to mandamus review cracked ajar. Pet.App.14a. But in doing so, the panel stated that "it is difficult to imagine a mandamus petition that challenges a denial of institution and identifies a clear and indisputable right to relief," because, in the panel's view, the Director had virtually unfettered discretion to deny review. Id. Indeed, the Federal Circuit has previously "made clear that where section 314(d) bars an appeal from a Board decision not to institute *inter partes* review, the petitioning party 'has no "clear and indisputable" right to challenge [the] non-institution decision directly in this court, including by way of mandamus." In re Power Integrations, Inc., 899 F.3d 1316, 1320 (Fed. Cir. 2018) (quoting In re Dominion Dealer Sols., LLC, 749 F.3d 1379, 1381 (Fed. Cir. 2014)). Given this precedent, it is hard to see how mandamus is anything but a toothless remedy.

These problems are compounded by the fact that the decision below created a three-way intra-circuit split on the Federal Circuit's IPR jurisdiction under 28 U.S.C. § 1295—an issue the *en banc* court has already refused to fix. Back in 2014, a Federal Circuit panel said in dicta that the broad jurisdictional language in 28 U.S.C. § 1295(a)(4)(A) is limited exclusively to IPRs that proceed to a final written decision

under 35 U.S.C. §§ 318 and 141(c). St. Jude Med., Cardiology Div., Inc. v. Volcano Corp., 749 F.3d 1373, 1375-76 (Fed. Cir. 2014). A few years later, another panel authoritatively rejected that view. Arthrex, Inc. v. Smith & Nephew, Inc., 880 F.3d 1345, 1349 (Fed. Cir. 2018) (concluding it was "not bound by the language in St. Jude" related to § 1295 because it did not "squarely address" the issue). Arthrex held—correctly—that "a final decision ... dispos[ing] of an IPR proceeding ... is a 'decision' from the Board with respect to IPRs" for jurisdictional purposes under § 1295. Id. The decision below now partially resurrects the dicta from St. Jude by using a flawed understanding of § 314(d) to limit the plain language of § 1295. Pet.App.6a-7a. Notably, the panel below relegated Arthrex to a curt footnote, stating (without explanation) that the panel saw "no conflict" with its decision. Pet.App.6a.

Litigants have rightly disagreed on that last point. Three *en banc* petitions have presented the irreconcilable conflict on this issue to the full Federal Circuit—two of which have already been denied.³ Granting certiorari and reversing the decision below, whether here or in *Apple*, *Inc.* v. *Optis Cellular Tech.*, *LLC*, No. 21-118 (filed July 26, 2021), will have the additional benefit of clearing up the confusion on this issue.

³ Apple Inc. v. Maxell, Ltd., No. 20-2132, ECF No. 49 (Fed. Cir. Feb. 22, 2021); Apple Inc. v. Optis Cellular Tech., LLC, No. 21-1043, ECF No. 22 (Fed. Cir. Feb. 26, 2021); Intel Corp. v. VLSI Tech. LLC, No. 21-1614, ECF No. 22 (Fed. Cir. June 21, 2021).

B. The *NHK-Fintiv* Rule Has Evaded Judicial Review and Continues to Disrupt the IPR System.

The lawfulness of the *NHK-Fintiv* Rule likewise warrants this Court's review. That rule is wrong, exceeds congressionally mandated limits on the Director's power, and is disrupting Congress's careful design of the IPR system. Yet, notwithstanding multiple attempts by numerous litigants in a variety of fora, the rule has evaded judicial review for months. No court has addressed the merits of the *NHK-Fintiv* Rule.

This is due in no small measure to a concerted effort by the Director to prevent such review. At least twenty-two appeals have been filed in the Federal Circuit from *NHK-Fintiv* denials. The Director has intervened in all of them and successfully argued that they must be dismissed on jurisdictional grounds. As just noted, the Federal Circuit has been presented with three *en banc* petitions urging it to review panel decisions dismissing *NHK-Fintiv* appeals, two of which have already been rejected. *See supra* p. 31. Finally, a group of plaintiffs has filed an

In addition to this case: Cisco Sys. Inc. v. Ramot at Tel Aviv Univ. Ltd., 834 F. App'x 571 (Fed. Cir. 2020); Apple Inc. v. Maxell, Ltd., Nos. 20-2132, -2211-2213, 21-1033, ECF No. 38 (Fed. Cir. Oct. 30, 2020) (dismissing five consolidated appeals); Google LLC v. Uniloc 2017 LLC, No. 20-2040, ECF No. 21 (Fed. Cir. Oct. 30, 2020); Apple Inc. v. Optis Cellular Tech., LLC, Nos. 21-1043, -1044, -1046, ECF No. 19 (Fed. Cir. Dec. 21, 2020) (dismissing three consolidated appeals); Intel Corp. v. VLSI Tech. LLC, Nos. 21-1614, -1616-1617, -1673-1677, -1738-1741, ECF No. 21 (Fed. Cir. May 5, 2021) (dismissing twelve consolidated and related appeals).

APA action against the Director challenging *NHK-Fintiv*. The Director has moved to dismiss, arguing the plaintiffs lack standing because his "unreviewable discretion" supposedly "displaces any cause of action" under the APA.⁵ The matter is pending. Taken as whole, the message from the Director's various litigation positions is clear: no court can touch *NHK-Fintiv*—a troubling and unacceptable proposition.

Absent judicial review, the *NHK-Fintiv* Rule will continue to create chaos for the IPR system. Since its inception, the Director has wielded the *NHK-Fintiv* Rule to dispose of numerous IPR petitions. By one count, *NHK-Fintiv* was responsible for 85 denials in 2020.⁶ The number is in the hundreds today and will doubtlessly continue to rise without this Court's intervention.⁷

Worse, the rule has created a host of perverse incentives that jeopardize the congressional purpose of IPR. By pegging the prospect of a discretionary denial to the speed of the schedule set by the district court, patent plaintiffs are incentivized to file suit in

⁵ Apple Inc. v. Iancu, No. 20-cv-6128, ECF No. 64 at 1 (N.D. Cal. Nov. 23, 2020). A separate group of plaintiffs filed a different APA action in the Eastern District of Texas seeking to compel a formal rulemaking on NHK-Fintiv and to enjoin all IPRs in the meantime. That action has been dismissed for lack of standing. US Inventor Inc. v. Hirshfeld, No. 21-CV-00047, 2021 WL 2936385, at *6 (E.D. Tex. July 13, 2021).

⁶ Unified Patents, *PTAB Discretionary Denials Up 60%+ in 2020: Fueled Entirely by 314(a) Denials* (Jan. 5, 2021), https://www.unifiedpatents.com/insights/2020-ptab-discretionary-denials-report

⁷ Unified Patents, *Portal*, https://bit.ly/3fCDI5b (last visited Aug. 5, 2021).

jurisdictions that advertise fast-moving dockets. As an example, many patent plaintiffs are flocking to Waco in the Western District of Texas because the judge's "aggressive default schedule helps ensure that, in most cases, [the *NHK-Fintiv*] factors will favor denying institution." Indeed, the judge in Waco has "explicitly stated that part of his motivation [for] setting such early trial dates is to allow litigants in his courtroom to avoid PTAB review."

This type of gamesmanship frustrates Congress's objective in creating the IPR system. "Setting a case schedule that essentially eliminates the prospect of PTAB review undermines the system Congress set up in the AIA to weed out low quality patents." But this behavior is exactly what the *NHK-Fintiv* Rule allows and tacitly encourages. Indeed, as one commentator has observed, the *NHK-Fintiv* Rule has created "significant blackout zones"—federal districts like the Eastern District of Virginia, the Eastern District of Texas, and the Western District of Texas that move so fast that "it will not be possible for a litigation defendant to use PTAB review." ¹¹ The

⁸ J. Jonas Anderson & Paul Gugliuzza, Federal Judge Seeks Patent Cases, 71 DUKE L.J. (forthcoming 2021) (manuscript at 46), available at https://papers.ssrn.com/sol3/papers.cfm? abstract_id=3668514

⁹ *Id.* (manuscript at 47).

¹⁰ *Id*.

¹¹ Mapping the Contours of PTAB Discretionary Denials In 2020, LAW360 (Dec. 15, 2020), https://www.law360.com/articles/1335699/mapping-the-contours-of-ptab-discretionary-denials-in-2020

two Texas districts are already among the most popular for patent plaintiffs. 12

The *NHK-Fintiv* Rule needs to be reviewed and overturned—and soon. Given the Director's so-far successful campaign to preclude review, intervention by this Court is necessary.

CONCLUSION

The petition for a writ of certiorari 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

KATTEN MUCHIN

ROSENMAN LLP

2900 K Street, NW

Washington, DC 20007

August 9, 2021

Counsel for Petitioner

 $^{^{12}}$ Judge Albright Now Oversees 20% of New US Patent Cases, Law360 (Mar. 10, 2021), https://www.law360.com/articles/1361071/judge-albright-now-oversees-20-of-new-us-patent-cases.