No. 2022-1249

IN THE

United States Court of Appeals for the Federal Circuit

APPLE INC., CISCO SYSTEMS, INC., GOOGLE LLC, INTEL CORPORATION, EDWARDS LIFESCIENCES CORPORATION, EDWARDS LIFESCIENCES LLC,

Plaintiffs-Appellants,

– v. –

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,

Defendant-Appellee.

On Appeal From a Final Judgment of the United States District Court for the Northern District of California, No. 5:20-cv-06128 (Davila, J.)

BRIEF OF MYLAN PHARMACEUTICALS INC. AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFFS-APPELLANTS AND REVERSAL

Deepro R. Mukerjee
Lance A. Soderstrom
KATTEN MUCHIN ROSENMAN LLP
575 Madison Avenue
New York, NY 10022-2585
212-940-8800
deepro.mukerjee@katten.com
lance.soderstrom@katten.com

Robert T. Smith
Eric T. Werlinger
Rajesh R. Srinivasan
KATTEN MUCHIN ROSENMAN LLP
2900 K Street, NW – Suite 200
Washington, DC 20007-5118
202-625-3500
robert.smith1@katten.com
eric.werlinger@katten.com
rajesh.srinivasan@katten.com

Counsel for Amicus Curiae *Mylan Pharmaceuticals Inc.*

CERTIFICATE OF INTEREST

Counsel for *amicus curiae* Mylan Pharmaceuticals Inc. certifies as follows:

1. Represented Entities. Provide the full names of all entities represented by undersigned counsel in this case. Fed. Cir. R. 47.4(a)(1).

Mylan Pharmaceuticals Inc.

2. Real Party in Interest. Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. Fed. Cir. R. 47.4(a)(2).

None.

3. Parent Corporations and Stockholders. Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. Fed. Cir. R. 47.4(a)(3).

Mylan, Inc. and Viatris Inc.

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

Orrick, Herrington & Sutcliffe LLP; Thomas King-Sun Fu; Mark S. Davies; and Rachel G. Shavel.

5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5); *see also* Fed. Cir. R. 47.5(b).

None.

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

None.

Dated: February 15, 2022

/s/ Robert T. Smith

Robert T. Smith
KATTEN MUCHIN ROSENMAN LLP
2900 K Street, NW – Suite 200
Washington, DC 20007-5118
202-625-3500
robert.smith1@katten.com

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases:

Statutes:

Decisions of the Patent Trial and Appeal Board:

Regulations and Rulemakings:

Other Authorities:

STATEMENT OF INTEREST OF *AMICUS CURIAE*[*]

Mylan Pharmaceuticals Inc. (Mylan) is one of the world's leading pharmaceutical companies. It provides people all over the world with greater access to medicines through the development and sale of high-quality generic drugs at a fraction of the cost of their branded equivalents.

In the United States in particular, Mylan has filed and received approval for hundreds of generic drugs through Abbreviated New Drug Applications. These applications frequently set up disputes over the validity of patents held by the manufacturers of branded drugs. *See* Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585 (1984).

Over the years, Mylan and other generic manufacturers have successfully invalidated hundreds of patents that the Patent and Trademark Office should never have issued in the first place—patents that do not reward innovation but instead serve only to stifle competition and increase prices for consumers. In some instances, Mylan has established invalidity

[*] All parties consent to the filing of this brief. No counsel for any party in this case authored this brief in whole or in part. No person or entity—other than *amicus curiae* and its counsel—made a monetary contribution specifically for the preparation or submission of this brief.

through litigation. In others, Mylan has successfully invoked *inter partes* review—a process established by Congress as a more efficient and less costly alternative to litigation for challenging the validity of patents. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

Mylan has a significant interest in ensuring that the Patent and Trademark Office establishes rules governing the institution of *inter partes* review that are consistent with the agency's obligations under the America Invents Act and the Administrative Procedure Act (APA). Mylan depends on fair and prompt adjudication of patent claims that block its efforts to bring lower-cost drugs to patients. And because Mylan is frequently sued for infringement before it can institute *inter partes* review, Mylan is increasingly affected by the so-called *NHK-Fintiv* Rule. That rule requires the Patent Trial and Appeal Board to deny institution of *inter partes* review if it determines that such review would be inefficient in light of overlapping litigation. *See NHK Spring Co. v. Intri-Plex Techs., Inc.*, No. IPR2018-00752, 2018 WL 4373643 (P.T.A.B. Sept. 12, 2018); *Apple Inc. v. Fintiv, Inc.*, No. IPR2020-00019, 2020 WL 2126495 (P.T.A.B. Mar. 20, 2020).

Mylan agrees with Plaintiffs that the district court erred in holding that the America Invents Act's appeal bar precludes their challenge to the *NHK-*

Fintiv Rule under the APA. As Plaintiffs ably demonstrate, their substantive and procedural challenges to the *NHK-Fintiv* Rule do not involve the appeal bar, which shields from appellate review only the Board's decision whether to "institute an inter partes review" of a specific patent. 35 U.S.C. § 314(d). In contrast, Plaintiffs seek only prospective injunctive relief precluding the Director from continuing to apply the *NHK-Fintiv* Rule.

Mylan submits this *amicus* brief to focus the Court on the failure of the Director of the Patent and Trademark Office to adopt the *NHK-Fintiv* Rule through notice-and-comment rulemaking as required by the APA. That failure reinforces why Plaintiffs' challenge does not seek to appeal any decision of the Board whether to "institute an inter partes review" of any patent, and why it therefore does not trigger the appeal bar. 35 U.S.C. § 314(d). In addition, the Director's failure to take in information through notice-and-comment rulemaking has allowed the Director (and his predecessor) to ignore the many ways in which the *NHK-Fintiv* Rule is subject to abuse and manipulation by litigants hoping to avoid *inter partes* review—and that failure has permitted the Director to avoid legal and political accountability for the rule.

ARGUMENT

I. Plaintiffs May Challenge the *NHK-Fintiv* Rule Under the APA.

The America Invents Act's appeal bar does not stand as a barrier to Plaintiffs' challenge to the *NHK-Fintiv* Rule. Indeed, Plaintiffs' procedural challenge—most notably, contesting the Director's failure to promulgate notice-and-comment regulations as commanded by Congress—reinforces the conclusion that their challenge has nothing to do with that bar. The judgment of the district court should be reversed.

A. The America Invents Act's bar on review of decisions whether to institute *inter partes* review does not block Plaintiffs' challenge to the *NHK-Fintiv* Rule under the APA.

The district court dismissed Plaintiffs' challenge to the *NHK-Fintiv* Rule as a non-justiciable controversy, pointing to the America Invents Act's appellate bar in 35 U.S.C. § 314(d) as the basis for this conclusion. The bar provides that "[t]he determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable." *Id.* But the bar does not apply to district-court proceedings under the APA seeking purely prospective relief; it applies only to review of decisions to institute *inter partes* review of a patent. Both the plain text of § 314(d) and Supreme Court precedent undermine the district court's contrary view.

This Court must "start with the text of the statute," and here, it need not go beyond that text to reverse the district court. *Babb v. Wilkie*, 140 S. Ct. 1168, 1172 (2020). The statutory text offers no support for the district court's reading. On its face, the America Invents Act establishes a procedure where "a person who is not the owner of a patent may file with the Office a petition to institute an inter partes review of the patent." 35 U.S.C. § 311(a). The Act vests the Director with discretion whether to institute such review of a patent—provided such discretion is exercised consistent with the Act. *See id.* § 314(a). And the Act includes an appeal bar, which provides 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).

The case below does not involve review of any decision whether to institute *inter partes* review of any specific patent. Rather, Plaintiffs challenge the *NHK-Fintiv* Rule as improperly promulgated under the APA, which § 314(d) does not address. Moreover, § 314(d)'s bar applies only to appeals. A district-court action initiated under the APA, of course, is not an appeal. Thus, the statutory text alone shows that the district court's reading is wrong.

Instead of looking to the statutory language, the district court relied on *Cuozzo Speed Technologies, LLC v. Lee*, 579 U.S. 261 (2016), and *Thryv, Inc. v. Click-to-Call Technologies, LP*, 140 S. Ct. 1367 (2020). But as Plaintiffs explain, the district court's reliance on these cases is misplaced.

Cuozzo and *Thryv* involved appeals from determinations whether to institute *inter partes* review of specific patents. *Cuozzo*, 579 U.S. 269-71; *Thryv*, 140 S. Ct. at 1370-72. As noted above, this case is not an appeal from a petition to institute *inter partes* review, and it does not seek to set aside any decision of the Patent Trial and Appeal Board related to any such review. Rather, it is a district-court challenge to an administrative rule under the APA, and it seeks to set aside the application and enforcement of that rule as substantively and procedurally unlawful. Simply put, *Cuozzo* and *Thryv* have no application here.

Moreover, *Cuozzo* includes an important reminder that courts must start with "the 'strong presumption' in favor of judicial review," 579 U.S. at 273—a presumption that exists under the APA as well. *E.g.*, *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1905 (2020). To overcome that presumption, *Cuozzo* explained, the Supreme Court has

required "clear and convincing indications" that Congress meant to foreclose review. 579 U.S. at 273 (internal quotation marks omitted).

Here, given the strength of the presumption and the statute's text, which is limited to barring appeals from a "determination by the Director whether to institute an inter partes review" of a specific patent, 35 U.S.C. § 314(d), the district court plainly erred. There is simply no way to read that language to extend to substantive and procedural challenges seeking prospective relief under the APA—let alone read that language as a clear and convincing indication that Congress meant to foreclose such review.

Finally, even if the appeal bar were implicated here, review is still available under *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018). That case involved a challenge to the Director's decision to institute *inter partes* review on less than all claims raised in a petition seeking such review. *Id.* at 1354. And yet, the Supreme Court clarified that "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.* at 1359 (quoting *Cuozzo*, 579 U.S. at 275, and 5 U.S.C. § 706(2)(A), (C)). Thus, in *SAS*, the Supreme Court found § 314(d) inapplicable to an appeal of the Director's decision to institute *inter*

partes review on "fewer than all of the claims [the petitioner] challenged" because the petitioner claimed the decision "exceeded [the Director's] statutory authority." *Id.* Without the availability of this review, the Court reasoned, the Director would be able to engage in "'"shenanigans"' by exceeding [his] statutory bounds." *Id.* (quoting *Cuozzo*, 579 U.S. at 275).

To be clear, this Court need not rely on *SAS* to resolve this appeal. It is enough that the text of the appeal bar plainly does not apply here. The Court should permit Plaintiffs' challenge to proceed under the APA.

B. The Director's failure to adopt *NHK-Fintiv* through notice-and-comment rulemaking reinforces why the appeal bar has no application here.

The APA includes a variety of important procedural requirements. For instance, before issuing a rule, an agency is required to publish a notice, generally in the Federal Register, that provides "the time, place, and nature of public rule making proceedings," "reference to the legal authority under which the rule is proposed," and "either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b). After notice is published, the agency "shall"—that is, must—"give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without

opportunity for oral presentation." *Id.* § 553(c). And only after consideration of these comments may the agency issue its rule. *See id.*

The Director circumvented these procedures by designating two Board-issued decisions as precedential without allowing for notice and comment on the substantive rule they establish for deciding whether to institute *inter partes* review. *See generally NHK*, 2018 WL 4373643; *Fintiv*, 2020 WL 2126495. This method of rulemaking undermines the APA's procedural safeguards, which help ensure that the Director is acting within the scope of his statutory authority.

Relevant to the limited issue now before this Court, the Director's failure to adopt *NHK-Fintiv* through notice-and-comment rulemaking underscores why the America Invents Act's appeal bar has no application here. As noted above, that bar preludes appellate review of the Board's decision whether to "institute *an* inter partes review" of a particular patent. 35 U.S.C. § 314(d) (emphasis added). It has no bearing on a court's authority to declare a substantive rule invalid and unenforceable on a prospective basis under the APA. The procedural side of Plaintiffs' challenge makes this particularly apparent. A court need not even look to the America Invents Act

to declare that the *NHK-Fintiv* Rule is procedurally unlawful because the Director failed to take the necessary steps of notice and public comment.

The district court's contrary decision also creates a perverse incentive for the Director not to follow the APA. If § 314(d)'s appeal bar applies to district-court challenges under the APA that do not seek review of a decision to institute *inter partes* review of a specific patent, then the Director would have no reason to follow the APA's procedural or substantive requirements in the future. He could, as an earlier Director did here, decree a substantive rule without notice and public comment.

In fact, even if the Director engaged in notice-and-comment rulemaking, he would still be able to avoid review: Under the district court's reasoning, the issuance of a regulation "closely related to [the Director's decision] whether to institute inter partes review" would still be unreviewable. Appx10 (quoting *Thryv*, 140 S. Ct. at 1370). That cannot be correct.

The district court's ruling closes the only avenue for challenging the *NHK-Fintiv* Rule and other rules bearing on institution of *inter partes* review that violate the APA. This Court has now held that the *NHK-Fintiv* Rule cannot be challenged on appeal from a decision denying institution of *inter*

partes review. *E.g.*, *Mylan Lab'ys Ltd. v. Janssen Pharmaceutica, N.V.*, 989 F.3d 1375, 1377 (Fed. Cir. 2021), *cert. denied*, 142 S. Ct. 874 (2022); *Apple Inc. v. Optis Cellular Tech., LLC*, No. 2021-1043, 2020 WL 7753630, at *1 (Fed. Cir. Dec. 21, 2020), *cert. denied*, 142 S. Ct. 859 (2022); *Cisco Sys. Inc. v. Ramot at Tel Aviv Univ. Ltd.*, 834 F. App'x 571, 572-73 (Fed. Cir. 2020). Thus, a challenge under the APA is the only way to contest a procedurally or substantively invalid regulation that sets substantive rules governing institution of *inter partes* review. The district court's ruling cuts off this avenue of relief by transforming a limited bar on appeals from a Director's decision whether to institute review of a patent into a far-reaching bar on judicial review of the Director's rulemaking actions.

The district court's judicially created loophole will allow the Director to avoid receiving and considering input from the public on highly consequential rules and to exceed his statutory authority on *inter partes* review without judicial oversight. If the APA's requirements and the limits on the Director's statutory authority over *inter partes* review are to mean anything, then challenges to rules governing such review must remain available under the APA.

II. The Director's Failure to Abide by the Procedural Requirements of the APA Circumvented a Vital Check on Administrative Power and Resulted in Flawed Policy.

When the Director bypassed notice and comment to enact the *NHK-Fintiv* Rule, he skipped over one of the most important elements of the administrative rule-making process. As Congress, the courts, and commentators have long recognized, notice and the opportunity for public comment are vital to ensuring high-quality regulations, protecting basic notions of fairness, and facilitating judicial review of agency action. Promulgating the *NHK-Fintiv* Rule in the back-door manner utilized by the Director led to the very problem that the notice-and-comment process was designed to combat: a regulation marred by obvious shortcomings that was forced upon stakeholders with no warning or chance for input. Worse still, because the Director ducked the notice-and-comment process, the *NHK-Fintiv* Rule has so far not been tested in court, as it would have been if it were promulgated through the normal course under the APA. These flaws—all of which could have been cured by following appropriate processes—underscore the need to allow Plaintiffs' challenge to proceed.

A. The APA's requirement of public notice and opportunity for comment is foundational to fair and effective agency decision-making.

"In enacting the APA, Congress made a judgment that notions of fairness and informed administrative decisionmaking require that agency decisions be made only after affording interested persons notice and an opportunity to comment." *Chrysler Corp. v. Brown*, 441 U.S. 281, 316 (1979). Moreover—and significantly—notice and comment serve "as a check upon administrators whose zeal might otherwise have carried them to excesses not contemplated in legislation creating their offices." *United States v. Morton Salt Co.*, 338 U.S. 632, 644 (1950). Thus, as Justice Scalia once observed, the notice-and-comment process is "probably the most significant innovation" of the APA. Antonin Scalia, *Judicial Deference to Administrative Interpretations of Law*, 1989 Duke L.J. 511, 514 (1989).

As explained above, the APA requires substantive rules like *NHK-Fintiv* to go through the notice-and-comment process. Indeed, the Director previously established a number of rules related to *inter partes* review through notice-and-comment rulemaking. *E.g.*, 77 Fed. Reg. 48,612 (Aug. 14, 2012) (adopting final rules governing trial practice before the Patent Trial and Appeal Board); 77 Fed. Reg. 48,680 (Aug. 14, 2012) (adopting final rules

governing *inter partes* review, including procedures bearing on institution); 83 Fed. Reg. 51,340 (Oct. 11, 2018) (adopting final rule amending regulations governing *inter partes* review, including procedures bearing on institution).

That the law requires this process is reason enough to compel the Director to follow it. *Berkovitz v. United States*, 486 U.S. 531, 544 (1988) (noting that "[t]he agency has no discretion to deviate" from the procedure mandated by its regulatory scheme). And Congress mandated that agencies follow this process for good reason. The notice-and-comment process "serves three distinct purposes" that are indispensable to fair and effective agency rule-making. *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 547 (D.C. Cir. 1983).

First, "notice improves the quality of agency rulemaking by ensuring that agency regulations will be 'tested by exposure to diverse public comment.'" *Id.* (quoting *BASF Wyandotte Corp. v. Costle*, 598 F.2d 637, 641 (1st Cir. 1979)). Robust public comment leads to better decision-making. As the Supreme Court recently observed, "[n]otice and comment gives affected parties fair warning of potential changes in the law and an opportunity to be heard on those changes—and it affords the agency a chance to avoid errors and make a more informed decision." *Azar v. Allina Health Servs.*, 139 S. Ct.

1804 (2019). "Indeed, '[t]he whole rationale of notice and comment rests on the expectation that the final rules will be somewhat different and improved from the rules originally proposed by the agency.'" *Veterans Just. Grp., LLC v. Sec'y of Veterans Affs.*, 818 F.3d 1336, 1344 (Fed. Cir. 2016) (quoting *Trans–Pac. Freight Conference of Japan/Korea v. Fed. Mar. Comm'n*, 650 F.2d 1235, 1249 (D.C. Cir. 1980)).

Second and relatedly, "notice and the opportunity to be heard are an essential component of 'fairness to affected parties.'" *Small Refiner Lead Phase-Down Task Force*, 705 F.2d at 547 (quoting *Nat'l Assoc. of Home Health Agencies v. Schweiker,* 690 F.2d 932, 949 (D.C. Cir. 1982)). Fair notice and public participation in the rule-making process are "value[s] basic to American administrative law." *Ivy Sports Med., LLC v. Burwell*, 767 F.3d 81, 87-88 (D.C. Cir. 2014). Without it, unelected bureaucrats could spring new rules on an unwitting public following closed-door proceedings. Avoiding this offensive and decidedly un-American outcome is precisely why Congress made notice-and-comment process such an important part of the APA. *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2385 (2020) ("The object of notice and comment, in short, is one of fair notice." (cleaned up)).

Third and finally, "by giving affected parties an opportunity to develop evidence in the record to support their objections to a rule, notice enhances the quality of judicial review." *Small Refiner Lead Phase-Down Task Force*, 705 F.2d at 547 (citing *Marathon Oil Co. v. EPA*, 564 F.2d 1253, 1271 n.54 (9th Cir. 1977)). Comments produced during the notice-and-comment period are "often an invaluable source of information to a reviewing court." *Marathon Oil Co.*, 564 F.2d at 1271 n.54. And an agency acts arbitrarily and capriciously if it (among other things) "offered an explanation for its decision that runs counter to the evidence before the agency." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). In fact, agencies "must consider and respond to significant comments received during the period for public comment." *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015).

B. The *NHK-Fintiv* Rule suffers from the very flaws that the notice-and-comment procedure is meant to remedy.

The *NHK-Fintiv* Rule did not go through notice-and-comment rulemaking, and thus none of the important, congressionally mandated goals discussed above were fulfilled. Unsurprisingly, the rule is plagued by

the exact maladies that Congress intended to eliminate with the notice-and-comment process.

1. The rule enshrines bad policy that runs counter to Congress's design for *inter partes* review.

For starters, the *NHK-Fintiv* rule is bad policy in general. By heavily weighting the existence of parallel litigation—and the prospect that such litigation *might* go to trial before *inter partes* review would be resolved—the *NHK-Fintiv* Rule forces the Board to make predictive (and oftentimes arbitrary) judgments about when a trial might outpace *inter partes* review. Equally problematic, the Board has interpreted the rule to require it to accept unrealistic trial schedules at "face value"—absent compelling evidence to the contrary. *E.g.*, *Samsung Elecs. Co. v. Ancora Techs., Inc.*, No. IPR2020-01184, 2021 WL 42429, at *5 (P.T.A.B. Jan. 5, 2021).

Not surprisingly, the rule encourages forum shopping by incentivizing plaintiffs to file suit in jurisdictions that advertise fast-moving dockets. As an example, many plaintiffs are flocking to the Waco Division in the Western District of Texas because that division sets an "aggressive default schedule [that] helps ensure that, in most cases, [the *NHK-Fintiv*] factors will favor denying institution." J. Jonas Anderson & Paul Gugliuzza,

Federal Judge Seeks Patent Cases, 71 Duke L.J. 419, 467 (2021). According to two commentators, the court in Waco has "explicitly stated that part of [its] motivation [for] setting early trial dates is to allow litigants to avoid PTAB review." *Id.* at 468. And today, roughly 25 percent of all patent litigation in the entire United States is pending in this district. Ltr. from Sens. Patrick Leahy & Thom Tillis to Chief Justice Roberts, U.S. Supreme Court (Nov. 2, 2021), https://tinyurl.com/ynf445h9.

Meanwhile, the Board's reliance on the *NHK-Fintiv* Rule's non-statutory factors threatens the system Congress enacted to weed out junk patents. Since the Rule's inception, the Director has wielded it to dispose of numerous petitions for *inter partes* review—by one count, 85 denials in 2020 and likely hundreds as of today. *See* Unified Patents, *Portal*, https://tinyurl.com/y7wej842 (last visited Feb. 15, 2022); Unified Patents, *PTAB Discretionary Denials Up 60%+ in 2020: Fueled Entirely by 314(a) Denials* (Jan. 5, 2021), https://tinyurl.com/2p8nxfff. On top of that, the break-neck trial schedules that the Board relies upon to trigger the *NHK-Fintiv* Rule "almost always get pushed back." *Fintiv Fails: PTAB Uses 'Remarkably Inaccurate' Trial Dates* (Nov. 2, 2021), Law360, https://tinyurl.com/4ysekwpm.

These basic facts are well known in the patent community. Had there been public notice of the *NHK-Fintiv* Rule and an opportunity for comment, stakeholders could have shared these concerns with the Director—who hopefully would have crafted a better rule or abandoned the idea altogether. But because the Director decided to take a non-public (and illegal) shortcut, the *NHK-Fintiv* Rule came into being with obvious substantive problems. This outcome is a textbook example of what the APA's notice-and-comment regime is designed to prevent—further proof that the *NHK-Fintiv* Rule should have gone through notice and comment in the first place.

2. The rule has a particularly negative impact on the generic pharmaceutical industry and patients who rely upon low-cost generic drugs.

The *NHK-Fintiv* Rule has a particularly negative effect on generic pharmaceutical companies and patients who rely upon the low-cost drugs they provide. Branded manufacturers often obtain an array of successive and overlapping patents covering a single drug, in the hopes of extending their monopolies beyond the term set by Congress and keeping competitors off the market. Mylan and other generic pharmaceutical companies have long relied upon patent litigation to invalidate patents that never should have been issued in the first place, which helps get low-cost, high-quality

generic drugs into the hands of patients who sorely need them. Indeed, this process is baked into the Hatch-Waxman Act. 21 U.S.C. § 355(j). Since 2011, Mylan has regularly turned to *inter partes* review as a quick and efficient alternative to district-court litigation, which is exactly what Congress intended.[1]

By the very nature of Hatch-Waxman litigation, generic manufacturers like Mylan typically do not petition for *inter partes* review until after they have been sued for patent infringement in district court. There is a simple reason why. A generic manufacturer usually does not know which of the dozens of patents in the branded manufacturer's portfolio will be asserted against it until it is served with a complaint. So the only way to seek *inter partes* review would be to preemptively file dozens of separate petitions for *inter partes* review challenging the entire suite of patents covering a single brand-name drug. This option is inefficient for both generic pharmaceutical

[1] The objective of bringing low-cost generic drugs to market is more important than ever. Massive increases in prescription drug costs are crippling family budgets and inhibiting America's economic recovery. Kate Sullivan et al., *Biden Argues Lowering Prescription Drug Costs Is Key to Easing Everyday Costs for American Families*, CNN, https://www.cnn.com/2022/02/10/politics/biden-prescription-drug-speech-virginia/ (last visited Feb. 15, 2022).

companies and the Patent and Trademark Office. A petitioner must marshal its entire case-in-chief in a petition for *inter partes* review, 35 U.S.C. § 312(a)(3); 37 C.F.R. § 42.22(a)(2), a process that usually requires at least five to six months of work. And the Board must then review and address the arguments and evidence in the petition in a written decision. 35 U.S.C. § 314. Repeating this process multiple times to bring a single generic drug to market—including for patents that the brand manufacturer may never assert—would be shockingly inefficient.[2]

Congress understood that filing a petition for *inter partes* review would take time. That is why it gave generic manufacturers (and other patent defendants) up to one year after they have been served with a patent-infringement complaint to seek *inter partes* review. 35 U.S.C § 315(b). The *NHK-Fintiv* Rule unlawfully countermands the congressional design of such review, and it forces generic pharmaceutical companies to choose between

[2] This problem is compounded by the fact that multiple generic pharmaceutical companies will often file applications to bring a generic drug to market. This is a normal and healthy part of the process—more competition means lower prices, higher availability, and better products. Yet the *NHK-Fintiv* Rule makes it virtually impossible for subsequent filers to avail themselves of *inter partes* review, as the Board may hold against second-comers the trial schedule of the first filer. *See Mylan Lab'ys Ltd.*, 989 F.3d at 1378.

filing needlessly overbroad petitions for *inter partes* review or potentially foregoing such review altogether.

Stakeholders in the pharmaceutical industry had no say in the design of the *NHK-Fintiv* Rule. Because the rule did not go through notice-and-comment rulemaking, affected parties, like Mylan, have not had an opportunity to point out the serious flaws outlined above.

3. The procedurally defective manner in which the rule was passed has so far thwarted judicial review.

Finally, the failure to promulgate the *NHK-Fintiv* Rule through the notice-and-comment process has frustrated judicial review. As noted above, this Court has held that the *NHK-Fintiv* Rule may not be challenged through a direct appeal from the denial of institution of an *inter partes* review of a specific patent. *See Mylan*, 989 F.3d at 1377. The only other conceivable route by which the courts will ever review the substance of the *NHK-Fintiv* Rule is an APA suit like this one.

The Director claims the fact that the *NHK-Fintiv* Rule did *not* go through the notice-and-comment process means that the rule is categorically unreviewable by the courts. For the reasons stated by the Plaintiffs in their principal brief, that is wrong as a matter of law.

The Director's position also runs contrary to the clear policy goals of the APA discussed above. Judicial review—the ability of the courts to set aside arbitrary, capricious, and unlawful agency behavior—is foundational to the APA. Indeed, the statute "establishes a 'basic presumption of judicial review [for] one "suffering legal wrong because of agency action."'" *Regents of the Univ. of Cal.*, 140 S. Ct. at 1905 (quoting *Abbott Lab'ys v. Gardner*, 387 U.S. 136, 140 (1967)).

The Director has not overcome that presumption here. The America Invents Act's appeal bar does not manifest a "clear and convincing" intent on the part of Congress to foreclose judicial review of an APA challenge to rules that the Director has made binding on the Board and parties to *inter partes* review proceedings. Just the opposite. The appeal bar, by its plain terms, does not apply here.

CONCLUSION

The judgment of the district court should be reversed.

Dated: February 15, 2022

Respectfully submitted,

/s/ Robert T. Smith

Deepro R. Mukerjee
Lance A. Soderstrom
KATTEN MUCHIN ROSENMAN LLP
575 Madison Avenue
New York, NY 10022-2585
212-940-8800
deepro.mukerjee@katten.com
lance.soderstrom@katten.com

Robert T. Smith
Eric T. Werlinger
Rajesh R. Srinivasan
KATTEN MUCHIN ROSENMAN LLP
2900 K Street, NW – Suite 200
Washington, DC 20007-5118
202-625-3500
robert.smith1@katten.com
eric.werlinger@katten.com
rajesh.srinivasan@katten.com

Counsel for Amicus Curiae *Mylan Pharmaceuticals Inc.*

CERTIFICATE OF COMPLIANCE

Pursuant Federal Circuit Rule of Practice 29(b) and Federal Rules of Appellate Procedure 32(a)(5) and 32(a)(6), I hereby certify that this brief is in compliance with the type form and volume requirements. Specifically, the foregoing brief is proportionately spaced; uses a Roman-style, serif typeface (Book Antiqua) of 14-point; and contains 4,712 words, exclusive of the material not counted under Rule 32(f) of the Federal Rules of Appellate Procedure and Federal Circuit Rule 32(b)(2).

Date: February 15, 2022

/s/ Robert T. Smith
Counsel for Amicus Curiae
Mylan Pharmaceuticals Inc.

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing brief by tendering it via the CM/ECF system to the Office of the Clerk of the United States Court of Appeals for the Federal Circuit on February 15, 2022. I certify that all counsel of record are registered ECF filers and that they will be served by electronic means via the CM/ECF system.

/s/ Robert T. Smith
Robert T. Smith
Counsel for Amicus Curiae
Mylan Pharmaceuticals Inc.